



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

November 2, 2018

Dr. Timothy Stenzel
Director, Office of In Vitro Diagnostics and Radiological Health
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Via e-mail to Timothy.Stenzel@fda.hhs.gov

SUBJECT: TRAINING AND EXPERIENCE REQUIREMENTS FOR DIFFERENT CATEGORIES OF RADIOPHARMACEUTICALS

Dear Dr. Stenzel,

The U.S. Nuclear Regulatory Commission (NRC) is evaluating its regulations related to the training and experience (T&E) required for a physician to become an authorized user for medical uses under Subpart E, “Unsealed Byproduct Material—Written Directive Required,” of [Title 10 of the Code of Federal Regulations \(10 CFR\) Part 35, “Medical Use of Byproduct Material.”](#)

The T&E requirements in Subpart E of 10 CFR Part 35 provide three ways that a physician can be authorized to administer unsealed byproduct materials or radiopharmaceuticals requiring a written directive:

1. A physician can be certified by a medical specialty board, whose certification process is recognized by the NRC or an Agreement State.
2. A physician can complete a structured educational program and supervised work experience under an alternate pathway. This alternate pathway includes a requirement for 700 hours of training and experience, which consists of a minimum of 200 hours of classroom and laboratory training and 500 hours of supervised work experience.
3. A physician can be authorized if previously identified as an authorized user on an NRC or Agreement State license or permit (i.e., grandfathered).

In its evaluation of the T&E requirements, the NRC staff is considering whether an additional pathway should be created or if the alternate pathway should be revised. Specifically, the staff is evaluating: (1) whether it makes sense to establish tailored T&E requirements for different categories of radiopharmaceuticals; (2) how those categories should be determined; (3) what the appropriate T&E requirements would be for each category; and (4) whether those requirements should be based on hours of training and experience, or focused more on competency.

On October 29, 2018, the NRC published a series of questions on T&E in the *Federal Register* (83 FR 54380). The *Federal Register* notice is enclosed with this letter and can also be accessed at: <https://www.gpo.gov/fdsys/pkg/FR-2018-10-29/pdf/2018-23521.pdf>. The NRC will carefully consider responses to these questions and would appreciate your feedback on whether changes to the current T&E regulations are warranted. The comment period for the T&E evaluation will end on January 29, 2019. Please follow the directions in the notice on how to submit written comments. The NRC is using the Federal rulemaking Web site, [Regulations.gov](#), to accept written comments on the docket (NRC-2018-0230).

The NRC will also conduct four public meetings scheduled for November 14 and December 11, 2018, and January 10 and January 22, 2019, and will accept oral comments provided during the meetings. The meetings on December 11 and January 10 will be held at NRC Headquarters in Rockville, MD, and all four meetings will be accessible for remote participation by moderated bridge line and webinar. The NRC's public meeting page has been updated with meeting details and registration instructions for each meeting: <https://www.nrc.gov/pmns/mtg>.

Additional information on the NRC's T&E evaluation can be found at: <https://www.nrc.gov/materials/miau/med-use-toolkit/training-experience-evaluation.html>. If you have any questions on this correspondence, please contact Sarah Lopas of my staff at (301) 415-6360 or Sarah.Lopas@nrc.gov.



Christian Einberg, Chief
Medical Safety and Events Assessment Branch
Division of Materials Safety, Security, State
and Tribal Programs
Office of Nuclear Material Safety
and Safeguards

Enclosure:
Training and Experience
Federal Register notice

SUBJECT: TRAINING AND EXPERIENCE REQUIREMENTS FOR DIFFERENT
CATEGORIES OF RADIOPHARMACEUTICALS

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Training and Experience
Federal Register notice

IDENTICAL LETTERS SENT TO: See Attached

ML18306A926

OFC	NMSS/MSST	NMSS/MSST	NMSS/MSST	NMSS/MSST
NAME	SLopas	LDimmick (via e-mail)	SAttack (via e-mail)	CEinberg
DATE	10/25/18	10/31/18	11/1/18	11/2/18

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NUCLEAR REGULATORY COMMISSION

[NRC-2018-0230]

**Training and Experience Requirements for Different Categories of
Radiopharmaceuticals**

AGENCY: Nuclear Regulatory Commission.

ACTION: Training and experience requirements; request for comment.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is requesting comments on its training and experience (T&E) requirements. Specifically, the NRC would like input on whether it should establish tailored T&E requirements for different categories of radiopharmaceuticals for which a written directive is required in accordance with its regulations. The input will be used to determine whether significant regulatory changes to the NRC's T&E requirements for authorized users (AUs) are warranted.

DATES: Submit comments by January 29, 2019. Comments received after this date will be considered if it is practical to do so, but the NRC is only able to ensure consideration for comments received on or before this date.

ADDRESSES: You may submit comments by any of the following methods:

- **Federal Rulemaking Web Site:** Go to <http://www.regulations.gov>

and search for Docket ID **NRC-2018-0230**. Address questions about Docket IDs in Regulations.gov to Jennifer Borges; telephone: 301-287-9127; e-mail: Jennifer.Borges@nrc.gov. For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.

- **Mail comments to:** May Ma, Office of Administration, Mail Stop: TWFN-7-A60M, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001.

For additional direction on obtaining information and submitting comments, see “Obtaining Information and Submitting Comments” in the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: Sarah Lopas, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001; telephone: 301-415-6360, e-mail: Sarah.Lopas@nrc.gov.

SUPPLEMENTARY INFORMATION:

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- **NRC's PDR:** You may examine and purchase copies of public documents at the NRC's PDR, Room O1-F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.

B. Submitting Comments

Please include Docket ID **NRC-2018-0230** in your comment submission.

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II. Background

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radionuclides or by delivery method), (3) what the appropriate T&E requirements would be for each category, and (4) whether those requirements should be based on hours of T&E or focused more on competency. In response to the SRM, the NRC staff documented its initial results, status, and next steps related to this evaluation in SECY-18-0084, "Staff Evaluation of Training and Experience Requirements for Administering Different Categories of Radiopharmaceuticals in Response to SRM-M170817" (ADAMS Accession No. ML18135A276). In SECY-18-0084, the staff concluded that additional outreach with the medical community is needed to determine whether and how to tailor the T&E requirements to establish a limited AU status, the specific T&E requirements that should apply, how the T&E requirements should be met (e.g., hours of training, demonstration of competency), and whether a competency-based approach makes sense for the T&E requirements for all the medical uses authorized under 10 CFR 35.300, "Use of unsealed byproduct material for which a written directive is required."

The NRC is interested in obtaining input from as many stakeholders as possible, including members of the Advisory Committee on the Medical Uses of Isotopes, professional organizations, physicians, patients, patient advocacy groups, licensees, Agreement States, and other interested individuals. The focus of this request is to gather information that will permit the NRC staff to determine whether changes to the T&E requirements are warranted for different categories of radiopharmaceuticals for physicians seeking AU status for the medical use of specific categories of radiopharmaceuticals requiring a written directive under 10 CFR 35.300.

During the comment period between October 29, 2018 and January 29, 2019, the NRC will hold four public meetings that will discuss the information being requested and to accept comments on the docket. All four public meetings

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The NRC may post additional materials related to this document, including public comments, on the Federal Rulemaking Web site. The Federal Rulemaking Web site allows you to receive alerts when changes or additions occur in a docket folder. To subscribe: (1) Navigate to the docket folder **NRC-2018-0230**; (2) click the “Sign up for E-mail Alerts” link; and (3) enter your email address and select how frequently you would like to receive emails (daily, weekly, or monthly).

III. Specific Requests for Comments

A. Tailored Training & Experience Requirements

The NRC is requesting comments on whether it should establish tailored T&E requirements for different categories of radiopharmaceuticals for physicians seeking AU status for the medical use of specific categories of radiopharmaceuticals requiring a written directive under 10 CFR 35.300 (i.e., a limited AU status). This would be for physicians seeking AU status via the alternate non-board certified pathway, and for physicians certified by a medical

specialty board that is not currently recognized by the NRC under 10 CFR 35.390, 35.392, 35.394, or 35.396 (Unsealed Byproduct Material—Written Directive Required).

1. Are the current pathways for obtaining AU status reasonable and accessible? Provide a rationale for your answer.
2. Are the current pathways for obtaining AU status adequate for protecting public health and safety? Provide a rationale for your answer.
3. Should the NRC develop a new tailored T&E pathway for these physicians? If so, what would be the appropriate way to categorize radiopharmaceuticals for tailored T&E requirements? If not, explain why the regulations should remain unchanged. [Some options to categorize radiopharmaceuticals include radiopharmaceuticals with similar delivery methods (oral, parenteral); same type of radiation characteristics or emission (alpha, beta, gamma, low-energy photon); similar preparation method (patient-ready doses); or a combination thereof (e.g., radiopharmaceuticals containing alpha- and beta-emitting radioisotopes that are administered intravenously and are prepared as patient-ready doses).]
4. Should the fundamental T&E required of physicians seeking limited AU status need to have the same fundamental T&E required of physicians seeking full AU status for all oral and parenteral administrations under 10 CFR 35.300?
5. How should the requirements for this fundamental T&E be structured for a specific category of radiopharmaceuticals?
 - a. Describe what the requirements should include:

- i. Classroom and laboratory training – What topics need to be covered in this training requirement? How many hours of classroom and laboratory training should be required? Provide the basis for the number of hours. If not hours, explain how this training should be quantified. [Note: The topics currently required in the regulations to be included in the classroom and laboratory training and work experience are listed in 10 CFR 35.390, 35.392, 35.394, and 35.396.]
 - ii. Work experience - What should the work experience requirement involve? How many hours of work experience should be required and what is the minimum number of patient or human research subject administrations that an individual must perform? Provide the basis for the number of hours and administrations. What should be the qualifications of the supervising individual?
 - iii. Competency - How should competency be evaluated? Should a written and/or practical examination by an independent examining committee be administered? Provide a rationale for your answer.
- b. Should a preceptor attestation be required for the fundamental T&E? Provide a rationale for your answer.
- c. Should the radiopharmaceutical manufacturer be able to provide the preceptor attestation? Provide a rational for your answer.

- d. Who should establish and administer the curriculum and examination? Provide specific group(s). [Some options are: NRC, medical specialty boards, medical professional societies, educational professional groups, and NRC in collaboration with any or more of the aforementioned groups.]
- e. Should AU competency be periodically assessed? If so, how should it be assessed, how often, and by whom?

B. NRC's Recognition of Medical Specialty Boards

The NRC is requesting comments on its recognition of medical specialty boards. The NRC's procedures for recognizing medical specialty boards are located on the Medical Uses Licensee Toolkit Web site (<https://www.nrc.gov/materials/miau/med-use-toolkit/certif-process-boards.html>). The NRC staff periodically reviews information to determine a board's continued eligibility for recognition.

- 1. What boards other than those already recognized by the NRC (American Board of Nuclear Medicine [ABNM], American Board of Radiology [ABR], American Osteopathic Board of Radiology [AOBR], Certification Board of Nuclear Endocrinology [CBNE]) could be considered for recognition for medical uses under 10 CFR 35.300?
- 2. Are the current NRC medical specialty board recognition criteria sufficient? If not, what additional criteria should the NRC use?

C. Patient Access

The NRC is requesting comments on whether there is a shortage in the number of AUs for 10 CFR 35.300.

1. Is there a shortage in the number of AUs for medical uses under 10 CFR 35.300? If so, is the shortage associated with the use of a specific radiopharmaceutical? Explain how.
2. Are there certain geographic areas with an inadequate number of AUs? Identify these areas.
3. Do current NRC regulations on AU T&E requirements unnecessarily limit patient access to procedures involving radiopharmaceuticals? Explain how.
4. Do current NRC regulations on AU T&E requirements unnecessarily limit research and development in nuclear medicine? Explain how.

D. Other Suggested Changes to the T&E Regulations

In 2002, the NRC revised its regulatory framework for medical use. The goal was to focus the NRC's regulations on those medical procedures that pose the highest risk to workers, the general public, patients, and human research subjects and to structure the regulations to be more risk-informed and more performance-based. The 2002 rule reduced the unnecessary regulatory burden by either reducing or eliminating the prescriptiveness of some regulations. Instead, the rule provided for a performance-based approach that relied on the training and experience of the AUs, authorized nuclear pharmacists, and radiation safety officers. The NRC is requesting comments on whether there are any other changes to the T&E regulations in 10 CFR part 35 that should be considered. Please discuss your suggested changes.

1. Should the NRC regulate the T&E of physicians for medical uses?
2. Are there requirements in the NRC's T&E regulatory framework for physicians that are non-safety related?

3. How can the NRC transform its regulatory approach for T&E while still ensuring that adequate protection is maintained for workers, the general public, patients, and human research subjects?

Dated at Rockville, Maryland, this 23rd day of October 2018.

For the Nuclear Regulatory
Commission.

/RA/

Daniel S. Collins, Director,
Division of Materials Safety,
Security,
State, and Tribal Programs,
Office of Nuclear Material Safety
and Safeguards.



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

November 2, 2018

American Association of Physicists in Medicine
1631 Prince Street
Alexandria, VA 22314

Via e-mail to 2018.aapm@aapm.org

SUBJECT: TRAINING AND EXPERIENCE REQUIREMENTS FOR DIFFERENT CATEGORIES OF RADIOPHARMACEUTICALS

Dear Sir or Madam,

The U.S. Nuclear Regulatory Commission (NRC) is evaluating its regulations related to the training and experience (T&E) required for a physician to become an authorized user for medical uses under Subpart E, “Unsealed Byproduct Material—Written Directive Required,” of [Title 10 of the Code of Federal Regulations \(10 CFR\) Part 35, “Medical Use of Byproduct Material.”](#)

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A handwritten signature in black ink, appearing to read "C Einberg".

Christian Einberg, Chief
Medical Safety and Events Assessment Branch
Division of Materials Safety, Security, State
and Tribal Programs
Office of Nuclear Material Safety
and Safeguards

Enclosure:
Training and Experience
Federal Register notice

NUCLEAR REGULATORY COMMISSION

[NRC-2018-0230]

**Training and Experience Requirements for Different Categories of
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AGENCY: Nuclear Regulatory Commission.

ACTION: Training and experience requirements; request for comment.

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B. NRC's Recognition of Medical Specialty Boards

The NRC is requesting comments on its recognition of medical specialty boards. The NRC's procedures for recognizing medical specialty boards are located on the Medical Uses Licensee Toolkit Web site (<https://www.nrc.gov/materials/miau/med-use-toolkit/certif-process-boards.html>). The NRC staff periodically reviews information to determine a board's continued eligibility for recognition.

- 1. What boards other than those already recognized by the NRC (American Board of Nuclear Medicine [ABNM], American Board of Radiology [ABR], American Osteopathic Board of Radiology [AOBR], Certification Board of Nuclear Endocrinology [CBNE]) could be considered for recognition for medical uses under 10 CFR 35.300?
- 2. Are the current NRC medical specialty board recognition criteria sufficient? If not, what additional criteria should the NRC use?

C. Patient Access

The NRC is requesting comments on whether there is a shortage in the number of AUs for 10 CFR 35.300.

1. Is there a shortage in the number of AUs for medical uses under 10 CFR 35.300? If so, is the shortage associated with the use of a specific radiopharmaceutical? Explain how.
2. Are there certain geographic areas with an inadequate number of AUs? Identify these areas.
3. Do current NRC regulations on AU T&E requirements unnecessarily limit patient access to procedures involving radiopharmaceuticals? Explain how.
4. Do current NRC regulations on AU T&E requirements unnecessarily limit research and development in nuclear medicine? Explain how.

D. Other Suggested Changes to the T&E Regulations

In 2002, the NRC revised its regulatory framework for medical use. The goal was to focus the NRC's regulations on those medical procedures that pose the highest risk to workers, the general public, patients, and human research subjects and to structure the regulations to be more risk-informed and more performance-based. The 2002 rule reduced the unnecessary regulatory burden by either reducing or eliminating the prescriptiveness of some regulations. Instead, the rule provided for a performance-based approach that relied on the training and experience of the AUs, authorized nuclear pharmacists, and radiation safety officers. The NRC is requesting comments on whether there are any other changes to the T&E regulations in 10 CFR part 35 that should be considered. Please discuss your suggested changes.

1. Should the NRC regulate the T&E of physicians for medical uses?
2. Are there requirements in the NRC's T&E regulatory framework for physicians that are non-safety related?

3. How can the NRC transform its regulatory approach for T&E while still ensuring that adequate protection is maintained for workers, the general public, patients, and human research subjects?

Dated at Rockville, Maryland, this 23rd day of October 2018.

For the Nuclear Regulatory
Commission.

/RA/

Daniel S. Collins, Director,
Division of Materials Safety,
Security,
State, and Tribal Programs,
Office of Nuclear Material Safety
and Safeguards.



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

November 2, 2018

American Brachytherapy Society
11130 Sunrise Valley Dr., Suite 350
Reston, VA 20191

Via e-mail to abs@americanbrachytherapy.org

SUBJECT: TRAINING AND EXPERIENCE REQUIREMENTS FOR DIFFERENT CATEGORIES OF RADIOPHARMACEUTICALS

Dear Sir or Madam,

The U.S. Nuclear Regulatory Commission (NRC) is evaluating its regulations related to the training and experience (T&E) required for a physician to become an authorized user for medical uses under Subpart E, “Unsealed Byproduct Material—Written Directive Required,” of [Title 10 of the Code of Federal Regulations \(10 CFR\) Part 35, “Medical Use of Byproduct Material.”](#)

The T&E requirements in Subpart E of 10 CFR Part 35 provide three ways that a physician can be authorized to administer unsealed byproduct materials or radiopharmaceuticals requiring a written directive:

1. A physician can be certified by a medical specialty board, whose certification process is recognized by the NRC or an Agreement State.
2. A physician can complete a structured educational program and supervised work experience under an alternate pathway. This alternate pathway includes a requirement for 700 hours of training and experience, which consists of a minimum of 200 hours of classroom and laboratory training and 500 hours of supervised work experience.
3. A physician can be authorized if previously identified as an authorized user on an NRC or Agreement State license or permit (i.e., grandfathered).

In its evaluation of the T&E requirements, the NRC staff is considering whether an additional pathway should be created or if the alternate pathway should be revised. Specifically, the staff is evaluating: (1) whether it makes sense to establish tailored T&E requirements for different categories of radiopharmaceuticals; (2) how those categories should be determined; (3) what the appropriate T&E requirements would be for each category; and (4) whether those requirements should be based on hours of training and experience, or focused more on competency.

On October 29, 2018, the NRC published a series of questions on T&E in the *Federal Register* (83 FR 54380). The *Federal Register* notice is enclosed with this letter and can also be accessed at: <https://www.gpo.gov/fdsys/pkg/FR-2018-10-29/pdf/2018-23521.pdf>. The NRC will carefully consider responses to these questions and would appreciate your feedback on whether changes to the current T&E regulations are warranted. The comment period for the T&E evaluation will end on January 29, 2019. Please follow the directions in the notice on how to submit written comments. The NRC is using the Federal rulemaking Web site, [Regulations.gov](#), to accept written comments on the docket (NRC-2018-0230).

The NRC will also conduct four public meetings scheduled for November 14 and December 11, 2018, and January 10 and January 22, 2019, and will accept oral comments provided during the meetings. The meetings on December 11 and January 10 will be held at NRC Headquarters in Rockville, MD, and all four meetings will be accessible for remote participation by moderated bridge line and webinar. The NRC's public meeting page has been updated with meeting details and registration instructions for each meeting: <https://www.nrc.gov/pmns/mtg>.

Additional information on the NRC's T&E evaluation can be found at: <https://www.nrc.gov/materials/miau/med-use-toolkit/training-experience-evaluation.html>. If you have any questions on this correspondence, please contact Sarah Lopas of my staff at (301) 415-6360 or Sarah.Lopas@nrc.gov.



Christian Einberg, Chief
Medical Safety and Events Assessment Branch
Division of Materials Safety, Security, State
and Tribal Programs
Office of Nuclear Material Safety
and Safeguards

Enclosure:
Training and Experience
Federal Register notice

NUCLEAR REGULATORY COMMISSION

[NRC-2018-0230]

**Training and Experience Requirements for Different Categories of
Radiopharmaceuticals**

AGENCY: Nuclear Regulatory Commission.

ACTION: Training and experience requirements; request for comment.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is requesting comments on its training and experience (T&E) requirements. Specifically, the NRC would like input on whether it should establish tailored T&E requirements for different categories of radiopharmaceuticals for which a written directive is required in accordance with its regulations. The input will be used to determine whether significant regulatory changes to the NRC's T&E requirements for authorized users (AUs) are warranted.

DATES: Submit comments by January 29, 2019. Comments received after this date will be considered if it is practical to do so, but the NRC is only able to ensure consideration for comments received on or before this date.

ADDRESSES: You may submit comments by any of the following methods:

- **Federal Rulemaking Web Site:** Go to <http://www.regulations.gov>

and search for Docket ID **NRC-2018-0230**. Address questions about Docket IDs in Regulations.gov to Jennifer Borges; telephone: 301-287-9127; e-mail: Jennifer.Borges@nrc.gov. For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.

- **Mail comments to:** May Ma, Office of Administration, Mail Stop: TWFN-7-A60M, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001.

For additional direction on obtaining information and submitting comments, see “Obtaining Information and Submitting Comments” in the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: Sarah Lopas, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001; telephone: 301-415-6360, e-mail: Sarah.Lopas@nrc.gov.

SUPPLEMENTARY INFORMATION:

I. Obtaining Information and Submitting Comments

A. Obtaining Information

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B. Submitting Comments

Please include Docket ID **NRC-2018-0230** in your comment submission.

The NRC cautions you not to include identifying or contact information in comment submissions that you do not want to be publicly disclosed in your comment submission. All comment submissions are posted at <http://www.regulations.gov> and entered into ADAMS. Comment submissions are not routinely edited to remove identifying or contact information.

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II. Background

On August 17, 2017, the Commission issued a staff requirements memorandum (SRM), SRM-M170817 (ADAMS Accession No. ML17229B284), approving the final rule revising parts 30, 32, and 35 of title 10 of the *Code of Federal Regulations* (10 CFR), "Medical Use of Byproduct Material – Medical Event Definitions, Training and Experience, and Clarifying Amendments," and directing the staff to evaluate (1) whether it makes sense to establish tailored T&E requirements for different categories of radiopharmaceuticals, (2) how those categories should be determined (such as by risks posed by groups of

radionuclides or by delivery method), (3) what the appropriate T&E requirements would be for each category, and (4) whether those requirements should be based on hours of T&E or focused more on competency. In response to the SRM, the NRC staff documented its initial results, status, and next steps related to this evaluation in SECY-18-0084, "Staff Evaluation of Training and Experience Requirements for Administering Different Categories of Radiopharmaceuticals in Response to SRM-M170817" (ADAMS Accession No. ML18135A276). In SECY-18-0084, the staff concluded that additional outreach with the medical community is needed to determine whether and how to tailor the T&E requirements to establish a limited AU status, the specific T&E requirements that should apply, how the T&E requirements should be met (e.g., hours of training, demonstration of competency), and whether a competency-based approach makes sense for the T&E requirements for all the medical uses authorized under 10 CFR 35.300, "Use of unsealed byproduct material for which a written directive is required."

The NRC is interested in obtaining input from as many stakeholders as possible, including members of the Advisory Committee on the Medical Uses of Isotopes, professional organizations, physicians, patients, patient advocacy groups, licensees, Agreement States, and other interested individuals. The focus of this request is to gather information that will permit the NRC staff to determine whether changes to the T&E requirements are warranted for different categories of radiopharmaceuticals for physicians seeking AU status for the medical use of specific categories of radiopharmaceuticals requiring a written directive under 10 CFR 35.300.

During the comment period between October 29, 2018 and January 29, 2019, the NRC will hold four public meetings that will discuss the information being requested and to accept comments on the docket. All four public meetings

will be available for remote participation by moderated bridge line and webinar, and two of the four meetings will be open for in-person attendance at NRC's headquarters in Rockville, Maryland.

The public meetings are scheduled for November 14, 2018 (webinar-only); December 11, 2018 (webinar and in-person attendance); January 10, 2019 (webinar and in-person attendance); and January 22, 2019 (webinar-only). The public meetings will be noticed on the NRC's public meeting Web site at least 10 calendar days before the meeting. Members of the public should monitor the NRC's public meeting Web site at <https://www.nrc.gov/pmns/mtg>. The NRC will also post the meeting notices on the Federal Rulemaking Web site at <https://www.regulations.gov/> under Docket ID **NRC-2018-0230**.

The NRC may post additional materials related to this document, including public comments, on the Federal Rulemaking Web site. The Federal Rulemaking Web site allows you to receive alerts when changes or additions occur in a docket folder. To subscribe: (1) Navigate to the docket folder **NRC-2018-0230**; (2) click the “Sign up for E-mail Alerts” link; and (3) enter your email address and select how frequently you would like to receive emails (daily, weekly, or monthly).

III. Specific Requests for Comments

A. Tailored Training & Experience Requirements

The NRC is requesting comments on whether it should establish tailored T&E requirements for different categories of radiopharmaceuticals for physicians seeking AU status for the medical use of specific categories of radiopharmaceuticals requiring a written directive under 10 CFR 35.300 (i.e., a limited AU status). This would be for physicians seeking AU status via the alternate non-board certified pathway, and for physicians certified by a medical

specialty board that is not currently recognized by the NRC under 10 CFR 35.390, 35.392, 35.394, or 35.396 (Unsealed Byproduct Material—Written Directive Required).

1. Are the current pathways for obtaining AU status reasonable and accessible? Provide a rationale for your answer.
2. Are the current pathways for obtaining AU status adequate for protecting public health and safety? Provide a rationale for your answer.
3. Should the NRC develop a new tailored T&E pathway for these physicians? If so, what would be the appropriate way to categorize radiopharmaceuticals for tailored T&E requirements? If not, explain why the regulations should remain unchanged. [Some options to categorize radiopharmaceuticals include radiopharmaceuticals with similar delivery methods (oral, parenteral); same type of radiation characteristics or emission (alpha, beta, gamma, low-energy photon); similar preparation method (patient-ready doses); or a combination thereof (e.g., radiopharmaceuticals containing alpha- and beta-emitting radioisotopes that are administered intravenously and are prepared as patient-ready doses).]
4. Should the fundamental T&E required of physicians seeking limited AU status need to have the same fundamental T&E required of physicians seeking full AU status for all oral and parenteral administrations under 10 CFR 35.300?
5. How should the requirements for this fundamental T&E be structured for a specific category of radiopharmaceuticals?
 - a. Describe what the requirements should include:

- i. Classroom and laboratory training – What topics need to be covered in this training requirement? How many hours of classroom and laboratory training should be required? Provide the basis for the number of hours. If not hours, explain how this training should be quantified. [Note: The topics currently required in the regulations to be included in the classroom and laboratory training and work experience are listed in 10 CFR 35.390, 35.392, 35.394, and 35.396.]
 - ii. Work experience - What should the work experience requirement involve? How many hours of work experience should be required and what is the minimum number of patient or human research subject administrations that an individual must perform? Provide the basis for the number of hours and administrations. What should be the qualifications of the supervising individual?
 - iii. Competency - How should competency be evaluated? Should a written and/or practical examination by an independent examining committee be administered? Provide a rationale for your answer.
- b. Should a preceptor attestation be required for the fundamental T&E? Provide a rationale for your answer.
- c. Should the radiopharmaceutical manufacturer be able to provide the preceptor attestation? Provide a rational for your answer.

- d. Who should establish and administer the curriculum and examination? Provide specific group(s). [Some options are: NRC, medical specialty boards, medical professional societies, educational professional groups, and NRC in collaboration with any or more of the aforementioned groups.]
- e. Should AU competency be periodically assessed? If so, how should it be assessed, how often, and by whom?

B. NRC's Recognition of Medical Specialty Boards

The NRC is requesting comments on its recognition of medical specialty boards. The NRC's procedures for recognizing medical specialty boards are located on the Medical Uses Licensee Toolkit Web site (<https://www.nrc.gov/materials/miau/med-use-toolkit/certif-process-boards.html>). The NRC staff periodically reviews information to determine a board's continued eligibility for recognition.

- 1. What boards other than those already recognized by the NRC (American Board of Nuclear Medicine [ABNM], American Board of Radiology [ABR], American Osteopathic Board of Radiology [AOBR], Certification Board of Nuclear Endocrinology [CBNE]) could be considered for recognition for medical uses under 10 CFR 35.300?
- 2. Are the current NRC medical specialty board recognition criteria sufficient? If not, what additional criteria should the NRC use?

C. Patient Access

The NRC is requesting comments on whether there is a shortage in the number of AUs for 10 CFR 35.300.

1. Is there a shortage in the number of AUs for medical uses under 10 CFR 35.300? If so, is the shortage associated with the use of a specific radiopharmaceutical? Explain how.
2. Are there certain geographic areas with an inadequate number of AUs? Identify these areas.
3. Do current NRC regulations on AU T&E requirements unnecessarily limit patient access to procedures involving radiopharmaceuticals? Explain how.
4. Do current NRC regulations on AU T&E requirements unnecessarily limit research and development in nuclear medicine? Explain how.

D. Other Suggested Changes to the T&E Regulations

In 2002, the NRC revised its regulatory framework for medical use. The goal was to focus the NRC's regulations on those medical procedures that pose the highest risk to workers, the general public, patients, and human research subjects and to structure the regulations to be more risk-informed and more performance-based. The 2002 rule reduced the unnecessary regulatory burden by either reducing or eliminating the prescriptiveness of some regulations. Instead, the rule provided for a performance-based approach that relied on the training and experience of the AUs, authorized nuclear pharmacists, and radiation safety officers. The NRC is requesting comments on whether there are any other changes to the T&E regulations in 10 CFR part 35 that should be considered. Please discuss your suggested changes.

1. Should the NRC regulate the T&E of physicians for medical uses?
2. Are there requirements in the NRC's T&E regulatory framework for physicians that are non-safety related?

3. How can the NRC transform its regulatory approach for T&E while still ensuring that adequate protection is maintained for workers, the general public, patients, and human research subjects?

Dated at Rockville, Maryland, this 23rd day of October 2018.

For the Nuclear Regulatory
Commission.

/RA/

Daniel S. Collins, Director,
Division of Materials Safety,
Security,
State, and Tribal Programs,
Office of Nuclear Material Safety
and Safeguards.



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

November 2, 2018

American Thyroid Association
6606 Leesburg Pike, Suite 550
Falls Church, VA 22401

Via e-mail to thyroid@thyroid.org

SUBJECT: TRAINING AND EXPERIENCE REQUIREMENTS FOR DIFFERENT CATEGORIES OF RADIOPHARMACEUTICALS

Dear Sir or Madam,

The U.S. Nuclear Regulatory Commission (NRC) is evaluating its regulations related to the training and experience (T&E) required for a physician to become an authorized user for medical uses under Subpart E, “Unsealed Byproduct Material—Written Directive Required,” of [Title 10 of the Code of Federal Regulations \(10 CFR\) Part 35, “Medical Use of Byproduct Material.”](#)

The T&E requirements in Subpart E of 10 CFR Part 35 provide three ways that a physician can be authorized to administer unsealed byproduct materials or radiopharmaceuticals requiring a written directive:

1. A physician can be certified by a medical specialty board, whose certification process is recognized by the NRC or an Agreement State.
2. A physician can complete a structured educational program and supervised work experience under an alternate pathway. This alternate pathway includes a requirement for 700 hours of training and experience, which consists of a minimum of 200 hours of classroom and laboratory training and 500 hours of supervised work experience.
3. A physician can be authorized if previously identified as an authorized user on an NRC or Agreement State license or permit (i.e., grandfathered).

In its evaluation of the T&E requirements, the NRC staff is considering whether an additional pathway should be created or if the alternate pathway should be revised. Specifically, the staff is evaluating: (1) whether it makes sense to establish tailored T&E requirements for different categories of radiopharmaceuticals; (2) how those categories should be determined; (3) what the appropriate T&E requirements would be for each category; and (4) whether those requirements should be based on hours of training and experience, or focused more on competency.

On October 29, 2018, the NRC published a series of questions on T&E in the *Federal Register* (83 FR 54380). The *Federal Register* notice is enclosed with this letter and can also be accessed at: <https://www.gpo.gov/fdsys/pkg/FR-2018-10-29/pdf/2018-23521.pdf>. The NRC will carefully consider responses to these questions and would appreciate your feedback on whether changes to the current T&E regulations are warranted. The comment period for the T&E evaluation will end on January 29, 2019. Please follow the directions in the notice on how to submit written comments. The NRC is using the Federal rulemaking Web site, [Regulations.gov](#), to accept written comments on the docket (NRC-2018-0230).

The NRC will also conduct four public meetings scheduled for November 14 and December 11, 2018, and January 10 and January 22, 2019, and will accept oral comments provided during the meetings. The meetings on December 11 and January 10 will be held at NRC Headquarters in Rockville, MD, and all four meetings will be accessible for remote participation by moderated bridge line and webinar. The NRC's public meeting page has been updated with meeting details and registration instructions for each meeting: <https://www.nrc.gov/pmns/mtg>.

Additional information on the NRC's T&E evaluation can be found at: <https://www.nrc.gov/materials/miau/med-use-toolkit/training-experience-evaluation.html>. If you have any questions on this correspondence, please contact Sarah Lopas of my staff at (301) 415-6360 or Sarah.Lopas@nrc.gov.



Christian Einberg, Chief
Medical Safety and Events Assessment Branch
Division of Materials Safety, Security, State
and Tribal Programs
Office of Nuclear Material Safety
and Safeguards

Enclosure:
Training and Experience
Federal Register notice

NUCLEAR REGULATORY COMMISSION

[NRC-2018-0230]

**Training and Experience Requirements for Different Categories of
Radiopharmaceuticals**

AGENCY: Nuclear Regulatory Commission.

ACTION: Training and experience requirements; request for comment.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is requesting comments on its training and experience (T&E) requirements. Specifically, the NRC would like input on whether it should establish tailored T&E requirements for different categories of radiopharmaceuticals for which a written directive is required in accordance with its regulations. The input will be used to determine whether significant regulatory changes to the NRC's T&E requirements for authorized users (AUs) are warranted.

DATES: Submit comments by January 29, 2019. Comments received after this date will be considered if it is practical to do so, but the NRC is only able to ensure consideration for comments received on or before this date.

ADDRESSES: You may submit comments by any of the following methods:

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For additional direction on obtaining information and submitting comments, see “Obtaining Information and Submitting Comments” in the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: Sarah Lopas, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001; telephone: 301-415-6360, e-mail: Sarah.Lopas@nrc.gov.

SUPPLEMENTARY INFORMATION:

I. Obtaining Information and Submitting Comments

A. Obtaining Information

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III. Specific Requests for Comments

A. Tailored Training & Experience Requirements

The NRC is requesting comments on whether it should establish tailored T&E requirements for different categories of radiopharmaceuticals for physicians seeking AU status for the medical use of specific categories of radiopharmaceuticals requiring a written directive under 10 CFR 35.300 (i.e., a limited AU status). This would be for physicians seeking AU status via the alternate non-board certified pathway, and for physicians certified by a medical

NUCLEAR REGULATORY COMMISSION

[NRC-2018-0230]

**Training and Experience Requirements for Different Categories of
Radiopharmaceuticals**

AGENCY: Nuclear Regulatory Commission.

ACTION: Training and experience requirements; request for comment.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is requesting comments on its training and experience (T&E) requirements. Specifically, the NRC would like input on whether it should establish tailored T&E requirements for different categories of radiopharmaceuticals for which a written directive is required in accordance with its regulations. The input will be used to determine whether significant regulatory changes to the NRC's T&E requirements for authorized users (AUs) are warranted.

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The NRC is interested in obtaining input from as many stakeholders as possible, including members of the Advisory Committee on the Medical Uses of Isotopes, professional organizations, physicians, patients, patient advocacy groups, licensees, Agreement States, and other interested individuals. The focus of this request is to gather information that will permit the NRC staff to determine whether changes to the T&E requirements are warranted for different categories of radiopharmaceuticals for physicians seeking AU status for the medical use of specific categories of radiopharmaceuticals requiring a written directive under 10 CFR 35.300.

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A. Tailored Training & Experience Requirements

The NRC is requesting comments on whether it should establish tailored T&E requirements for different categories of radiopharmaceuticals for physicians seeking AU status for the medical use of specific categories of radiopharmaceuticals requiring a written directive under 10 CFR 35.300 (i.e., a limited AU status). This would be for physicians seeking AU status via the alternate non-board certified pathway, and for physicians certified by a medical

specialty board that is not currently recognized by the NRC under 10 CFR 35.390, 35.392, 35.394, or 35.396 (Unsealed Byproduct Material—Written Directive Required).

1. Are the current pathways for obtaining AU status reasonable and accessible? Provide a rationale for your answer.
2. Are the current pathways for obtaining AU status adequate for protecting public health and safety? Provide a rationale for your answer.
3. Should the NRC develop a new tailored T&E pathway for these physicians? If so, what would be the appropriate way to categorize radiopharmaceuticals for tailored T&E requirements? If not, explain why the regulations should remain unchanged. [Some options to categorize radiopharmaceuticals include radiopharmaceuticals with similar delivery methods (oral, parenteral); same type of radiation characteristics or emission (alpha, beta, gamma, low-energy photon); similar preparation method (patient-ready doses); or a combination thereof (e.g., radiopharmaceuticals containing alpha- and beta-emitting radioisotopes that are administered intravenously and are prepared as patient-ready doses).]
4. Should the fundamental T&E required of physicians seeking limited AU status need to have the same fundamental T&E required of physicians seeking full AU status for all oral and parenteral administrations under 10 CFR 35.300?
5. How should the requirements for this fundamental T&E be structured for a specific category of radiopharmaceuticals?
 - a. Describe what the requirements should include:

- i. Classroom and laboratory training – What topics need to be covered in this training requirement? How many hours of classroom and laboratory training should be required? Provide the basis for the number of hours. If not hours, explain how this training should be quantified. [Note: The topics currently required in the regulations to be included in the classroom and laboratory training and work experience are listed in 10 CFR 35.390, 35.392, 35.394, and 35.396.]
 - ii. Work experience - What should the work experience requirement involve? How many hours of work experience should be required and what is the minimum number of patient or human research subject administrations that an individual must perform? Provide the basis for the number of hours and administrations. What should be the qualifications of the supervising individual?
 - iii. Competency - How should competency be evaluated? Should a written and/or practical examination by an independent examining committee be administered? Provide a rationale for your answer.
- b. Should a preceptor attestation be required for the fundamental T&E? Provide a rationale for your answer.
- c. Should the radiopharmaceutical manufacturer be able to provide the preceptor attestation? Provide a rational for your answer.

- d. Who should establish and administer the curriculum and examination? Provide specific group(s). [Some options are: NRC, medical specialty boards, medical professional societies, educational professional groups, and NRC in collaboration with any or more of the aforementioned groups.]
- e. Should AU competency be periodically assessed? If so, how should it be assessed, how often, and by whom?

B. NRC's Recognition of Medical Specialty Boards

The NRC is requesting comments on its recognition of medical specialty boards. The NRC's procedures for recognizing medical specialty boards are located on the Medical Uses Licensee Toolkit Web site (<https://www.nrc.gov/materials/miau/med-use-toolkit/certif-process-boards.html>). The NRC staff periodically reviews information to determine a board's continued eligibility for recognition.

- 1. What boards other than those already recognized by the NRC (American Board of Nuclear Medicine [ABNM], American Board of Radiology [ABR], American Osteopathic Board of Radiology [AOBR], Certification Board of Nuclear Endocrinology [CBNE]) could be considered for recognition for medical uses under 10 CFR 35.300?
- 2. Are the current NRC medical specialty board recognition criteria sufficient? If not, what additional criteria should the NRC use?

C. Patient Access

The NRC is requesting comments on whether there is a shortage in the number of AUs for 10 CFR 35.300.

1. Is there a shortage in the number of AUs for medical uses under 10 CFR 35.300? If so, is the shortage associated with the use of a specific radiopharmaceutical? Explain how.
2. Are there certain geographic areas with an inadequate number of AUs? Identify these areas.
3. Do current NRC regulations on AU T&E requirements unnecessarily limit patient access to procedures involving radiopharmaceuticals? Explain how.
4. Do current NRC regulations on AU T&E requirements unnecessarily limit research and development in nuclear medicine? Explain how.

D. Other Suggested Changes to the T&E Regulations

In 2002, the NRC revised its regulatory framework for medical use. The goal was to focus the NRC's regulations on those medical procedures that pose the highest risk to workers, the general public, patients, and human research subjects and to structure the regulations to be more risk-informed and more performance-based. The 2002 rule reduced the unnecessary regulatory burden by either reducing or eliminating the prescriptiveness of some regulations. Instead, the rule provided for a performance-based approach that relied on the training and experience of the AUs, authorized nuclear pharmacists, and radiation safety officers. The NRC is requesting comments on whether there are any other changes to the T&E regulations in 10 CFR part 35 that should be considered. Please discuss your suggested changes.

1. Should the NRC regulate the T&E of physicians for medical uses?
2. Are there requirements in the NRC's T&E regulatory framework for physicians that are non-safety related?

3. How can the NRC transform its regulatory approach for T&E while still ensuring that adequate protection is maintained for workers, the general public, patients, and human research subjects?

Dated at Rockville, Maryland, this 23rd day of October 2018.

For the Nuclear Regulatory
Commission.

/RA/

Daniel S. Collins, Director,
Division of Materials Safety,
Security,
State, and Tribal Programs,
Office of Nuclear Material Safety
and Safeguards.

NUCLEAR REGULATORY COMMISSION

[NRC-2018-0230]

**Training and Experience Requirements for Different Categories of
Radiopharmaceuticals**

AGENCY: Nuclear Regulatory Commission.

ACTION: Training and experience requirements; request for comment.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is requesting comments on its training and experience (T&E) requirements. Specifically, the NRC would like input on whether it should establish tailored T&E requirements for different categories of radiopharmaceuticals for which a written directive is required in accordance with its regulations. The input will be used to determine whether significant regulatory changes to the NRC's T&E requirements for authorized users (AUs) are warranted.

DATES: Submit comments by January 29, 2019. Comments received after this date will be considered if it is practical to do so, but the NRC is only able to ensure consideration for comments received on or before this date.

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NUCLEAR REGULATORY COMMISSION

[NRC-2018-0230]

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III. Specific Requests for Comments

A. Tailored Training & Experience Requirements

The NRC is requesting comments on whether it should establish tailored T&E requirements for different categories of radiopharmaceuticals for physicians seeking AU status for the medical use of specific categories of radiopharmaceuticals requiring a written directive under 10 CFR 35.300 (i.e., a limited AU status). This would be for physicians seeking AU status via the alternate non-board certified pathway, and for physicians certified by a medical

specialty board that is not currently recognized by the NRC under 10 CFR 35.390, 35.392, 35.394, or 35.396 (Unsealed Byproduct Material—Written Directive Required).

1. Are the current pathways for obtaining AU status reasonable and accessible? Provide a rationale for your answer.
2. Are the current pathways for obtaining AU status adequate for protecting public health and safety? Provide a rationale for your answer.
3. Should the NRC develop a new tailored T&E pathway for these physicians? If so, what would be the appropriate way to categorize radiopharmaceuticals for tailored T&E requirements? If not, explain why the regulations should remain unchanged. [Some options to categorize radiopharmaceuticals include radiopharmaceuticals with similar delivery methods (oral, parenteral); same type of radiation characteristics or emission (alpha, beta, gamma, low-energy photon); similar preparation method (patient-ready doses); or a combination thereof (e.g., radiopharmaceuticals containing alpha- and beta-emitting radioisotopes that are administered intravenously and are prepared as patient-ready doses).]
4. Should the fundamental T&E required of physicians seeking limited AU status need to have the same fundamental T&E required of physicians seeking full AU status for all oral and parenteral administrations under 10 CFR 35.300?
5. How should the requirements for this fundamental T&E be structured for a specific category of radiopharmaceuticals?
 - a. Describe what the requirements should include:

specialty board that is not currently recognized by the NRC under 10 CFR 35.390, 35.392, 35.394, or 35.396 (Unsealed Byproduct Material—Written Directive Required).

1. Are the current pathways for obtaining AU status reasonable and accessible? Provide a rationale for your answer.
2. Are the current pathways for obtaining AU status adequate for protecting public health and safety? Provide a rationale for your answer.
3. Should the NRC develop a new tailored T&E pathway for these physicians? If so, what would be the appropriate way to categorize radiopharmaceuticals for tailored T&E requirements? If not, explain why the regulations should remain unchanged. [Some options to categorize radiopharmaceuticals include radiopharmaceuticals with similar delivery methods (oral, parenteral); same type of radiation characteristics or emission (alpha, beta, gamma, low-energy photon); similar preparation method (patient-ready doses); or a combination thereof (e.g., radiopharmaceuticals containing alpha- and beta-emitting radioisotopes that are administered intravenously and are prepared as patient-ready doses).]
4. Should the fundamental T&E required of physicians seeking limited AU status need to have the same fundamental T&E required of physicians seeking full AU status for all oral and parenteral administrations under 10 CFR 35.300?
5. How should the requirements for this fundamental T&E be structured for a specific category of radiopharmaceuticals?
 - a. Describe what the requirements should include:

- i. Classroom and laboratory training – What topics need to be covered in this training requirement? How many hours of classroom and laboratory training should be required? Provide the basis for the number of hours. If not hours, explain how this training should be quantified. [Note: The topics currently required in the regulations to be included in the classroom and laboratory training and work experience are listed in 10 CFR 35.390, 35.392, 35.394, and 35.396.]
 - ii. Work experience - What should the work experience requirement involve? How many hours of work experience should be required and what is the minimum number of patient or human research subject administrations that an individual must perform? Provide the basis for the number of hours and administrations. What should be the qualifications of the supervising individual?
 - iii. Competency - How should competency be evaluated? Should a written and/or practical examination by an independent examining committee be administered? Provide a rationale for your answer.
- b. Should a preceptor attestation be required for the fundamental T&E? Provide a rationale for your answer.
- c. Should the radiopharmaceutical manufacturer be able to provide the preceptor attestation? Provide a rational for your answer.

- d. Who should establish and administer the curriculum and examination? Provide specific group(s). [Some options are: NRC, medical specialty boards, medical professional societies, educational professional groups, and NRC in collaboration with any or more of the aforementioned groups.]
- e. Should AU competency be periodically assessed? If so, how should it be assessed, how often, and by whom?

B. NRC's Recognition of Medical Specialty Boards

The NRC is requesting comments on its recognition of medical specialty boards. The NRC's procedures for recognizing medical specialty boards are located on the Medical Uses Licensee Toolkit Web site (<https://www.nrc.gov/materials/miau/med-use-toolkit/certif-process-boards.html>). The NRC staff periodically reviews information to determine a board's continued eligibility for recognition.

- 1. What boards other than those already recognized by the NRC (American Board of Nuclear Medicine [ABNM], American Board of Radiology [ABR], American Osteopathic Board of Radiology [AOBR], Certification Board of Nuclear Endocrinology [CBNE]) could be considered for recognition for medical uses under 10 CFR 35.300?
- 2. Are the current NRC medical specialty board recognition criteria sufficient? If not, what additional criteria should the NRC use?

C. Patient Access

The NRC is requesting comments on whether there is a shortage in the number of AUs for 10 CFR 35.300.

1. Is there a shortage in the number of AUs for medical uses under 10 CFR 35.300? If so, is the shortage associated with the use of a specific radiopharmaceutical? Explain how.
2. Are there certain geographic areas with an inadequate number of AUs? Identify these areas.
3. Do current NRC regulations on AU T&E requirements unnecessarily limit patient access to procedures involving radiopharmaceuticals? Explain how.
4. Do current NRC regulations on AU T&E requirements unnecessarily limit research and development in nuclear medicine? Explain how.

D. Other Suggested Changes to the T&E Regulations

In 2002, the NRC revised its regulatory framework for medical use. The goal was to focus the NRC's regulations on those medical procedures that pose the highest risk to workers, the general public, patients, and human research subjects and to structure the regulations to be more risk-informed and more performance-based. The 2002 rule reduced the unnecessary regulatory burden by either reducing or eliminating the prescriptiveness of some regulations. Instead, the rule provided for a performance-based approach that relied on the training and experience of the AUs, authorized nuclear pharmacists, and radiation safety officers. The NRC is requesting comments on whether there are any other changes to the T&E regulations in 10 CFR part 35 that should be considered. Please discuss your suggested changes.

1. Should the NRC regulate the T&E of physicians for medical uses?
2. Are there requirements in the NRC's T&E regulatory framework for physicians that are non-safety related?

3. How can the NRC transform its regulatory approach for T&E while still ensuring that adequate protection is maintained for workers, the general public, patients, and human research subjects?

Dated at Rockville, Maryland, this 23rd day of October 2018.

For the Nuclear Regulatory
Commission.

/RA/

Daniel S. Collins, Director,
Division of Materials Safety,
Security,
State, and Tribal Programs,
Office of Nuclear Material Safety
and Safeguards.



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

November 2, 2018

American Nurses Association
8515 Georgia Avenue, Suite 400
Silver Spring, MD 20910-3492

Via e-mail to customerservice@ana.org

SUBJECT: TRAINING AND EXPERIENCE REQUIREMENTS FOR DIFFERENT CATEGORIES OF RADIOPHARMACEUTICALS

Dear Sir or Madam,

The U.S. Nuclear Regulatory Commission (NRC) is evaluating its regulations related to the training and experience (T&E) required for a physician to become an authorized user for medical uses under Subpart E, “Unsealed Byproduct Material—Written Directive Required,” of [Title 10 of the Code of Federal Regulations \(10 CFR\) Part 35, “Medical Use of Byproduct Material.”](#)

The T&E requirements in Subpart E of 10 CFR Part 35 provide three ways that a physician can be authorized to administer unsealed byproduct materials or radiopharmaceuticals requiring a written directive:

1. A physician can be certified by a medical specialty board, whose certification process is recognized by the NRC or an Agreement State.
2. A physician can complete a structured educational program and supervised work experience under an alternate pathway. This alternate pathway includes a requirement for 700 hours of training and experience, which consists of a minimum of 200 hours of classroom and laboratory training and 500 hours of supervised work experience.
3. A physician can be authorized if previously identified as an authorized user on an NRC or Agreement State license or permit (i.e., grandfathered).

In its evaluation of the T&E requirements, the NRC staff is considering whether an additional pathway should be created or if the alternate pathway should be revised. Specifically, the staff is evaluating: (1) whether it makes sense to establish tailored T&E requirements for different categories of radiopharmaceuticals; (2) how those categories should be determined; (3) what the appropriate T&E requirements would be for each category; and (4) whether those requirements should be based on hours of training and experience, or focused more on competency.

On October 29, 2018, the NRC published a series of questions on T&E in the *Federal Register* (83 FR 54380). The *Federal Register* notice is enclosed with this letter and can also be accessed at: <https://www.gpo.gov/fdsys/pkg/FR-2018-10-29/pdf/2018-23521.pdf>. The NRC will carefully consider responses to these questions and would appreciate your feedback on whether changes to the current T&E regulations are warranted. The comment period for the T&E evaluation will end on January 29, 2019. Please follow the directions in the notice on how to submit written comments. The NRC is using the Federal rulemaking Web site, [Regulations.gov](#), to accept written comments on the docket (NRC-2018-0230).

The NRC will also conduct four public meetings scheduled for November 14 and December 11, 2018, and January 10 and January 22, 2019, and will accept oral comments provided during the meetings. The meetings on December 11 and January 10 will be held at NRC Headquarters in Rockville, MD, and all four meetings will be accessible for remote participation by moderated bridge line and webinar. The NRC's public meeting page has been updated with meeting details and registration instructions for each meeting: <https://www.nrc.gov/pmns/mtg>.

Additional information on the NRC's T&E evaluation can be found at: <https://www.nrc.gov/materials/miau/med-use-toolkit/training-experience-evaluation.html>. If you have any questions on this correspondence, please contact Sarah Lopas of my staff at (301) 415-6360 or Sarah.Lopas@nrc.gov.



Christian Einberg, Chief
Medical Safety and Events Assessment Branch
Division of Materials Safety, Security, State
and Tribal Programs
Office of Nuclear Material Safety
and Safeguards

Enclosure:
Training and Experience
Federal Register notice

NUCLEAR REGULATORY COMMISSION

[NRC-2018-0230]

**Training and Experience Requirements for Different Categories of
Radiopharmaceuticals**

AGENCY: Nuclear Regulatory Commission.

ACTION: Training and experience requirements; request for comment.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is requesting comments on its training and experience (T&E) requirements. Specifically, the NRC would like input on whether it should establish tailored T&E requirements for different categories of radiopharmaceuticals for which a written directive is required in accordance with its regulations. The input will be used to determine whether significant regulatory changes to the NRC's T&E requirements for authorized users (AUs) are warranted.

DATES: Submit comments by January 29, 2019. Comments received after this date will be considered if it is practical to do so, but the NRC is only able to ensure consideration for comments received on or before this date.

ADDRESSES: You may submit comments by any of the following methods:

- **Federal Rulemaking Web Site:** Go to <http://www.regulations.gov>

and search for Docket ID **NRC-2018-0230**. Address questions about Docket IDs in Regulations.gov to Jennifer Borges; telephone: 301-287-9127; e-mail: Jennifer.Borges@nrc.gov. For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.

- **Mail comments to:** May Ma, Office of Administration, Mail Stop: TWFN-7-A60M, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001.

For additional direction on obtaining information and submitting comments, see “Obtaining Information and Submitting Comments” in the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: Sarah Lopas, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001; telephone: 301-415-6360, e-mail: Sarah.Lopas@nrc.gov.

SUPPLEMENTARY INFORMATION:

I. Obtaining Information and Submitting Comments

A. Obtaining Information

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- **NRC's PDR:** You may examine and purchase copies of public documents at the NRC's PDR, Room O1-F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.

B. Submitting Comments

Please include Docket ID **NRC-2018-0230** in your comment submission.

The NRC cautions you not to include identifying or contact information in comment submissions that you do not want to be publicly disclosed in your comment submission. All comment submissions are posted at <http://www.regulations.gov> and entered into ADAMS. Comment submissions are not routinely edited to remove identifying or contact information.

If you are requesting or aggregating comments from other persons for submission to the NRC, then you should inform those persons not to include identifying or contact information that they do not want to be publicly disclosed in their comment submission. Your request should state that the NRC does not routinely edit comment submissions to remove such information before making the comment submissions available to the public or entering the comment into ADAMS.

II. Background

On August 17, 2017, the Commission issued a staff requirements memorandum (SRM), SRM-M170817 (ADAMS Accession No. ML17229B284), approving the final rule revising parts 30, 32, and 35 of title 10 of the *Code of Federal Regulations* (10 CFR), "Medical Use of Byproduct Material – Medical Event Definitions, Training and Experience, and Clarifying Amendments," and directing the staff to evaluate (1) whether it makes sense to establish tailored T&E requirements for different categories of radiopharmaceuticals, (2) how those categories should be determined (such as by risks posed by groups of

radionuclides or by delivery method), (3) what the appropriate T&E requirements would be for each category, and (4) whether those requirements should be based on hours of T&E or focused more on competency. In response to the SRM, the NRC staff documented its initial results, status, and next steps related to this evaluation in SECY-18-0084, "Staff Evaluation of Training and Experience Requirements for Administering Different Categories of Radiopharmaceuticals in Response to SRM-M170817" (ADAMS Accession No. ML18135A276). In SECY-18-0084, the staff concluded that additional outreach with the medical community is needed to determine whether and how to tailor the T&E requirements to establish a limited AU status, the specific T&E requirements that should apply, how the T&E requirements should be met (e.g., hours of training, demonstration of competency), and whether a competency-based approach makes sense for the T&E requirements for all the medical uses authorized under 10 CFR 35.300, "Use of unsealed byproduct material for which a written directive is required."

The NRC is interested in obtaining input from as many stakeholders as possible, including members of the Advisory Committee on the Medical Uses of Isotopes, professional organizations, physicians, patients, patient advocacy groups, licensees, Agreement States, and other interested individuals. The focus of this request is to gather information that will permit the NRC staff to determine whether changes to the T&E requirements are warranted for different categories of radiopharmaceuticals for physicians seeking AU status for the medical use of specific categories of radiopharmaceuticals requiring a written directive under 10 CFR 35.300.

During the comment period between October 29, 2018 and January 29, 2019, the NRC will hold four public meetings that will discuss the information being requested and to accept comments on the docket. All four public meetings

will be available for remote participation by moderated bridge line and webinar, and two of the four meetings will be open for in-person attendance at NRC's headquarters in Rockville, Maryland.

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III. Specific Requests for Comments

A. Tailored Training & Experience Requirements

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specialty board that is not currently recognized by the NRC under 10 CFR 35.390, 35.392, 35.394, or 35.396 (Unsealed Byproduct Material—Written Directive Required).

1. Are the current pathways for obtaining AU status reasonable and accessible? Provide a rationale for your answer.
2. Are the current pathways for obtaining AU status adequate for protecting public health and safety? Provide a rationale for your answer.
3. Should the NRC develop a new tailored T&E pathway for these physicians? If so, what would be the appropriate way to categorize radiopharmaceuticals for tailored T&E requirements? If not, explain why the regulations should remain unchanged. [Some options to categorize radiopharmaceuticals include radiopharmaceuticals with similar delivery methods (oral, parenteral); same type of radiation characteristics or emission (alpha, beta, gamma, low-energy photon); similar preparation method (patient-ready doses); or a combination thereof (e.g., radiopharmaceuticals containing alpha- and beta-emitting radioisotopes that are administered intravenously and are prepared as patient-ready doses).]
4. Should the fundamental T&E required of physicians seeking limited AU status need to have the same fundamental T&E required of physicians seeking full AU status for all oral and parenteral administrations under 10 CFR 35.300?
5. How should the requirements for this fundamental T&E be structured for a specific category of radiopharmaceuticals?
 - a. Describe what the requirements should include:

- i. Classroom and laboratory training – What topics need to be covered in this training requirement? How many hours of classroom and laboratory training should be required? Provide the basis for the number of hours. If not hours, explain how this training should be quantified. [Note: The topics currently required in the regulations to be included in the classroom and laboratory training and work experience are listed in 10 CFR 35.390, 35.392, 35.394, and 35.396.]
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 - iii. Competency - How should competency be evaluated? Should a written and/or practical examination by an independent examining committee be administered? Provide a rationale for your answer.
- b. Should a preceptor attestation be required for the fundamental T&E? Provide a rationale for your answer.
- c. Should the radiopharmaceutical manufacturer be able to provide the preceptor attestation? Provide a rational for your answer.

- d. Who should establish and administer the curriculum and examination? Provide specific group(s). [Some options are: NRC, medical specialty boards, medical professional societies, educational professional groups, and NRC in collaboration with any or more of the aforementioned groups.]
- e. Should AU competency be periodically assessed? If so, how should it be assessed, how often, and by whom?

B. NRC's Recognition of Medical Specialty Boards

The NRC is requesting comments on its recognition of medical specialty boards. The NRC's procedures for recognizing medical specialty boards are located on the Medical Uses Licensee Toolkit Web site (<https://www.nrc.gov/materials/miau/med-use-toolkit/certif-process-boards.html>). The NRC staff periodically reviews information to determine a board's continued eligibility for recognition.

- 1. What boards other than those already recognized by the NRC (American Board of Nuclear Medicine [ABNM], American Board of Radiology [ABR], American Osteopathic Board of Radiology [AOBR], Certification Board of Nuclear Endocrinology [CBNE]) could be considered for recognition for medical uses under 10 CFR 35.300?
- 2. Are the current NRC medical specialty board recognition criteria sufficient? If not, what additional criteria should the NRC use?

C. Patient Access

The NRC is requesting comments on whether there is a shortage in the number of AUs for 10 CFR 35.300.

1. Is there a shortage in the number of AUs for medical uses under 10 CFR 35.300? If so, is the shortage associated with the use of a specific radiopharmaceutical? Explain how.
2. Are there certain geographic areas with an inadequate number of AUs? Identify these areas.
3. Do current NRC regulations on AU T&E requirements unnecessarily limit patient access to procedures involving radiopharmaceuticals? Explain how.
4. Do current NRC regulations on AU T&E requirements unnecessarily limit research and development in nuclear medicine? Explain how.

D. Other Suggested Changes to the T&E Regulations

In 2002, the NRC revised its regulatory framework for medical use. The goal was to focus the NRC's regulations on those medical procedures that pose the highest risk to workers, the general public, patients, and human research subjects and to structure the regulations to be more risk-informed and more performance-based. The 2002 rule reduced the unnecessary regulatory burden by either reducing or eliminating the prescriptiveness of some regulations. Instead, the rule provided for a performance-based approach that relied on the training and experience of the AUs, authorized nuclear pharmacists, and radiation safety officers. The NRC is requesting comments on whether there are any other changes to the T&E regulations in 10 CFR part 35 that should be considered. Please discuss your suggested changes.

1. Should the NRC regulate the T&E of physicians for medical uses?
2. Are there requirements in the NRC's T&E regulatory framework for physicians that are non-safety related?

3. How can the NRC transform its regulatory approach for T&E while still ensuring that adequate protection is maintained for workers, the general public, patients, and human research subjects?

Dated at Rockville, Maryland, this 23rd day of October 2018.

For the Nuclear Regulatory
Commission.

/RA/

Daniel S. Collins, Director,
Division of Materials Safety,
Security,
State, and Tribal Programs,
Office of Nuclear Material Safety
and Safeguards.



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

November 2, 2018

Mr. Richard Anderson, BS, RRPT
Radiation Safety Office, UC Health
University of Cincinnati Medical Center
234 Goodman St.
Cincinnati, Oh 45219

Via e-mail to Richard.Anderson@UCHealth.com

SUBJECT: TRAINING AND EXPERIENCE REQUIREMENTS FOR DIFFERENT CATEGORIES OF RADIOPHARMACEUTICALS

Dear Mr. Anderson,

The U.S. Nuclear Regulatory Commission (NRC) is evaluating its regulations related to the training and experience (T&E) required for a physician to become an authorized user for medical uses under Subpart E, “Unsealed Byproduct Material—Written Directive Required,” of [Title 10 of the Code of Federal Regulations \(10 CFR\) Part 35, “Medical Use of Byproduct Material.”](#)

The T&E requirements in Subpart E of 10 CFR Part 35 provide three ways that a physician can be authorized to administer unsealed byproduct materials or radiopharmaceuticals requiring a written directive:

1. A physician can be certified by a medical specialty board, whose certification process is recognized by the NRC or an Agreement State.
2. A physician can complete a structured educational program and supervised work experience under an alternate pathway. This alternate pathway includes a requirement for 700 hours of training and experience, which consists of a minimum of 200 hours of classroom and laboratory training and 500 hours of supervised work experience.
3. A physician can be authorized if previously identified as an authorized user on an NRC or Agreement State license or permit (i.e., grandfathered).

In its evaluation of the T&E requirements, the NRC staff is considering whether an additional pathway should be created or if the alternate pathway should be revised. Specifically, the staff is evaluating: (1) whether it makes sense to establish tailored T&E requirements for different categories of radiopharmaceuticals; (2) how those categories should be determined; (3) what the appropriate T&E requirements would be for each category; and (4) whether those requirements should be based on hours of training and experience, or focused more on competency.

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Additional information on the NRC's T&E evaluation can be found at: <https://www.nrc.gov/materials/miau/med-use-toolkit/training-experience-evaluation.html>. If you have any questions on this correspondence, please contact Sarah Lopas of my staff at (301) 415-6360 or Sarah.Lopas@nrc.gov.

A handwritten signature in black ink, appearing to read "C Einberg".

Christian Einberg, Chief
Medical Safety and Events Assessment Branch
Division of Materials Safety, Security, State
and Tribal Programs
Office of Nuclear Material Safety
and Safeguards

Enclosure:
Training and Experience
Federal Register notice

NUCLEAR REGULATORY COMMISSION

[NRC-2018-0230]

**Training and Experience Requirements for Different Categories of
Radiopharmaceuticals**

AGENCY: Nuclear Regulatory Commission.

ACTION: Training and experience requirements; request for comment.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is requesting comments on its training and experience (T&E) requirements. Specifically, the NRC would like input on whether it should establish tailored T&E requirements for different categories of radiopharmaceuticals for which a written directive is required in accordance with its regulations. The input will be used to determine whether significant regulatory changes to the NRC's T&E requirements for authorized users (AUs) are warranted.

DATES: Submit comments by January 29, 2019. Comments received after this date will be considered if it is practical to do so, but the NRC is only able to ensure consideration for comments received on or before this date.

ADDRESSES: You may submit comments by any of the following methods:

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and search for Docket ID **NRC-2018-0230**. Address questions about Docket IDs in Regulations.gov to Jennifer Borges; telephone: 301-287-9127; e-mail: Jennifer.Borges@nrc.gov. For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.

- **Mail comments to:** May Ma, Office of Administration, Mail Stop: TWFN-7-A60M, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001.

For additional direction on obtaining information and submitting comments, see “Obtaining Information and Submitting Comments” in the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: Sarah Lopas, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001; telephone: 301-415-6360, e-mail: Sarah.Lopas@nrc.gov.

SUPPLEMENTARY INFORMATION:

I. Obtaining Information and Submitting Comments

A. Obtaining Information

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radionuclides or by delivery method), (3) what the appropriate T&E requirements would be for each category, and (4) whether those requirements should be based on hours of T&E or focused more on competency. In response to the SRM, the NRC staff documented its initial results, status, and next steps related to this evaluation in SECY-18-0084, "Staff Evaluation of Training and Experience Requirements for Administering Different Categories of Radiopharmaceuticals in Response to SRM-M170817" (ADAMS Accession No. ML18135A276). In SECY-18-0084, the staff concluded that additional outreach with the medical community is needed to determine whether and how to tailor the T&E requirements to establish a limited AU status, the specific T&E requirements that should apply, how the T&E requirements should be met (e.g., hours of training, demonstration of competency), and whether a competency-based approach makes sense for the T&E requirements for all the medical uses authorized under 10 CFR 35.300, "Use of unsealed byproduct material for which a written directive is required."

The NRC is interested in obtaining input from as many stakeholders as possible, including members of the Advisory Committee on the Medical Uses of Isotopes, professional organizations, physicians, patients, patient advocacy groups, licensees, Agreement States, and other interested individuals. The focus of this request is to gather information that will permit the NRC staff to determine whether changes to the T&E requirements are warranted for different categories of radiopharmaceuticals for physicians seeking AU status for the medical use of specific categories of radiopharmaceuticals requiring a written directive under 10 CFR 35.300.

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III. Specific Requests for Comments

A. Tailored Training & Experience Requirements

The NRC is requesting comments on whether it should establish tailored T&E requirements for different categories of radiopharmaceuticals for physicians seeking AU status for the medical use of specific categories of radiopharmaceuticals requiring a written directive under 10 CFR 35.300 (i.e., a limited AU status). This would be for physicians seeking AU status via the alternate non-board certified pathway, and for physicians certified by a medical

specialty board that is not currently recognized by the NRC under 10 CFR 35.390, 35.392, 35.394, or 35.396 (Unsealed Byproduct Material—Written Directive Required).

1. Are the current pathways for obtaining AU status reasonable and accessible? Provide a rationale for your answer.
2. Are the current pathways for obtaining AU status adequate for protecting public health and safety? Provide a rationale for your answer.
3. Should the NRC develop a new tailored T&E pathway for these physicians? If so, what would be the appropriate way to categorize radiopharmaceuticals for tailored T&E requirements? If not, explain why the regulations should remain unchanged. [Some options to categorize radiopharmaceuticals include radiopharmaceuticals with similar delivery methods (oral, parenteral); same type of radiation characteristics or emission (alpha, beta, gamma, low-energy photon); similar preparation method (patient-ready doses); or a combination thereof (e.g., radiopharmaceuticals containing alpha- and beta-emitting radioisotopes that are administered intravenously and are prepared as patient-ready doses).]
4. Should the fundamental T&E required of physicians seeking limited AU status need to have the same fundamental T&E required of physicians seeking full AU status for all oral and parenteral administrations under 10 CFR 35.300?
5. How should the requirements for this fundamental T&E be structured for a specific category of radiopharmaceuticals?
 - a. Describe what the requirements should include:

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 - iii. Competency - How should competency be evaluated? Should a written and/or practical examination by an independent examining committee be administered? Provide a rationale for your answer.
- b. Should a preceptor attestation be required for the fundamental T&E? Provide a rationale for your answer.
- c. Should the radiopharmaceutical manufacturer be able to provide the preceptor attestation? Provide a rational for your answer.

- d. Who should establish and administer the curriculum and examination? Provide specific group(s). [Some options are: NRC, medical specialty boards, medical professional societies, educational professional groups, and NRC in collaboration with any or more of the aforementioned groups.]
- e. Should AU competency be periodically assessed? If so, how should it be assessed, how often, and by whom?

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- 1. What boards other than those already recognized by the NRC (American Board of Nuclear Medicine [ABNM], American Board of Radiology [ABR], American Osteopathic Board of Radiology [AOBR], Certification Board of Nuclear Endocrinology [CBNE]) could be considered for recognition for medical uses under 10 CFR 35.300?
- 2. Are the current NRC medical specialty board recognition criteria sufficient? If not, what additional criteria should the NRC use?

C. Patient Access

The NRC is requesting comments on whether there is a shortage in the number of AUs for 10 CFR 35.300.

1. Is there a shortage in the number of AUs for medical uses under 10 CFR 35.300? If so, is the shortage associated with the use of a specific radiopharmaceutical? Explain how.
2. Are there certain geographic areas with an inadequate number of AUs? Identify these areas.
3. Do current NRC regulations on AU T&E requirements unnecessarily limit patient access to procedures involving radiopharmaceuticals? Explain how.
4. Do current NRC regulations on AU T&E requirements unnecessarily limit research and development in nuclear medicine? Explain how.

D. Other Suggested Changes to the T&E Regulations

In 2002, the NRC revised its regulatory framework for medical use. The goal was to focus the NRC's regulations on those medical procedures that pose the highest risk to workers, the general public, patients, and human research subjects and to structure the regulations to be more risk-informed and more performance-based. The 2002 rule reduced the unnecessary regulatory burden by either reducing or eliminating the prescriptiveness of some regulations. Instead, the rule provided for a performance-based approach that relied on the training and experience of the AUs, authorized nuclear pharmacists, and radiation safety officers. The NRC is requesting comments on whether there are any other changes to the T&E regulations in 10 CFR part 35 that should be considered. Please discuss your suggested changes.

1. Should the NRC regulate the T&E of physicians for medical uses?
2. Are there requirements in the NRC's T&E regulatory framework for physicians that are non-safety related?

3. How can the NRC transform its regulatory approach for T&E while still ensuring that adequate protection is maintained for workers, the general public, patients, and human research subjects?

Dated at Rockville, Maryland, this 23rd day of October 2018.

For the Nuclear Regulatory
Commission.

/RA/

Daniel S. Collins, Director,
Division of Materials Safety,
Security,
State, and Tribal Programs,
Office of Nuclear Material Safety
and Safeguards.



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

November 2, 2018

American Society of Clinical Oncology
2318 Mill Rd., Suite 800
Alexandria, VA 22314

Via e-mail to customerservice@asco.org

SUBJECT: TRAINING AND EXPERIENCE REQUIREMENTS FOR DIFFERENT CATEGORIES OF RADIOPHARMACEUTICALS

Dear Sir or Madam,

The U.S. Nuclear Regulatory Commission (NRC) is evaluating its regulations related to the training and experience (T&E) required for a physician to become an authorized user for medical uses under Subpart E, “Unsealed Byproduct Material—Written Directive Required,” of [Title 10 of the Code of Federal Regulations \(10 CFR\) Part 35, “Medical Use of Byproduct Material.”](#)

The T&E requirements in Subpart E of 10 CFR Part 35 provide three ways that a physician can be authorized to administer unsealed byproduct materials or radiopharmaceuticals requiring a written directive:

1. A physician can be certified by a medical specialty board, whose certification process is recognized by the NRC or an Agreement State.
2. A physician can complete a structured educational program and supervised work experience under an alternate pathway. This alternate pathway includes a requirement for 700 hours of training and experience, which consists of a minimum of 200 hours of classroom and laboratory training and 500 hours of supervised work experience.
3. A physician can be authorized if previously identified as an authorized user on an NRC or Agreement State license or permit (i.e., grandfathered).

In its evaluation of the T&E requirements, the NRC staff is considering whether an additional pathway should be created or if the alternate pathway should be revised. Specifically, the staff is evaluating: (1) whether it makes sense to establish tailored T&E requirements for different categories of radiopharmaceuticals; (2) how those categories should be determined; (3) what the appropriate T&E requirements would be for each category; and (4) whether those requirements should be based on hours of training and experience, or focused more on competency.

On October 29, 2018, the NRC published a series of questions on T&E in the *Federal Register* (83 FR 54380). The *Federal Register* notice is enclosed with this letter and can also be accessed at: <https://www.gpo.gov/fdsys/pkg/FR-2018-10-29/pdf/2018-23521.pdf>. The NRC will carefully consider responses to these questions and would appreciate your feedback on whether changes to the current T&E regulations are warranted. The comment period for the T&E evaluation will end on January 29, 2019. Please follow the directions in the notice on how to submit written comments. The NRC is using the Federal rulemaking Web site, [Regulations.gov](#), to accept written comments on the docket (NRC-2018-0230).

The NRC will also conduct four public meetings scheduled for November 14 and December 11, 2018, and January 10 and January 22, 2019, and will accept oral comments provided during the meetings. The meetings on December 11 and January 10 will be held at NRC Headquarters in Rockville, MD, and all four meetings will be accessible for remote participation by moderated bridge line and webinar. The NRC's public meeting page has been updated with meeting details and registration instructions for each meeting: <https://www.nrc.gov/pmns/mtg>.

Additional information on the NRC's T&E evaluation can be found at: <https://www.nrc.gov/materials/miau/med-use-toolkit/training-experience-evaluation.html>. If you have any questions on this correspondence, please contact Sarah Lopas of my staff at (301) 415-6360 or Sarah.Lopas@nrc.gov.



Christian Einberg, Chief
Medical Safety and Events Assessment Branch
Division of Materials Safety, Security, State
and Tribal Programs
Office of Nuclear Material Safety
and Safeguards

Enclosure:
Training and Experience
Federal Register notice

NUCLEAR REGULATORY COMMISSION

[NRC-2018-0230]

**Training and Experience Requirements for Different Categories of
Radiopharmaceuticals**

AGENCY: Nuclear Regulatory Commission.

ACTION: Training and experience requirements; request for comment.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is requesting comments on its training and experience (T&E) requirements. Specifically, the NRC would like input on whether it should establish tailored T&E requirements for different categories of radiopharmaceuticals for which a written directive is required in accordance with its regulations. The input will be used to determine whether significant regulatory changes to the NRC's T&E requirements for authorized users (AUs) are warranted.

DATES: Submit comments by January 29, 2019. Comments received after this date will be considered if it is practical to do so, but the NRC is only able to ensure consideration for comments received on or before this date.

ADDRESSES: You may submit comments by any of the following methods:

- **Federal Rulemaking Web Site:** Go to <http://www.regulations.gov>

and search for Docket ID **NRC-2018-0230**. Address questions about Docket IDs in Regulations.gov to Jennifer Borges; telephone: 301-287-9127; e-mail: Jennifer.Borges@nrc.gov. For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.

- **Mail comments to:** May Ma, Office of Administration, Mail Stop: TWFN-7-A60M, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001.

For additional direction on obtaining information and submitting comments, see “Obtaining Information and Submitting Comments” in the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: Sarah Lopas, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001; telephone: 301-415-6360, e-mail: Sarah.Lopas@nrc.gov.

SUPPLEMENTARY INFORMATION:

I. Obtaining Information and Submitting Comments

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3. How can the NRC transform its regulatory approach for T&E while still ensuring that adequate protection is maintained for workers, the general public, patients, and human research subjects?

Dated at Rockville, Maryland, this 23rd day of October 2018.

For the Nuclear Regulatory
Commission.

/RA/

Daniel S. Collins, Director,
Division of Materials Safety,
Security,
State, and Tribal Programs,
Office of Nuclear Material Safety
and Safeguards.



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

November 2, 2018

American Society of Nuclear Cardiology
9302 Lee Highway, Suite 1210
Fairfax, VA 22301

Via e-mail to info@asnc.org

SUBJECT: TRAINING AND EXPERIENCE REQUIREMENTS FOR DIFFERENT CATEGORIES OF RADIOPHARMACEUTICALS

Dear Sir or Madam,

The U.S. Nuclear Regulatory Commission (NRC) is evaluating its regulations related to the training and experience (T&E) required for a physician to become an authorized user for medical uses under Subpart E, “Unsealed Byproduct Material—Written Directive Required,” of [Title 10 of the Code of Federal Regulations \(10 CFR\) Part 35, “Medical Use of Byproduct Material.”](#)

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Additional information on the NRC's T&E evaluation can be found at: <https://www.nrc.gov/materials/miau/med-use-toolkit/training-experience-evaluation.html>. If you have any questions on this correspondence, please contact Sarah Lopas of my staff at (301) 415-6360 or Sarah.Lopas@nrc.gov.

A handwritten signature in black ink, appearing to read "C Einberg".

Christian Einberg, Chief
Medical Safety and Events Assessment Branch
Division of Materials Safety, Security, State
and Tribal Programs
Office of Nuclear Material Safety
and Safeguards

Enclosure:
Training and Experience
Federal Register notice

NUCLEAR REGULATORY COMMISSION

[NRC-2018-0230]

**Training and Experience Requirements for Different Categories of
Radiopharmaceuticals**

AGENCY: Nuclear Regulatory Commission.

ACTION: Training and experience requirements; request for comment.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is requesting comments on its training and experience (T&E) requirements. Specifically, the NRC would like input on whether it should establish tailored T&E requirements for different categories of radiopharmaceuticals for which a written directive is required in accordance with its regulations. The input will be used to determine whether significant regulatory changes to the NRC's T&E requirements for authorized users (AUs) are warranted.

DATES: Submit comments by January 29, 2019. Comments received after this date will be considered if it is practical to do so, but the NRC is only able to ensure consideration for comments received on or before this date.

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and search for Docket ID **NRC-2018-0230**. Address questions about Docket IDs in Regulations.gov to Jennifer Borges; telephone: 301-287-9127; e-mail: Jennifer.Borges@nrc.gov. For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.

- **Mail comments to:** May Ma, Office of Administration, Mail Stop: TWFN-7-A60M, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001.

For additional direction on obtaining information and submitting comments, see “Obtaining Information and Submitting Comments” in the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: Sarah Lopas, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001; telephone: 301-415-6360, e-mail: Sarah.Lopas@nrc.gov.

SUPPLEMENTARY INFORMATION:

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radionuclides or by delivery method), (3) what the appropriate T&E requirements would be for each category, and (4) whether those requirements should be based on hours of T&E or focused more on competency. In response to the SRM, the NRC staff documented its initial results, status, and next steps related to this evaluation in SECY-18-0084, "Staff Evaluation of Training and Experience Requirements for Administering Different Categories of Radiopharmaceuticals in Response to SRM-M170817" (ADAMS Accession No. ML18135A276). In SECY-18-0084, the staff concluded that additional outreach with the medical community is needed to determine whether and how to tailor the T&E requirements to establish a limited AU status, the specific T&E requirements that should apply, how the T&E requirements should be met (e.g., hours of training, demonstration of competency), and whether a competency-based approach makes sense for the T&E requirements for all the medical uses authorized under 10 CFR 35.300, "Use of unsealed byproduct material for which a written directive is required."

The NRC is interested in obtaining input from as many stakeholders as possible, including members of the Advisory Committee on the Medical Uses of Isotopes, professional organizations, physicians, patients, patient advocacy groups, licensees, Agreement States, and other interested individuals. The focus of this request is to gather information that will permit the NRC staff to determine whether changes to the T&E requirements are warranted for different categories of radiopharmaceuticals for physicians seeking AU status for the medical use of specific categories of radiopharmaceuticals requiring a written directive under 10 CFR 35.300.

During the comment period between October 29, 2018 and January 29, 2019, the NRC will hold four public meetings that will discuss the information being requested and to accept comments on the docket. All four public meetings

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III. Specific Requests for Comments

A. Tailored Training & Experience Requirements

The NRC is requesting comments on whether it should establish tailored T&E requirements for different categories of radiopharmaceuticals for physicians seeking AU status for the medical use of specific categories of radiopharmaceuticals requiring a written directive under 10 CFR 35.300 (i.e., a limited AU status). This would be for physicians seeking AU status via the alternate non-board certified pathway, and for physicians certified by a medical

specialty board that is not currently recognized by the NRC under 10 CFR 35.390, 35.392, 35.394, or 35.396 (Unsealed Byproduct Material—Written Directive Required).

1. Are the current pathways for obtaining AU status reasonable and accessible? Provide a rationale for your answer.
2. Are the current pathways for obtaining AU status adequate for protecting public health and safety? Provide a rationale for your answer.
3. Should the NRC develop a new tailored T&E pathway for these physicians? If so, what would be the appropriate way to categorize radiopharmaceuticals for tailored T&E requirements? If not, explain why the regulations should remain unchanged. [Some options to categorize radiopharmaceuticals include radiopharmaceuticals with similar delivery methods (oral, parenteral); same type of radiation characteristics or emission (alpha, beta, gamma, low-energy photon); similar preparation method (patient-ready doses); or a combination thereof (e.g., radiopharmaceuticals containing alpha- and beta-emitting radioisotopes that are administered intravenously and are prepared as patient-ready doses).]
4. Should the fundamental T&E required of physicians seeking limited AU status need to have the same fundamental T&E required of physicians seeking full AU status for all oral and parenteral administrations under 10 CFR 35.300?
5. How should the requirements for this fundamental T&E be structured for a specific category of radiopharmaceuticals?
 - a. Describe what the requirements should include:

- i. Classroom and laboratory training – What topics need to be covered in this training requirement? How many hours of classroom and laboratory training should be required? Provide the basis for the number of hours. If not hours, explain how this training should be quantified. [Note: The topics currently required in the regulations to be included in the classroom and laboratory training and work experience are listed in 10 CFR 35.390, 35.392, 35.394, and 35.396.]
 - ii. Work experience - What should the work experience requirement involve? How many hours of work experience should be required and what is the minimum number of patient or human research subject administrations that an individual must perform? Provide the basis for the number of hours and administrations. What should be the qualifications of the supervising individual?
 - iii. Competency - How should competency be evaluated? Should a written and/or practical examination by an independent examining committee be administered? Provide a rationale for your answer.
- b. Should a preceptor attestation be required for the fundamental T&E? Provide a rationale for your answer.
- c. Should the radiopharmaceutical manufacturer be able to provide the preceptor attestation? Provide a rational for your answer.

- d. Who should establish and administer the curriculum and examination? Provide specific group(s). [Some options are: NRC, medical specialty boards, medical professional societies, educational professional groups, and NRC in collaboration with any or more of the aforementioned groups.]
- e. Should AU competency be periodically assessed? If so, how should it be assessed, how often, and by whom?

B. NRC's Recognition of Medical Specialty Boards

The NRC is requesting comments on its recognition of medical specialty boards. The NRC's procedures for recognizing medical specialty boards are located on the Medical Uses Licensee Toolkit Web site (<https://www.nrc.gov/materials/miau/med-use-toolkit/certif-process-boards.html>). The NRC staff periodically reviews information to determine a board's continued eligibility for recognition.

- 1. What boards other than those already recognized by the NRC (American Board of Nuclear Medicine [ABNM], American Board of Radiology [ABR], American Osteopathic Board of Radiology [AOBR], Certification Board of Nuclear Endocrinology [CBNE]) could be considered for recognition for medical uses under 10 CFR 35.300?
- 2. Are the current NRC medical specialty board recognition criteria sufficient? If not, what additional criteria should the NRC use?

C. Patient Access

The NRC is requesting comments on whether there is a shortage in the number of AUs for 10 CFR 35.300.

1. Is there a shortage in the number of AUs for medical uses under 10 CFR 35.300? If so, is the shortage associated with the use of a specific radiopharmaceutical? Explain how.
2. Are there certain geographic areas with an inadequate number of AUs? Identify these areas.
3. Do current NRC regulations on AU T&E requirements unnecessarily limit patient access to procedures involving radiopharmaceuticals? Explain how.
4. Do current NRC regulations on AU T&E requirements unnecessarily limit research and development in nuclear medicine? Explain how.

D. Other Suggested Changes to the T&E Regulations

In 2002, the NRC revised its regulatory framework for medical use. The goal was to focus the NRC's regulations on those medical procedures that pose the highest risk to workers, the general public, patients, and human research subjects and to structure the regulations to be more risk-informed and more performance-based. The 2002 rule reduced the unnecessary regulatory burden by either reducing or eliminating the prescriptiveness of some regulations. Instead, the rule provided for a performance-based approach that relied on the training and experience of the AUs, authorized nuclear pharmacists, and radiation safety officers. The NRC is requesting comments on whether there are any other changes to the T&E regulations in 10 CFR part 35 that should be considered. Please discuss your suggested changes.

1. Should the NRC regulate the T&E of physicians for medical uses?
2. Are there requirements in the NRC's T&E regulatory framework for physicians that are non-safety related?

3. How can the NRC transform its regulatory approach for T&E while still ensuring that adequate protection is maintained for workers, the general public, patients, and human research subjects?

Dated at Rockville, Maryland, this 23rd day of October 2018.

For the Nuclear Regulatory
Commission.

/RA/

Daniel S. Collins, Director,
Division of Materials Safety,
Security,
State, and Tribal Programs,
Office of Nuclear Material Safety
and Safeguards.



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

November 2, 2018

Ms. Cindy Tomlinson
Senior Patient Safety and
Regulatory Affairs Manager
American Society for Radiation Oncology
251 18th St. South, 8th Fl.
Arlington, VA 22202

Via e-mail to cindy.tomlinson@astro.org

SUBJECT: TRAINING AND EXPERIENCE REQUIREMENTS FOR DIFFERENT CATEGORIES OF RADIOPHARMACEUTICALS

Dear Ms. Tomlinson,

The U.S. Nuclear Regulatory Commission (NRC) is evaluating its regulations related to the training and experience (T&E) required for a physician to become an authorized user for medical uses under Subpart E, “Unsealed Byproduct Material—Written Directive Required,” of [Title 10 of the Code of Federal Regulations \(10 CFR\) Part 35, “Medical Use of Byproduct Material.”](#)

The T&E requirements in Subpart E of 10 CFR Part 35 provide three ways that a physician can be authorized to administer unsealed byproduct materials or radiopharmaceuticals requiring a written directive:

1. A physician can be certified by a medical specialty board, whose certification process is recognized by the NRC or an Agreement State.
2. A physician can complete a structured educational program and supervised work experience under an alternate pathway. This alternate pathway includes a requirement for 700 hours of training and experience, which consists of a minimum of 200 hours of classroom and laboratory training and 500 hours of supervised work experience.
3. A physician can be authorized if previously identified as an authorized user on an NRC or Agreement State license or permit (i.e., grandfathered).

In its evaluation of the T&E requirements, the NRC staff is considering whether an additional pathway should be created or if the alternate pathway should be revised. Specifically, the staff is evaluating: (1) whether it makes sense to establish tailored T&E requirements for different categories of radiopharmaceuticals; (2) how those categories should be determined; (3) what the appropriate T&E requirements would be for each category; and (4) whether those requirements should be based on hours of training and experience, or focused more on competency.

On October 29, 2018, the NRC published a series of questions on T&E in the *Federal Register* (83 FR 54380). The *Federal Register* notice is enclosed with this letter and can also be accessed at: <https://www.gpo.gov/fdsys/pkg/FR-2018-10-29/pdf/2018-23521.pdf>. The NRC will carefully consider responses to these questions and would appreciate your feedback on whether changes to the current T&E regulations are warranted. The comment period for the T&E evaluation will end on January 29, 2019. Please follow the directions in the notice on how to submit written comments. The NRC is using the Federal rulemaking Web site, [Regulations.gov](#), to accept written comments on the docket (NRC-2018-0230).

The NRC will also conduct four public meetings scheduled for November 14 and December 11, 2018, and January 10 and January 22, 2019, and will accept oral comments provided during the meetings. The meetings on December 11 and January 10 will be held at NRC Headquarters in Rockville, MD, and all four meetings will be accessible for remote participation by moderated bridge line and webinar. The NRC's public meeting page has been updated with meeting details and registration instructions for each meeting: <https://www.nrc.gov/pmns/mtg>.

Additional information on the NRC's T&E evaluation can be found at: <https://www.nrc.gov/materials/miau/med-use-toolkit/training-experience-evaluation.html>. If you have any questions on this correspondence, please contact Sarah Lopas of my staff at (301) 415-6360 or Sarah.Lopas@nrc.gov.

A handwritten signature in black ink, appearing to read "C. Einberg".

Christian Einberg, Chief
Medical Safety and Events Assessment Branch
Division of Materials Safety, Security, State
and Tribal Programs
Office of Nuclear Material Safety
and Safeguards

Enclosure:
Training and Experience
Federal Register notice

NUCLEAR REGULATORY COMMISSION

[NRC-2018-0230]

**Training and Experience Requirements for Different Categories of
Radiopharmaceuticals**

AGENCY: Nuclear Regulatory Commission.

ACTION: Training and experience requirements; request for comment.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is requesting comments on its training and experience (T&E) requirements. Specifically, the NRC would like input on whether it should establish tailored T&E requirements for different categories of radiopharmaceuticals for which a written directive is required in accordance with its regulations. The input will be used to determine whether significant regulatory changes to the NRC's T&E requirements for authorized users (AUs) are warranted.

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Dated at Rockville, Maryland, this 23rd day of October 2018.

For the Nuclear Regulatory
Commission.

/RA/

Daniel S. Collins, Director,
Division of Materials Safety,
Security,
State, and Tribal Programs,
Office of Nuclear Material Safety
and Safeguards.



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

November 2, 2018

Dr. Alan J. Balch, PhD
Chief Executive Officer
Patient Advocate Foundation
421 Butler Farm Rd.
Hampton, VA 23666

Via e-mail to help@patientadvocate.org

SUBJECT: TRAINING AND EXPERIENCE REQUIREMENTS FOR DIFFERENT CATEGORIES OF RADIOPHARMACEUTICALS

Dear Dr. Balch,

The U.S. Nuclear Regulatory Commission (NRC) is evaluating its regulations related to the training and experience (T&E) required for a physician to become an authorized user for medical uses under Subpart E, “Unsealed Byproduct Material—Written Directive Required,” of [Title 10 of the Code of Federal Regulations \(10 CFR\) Part 35, “Medical Use of Byproduct Material.”](#)

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3. A physician can be authorized if previously identified as an authorized user on an NRC or Agreement State license or permit (i.e., grandfathered).

In its evaluation of the T&E requirements, the NRC staff is considering whether an additional pathway should be created or if the alternate pathway should be revised. Specifically, the staff is evaluating: (1) whether it makes sense to establish tailored T&E requirements for different categories of radiopharmaceuticals; (2) how those categories should be determined; (3) what the appropriate T&E requirements would be for each category; and (4) whether those requirements should be based on hours of training and experience, or focused more on competency.

On October 29, 2018, the NRC published a series of questions on T&E in the *Federal Register* (83 FR 54380). The *Federal Register* notice is enclosed with this letter and can also be accessed at: <https://www.gpo.gov/fdsys/pkg/FR-2018-10-29/pdf/2018-23521.pdf>. The NRC will carefully consider responses to these questions and would appreciate your feedback on whether changes to the current T&E regulations are warranted. The comment period for the T&E evaluation will end on January 29, 2019. Please follow the directions in the notice on how to submit written comments. The NRC is using the Federal rulemaking Web site, [Regulations.gov](#), to accept written comments on the docket (NRC-2018-0230).

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A handwritten signature in black ink, appearing to read "C Einberg".

Christian Einberg, Chief
Medical Safety and Events Assessment Branch
Division of Materials Safety, Security, State
and Tribal Programs
Office of Nuclear Material Safety
and Safeguards

Enclosure:
Training and Experience
Federal Register notice

NUCLEAR REGULATORY COMMISSION

[NRC-2018-0230]

**Training and Experience Requirements for Different Categories of
Radiopharmaceuticals**

AGENCY: Nuclear Regulatory Commission.

ACTION: Training and experience requirements; request for comment.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is requesting comments on its training and experience (T&E) requirements. Specifically, the NRC would like input on whether it should establish tailored T&E requirements for different categories of radiopharmaceuticals for which a written directive is required in accordance with its regulations. The input will be used to determine whether significant regulatory changes to the NRC's T&E requirements for authorized users (AUs) are warranted.

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The NRC is interested in obtaining input from as many stakeholders as possible, including members of the Advisory Committee on the Medical Uses of Isotopes, professional organizations, physicians, patients, patient advocacy groups, licensees, Agreement States, and other interested individuals. The focus of this request is to gather information that will permit the NRC staff to determine whether changes to the T&E requirements are warranted for different categories of radiopharmaceuticals for physicians seeking AU status for the medical use of specific categories of radiopharmaceuticals requiring a written directive under 10 CFR 35.300.

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III. Specific Requests for Comments

A. Tailored Training & Experience Requirements

The NRC is requesting comments on whether it should establish tailored T&E requirements for different categories of radiopharmaceuticals for physicians seeking AU status for the medical use of specific categories of radiopharmaceuticals requiring a written directive under 10 CFR 35.300 (i.e., a limited AU status). This would be for physicians seeking AU status via the alternate non-board certified pathway, and for physicians certified by a medical

specialty board that is not currently recognized by the NRC under 10 CFR 35.390, 35.392, 35.394, or 35.396 (Unsealed Byproduct Material—Written Directive Required).

1. Are the current pathways for obtaining AU status reasonable and accessible? Provide a rationale for your answer.
2. Are the current pathways for obtaining AU status adequate for protecting public health and safety? Provide a rationale for your answer.
3. Should the NRC develop a new tailored T&E pathway for these physicians? If so, what would be the appropriate way to categorize radiopharmaceuticals for tailored T&E requirements? If not, explain why the regulations should remain unchanged. [Some options to categorize radiopharmaceuticals include radiopharmaceuticals with similar delivery methods (oral, parenteral); same type of radiation characteristics or emission (alpha, beta, gamma, low-energy photon); similar preparation method (patient-ready doses); or a combination thereof (e.g., radiopharmaceuticals containing alpha- and beta-emitting radioisotopes that are administered intravenously and are prepared as patient-ready doses).]
4. Should the fundamental T&E required of physicians seeking limited AU status need to have the same fundamental T&E required of physicians seeking full AU status for all oral and parenteral administrations under 10 CFR 35.300?
5. How should the requirements for this fundamental T&E be structured for a specific category of radiopharmaceuticals?
 - a. Describe what the requirements should include:

- i. Classroom and laboratory training – What topics need to be covered in this training requirement? How many hours of classroom and laboratory training should be required? Provide the basis for the number of hours. If not hours, explain how this training should be quantified. [Note: The topics currently required in the regulations to be included in the classroom and laboratory training and work experience are listed in 10 CFR 35.390, 35.392, 35.394, and 35.396.]
 - ii. Work experience - What should the work experience requirement involve? How many hours of work experience should be required and what is the minimum number of patient or human research subject administrations that an individual must perform? Provide the basis for the number of hours and administrations. What should be the qualifications of the supervising individual?
 - iii. Competency - How should competency be evaluated? Should a written and/or practical examination by an independent examining committee be administered? Provide a rationale for your answer.
- b. Should a preceptor attestation be required for the fundamental T&E? Provide a rationale for your answer.
- c. Should the radiopharmaceutical manufacturer be able to provide the preceptor attestation? Provide a rational for your answer.

- d. Who should establish and administer the curriculum and examination? Provide specific group(s). [Some options are: NRC, medical specialty boards, medical professional societies, educational professional groups, and NRC in collaboration with any or more of the aforementioned groups.]
- e. Should AU competency be periodically assessed? If so, how should it be assessed, how often, and by whom?

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The NRC is requesting comments on its recognition of medical specialty boards. The NRC's procedures for recognizing medical specialty boards are located on the Medical Uses Licensee Toolkit Web site (<https://www.nrc.gov/materials/miau/med-use-toolkit/certif-process-boards.html>). The NRC staff periodically reviews information to determine a board's continued eligibility for recognition.

- 1. What boards other than those already recognized by the NRC (American Board of Nuclear Medicine [ABNM], American Board of Radiology [ABR], American Osteopathic Board of Radiology [AOBR], Certification Board of Nuclear Endocrinology [CBNE]) could be considered for recognition for medical uses under 10 CFR 35.300?
- 2. Are the current NRC medical specialty board recognition criteria sufficient? If not, what additional criteria should the NRC use?

C. Patient Access

The NRC is requesting comments on whether there is a shortage in the number of AUs for 10 CFR 35.300.

1. Is there a shortage in the number of AUs for medical uses under 10 CFR 35.300? If so, is the shortage associated with the use of a specific radiopharmaceutical? Explain how.
2. Are there certain geographic areas with an inadequate number of AUs? Identify these areas.
3. Do current NRC regulations on AU T&E requirements unnecessarily limit patient access to procedures involving radiopharmaceuticals? Explain how.
4. Do current NRC regulations on AU T&E requirements unnecessarily limit research and development in nuclear medicine? Explain how.

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In 2002, the NRC revised its regulatory framework for medical use. The goal was to focus the NRC's regulations on those medical procedures that pose the highest risk to workers, the general public, patients, and human research subjects and to structure the regulations to be more risk-informed and more performance-based. The 2002 rule reduced the unnecessary regulatory burden by either reducing or eliminating the prescriptiveness of some regulations. Instead, the rule provided for a performance-based approach that relied on the training and experience of the AUs, authorized nuclear pharmacists, and radiation safety officers. The NRC is requesting comments on whether there are any other changes to the T&E regulations in 10 CFR part 35 that should be considered. Please discuss your suggested changes.

1. Should the NRC regulate the T&E of physicians for medical uses?
2. Are there requirements in the NRC's T&E regulatory framework for physicians that are non-safety related?

3. How can the NRC transform its regulatory approach for T&E while still ensuring that adequate protection is maintained for workers, the general public, patients, and human research subjects?

Dated at Rockville, Maryland, this 23rd day of October 2018.

For the Nuclear Regulatory
Commission.

/RA/

Daniel S. Collins, Director,
Division of Materials Safety,
Security,
State, and Tribal Programs,
Office of Nuclear Material Safety
and Safeguards.



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

November 2, 2018

Ms. Nancy Barrett
Executive Director,
Canadian College of Physicists in Medicine
300 March Rd., Suite 202
Kanata Ontario K2K 2E2
Canada

Via e-mail to nancy.barrett@ccpm.ca

SUBJECT: TRAINING AND EXPERIENCE REQUIREMENTS FOR DIFFERENT CATEGORIES OF RADIOPHARMACEUTICALS

Dear Ms. Barrett,

The U.S. Nuclear Regulatory Commission (NRC) is evaluating its regulations related to the training and experience (T&E) required for a physician to become an authorized user for medical uses under Subpart E, “Unsealed Byproduct Material—Written Directive Required,” of [Title 10 of the Code of Federal Regulations \(10 CFR\) Part 35, “Medical Use of Byproduct Material.”](#)

The T&E requirements in Subpart E of 10 CFR Part 35 provide three ways that a physician can be authorized to administer unsealed byproduct materials or radiopharmaceuticals requiring a written directive:

1. A physician can be certified by a medical specialty board, whose certification process is recognized by the NRC or an Agreement State.
2. A physician can complete a structured educational program and supervised work experience under an alternate pathway. This alternate pathway includes a requirement for 700 hours of training and experience, which consists of a minimum of 200 hours of classroom and laboratory training and 500 hours of supervised work experience.
3. A physician can be authorized if previously identified as an authorized user on an NRC or Agreement State license or permit (i.e., grandfathered).

In its evaluation of the T&E requirements, the NRC staff is considering whether an additional pathway should be created or if the alternate pathway should be revised. Specifically, the staff is evaluating: (1) whether it makes sense to establish tailored T&E requirements for different categories of radiopharmaceuticals; (2) how those categories should be determined; (3) what the appropriate T&E requirements would be for each category; and (4) whether those requirements should be based on hours of training and experience, or focused more on competency.

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Christian Einberg, 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:
Training and Experience
Federal Register notice

NUCLEAR REGULATORY COMMISSION

[NRC-2018-0230]

**Training and Experience Requirements for Different Categories of
Radiopharmaceuticals**

AGENCY: Nuclear Regulatory Commission.

ACTION: Training and experience requirements; request for comment.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is requesting comments on its training and experience (T&E) requirements. Specifically, the NRC would like input on whether it should establish tailored T&E requirements for different categories of radiopharmaceuticals for which a written directive is required in accordance with its regulations. The input will be used to determine whether significant regulatory changes to the NRC's T&E requirements for authorized users (AUs) are warranted.

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Dated at Rockville, Maryland, this 23rd day of October 2018.

For the Nuclear Regulatory
Commission.

/RA/

Daniel S. Collins, Director,
Division of Materials Safety,
Security,
State, and Tribal Programs,
Office of Nuclear Material Safety
and Safeguards.



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

November 2, 2018

Dr. Greg Beavers
Executive Director,
American Board of Science in Nuclear Medicine
1037 N. Main St.
Kernersville, NC 27284

Via e-mail to ABSNM.mgr@gmail.com

SUBJECT: TRAINING AND EXPERIENCE REQUIREMENTS FOR DIFFERENT CATEGORIES OF RADIOPHARMACEUTICALS

Dear Dr. Beavers,

The U.S. Nuclear Regulatory Commission (NRC) is evaluating its regulations related to the training and experience (T&E) required for a physician to become an authorized user for medical uses under Subpart E, “Unsealed Byproduct Material—Written Directive Required,” of [Title 10 of the Code of Federal Regulations \(10 CFR\) Part 35, “Medical Use of Byproduct Material.”](#)

The T&E requirements in Subpart E of 10 CFR Part 35 provide three ways that a physician can be authorized to administer unsealed byproduct materials or radiopharmaceuticals requiring a written directive:

1. A physician can be certified by a medical specialty board, whose certification process is recognized by the NRC or an Agreement State.
2. A physician can complete a structured educational program and supervised work experience under an alternate pathway. This alternate pathway includes a requirement for 700 hours of training and experience, which consists of a minimum of 200 hours of classroom and laboratory training and 500 hours of supervised work experience.
3. A physician can be authorized if previously identified as an authorized user on an NRC or Agreement State license or permit (i.e., grandfathered).

In its evaluation of the T&E requirements, the NRC staff is considering whether an additional pathway should be created or if the alternate pathway should be revised. Specifically, the staff is evaluating: (1) whether it makes sense to establish tailored T&E requirements for different categories of radiopharmaceuticals; (2) how those categories should be determined; (3) what the appropriate T&E requirements would be for each category; and (4) whether those requirements should be based on hours of training and experience, or focused more on competency.

On October 29, 2018, the NRC published a series of questions on T&E in the *Federal Register* (83 FR 54380). The *Federal Register* notice is enclosed with this letter and can also be accessed at: <https://www.gpo.gov/fdsys/pkg/FR-2018-10-29/pdf/2018-23521.pdf>. The NRC will carefully consider responses to these questions and would appreciate your feedback on whether changes to the current T&E regulations are warranted. The comment period for the T&E evaluation will end on January 29, 2019. Please follow the directions in the notice on how to submit written comments. The NRC is using the Federal rulemaking Web site, [Regulations.gov](#), to accept written comments on the docket (NRC-2018-0230).

The NRC will also conduct four public meetings scheduled for November 14 and December 11, 2018, and January 10 and January 22, 2019, and will accept oral comments provided during the meetings. The meetings on December 11 and January 10 will be held at NRC Headquarters in Rockville, MD, and all four meetings will be accessible for remote participation by moderated bridge line and webinar. The NRC's public meeting page has been updated with meeting details and registration instructions for each meeting: <https://www.nrc.gov/pmns/mtg>.

Additional information on the NRC's T&E evaluation can be found at: <https://www.nrc.gov/materials/miau/med-use-toolkit/training-experience-evaluation.html>. If you have any questions on this correspondence, please contact Sarah Lopas of my staff at (301) 415-6360 or Sarah.Lopas@nrc.gov.

A handwritten signature in black ink, appearing to read "C Einberg".

Christian Einberg, Chief
Medical Safety and Events Assessment Branch
Division of Materials Safety, Security, State
and Tribal Programs
Office of Nuclear Material Safety
and Safeguards

Enclosure:
Training and Experience
Federal Register notice

NUCLEAR REGULATORY COMMISSION

[NRC-2018-0230]

**Training and Experience Requirements for Different Categories of
Radiopharmaceuticals**

AGENCY: Nuclear Regulatory Commission.

ACTION: Training and experience requirements; request for comment.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is requesting comments on its training and experience (T&E) requirements. Specifically, the NRC would like input on whether it should establish tailored T&E requirements for different categories of radiopharmaceuticals for which a written directive is required in accordance with its regulations. The input will be used to determine whether significant regulatory changes to the NRC's T&E requirements for authorized users (AUs) are warranted.

DATES: Submit comments by January 29, 2019. Comments received after this date will be considered if it is practical to do so, but the NRC is only able to ensure consideration for comments received on or before this date.

ADDRESSES: You may submit comments by any of the following methods:

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Please include Docket ID **NRC-2018-0230** in your comment submission.

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The NRC is interested in obtaining input from as many stakeholders as possible, including members of the Advisory Committee on the Medical Uses of Isotopes, professional organizations, physicians, patients, patient advocacy groups, licensees, Agreement States, and other interested individuals. The focus of this request is to gather information that will permit the NRC staff to determine whether changes to the T&E requirements are warranted for different categories of radiopharmaceuticals for physicians seeking AU status for the medical use of specific categories of radiopharmaceuticals requiring a written directive under 10 CFR 35.300.

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III. Specific Requests for Comments

A. Tailored Training & Experience Requirements

The NRC is requesting comments on whether it should establish tailored T&E requirements for different categories of radiopharmaceuticals for physicians seeking AU status for the medical use of specific categories of radiopharmaceuticals requiring a written directive under 10 CFR 35.300 (i.e., a limited AU status). This would be for physicians seeking AU status via the alternate non-board certified pathway, and for physicians certified by a medical

specialty board that is not currently recognized by the NRC under 10 CFR 35.390, 35.392, 35.394, or 35.396 (Unsealed Byproduct Material—Written Directive Required).

1. Are the current pathways for obtaining AU status reasonable and accessible? Provide a rationale for your answer.
2. Are the current pathways for obtaining AU status adequate for protecting public health and safety? Provide a rationale for your answer.
3. Should the NRC develop a new tailored T&E pathway for these physicians? If so, what would be the appropriate way to categorize radiopharmaceuticals for tailored T&E requirements? If not, explain why the regulations should remain unchanged. [Some options to categorize radiopharmaceuticals include radiopharmaceuticals with similar delivery methods (oral, parenteral); same type of radiation characteristics or emission (alpha, beta, gamma, low-energy photon); similar preparation method (patient-ready doses); or a combination thereof (e.g., radiopharmaceuticals containing alpha- and beta-emitting radioisotopes that are administered intravenously and are prepared as patient-ready doses).]
4. Should the fundamental T&E required of physicians seeking limited AU status need to have the same fundamental T&E required of physicians seeking full AU status for all oral and parenteral administrations under 10 CFR 35.300?
5. How should the requirements for this fundamental T&E be structured for a specific category of radiopharmaceuticals?
 - a. Describe what the requirements should include:

- i. Classroom and laboratory training – What topics need to be covered in this training requirement? How many hours of classroom and laboratory training should be required? Provide the basis for the number of hours. If not hours, explain how this training should be quantified. [Note: The topics currently required in the regulations to be included in the classroom and laboratory training and work experience are listed in 10 CFR 35.390, 35.392, 35.394, and 35.396.]
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 - iii. Competency - How should competency be evaluated? Should a written and/or practical examination by an independent examining committee be administered? Provide a rationale for your answer.
- b. Should a preceptor attestation be required for the fundamental T&E? Provide a rationale for your answer.
- c. Should the radiopharmaceutical manufacturer be able to provide the preceptor attestation? Provide a rational for your answer.

- d. Who should establish and administer the curriculum and examination? Provide specific group(s). [Some options are: NRC, medical specialty boards, medical professional societies, educational professional groups, and NRC in collaboration with any or more of the aforementioned groups.]
- e. Should AU competency be periodically assessed? If so, how should it be assessed, how often, and by whom?

B. NRC's Recognition of Medical Specialty Boards

The NRC is requesting comments on its recognition of medical specialty boards. The NRC's procedures for recognizing medical specialty boards are located on the Medical Uses Licensee Toolkit Web site (<https://www.nrc.gov/materials/miau/med-use-toolkit/certif-process-boards.html>). The NRC staff periodically reviews information to determine a board's continued eligibility for recognition.

- 1. What boards other than those already recognized by the NRC (American Board of Nuclear Medicine [ABNM], American Board of Radiology [ABR], American Osteopathic Board of Radiology [AOBR], Certification Board of Nuclear Endocrinology [CBNE]) could be considered for recognition for medical uses under 10 CFR 35.300?
- 2. Are the current NRC medical specialty board recognition criteria sufficient? If not, what additional criteria should the NRC use?

C. Patient Access

The NRC is requesting comments on whether there is a shortage in the number of AUs for 10 CFR 35.300.

1. Is there a shortage in the number of AUs for medical uses under 10 CFR 35.300? If so, is the shortage associated with the use of a specific radiopharmaceutical? Explain how.
2. Are there certain geographic areas with an inadequate number of AUs? Identify these areas.
3. Do current NRC regulations on AU T&E requirements unnecessarily limit patient access to procedures involving radiopharmaceuticals? Explain how.
4. Do current NRC regulations on AU T&E requirements unnecessarily limit research and development in nuclear medicine? Explain how.

D. Other Suggested Changes to the T&E Regulations

In 2002, the NRC revised its regulatory framework for medical use. The goal was to focus the NRC's regulations on those medical procedures that pose the highest risk to workers, the general public, patients, and human research subjects and to structure the regulations to be more risk-informed and more performance-based. The 2002 rule reduced the unnecessary regulatory burden by either reducing or eliminating the prescriptiveness of some regulations. Instead, the rule provided for a performance-based approach that relied on the training and experience of the AUs, authorized nuclear pharmacists, and radiation safety officers. The NRC is requesting comments on whether there are any other changes to the T&E regulations in 10 CFR part 35 that should be considered. Please discuss your suggested changes.

1. Should the NRC regulate the T&E of physicians for medical uses?
2. Are there requirements in the NRC's T&E regulatory framework for physicians that are non-safety related?

3. How can the NRC transform its regulatory approach for T&E while still ensuring that adequate protection is maintained for workers, the general public, patients, and human research subjects?

Dated at Rockville, Maryland, this 23rd day of October 2018.

For the Nuclear Regulatory
Commission.

/RA/

Daniel S. Collins, Director,
Division of Materials Safety,
Security,
State, and Tribal Programs,
Office of Nuclear Material Safety
and Safeguards.



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

November 2, 2018

Dr. Angela Bires
Nuclear Medicine Technology Program Director
School of Nursing and Health Sciences
Robert Morris University
6001 University Blvd.
Moon Township, PA 15108

Via e-mail to bires@rmu.edu

SUBJECT: TRAINING AND EXPERIENCE REQUIREMENTS FOR DIFFERENT CATEGORIES OF RADIOPHARMACEUTICALS

Dear Dr. Bires,

The U.S. Nuclear Regulatory Commission (NRC) is evaluating its regulations related to the training and experience (T&E) required for a physician to become an authorized user for medical uses under Subpart E, “Unsealed Byproduct Material—Written Directive Required,” of [Title 10 of the Code of Federal Regulations \(10 CFR\) Part 35, “Medical Use of Byproduct Material.”](#)

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Christian Einberg, Chief
Medical Safety and Events Assessment Branch
Division of Materials Safety, Security, State
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Enclosure:
Training and Experience
Federal Register notice

NUCLEAR REGULATORY COMMISSION

[NRC-2018-0230]

**Training and Experience Requirements for Different Categories of
Radiopharmaceuticals**

AGENCY: Nuclear Regulatory Commission.

ACTION: Training and experience requirements; request for comment.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is requesting comments on its training and experience (T&E) requirements. Specifically, the NRC would like input on whether it should establish tailored T&E requirements for different categories of radiopharmaceuticals for which a written directive is required in accordance with its regulations. The input will be used to determine whether significant regulatory changes to the NRC's T&E requirements for authorized users (AUs) are warranted.

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C. Patient Access

The NRC is requesting comments on whether there is a shortage in the number of AUs for 10 CFR 35.300.

1. Is there a shortage in the number of AUs for medical uses under 10 CFR 35.300? If so, is the shortage associated with the use of a specific radiopharmaceutical? Explain how.
2. Are there certain geographic areas with an inadequate number of AUs? Identify these areas.
3. Do current NRC regulations on AU T&E requirements unnecessarily limit patient access to procedures involving radiopharmaceuticals? Explain how.
4. Do current NRC regulations on AU T&E requirements unnecessarily limit research and development in nuclear medicine? Explain how.

D. Other Suggested Changes to the T&E Regulations

In 2002, the NRC revised its regulatory framework for medical use. The goal was to focus the NRC's regulations on those medical procedures that pose the highest risk to workers, the general public, patients, and human research subjects and to structure the regulations to be more risk-informed and more performance-based. The 2002 rule reduced the unnecessary regulatory burden by either reducing or eliminating the prescriptiveness of some regulations. Instead, the rule provided for a performance-based approach that relied on the training and experience of the AUs, authorized nuclear pharmacists, and radiation safety officers. The NRC is requesting comments on whether there are any other changes to the T&E regulations in 10 CFR part 35 that should be considered. Please discuss your suggested changes.

1. Should the NRC regulate the T&E of physicians for medical uses?
2. Are there requirements in the NRC's T&E regulatory framework for physicians that are non-safety related?

3. How can the NRC transform its regulatory approach for T&E while still ensuring that adequate protection is maintained for workers, the general public, patients, and human research subjects?

Dated at Rockville, Maryland, this 23rd day of October 2018.

For the Nuclear Regulatory
Commission.

/RA/

Daniel S. Collins, Director,
Division of Materials Safety,
Security,
State, and Tribal Programs,
Office of Nuclear Material Safety
and Safeguards.



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

November 2, 2018

Dr. Norman E. Bolus
Program Director, Assistant Professor
Nuclear Medicine Technology, University of Alabama at Birmingham
1705 University Blvd.
Birmingham, AL 35294

Via e-mail to bolusn@uab.edu

SUBJECT: TRAINING AND EXPERIENCE REQUIREMENTS FOR DIFFERENT CATEGORIES OF RADIOPHARMACEUTICALS

Dear Dr. Bolus,

The U.S. Nuclear Regulatory Commission (NRC) is evaluating its regulations related to the training and experience (T&E) required for a physician to become an authorized user for medical uses under Subpart E, “Unsealed Byproduct Material—Written Directive Required,” of [Title 10 of the Code of Federal Regulations \(10 CFR\) Part 35, “Medical Use of Byproduct Material.”](#)

The T&E requirements in Subpart E of 10 CFR Part 35 provide three ways that a physician can be authorized to administer unsealed byproduct materials or radiopharmaceuticals requiring a written directive:

1. A physician can be certified by a medical specialty board, whose certification process is recognized by the NRC or an Agreement State.
2. A physician can complete a structured educational program and supervised work experience under an alternate pathway. This alternate pathway includes a requirement for 700 hours of training and experience, which consists of a minimum of 200 hours of classroom and laboratory training and 500 hours of supervised work experience.
3. A physician can be authorized if previously identified as an authorized user on an NRC or Agreement State license or permit (i.e., grandfathered).

In its evaluation of the T&E requirements, the NRC staff is considering whether an additional pathway should be created or if the alternate pathway should be revised. Specifically, the staff is evaluating: (1) whether it makes sense to establish tailored T&E requirements for different categories of radiopharmaceuticals; (2) how those categories should be determined; (3) what the appropriate T&E requirements would be for each category; and (4) whether those requirements should be based on hours of training and experience, or focused more on competency.

On October 29, 2018, the NRC published a series of questions on T&E in the *Federal Register* (83 FR 54380). The *Federal Register* notice is enclosed with this letter and can also be accessed at: <https://www.gpo.gov/fdsys/pkg/FR-2018-10-29/pdf/2018-23521.pdf>. The NRC will carefully consider responses to these questions and would appreciate your feedback on whether changes to the current T&E regulations are warranted. The comment period for the T&E evaluation will end on January 29, 2019. Please follow the directions in the notice on how to submit written comments. The NRC is using the Federal rulemaking Web site, [Regulations.gov](#), to accept written comments on the docket (NRC-2018-0230).

The NRC will also conduct four public meetings scheduled for November 14 and December 11, 2018, and January 10 and January 22, 2019, and will accept oral comments provided during the meetings. The meetings on December 11 and January 10 will be held at NRC Headquarters in Rockville, MD, and all four meetings will be accessible for remote participation by moderated bridge line and webinar. The NRC's public meeting page has been updated with meeting details and registration instructions for each meeting: <https://www.nrc.gov/pmns/mtg>.

Additional information on the NRC's T&E evaluation can be found at: <https://www.nrc.gov/materials/miau/med-use-toolkit/training-experience-evaluation.html>. If you have any questions on this correspondence, please contact Sarah Lopas of my staff at (301) 415-6360 or Sarah.Lopas@nrc.gov.

A handwritten signature in black ink, appearing to read "C Einberg".

Christian Einberg, Chief
Medical Safety and Events Assessment Branch
Division of Materials Safety, Security, State
and Tribal Programs
Office of Nuclear Material Safety
and Safeguards

Enclosure:
Training and Experience
Federal Register notice

NUCLEAR REGULATORY COMMISSION

[NRC-2018-0230]

**Training and Experience Requirements for Different Categories of
Radiopharmaceuticals**

AGENCY: Nuclear Regulatory Commission.

ACTION: Training and experience requirements; request for comment.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is requesting comments on its training and experience (T&E) requirements. Specifically, the NRC would like input on whether it should establish tailored T&E requirements for different categories of radiopharmaceuticals for which a written directive is required in accordance with its regulations. The input will be used to determine whether significant regulatory changes to the NRC's T&E requirements for authorized users (AUs) are warranted.

DATES: Submit comments by January 29, 2019. Comments received after this date will be considered if it is practical to do so, but the NRC is only able to ensure consideration for comments received on or before this date.

ADDRESSES: You may submit comments by any of the following methods:

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For additional direction on obtaining information and submitting comments, see “Obtaining Information and Submitting Comments” in the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: Sarah Lopas, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001; telephone: 301-415-6360, e-mail: Sarah.Lopas@nrc.gov.

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B. Submitting Comments

Please include Docket ID **NRC-2018-0230** in your comment submission.

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II. Background

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radionuclides or by delivery method), (3) what the appropriate T&E requirements would be for each category, and (4) whether those requirements should be based on hours of T&E or focused more on competency. In response to the SRM, the NRC staff documented its initial results, status, and next steps related to this evaluation in SECY-18-0084, "Staff Evaluation of Training and Experience Requirements for Administering Different Categories of Radiopharmaceuticals in Response to SRM-M170817" (ADAMS Accession No. ML18135A276). In SECY-18-0084, the staff concluded that additional outreach with the medical community is needed to determine whether and how to tailor the T&E requirements to establish a limited AU status, the specific T&E requirements that should apply, how the T&E requirements should be met (e.g., hours of training, demonstration of competency), and whether a competency-based approach makes sense for the T&E requirements for all the medical uses authorized under 10 CFR 35.300, "Use of unsealed byproduct material for which a written directive is required."

The NRC is interested in obtaining input from as many stakeholders as possible, including members of the Advisory Committee on the Medical Uses of Isotopes, professional organizations, physicians, patients, patient advocacy groups, licensees, Agreement States, and other interested individuals. The focus of this request is to gather information that will permit the NRC staff to determine whether changes to the T&E requirements are warranted for different categories of radiopharmaceuticals for physicians seeking AU status for the medical use of specific categories of radiopharmaceuticals requiring a written directive under 10 CFR 35.300.

During the comment period between October 29, 2018 and January 29, 2019, the NRC will hold four public meetings that will discuss the information being requested and to accept comments on the docket. All four public meetings

will be available for remote participation by moderated bridge line and webinar, and two of the four meetings will be open for in-person attendance at NRC's headquarters in Rockville, Maryland.

The public meetings are scheduled for November 14, 2018 (webinar-only); December 11, 2018 (webinar and in-person attendance); January 10, 2019 (webinar and in-person attendance); and January 22, 2019 (webinar-only). The public meetings will be noticed on the NRC's public meeting Web site at least 10 calendar days before the meeting. Members of the public should monitor the NRC's public meeting Web site at <https://www.nrc.gov/pmns/mtg>. The NRC will also post the meeting notices on the Federal Rulemaking Web site at <https://www.regulations.gov/> under Docket ID **NRC-2018-0230**.

The NRC may post additional materials related to this document, including public comments, on the Federal Rulemaking Web site. The Federal Rulemaking Web site allows you to receive alerts when changes or additions occur in a docket folder. To subscribe: (1) Navigate to the docket folder **NRC-2018-0230**; (2) click the “Sign up for E-mail Alerts” link; and (3) enter your email address and select how frequently you would like to receive emails (daily, weekly, or monthly).

III. Specific Requests for Comments

A. Tailored Training & Experience Requirements

The NRC is requesting comments on whether it should establish tailored T&E requirements for different categories of radiopharmaceuticals for physicians seeking AU status for the medical use of specific categories of radiopharmaceuticals requiring a written directive under 10 CFR 35.300 (i.e., a limited AU status). This would be for physicians seeking AU status via the alternate non-board certified pathway, and for physicians certified by a medical

specialty board that is not currently recognized by the NRC under 10 CFR 35.390, 35.392, 35.394, or 35.396 (Unsealed Byproduct Material—Written Directive Required).

1. Are the current pathways for obtaining AU status reasonable and accessible? Provide a rationale for your answer.
2. Are the current pathways for obtaining AU status adequate for protecting public health and safety? Provide a rationale for your answer.
3. Should the NRC develop a new tailored T&E pathway for these physicians? If so, what would be the appropriate way to categorize radiopharmaceuticals for tailored T&E requirements? If not, explain why the regulations should remain unchanged. [Some options to categorize radiopharmaceuticals include radiopharmaceuticals with similar delivery methods (oral, parenteral); same type of radiation characteristics or emission (alpha, beta, gamma, low-energy photon); similar preparation method (patient-ready doses); or a combination thereof (e.g., radiopharmaceuticals containing alpha- and beta-emitting radioisotopes that are administered intravenously and are prepared as patient-ready doses).]
4. Should the fundamental T&E required of physicians seeking limited AU status need to have the same fundamental T&E required of physicians seeking full AU status for all oral and parenteral administrations under 10 CFR 35.300?
5. How should the requirements for this fundamental T&E be structured for a specific category of radiopharmaceuticals?
 - a. Describe what the requirements should include:

- i. Classroom and laboratory training – What topics need to be covered in this training requirement? How many hours of classroom and laboratory training should be required? Provide the basis for the number of hours. If not hours, explain how this training should be quantified. [Note: The topics currently required in the regulations to be included in the classroom and laboratory training and work experience are listed in 10 CFR 35.390, 35.392, 35.394, and 35.396.]
 - ii. Work experience - What should the work experience requirement involve? How many hours of work experience should be required and what is the minimum number of patient or human research subject administrations that an individual must perform? Provide the basis for the number of hours and administrations. What should be the qualifications of the supervising individual?
 - iii. Competency - How should competency be evaluated? Should a written and/or practical examination by an independent examining committee be administered? Provide a rationale for your answer.
- b. Should a preceptor attestation be required for the fundamental T&E? Provide a rationale for your answer.
- c. Should the radiopharmaceutical manufacturer be able to provide the preceptor attestation? Provide a rational for your answer.

- d. Who should establish and administer the curriculum and examination? Provide specific group(s). [Some options are: NRC, medical specialty boards, medical professional societies, educational professional groups, and NRC in collaboration with any or more of the aforementioned groups.]
- e. Should AU competency be periodically assessed? If so, how should it be assessed, how often, and by whom?

B. NRC's Recognition of Medical Specialty Boards

The NRC is requesting comments on its recognition of medical specialty boards. The NRC's procedures for recognizing medical specialty boards are located on the Medical Uses Licensee Toolkit Web site (<https://www.nrc.gov/materials/miau/med-use-toolkit/certif-process-boards.html>). The NRC staff periodically reviews information to determine a board's continued eligibility for recognition.

- 1. What boards other than those already recognized by the NRC (American Board of Nuclear Medicine [ABNM], American Board of Radiology [ABR], American Osteopathic Board of Radiology [AOBR], Certification Board of Nuclear Endocrinology [CBNE]) could be considered for recognition for medical uses under 10 CFR 35.300?
- 2. Are the current NRC medical specialty board recognition criteria sufficient? If not, what additional criteria should the NRC use?

C. Patient Access

The NRC is requesting comments on whether there is a shortage in the number of AUs for 10 CFR 35.300.

1. Is there a shortage in the number of AUs for medical uses under 10 CFR 35.300? If so, is the shortage associated with the use of a specific radiopharmaceutical? Explain how.
2. Are there certain geographic areas with an inadequate number of AUs? Identify these areas.
3. Do current NRC regulations on AU T&E requirements unnecessarily limit patient access to procedures involving radiopharmaceuticals? Explain how.
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D. Other Suggested Changes to the T&E Regulations

In 2002, the NRC revised its regulatory framework for medical use. The goal was to focus the NRC's regulations on those medical procedures that pose the highest risk to workers, the general public, patients, and human research subjects and to structure the regulations to be more risk-informed and more performance-based. The 2002 rule reduced the unnecessary regulatory burden by either reducing or eliminating the prescriptiveness of some regulations. Instead, the rule provided for a performance-based approach that relied on the training and experience of the AUs, authorized nuclear pharmacists, and radiation safety officers. The NRC is requesting comments on whether there are any other changes to the T&E regulations in 10 CFR part 35 that should be considered. Please discuss your suggested changes.

1. Should the NRC regulate the T&E of physicians for medical uses?
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Dated at Rockville, Maryland, this 23rd day of October 2018.

For the Nuclear Regulatory
Commission.

/RA/

Daniel S. Collins, Director,
Division of Materials Safety,
Security,
State, and Tribal Programs,
Office of Nuclear Material Safety
and Safeguards.



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

November 2, 2018

Ms. Crystal Botkin
St. Louis University
Nuclear Medicine Technology
Allied Heath Building, 3437 Caroline St., 3004
St. Louis, MO 63104

Via e-mail to Crystal.Botkin@Health.SLU.edu

SUBJECT: TRAINING AND EXPERIENCE REQUIREMENTS FOR DIFFERENT CATEGORIES OF RADIOPHARMACEUTICALS

Dear Ms. Botkin,

The U.S. Nuclear Regulatory Commission (NRC) is evaluating its regulations related to the training and experience (T&E) required for a physician to become an authorized user for medical uses under Subpart E, “Unsealed Byproduct Material—Written Directive Required,” of [Title 10 of the Code of Federal Regulations \(10 CFR\) Part 35, “Medical Use of Byproduct Material.”](#)

The T&E requirements in Subpart E of 10 CFR Part 35 provide three ways that a physician can be authorized to administer unsealed byproduct materials or radiopharmaceuticals requiring a written directive:

1. A physician can be certified by a medical specialty board, whose certification process is recognized by the NRC or an Agreement State.
2. A physician can complete a structured educational program and supervised work experience under an alternate pathway. This alternate pathway includes a requirement for 700 hours of training and experience, which consists of a minimum of 200 hours of classroom and laboratory training and 500 hours of supervised work experience.
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In its evaluation of the T&E requirements, the NRC staff is considering whether an additional pathway should be created or if the alternate pathway should be revised. Specifically, the staff is evaluating: (1) whether it makes sense to establish tailored T&E requirements for different categories of radiopharmaceuticals; (2) how those categories should be determined; (3) what the appropriate T&E requirements would be for each category; and (4) whether those requirements should be based on hours of training and experience, or focused more on competency.

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Christian Einberg, Chief
Medical Safety and Events Assessment Branch
Division of Materials Safety, Security, State
and Tribal Programs
Office of Nuclear Material Safety
and Safeguards

Enclosure:
Training and Experience
Federal Register notice

NUCLEAR REGULATORY COMMISSION

[NRC-2018-0230]

**Training and Experience Requirements for Different Categories of
Radiopharmaceuticals**

AGENCY: Nuclear Regulatory Commission.

ACTION: Training and experience requirements; request for comment.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is requesting comments on its training and experience (T&E) requirements. Specifically, the NRC would like input on whether it should establish tailored T&E requirements for different categories of radiopharmaceuticals for which a written directive is required in accordance with its regulations. The input will be used to determine whether significant regulatory changes to the NRC's T&E requirements for authorized users (AUs) are warranted.

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5. How should the requirements for this fundamental T&E be structured for a specific category of radiopharmaceuticals?
 - a. Describe what the requirements should include:

- i. Classroom and laboratory training – What topics need to be covered in this training requirement? How many hours of classroom and laboratory training should be required? Provide the basis for the number of hours. If not hours, explain how this training should be quantified. [Note: The topics currently required in the regulations to be included in the classroom and laboratory training and work experience are listed in 10 CFR 35.390, 35.392, 35.394, and 35.396.]
 - ii. Work experience - What should the work experience requirement involve? How many hours of work experience should be required and what is the minimum number of patient or human research subject administrations that an individual must perform? Provide the basis for the number of hours and administrations. What should be the qualifications of the supervising individual?
 - iii. Competency - How should competency be evaluated? Should a written and/or practical examination by an independent examining committee be administered? Provide a rationale for your answer.
- b. Should a preceptor attestation be required for the fundamental T&E? Provide a rationale for your answer.
- c. Should the radiopharmaceutical manufacturer be able to provide the preceptor attestation? Provide a rational for your answer.

- d. Who should establish and administer the curriculum and examination? Provide specific group(s). [Some options are: NRC, medical specialty boards, medical professional societies, educational professional groups, and NRC in collaboration with any or more of the aforementioned groups.]
- e. Should AU competency be periodically assessed? If so, how should it be assessed, how often, and by whom?

B. NRC's Recognition of Medical Specialty Boards

The NRC is requesting comments on its recognition of medical specialty boards. The NRC's procedures for recognizing medical specialty boards are located on the Medical Uses Licensee Toolkit Web site (<https://www.nrc.gov/materials/miau/med-use-toolkit/certif-process-boards.html>). The NRC staff periodically reviews information to determine a board's continued eligibility for recognition.

- 1. What boards other than those already recognized by the NRC (American Board of Nuclear Medicine [ABNM], American Board of Radiology [ABR], American Osteopathic Board of Radiology [AOBR], Certification Board of Nuclear Endocrinology [CBNE]) could be considered for recognition for medical uses under 10 CFR 35.300?
- 2. Are the current NRC medical specialty board recognition criteria sufficient? If not, what additional criteria should the NRC use?

C. Patient Access

The NRC is requesting comments on whether there is a shortage in the number of AUs for 10 CFR 35.300.

1. Is there a shortage in the number of AUs for medical uses under 10 CFR 35.300? If so, is the shortage associated with the use of a specific radiopharmaceutical? Explain how.
2. Are there certain geographic areas with an inadequate number of AUs? Identify these areas.
3. Do current NRC regulations on AU T&E requirements unnecessarily limit patient access to procedures involving radiopharmaceuticals? Explain how.
4. Do current NRC regulations on AU T&E requirements unnecessarily limit research and development in nuclear medicine? Explain how.

D. Other Suggested Changes to the T&E Regulations

In 2002, the NRC revised its regulatory framework for medical use. The goal was to focus the NRC's regulations on those medical procedures that pose the highest risk to workers, the general public, patients, and human research subjects and to structure the regulations to be more risk-informed and more performance-based. The 2002 rule reduced the unnecessary regulatory burden by either reducing or eliminating the prescriptiveness of some regulations. Instead, the rule provided for a performance-based approach that relied on the training and experience of the AUs, authorized nuclear pharmacists, and radiation safety officers. The NRC is requesting comments on whether there are any other changes to the T&E regulations in 10 CFR part 35 that should be considered. Please discuss your suggested changes.

1. Should the NRC regulate the T&E of physicians for medical uses?
2. Are there requirements in the NRC's T&E regulatory framework for physicians that are non-safety related?

3. How can the NRC transform its regulatory approach for T&E while still ensuring that adequate protection is maintained for workers, the general public, patients, and human research subjects?

Dated at Rockville, Maryland, this 23rd day of October 2018.

For the Nuclear Regulatory
Commission.

/RA/

Daniel S. Collins, Director,
Division of Materials Safety,
Security,
State, and Tribal Programs,
Office of Nuclear Material Safety
and Safeguards.



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

November 2, 2018

Dr. Otis W. Brawley, MD
Chief Medical and Scientific Officer
American Cancer Society
250 Williams St. NW
Atlanta, GA 30303

Via e-mail to otis.brawley@cancer.org

SUBJECT: TRAINING AND EXPERIENCE REQUIREMENTS FOR DIFFERENT CATEGORIES OF RADIOPHARMACEUTICALS

Dear Dr. Brawley,

The U.S. Nuclear Regulatory Commission (NRC) is evaluating its regulations related to the training and experience (T&E) required for a physician to become an authorized user for medical uses under Subpart E, “Unsealed Byproduct Material—Written Directive Required,” of [Title 10 of the Code of Federal Regulations \(10 CFR\) Part 35, “Medical Use of Byproduct Material.”](#)

The T&E requirements in Subpart E of 10 CFR Part 35 provide three ways that a physician can be authorized to administer unsealed byproduct materials or radiopharmaceuticals requiring a written directive:

1. A physician can be certified by a medical specialty board, whose certification process is recognized by the NRC or an Agreement State.
2. A physician can complete a structured educational program and supervised work experience under an alternate pathway. This alternate pathway includes a requirement for 700 hours of training and experience, which consists of a minimum of 200 hours of classroom and laboratory training and 500 hours of supervised work experience.
3. A physician can be authorized if previously identified as an authorized user on an NRC or Agreement State license or permit (i.e., grandfathered).

In its evaluation of the T&E requirements, the NRC staff is considering whether an additional pathway should be created or if the alternate pathway should be revised. Specifically, the staff is evaluating: (1) whether it makes sense to establish tailored T&E requirements for different categories of radiopharmaceuticals; (2) how those categories should be determined; (3) what the appropriate T&E requirements would be for each category; and (4) whether those requirements should be based on hours of training and experience, or focused more on competency.

On October 29, 2018, the NRC published a series of questions on T&E in the *Federal Register* (83 FR 54380). The *Federal Register* notice is enclosed with this letter and can also be accessed at: <https://www.gpo.gov/fdsys/pkg/FR-2018-10-29/pdf/2018-23521.pdf>. The NRC will carefully consider responses to these questions and would appreciate your feedback on whether changes to the current T&E regulations are warranted. The comment period for the T&E evaluation will end on January 29, 2019. Please follow the directions in the notice on how to submit written comments. The NRC is using the Federal rulemaking Web site, [Regulations.gov](#), to accept written comments on the docket (NRC-2018-0230).

The NRC will also conduct four public meetings scheduled for November 14 and December 11, 2018, and January 10 and January 22, 2019, and will accept oral comments provided during the meetings. The meetings on December 11 and January 10 will be held at NRC Headquarters in Rockville, MD, and all four meetings will be accessible for remote participation by moderated bridge line and webinar. The NRC's public meeting page has been updated with meeting details and registration instructions for each meeting: <https://www.nrc.gov/pmns/mtg>.

Additional information on the NRC's T&E evaluation can be found at: <https://www.nrc.gov/materials/miau/med-use-toolkit/training-experience-evaluation.html>. If you have any questions on this correspondence, please contact Sarah Lopas of my staff at (301) 415-6360 or Sarah.Lopas@nrc.gov.

A handwritten signature in black ink, appearing to read "C Einberg".

Christian Einberg, Chief
Medical Safety and Events Assessment Branch
Division of Materials Safety, Security, State
and Tribal Programs
Office of Nuclear Material Safety
and Safeguards

Enclosure:
Training and Experience
Federal Register notice

NUCLEAR REGULATORY COMMISSION

[NRC-2018-0230]

**Training and Experience Requirements for Different Categories of
Radiopharmaceuticals**

AGENCY: Nuclear Regulatory Commission.

ACTION: Training and experience requirements; request for comment.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is requesting comments on its training and experience (T&E) requirements. Specifically, the NRC would like input on whether it should establish tailored T&E requirements for different categories of radiopharmaceuticals for which a written directive is required in accordance with its regulations. The input will be used to determine whether significant regulatory changes to the NRC's T&E requirements for authorized users (AUs) are warranted.

DATES: Submit comments by January 29, 2019. Comments received after this date will be considered if it is practical to do so, but the NRC is only able to ensure consideration for comments received on or before this date.

ADDRESSES: You may submit comments by any of the following methods:

- **Federal Rulemaking Web Site:** Go to <http://www.regulations.gov>

and search for Docket ID **NRC-2018-0230**. Address questions about Docket IDs in Regulations.gov to Jennifer Borges; telephone: 301-287-9127; e-mail: Jennifer.Borges@nrc.gov. For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.

- **Mail comments to:** May Ma, Office of Administration, Mail Stop: TWFN-7-A60M, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001.

For additional direction on obtaining information and submitting comments, see “Obtaining Information and Submitting Comments” in the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: Sarah Lopas, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001; telephone: 301-415-6360, e-mail: Sarah.Lopas@nrc.gov.

SUPPLEMENTARY INFORMATION:

I. Obtaining Information and Submitting Comments

A. Obtaining Information

Please refer to Docket ID **NRC-2018-0230** when contacting the NRC about the availability of information for this action. You may obtain publicly-available information related to this action by any of the following methods:

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- **NRC's PDR:** You may examine and purchase copies of public documents at the NRC's PDR, Room O1-F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.

B. Submitting Comments

Please include Docket ID **NRC-2018-0230** in your comment submission.

The NRC cautions you not to include identifying or contact information in comment submissions that you do not want to be publicly disclosed in your comment submission. All comment submissions are posted at <http://www.regulations.gov> and entered into ADAMS. Comment submissions are not routinely edited to remove identifying or contact information.

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II. Background

On August 17, 2017, the Commission issued a staff requirements memorandum (SRM), SRM-M170817 (ADAMS Accession No. ML17229B284), approving the final rule revising parts 30, 32, and 35 of title 10 of the *Code of Federal Regulations* (10 CFR), "Medical Use of Byproduct Material – Medical Event Definitions, Training and Experience, and Clarifying Amendments," and directing the staff to evaluate (1) whether it makes sense to establish tailored T&E requirements for different categories of radiopharmaceuticals, (2) how those categories should be determined (such as by risks posed by groups of

radionuclides or by delivery method), (3) what the appropriate T&E requirements would be for each category, and (4) whether those requirements should be based on hours of T&E or focused more on competency. In response to the SRM, the NRC staff documented its initial results, status, and next steps related to this evaluation in SECY-18-0084, "Staff Evaluation of Training and Experience Requirements for Administering Different Categories of Radiopharmaceuticals in Response to SRM-M170817" (ADAMS Accession No. ML18135A276). In SECY-18-0084, the staff concluded that additional outreach with the medical community is needed to determine whether and how to tailor the T&E requirements to establish a limited AU status, the specific T&E requirements that should apply, how the T&E requirements should be met (e.g., hours of training, demonstration of competency), and whether a competency-based approach makes sense for the T&E requirements for all the medical uses authorized under 10 CFR 35.300, "Use of unsealed byproduct material for which a written directive is required."

The NRC is interested in obtaining input from as many stakeholders as possible, including members of the Advisory Committee on the Medical Uses of Isotopes, professional organizations, physicians, patients, patient advocacy groups, licensees, Agreement States, and other interested individuals. The focus of this request is to gather information that will permit the NRC staff to determine whether changes to the T&E requirements are warranted for different categories of radiopharmaceuticals for physicians seeking AU status for the medical use of specific categories of radiopharmaceuticals requiring a written directive under 10 CFR 35.300.

During the comment period between October 29, 2018 and January 29, 2019, the NRC will hold four public meetings that will discuss the information being requested and to accept comments on the docket. All four public meetings

will be available for remote participation by moderated bridge line and webinar, and two of the four meetings will be open for in-person attendance at NRC's headquarters in Rockville, Maryland.

The public meetings are scheduled for November 14, 2018 (webinar-only); December 11, 2018 (webinar and in-person attendance); January 10, 2019 (webinar and in-person attendance); and January 22, 2019 (webinar-only). The public meetings will be noticed on the NRC's public meeting Web site at least 10 calendar days before the meeting. Members of the public should monitor the NRC's public meeting Web site at <https://www.nrc.gov/pmns/mtg>. The NRC will also post the meeting notices on the Federal Rulemaking Web site at <https://www.regulations.gov/> under Docket ID **NRC-2018-0230**.

The NRC may post additional materials related to this document, including public comments, on the Federal Rulemaking Web site. The Federal Rulemaking Web site allows you to receive alerts when changes or additions occur in a docket folder. To subscribe: (1) Navigate to the docket folder **NRC-2018-0230**; (2) click the “Sign up for E-mail Alerts” link; and (3) enter your email address and select how frequently you would like to receive emails (daily, weekly, or monthly).

III. Specific Requests for Comments

A. Tailored Training & Experience Requirements

The NRC is requesting comments on whether it should establish tailored T&E requirements for different categories of radiopharmaceuticals for physicians seeking AU status for the medical use of specific categories of radiopharmaceuticals requiring a written directive under 10 CFR 35.300 (i.e., a limited AU status). This would be for physicians seeking AU status via the alternate non-board certified pathway, and for physicians certified by a medical

specialty board that is not currently recognized by the NRC under 10 CFR 35.390, 35.392, 35.394, or 35.396 (Unsealed Byproduct Material—Written Directive Required).

1. Are the current pathways for obtaining AU status reasonable and accessible? Provide a rationale for your answer.
2. Are the current pathways for obtaining AU status adequate for protecting public health and safety? Provide a rationale for your answer.
3. Should the NRC develop a new tailored T&E pathway for these physicians? If so, what would be the appropriate way to categorize radiopharmaceuticals for tailored T&E requirements? If not, explain why the regulations should remain unchanged. [Some options to categorize radiopharmaceuticals include radiopharmaceuticals with similar delivery methods (oral, parenteral); same type of radiation characteristics or emission (alpha, beta, gamma, low-energy photon); similar preparation method (patient-ready doses); or a combination thereof (e.g., radiopharmaceuticals containing alpha- and beta-emitting radioisotopes that are administered intravenously and are prepared as patient-ready doses).]
4. Should the fundamental T&E required of physicians seeking limited AU status need to have the same fundamental T&E required of physicians seeking full AU status for all oral and parenteral administrations under 10 CFR 35.300?
5. How should the requirements for this fundamental T&E be structured for a specific category of radiopharmaceuticals?
 - a. Describe what the requirements should include:

- i. Classroom and laboratory training – What topics need to be covered in this training requirement? How many hours of classroom and laboratory training should be required? Provide the basis for the number of hours. If not hours, explain how this training should be quantified. [Note: The topics currently required in the regulations to be included in the classroom and laboratory training and work experience are listed in 10 CFR 35.390, 35.392, 35.394, and 35.396.]
 - ii. Work experience - What should the work experience requirement involve? How many hours of work experience should be required and what is the minimum number of patient or human research subject administrations that an individual must perform? Provide the basis for the number of hours and administrations. What should be the qualifications of the supervising individual?
 - iii. Competency - How should competency be evaluated? Should a written and/or practical examination by an independent examining committee be administered? Provide a rationale for your answer.
- b. Should a preceptor attestation be required for the fundamental T&E? Provide a rationale for your answer.
- c. Should the radiopharmaceutical manufacturer be able to provide the preceptor attestation? Provide a rational for your answer.

- d. Who should establish and administer the curriculum and examination? Provide specific group(s). [Some options are: NRC, medical specialty boards, medical professional societies, educational professional groups, and NRC in collaboration with any or more of the aforementioned groups.]
- e. Should AU competency be periodically assessed? If so, how should it be assessed, how often, and by whom?

B. NRC's Recognition of Medical Specialty Boards

The NRC is requesting comments on its recognition of medical specialty boards. The NRC's procedures for recognizing medical specialty boards are located on the Medical Uses Licensee Toolkit Web site (<https://www.nrc.gov/materials/miau/med-use-toolkit/certif-process-boards.html>). The NRC staff periodically reviews information to determine a board's continued eligibility for recognition.

- 1. What boards other than those already recognized by the NRC (American Board of Nuclear Medicine [ABNM], American Board of Radiology [ABR], American Osteopathic Board of Radiology [AOBR], Certification Board of Nuclear Endocrinology [CBNE]) could be considered for recognition for medical uses under 10 CFR 35.300?
- 2. Are the current NRC medical specialty board recognition criteria sufficient? If not, what additional criteria should the NRC use?

C. Patient Access

The NRC is requesting comments on whether there is a shortage in the number of AUs for 10 CFR 35.300.

1. Is there a shortage in the number of AUs for medical uses under 10 CFR 35.300? If so, is the shortage associated with the use of a specific radiopharmaceutical? Explain how.
2. Are there certain geographic areas with an inadequate number of AUs? Identify these areas.
3. Do current NRC regulations on AU T&E requirements unnecessarily limit patient access to procedures involving radiopharmaceuticals? Explain how.
4. Do current NRC regulations on AU T&E requirements unnecessarily limit research and development in nuclear medicine? Explain how.

D. Other Suggested Changes to the T&E Regulations

In 2002, the NRC revised its regulatory framework for medical use. The goal was to focus the NRC's regulations on those medical procedures that pose the highest risk to workers, the general public, patients, and human research subjects and to structure the regulations to be more risk-informed and more performance-based. The 2002 rule reduced the unnecessary regulatory burden by either reducing or eliminating the prescriptiveness of some regulations. Instead, the rule provided for a performance-based approach that relied on the training and experience of the AUs, authorized nuclear pharmacists, and radiation safety officers. The NRC is requesting comments on whether there are any other changes to the T&E regulations in 10 CFR part 35 that should be considered. Please discuss your suggested changes.

1. Should the NRC regulate the T&E of physicians for medical uses?
2. Are there requirements in the NRC's T&E regulatory framework for physicians that are non-safety related?

3. How can the NRC transform its regulatory approach for T&E while still ensuring that adequate protection is maintained for workers, the general public, patients, and human research subjects?

Dated at Rockville, Maryland, this 23rd day of October 2018.

For the Nuclear Regulatory
Commission.

/RA/

Daniel S. Collins, Director,
Division of Materials Safety,
Security,
State, and Tribal Programs,
Office of Nuclear Material Safety
and Safeguards.



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

November 2, 2018

Ms. Patricia J. Goldsmith
Chief Executive Office
CancerCare
275 Seventh Ave.
New York, NY 10001

Via e-mail to info@cancercare.org

SUBJECT: TRAINING AND EXPERIENCE REQUIREMENTS FOR DIFFERENT CATEGORIES OF RADIOPHARMACEUTICALS

Dear Ms. Goldsmith,

The U.S. Nuclear Regulatory Commission (NRC) is evaluating its regulations related to the training and experience (T&E) required for a physician to become an authorized user for medical uses under Subpart E, “Unsealed Byproduct Material—Written Directive Required,” of [Title 10 of the Code of Federal Regulations \(10 CFR\) Part 35, “Medical Use of Byproduct Material.”](#)

The T&E requirements in Subpart E of 10 CFR Part 35 provide three ways that a physician can be authorized to administer unsealed byproduct materials or radiopharmaceuticals requiring a written directive:

1. A physician can be certified by a medical specialty board, whose certification process is recognized by the NRC or an Agreement State.
2. A physician can complete a structured educational program and supervised work experience under an alternate pathway. This alternate pathway includes a requirement for 700 hours of training and experience, which consists of a minimum of 200 hours of classroom and laboratory training and 500 hours of supervised work experience.
3. A physician can be authorized if previously identified as an authorized user on an NRC or Agreement State license or permit (i.e., grandfathered).

In its evaluation of the T&E requirements, the NRC staff is considering whether an additional pathway should be created or if the alternate pathway should be revised. Specifically, the staff is evaluating: (1) whether it makes sense to establish tailored T&E requirements for different categories of radiopharmaceuticals; (2) how those categories should be determined; (3) what the appropriate T&E requirements would be for each category; and (4) whether those requirements should be based on hours of training and experience, or focused more on competency.

On October 29, 2018, the NRC published a series of questions on T&E in the *Federal Register* (83 FR 54380). The *Federal Register* notice is enclosed with this letter and can also be accessed at: <https://www.gpo.gov/fdsys/pkg/FR-2018-10-29/pdf/2018-23521.pdf>. The NRC will carefully consider responses to these questions and would appreciate your feedback on whether changes to the current T&E regulations are warranted. The comment period for the T&E evaluation will end on January 29, 2019. Please follow the directions in the notice on how to submit written comments. The NRC is using the Federal rulemaking Web site, [Regulations.gov](#), to accept written comments on the docket (NRC-2018-0230).

The NRC will also conduct four public meetings scheduled for November 14 and December 11, 2018, and January 10 and January 22, 2019, and will accept oral comments provided during the meetings. The meetings on December 11 and January 10 will be held at NRC Headquarters in Rockville, MD, and all four meetings will be accessible for remote participation by moderated bridge line and webinar. The NRC's public meeting page has been updated with meeting details and registration instructions for each meeting: <https://www.nrc.gov/pmns/mtg>.

Additional information on the NRC's T&E evaluation can be found at: <https://www.nrc.gov/materials/miau/med-use-toolkit/training-experience-evaluation.html>. If you have any questions on this correspondence, please contact Sarah Lopas of my staff at (301) 415-6360 or Sarah.Lopas@nrc.gov.

A handwritten signature in black ink, appearing to read "C Einberg".

Christian Einberg, Chief
Medical Safety and Events Assessment Branch
Division of Materials Safety, Security, State
and Tribal Programs
Office of Nuclear Material Safety
and Safeguards

Enclosure:
Training and Experience
Federal Register notice

NUCLEAR REGULATORY COMMISSION

[NRC-2018-0230]

**Training and Experience Requirements for Different Categories of
Radiopharmaceuticals**

AGENCY: Nuclear Regulatory Commission.

ACTION: Training and experience requirements; request for comment.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is requesting comments on its training and experience (T&E) requirements. Specifically, the NRC would like input on whether it should establish tailored T&E requirements for different categories of radiopharmaceuticals for which a written directive is required in accordance with its regulations. The input will be used to determine whether significant regulatory changes to the NRC's T&E requirements for authorized users (AUs) are warranted.

DATES: Submit comments by January 29, 2019. Comments received after this date will be considered if it is practical to do so, but the NRC is only able to ensure consideration for comments received on or before this date.

ADDRESSES: You may submit comments by any of the following methods:

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For additional direction on obtaining information and submitting comments, see “Obtaining Information and Submitting Comments” in the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: Sarah Lopas, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001; telephone: 301-415-6360, e-mail: Sarah.Lopas@nrc.gov.

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I. Obtaining Information and Submitting Comments

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B. Submitting Comments

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The NRC is interested in obtaining input from as many stakeholders as possible, including members of the Advisory Committee on the Medical Uses of Isotopes, professional organizations, physicians, patients, patient advocacy groups, licensees, Agreement States, and other interested individuals. The focus of this request is to gather information that will permit the NRC staff to determine whether changes to the T&E requirements are warranted for different categories of radiopharmaceuticals for physicians seeking AU status for the medical use of specific categories of radiopharmaceuticals requiring a written directive under 10 CFR 35.300.

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III. Specific Requests for Comments

A. Tailored Training & Experience Requirements

The NRC is requesting comments on whether it should establish tailored T&E requirements for different categories of radiopharmaceuticals for physicians seeking AU status for the medical use of specific categories of radiopharmaceuticals requiring a written directive under 10 CFR 35.300 (i.e., a limited AU status). This would be for physicians seeking AU status via the alternate non-board certified pathway, and for physicians certified by a medical

specialty board that is not currently recognized by the NRC under 10 CFR 35.390, 35.392, 35.394, or 35.396 (Unsealed Byproduct Material—Written Directive Required).

1. Are the current pathways for obtaining AU status reasonable and accessible? Provide a rationale for your answer.
2. Are the current pathways for obtaining AU status adequate for protecting public health and safety? Provide a rationale for your answer.
3. Should the NRC develop a new tailored T&E pathway for these physicians? If so, what would be the appropriate way to categorize radiopharmaceuticals for tailored T&E requirements? If not, explain why the regulations should remain unchanged. [Some options to categorize radiopharmaceuticals include radiopharmaceuticals with similar delivery methods (oral, parenteral); same type of radiation characteristics or emission (alpha, beta, gamma, low-energy photon); similar preparation method (patient-ready doses); or a combination thereof (e.g., radiopharmaceuticals containing alpha- and beta-emitting radioisotopes that are administered intravenously and are prepared as patient-ready doses).]
4. Should the fundamental T&E required of physicians seeking limited AU status need to have the same fundamental T&E required of physicians seeking full AU status for all oral and parenteral administrations under 10 CFR 35.300?
5. How should the requirements for this fundamental T&E be structured for a specific category of radiopharmaceuticals?
 - a. Describe what the requirements should include:

- i. Classroom and laboratory training – What topics need to be covered in this training requirement? How many hours of classroom and laboratory training should be required? Provide the basis for the number of hours. If not hours, explain how this training should be quantified. [Note: The topics currently required in the regulations to be included in the classroom and laboratory training and work experience are listed in 10 CFR 35.390, 35.392, 35.394, and 35.396.]
 - ii. Work experience - What should the work experience requirement involve? How many hours of work experience should be required and what is the minimum number of patient or human research subject administrations that an individual must perform? Provide the basis for the number of hours and administrations. What should be the qualifications of the supervising individual?
 - iii. Competency - How should competency be evaluated? Should a written and/or practical examination by an independent examining committee be administered? Provide a rationale for your answer.
- b. Should a preceptor attestation be required for the fundamental T&E? Provide a rationale for your answer.
- c. Should the radiopharmaceutical manufacturer be able to provide the preceptor attestation? Provide a rational for your answer.

- d. Who should establish and administer the curriculum and examination? Provide specific group(s). [Some options are: NRC, medical specialty boards, medical professional societies, educational professional groups, and NRC in collaboration with any or more of the aforementioned groups.]
- e. Should AU competency be periodically assessed? If so, how should it be assessed, how often, and by whom?

B. NRC's Recognition of Medical Specialty Boards

The NRC is requesting comments on its recognition of medical specialty boards. The NRC's procedures for recognizing medical specialty boards are located on the Medical Uses Licensee Toolkit Web site (<https://www.nrc.gov/materials/miau/med-use-toolkit/certif-process-boards.html>). The NRC staff periodically reviews information to determine a board's continued eligibility for recognition.

- 1. What boards other than those already recognized by the NRC (American Board of Nuclear Medicine [ABNM], American Board of Radiology [ABR], American Osteopathic Board of Radiology [AOBR], Certification Board of Nuclear Endocrinology [CBNE]) could be considered for recognition for medical uses under 10 CFR 35.300?
- 2. Are the current NRC medical specialty board recognition criteria sufficient? If not, what additional criteria should the NRC use?

C. Patient Access

The NRC is requesting comments on whether there is a shortage in the number of AUs for 10 CFR 35.300.

1. Is there a shortage in the number of AUs for medical uses under 10 CFR 35.300? If so, is the shortage associated with the use of a specific radiopharmaceutical? Explain how.
2. Are there certain geographic areas with an inadequate number of AUs? Identify these areas.
3. Do current NRC regulations on AU T&E requirements unnecessarily limit patient access to procedures involving radiopharmaceuticals? Explain how.
4. Do current NRC regulations on AU T&E requirements unnecessarily limit research and development in nuclear medicine? Explain how.

D. Other Suggested Changes to the T&E Regulations

In 2002, the NRC revised its regulatory framework for medical use. The goal was to focus the NRC's regulations on those medical procedures that pose the highest risk to workers, the general public, patients, and human research subjects and to structure the regulations to be more risk-informed and more performance-based. The 2002 rule reduced the unnecessary regulatory burden by either reducing or eliminating the prescriptiveness of some regulations. Instead, the rule provided for a performance-based approach that relied on the training and experience of the AUs, authorized nuclear pharmacists, and radiation safety officers. The NRC is requesting comments on whether there are any other changes to the T&E regulations in 10 CFR part 35 that should be considered. Please discuss your suggested changes.

1. Should the NRC regulate the T&E of physicians for medical uses?
2. Are there requirements in the NRC's T&E regulatory framework for physicians that are non-safety related?

3. How can the NRC transform its regulatory approach for T&E while still ensuring that adequate protection is maintained for workers, the general public, patients, and human research subjects?

Dated at Rockville, Maryland, this 23rd day of October 2018.

For the Nuclear Regulatory
Commission.

/RA/

Daniel S. Collins, Director,
Division of Materials Safety,
Security,
State, and Tribal Programs,
Office of Nuclear Material Safety
and Safeguards.



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

November 2, 2018

Dr. Otto Casal
Radiology Tech Administrator
Department of Radiology, University of Utah
30 North 1900 East
Salt Lake City, UT 84132

Via e-mail to otto.casal@hsc.utah.edu

SUBJECT: TRAINING AND EXPERIENCE REQUIREMENTS FOR DIFFERENT CATEGORIES OF RADIOPHARMACEUTICALS

Dear Dr. Casal,

The U.S. Nuclear Regulatory Commission (NRC) is evaluating its regulations related to the training and experience (T&E) required for a physician to become an authorized user for medical uses under Subpart E, “Unsealed Byproduct Material—Written Directive Required,” of [Title 10 of the Code of Federal Regulations \(10 CFR\) Part 35, “Medical Use of Byproduct Material.”](#)

The T&E requirements in Subpart E of 10 CFR Part 35 provide three ways that a physician can be authorized to administer unsealed byproduct materials or radiopharmaceuticals requiring a written directive:

1. A physician can be certified by a medical specialty board, whose certification process is recognized by the NRC or an Agreement State.
2. A physician can complete a structured educational program and supervised work experience under an alternate pathway. This alternate pathway includes a requirement for 700 hours of training and experience, which consists of a minimum of 200 hours of classroom and laboratory training and 500 hours of supervised work experience.
3. A physician can be authorized if previously identified as an authorized user on an NRC or Agreement State license or permit (i.e., grandfathered).

In its evaluation of the T&E requirements, the NRC staff is considering whether an additional pathway should be created or if the alternate pathway should be revised. Specifically, the staff is evaluating: (1) whether it makes sense to establish tailored T&E requirements for different categories of radiopharmaceuticals; (2) how those categories should be determined; (3) what the appropriate T&E requirements would be for each category; and (4) whether those requirements should be based on hours of training and experience, or focused more on competency.

On October 29, 2018, the NRC published a series of questions on T&E in the *Federal Register* (83 FR 54380). The *Federal Register* notice is enclosed with this letter and can also be accessed at: <https://www.gpo.gov/fdsys/pkg/FR-2018-10-29/pdf/2018-23521.pdf>. The NRC will carefully consider responses to these questions and would appreciate your feedback on whether changes to the current T&E regulations are warranted. The comment period for the T&E evaluation will end on January 29, 2019. Please follow the directions in the notice on how to submit written comments. The NRC is using the Federal rulemaking Web site, [Regulations.gov](#), to accept written comments on the docket (NRC-2018-0230).

The NRC will also conduct four public meetings scheduled for November 14 and December 11, 2018, and January 10 and January 22, 2019, and will accept oral comments provided during the meetings. The meetings on December 11 and January 10 will be held at NRC Headquarters in Rockville, MD, and all four meetings will be accessible for remote participation by moderated bridge line and webinar. The NRC's public meeting page has been updated with meeting details and registration instructions for each meeting: <https://www.nrc.gov/pmns/mtg>.

Additional information on the NRC's T&E evaluation can be found at: <https://www.nrc.gov/materials/miau/med-use-toolkit/training-experience-evaluation.html>. If you have any questions on this correspondence, please contact Sarah Lopas of my staff at (301) 415-6360 or Sarah.Lopas@nrc.gov.

A handwritten signature in black ink, appearing to read "C Einberg".

Christian Einberg, Chief
Medical Safety and Events Assessment Branch
Division of Materials Safety, Security, State
and Tribal Programs
Office of Nuclear Material Safety
and Safeguards

Enclosure:
Training and Experience
Federal Register notice

NUCLEAR REGULATORY COMMISSION

[NRC-2018-0230]

**Training and Experience Requirements for Different Categories of
Radiopharmaceuticals**

AGENCY: Nuclear Regulatory Commission.

ACTION: Training and experience requirements; request for comment.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is requesting comments on its training and experience (T&E) requirements. Specifically, the NRC would like input on whether it should establish tailored T&E requirements for different categories of radiopharmaceuticals for which a written directive is required in accordance with its regulations. The input will be used to determine whether significant regulatory changes to the NRC's T&E requirements for authorized users (AUs) are warranted.

DATES: Submit comments by January 29, 2019. Comments received after this date will be considered if it is practical to do so, but the NRC is only able to ensure consideration for comments received on or before this date.

ADDRESSES: You may submit comments by any of the following methods:

- **Federal Rulemaking Web Site:** Go to <http://www.regulations.gov>

and search for Docket ID **NRC-2018-0230**. Address questions about Docket IDs in Regulations.gov to Jennifer Borges; telephone: 301-287-9127; e-mail: Jennifer.Borges@nrc.gov. For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.

- **Mail comments to:** May Ma, Office of Administration, Mail Stop: TWFN-7-A60M, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001.

For additional direction on obtaining information and submitting comments, see “Obtaining Information and Submitting Comments” in the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: Sarah Lopas, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001; telephone: 301-415-6360, e-mail: Sarah.Lopas@nrc.gov.

SUPPLEMENTARY INFORMATION:

I. Obtaining Information and Submitting Comments

A. Obtaining Information

Please refer to Docket ID **NRC-2018-0230** when contacting the NRC about the availability of information for this action. You may obtain publicly-available information related to this action by any of the following methods:

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- **NRC's PDR:** You may examine and purchase copies of public documents at the NRC's PDR, Room O1-F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.

B. Submitting Comments

Please include Docket ID **NRC-2018-0230** in your comment submission.

The NRC cautions you not to include identifying or contact information in comment submissions that you do not want to be publicly disclosed in your comment submission. All comment submissions are posted at <http://www.regulations.gov> and entered into ADAMS. Comment submissions are not routinely edited to remove identifying or contact information.

If you are requesting or aggregating comments from other persons for submission to the NRC, then you should inform those persons not to include identifying or contact information that they do not want to be publicly disclosed in their comment submission. Your request should state that the NRC does not routinely edit comment submissions to remove such information before making the comment submissions available to the public or entering the comment into ADAMS.

II. Background

On August 17, 2017, the Commission issued a staff requirements memorandum (SRM), SRM-M170817 (ADAMS Accession No. ML17229B284), approving the final rule revising parts 30, 32, and 35 of title 10 of the *Code of Federal Regulations* (10 CFR), "Medical Use of Byproduct Material – Medical Event Definitions, Training and Experience, and Clarifying Amendments," and directing the staff to evaluate (1) whether it makes sense to establish tailored T&E requirements for different categories of radiopharmaceuticals, (2) how those categories should be determined (such as by risks posed by groups of

radionuclides or by delivery method), (3) what the appropriate T&E requirements would be for each category, and (4) whether those requirements should be based on hours of T&E or focused more on competency. In response to the SRM, the NRC staff documented its initial results, status, and next steps related to this evaluation in SECY-18-0084, "Staff Evaluation of Training and Experience Requirements for Administering Different Categories of Radiopharmaceuticals in Response to SRM-M170817" (ADAMS Accession No. ML18135A276). In SECY-18-0084, the staff concluded that additional outreach with the medical community is needed to determine whether and how to tailor the T&E requirements to establish a limited AU status, the specific T&E requirements that should apply, how the T&E requirements should be met (e.g., hours of training, demonstration of competency), and whether a competency-based approach makes sense for the T&E requirements for all the medical uses authorized under 10 CFR 35.300, "Use of unsealed byproduct material for which a written directive is required."

The NRC is interested in obtaining input from as many stakeholders as possible, including members of the Advisory Committee on the Medical Uses of Isotopes, professional organizations, physicians, patients, patient advocacy groups, licensees, Agreement States, and other interested individuals. The focus of this request is to gather information that will permit the NRC staff to determine whether changes to the T&E requirements are warranted for different categories of radiopharmaceuticals for physicians seeking AU status for the medical use of specific categories of radiopharmaceuticals requiring a written directive under 10 CFR 35.300.

During the comment period between October 29, 2018 and January 29, 2019, the NRC will hold four public meetings that will discuss the information being requested and to accept comments on the docket. All four public meetings

will be available for remote participation by moderated bridge line and webinar, and two of the four meetings will be open for in-person attendance at NRC's headquarters in Rockville, Maryland.

The public meetings are scheduled for November 14, 2018 (webinar-only); December 11, 2018 (webinar and in-person attendance); January 10, 2019 (webinar and in-person attendance); and January 22, 2019 (webinar-only). The public meetings will be noticed on the NRC's public meeting Web site at least 10 calendar days before the meeting. Members of the public should monitor the NRC's public meeting Web site at <https://www.nrc.gov/pmns/mtg>. The NRC will also post the meeting notices on the Federal Rulemaking Web site at <https://www.regulations.gov/> under Docket ID **NRC-2018-0230**.

The NRC may post additional materials related to this document, including public comments, on the Federal Rulemaking Web site. The Federal Rulemaking Web site allows you to receive alerts when changes or additions occur in a docket folder. To subscribe: (1) Navigate to the docket folder **NRC-2018-0230**; (2) click the “Sign up for E-mail Alerts” link; and (3) enter your email address and select how frequently you would like to receive emails (daily, weekly, or monthly).

III. Specific Requests for Comments

A. Tailored Training & Experience Requirements

The NRC is requesting comments on whether it should establish tailored T&E requirements for different categories of radiopharmaceuticals for physicians seeking AU status for the medical use of specific categories of radiopharmaceuticals requiring a written directive under 10 CFR 35.300 (i.e., a limited AU status). This would be for physicians seeking AU status via the alternate non-board certified pathway, and for physicians certified by a medical

specialty board that is not currently recognized by the NRC under 10 CFR 35.390, 35.392, 35.394, or 35.396 (Unsealed Byproduct Material—Written Directive Required).

1. Are the current pathways for obtaining AU status reasonable and accessible? Provide a rationale for your answer.
2. Are the current pathways for obtaining AU status adequate for protecting public health and safety? Provide a rationale for your answer.
3. Should the NRC develop a new tailored T&E pathway for these physicians? If so, what would be the appropriate way to categorize radiopharmaceuticals for tailored T&E requirements? If not, explain why the regulations should remain unchanged. [Some options to categorize radiopharmaceuticals include radiopharmaceuticals with similar delivery methods (oral, parenteral); same type of radiation characteristics or emission (alpha, beta, gamma, low-energy photon); similar preparation method (patient-ready doses); or a combination thereof (e.g., radiopharmaceuticals containing alpha- and beta-emitting radioisotopes that are administered intravenously and are prepared as patient-ready doses).]
4. Should the fundamental T&E required of physicians seeking limited AU status need to have the same fundamental T&E required of physicians seeking full AU status for all oral and parenteral administrations under 10 CFR 35.300?
5. How should the requirements for this fundamental T&E be structured for a specific category of radiopharmaceuticals?
 - a. Describe what the requirements should include:

- i. Classroom and laboratory training – What topics need to be covered in this training requirement? How many hours of classroom and laboratory training should be required? Provide the basis for the number of hours. If not hours, explain how this training should be quantified. [Note: The topics currently required in the regulations to be included in the classroom and laboratory training and work experience are listed in 10 CFR 35.390, 35.392, 35.394, and 35.396.]
 - ii. Work experience - What should the work experience requirement involve? How many hours of work experience should be required and what is the minimum number of patient or human research subject administrations that an individual must perform? Provide the basis for the number of hours and administrations. What should be the qualifications of the supervising individual?
 - iii. Competency - How should competency be evaluated? Should a written and/or practical examination by an independent examining committee be administered? Provide a rationale for your answer.
- b. Should a preceptor attestation be required for the fundamental T&E? Provide a rationale for your answer.
- c. Should the radiopharmaceutical manufacturer be able to provide the preceptor attestation? Provide a rational for your answer.

- d. Who should establish and administer the curriculum and examination? Provide specific group(s). [Some options are: NRC, medical specialty boards, medical professional societies, educational professional groups, and NRC in collaboration with any or more of the aforementioned groups.]
- e. Should AU competency be periodically assessed? If so, how should it be assessed, how often, and by whom?

B. NRC's Recognition of Medical Specialty Boards

The NRC is requesting comments on its recognition of medical specialty boards. The NRC's procedures for recognizing medical specialty boards are located on the Medical Uses Licensee Toolkit Web site (<https://www.nrc.gov/materials/miau/med-use-toolkit/certif-process-boards.html>). The NRC staff periodically reviews information to determine a board's continued eligibility for recognition.

- 1. What boards other than those already recognized by the NRC (American Board of Nuclear Medicine [ABNM], American Board of Radiology [ABR], American Osteopathic Board of Radiology [AOBR], Certification Board of Nuclear Endocrinology [CBNE]) could be considered for recognition for medical uses under 10 CFR 35.300?
- 2. Are the current NRC medical specialty board recognition criteria sufficient? If not, what additional criteria should the NRC use?

C. Patient Access

The NRC is requesting comments on whether there is a shortage in the number of AUs for 10 CFR 35.300.

1. Is there a shortage in the number of AUs for medical uses under 10 CFR 35.300? If so, is the shortage associated with the use of a specific radiopharmaceutical? Explain how.
2. Are there certain geographic areas with an inadequate number of AUs? Identify these areas.
3. Do current NRC regulations on AU T&E requirements unnecessarily limit patient access to procedures involving radiopharmaceuticals? Explain how.
4. Do current NRC regulations on AU T&E requirements unnecessarily limit research and development in nuclear medicine? Explain how.

D. Other Suggested Changes to the T&E Regulations

In 2002, the NRC revised its regulatory framework for medical use. The goal was to focus the NRC's regulations on those medical procedures that pose the highest risk to workers, the general public, patients, and human research subjects and to structure the regulations to be more risk-informed and more performance-based. The 2002 rule reduced the unnecessary regulatory burden by either reducing or eliminating the prescriptiveness of some regulations. Instead, the rule provided for a performance-based approach that relied on the training and experience of the AUs, authorized nuclear pharmacists, and radiation safety officers. The NRC is requesting comments on whether there are any other changes to the T&E regulations in 10 CFR part 35 that should be considered. Please discuss your suggested changes.

1. Should the NRC regulate the T&E of physicians for medical uses?
2. Are there requirements in the NRC's T&E regulatory framework for physicians that are non-safety related?

3. How can the NRC transform its regulatory approach for T&E while still ensuring that adequate protection is maintained for workers, the general public, patients, and human research subjects?

Dated at Rockville, Maryland, this 23rd day of October 2018.

For the Nuclear Regulatory
Commission.

/RA/

Daniel S. Collins, Director,
Division of Materials Safety,
Security,
State, and Tribal Programs,
Office of Nuclear Material Safety
and Safeguards.



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

November 2, 2018

Dr. Martin Charron
Virginia Commonwealth University
Medical Center
School of Medicine, Dept. of Radiology
1200 E. Broad St., West Hospital
Room 2-013
Richmond, VA 23298

Via e-mail to martin.charron@vcuhealth.org

**SUBJECT: TRAINING AND EXPERIENCE REQUIREMENTS FOR DIFFERENT
CATEGORIES OF RADIOPHARMACEUTICALS**

Dear Dr. Charron,

The U.S. Nuclear Regulatory Commission (NRC) is evaluating its regulations related to the training and experience (T&E) required for a physician to become an authorized user for medical uses under Subpart E, “Unsealed Byproduct Material—Written Directive Required,” of [Title 10 of the Code of Federal Regulations \(10 CFR\) Part 35, “Medical Use of Byproduct Material.”](#)

The T&E requirements in Subpart E of 10 CFR Part 35 provide three ways that a physician can be authorized to administer unsealed byproduct materials or radiopharmaceuticals requiring a written directive:

1. A physician can be certified by a medical specialty board, whose certification process is recognized by the NRC or an Agreement State.
2. A physician can complete a structured educational program and supervised work experience under an alternate pathway. This alternate pathway includes a requirement for 700 hours of training and experience, which consists of a minimum of 200 hours of classroom and laboratory training and 500 hours of supervised work experience.
3. A physician can be authorized if previously identified as an authorized user on an NRC or Agreement State license or permit (i.e., grandfathered).

In its evaluation of the T&E requirements, the NRC staff is considering whether an additional pathway should be created or if the alternate pathway should be revised. Specifically, the staff is evaluating: (1) whether it makes sense to establish tailored T&E requirements for different categories of radiopharmaceuticals; (2) how those categories should be determined; (3) what the appropriate T&E requirements would be for each category; and (4) whether those requirements should be based on hours of training and experience, or focused more on competency.

On October 29, 2018, the NRC published a series of questions on T&E in the *Federal Register* (83 FR 54380). The *Federal Register* notice is enclosed with this letter and can also be accessed at: <https://www.gpo.gov/fdsys/pkg/FR-2018-10-29/pdf/2018-23521.pdf>. The NRC will carefully consider responses to these questions and would appreciate your feedback on whether changes to the current T&E regulations are warranted. The comment period for the T&E evaluation will end on January 29, 2019. Please follow the directions in the notice on how to submit written comments. The NRC is using the Federal rulemaking Web site, [Regulations.gov](#), to accept written comments on the docket (NRC-2018-0230).

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Additional information on the NRC's T&E evaluation can be found at: <https://www.nrc.gov/materials/miau/med-use-toolkit/training-experience-evaluation.html>. If you have any questions on this correspondence, please contact Sarah Lopas of my staff at (301) 415-6360 or Sarah.Lopas@nrc.gov.

A handwritten signature in black ink, appearing to read "C Einberg".

Christian Einberg, Chief
Medical Safety and Events Assessment Branch
Division of Materials Safety, Security, State
and Tribal Programs
Office of Nuclear Material Safety
and Safeguards

Enclosure:
Training and Experience
Federal Register notice

NUCLEAR REGULATORY COMMISSION

[NRC-2018-0230]

**Training and Experience Requirements for Different Categories of
Radiopharmaceuticals**

AGENCY: Nuclear Regulatory Commission.

ACTION: Training and experience requirements; request for comment.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is requesting comments on its training and experience (T&E) requirements. Specifically, the NRC would like input on whether it should establish tailored T&E requirements for different categories of radiopharmaceuticals for which a written directive is required in accordance with its regulations. The input will be used to determine whether significant regulatory changes to the NRC's T&E requirements for authorized users (AUs) are warranted.

DATES: Submit comments by January 29, 2019. Comments received after this date will be considered if it is practical to do so, but the NRC is only able to ensure consideration for comments received on or before this date.

ADDRESSES: You may submit comments by any of the following methods:

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For additional direction on obtaining information and submitting comments, see “Obtaining Information and Submitting Comments” in the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: Sarah Lopas, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001; telephone: 301-415-6360, e-mail: Sarah.Lopas@nrc.gov.

SUPPLEMENTARY INFORMATION:

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B. Submitting Comments

Please include Docket ID **NRC-2018-0230** in your comment submission.

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radionuclides or by delivery method), (3) what the appropriate T&E requirements would be for each category, and (4) whether those requirements should be based on hours of T&E or focused more on competency. In response to the SRM, the NRC staff documented its initial results, status, and next steps related to this evaluation in SECY-18-0084, "Staff Evaluation of Training and Experience Requirements for Administering Different Categories of Radiopharmaceuticals in Response to SRM-M170817" (ADAMS Accession No. ML18135A276). In SECY-18-0084, the staff concluded that additional outreach with the medical community is needed to determine whether and how to tailor the T&E requirements to establish a limited AU status, the specific T&E requirements that should apply, how the T&E requirements should be met (e.g., hours of training, demonstration of competency), and whether a competency-based approach makes sense for the T&E requirements for all the medical uses authorized under 10 CFR 35.300, "Use of unsealed byproduct material for which a written directive is required."

The NRC is interested in obtaining input from as many stakeholders as possible, including members of the Advisory Committee on the Medical Uses of Isotopes, professional organizations, physicians, patients, patient advocacy groups, licensees, Agreement States, and other interested individuals. The focus of this request is to gather information that will permit the NRC staff to determine whether changes to the T&E requirements are warranted for different categories of radiopharmaceuticals for physicians seeking AU status for the medical use of specific categories of radiopharmaceuticals requiring a written directive under 10 CFR 35.300.

During the comment period between October 29, 2018 and January 29, 2019, the NRC will hold four public meetings that will discuss the information being requested and to accept comments on the docket. All four public meetings

will be available for remote participation by moderated bridge line and webinar, and two of the four meetings will be open for in-person attendance at NRC's headquarters in Rockville, Maryland.

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III. Specific Requests for Comments

A. Tailored Training & Experience Requirements

The NRC is requesting comments on whether it should establish tailored T&E requirements for different categories of radiopharmaceuticals for physicians seeking AU status for the medical use of specific categories of radiopharmaceuticals requiring a written directive under 10 CFR 35.300 (i.e., a limited AU status). This would be for physicians seeking AU status via the alternate non-board certified pathway, and for physicians certified by a medical

specialty board that is not currently recognized by the NRC under 10 CFR 35.390, 35.392, 35.394, or 35.396 (Unsealed Byproduct Material—Written Directive Required).

1. Are the current pathways for obtaining AU status reasonable and accessible? Provide a rationale for your answer.
2. Are the current pathways for obtaining AU status adequate for protecting public health and safety? Provide a rationale for your answer.
3. Should the NRC develop a new tailored T&E pathway for these physicians? If so, what would be the appropriate way to categorize radiopharmaceuticals for tailored T&E requirements? If not, explain why the regulations should remain unchanged. [Some options to categorize radiopharmaceuticals include radiopharmaceuticals with similar delivery methods (oral, parenteral); same type of radiation characteristics or emission (alpha, beta, gamma, low-energy photon); similar preparation method (patient-ready doses); or a combination thereof (e.g., radiopharmaceuticals containing alpha- and beta-emitting radioisotopes that are administered intravenously and are prepared as patient-ready doses).]
4. Should the fundamental T&E required of physicians seeking limited AU status need to have the same fundamental T&E required of physicians seeking full AU status for all oral and parenteral administrations under 10 CFR 35.300?
5. How should the requirements for this fundamental T&E be structured for a specific category of radiopharmaceuticals?
 - a. Describe what the requirements should include:

- i. Classroom and laboratory training – What topics need to be covered in this training requirement? How many hours of classroom and laboratory training should be required? Provide the basis for the number of hours. If not hours, explain how this training should be quantified. [Note: The topics currently required in the regulations to be included in the classroom and laboratory training and work experience are listed in 10 CFR 35.390, 35.392, 35.394, and 35.396.]
 - ii. Work experience - What should the work experience requirement involve? How many hours of work experience should be required and what is the minimum number of patient or human research subject administrations that an individual must perform? Provide the basis for the number of hours and administrations. What should be the qualifications of the supervising individual?
 - iii. Competency - How should competency be evaluated? Should a written and/or practical examination by an independent examining committee be administered? Provide a rationale for your answer.
- b. Should a preceptor attestation be required for the fundamental T&E? Provide a rationale for your answer.
- c. Should the radiopharmaceutical manufacturer be able to provide the preceptor attestation? Provide a rational for your answer.

- d. Who should establish and administer the curriculum and examination? Provide specific group(s). [Some options are: NRC, medical specialty boards, medical professional societies, educational professional groups, and NRC in collaboration with any or more of the aforementioned groups.]
- e. Should AU competency be periodically assessed? If so, how should it be assessed, how often, and by whom?

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The NRC is requesting comments on its recognition of medical specialty boards. The NRC's procedures for recognizing medical specialty boards are located on the Medical Uses Licensee Toolkit Web site (<https://www.nrc.gov/materials/miau/med-use-toolkit/certif-process-boards.html>). The NRC staff periodically reviews information to determine a board's continued eligibility for recognition.

- 1. What boards other than those already recognized by the NRC (American Board of Nuclear Medicine [ABNM], American Board of Radiology [ABR], American Osteopathic Board of Radiology [AOBR], Certification Board of Nuclear Endocrinology [CBNE]) could be considered for recognition for medical uses under 10 CFR 35.300?
- 2. Are the current NRC medical specialty board recognition criteria sufficient? If not, what additional criteria should the NRC use?

C. Patient Access

The NRC is requesting comments on whether there is a shortage in the number of AUs for 10 CFR 35.300.

1. Is there a shortage in the number of AUs for medical uses under 10 CFR 35.300? If so, is the shortage associated with the use of a specific radiopharmaceutical? Explain how.
2. Are there certain geographic areas with an inadequate number of AUs? Identify these areas.
3. Do current NRC regulations on AU T&E requirements unnecessarily limit patient access to procedures involving radiopharmaceuticals? Explain how.
4. Do current NRC regulations on AU T&E requirements unnecessarily limit research and development in nuclear medicine? Explain how.

D. Other Suggested Changes to the T&E Regulations

In 2002, the NRC revised its regulatory framework for medical use. The goal was to focus the NRC's regulations on those medical procedures that pose the highest risk to workers, the general public, patients, and human research subjects and to structure the regulations to be more risk-informed and more performance-based. The 2002 rule reduced the unnecessary regulatory burden by either reducing or eliminating the prescriptiveness of some regulations. Instead, the rule provided for a performance-based approach that relied on the training and experience of the AUs, authorized nuclear pharmacists, and radiation safety officers. The NRC is requesting comments on whether there are any other changes to the T&E regulations in 10 CFR part 35 that should be considered. Please discuss your suggested changes.

1. Should the NRC regulate the T&E of physicians for medical uses?
2. Are there requirements in the NRC's T&E regulatory framework for physicians that are non-safety related?

3. How can the NRC transform its regulatory approach for T&E while still ensuring that adequate protection is maintained for workers, the general public, patients, and human research subjects?

Dated at Rockville, Maryland, this 23rd day of October 2018.

For the Nuclear Regulatory
Commission.

/RA/

Daniel S. Collins, Director,
Division of Materials Safety,
Security,
State, and Tribal Programs,
Office of Nuclear Material Safety
and Safeguards.



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

November 2, 2018

Dr. Patricia M. Conolly
American Board of Internal Medicine
510 Walnut St., Suite 1700
Philadelphia, PA 19106

Via e-mail to info@abim.org

SUBJECT: TRAINING AND EXPERIENCE REQUIREMENTS FOR DIFFERENT CATEGORIES OF RADIOPHARMACEUTICALS

Dear Dr. Conolly,

The U.S. Nuclear Regulatory Commission (NRC) is evaluating its regulations related to the training and experience (T&E) required for a physician to become an authorized user for medical uses under Subpart E, “Unsealed Byproduct Material—Written Directive Required,” of [Title 10 of the Code of Federal Regulations \(10 CFR\) Part 35, “Medical Use of Byproduct Material.”](#)

The T&E requirements in Subpart E of 10 CFR Part 35 provide three ways that a physician can be authorized to administer unsealed byproduct materials or radiopharmaceuticals requiring a written directive:

1. A physician can be certified by a medical specialty board, whose certification process is recognized by the NRC or an Agreement State.
2. A physician can complete a structured educational program and supervised work experience under an alternate pathway. This alternate pathway includes a requirement for 700 hours of training and experience, which consists of a minimum of 200 hours of classroom and laboratory training and 500 hours of supervised work experience.
3. A physician can be authorized if previously identified as an authorized user on an NRC or Agreement State license or permit (i.e., grandfathered).

In its evaluation of the T&E requirements, the NRC staff is considering whether an additional pathway should be created or if the alternate pathway should be revised. Specifically, the staff is evaluating: (1) whether it makes sense to establish tailored T&E requirements for different categories of radiopharmaceuticals; (2) how those categories should be determined; (3) what the appropriate T&E requirements would be for each category; and (4) whether those requirements should be based on hours of training and experience, or focused more on competency.

On October 29, 2018, the NRC published a series of questions on T&E in the *Federal Register* (83 FR 54380). The *Federal Register* notice is enclosed with this letter and can also be accessed at: <https://www.gpo.gov/fdsys/pkg/FR-2018-10-29/pdf/2018-23521.pdf>. The NRC will carefully consider responses to these questions and would appreciate your feedback on whether changes to the current T&E regulations are warranted. The comment period for the T&E evaluation will end on January 29, 2019. Please follow the directions in the notice on how to submit written comments. The NRC is using the Federal rulemaking Web site, [Regulations.gov](#), to accept written comments on the docket (NRC-2018-0230).

The NRC will also conduct four public meetings scheduled for November 14 and December 11, 2018, and January 10 and January 22, 2019, and will accept oral comments provided during the meetings. The meetings on December 11 and January 10 will be held at NRC Headquarters in Rockville, MD, and all four meetings will be accessible for remote participation by moderated bridge line and webinar. The NRC's public meeting page has been updated with meeting details and registration instructions for each meeting: <https://www.nrc.gov/pmns/mtg>.

Additional information on the NRC's T&E evaluation can be found at: <https://www.nrc.gov/materials/miau/med-use-toolkit/training-experience-evaluation.html>. If you have any questions on this correspondence, please contact Sarah Lopas of my staff at (301) 415-6360 or Sarah.Lopas@nrc.gov.

A handwritten signature in black ink, appearing to read "C Einberg".

Christian Einberg, Chief
Medical Safety and Events Assessment Branch
Division of Materials Safety, Security, State
and Tribal Programs
Office of Nuclear Material Safety
and Safeguards

Enclosure:
Training and Experience
Federal Register notice

NUCLEAR REGULATORY COMMISSION

[NRC-2018-0230]

**Training and Experience Requirements for Different Categories of
Radiopharmaceuticals**

AGENCY: Nuclear Regulatory Commission.

ACTION: Training and experience requirements; request for comment.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is requesting comments on its training and experience (T&E) requirements. Specifically, the NRC would like input on whether it should establish tailored T&E requirements for different categories of radiopharmaceuticals for which a written directive is required in accordance with its regulations. The input will be used to determine whether significant regulatory changes to the NRC's T&E requirements for authorized users (AUs) are warranted.

DATES: Submit comments by January 29, 2019. Comments received after this date will be considered if it is practical to do so, but the NRC is only able to ensure consideration for comments received on or before this date.

ADDRESSES: You may submit comments by any of the following methods:

- **Federal Rulemaking Web Site:** Go to <http://www.regulations.gov>

and search for Docket ID **NRC-2018-0230**. Address questions about Docket IDs in Regulations.gov to Jennifer Borges; telephone: 301-287-9127; e-mail: Jennifer.Borges@nrc.gov. For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.

- **Mail comments to:** May Ma, Office of Administration, Mail Stop: TWFN-7-A60M, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001.

For additional direction on obtaining information and submitting comments, see “Obtaining Information and Submitting Comments” in the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: Sarah Lopas, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001; telephone: 301-415-6360, e-mail: Sarah.Lopas@nrc.gov.

SUPPLEMENTARY INFORMATION:

I. Obtaining Information and Submitting Comments

A. Obtaining Information

Please refer to Docket ID **NRC-2018-0230** when contacting the NRC about the availability of information for this action. You may obtain publicly-available information related to this action by any of the following methods:

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- **NRC’s Agencywide Documents Access and Management System (ADAMS):** You may obtain publicly-available documents online in the ADAMS Public Documents collection at <http://www.nrc.gov/reading-rm/adams.html>. To begin the search, select “[Begin Web-based ADAMS Search](#).” For problems with ADAMS, please contact the NRC’s Public Document Room (PDR) reference staff at 1-800-397-4209, 301-415-4737, or by e-mail to pdr.resource@nrc.gov. The ADAMS accession number for each document referenced is provided the first time that it is mentioned in the **SUPPLEMENTARY INFORMATION** section.

- **NRC's PDR:** You may examine and purchase copies of public documents at the NRC's PDR, Room O1-F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.

B. Submitting Comments

Please include Docket ID **NRC-2018-0230** in your comment submission.

The NRC cautions you not to include identifying or contact information in comment submissions that you do not want to be publicly disclosed in your comment submission. All comment submissions are posted at <http://www.regulations.gov> and entered into ADAMS. Comment submissions are not routinely edited to remove identifying or contact information.

If you are requesting or aggregating comments from other persons for submission to the NRC, then you should inform those persons not to include identifying or contact information that they do not want to be publicly disclosed in their comment submission. Your request should state that the NRC does not routinely edit comment submissions to remove such information before making the comment submissions available to the public or entering the comment into ADAMS.

II. Background

On August 17, 2017, the Commission issued a staff requirements memorandum (SRM), SRM-M170817 (ADAMS Accession No. ML17229B284), approving the final rule revising parts 30, 32, and 35 of title 10 of the *Code of Federal Regulations* (10 CFR), "Medical Use of Byproduct Material – Medical Event Definitions, Training and Experience, and Clarifying Amendments," and directing the staff to evaluate (1) whether it makes sense to establish tailored T&E requirements for different categories of radiopharmaceuticals, (2) how those categories should be determined (such as by risks posed by groups of

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- b. Should a preceptor attestation be required for the fundamental T&E? Provide a rationale for your answer.
- c. Should the radiopharmaceutical manufacturer be able to provide the preceptor attestation? Provide a rational for your answer.

- d. Who should establish and administer the curriculum and examination? Provide specific group(s). [Some options are: NRC, medical specialty boards, medical professional societies, educational professional groups, and NRC in collaboration with any or more of the aforementioned groups.]
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- 2. Are the current NRC medical specialty board recognition criteria sufficient? If not, what additional criteria should the NRC use?

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1. Is there a shortage in the number of AUs for medical uses under 10 CFR 35.300? If so, is the shortage associated with the use of a specific radiopharmaceutical? Explain how.
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1. Should the NRC regulate the T&E of physicians for medical uses?
2. Are there requirements in the NRC's T&E regulatory framework for physicians that are non-safety related?

3. How can the NRC transform its regulatory approach for T&E while still ensuring that adequate protection is maintained for workers, the general public, patients, and human research subjects?

Dated at Rockville, Maryland, this 23rd day of October 2018.

For the Nuclear Regulatory
Commission.

/RA/

Daniel S. Collins, Director,
Division of Materials Safety,
Security,
State, and Tribal Programs,
Office of Nuclear Material Safety
and Safeguards.



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

November 2, 2018

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

Via e-mail to michael.guastella@corar.org

SUBJECT: TRAINING AND EXPERIENCE REQUIREMENTS FOR DIFFERENT CATEGORIES OF RADIOPHARMACEUTICALS

Dear Mr. Guastella,

The U.S. Nuclear Regulatory Commission (NRC) is evaluating its regulations related to the training and experience (T&E) required for a physician to become an authorized user for medical uses under Subpart E, “Unsealed Byproduct Material—Written Directive Required,” of [Title 10 of the Code of Federal Regulations \(10 CFR\) Part 35, “Medical Use of Byproduct Material.”](#)

The T&E requirements in Subpart E of 10 CFR Part 35 provide three ways that a physician can be authorized to administer unsealed byproduct materials or radiopharmaceuticals requiring a written directive:

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In its evaluation of the T&E requirements, the NRC staff is considering whether an additional pathway should be created or if the alternate pathway should be revised. Specifically, the staff is evaluating: (1) whether it makes sense to establish tailored T&E requirements for different categories of radiopharmaceuticals; (2) how those categories should be determined; (3) what the appropriate T&E requirements would be for each category; and (4) whether those requirements should be based on hours of training and experience, or focused more on competency.

On October 29, 2018, the NRC published a series of questions on T&E in the *Federal Register* (83 FR 54380). The *Federal Register* notice is enclosed with this letter and can also be accessed at: <https://www.gpo.gov/fdsys/pkg/FR-2018-10-29/pdf/2018-23521.pdf>. The NRC will carefully consider responses to these questions and would appreciate your feedback on whether changes to the current T&E regulations are warranted. The comment period for the T&E evaluation will end on January 29, 2019. Please follow the directions in the notice on how to submit written comments. The NRC is using the Federal rulemaking Web site, [Regulations.gov](#), to accept written comments on the docket (NRC-2018-0230).

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Additional information on the NRC's T&E evaluation can be found at: <https://www.nrc.gov/materials/miau/med-use-toolkit/training-experience-evaluation.html>. If you have any questions on this correspondence, please contact Sarah Lopas of my staff at (301) 415-6360 or Sarah.Lopas@nrc.gov.

A handwritten signature in black ink, appearing to read "C Einberg".

Christian Einberg, Chief
Medical Safety and Events Assessment Branch
Division of Materials Safety, Security, State
and Tribal Programs
Office of Nuclear Material Safety
and Safeguards

Enclosure:
Training and Experience
Federal Register notice

NUCLEAR REGULATORY COMMISSION

[NRC-2018-0230]

**Training and Experience Requirements for Different Categories of
Radiopharmaceuticals**

AGENCY: Nuclear Regulatory Commission.

ACTION: Training and experience requirements; request for comment.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is requesting comments on its training and experience (T&E) requirements. Specifically, the NRC would like input on whether it should establish tailored T&E requirements for different categories of radiopharmaceuticals for which a written directive is required in accordance with its regulations. The input will be used to determine whether significant regulatory changes to the NRC's T&E requirements for authorized users (AUs) are warranted.

DATES: Submit comments by January 29, 2019. Comments received after this date will be considered if it is practical to do so, but the NRC is only able to ensure consideration for comments received on or before this date.

ADDRESSES: You may submit comments by any of the following methods:

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and search for Docket ID **NRC-2018-0230**. Address questions about Docket IDs in Regulations.gov to Jennifer Borges; telephone: 301-287-9127; e-mail: Jennifer.Borges@nrc.gov. For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.

- **Mail comments to:** May Ma, Office of Administration, Mail Stop: TWFN-7-A60M, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001.

For additional direction on obtaining information and submitting comments, see “Obtaining Information and Submitting Comments” in the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: Sarah Lopas, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001; telephone: 301-415-6360, e-mail: Sarah.Lopas@nrc.gov.

SUPPLEMENTARY INFORMATION:

I. Obtaining Information and Submitting Comments

A. Obtaining Information

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radionuclides or by delivery method), (3) what the appropriate T&E requirements would be for each category, and (4) whether those requirements should be based on hours of T&E or focused more on competency. In response to the SRM, the NRC staff documented its initial results, status, and next steps related to this evaluation in SECY-18-0084, "Staff Evaluation of Training and Experience Requirements for Administering Different Categories of Radiopharmaceuticals in Response to SRM-M170817" (ADAMS Accession No. ML18135A276). In SECY-18-0084, the staff concluded that additional outreach with the medical community is needed to determine whether and how to tailor the T&E requirements to establish a limited AU status, the specific T&E requirements that should apply, how the T&E requirements should be met (e.g., hours of training, demonstration of competency), and whether a competency-based approach makes sense for the T&E requirements for all the medical uses authorized under 10 CFR 35.300, "Use of unsealed byproduct material for which a written directive is required."

The NRC is interested in obtaining input from as many stakeholders as possible, including members of the Advisory Committee on the Medical Uses of Isotopes, professional organizations, physicians, patients, patient advocacy groups, licensees, Agreement States, and other interested individuals. The focus of this request is to gather information that will permit the NRC staff to determine whether changes to the T&E requirements are warranted for different categories of radiopharmaceuticals for physicians seeking AU status for the medical use of specific categories of radiopharmaceuticals requiring a written directive under 10 CFR 35.300.

During the comment period between October 29, 2018 and January 29, 2019, the NRC will hold four public meetings that will discuss the information being requested and to accept comments on the docket. All four public meetings

will be available for remote participation by moderated bridge line and webinar, and two of the four meetings will be open for in-person attendance at NRC's headquarters in Rockville, Maryland.

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III. Specific Requests for Comments

A. Tailored Training & Experience Requirements

The NRC is requesting comments on whether it should establish tailored T&E requirements for different categories of radiopharmaceuticals for physicians seeking AU status for the medical use of specific categories of radiopharmaceuticals requiring a written directive under 10 CFR 35.300 (i.e., a limited AU status). This would be for physicians seeking AU status via the alternate non-board certified pathway, and for physicians certified by a medical

specialty board that is not currently recognized by the NRC under 10 CFR 35.390, 35.392, 35.394, or 35.396 (Unsealed Byproduct Material—Written Directive Required).

1. Are the current pathways for obtaining AU status reasonable and accessible? Provide a rationale for your answer.
2. Are the current pathways for obtaining AU status adequate for protecting public health and safety? Provide a rationale for your answer.
3. Should the NRC develop a new tailored T&E pathway for these physicians? If so, what would be the appropriate way to categorize radiopharmaceuticals for tailored T&E requirements? If not, explain why the regulations should remain unchanged. [Some options to categorize radiopharmaceuticals include radiopharmaceuticals with similar delivery methods (oral, parenteral); same type of radiation characteristics or emission (alpha, beta, gamma, low-energy photon); similar preparation method (patient-ready doses); or a combination thereof (e.g., radiopharmaceuticals containing alpha- and beta-emitting radioisotopes that are administered intravenously and are prepared as patient-ready doses).]
4. Should the fundamental T&E required of physicians seeking limited AU status need to have the same fundamental T&E required of physicians seeking full AU status for all oral and parenteral administrations under 10 CFR 35.300?
5. How should the requirements for this fundamental T&E be structured for a specific category of radiopharmaceuticals?
 - a. Describe what the requirements should include:

- i. Classroom and laboratory training – What topics need to be covered in this training requirement? How many hours of classroom and laboratory training should be required? Provide the basis for the number of hours. If not hours, explain how this training should be quantified. [Note: The topics currently required in the regulations to be included in the classroom and laboratory training and work experience are listed in 10 CFR 35.390, 35.392, 35.394, and 35.396.]
 - ii. Work experience - What should the work experience requirement involve? How many hours of work experience should be required and what is the minimum number of patient or human research subject administrations that an individual must perform? Provide the basis for the number of hours and administrations. What should be the qualifications of the supervising individual?
 - iii. Competency - How should competency be evaluated? Should a written and/or practical examination by an independent examining committee be administered? Provide a rationale for your answer.
- b. Should a preceptor attestation be required for the fundamental T&E? Provide a rationale for your answer.
- c. Should the radiopharmaceutical manufacturer be able to provide the preceptor attestation? Provide a rational for your answer.

- d. Who should establish and administer the curriculum and examination? Provide specific group(s). [Some options are: NRC, medical specialty boards, medical professional societies, educational professional groups, and NRC in collaboration with any or more of the aforementioned groups.]
- e. Should AU competency be periodically assessed? If so, how should it be assessed, how often, and by whom?

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The NRC is requesting comments on its recognition of medical specialty boards. The NRC's procedures for recognizing medical specialty boards are located on the Medical Uses Licensee Toolkit Web site (<https://www.nrc.gov/materials/miau/med-use-toolkit/certif-process-boards.html>). The NRC staff periodically reviews information to determine a board's continued eligibility for recognition.

- 1. What boards other than those already recognized by the NRC (American Board of Nuclear Medicine [ABNM], American Board of Radiology [ABR], American Osteopathic Board of Radiology [AOBR], Certification Board of Nuclear Endocrinology [CBNE]) could be considered for recognition for medical uses under 10 CFR 35.300?
- 2. Are the current NRC medical specialty board recognition criteria sufficient? If not, what additional criteria should the NRC use?

C. Patient Access

The NRC is requesting comments on whether there is a shortage in the number of AUs for 10 CFR 35.300.

1. Is there a shortage in the number of AUs for medical uses under 10 CFR 35.300? If so, is the shortage associated with the use of a specific radiopharmaceutical? Explain how.
2. Are there certain geographic areas with an inadequate number of AUs? Identify these areas.
3. Do current NRC regulations on AU T&E requirements unnecessarily limit patient access to procedures involving radiopharmaceuticals? Explain how.
4. Do current NRC regulations on AU T&E requirements unnecessarily limit research and development in nuclear medicine? Explain how.

D. Other Suggested Changes to the T&E Regulations

In 2002, the NRC revised its regulatory framework for medical use. The goal was to focus the NRC's regulations on those medical procedures that pose the highest risk to workers, the general public, patients, and human research subjects and to structure the regulations to be more risk-informed and more performance-based. The 2002 rule reduced the unnecessary regulatory burden by either reducing or eliminating the prescriptiveness of some regulations. Instead, the rule provided for a performance-based approach that relied on the training and experience of the AUs, authorized nuclear pharmacists, and radiation safety officers. The NRC is requesting comments on whether there are any other changes to the T&E regulations in 10 CFR part 35 that should be considered. Please discuss your suggested changes.

1. Should the NRC regulate the T&E of physicians for medical uses?
2. Are there requirements in the NRC's T&E regulatory framework for physicians that are non-safety related?

3. How can the NRC transform its regulatory approach for T&E while still ensuring that adequate protection is maintained for workers, the general public, patients, and human research subjects?

Dated at Rockville, Maryland, this 23rd day of October 2018.

For the Nuclear Regulatory
Commission.

/RA/

Daniel S. Collins, Director,
Division of Materials Safety,
Security,
State, and Tribal Programs,
Office of Nuclear Material Safety
and Safeguards.



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

November 2, 2018

Ms. Ruth McBurney
Executive Director
Conference of Radiation Control Program Directors
1030 Burlington Lane, Suite 4B
Frankfort, KY 40601

Via e-mail to rmburney@crcpd.org

SUBJECT: TRAINING AND EXPERIENCE REQUIREMENTS FOR DIFFERENT CATEGORIES OF RADIOPHARMACEUTICALS

Dear Ms. McBurney,

The U.S. Nuclear Regulatory Commission (NRC) is evaluating its regulations related to the training and experience (T&E) required for a physician to become an authorized user for medical uses under Subpart E, “Unsealed Byproduct Material—Written Directive Required,” of [Title 10 of the Code of Federal Regulations \(10 CFR\) Part 35, “Medical Use of Byproduct Material.”](#)

The T&E requirements in Subpart E of 10 CFR Part 35 provide three ways that a physician can be authorized to administer unsealed byproduct materials or radiopharmaceuticals requiring a written directive:

1. A physician can be certified by a medical specialty board, whose certification process is recognized by the NRC or an Agreement State.
2. A physician can complete a structured educational program and supervised work experience under an alternate pathway. This alternate pathway includes a requirement for 700 hours of training and experience, which consists of a minimum of 200 hours of classroom and laboratory training and 500 hours of supervised work experience.
3. A physician can be authorized if previously identified as an authorized user on an NRC or Agreement State license or permit (i.e., grandfathered).

In its evaluation of the T&E requirements, the NRC staff is considering whether an additional pathway should be created or if the alternate pathway should be revised. Specifically, the staff is evaluating: (1) whether it makes sense to establish tailored T&E requirements for different categories of radiopharmaceuticals; (2) how those categories should be determined; (3) what the appropriate T&E requirements would be for each category; and (4) whether those requirements should be based on hours of training and experience, or focused more on competency.

On October 29, 2018, the NRC published a series of questions on T&E in the *Federal Register* (83 FR 54380). The *Federal Register* notice is enclosed with this letter and can also be accessed at: <https://www.gpo.gov/fdsys/pkg/FR-2018-10-29/pdf/2018-23521.pdf>. The NRC will carefully consider responses to these questions and would appreciate your feedback on whether changes to the current T&E regulations are warranted. The comment period for the T&E evaluation will end on January 29, 2019. Please follow the directions in the notice on how to submit written comments. The NRC is using the Federal rulemaking Web site, [Regulations.gov](#), to accept written comments on the docket (NRC-2018-0230).

The NRC will also conduct four public meetings scheduled for November 14 and December 11, 2018, and January 10 and January 22, 2019, and will accept oral comments provided during the meetings. The meetings on December 11 and January 10 will be held at NRC Headquarters in Rockville, MD, and all four meetings will be accessible for remote participation by moderated bridge line and webinar. The NRC's public meeting page has been updated with meeting details and registration instructions for each meeting: <https://www.nrc.gov/pmns/mtg>.

Additional information on the NRC's T&E evaluation can be found at: <https://www.nrc.gov/materials/miau/med-use-toolkit/training-experience-evaluation.html>. If you have any questions on this correspondence, please contact Sarah Lopas of my staff at (301) 415-6360 or Sarah.Lopas@nrc.gov.

A handwritten signature in black ink, appearing to read "C Einberg".

Christian Einberg, Chief
Medical Safety and Events Assessment Branch
Division of Materials Safety, Security, State
and Tribal Programs
Office of Nuclear Material Safety
and Safeguards

Enclosure:
Training and Experience
Federal Register notice

NUCLEAR REGULATORY COMMISSION

[NRC-2018-0230]

**Training and Experience Requirements for Different Categories of
Radiopharmaceuticals**

AGENCY: Nuclear Regulatory Commission.

ACTION: Training and experience requirements; request for comment.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is requesting comments on its training and experience (T&E) requirements. Specifically, the NRC would like input on whether it should establish tailored T&E requirements for different categories of radiopharmaceuticals for which a written directive is required in accordance with its regulations. The input will be used to determine whether significant regulatory changes to the NRC's T&E requirements for authorized users (AUs) are warranted.

DATES: Submit comments by January 29, 2019. Comments received after this date will be considered if it is practical to do so, but the NRC is only able to ensure consideration for comments received on or before this date.

ADDRESSES: You may submit comments by any of the following methods:

- **Federal Rulemaking Web Site:** Go to <http://www.regulations.gov>

and search for Docket ID **NRC-2018-0230**. Address questions about Docket IDs in Regulations.gov to Jennifer Borges; telephone: 301-287-9127; e-mail: Jennifer.Borges@nrc.gov. For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.

- **Mail comments to:** May Ma, Office of Administration, Mail Stop: TWFN-7-A60M, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001.

For additional direction on obtaining information and submitting comments, see “Obtaining Information and Submitting Comments” in the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: Sarah Lopas, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001; telephone: 301-415-6360, e-mail: Sarah.Lopas@nrc.gov.

SUPPLEMENTARY INFORMATION:

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- b. Should a preceptor attestation be required for the fundamental T&E? Provide a rationale for your answer.
- c. Should the radiopharmaceutical manufacturer be able to provide the preceptor attestation? Provide a rational for your answer.

- d. Who should establish and administer the curriculum and examination? Provide specific group(s). [Some options are: NRC, medical specialty boards, medical professional societies, educational professional groups, and NRC in collaboration with any or more of the aforementioned groups.]
- e. Should AU competency be periodically assessed? If so, how should it be assessed, how often, and by whom?

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The NRC is requesting comments on whether there is a shortage in the number of AUs for 10 CFR 35.300.

1. Is there a shortage in the number of AUs for medical uses under 10 CFR 35.300? If so, is the shortage associated with the use of a specific radiopharmaceutical? Explain how.
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1. Should the NRC regulate the T&E of physicians for medical uses?
2. Are there requirements in the NRC's T&E regulatory framework for physicians that are non-safety related?

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Dated at Rockville, Maryland, this 23rd day of October 2018.

For the Nuclear Regulatory
Commission.

/RA/

Daniel S. Collins, Director,
Division of Materials Safety,
Security,
State, and Tribal Programs,
Office of Nuclear Material Safety
and Safeguards.



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

November 2, 2018

Ms. Jacqueline Cross
Medical Training Coordinator
Johns Hopkins University
601 N. Caroline St., Suite 3233
Baltimore, MD 21287

Via e-mail to jcross1@jhmi.edu

SUBJECT: TRAINING AND EXPERIENCE REQUIREMENTS FOR DIFFERENT CATEGORIES OF RADIOPHARMACEUTICALS

Dear Ms. Cross,

The U.S. Nuclear Regulatory Commission (NRC) is evaluating its regulations related to the training and experience (T&E) required for a physician to become an authorized user for medical uses under Subpart E, "Unsealed Byproduct Material—Written Directive Required," of [Title 10 of the Code of Federal Regulations \(10 CFR\) Part 35, "Medical Use of Byproduct Material."](#)

The T&E requirements in Subpart E of 10 CFR Part 35 provide three ways that a physician can be authorized to administer unsealed byproduct materials or radiopharmaceuticals requiring a written directive:

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In its evaluation of the T&E requirements, the NRC staff is considering whether an additional pathway should be created or if the alternate pathway should be revised. Specifically, the staff is evaluating: (1) whether it makes sense to establish tailored T&E requirements for different categories of radiopharmaceuticals; (2) how those categories should be determined; (3) what the appropriate T&E requirements would be for each category; and (4) whether those requirements should be based on hours of training and experience, or focused more on competency.

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Additional information on the NRC's T&E evaluation can be found at: <https://www.nrc.gov/materials/miau/med-use-toolkit/training-experience-evaluation.html>. If you have any questions on this correspondence, please contact Sarah Lopas of my staff at (301) 415-6360 or Sarah.Lopas@nrc.gov.



Christian Einberg, Chief
Medical Safety and Events Assessment Branch
Division of Materials Safety, Security, State
and Tribal Programs
Office of Nuclear Material Safety
and Safeguards

Enclosure:
Training and Experience
Federal Register notice

NUCLEAR REGULATORY COMMISSION

[NRC-2018-0230]

**Training and Experience Requirements for Different Categories of
Radiopharmaceuticals**

AGENCY: Nuclear Regulatory Commission.

ACTION: Training and experience requirements; request for comment.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is requesting comments on its training and experience (T&E) requirements. Specifically, the NRC would like input on whether it should establish tailored T&E requirements for different categories of radiopharmaceuticals for which a written directive is required in accordance with its regulations. The input will be used to determine whether significant regulatory changes to the NRC's T&E requirements for authorized users (AUs) are warranted.

DATES: Submit comments by January 29, 2019. Comments received after this date will be considered if it is practical to do so, but the NRC is only able to ensure consideration for comments received on or before this date.

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and search for Docket ID **NRC-2018-0230**. Address questions about Docket IDs in Regulations.gov to Jennifer Borges; telephone: 301-287-9127; e-mail: Jennifer.Borges@nrc.gov. For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.

- **Mail comments to:** May Ma, Office of Administration, Mail Stop: TWFN-7-A60M, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001.

For additional direction on obtaining information and submitting comments, see “Obtaining Information and Submitting Comments” in the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: Sarah Lopas, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001; telephone: 301-415-6360, e-mail: Sarah.Lopas@nrc.gov.

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B. Submitting Comments

Please include Docket ID **NRC-2018-0230** in your comment submission.

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radionuclides or by delivery method), (3) what the appropriate T&E requirements would be for each category, and (4) whether those requirements should be based on hours of T&E or focused more on competency. In response to the SRM, the NRC staff documented its initial results, status, and next steps related to this evaluation in SECY-18-0084, "Staff Evaluation of Training and Experience Requirements for Administering Different Categories of Radiopharmaceuticals in Response to SRM-M170817" (ADAMS Accession No. ML18135A276). In SECY-18-0084, the staff concluded that additional outreach with the medical community is needed to determine whether and how to tailor the T&E requirements to establish a limited AU status, the specific T&E requirements that should apply, how the T&E requirements should be met (e.g., hours of training, demonstration of competency), and whether a competency-based approach makes sense for the T&E requirements for all the medical uses authorized under 10 CFR 35.300, "Use of unsealed byproduct material for which a written directive is required."

The NRC is interested in obtaining input from as many stakeholders as possible, including members of the Advisory Committee on the Medical Uses of Isotopes, professional organizations, physicians, patients, patient advocacy groups, licensees, Agreement States, and other interested individuals. The focus of this request is to gather information that will permit the NRC staff to determine whether changes to the T&E requirements are warranted for different categories of radiopharmaceuticals for physicians seeking AU status for the medical use of specific categories of radiopharmaceuticals requiring a written directive under 10 CFR 35.300.

During the comment period between October 29, 2018 and January 29, 2019, the NRC will hold four public meetings that will discuss the information being requested and to accept comments on the docket. All four public meetings

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III. Specific Requests for Comments

A. Tailored Training & Experience Requirements

The NRC is requesting comments on whether it should establish tailored T&E requirements for different categories of radiopharmaceuticals for physicians seeking AU status for the medical use of specific categories of radiopharmaceuticals requiring a written directive under 10 CFR 35.300 (i.e., a limited AU status). This would be for physicians seeking AU status via the alternate non-board certified pathway, and for physicians certified by a medical

specialty board that is not currently recognized by the NRC under 10 CFR 35.390, 35.392, 35.394, or 35.396 (Unsealed Byproduct Material—Written Directive Required).

1. Are the current pathways for obtaining AU status reasonable and accessible? Provide a rationale for your answer.
2. Are the current pathways for obtaining AU status adequate for protecting public health and safety? Provide a rationale for your answer.
3. Should the NRC develop a new tailored T&E pathway for these physicians? If so, what would be the appropriate way to categorize radiopharmaceuticals for tailored T&E requirements? If not, explain why the regulations should remain unchanged. [Some options to categorize radiopharmaceuticals include radiopharmaceuticals with similar delivery methods (oral, parenteral); same type of radiation characteristics or emission (alpha, beta, gamma, low-energy photon); similar preparation method (patient-ready doses); or a combination thereof (e.g., radiopharmaceuticals containing alpha- and beta-emitting radioisotopes that are administered intravenously and are prepared as patient-ready doses).]
4. Should the fundamental T&E required of physicians seeking limited AU status need to have the same fundamental T&E required of physicians seeking full AU status for all oral and parenteral administrations under 10 CFR 35.300?
5. How should the requirements for this fundamental T&E be structured for a specific category of radiopharmaceuticals?
 - a. Describe what the requirements should include:

- i. Classroom and laboratory training – What topics need to be covered in this training requirement? How many hours of classroom and laboratory training should be required? Provide the basis for the number of hours. If not hours, explain how this training should be quantified. [Note: The topics currently required in the regulations to be included in the classroom and laboratory training and work experience are listed in 10 CFR 35.390, 35.392, 35.394, and 35.396.]
 - ii. Work experience - What should the work experience requirement involve? How many hours of work experience should be required and what is the minimum number of patient or human research subject administrations that an individual must perform? Provide the basis for the number of hours and administrations. What should be the qualifications of the supervising individual?
 - iii. Competency - How should competency be evaluated? Should a written and/or practical examination by an independent examining committee be administered? Provide a rationale for your answer.
- b. Should a preceptor attestation be required for the fundamental T&E? Provide a rationale for your answer.
- c. Should the radiopharmaceutical manufacturer be able to provide the preceptor attestation? Provide a rational for your answer.

- d. Who should establish and administer the curriculum and examination? Provide specific group(s). [Some options are: NRC, medical specialty boards, medical professional societies, educational professional groups, and NRC in collaboration with any or more of the aforementioned groups.]
- e. Should AU competency be periodically assessed? If so, how should it be assessed, how often, and by whom?

B. NRC's Recognition of Medical Specialty Boards

The NRC is requesting comments on its recognition of medical specialty boards. The NRC's procedures for recognizing medical specialty boards are located on the Medical Uses Licensee Toolkit Web site (<https://www.nrc.gov/materials/miau/med-use-toolkit/certif-process-boards.html>). The NRC staff periodically reviews information to determine a board's continued eligibility for recognition.

- 1. What boards other than those already recognized by the NRC (American Board of Nuclear Medicine [ABNM], American Board of Radiology [ABR], American Osteopathic Board of Radiology [AOBR], Certification Board of Nuclear Endocrinology [CBNE]) could be considered for recognition for medical uses under 10 CFR 35.300?
- 2. Are the current NRC medical specialty board recognition criteria sufficient? If not, what additional criteria should the NRC use?

C. Patient Access

The NRC is requesting comments on whether there is a shortage in the number of AUs for 10 CFR 35.300.

1. Is there a shortage in the number of AUs for medical uses under 10 CFR 35.300? If so, is the shortage associated with the use of a specific radiopharmaceutical? Explain how.
2. Are there certain geographic areas with an inadequate number of AUs? Identify these areas.
3. Do current NRC regulations on AU T&E requirements unnecessarily limit patient access to procedures involving radiopharmaceuticals? Explain how.
4. Do current NRC regulations on AU T&E requirements unnecessarily limit research and development in nuclear medicine? Explain how.

D. Other Suggested Changes to the T&E Regulations

In 2002, the NRC revised its regulatory framework for medical use. The goal was to focus the NRC's regulations on those medical procedures that pose the highest risk to workers, the general public, patients, and human research subjects and to structure the regulations to be more risk-informed and more performance-based. The 2002 rule reduced the unnecessary regulatory burden by either reducing or eliminating the prescriptiveness of some regulations. Instead, the rule provided for a performance-based approach that relied on the training and experience of the AUs, authorized nuclear pharmacists, and radiation safety officers. The NRC is requesting comments on whether there are any other changes to the T&E regulations in 10 CFR part 35 that should be considered. Please discuss your suggested changes.

1. Should the NRC regulate the T&E of physicians for medical uses?
2. Are there requirements in the NRC's T&E regulatory framework for physicians that are non-safety related?

3. How can the NRC transform its regulatory approach for T&E while still ensuring that adequate protection is maintained for workers, the general public, patients, and human research subjects?

Dated at Rockville, Maryland, this 23rd day of October 2018.

For the Nuclear Regulatory
Commission.

/RA/

Daniel S. Collins, Director,
Division of Materials Safety,
Security,
State, and Tribal Programs,
Office of Nuclear Material Safety
and Safeguards.



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

November 2, 2018

Dr. Paula Deming
Endowed Professor of Health Sciences
Chair, Department of Medical Laboratory
and Radiation Sciences
College of Nursing and Health Sciences
University of Vermont
302B Rowell Building
Burlington , VT 05405

Via e-mail to Paula.Deming@med.uvm.edu

**SUBJECT: TRAINING AND EXPERIENCE REQUIREMENTS FOR DIFFERENT
CATEGORIES OF RADIOPHARMACEUTICALS**

Dear Dr. Deming,

The U.S. Nuclear Regulatory Commission (NRC) is evaluating its regulations related to the training and experience (T&E) required for a physician to become an authorized user for medical uses under Subpart E, “Unsealed Byproduct Material—Written Directive Required,” of [Title 10 of the Code of Federal Regulations \(10 CFR\) Part 35, “Medical Use of Byproduct Material.”](#)

The T&E requirements in Subpart E of 10 CFR Part 35 provide three ways that a physician can be authorized to administer unsealed byproduct materials or radiopharmaceuticals requiring a written directive:

1. A physician can be certified by a medical specialty board, whose certification process is recognized by the NRC or an Agreement State.
2. A physician can complete a structured educational program and supervised work experience under an alternate pathway. This alternate pathway includes a requirement for 700 hours of training and experience, which consists of a minimum of 200 hours of classroom and laboratory training and 500 hours of supervised work experience.
3. A physician can be authorized if previously identified as an authorized user on an NRC or Agreement State license or permit (i.e., grandfathered).

In its evaluation of the T&E requirements, the NRC staff is considering whether an additional pathway should be created or if the alternate pathway should be revised. Specifically, the staff is evaluating: (1) whether it makes sense to establish tailored T&E requirements for different categories of radiopharmaceuticals; (2) how those categories should be determined; (3) what the appropriate T&E requirements would be for each category; and (4) whether those requirements should be based on hours of training and experience, or focused more on competency.

On October 29, 2018, the NRC published a series of questions on T&E in the *Federal Register* (83 FR 54380). The *Federal Register* notice is enclosed with this letter and can also be accessed at: <https://www.gpo.gov/fdsys/pkg/FR-2018-10-29/pdf/2018-23521.pdf>. The NRC will carefully consider responses to these questions and would appreciate your feedback on whether changes to the current T&E regulations are warranted. The comment period for the T&E evaluation will end on January 29, 2019. Please follow the directions in the notice on how to submit written comments. The NRC is using the Federal rulemaking Web site, [Regulations.gov](#), to accept written comments on the docket (NRC-2018-0230).

The NRC will also conduct four public meetings scheduled for November 14 and December 11, 2018, and January 10 and January 22, 2019, and will accept oral comments provided during the meetings. The meetings on December 11 and January 10 will be held at NRC Headquarters in Rockville, MD, and all four meetings will be accessible for remote participation by moderated bridge line and webinar. The NRC's public meeting page has been updated with meeting details and registration instructions for each meeting: <https://www.nrc.gov/pmns/mtg>.

Additional information on the NRC's T&E evaluation can be found at: <https://www.nrc.gov/materials/miau/med-use-toolkit/training-experience-evaluation.html>. If you have any questions on this correspondence, please contact Sarah Lopas of my staff at (301) 415-6360 or Sarah.Lopas@nrc.gov.

A handwritten signature in black ink, appearing to read "C Einberg".

Christian Einberg, Chief
Medical Safety and Events Assessment Branch
Division of Materials Safety, Security, State
and Tribal Programs
Office of Nuclear Material Safety
and Safeguards

Enclosure:
Training and Experience
Federal Register notice

NUCLEAR REGULATORY COMMISSION

[NRC-2018-0230]

**Training and Experience Requirements for Different Categories of
Radiopharmaceuticals**

AGENCY: Nuclear Regulatory Commission.

ACTION: Training and experience requirements; request for comment.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is requesting comments on its training and experience (T&E) requirements. Specifically, the NRC would like input on whether it should establish tailored T&E requirements for different categories of radiopharmaceuticals for which a written directive is required in accordance with its regulations. The input will be used to determine whether significant regulatory changes to the NRC's T&E requirements for authorized users (AUs) are warranted.

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Dated at Rockville, Maryland, this 23rd day of October 2018.

For the Nuclear Regulatory
Commission.

/RA/

Daniel S. Collins, Director,
Division of Materials Safety,
Security,
State, and Tribal Programs,
Office of Nuclear Material Safety
and Safeguards.



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

November 2, 2018

Dr. Gerald Dodd
University of Colorado Denver,
Nuclear Medicine
Leprino Building. Dept. of Radiology
MS L954
12401 E. 17th Ave.
Aurora, CO 80045

Via e-mail to gerald.dodd@ucdenver.edu

**SUBJECT: TRAINING AND EXPERIENCE REQUIREMENTS FOR DIFFERENT
CATEGORIES OF RADIOPHARMACEUTICALS**

Dear Dr. Dodd,

The U.S. Nuclear Regulatory Commission (NRC) is evaluating its regulations related to the training and experience (T&E) required for a physician to become an authorized user for medical uses under Subpart E, “Unsealed Byproduct Material—Written Directive Required,” of [Title 10 of the Code of Federal Regulations \(10 CFR\) Part 35, “Medical Use of Byproduct Material.”](#)

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3. A physician can be authorized if previously identified as an authorized user on an NRC or Agreement State license or permit (i.e., grandfathered).

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On October 29, 2018, the NRC published a series of questions on T&E in the *Federal Register* (83 FR 54380). The *Federal Register* notice is enclosed with this letter and can also be accessed at: <https://www.gpo.gov/fdsys/pkg/FR-2018-10-29/pdf/2018-23521.pdf>. The NRC will carefully consider responses to these questions and would appreciate your feedback on whether changes to the current T&E regulations are warranted. The comment period for the T&E evaluation will end on January 29, 2019. Please follow the directions in the notice on how to submit written comments. The NRC is using the Federal rulemaking Web site, [Regulations.gov](#), to accept written comments on the docket (NRC-2018-0230).

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Additional information on the NRC's T&E evaluation can be found at: <https://www.nrc.gov/materials/miau/med-use-toolkit/training-experience-evaluation.html>. If you have any questions on this correspondence, please contact Sarah Lopas of my staff at (301) 415-6360 or Sarah.Lopas@nrc.gov.

A handwritten signature in black ink, appearing to read "C Einberg".

Christian Einberg, Chief
Medical Safety and Events Assessment Branch
Division of Materials Safety, Security, State
and Tribal Programs
Office of Nuclear Material Safety
and Safeguards

Enclosure:
Training and Experience
Federal Register notice

NUCLEAR REGULATORY COMMISSION

[NRC-2018-0230]

**Training and Experience Requirements for Different Categories of
Radiopharmaceuticals**

AGENCY: Nuclear Regulatory Commission.

ACTION: Training and experience requirements; request for comment.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is requesting comments on its training and experience (T&E) requirements. Specifically, the NRC would like input on whether it should establish tailored T&E requirements for different categories of radiopharmaceuticals for which a written directive is required in accordance with its regulations. The input will be used to determine whether significant regulatory changes to the NRC's T&E requirements for authorized users (AUs) are warranted.

DATES: Submit comments by January 29, 2019. Comments received after this date will be considered if it is practical to do so, but the NRC is only able to ensure consideration for comments received on or before this date.

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The NRC is interested in obtaining input from as many stakeholders as possible, including members of the Advisory Committee on the Medical Uses of Isotopes, professional organizations, physicians, patients, patient advocacy groups, licensees, Agreement States, and other interested individuals. The focus of this request is to gather information that will permit the NRC staff to determine whether changes to the T&E requirements are warranted for different categories of radiopharmaceuticals for physicians seeking AU status for the medical use of specific categories of radiopharmaceuticals requiring a written directive under 10 CFR 35.300.

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III. Specific Requests for Comments

A. Tailored Training & Experience Requirements

The NRC is requesting comments on whether it should establish tailored T&E requirements for different categories of radiopharmaceuticals for physicians seeking AU status for the medical use of specific categories of radiopharmaceuticals requiring a written directive under 10 CFR 35.300 (i.e., a limited AU status). This would be for physicians seeking AU status via the alternate non-board certified pathway, and for physicians certified by a medical

specialty board that is not currently recognized by the NRC under 10 CFR 35.390, 35.392, 35.394, or 35.396 (Unsealed Byproduct Material—Written Directive Required).

1. Are the current pathways for obtaining AU status reasonable and accessible? Provide a rationale for your answer.
2. Are the current pathways for obtaining AU status adequate for protecting public health and safety? Provide a rationale for your answer.
3. Should the NRC develop a new tailored T&E pathway for these physicians? If so, what would be the appropriate way to categorize radiopharmaceuticals for tailored T&E requirements? If not, explain why the regulations should remain unchanged. [Some options to categorize radiopharmaceuticals include radiopharmaceuticals with similar delivery methods (oral, parenteral); same type of radiation characteristics or emission (alpha, beta, gamma, low-energy photon); similar preparation method (patient-ready doses); or a combination thereof (e.g., radiopharmaceuticals containing alpha- and beta-emitting radioisotopes that are administered intravenously and are prepared as patient-ready doses).]
4. Should the fundamental T&E required of physicians seeking limited AU status need to have the same fundamental T&E required of physicians seeking full AU status for all oral and parenteral administrations under 10 CFR 35.300?
5. How should the requirements for this fundamental T&E be structured for a specific category of radiopharmaceuticals?
 - a. Describe what the requirements should include:

- i. Classroom and laboratory training – What topics need to be covered in this training requirement? How many hours of classroom and laboratory training should be required? Provide the basis for the number of hours. If not hours, explain how this training should be quantified. [Note: The topics currently required in the regulations to be included in the classroom and laboratory training and work experience are listed in 10 CFR 35.390, 35.392, 35.394, and 35.396.]
 - ii. Work experience - What should the work experience requirement involve? How many hours of work experience should be required and what is the minimum number of patient or human research subject administrations that an individual must perform? Provide the basis for the number of hours and administrations. What should be the qualifications of the supervising individual?
 - iii. Competency - How should competency be evaluated? Should a written and/or practical examination by an independent examining committee be administered? Provide a rationale for your answer.
- b. Should a preceptor attestation be required for the fundamental T&E? Provide a rationale for your answer.
- c. Should the radiopharmaceutical manufacturer be able to provide the preceptor attestation? Provide a rational for your answer.

- d. Who should establish and administer the curriculum and examination? Provide specific group(s). [Some options are: NRC, medical specialty boards, medical professional societies, educational professional groups, and NRC in collaboration with any or more of the aforementioned groups.]
- e. Should AU competency be periodically assessed? If so, how should it be assessed, how often, and by whom?

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The NRC is requesting comments on its recognition of medical specialty boards. The NRC's procedures for recognizing medical specialty boards are located on the Medical Uses Licensee Toolkit Web site (<https://www.nrc.gov/materials/miau/med-use-toolkit/certif-process-boards.html>). The NRC staff periodically reviews information to determine a board's continued eligibility for recognition.

- 1. What boards other than those already recognized by the NRC (American Board of Nuclear Medicine [ABNM], American Board of Radiology [ABR], American Osteopathic Board of Radiology [AOBR], Certification Board of Nuclear Endocrinology [CBNE]) could be considered for recognition for medical uses under 10 CFR 35.300?
- 2. Are the current NRC medical specialty board recognition criteria sufficient? If not, what additional criteria should the NRC use?

C. Patient Access

The NRC is requesting comments on whether there is a shortage in the number of AUs for 10 CFR 35.300.

1. Is there a shortage in the number of AUs for medical uses under 10 CFR 35.300? If so, is the shortage associated with the use of a specific radiopharmaceutical? Explain how.
2. Are there certain geographic areas with an inadequate number of AUs? Identify these areas.
3. Do current NRC regulations on AU T&E requirements unnecessarily limit patient access to procedures involving radiopharmaceuticals? Explain how.
4. Do current NRC regulations on AU T&E requirements unnecessarily limit research and development in nuclear medicine? Explain how.

D. Other Suggested Changes to the T&E Regulations

In 2002, the NRC revised its regulatory framework for medical use. The goal was to focus the NRC's regulations on those medical procedures that pose the highest risk to workers, the general public, patients, and human research subjects and to structure the regulations to be more risk-informed and more performance-based. The 2002 rule reduced the unnecessary regulatory burden by either reducing or eliminating the prescriptiveness of some regulations. Instead, the rule provided for a performance-based approach that relied on the training and experience of the AUs, authorized nuclear pharmacists, and radiation safety officers. The NRC is requesting comments on whether there are any other changes to the T&E regulations in 10 CFR part 35 that should be considered. Please discuss your suggested changes.

1. Should the NRC regulate the T&E of physicians for medical uses?
2. Are there requirements in the NRC's T&E regulatory framework for physicians that are non-safety related?

3. How can the NRC transform its regulatory approach for T&E while still ensuring that adequate protection is maintained for workers, the general public, patients, and human research subjects?

Dated at Rockville, Maryland, this 23rd day of October 2018.

For the Nuclear Regulatory
Commission.

/RA/

Daniel S. Collins, Director,
Division of Materials Safety,
Security,
State, and Tribal Programs,
Office of Nuclear Material Safety
and Safeguards.



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

November 2, 2018

Ms. Dawn Edgerton
Director of Cardiovascular Imaging
Certification Board of Nuclear Cardiology
1401 Rockville Pike, Suite 600
Rockville, MD 20852

Via e-mail to cbnc@apca.org

SUBJECT: TRAINING AND EXPERIENCE REQUIREMENTS FOR DIFFERENT CATEGORIES OF RADIOPHARMACEUTICALS

Dear Ms. Edgerton,

The U.S. Nuclear Regulatory Commission (NRC) is evaluating its regulations related to the training and experience (T&E) required for a physician to become an authorized user for medical uses under Subpart E, “Unsealed Byproduct Material—Written Directive Required,” of [Title 10 of the Code of Federal Regulations \(10 CFR\) Part 35, “Medical Use of Byproduct Material.”](#)

The T&E requirements in Subpart E of 10 CFR Part 35 provide three ways that a physician can be authorized to administer unsealed byproduct materials or radiopharmaceuticals requiring a written directive:

1. A physician can be certified by a medical specialty board, whose certification process is recognized by the NRC or an Agreement State.
2. A physician can complete a structured educational program and supervised work experience under an alternate pathway. This alternate pathway includes a requirement for 700 hours of training and experience, which consists of a minimum of 200 hours of classroom and laboratory training and 500 hours of supervised work experience.
3. A physician can be authorized if previously identified as an authorized user on an NRC or Agreement State license or permit (i.e., grandfathered).

In its evaluation of the T&E requirements, the NRC staff is considering whether an additional pathway should be created or if the alternate pathway should be revised. Specifically, the staff is evaluating: (1) whether it makes sense to establish tailored T&E requirements for different categories of radiopharmaceuticals; (2) how those categories should be determined; (3) what the appropriate T&E requirements would be for each category; and (4) whether those requirements should be based on hours of training and experience, or focused more on competency.

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Christian Einberg, 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:
Training and Experience
Federal Register notice

NUCLEAR REGULATORY COMMISSION

[NRC-2018-0230]

**Training and Experience Requirements for Different Categories of
Radiopharmaceuticals**

AGENCY: Nuclear Regulatory Commission.

ACTION: Training and experience requirements; request for comment.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is requesting comments on its training and experience (T&E) requirements. Specifically, the NRC would like input on whether it should establish tailored T&E requirements for different categories of radiopharmaceuticals for which a written directive is required in accordance with its regulations. The input will be used to determine whether significant regulatory changes to the NRC's T&E requirements for authorized users (AUs) are warranted.

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Dated at Rockville, Maryland, this 23rd day of October 2018.

For the Nuclear Regulatory
Commission.

/RA/

Daniel S. Collins, Director,
Division of Materials Safety,
Security,
State, and Tribal Programs,
Office of Nuclear Material Safety
and Safeguards.



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

November 2, 2018

Dr. Matthew Foradori
Professor & Director of Medical Technology
& Nuclear Medicine Technology
Department of Biology and Health Services
Edinboro University of Pennsylvania
Cooper Hall, 127B, 219 Meadville St.
Edinboro, PA 16444

Via e-mail to mforadori@edinboro.edu

SUBJECT: TRAINING AND EXPERIENCE REQUIREMENTS FOR DIFFERENT
CATEGORIES OF RADIOPHARMACEUTICALS

Dear Dr. Foradori,

The U.S. Nuclear Regulatory Commission (NRC) is evaluating its regulations related to the training and experience (T&E) required for a physician to become an authorized user for medical uses under Subpart E, “Unsealed Byproduct Material—Written Directive Required,” of [Title 10 of the Code of Federal Regulations \(10 CFR\) Part 35, “Medical Use of Byproduct Material.”](#)

The T&E requirements in Subpart E of 10 CFR Part 35 provide three ways that a physician can be authorized to administer unsealed byproduct materials or radiopharmaceuticals requiring a written directive:

1. A physician can be certified by a medical specialty board, whose certification process is recognized by the NRC or an Agreement State.
2. A physician can complete a structured educational program and supervised work experience under an alternate pathway. This alternate pathway includes a requirement for 700 hours of training and experience, which consists of a minimum of 200 hours of classroom and laboratory training and 500 hours of supervised work experience.
3. A physician can be authorized if previously identified as an authorized user on an NRC or Agreement State license or permit (i.e., grandfathered).

In its evaluation of the T&E requirements, the NRC staff is considering whether an additional pathway should be created or if the alternate pathway should be revised. Specifically, the staff is evaluating: (1) whether it makes sense to establish tailored T&E requirements for different categories of radiopharmaceuticals; (2) how those categories should be determined; (3) what the appropriate T&E requirements would be for each category; and (4) whether those requirements should be based on hours of training and experience, or focused more on competency.

On October 29, 2018, the NRC published a series of questions on T&E in the *Federal Register* (83 FR 54380). The *Federal Register* notice is enclosed with this letter and can also be accessed at: <https://www.gpo.gov/fdsys/pkg/FR-2018-10-29/pdf/2018-23521.pdf>. The NRC will carefully consider responses to these questions and would appreciate your feedback on whether changes to the current T&E regulations are warranted. The comment period for the T&E evaluation will end on January 29, 2019. Please follow the directions in the notice on how to submit written comments. The NRC is using the Federal rulemaking Web site, [Regulations.gov](#), to accept written comments on the docket (NRC-2018-0230).

The NRC will also conduct four public meetings scheduled for November 14 and December 11, 2018, and January 10 and January 22, 2019, and will accept oral comments provided during the meetings. The meetings on December 11 and January 10 will be held at NRC Headquarters in Rockville, MD, and all four meetings will be accessible for remote participation by moderated bridge line and webinar. The NRC's public meeting page has been updated with meeting details and registration instructions for each meeting: <https://www.nrc.gov/pmns/mtg>.

Additional information on the NRC's T&E evaluation can be found at: <https://www.nrc.gov/materials/miau/med-use-toolkit/training-experience-evaluation.html>. If you have any questions on this correspondence, please contact Sarah Lopas of my staff at (301) 415-6360 or Sarah.Lopas@nrc.gov.

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Christian Einberg, 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:
Training and Experience
Federal Register notice

NUCLEAR REGULATORY COMMISSION

[NRC-2018-0230]

**Training and Experience Requirements for Different Categories of
Radiopharmaceuticals**

AGENCY: Nuclear Regulatory Commission.

ACTION: Training and experience requirements; request for comment.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is requesting comments on its training and experience (T&E) requirements. Specifically, the NRC would like input on whether it should establish tailored T&E requirements for different categories of radiopharmaceuticals for which a written directive is required in accordance with its regulations. The input will be used to determine whether significant regulatory changes to the NRC's T&E requirements for authorized users (AUs) are warranted.

DATES: Submit comments by January 29, 2019. Comments received after this date will be considered if it is practical to do so, but the NRC is only able to ensure consideration for comments received on or before this date.

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Please include Docket ID **NRC-2018-0230** in your comment submission.

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The NRC is interested in obtaining input from as many stakeholders as possible, including members of the Advisory Committee on the Medical Uses of Isotopes, professional organizations, physicians, patients, patient advocacy groups, licensees, Agreement States, and other interested individuals. The focus of this request is to gather information that will permit the NRC staff to determine whether changes to the T&E requirements are warranted for different categories of radiopharmaceuticals for physicians seeking AU status for the medical use of specific categories of radiopharmaceuticals requiring a written directive under 10 CFR 35.300.

During the comment period between October 29, 2018 and January 29, 2019, the NRC will hold four public meetings that will discuss the information being requested and to accept comments on the docket. All four public meetings

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III. Specific Requests for Comments

A. Tailored Training & Experience Requirements

The NRC is requesting comments on whether it should establish tailored T&E requirements for different categories of radiopharmaceuticals for physicians seeking AU status for the medical use of specific categories of radiopharmaceuticals requiring a written directive under 10 CFR 35.300 (i.e., a limited AU status). This would be for physicians seeking AU status via the alternate non-board certified pathway, and for physicians certified by a medical

specialty board that is not currently recognized by the NRC under 10 CFR 35.390, 35.392, 35.394, or 35.396 (Unsealed Byproduct Material—Written Directive Required).

1. Are the current pathways for obtaining AU status reasonable and accessible? Provide a rationale for your answer.
2. Are the current pathways for obtaining AU status adequate for protecting public health and safety? Provide a rationale for your answer.
3. Should the NRC develop a new tailored T&E pathway for these physicians? If so, what would be the appropriate way to categorize radiopharmaceuticals for tailored T&E requirements? If not, explain why the regulations should remain unchanged. [Some options to categorize radiopharmaceuticals include radiopharmaceuticals with similar delivery methods (oral, parenteral); same type of radiation characteristics or emission (alpha, beta, gamma, low-energy photon); similar preparation method (patient-ready doses); or a combination thereof (e.g., radiopharmaceuticals containing alpha- and beta-emitting radioisotopes that are administered intravenously and are prepared as patient-ready doses).]
4. Should the fundamental T&E required of physicians seeking limited AU status need to have the same fundamental T&E required of physicians seeking full AU status for all oral and parenteral administrations under 10 CFR 35.300?
5. How should the requirements for this fundamental T&E be structured for a specific category of radiopharmaceuticals?
 - a. Describe what the requirements should include:

- i. Classroom and laboratory training – What topics need to be covered in this training requirement? How many hours of classroom and laboratory training should be required? Provide the basis for the number of hours. If not hours, explain how this training should be quantified. [Note: The topics currently required in the regulations to be included in the classroom and laboratory training and work experience are listed in 10 CFR 35.390, 35.392, 35.394, and 35.396.]
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- c. Should the radiopharmaceutical manufacturer be able to provide the preceptor attestation? Provide a rational for your answer.

- d. Who should establish and administer the curriculum and examination? Provide specific group(s). [Some options are: NRC, medical specialty boards, medical professional societies, educational professional groups, and NRC in collaboration with any or more of the aforementioned groups.]
- e. Should AU competency be periodically assessed? If so, how should it be assessed, how often, and by whom?

B. NRC's Recognition of Medical Specialty Boards

The NRC is requesting comments on its recognition of medical specialty boards. The NRC's procedures for recognizing medical specialty boards are located on the Medical Uses Licensee Toolkit Web site (<https://www.nrc.gov/materials/miau/med-use-toolkit/certif-process-boards.html>). The NRC staff periodically reviews information to determine a board's continued eligibility for recognition.

- 1. What boards other than those already recognized by the NRC (American Board of Nuclear Medicine [ABNM], American Board of Radiology [ABR], American Osteopathic Board of Radiology [AOBR], Certification Board of Nuclear Endocrinology [CBNE]) could be considered for recognition for medical uses under 10 CFR 35.300?
- 2. Are the current NRC medical specialty board recognition criteria sufficient? If not, what additional criteria should the NRC use?

C. Patient Access

The NRC is requesting comments on whether there is a shortage in the number of AUs for 10 CFR 35.300.

1. Is there a shortage in the number of AUs for medical uses under 10 CFR 35.300? If so, is the shortage associated with the use of a specific radiopharmaceutical? Explain how.
2. Are there certain geographic areas with an inadequate number of AUs? Identify these areas.
3. Do current NRC regulations on AU T&E requirements unnecessarily limit patient access to procedures involving radiopharmaceuticals? Explain how.
4. Do current NRC regulations on AU T&E requirements unnecessarily limit research and development in nuclear medicine? Explain how.

D. Other Suggested Changes to the T&E Regulations

In 2002, the NRC revised its regulatory framework for medical use. The goal was to focus the NRC's regulations on those medical procedures that pose the highest risk to workers, the general public, patients, and human research subjects and to structure the regulations to be more risk-informed and more performance-based. The 2002 rule reduced the unnecessary regulatory burden by either reducing or eliminating the prescriptiveness of some regulations. Instead, the rule provided for a performance-based approach that relied on the training and experience of the AUs, authorized nuclear pharmacists, and radiation safety officers. The NRC is requesting comments on whether there are any other changes to the T&E regulations in 10 CFR part 35 that should be considered. Please discuss your suggested changes.

1. Should the NRC regulate the T&E of physicians for medical uses?
2. Are there requirements in the NRC's T&E regulatory framework for physicians that are non-safety related?

3. How can the NRC transform its regulatory approach for T&E while still ensuring that adequate protection is maintained for workers, the general public, patients, and human research subjects?

Dated at Rockville, Maryland, this 23rd day of October 2018.

For the Nuclear Regulatory
Commission.

/RA/

Daniel S. Collins, Director,
Division of Materials Safety,
Security,
State, and Tribal Programs,
Office of Nuclear Material Safety
and Safeguards.



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

November 2, 2018

Ms. Peggy Fortsch
Dean, School of Health Sciences
Radiography Program Director, Professor
Allen College
1825 Logan Avenue
Waterloo, IA 50703

Via e-mail to Peggy.Fortsch@allencollege.edu

SUBJECT: TRAINING AND EXPERIENCE REQUIREMENTS FOR DIFFERENT CATEGORIES OF RADIOPHARMACEUTICALS

Dear Ms. Fortsch,

The U.S. Nuclear Regulatory Commission (NRC) is evaluating its regulations related to the training and experience (T&E) required for a physician to become an authorized user for medical uses under Subpart E, “Unsealed Byproduct Material—Written Directive Required,” of [Title 10 of the Code of Federal Regulations \(10 CFR\) Part 35, “Medical Use of Byproduct Material.”](#)

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Christian Einberg, Chief
Medical Safety and Events Assessment Branch
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Enclosure:
Training and Experience
Federal Register notice

NUCLEAR REGULATORY COMMISSION

[NRC-2018-0230]

**Training and Experience Requirements for Different Categories of
Radiopharmaceuticals**

AGENCY: Nuclear Regulatory Commission.

ACTION: Training and experience requirements; request for comment.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is requesting comments on its training and experience (T&E) requirements. Specifically, the NRC would like input on whether it should establish tailored T&E requirements for different categories of radiopharmaceuticals for which a written directive is required in accordance with its regulations. The input will be used to determine whether significant regulatory changes to the NRC's T&E requirements for authorized users (AUs) are warranted.

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- 2. Are the current NRC medical specialty board recognition criteria sufficient? If not, what additional criteria should the NRC use?

C. Patient Access

The NRC is requesting comments on whether there is a shortage in the number of AUs for 10 CFR 35.300.

1. Is there a shortage in the number of AUs for medical uses under 10 CFR 35.300? If so, is the shortage associated with the use of a specific radiopharmaceutical? Explain how.
2. Are there certain geographic areas with an inadequate number of AUs? Identify these areas.
3. Do current NRC regulations on AU T&E requirements unnecessarily limit patient access to procedures involving radiopharmaceuticals? Explain how.
4. Do current NRC regulations on AU T&E requirements unnecessarily limit research and development in nuclear medicine? Explain how.

D. Other Suggested Changes to the T&E Regulations

In 2002, the NRC revised its regulatory framework for medical use. The goal was to focus the NRC's regulations on those medical procedures that pose the highest risk to workers, the general public, patients, and human research subjects and to structure the regulations to be more risk-informed and more performance-based. The 2002 rule reduced the unnecessary regulatory burden by either reducing or eliminating the prescriptiveness of some regulations. Instead, the rule provided for a performance-based approach that relied on the training and experience of the AUs, authorized nuclear pharmacists, and radiation safety officers. The NRC is requesting comments on whether there are any other changes to the T&E regulations in 10 CFR part 35 that should be considered. Please discuss your suggested changes.

1. Should the NRC regulate the T&E of physicians for medical uses?
2. Are there requirements in the NRC's T&E regulatory framework for physicians that are non-safety related?

3. How can the NRC transform its regulatory approach for T&E while still ensuring that adequate protection is maintained for workers, the general public, patients, and human research subjects?

Dated at Rockville, Maryland, this 23rd day of October 2018.

For the Nuclear Regulatory
Commission.

/RA/

Daniel S. Collins, Director,
Division of Materials Safety,
Security,
State, and Tribal Programs,
Office of Nuclear Material Safety
and Safeguards.



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

November 2, 2018

Dr. Emogene Fox Ed.D., CHES
Professor and Chairperson
Department of Health Sciences
University of Central Arkansas
201 Donaghey Ave.
Conway, AR 72035

Via e-mail to emogenef@uca.edu

SUBJECT: TRAINING AND EXPERIENCE REQUIREMENTS FOR DIFFERENT CATEGORIES OF RADIOPHARMACEUTICALS

Dear Dr. Fox,

The U.S. Nuclear Regulatory Commission (NRC) is evaluating its regulations related to the training and experience (T&E) required for a physician to become an authorized user for medical uses under Subpart E, “Unsealed Byproduct Material—Written Directive Required,” of [Title 10 of the Code of Federal Regulations \(10 CFR\) Part 35, “Medical Use of Byproduct Material.”](#)

The T&E requirements in Subpart E of 10 CFR Part 35 provide three ways that a physician can be authorized to administer unsealed byproduct materials or radiopharmaceuticals requiring a written directive:

1. A physician can be certified by a medical specialty board, whose certification process is recognized by the NRC or an Agreement State.
2. A physician can complete a structured educational program and supervised work experience under an alternate pathway. This alternate pathway includes a requirement for 700 hours of training and experience, which consists of a minimum of 200 hours of classroom and laboratory training and 500 hours of supervised work experience.
3. A physician can be authorized if previously identified as an authorized user on an NRC or Agreement State license or permit (i.e., grandfathered).

In its evaluation of the T&E requirements, the NRC staff is considering whether an additional pathway should be created or if the alternate pathway should be revised. Specifically, the staff is evaluating: (1) whether it makes sense to establish tailored T&E requirements for different categories of radiopharmaceuticals; (2) how those categories should be determined; (3) what the appropriate T&E requirements would be for each category; and (4) whether those requirements should be based on hours of training and experience, or focused more on competency.

On October 29, 2018, the NRC published a series of questions on T&E in the *Federal Register* (83 FR 54380). The *Federal Register* notice is enclosed with this letter and can also be accessed at: <https://www.gpo.gov/fdsys/pkg/FR-2018-10-29/pdf/2018-23521.pdf>. The NRC will carefully consider responses to these questions and would appreciate your feedback on whether changes to the current T&E regulations are warranted. The comment period for the T&E evaluation will end on January 29, 2019. Please follow the directions in the notice on how to submit written comments. The NRC is using the Federal rulemaking Web site, [Regulations.gov](#), to accept written comments on the docket (NRC-2018-0230).

The NRC will also conduct four public meetings scheduled for November 14 and December 11, 2018, and January 10 and January 22, 2019, and will accept oral comments provided during the meetings. The meetings on December 11 and January 10 will be held at NRC Headquarters in Rockville, MD, and all four meetings will be accessible for remote participation by moderated bridge line and webinar. The NRC's public meeting page has been updated with meeting details and registration instructions for each meeting: <https://www.nrc.gov/pmns/mtg>.

Additional information on the NRC's T&E evaluation can be found at: <https://www.nrc.gov/materials/miau/med-use-toolkit/training-experience-evaluation.html>. If you have any questions on this correspondence, please contact Sarah Lopas of my staff at (301) 415-6360 or Sarah.Lopas@nrc.gov.



Christian Einberg, Chief
Medical Safety and Events Assessment Branch
Division of Materials Safety, Security, State
and Tribal Programs
Office of Nuclear Material Safety
and Safeguards

Enclosure:
Training and Experience
Federal Register notice

NUCLEAR REGULATORY COMMISSION

[NRC-2018-0230]

**Training and Experience Requirements for Different Categories of
Radiopharmaceuticals**

AGENCY: Nuclear Regulatory Commission.

ACTION: Training and experience requirements; request for comment.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is requesting comments on its training and experience (T&E) requirements. Specifically, the NRC would like input on whether it should establish tailored T&E requirements for different categories of radiopharmaceuticals for which a written directive is required in accordance with its regulations. The input will be used to determine whether significant regulatory changes to the NRC's T&E requirements for authorized users (AUs) are warranted.

DATES: Submit comments by January 29, 2019. Comments received after this date will be considered if it is practical to do so, but the NRC is only able to ensure consideration for comments received on or before this date.

ADDRESSES: You may submit comments by any of the following methods:

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FOR FURTHER INFORMATION CONTACT: Sarah Lopas, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001; telephone: 301-415-6360, e-mail: Sarah.Lopas@nrc.gov.

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A. Obtaining Information

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Please include Docket ID **NRC-2018-0230** in your comment submission.

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II. Background

On August 17, 2017, the Commission issued a staff requirements memorandum (SRM), SRM-M170817 (ADAMS Accession No. ML17229B284), approving the final rule revising parts 30, 32, and 35 of title 10 of the *Code of Federal Regulations* (10 CFR), "Medical Use of Byproduct Material – Medical Event Definitions, Training and Experience, and Clarifying Amendments," and directing the staff to evaluate (1) whether it makes sense to establish tailored T&E requirements for different categories of radiopharmaceuticals, (2) how those categories should be determined (such as by risks posed by groups of

radionuclides or by delivery method), (3) what the appropriate T&E requirements would be for each category, and (4) whether those requirements should be based on hours of T&E or focused more on competency. In response to the SRM, the NRC staff documented its initial results, status, and next steps related to this evaluation in SECY-18-0084, "Staff Evaluation of Training and Experience Requirements for Administering Different Categories of Radiopharmaceuticals in Response to SRM-M170817" (ADAMS Accession No. ML18135A276). In SECY-18-0084, the staff concluded that additional outreach with the medical community is needed to determine whether and how to tailor the T&E requirements to establish a limited AU status, the specific T&E requirements that should apply, how the T&E requirements should be met (e.g., hours of training, demonstration of competency), and whether a competency-based approach makes sense for the T&E requirements for all the medical uses authorized under 10 CFR 35.300, "Use of unsealed byproduct material for which a written directive is required."

The NRC is interested in obtaining input from as many stakeholders as possible, including members of the Advisory Committee on the Medical Uses of Isotopes, professional organizations, physicians, patients, patient advocacy groups, licensees, Agreement States, and other interested individuals. The focus of this request is to gather information that will permit the NRC staff to determine whether changes to the T&E requirements are warranted for different categories of radiopharmaceuticals for physicians seeking AU status for the medical use of specific categories of radiopharmaceuticals requiring a written directive under 10 CFR 35.300.

During the comment period between October 29, 2018 and January 29, 2019, the NRC will hold four public meetings that will discuss the information being requested and to accept comments on the docket. All four public meetings

will be available for remote participation by moderated bridge line and webinar, and two of the four meetings will be open for in-person attendance at NRC's headquarters in Rockville, Maryland.

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The NRC may post additional materials related to this document, including public comments, on the Federal Rulemaking Web site. The Federal Rulemaking Web site allows you to receive alerts when changes or additions occur in a docket folder. To subscribe: (1) Navigate to the docket folder **NRC-2018-0230**; (2) click the “Sign up for E-mail Alerts” link; and (3) enter your email address and select how frequently you would like to receive emails (daily, weekly, or monthly).

III. Specific Requests for Comments

A. Tailored Training & Experience Requirements

The NRC is requesting comments on whether it should establish tailored T&E requirements for different categories of radiopharmaceuticals for physicians seeking AU status for the medical use of specific categories of radiopharmaceuticals requiring a written directive under 10 CFR 35.300 (i.e., a limited AU status). This would be for physicians seeking AU status via the alternate non-board certified pathway, and for physicians certified by a medical

specialty board that is not currently recognized by the NRC under 10 CFR 35.390, 35.392, 35.394, or 35.396 (Unsealed Byproduct Material—Written Directive Required).

1. Are the current pathways for obtaining AU status reasonable and accessible? Provide a rationale for your answer.
2. Are the current pathways for obtaining AU status adequate for protecting public health and safety? Provide a rationale for your answer.
3. Should the NRC develop a new tailored T&E pathway for these physicians? If so, what would be the appropriate way to categorize radiopharmaceuticals for tailored T&E requirements? If not, explain why the regulations should remain unchanged. [Some options to categorize radiopharmaceuticals include radiopharmaceuticals with similar delivery methods (oral, parenteral); same type of radiation characteristics or emission (alpha, beta, gamma, low-energy photon); similar preparation method (patient-ready doses); or a combination thereof (e.g., radiopharmaceuticals containing alpha- and beta-emitting radioisotopes that are administered intravenously and are prepared as patient-ready doses).]
4. Should the fundamental T&E required of physicians seeking limited AU status need to have the same fundamental T&E required of physicians seeking full AU status for all oral and parenteral administrations under 10 CFR 35.300?
5. How should the requirements for this fundamental T&E be structured for a specific category of radiopharmaceuticals?
 - a. Describe what the requirements should include:

- i. Classroom and laboratory training – What topics need to be covered in this training requirement? How many hours of classroom and laboratory training should be required? Provide the basis for the number of hours. If not hours, explain how this training should be quantified. [Note: The topics currently required in the regulations to be included in the classroom and laboratory training and work experience are listed in 10 CFR 35.390, 35.392, 35.394, and 35.396.]
 - ii. Work experience - What should the work experience requirement involve? How many hours of work experience should be required and what is the minimum number of patient or human research subject administrations that an individual must perform? Provide the basis for the number of hours and administrations. What should be the qualifications of the supervising individual?
 - iii. Competency - How should competency be evaluated? Should a written and/or practical examination by an independent examining committee be administered? Provide a rationale for your answer.
- b. Should a preceptor attestation be required for the fundamental T&E? Provide a rationale for your answer.
- c. Should the radiopharmaceutical manufacturer be able to provide the preceptor attestation? Provide a rational for your answer.

- d. Who should establish and administer the curriculum and examination? Provide specific group(s). [Some options are: NRC, medical specialty boards, medical professional societies, educational professional groups, and NRC in collaboration with any or more of the aforementioned groups.]
- e. Should AU competency be periodically assessed? If so, how should it be assessed, how often, and by whom?

B. NRC's Recognition of Medical Specialty Boards

The NRC is requesting comments on its recognition of medical specialty boards. The NRC's procedures for recognizing medical specialty boards are located on the Medical Uses Licensee Toolkit Web site (<https://www.nrc.gov/materials/miau/med-use-toolkit/certif-process-boards.html>). The NRC staff periodically reviews information to determine a board's continued eligibility for recognition.

- 1. What boards other than those already recognized by the NRC (American Board of Nuclear Medicine [ABNM], American Board of Radiology [ABR], American Osteopathic Board of Radiology [AOBR], Certification Board of Nuclear Endocrinology [CBNE]) could be considered for recognition for medical uses under 10 CFR 35.300?
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C. Patient Access

The NRC is requesting comments on whether there is a shortage in the number of AUs for 10 CFR 35.300.

1. Is there a shortage in the number of AUs for medical uses under 10 CFR 35.300? If so, is the shortage associated with the use of a specific radiopharmaceutical? Explain how.
2. Are there certain geographic areas with an inadequate number of AUs? Identify these areas.
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D. Other Suggested Changes to the T&E Regulations

In 2002, the NRC revised its regulatory framework for medical use. The goal was to focus the NRC's regulations on those medical procedures that pose the highest risk to workers, the general public, patients, and human research subjects and to structure the regulations to be more risk-informed and more performance-based. The 2002 rule reduced the unnecessary regulatory burden by either reducing or eliminating the prescriptiveness of some regulations. Instead, the rule provided for a performance-based approach that relied on the training and experience of the AUs, authorized nuclear pharmacists, and radiation safety officers. The NRC is requesting comments on whether there are any other changes to the T&E regulations in 10 CFR part 35 that should be considered. Please discuss your suggested changes.

1. Should the NRC regulate the T&E of physicians for medical uses?
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Dated at Rockville, Maryland, this 23rd day of October 2018.

For the Nuclear Regulatory
Commission.

/RA/

Daniel S. Collins, Director,
Division of Materials Safety,
Security,
State, and Tribal Programs,
Office of Nuclear Material Safety
and Safeguards.



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

November 2, 2018

Dr. Jeff Galen
Program Director, Nuclear Medicine
University of Missouri
611 Lewis Hall, 701 S. 5th St.
Columbia, MO 65211

Via e-mail to galenja@health.missouri.edu

SUBJECT: TRAINING AND EXPERIENCE REQUIREMENTS FOR DIFFERENT CATEGORIES OF RADIOPHARMACEUTICALS

Dear Dr. Galen,

The U.S. Nuclear Regulatory Commission (NRC) is evaluating its regulations related to the training and experience (T&E) required for a physician to become an authorized user for medical uses under Subpart E, “Unsealed Byproduct Material—Written Directive Required,” of [Title 10 of the Code of Federal Regulations \(10 CFR\) Part 35, “Medical Use of Byproduct Material.”](#)

The T&E requirements in Subpart E of 10 CFR Part 35 provide three ways that a physician can be authorized to administer unsealed byproduct materials or radiopharmaceuticals requiring a written directive:

1. A physician can be certified by a medical specialty board, whose certification process is recognized by the NRC or an Agreement State.
2. A physician can complete a structured educational program and supervised work experience under an alternate pathway. This alternate pathway includes a requirement for 700 hours of training and experience, which consists of a minimum of 200 hours of classroom and laboratory training and 500 hours of supervised work experience.
3. A physician can be authorized if previously identified as an authorized user on an NRC or Agreement State license or permit (i.e., grandfathered).

In its evaluation of the T&E requirements, the NRC staff is considering whether an additional pathway should be created or if the alternate pathway should be revised. Specifically, the staff is evaluating: (1) whether it makes sense to establish tailored T&E requirements for different categories of radiopharmaceuticals; (2) how those categories should be determined; (3) what the appropriate T&E requirements would be for each category; and (4) whether those requirements should be based on hours of training and experience, or focused more on competency.

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Additional information on the NRC's T&E evaluation can be found at: <https://www.nrc.gov/materials/miau/med-use-toolkit/training-experience-evaluation.html>. If you have any questions on this correspondence, please contact Sarah Lopas of my staff at (301) 415-6360 or Sarah.Lopas@nrc.gov.

A handwritten signature in black ink, appearing to read "C Einberg".

Christian Einberg, Chief
Medical Safety and Events Assessment Branch
Division of Materials Safety, Security, State
and Tribal Programs
Office of Nuclear Material Safety
and Safeguards

Enclosure:
Training and Experience
Federal Register notice

NUCLEAR REGULATORY COMMISSION

[NRC-2018-0230]

**Training and Experience Requirements for Different Categories of
Radiopharmaceuticals**

AGENCY: Nuclear Regulatory Commission.

ACTION: Training and experience requirements; request for comment.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is requesting comments on its training and experience (T&E) requirements. Specifically, the NRC would like input on whether it should establish tailored T&E requirements for different categories of radiopharmaceuticals for which a written directive is required in accordance with its regulations. The input will be used to determine whether significant regulatory changes to the NRC's T&E requirements for authorized users (AUs) are warranted.

DATES: Submit comments by January 29, 2019. Comments received after this date will be considered if it is practical to do so, but the NRC is only able to ensure consideration for comments received on or before this date.

ADDRESSES: You may submit comments by any of the following methods:

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For additional direction on obtaining information and submitting comments, see “Obtaining Information and Submitting Comments” in the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: Sarah Lopas, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001; telephone: 301-415-6360, e-mail: Sarah.Lopas@nrc.gov.

SUPPLEMENTARY INFORMATION:

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A. Tailored Training & Experience Requirements

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1. Are the current pathways for obtaining AU status reasonable and accessible? Provide a rationale for your answer.
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3. Should the NRC develop a new tailored T&E pathway for these physicians? If so, what would be the appropriate way to categorize radiopharmaceuticals for tailored T&E requirements? If not, explain why the regulations should remain unchanged. [Some options to categorize radiopharmaceuticals include radiopharmaceuticals with similar delivery methods (oral, parenteral); same type of radiation characteristics or emission (alpha, beta, gamma, low-energy photon); similar preparation method (patient-ready doses); or a combination thereof (e.g., radiopharmaceuticals containing alpha- and beta-emitting radioisotopes that are administered intravenously and are prepared as patient-ready doses).]
4. Should the fundamental T&E required of physicians seeking limited AU status need to have the same fundamental T&E required of physicians seeking full AU status for all oral and parenteral administrations under 10 CFR 35.300?
5. How should the requirements for this fundamental T&E be structured for a specific category of radiopharmaceuticals?
 - a. Describe what the requirements should include:

- i. Classroom and laboratory training – What topics need to be covered in this training requirement? How many hours of classroom and laboratory training should be required? Provide the basis for the number of hours. If not hours, explain how this training should be quantified. [Note: The topics currently required in the regulations to be included in the classroom and laboratory training and work experience are listed in 10 CFR 35.390, 35.392, 35.394, and 35.396.]
 - ii. Work experience - What should the work experience requirement involve? How many hours of work experience should be required and what is the minimum number of patient or human research subject administrations that an individual must perform? Provide the basis for the number of hours and administrations. What should be the qualifications of the supervising individual?
 - iii. Competency - How should competency be evaluated? Should a written and/or practical examination by an independent examining committee be administered? Provide a rationale for your answer.
- b. Should a preceptor attestation be required for the fundamental T&E? Provide a rationale for your answer.
- c. Should the radiopharmaceutical manufacturer be able to provide the preceptor attestation? Provide a rational for your answer.

- d. Who should establish and administer the curriculum and examination? Provide specific group(s). [Some options are: NRC, medical specialty boards, medical professional societies, educational professional groups, and NRC in collaboration with any or more of the aforementioned groups.]
- e. Should AU competency be periodically assessed? If so, how should it be assessed, how often, and by whom?

B. NRC's Recognition of Medical Specialty Boards

The NRC is requesting comments on its recognition of medical specialty boards. The NRC's procedures for recognizing medical specialty boards are located on the Medical Uses Licensee Toolkit Web site (<https://www.nrc.gov/materials/miau/med-use-toolkit/certif-process-boards.html>). The NRC staff periodically reviews information to determine a board's continued eligibility for recognition.

- 1. What boards other than those already recognized by the NRC (American Board of Nuclear Medicine [ABNM], American Board of Radiology [ABR], American Osteopathic Board of Radiology [AOBR], Certification Board of Nuclear Endocrinology [CBNE]) could be considered for recognition for medical uses under 10 CFR 35.300?
- 2. Are the current NRC medical specialty board recognition criteria sufficient? If not, what additional criteria should the NRC use?

C. Patient Access

The NRC is requesting comments on whether there is a shortage in the number of AUs for 10 CFR 35.300.

1. Is there a shortage in the number of AUs for medical uses under 10 CFR 35.300? If so, is the shortage associated with the use of a specific radiopharmaceutical? Explain how.
2. Are there certain geographic areas with an inadequate number of AUs? Identify these areas.
3. Do current NRC regulations on AU T&E requirements unnecessarily limit patient access to procedures involving radiopharmaceuticals? Explain how.
4. Do current NRC regulations on AU T&E requirements unnecessarily limit research and development in nuclear medicine? Explain how.

D. Other Suggested Changes to the T&E Regulations

In 2002, the NRC revised its regulatory framework for medical use. The goal was to focus the NRC's regulations on those medical procedures that pose the highest risk to workers, the general public, patients, and human research subjects and to structure the regulations to be more risk-informed and more performance-based. The 2002 rule reduced the unnecessary regulatory burden by either reducing or eliminating the prescriptiveness of some regulations. Instead, the rule provided for a performance-based approach that relied on the training and experience of the AUs, authorized nuclear pharmacists, and radiation safety officers. The NRC is requesting comments on whether there are any other changes to the T&E regulations in 10 CFR part 35 that should be considered. Please discuss your suggested changes.

1. Should the NRC regulate the T&E of physicians for medical uses?
2. Are there requirements in the NRC's T&E regulatory framework for physicians that are non-safety related?

3. How can the NRC transform its regulatory approach for T&E while still ensuring that adequate protection is maintained for workers, the general public, patients, and human research subjects?

Dated at Rockville, Maryland, this 23rd day of October 2018.

For the Nuclear Regulatory
Commission.

/RA/

Daniel S. Collins, Director,
Division of Materials Safety,
Security,
State, and Tribal Programs,
Office of Nuclear Material Safety
and Safeguards.



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

November 2, 2018

Ms. Tina Getachew
Program Specialist, Government Relations
American College of Radiology
505 9th St. NW, Suite 910
Washington, DC 20004

Via e-mail to tgetachew@acr.org

SUBJECT: TRAINING AND EXPERIENCE REQUIREMENTS FOR DIFFERENT CATEGORIES OF RADIOPHARMACEUTICALS

Dear Ms. Getachew,

The U.S. Nuclear Regulatory Commission (NRC) is evaluating its regulations related to the training and experience (T&E) required for a physician to become an authorized user for medical uses under Subpart E, “Unsealed Byproduct Material—Written Directive Required,” of [Title 10 of the Code of Federal Regulations \(10 CFR\) Part 35, “Medical Use of Byproduct Material.”](#)

The T&E requirements in Subpart E of 10 CFR Part 35 provide three ways that a physician can be authorized to administer unsealed byproduct materials or radiopharmaceuticals requiring a written directive:

1. A physician can be certified by a medical specialty board, whose certification process is recognized by the NRC or an Agreement State.
2. A physician can complete a structured educational program and supervised work experience under an alternate pathway. This alternate pathway includes a requirement for 700 hours of training and experience, which consists of a minimum of 200 hours of classroom and laboratory training and 500 hours of supervised work experience.
3. A physician can be authorized if previously identified as an authorized user on an NRC or Agreement State license or permit (i.e., grandfathered).

In its evaluation of the T&E requirements, the NRC staff is considering whether an additional pathway should be created or if the alternate pathway should be revised. Specifically, the staff is evaluating: (1) whether it makes sense to establish tailored T&E requirements for different categories of radiopharmaceuticals; (2) how those categories should be determined; (3) what the appropriate T&E requirements would be for each category; and (4) whether those requirements should be based on hours of training and experience, or focused more on competency.

On October 29, 2018, the NRC published a series of questions on T&E in the *Federal Register* (83 FR 54380). The *Federal Register* notice is enclosed with this letter and can also be accessed at: <https://www.gpo.gov/fdsys/pkg/FR-2018-10-29/pdf/2018-23521.pdf>. The NRC will carefully consider responses to these questions and would appreciate your feedback on whether changes to the current T&E regulations are warranted. The comment period for the T&E evaluation will end on January 29, 2019. Please follow the directions in the notice on how to submit written comments. The NRC is using the Federal rulemaking Web site, [Regulations.gov](#), to accept written comments on the docket (NRC-2018-0230).

The NRC will also conduct four public meetings scheduled for November 14 and December 11, 2018, and January 10 and January 22, 2019, and will accept oral comments provided during the meetings. The meetings on December 11 and January 10 will be held at NRC Headquarters in Rockville, MD, and all four meetings will be accessible for remote participation by moderated bridge line and webinar. The NRC's public meeting page has been updated with meeting details and registration instructions for each meeting: <https://www.nrc.gov/pmns/mtg>.

Additional information on the NRC's T&E evaluation can be found at: <https://www.nrc.gov/materials/miau/med-use-toolkit/training-experience-evaluation.html>. If you have any questions on this correspondence, please contact Sarah Lopas of my staff at (301) 415-6360 or Sarah.Lopas@nrc.gov.

A handwritten signature in black ink, appearing to read "C Einberg".

Christian Einberg, Chief
Medical Safety and Events Assessment Branch
Division of Materials Safety, Security, State
and Tribal Programs
Office of Nuclear Material Safety
and Safeguards

Enclosure:
Training and Experience
Federal Register notice

NUCLEAR REGULATORY COMMISSION

[NRC-2018-0230]

**Training and Experience Requirements for Different Categories of
Radiopharmaceuticals**

AGENCY: Nuclear Regulatory Commission.

ACTION: Training and experience requirements; request for comment.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is requesting comments on its training and experience (T&E) requirements. Specifically, the NRC would like input on whether it should establish tailored T&E requirements for different categories of radiopharmaceuticals for which a written directive is required in accordance with its regulations. The input will be used to determine whether significant regulatory changes to the NRC's T&E requirements for authorized users (AUs) are warranted.

DATES: Submit comments by January 29, 2019. Comments received after this date will be considered if it is practical to do so, but the NRC is only able to ensure consideration for comments received on or before this date.

ADDRESSES: You may submit comments by any of the following methods:

- **Federal Rulemaking Web Site:** Go to <http://www.regulations.gov>

and search for Docket ID **NRC-2018-0230**. Address questions about Docket IDs in Regulations.gov to Jennifer Borges; telephone: 301-287-9127; e-mail: Jennifer.Borges@nrc.gov. For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.

- **Mail comments to:** May Ma, Office of Administration, Mail Stop: TWFN-7-A60M, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001.

For additional direction on obtaining information and submitting comments, see “Obtaining Information and Submitting Comments” in the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: Sarah Lopas, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001; telephone: 301-415-6360, e-mail: Sarah.Lopas@nrc.gov.

SUPPLEMENTARY INFORMATION:

I. Obtaining Information and Submitting Comments

A. Obtaining Information

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- **NRC's PDR:** You may examine and purchase copies of public documents at the NRC's PDR, Room O1-F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.

B. Submitting Comments

Please include Docket ID **NRC-2018-0230** in your comment submission.

The NRC cautions you not to include identifying or contact information in comment submissions that you do not want to be publicly disclosed in your comment submission. All comment submissions are posted at <http://www.regulations.gov> and entered into ADAMS. Comment submissions are not routinely edited to remove identifying or contact information.

If you are requesting or aggregating comments from other persons for submission to the NRC, then you should inform those persons not to include identifying or contact information that they do not want to be publicly disclosed in their comment submission. Your request should state that the NRC does not routinely edit comment submissions to remove such information before making the comment submissions available to the public or entering the comment into ADAMS.

II. Background

On August 17, 2017, the Commission issued a staff requirements memorandum (SRM), SRM-M170817 (ADAMS Accession No. ML17229B284), approving the final rule revising parts 30, 32, and 35 of title 10 of the *Code of Federal Regulations* (10 CFR), "Medical Use of Byproduct Material – Medical Event Definitions, Training and Experience, and Clarifying Amendments," and directing the staff to evaluate (1) whether it makes sense to establish tailored T&E requirements for different categories of radiopharmaceuticals, (2) how those categories should be determined (such as by risks posed by groups of

radionuclides or by delivery method), (3) what the appropriate T&E requirements would be for each category, and (4) whether those requirements should be based on hours of T&E or focused more on competency. In response to the SRM, the NRC staff documented its initial results, status, and next steps related to this evaluation in SECY-18-0084, "Staff Evaluation of Training and Experience Requirements for Administering Different Categories of Radiopharmaceuticals in Response to SRM-M170817" (ADAMS Accession No. ML18135A276). In SECY-18-0084, the staff concluded that additional outreach with the medical community is needed to determine whether and how to tailor the T&E requirements to establish a limited AU status, the specific T&E requirements that should apply, how the T&E requirements should be met (e.g., hours of training, demonstration of competency), and whether a competency-based approach makes sense for the T&E requirements for all the medical uses authorized under 10 CFR 35.300, "Use of unsealed byproduct material for which a written directive is required."

The NRC is interested in obtaining input from as many stakeholders as possible, including members of the Advisory Committee on the Medical Uses of Isotopes, professional organizations, physicians, patients, patient advocacy groups, licensees, Agreement States, and other interested individuals. The focus of this request is to gather information that will permit the NRC staff to determine whether changes to the T&E requirements are warranted for different categories of radiopharmaceuticals for physicians seeking AU status for the medical use of specific categories of radiopharmaceuticals requiring a written directive under 10 CFR 35.300.

During the comment period between October 29, 2018 and January 29, 2019, the NRC will hold four public meetings that will discuss the information being requested and to accept comments on the docket. All four public meetings

will be available for remote participation by moderated bridge line and webinar, and two of the four meetings will be open for in-person attendance at NRC's headquarters in Rockville, Maryland.

The public meetings are scheduled for November 14, 2018 (webinar-only); December 11, 2018 (webinar and in-person attendance); January 10, 2019 (webinar and in-person attendance); and January 22, 2019 (webinar-only). The public meetings will be noticed on the NRC's public meeting Web site at least 10 calendar days before the meeting. Members of the public should monitor the NRC's public meeting Web site at <https://www.nrc.gov/pmns/mtg>. The NRC will also post the meeting notices on the Federal Rulemaking Web site at <https://www.regulations.gov/> under Docket ID **NRC-2018-0230**.

The NRC may post additional materials related to this document, including public comments, on the Federal Rulemaking Web site. The Federal Rulemaking Web site allows you to receive alerts when changes or additions occur in a docket folder. To subscribe: (1) Navigate to the docket folder **NRC-2018-0230**; (2) click the “Sign up for E-mail Alerts” link; and (3) enter your email address and select how frequently you would like to receive emails (daily, weekly, or monthly).

III. Specific Requests for Comments

A. Tailored Training & Experience Requirements

The NRC is requesting comments on whether it should establish tailored T&E requirements for different categories of radiopharmaceuticals for physicians seeking AU status for the medical use of specific categories of radiopharmaceuticals requiring a written directive under 10 CFR 35.300 (i.e., a limited AU status). This would be for physicians seeking AU status via the alternate non-board certified pathway, and for physicians certified by a medical

specialty board that is not currently recognized by the NRC under 10 CFR 35.390, 35.392, 35.394, or 35.396 (Unsealed Byproduct Material—Written Directive Required).

1. Are the current pathways for obtaining AU status reasonable and accessible? Provide a rationale for your answer.
2. Are the current pathways for obtaining AU status adequate for protecting public health and safety? Provide a rationale for your answer.
3. Should the NRC develop a new tailored T&E pathway for these physicians? If so, what would be the appropriate way to categorize radiopharmaceuticals for tailored T&E requirements? If not, explain why the regulations should remain unchanged. [Some options to categorize radiopharmaceuticals include radiopharmaceuticals with similar delivery methods (oral, parenteral); same type of radiation characteristics or emission (alpha, beta, gamma, low-energy photon); similar preparation method (patient-ready doses); or a combination thereof (e.g., radiopharmaceuticals containing alpha- and beta-emitting radioisotopes that are administered intravenously and are prepared as patient-ready doses).]
4. Should the fundamental T&E required of physicians seeking limited AU status need to have the same fundamental T&E required of physicians seeking full AU status for all oral and parenteral administrations under 10 CFR 35.300?
5. How should the requirements for this fundamental T&E be structured for a specific category of radiopharmaceuticals?
 - a. Describe what the requirements should include:

- i. Classroom and laboratory training – What topics need to be covered in this training requirement? How many hours of classroom and laboratory training should be required? Provide the basis for the number of hours. If not hours, explain how this training should be quantified. [Note: The topics currently required in the regulations to be included in the classroom and laboratory training and work experience are listed in 10 CFR 35.390, 35.392, 35.394, and 35.396.]
 - ii. Work experience - What should the work experience requirement involve? How many hours of work experience should be required and what is the minimum number of patient or human research subject administrations that an individual must perform? Provide the basis for the number of hours and administrations. What should be the qualifications of the supervising individual?
 - iii. Competency - How should competency be evaluated? Should a written and/or practical examination by an independent examining committee be administered? Provide a rationale for your answer.
- b. Should a preceptor attestation be required for the fundamental T&E? Provide a rationale for your answer.
- c. Should the radiopharmaceutical manufacturer be able to provide the preceptor attestation? Provide a rational for your answer.

- d. Who should establish and administer the curriculum and examination? Provide specific group(s). [Some options are: NRC, medical specialty boards, medical professional societies, educational professional groups, and NRC in collaboration with any or more of the aforementioned groups.]
- e. Should AU competency be periodically assessed? If so, how should it be assessed, how often, and by whom?

B. NRC's Recognition of Medical Specialty Boards

The NRC is requesting comments on its recognition of medical specialty boards. The NRC's procedures for recognizing medical specialty boards are located on the Medical Uses Licensee Toolkit Web site (<https://www.nrc.gov/materials/miau/med-use-toolkit/certif-process-boards.html>). The NRC staff periodically reviews information to determine a board's continued eligibility for recognition.

- 1. What boards other than those already recognized by the NRC (American Board of Nuclear Medicine [ABNM], American Board of Radiology [ABR], American Osteopathic Board of Radiology [AOBR], Certification Board of Nuclear Endocrinology [CBNE]) could be considered for recognition for medical uses under 10 CFR 35.300?
- 2. Are the current NRC medical specialty board recognition criteria sufficient? If not, what additional criteria should the NRC use?

C. Patient Access

The NRC is requesting comments on whether there is a shortage in the number of AUs for 10 CFR 35.300.

1. Is there a shortage in the number of AUs for medical uses under 10 CFR 35.300? If so, is the shortage associated with the use of a specific radiopharmaceutical? Explain how.
2. Are there certain geographic areas with an inadequate number of AUs? Identify these areas.
3. Do current NRC regulations on AU T&E requirements unnecessarily limit patient access to procedures involving radiopharmaceuticals? Explain how.
4. Do current NRC regulations on AU T&E requirements unnecessarily limit research and development in nuclear medicine? Explain how.

D. Other Suggested Changes to the T&E Regulations

In 2002, the NRC revised its regulatory framework for medical use. The goal was to focus the NRC's regulations on those medical procedures that pose the highest risk to workers, the general public, patients, and human research subjects and to structure the regulations to be more risk-informed and more performance-based. The 2002 rule reduced the unnecessary regulatory burden by either reducing or eliminating the prescriptiveness of some regulations. Instead, the rule provided for a performance-based approach that relied on the training and experience of the AUs, authorized nuclear pharmacists, and radiation safety officers. The NRC is requesting comments on whether there are any other changes to the T&E regulations in 10 CFR part 35 that should be considered. Please discuss your suggested changes.

1. Should the NRC regulate the T&E of physicians for medical uses?
2. Are there requirements in the NRC's T&E regulatory framework for physicians that are non-safety related?

3. How can the NRC transform its regulatory approach for T&E while still ensuring that adequate protection is maintained for workers, the general public, patients, and human research subjects?

Dated at Rockville, Maryland, this 23rd day of October 2018.

For the Nuclear Regulatory
Commission.

/RA/

Daniel S. Collins, Director,
Division of Materials Safety,
Security,
State, and Tribal Programs,
Office of Nuclear Material Safety
and Safeguards.



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

November 2, 2018

Dr. David Gilmore
Program Director & Associate Professor
Nuclear Medicine Technology
Massachusetts School of Pharmacy
and Health Sciences
179 Longwood Ave.
Boston, MA 02115

Via e-mail to David.Gilmore@mcphs.edu

**SUBJECT: TRAINING AND EXPERIENCE REQUIREMENTS FOR DIFFERENT
CATEGORIES OF RADIOPHARMACEUTICALS**

Dear Dr. Gilmore,

The U.S. Nuclear Regulatory Commission (NRC) is evaluating its regulations related to the training and experience (T&E) required for a physician to become an authorized user for medical uses under Subpart E, “Unsealed Byproduct Material—Written Directive Required,” of [Title 10 of the Code of Federal Regulations \(10 CFR\) Part 35, “Medical Use of Byproduct Material.”](#)

The T&E requirements in Subpart E of 10 CFR Part 35 provide three ways that a physician can be authorized to administer unsealed byproduct materials or radiopharmaceuticals requiring a written directive:

1. A physician can be certified by a medical specialty board, whose certification process is recognized by the NRC or an Agreement State.
2. A physician can complete a structured educational program and supervised work experience under an alternate pathway. This alternate pathway includes a requirement for 700 hours of training and experience, which consists of a minimum of 200 hours of classroom and laboratory training and 500 hours of supervised work experience.
3. A physician can be authorized if previously identified as an authorized user on an NRC or Agreement State license or permit (i.e., grandfathered).

In its evaluation of the T&E requirements, the NRC staff is considering whether an additional pathway should be created or if the alternate pathway should be revised. Specifically, the staff is evaluating: (1) whether it makes sense to establish tailored T&E requirements for different categories of radiopharmaceuticals; (2) how those categories should be determined; (3) what the appropriate T&E requirements would be for each category; and (4) whether those requirements should be based on hours of training and experience, or focused more on competency.

On October 29, 2018, the NRC published a series of questions on T&E in the *Federal Register* (83 FR 54380). The *Federal Register* notice is enclosed with this letter and can also be accessed at: <https://www.gpo.gov/fdsys/pkg/FR-2018-10-29/pdf/2018-23521.pdf>. The NRC will carefully consider responses to these questions and would appreciate your feedback on whether changes to the current T&E regulations are warranted. The comment period for the T&E evaluation will end on January 29, 2019. Please follow the directions in the notice on how to submit written comments. The NRC is using the Federal rulemaking Web site, [Regulations.gov](#), to accept written comments on the docket (NRC-2018-0230).

The NRC will also conduct four public meetings scheduled for November 14 and December 11, 2018, and January 10 and January 22, 2019, and will accept oral comments provided during the meetings. The meetings on December 11 and January 10 will be held at NRC Headquarters in Rockville, MD, and all four meetings will be accessible for remote participation by moderated bridge line and webinar. The NRC's public meeting page has been updated with meeting details and registration instructions for each meeting: <https://www.nrc.gov/pmns/mtg>.

Additional information on the NRC's T&E evaluation can be found at: <https://www.nrc.gov/materials/miau/med-use-toolkit/training-experience-evaluation.html>. If you have any questions on this correspondence, please contact Sarah Lopas of my staff at (301) 415-6360 or Sarah.Lopas@nrc.gov.

A handwritten signature in black ink, appearing to read "C Einberg".

Christian Einberg, Chief
Medical Safety and Events Assessment Branch
Division of Materials Safety, Security, State
and Tribal Programs
Office of Nuclear Material Safety
and Safeguards

Enclosure:
Training and Experience
Federal Register notice

NUCLEAR REGULATORY COMMISSION

[NRC-2018-0230]

**Training and Experience Requirements for Different Categories of
Radiopharmaceuticals**

AGENCY: Nuclear Regulatory Commission.

ACTION: Training and experience requirements; request for comment.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is requesting comments on its training and experience (T&E) requirements. Specifically, the NRC would like input on whether it should establish tailored T&E requirements for different categories of radiopharmaceuticals for which a written directive is required in accordance with its regulations. The input will be used to determine whether significant regulatory changes to the NRC's T&E requirements for authorized users (AUs) are warranted.

DATES: Submit comments by January 29, 2019. Comments received after this date will be considered if it is practical to do so, but the NRC is only able to ensure consideration for comments received on or before this date.

ADDRESSES: You may submit comments by any of the following methods:

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Please include Docket ID **NRC-2018-0230** in your comment submission.

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III. Specific Requests for Comments

A. Tailored Training & Experience Requirements

The NRC is requesting comments on whether it should establish tailored T&E requirements for different categories of radiopharmaceuticals for physicians seeking AU status for the medical use of specific categories of radiopharmaceuticals requiring a written directive under 10 CFR 35.300 (i.e., a limited AU status). This would be for physicians seeking AU status via the alternate non-board certified pathway, and for physicians certified by a medical

specialty board that is not currently recognized by the NRC under 10 CFR 35.390, 35.392, 35.394, or 35.396 (Unsealed Byproduct Material—Written Directive Required).

1. Are the current pathways for obtaining AU status reasonable and accessible? Provide a rationale for your answer.
2. Are the current pathways for obtaining AU status adequate for protecting public health and safety? Provide a rationale for your answer.
3. Should the NRC develop a new tailored T&E pathway for these physicians? If so, what would be the appropriate way to categorize radiopharmaceuticals for tailored T&E requirements? If not, explain why the regulations should remain unchanged. [Some options to categorize radiopharmaceuticals include radiopharmaceuticals with similar delivery methods (oral, parenteral); same type of radiation characteristics or emission (alpha, beta, gamma, low-energy photon); similar preparation method (patient-ready doses); or a combination thereof (e.g., radiopharmaceuticals containing alpha- and beta-emitting radioisotopes that are administered intravenously and are prepared as patient-ready doses).]
4. Should the fundamental T&E required of physicians seeking limited AU status need to have the same fundamental T&E required of physicians seeking full AU status for all oral and parenteral administrations under 10 CFR 35.300?
5. How should the requirements for this fundamental T&E be structured for a specific category of radiopharmaceuticals?
 - a. Describe what the requirements should include:

- i. Classroom and laboratory training – What topics need to be covered in this training requirement? How many hours of classroom and laboratory training should be required? Provide the basis for the number of hours. If not hours, explain how this training should be quantified. [Note: The topics currently required in the regulations to be included in the classroom and laboratory training and work experience are listed in 10 CFR 35.390, 35.392, 35.394, and 35.396.]
 - ii. Work experience - What should the work experience requirement involve? How many hours of work experience should be required and what is the minimum number of patient or human research subject administrations that an individual must perform? Provide the basis for the number of hours and administrations. What should be the qualifications of the supervising individual?
 - iii. Competency - How should competency be evaluated? Should a written and/or practical examination by an independent examining committee be administered? Provide a rationale for your answer.
- b. Should a preceptor attestation be required for the fundamental T&E? Provide a rationale for your answer.
- c. Should the radiopharmaceutical manufacturer be able to provide the preceptor attestation? Provide a rational for your answer.

- d. Who should establish and administer the curriculum and examination? Provide specific group(s). [Some options are: NRC, medical specialty boards, medical professional societies, educational professional groups, and NRC in collaboration with any or more of the aforementioned groups.]
- e. Should AU competency be periodically assessed? If so, how should it be assessed, how often, and by whom?

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The NRC is requesting comments on its recognition of medical specialty boards. The NRC's procedures for recognizing medical specialty boards are located on the Medical Uses Licensee Toolkit Web site (<https://www.nrc.gov/materials/miau/med-use-toolkit/certif-process-boards.html>). The NRC staff periodically reviews information to determine a board's continued eligibility for recognition.

- 1. What boards other than those already recognized by the NRC (American Board of Nuclear Medicine [ABNM], American Board of Radiology [ABR], American Osteopathic Board of Radiology [AOBR], Certification Board of Nuclear Endocrinology [CBNE]) could be considered for recognition for medical uses under 10 CFR 35.300?
- 2. Are the current NRC medical specialty board recognition criteria sufficient? If not, what additional criteria should the NRC use?

C. Patient Access

The NRC is requesting comments on whether there is a shortage in the number of AUs for 10 CFR 35.300.

1. Is there a shortage in the number of AUs for medical uses under 10 CFR 35.300? If so, is the shortage associated with the use of a specific radiopharmaceutical? Explain how.
2. Are there certain geographic areas with an inadequate number of AUs? Identify these areas.
3. Do current NRC regulations on AU T&E requirements unnecessarily limit patient access to procedures involving radiopharmaceuticals? Explain how.
4. Do current NRC regulations on AU T&E requirements unnecessarily limit research and development in nuclear medicine? Explain how.

D. Other Suggested Changes to the T&E Regulations

In 2002, the NRC revised its regulatory framework for medical use. The goal was to focus the NRC's regulations on those medical procedures that pose the highest risk to workers, the general public, patients, and human research subjects and to structure the regulations to be more risk-informed and more performance-based. The 2002 rule reduced the unnecessary regulatory burden by either reducing or eliminating the prescriptiveness of some regulations. Instead, the rule provided for a performance-based approach that relied on the training and experience of the AUs, authorized nuclear pharmacists, and radiation safety officers. The NRC is requesting comments on whether there are any other changes to the T&E regulations in 10 CFR part 35 that should be considered. Please discuss your suggested changes.

1. Should the NRC regulate the T&E of physicians for medical uses?
2. Are there requirements in the NRC's T&E regulatory framework for physicians that are non-safety related?

3. How can the NRC transform its regulatory approach for T&E while still ensuring that adequate protection is maintained for workers, the general public, patients, and human research subjects?

Dated at Rockville, Maryland, this 23rd day of October 2018.

For the Nuclear Regulatory
Commission.

/RA/

Daniel S. Collins, Director,
Division of Materials Safety,
Security,
State, and Tribal Programs,
Office of Nuclear Material Safety
and Safeguards.



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

November 2, 2018

Dr. Vesper Grantham
Program Director, Nuclear Medicine
Department of Medical Imagings and
Radiation Sciences
College of Allied Health
The University of Oklahoma
Health Sciences Center
1200 North Stonewall Ave.
Oklahoma City, OK 73126-0901

Via e-mail to Vesper-Grantham@ouhsc.edu

SUBJECT: TRAINING AND EXPERIENCE REQUIREMENTS FOR DIFFERENT CATEGORIES OF RADIOPHARMACEUTICALS

Dear Dr. Grantham,

The U.S. Nuclear Regulatory Commission (NRC) is evaluating its regulations related to the training and experience (T&E) required for a physician to become an authorized user for medical uses under Subpart E, “Unsealed Byproduct Material—Written Directive Required,” of [Title 10 of the Code of Federal Regulations \(10 CFR\) Part 35, “Medical Use of Byproduct Material.”](#)

The T&E requirements in Subpart E of 10 CFR Part 35 provide three ways that a physician can be authorized to administer unsealed byproduct materials or radiopharmaceuticals requiring a written directive:

1. A physician can be certified by a medical specialty board, whose certification process is recognized by the NRC or an Agreement State.
2. A physician can complete a structured educational program and supervised work experience under an alternate pathway. This alternate pathway includes a requirement for 700 hours of training and experience, which consists of a minimum of 200 hours of classroom and laboratory training and 500 hours of supervised work experience.
3. A physician can be authorized if previously identified as an authorized user on an NRC or Agreement State license or permit (i.e., grandfathered).

In its evaluation of the T&E requirements, the NRC staff is considering whether an additional pathway should be created or if the alternate pathway should be revised. Specifically, the staff is evaluating: (1) whether it makes sense to establish tailored T&E requirements for different categories of radiopharmaceuticals; (2) how those categories should be determined; (3) what the appropriate T&E requirements would be for each category; and (4) whether those requirements should be based on hours of training and experience, or focused more on competency.

On October 29, 2018, the NRC published a series of questions on T&E in the *Federal Register* (83 FR 54380). The *Federal Register* notice is enclosed with this letter and can also be accessed at: <https://www.gpo.gov/fdsys/pkg/FR-2018-10-29/pdf/2018-23521.pdf>. The NRC will carefully consider responses to these questions and would appreciate your feedback on whether changes to the current T&E regulations are warranted. The comment period for the T&E evaluation will end on January 29, 2019. Please follow the directions in the notice on how to submit written comments. The NRC is using the Federal rulemaking Web site, [Regulations.gov](#), to accept written comments on the docket (NRC-2018-0230).

The NRC will also conduct four public meetings scheduled for November 14 and December 11, 2018, and January 10 and January 22, 2019, and will accept oral comments provided during the meetings. The meetings on December 11 and January 10 will be held at NRC Headquarters in Rockville, MD, and all four meetings will be accessible for remote participation by moderated bridge line and webinar. The NRC's public meeting page has been updated with meeting details and registration instructions for each meeting: <https://www.nrc.gov/pmns/mtg>.

Additional information on the NRC's T&E evaluation can be found at: <https://www.nrc.gov/materials/miau/med-use-toolkit/training-experience-evaluation.html>. If you have any questions on this correspondence, please contact Sarah Lopas of my staff at (301) 415-6360 or Sarah.Lopas@nrc.gov.



Christian Einberg, Chief
Medical Safety and Events Assessment Branch
Division of Materials Safety, Security, State
and Tribal Programs
Office of Nuclear Material Safety
and Safeguards

Enclosure:
Training and Experience
Federal Register notice

NUCLEAR REGULATORY COMMISSION

[NRC-2018-0230]

**Training and Experience Requirements for Different Categories of
Radiopharmaceuticals**

AGENCY: Nuclear Regulatory Commission.

ACTION: Training and experience requirements; request for comment.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is requesting comments on its training and experience (T&E) requirements. Specifically, the NRC would like input on whether it should establish tailored T&E requirements for different categories of radiopharmaceuticals for which a written directive is required in accordance with its regulations. The input will be used to determine whether significant regulatory changes to the NRC's T&E requirements for authorized users (AUs) are warranted.

DATES: Submit comments by January 29, 2019. Comments received after this date will be considered if it is practical to do so, but the NRC is only able to ensure consideration for comments received on or before this date.

ADDRESSES: You may submit comments by any of the following methods:

- **Federal Rulemaking Web Site:** Go to <http://www.regulations.gov>

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- **Mail comments to:** May Ma, Office of Administration, Mail Stop: TWFN-7-A60M, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001.

For additional direction on obtaining information and submitting comments, see “Obtaining Information and Submitting Comments” in the **SUPPLEMENTARY INFORMATION** section of this document.

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SUPPLEMENTARY INFORMATION:

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B. Submitting Comments

Please include Docket ID **NRC-2018-0230** in your comment submission.

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II. Background

On August 17, 2017, the Commission issued a staff requirements memorandum (SRM), SRM-M170817 (ADAMS Accession No. ML17229B284), approving the final rule revising parts 30, 32, and 35 of title 10 of the *Code of Federal Regulations* (10 CFR), "Medical Use of Byproduct Material – Medical Event Definitions, Training and Experience, and Clarifying Amendments," and directing the staff to evaluate (1) whether it makes sense to establish tailored T&E requirements for different categories of radiopharmaceuticals, (2) how those categories should be determined (such as by risks posed by groups of

radionuclides or by delivery method), (3) what the appropriate T&E requirements would be for each category, and (4) whether those requirements should be based on hours of T&E or focused more on competency. In response to the SRM, the NRC staff documented its initial results, status, and next steps related to this evaluation in SECY-18-0084, "Staff Evaluation of Training and Experience Requirements for Administering Different Categories of Radiopharmaceuticals in Response to SRM-M170817" (ADAMS Accession No. ML18135A276). In SECY-18-0084, the staff concluded that additional outreach with the medical community is needed to determine whether and how to tailor the T&E requirements to establish a limited AU status, the specific T&E requirements that should apply, how the T&E requirements should be met (e.g., hours of training, demonstration of competency), and whether a competency-based approach makes sense for the T&E requirements for all the medical uses authorized under 10 CFR 35.300, "Use of unsealed byproduct material for which a written directive is required."

The NRC is interested in obtaining input from as many stakeholders as possible, including members of the Advisory Committee on the Medical Uses of Isotopes, professional organizations, physicians, patients, patient advocacy groups, licensees, Agreement States, and other interested individuals. The focus of this request is to gather information that will permit the NRC staff to determine whether changes to the T&E requirements are warranted for different categories of radiopharmaceuticals for physicians seeking AU status for the medical use of specific categories of radiopharmaceuticals requiring a written directive under 10 CFR 35.300.

During the comment period between October 29, 2018 and January 29, 2019, the NRC will hold four public meetings that will discuss the information being requested and to accept comments on the docket. All four public meetings

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1. Are the current pathways for obtaining AU status reasonable and accessible? Provide a rationale for your answer.
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- d. Who should establish and administer the curriculum and examination? Provide specific group(s). [Some options are: NRC, medical specialty boards, medical professional societies, educational professional groups, and NRC in collaboration with any or more of the aforementioned groups.]
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1. Is there a shortage in the number of AUs for medical uses under 10 CFR 35.300? If so, is the shortage associated with the use of a specific radiopharmaceutical? Explain how.
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1. Should the NRC regulate the T&E of physicians for medical uses?
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Dated at Rockville, Maryland, this 23rd day of October 2018.

For the Nuclear Regulatory
Commission.

/RA/

Daniel S. Collins, Director,
Division of Materials Safety,
Security,
State, and Tribal Programs,
Office of Nuclear Material Safety
and Safeguards.



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

November 2, 2018

Mr. Joseph Hawkins
Program Director, Nuclear Medicine Technology
Adventist University of Health Sciences
671 Winyah Drive
Orlando, FL 32803

Via e-mail to Joe.Hawkins@adu.edu

SUBJECT: TRAINING AND EXPERIENCE REQUIREMENTS FOR DIFFERENT CATEGORIES OF RADIOPHARMACEUTICALS

Dear Mr. Hawkins,

The U.S. Nuclear Regulatory Commission (NRC) is evaluating its regulations related to the training and experience (T&E) required for a physician to become an authorized user for medical uses under Subpart E, "Unsealed Byproduct Material—Written Directive Required," of [Title 10 of the Code of Federal Regulations \(10 CFR\) Part 35, "Medical Use of Byproduct Material."](#)

The T&E requirements in Subpart E of 10 CFR Part 35 provide three ways that a physician can be authorized to administer unsealed byproduct materials or radiopharmaceuticals requiring a written directive:

1. A physician can be certified by a medical specialty board, whose certification process is recognized by the NRC or an Agreement State.
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In its evaluation of the T&E requirements, the NRC staff is considering whether an additional pathway should be created or if the alternate pathway should be revised. Specifically, the staff is evaluating: (1) whether it makes sense to establish tailored T&E requirements for different categories of radiopharmaceuticals; (2) how those categories should be determined; (3) what the appropriate T&E requirements would be for each category; and (4) whether those requirements should be based on hours of training and experience, or focused more on competency.

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Additional information on the NRC's T&E evaluation can be found at: <https://www.nrc.gov/materials/miau/med-use-toolkit/training-experience-evaluation.html>. If you have any questions on this correspondence, please contact Sarah Lopas of my staff at (301) 415-6360 or Sarah.Lopas@nrc.gov.

A handwritten signature in black ink, appearing to read "C Einberg".

Christian Einberg, Chief
Medical Safety and Events Assessment Branch
Division of Materials Safety, Security, State
and Tribal Programs
Office of Nuclear Material Safety
and Safeguards

Enclosure:
Training and Experience
Federal Register notice

NUCLEAR REGULATORY COMMISSION

[NRC-2018-0230]

**Training and Experience Requirements for Different Categories of
Radiopharmaceuticals**

AGENCY: Nuclear Regulatory Commission.

ACTION: Training and experience requirements; request for comment.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is requesting comments on its training and experience (T&E) requirements. Specifically, the NRC would like input on whether it should establish tailored T&E requirements for different categories of radiopharmaceuticals for which a written directive is required in accordance with its regulations. The input will be used to determine whether significant regulatory changes to the NRC's T&E requirements for authorized users (AUs) are warranted.

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radionuclides or by delivery method), (3) what the appropriate T&E requirements would be for each category, and (4) whether those requirements should be based on hours of T&E or focused more on competency. In response to the SRM, the NRC staff documented its initial results, status, and next steps related to this evaluation in SECY-18-0084, "Staff Evaluation of Training and Experience Requirements for Administering Different Categories of Radiopharmaceuticals in Response to SRM-M170817" (ADAMS Accession No. ML18135A276). In SECY-18-0084, the staff concluded that additional outreach with the medical community is needed to determine whether and how to tailor the T&E requirements to establish a limited AU status, the specific T&E requirements that should apply, how the T&E requirements should be met (e.g., hours of training, demonstration of competency), and whether a competency-based approach makes sense for the T&E requirements for all the medical uses authorized under 10 CFR 35.300, "Use of unsealed byproduct material for which a written directive is required."

The NRC is interested in obtaining input from as many stakeholders as possible, including members of the Advisory Committee on the Medical Uses of Isotopes, professional organizations, physicians, patients, patient advocacy groups, licensees, Agreement States, and other interested individuals. The focus of this request is to gather information that will permit the NRC staff to determine whether changes to the T&E requirements are warranted for different categories of radiopharmaceuticals for physicians seeking AU status for the medical use of specific categories of radiopharmaceuticals requiring a written directive under 10 CFR 35.300.

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III. Specific Requests for Comments

A. Tailored Training & Experience Requirements

The NRC is requesting comments on whether it should establish tailored T&E requirements for different categories of radiopharmaceuticals for physicians seeking AU status for the medical use of specific categories of radiopharmaceuticals requiring a written directive under 10 CFR 35.300 (i.e., a limited AU status). This would be for physicians seeking AU status via the alternate non-board certified pathway, and for physicians certified by a medical

specialty board that is not currently recognized by the NRC under 10 CFR 35.390, 35.392, 35.394, or 35.396 (Unsealed Byproduct Material—Written Directive Required).

1. Are the current pathways for obtaining AU status reasonable and accessible? Provide a rationale for your answer.
2. Are the current pathways for obtaining AU status adequate for protecting public health and safety? Provide a rationale for your answer.
3. Should the NRC develop a new tailored T&E pathway for these physicians? If so, what would be the appropriate way to categorize radiopharmaceuticals for tailored T&E requirements? If not, explain why the regulations should remain unchanged. [Some options to categorize radiopharmaceuticals include radiopharmaceuticals with similar delivery methods (oral, parenteral); same type of radiation characteristics or emission (alpha, beta, gamma, low-energy photon); similar preparation method (patient-ready doses); or a combination thereof (e.g., radiopharmaceuticals containing alpha- and beta-emitting radioisotopes that are administered intravenously and are prepared as patient-ready doses).]
4. Should the fundamental T&E required of physicians seeking limited AU status need to have the same fundamental T&E required of physicians seeking full AU status for all oral and parenteral administrations under 10 CFR 35.300?
5. How should the requirements for this fundamental T&E be structured for a specific category of radiopharmaceuticals?
 - a. Describe what the requirements should include:

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 - iii. Competency - How should competency be evaluated? Should a written and/or practical examination by an independent examining committee be administered? Provide a rationale for your answer.
- b. Should a preceptor attestation be required for the fundamental T&E? Provide a rationale for your answer.
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- d. Who should establish and administer the curriculum and examination? Provide specific group(s). [Some options are: NRC, medical specialty boards, medical professional societies, educational professional groups, and NRC in collaboration with any or more of the aforementioned groups.]
- e. Should AU competency be periodically assessed? If so, how should it be assessed, how often, and by whom?

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The NRC is requesting comments on its recognition of medical specialty boards. The NRC's procedures for recognizing medical specialty boards are located on the Medical Uses Licensee Toolkit Web site (<https://www.nrc.gov/materials/miau/med-use-toolkit/certif-process-boards.html>). The NRC staff periodically reviews information to determine a board's continued eligibility for recognition.

- 1. What boards other than those already recognized by the NRC (American Board of Nuclear Medicine [ABNM], American Board of Radiology [ABR], American Osteopathic Board of Radiology [AOBR], Certification Board of Nuclear Endocrinology [CBNE]) could be considered for recognition for medical uses under 10 CFR 35.300?
- 2. Are the current NRC medical specialty board recognition criteria sufficient? If not, what additional criteria should the NRC use?

C. Patient Access

The NRC is requesting comments on whether there is a shortage in the number of AUs for 10 CFR 35.300.

1. Is there a shortage in the number of AUs for medical uses under 10 CFR 35.300? If so, is the shortage associated with the use of a specific radiopharmaceutical? Explain how.
2. Are there certain geographic areas with an inadequate number of AUs? Identify these areas.
3. Do current NRC regulations on AU T&E requirements unnecessarily limit patient access to procedures involving radiopharmaceuticals? Explain how.
4. Do current NRC regulations on AU T&E requirements unnecessarily limit research and development in nuclear medicine? Explain how.

D. Other Suggested Changes to the T&E Regulations

In 2002, the NRC revised its regulatory framework for medical use. The goal was to focus the NRC's regulations on those medical procedures that pose the highest risk to workers, the general public, patients, and human research subjects and to structure the regulations to be more risk-informed and more performance-based. The 2002 rule reduced the unnecessary regulatory burden by either reducing or eliminating the prescriptiveness of some regulations. Instead, the rule provided for a performance-based approach that relied on the training and experience of the AUs, authorized nuclear pharmacists, and radiation safety officers. The NRC is requesting comments on whether there are any other changes to the T&E regulations in 10 CFR part 35 that should be considered. Please discuss your suggested changes.

1. Should the NRC regulate the T&E of physicians for medical uses?
2. Are there requirements in the NRC's T&E regulatory framework for physicians that are non-safety related?

3. How can the NRC transform its regulatory approach for T&E while still ensuring that adequate protection is maintained for workers, the general public, patients, and human research subjects?

Dated at Rockville, Maryland, this 23rd day of October 2018.

For the Nuclear Regulatory
Commission.

/RA/

Daniel S. Collins, Director,
Division of Materials Safety,
Security,
State, and Tribal Programs,
Office of Nuclear Material Safety
and Safeguards.



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

November 2, 2018

Mr. Stephen Heinig
Office of Government Relations
Association of American Medical Colleges
655 K St. NW
Washington, DC 20001

Via e-mail to sheinig@aamc.org

SUBJECT: TRAINING AND EXPERIENCE REQUIREMENTS FOR DIFFERENT CATEGORIES OF RADIOPHARMACEUTICALS

Dear Mr. Heinig,

The U.S. Nuclear Regulatory Commission (NRC) is evaluating its regulations related to the training and experience (T&E) required for a physician to become an authorized user for medical uses under Subpart E, “Unsealed Byproduct Material—Written Directive Required,” of [Title 10 of the Code of Federal Regulations \(10 CFR\) Part 35, “Medical Use of Byproduct Material.”](#)

The T&E requirements in Subpart E of 10 CFR Part 35 provide three ways that a physician can be authorized to administer unsealed byproduct materials or radiopharmaceuticals requiring a written directive:

1. A physician can be certified by a medical specialty board, whose certification process is recognized by the NRC or an Agreement State.
2. A physician can complete a structured educational program and supervised work experience under an alternate pathway. This alternate pathway includes a requirement for 700 hours of training and experience, which consists of a minimum of 200 hours of classroom and laboratory training and 500 hours of supervised work experience.
3. A physician can be authorized if previously identified as an authorized user on an NRC or Agreement State license or permit (i.e., grandfathered).

In its evaluation of the T&E requirements, the NRC staff is considering whether an additional pathway should be created or if the alternate pathway should be revised. Specifically, the staff is evaluating: (1) whether it makes sense to establish tailored T&E requirements for different categories of radiopharmaceuticals; (2) how those categories should be determined; (3) what the appropriate T&E requirements would be for each category; and (4) whether those requirements should be based on hours of training and experience, or focused more on competency.

On October 29, 2018, the NRC published a series of questions on T&E in the *Federal Register* (83 FR 54380). The *Federal Register* notice is enclosed with this letter and can also be accessed at: <https://www.gpo.gov/fdsys/pkg/FR-2018-10-29/pdf/2018-23521.pdf>. The NRC will carefully consider responses to these questions and would appreciate your feedback on whether changes to the current T&E regulations are warranted. The comment period for the T&E evaluation will end on January 29, 2019. Please follow the directions in the notice on how to submit written comments. The NRC is using the Federal rulemaking Web site, [Regulations.gov](#), to accept written comments on the docket (NRC-2018-0230).

The NRC will also conduct four public meetings scheduled for November 14 and December 11, 2018, and January 10 and January 22, 2019, and will accept oral comments provided during the meetings. The meetings on December 11 and January 10 will be held at NRC Headquarters in Rockville, MD, and all four meetings will be accessible for remote participation by moderated bridge line and webinar. The NRC's public meeting page has been updated with meeting details and registration instructions for each meeting: <https://www.nrc.gov/pmns/mtg>.

Additional information on the NRC's T&E evaluation can be found at: <https://www.nrc.gov/materials/miau/med-use-toolkit/training-experience-evaluation.html>. If you have any questions on this correspondence, please contact Sarah Lopas of my staff at (301) 415-6360 or Sarah.Lopas@nrc.gov.



Christian Einberg, Chief
Medical Safety and Events Assessment Branch
Division of Materials Safety, Security, State
and Tribal Programs
Office of Nuclear Material Safety
and Safeguards

Enclosure:
Training and Experience
Federal Register notice

NUCLEAR REGULATORY COMMISSION

[NRC-2018-0230]

**Training and Experience Requirements for Different Categories of
Radiopharmaceuticals**

AGENCY: Nuclear Regulatory Commission.

ACTION: Training and experience requirements; request for comment.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is requesting comments on its training and experience (T&E) requirements. Specifically, the NRC would like input on whether it should establish tailored T&E requirements for different categories of radiopharmaceuticals for which a written directive is required in accordance with its regulations. The input will be used to determine whether significant regulatory changes to the NRC's T&E requirements for authorized users (AUs) are warranted.

DATES: Submit comments by January 29, 2019. Comments received after this date will be considered if it is practical to do so, but the NRC is only able to ensure consideration for comments received on or before this date.

ADDRESSES: You may submit comments by any of the following methods:

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FOR FURTHER INFORMATION CONTACT: Sarah Lopas, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001; telephone: 301-415-6360, e-mail: Sarah.Lopas@nrc.gov.

SUPPLEMENTARY INFORMATION:

I. Obtaining Information and Submitting Comments

A. Obtaining Information

Please refer to Docket ID **NRC-2018-0230** when contacting the NRC about the availability of information for this action. You may obtain publicly-available information related to this action by any of the following methods:

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- **NRC's PDR:** You may examine and purchase copies of public documents at the NRC's PDR, Room O1-F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.

B. Submitting Comments

Please include Docket ID **NRC-2018-0230** in your comment submission.

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Dated at Rockville, Maryland, this 23rd day of October 2018.

For the Nuclear Regulatory
Commission.

/RA/

Daniel S. Collins, Director,
Division of Materials Safety,
Security,
State, and Tribal Programs,
Office of Nuclear Material Safety
and Safeguards.



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

November 2, 2018

Ms. Elizabeth Hodgson
Coordinator, Nuclear Medicine Technology
York College of Pennsylvania
Appell Life Sciences, Room 224
444 Country Club Rd.
York, PA 17403-3651

Via e-mail to ehodgson@ycp.edu

SUBJECT: TRAINING AND EXPERIENCE REQUIREMENTS FOR DIFFERENT CATEGORIES OF RADIOPHARMACEUTICALS

Dear Ms. Hodgson,

The U.S. Nuclear Regulatory Commission (NRC) is evaluating its regulations related to the training and experience (T&E) required for a physician to become an authorized user for medical uses under Subpart E, “Unsealed Byproduct Material—Written Directive Required,” of [Title 10 of the Code of Federal Regulations \(10 CFR\) Part 35, “Medical Use of Byproduct Material.”](#)

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Christian Einberg, Chief
Medical Safety and Events Assessment Branch
Division of Materials Safety, Security, State
and Tribal Programs
Office of Nuclear Material Safety
and Safeguards

Enclosure:
Training and Experience
Federal Register notice

NUCLEAR REGULATORY COMMISSION

[NRC-2018-0230]

**Training and Experience Requirements for Different Categories of
Radiopharmaceuticals**

AGENCY: Nuclear Regulatory Commission.

ACTION: Training and experience requirements; request for comment.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is requesting comments on its training and experience (T&E) requirements. Specifically, the NRC would like input on whether it should establish tailored T&E requirements for different categories of radiopharmaceuticals for which a written directive is required in accordance with its regulations. The input will be used to determine whether significant regulatory changes to the NRC's T&E requirements for authorized users (AUs) are warranted.

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FOR FURTHER INFORMATION CONTACT: Sarah Lopas, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001; telephone: 301-415-6360, e-mail: Sarah.Lopas@nrc.gov.

SUPPLEMENTARY INFORMATION:

I. Obtaining Information and Submitting Comments

A. Obtaining Information

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radionuclides or by delivery method), (3) what the appropriate T&E requirements would be for each category, and (4) whether those requirements should be based on hours of T&E or focused more on competency. In response to the SRM, the NRC staff documented its initial results, status, and next steps related to this evaluation in SECY-18-0084, "Staff Evaluation of Training and Experience Requirements for Administering Different Categories of Radiopharmaceuticals in Response to SRM-M170817" (ADAMS Accession No. ML18135A276). In SECY-18-0084, the staff concluded that additional outreach with the medical community is needed to determine whether and how to tailor the T&E requirements to establish a limited AU status, the specific T&E requirements that should apply, how the T&E requirements should be met (e.g., hours of training, demonstration of competency), and whether a competency-based approach makes sense for the T&E requirements for all the medical uses authorized under 10 CFR 35.300, "Use of unsealed byproduct material for which a written directive is required."

The NRC is interested in obtaining input from as many stakeholders as possible, including members of the Advisory Committee on the Medical Uses of Isotopes, professional organizations, physicians, patients, patient advocacy groups, licensees, Agreement States, and other interested individuals. The focus of this request is to gather information that will permit the NRC staff to determine whether changes to the T&E requirements are warranted for different categories of radiopharmaceuticals for physicians seeking AU status for the medical use of specific categories of radiopharmaceuticals requiring a written directive under 10 CFR 35.300.

During the comment period between October 29, 2018 and January 29, 2019, the NRC will hold four public meetings that will discuss the information being requested and to accept comments on the docket. All four public meetings

will be available for remote participation by moderated bridge line and webinar, and two of the four meetings will be open for in-person attendance at NRC's headquarters in Rockville, Maryland.

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III. Specific Requests for Comments

A. Tailored Training & Experience Requirements

The NRC is requesting comments on whether it should establish tailored T&E requirements for different categories of radiopharmaceuticals for physicians seeking AU status for the medical use of specific categories of radiopharmaceuticals requiring a written directive under 10 CFR 35.300 (i.e., a limited AU status). This would be for physicians seeking AU status via the alternate non-board certified pathway, and for physicians certified by a medical

specialty board that is not currently recognized by the NRC under 10 CFR 35.390, 35.392, 35.394, or 35.396 (Unsealed Byproduct Material—Written Directive Required).

1. Are the current pathways for obtaining AU status reasonable and accessible? Provide a rationale for your answer.
2. Are the current pathways for obtaining AU status adequate for protecting public health and safety? Provide a rationale for your answer.
3. Should the NRC develop a new tailored T&E pathway for these physicians? If so, what would be the appropriate way to categorize radiopharmaceuticals for tailored T&E requirements? If not, explain why the regulations should remain unchanged. [Some options to categorize radiopharmaceuticals include radiopharmaceuticals with similar delivery methods (oral, parenteral); same type of radiation characteristics or emission (alpha, beta, gamma, low-energy photon); similar preparation method (patient-ready doses); or a combination thereof (e.g., radiopharmaceuticals containing alpha- and beta-emitting radioisotopes that are administered intravenously and are prepared as patient-ready doses).]
4. Should the fundamental T&E required of physicians seeking limited AU status need to have the same fundamental T&E required of physicians seeking full AU status for all oral and parenteral administrations under 10 CFR 35.300?
5. How should the requirements for this fundamental T&E be structured for a specific category of radiopharmaceuticals?
 - a. Describe what the requirements should include:

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 - iii. Competency - How should competency be evaluated? Should a written and/or practical examination by an independent examining committee be administered? Provide a rationale for your answer.
- b. Should a preceptor attestation be required for the fundamental T&E? Provide a rationale for your answer.
- c. Should the radiopharmaceutical manufacturer be able to provide the preceptor attestation? Provide a rational for your answer.

- d. Who should establish and administer the curriculum and examination? Provide specific group(s). [Some options are: NRC, medical specialty boards, medical professional societies, educational professional groups, and NRC in collaboration with any or more of the aforementioned groups.]
- e. Should AU competency be periodically assessed? If so, how should it be assessed, how often, and by whom?

B. NRC's Recognition of Medical Specialty Boards

The NRC is requesting comments on its recognition of medical specialty boards. The NRC's procedures for recognizing medical specialty boards are located on the Medical Uses Licensee Toolkit Web site (<https://www.nrc.gov/materials/miau/med-use-toolkit/certif-process-boards.html>). The NRC staff periodically reviews information to determine a board's continued eligibility for recognition.

- 1. What boards other than those already recognized by the NRC (American Board of Nuclear Medicine [ABNM], American Board of Radiology [ABR], American Osteopathic Board of Radiology [AOBR], Certification Board of Nuclear Endocrinology [CBNE]) could be considered for recognition for medical uses under 10 CFR 35.300?
- 2. Are the current NRC medical specialty board recognition criteria sufficient? If not, what additional criteria should the NRC use?

C. Patient Access

The NRC is requesting comments on whether there is a shortage in the number of AUs for 10 CFR 35.300.

1. Is there a shortage in the number of AUs for medical uses under 10 CFR 35.300? If so, is the shortage associated with the use of a specific radiopharmaceutical? Explain how.
2. Are there certain geographic areas with an inadequate number of AUs? Identify these areas.
3. Do current NRC regulations on AU T&E requirements unnecessarily limit patient access to procedures involving radiopharmaceuticals? Explain how.
4. Do current NRC regulations on AU T&E requirements unnecessarily limit research and development in nuclear medicine? Explain how.

D. Other Suggested Changes to the T&E Regulations

In 2002, the NRC revised its regulatory framework for medical use. The goal was to focus the NRC's regulations on those medical procedures that pose the highest risk to workers, the general public, patients, and human research subjects and to structure the regulations to be more risk-informed and more performance-based. The 2002 rule reduced the unnecessary regulatory burden by either reducing or eliminating the prescriptiveness of some regulations. Instead, the rule provided for a performance-based approach that relied on the training and experience of the AUs, authorized nuclear pharmacists, and radiation safety officers. The NRC is requesting comments on whether there are any other changes to the T&E regulations in 10 CFR part 35 that should be considered. Please discuss your suggested changes.

1. Should the NRC regulate the T&E of physicians for medical uses?
2. Are there requirements in the NRC's T&E regulatory framework for physicians that are non-safety related?

3. How can the NRC transform its regulatory approach for T&E while still ensuring that adequate protection is maintained for workers, the general public, patients, and human research subjects?

Dated at Rockville, Maryland, this 23rd day of October 2018.

For the Nuclear Regulatory
Commission.

/RA/

Daniel S. Collins, Director,
Division of Materials Safety,
Security,
State, and Tribal Programs,
Office of Nuclear Material Safety
and Safeguards.



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

November 2, 2018

Health Physics Society
950 Herndon Parkway, Suite 450
Herndon, VA 20170

Via e-mail to hps@burkinc.com

SUBJECT: TRAINING AND EXPERIENCE REQUIREMENTS FOR DIFFERENT CATEGORIES OF RADIOPHARMACEUTICALS

Dear Sir or Madam,

The U.S. Nuclear Regulatory Commission (NRC) is evaluating its regulations related to the training and experience (T&E) required for a physician to become an authorized user for medical uses under Subpart E, “Unsealed Byproduct Material—Written Directive Required,” of [Title 10 of the Code of Federal Regulations \(10 CFR\) Part 35, “Medical Use of Byproduct Material.”](#)

The T&E requirements in Subpart E of 10 CFR Part 35 provide three ways that a physician can be authorized to administer unsealed byproduct materials or radiopharmaceuticals requiring a written directive:

1. A physician can be certified by a medical specialty board, whose certification process is recognized by the NRC or an Agreement State.
2. A physician can complete a structured educational program and supervised work experience under an alternate pathway. This alternate pathway includes a requirement for 700 hours of training and experience, which consists of a minimum of 200 hours of classroom and laboratory training and 500 hours of supervised work experience.
3. A physician can be authorized if previously identified as an authorized user on an NRC or Agreement State license or permit (i.e., grandfathered).

In its evaluation of the T&E requirements, the NRC staff is considering whether an additional pathway should be created or if the alternate pathway should be revised. Specifically, the staff is evaluating: (1) whether it makes sense to establish tailored T&E requirements for different categories of radiopharmaceuticals; (2) how those categories should be determined; (3) what the appropriate T&E requirements would be for each category; and (4) whether those requirements should be based on hours of training and experience, or focused more on competency.

On October 29, 2018, the NRC published a series of questions on T&E in the *Federal Register* (83 FR 54380). The *Federal Register* notice is enclosed with this letter and can also be accessed at: <https://www.gpo.gov/fdsys/pkg/FR-2018-10-29/pdf/2018-23521.pdf>. The NRC will carefully consider responses to these questions and would appreciate your feedback on whether changes to the current T&E regulations are warranted. The comment period for the T&E evaluation will end on January 29, 2019. Please follow the directions in the notice on how to submit written comments. The NRC is using the Federal rulemaking Web site, [Regulations.gov](#), to accept written comments on the docket (NRC-2018-0230).

The NRC will also conduct four public meetings scheduled for November 14 and December 11, 2018, and January 10 and January 22, 2019, and will accept oral comments provided during the meetings. The meetings on December 11 and January 10 will be held at NRC Headquarters in Rockville, MD, and all four meetings will be accessible for remote participation by moderated bridge line and webinar. The NRC's public meeting page has been updated with meeting details and registration instructions for each meeting: <https://www.nrc.gov/pmns/mtg>.

Additional information on the NRC's T&E evaluation can be found at: <https://www.nrc.gov/materials/miau/med-use-toolkit/training-experience-evaluation.html>. If you have any questions on this correspondence, please contact Sarah Lopas of my staff at (301) 415-6360 or Sarah.Lopas@nrc.gov.



Christian Einberg, Chief
Medical Safety and Events Assessment Branch
Division of Materials Safety, Security, State
and Tribal Programs
Office of Nuclear Material Safety
and Safeguards

Enclosure:
Training and Experience
Federal Register notice

NUCLEAR REGULATORY COMMISSION

[NRC-2018-0230]

**Training and Experience Requirements for Different Categories of
Radiopharmaceuticals**

AGENCY: Nuclear Regulatory Commission.

ACTION: Training and experience requirements; request for comment.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is requesting comments on its training and experience (T&E) requirements. Specifically, the NRC would like input on whether it should establish tailored T&E requirements for different categories of radiopharmaceuticals for which a written directive is required in accordance with its regulations. The input will be used to determine whether significant regulatory changes to the NRC's T&E requirements for authorized users (AUs) are warranted.

DATES: Submit comments by January 29, 2019. Comments received after this date will be considered if it is practical to do so, but the NRC is only able to ensure consideration for comments received on or before this date.

ADDRESSES: You may submit comments by any of the following methods:

- **Federal Rulemaking Web Site:** Go to <http://www.regulations.gov>

and search for Docket ID **NRC-2018-0230**. Address questions about Docket IDs in Regulations.gov to Jennifer Borges; telephone: 301-287-9127; e-mail: Jennifer.Borges@nrc.gov. For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.

- **Mail comments to:** May Ma, Office of Administration, Mail Stop: TWFN-7-A60M, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001.

For additional direction on obtaining information and submitting comments, see “Obtaining Information and Submitting Comments” in the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: Sarah Lopas, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001; telephone: 301-415-6360, e-mail: Sarah.Lopas@nrc.gov.

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- b. Should a preceptor attestation be required for the fundamental T&E? Provide a rationale for your answer.
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- d. Who should establish and administer the curriculum and examination? Provide specific group(s). [Some options are: NRC, medical specialty boards, medical professional societies, educational professional groups, and NRC in collaboration with any or more of the aforementioned groups.]
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2. Are there certain geographic areas with an inadequate number of AUs? Identify these areas.
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2. Are there requirements in the NRC's T&E regulatory framework for physicians that are non-safety related?

3. How can the NRC transform its regulatory approach for T&E while still ensuring that adequate protection is maintained for workers, the general public, patients, and human research subjects?

Dated at Rockville, Maryland, this 23rd day of October 2018.

For the Nuclear Regulatory
Commission.

/RA/

Daniel S. Collins, Director,
Division of Materials Safety,
Security,
State, and Tribal Programs,
Office of Nuclear Material Safety
and Safeguards.



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

November 2, 2018

Ms. Karuna Jaggar
Executive Director
Breast Cancer Action
275 Fifth St., Suite 307
San Francisco, CA 94103

Via e-mail to info@bcaction.org

SUBJECT: TRAINING AND EXPERIENCE REQUIREMENTS FOR DIFFERENT CATEGORIES OF RADIOPHARMACEUTICALS

Dear Ms. Jaggar,

The U.S. Nuclear Regulatory Commission (NRC) is evaluating its regulations related to the training and experience (T&E) required for a physician to become an authorized user for medical uses under Subpart E, “Unsealed Byproduct Material—Written Directive Required,” of [Title 10 of the Code of Federal Regulations \(10 CFR\) Part 35, “Medical Use of Byproduct Material.”](#)

The T&E requirements in Subpart E of 10 CFR Part 35 provide three ways that a physician can be authorized to administer unsealed byproduct materials or radiopharmaceuticals requiring a written directive:

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Additional information on the NRC's T&E evaluation can be found at: <https://www.nrc.gov/materials/miau/med-use-toolkit/training-experience-evaluation.html>. If you have any questions on this correspondence, please contact Sarah Lopas of my staff at (301) 415-6360 or Sarah.Lopas@nrc.gov.

A handwritten signature in black ink, appearing to read "C Einberg".

Christian Einberg, Chief
Medical Safety and Events Assessment Branch
Division of Materials Safety, Security, State
and Tribal Programs
Office of Nuclear Material Safety
and Safeguards

Enclosure:
Training and Experience
Federal Register notice

NUCLEAR REGULATORY COMMISSION

[NRC-2018-0230]

**Training and Experience Requirements for Different Categories of
Radiopharmaceuticals**

AGENCY: Nuclear Regulatory Commission.

ACTION: Training and experience requirements; request for comment.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is requesting comments on its training and experience (T&E) requirements. Specifically, the NRC would like input on whether it should establish tailored T&E requirements for different categories of radiopharmaceuticals for which a written directive is required in accordance with its regulations. The input will be used to determine whether significant regulatory changes to the NRC's T&E requirements for authorized users (AUs) are warranted.

DATES: Submit comments by January 29, 2019. Comments received after this date will be considered if it is practical to do so, but the NRC is only able to ensure consideration for comments received on or before this date.

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- **Federal Rulemaking Web Site:** Go to <http://www.regulations.gov>

and search for Docket ID **NRC-2018-0230**. Address questions about Docket IDs in Regulations.gov to Jennifer Borges; telephone: 301-287-9127; e-mail: Jennifer.Borges@nrc.gov. For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.

- **Mail comments to:** May Ma, Office of Administration, Mail Stop: TWFN-7-A60M, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001.

For additional direction on obtaining information and submitting comments, see “Obtaining Information and Submitting Comments” in the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: Sarah Lopas, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001; telephone: 301-415-6360, e-mail: Sarah.Lopas@nrc.gov.

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radionuclides or by delivery method), (3) what the appropriate T&E requirements would be for each category, and (4) whether those requirements should be based on hours of T&E or focused more on competency. In response to the SRM, the NRC staff documented its initial results, status, and next steps related to this evaluation in SECY-18-0084, "Staff Evaluation of Training and Experience Requirements for Administering Different Categories of Radiopharmaceuticals in Response to SRM-M170817" (ADAMS Accession No. ML18135A276). In SECY-18-0084, the staff concluded that additional outreach with the medical community is needed to determine whether and how to tailor the T&E requirements to establish a limited AU status, the specific T&E requirements that should apply, how the T&E requirements should be met (e.g., hours of training, demonstration of competency), and whether a competency-based approach makes sense for the T&E requirements for all the medical uses authorized under 10 CFR 35.300, "Use of unsealed byproduct material for which a written directive is required."

The NRC is interested in obtaining input from as many stakeholders as possible, including members of the Advisory Committee on the Medical Uses of Isotopes, professional organizations, physicians, patients, patient advocacy groups, licensees, Agreement States, and other interested individuals. The focus of this request is to gather information that will permit the NRC staff to determine whether changes to the T&E requirements are warranted for different categories of radiopharmaceuticals for physicians seeking AU status for the medical use of specific categories of radiopharmaceuticals requiring a written directive under 10 CFR 35.300.

During the comment period between October 29, 2018 and January 29, 2019, the NRC will hold four public meetings that will discuss the information being requested and to accept comments on the docket. All four public meetings

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III. Specific Requests for Comments

A. Tailored Training & Experience Requirements

The NRC is requesting comments on whether it should establish tailored T&E requirements for different categories of radiopharmaceuticals for physicians seeking AU status for the medical use of specific categories of radiopharmaceuticals requiring a written directive under 10 CFR 35.300 (i.e., a limited AU status). This would be for physicians seeking AU status via the alternate non-board certified pathway, and for physicians certified by a medical

specialty board that is not currently recognized by the NRC under 10 CFR 35.390, 35.392, 35.394, or 35.396 (Unsealed Byproduct Material—Written Directive Required).

1. Are the current pathways for obtaining AU status reasonable and accessible? Provide a rationale for your answer.
2. Are the current pathways for obtaining AU status adequate for protecting public health and safety? Provide a rationale for your answer.
3. Should the NRC develop a new tailored T&E pathway for these physicians? If so, what would be the appropriate way to categorize radiopharmaceuticals for tailored T&E requirements? If not, explain why the regulations should remain unchanged. [Some options to categorize radiopharmaceuticals include radiopharmaceuticals with similar delivery methods (oral, parenteral); same type of radiation characteristics or emission (alpha, beta, gamma, low-energy photon); similar preparation method (patient-ready doses); or a combination thereof (e.g., radiopharmaceuticals containing alpha- and beta-emitting radioisotopes that are administered intravenously and are prepared as patient-ready doses).]
4. Should the fundamental T&E required of physicians seeking limited AU status need to have the same fundamental T&E required of physicians seeking full AU status for all oral and parenteral administrations under 10 CFR 35.300?
5. How should the requirements for this fundamental T&E be structured for a specific category of radiopharmaceuticals?
 - a. Describe what the requirements should include:

- i. Classroom and laboratory training – What topics need to be covered in this training requirement? How many hours of classroom and laboratory training should be required? Provide the basis for the number of hours. If not hours, explain how this training should be quantified. [Note: The topics currently required in the regulations to be included in the classroom and laboratory training and work experience are listed in 10 CFR 35.390, 35.392, 35.394, and 35.396.]
 - ii. Work experience - What should the work experience requirement involve? How many hours of work experience should be required and what is the minimum number of patient or human research subject administrations that an individual must perform? Provide the basis for the number of hours and administrations. What should be the qualifications of the supervising individual?
 - iii. Competency - How should competency be evaluated? Should a written and/or practical examination by an independent examining committee be administered? Provide a rationale for your answer.
- b. Should a preceptor attestation be required for the fundamental T&E? Provide a rationale for your answer.
- c. Should the radiopharmaceutical manufacturer be able to provide the preceptor attestation? Provide a rational for your answer.

- d. Who should establish and administer the curriculum and examination? Provide specific group(s). [Some options are: NRC, medical specialty boards, medical professional societies, educational professional groups, and NRC in collaboration with any or more of the aforementioned groups.]
- e. Should AU competency be periodically assessed? If so, how should it be assessed, how often, and by whom?

B. NRC's Recognition of Medical Specialty Boards

The NRC is requesting comments on its recognition of medical specialty boards. The NRC's procedures for recognizing medical specialty boards are located on the Medical Uses Licensee Toolkit Web site (<https://www.nrc.gov/materials/miau/med-use-toolkit/certif-process-boards.html>). The NRC staff periodically reviews information to determine a board's continued eligibility for recognition.

- 1. What boards other than those already recognized by the NRC (American Board of Nuclear Medicine [ABNM], American Board of Radiology [ABR], American Osteopathic Board of Radiology [AOBR], Certification Board of Nuclear Endocrinology [CBNE]) could be considered for recognition for medical uses under 10 CFR 35.300?
- 2. Are the current NRC medical specialty board recognition criteria sufficient? If not, what additional criteria should the NRC use?

C. Patient Access

The NRC is requesting comments on whether there is a shortage in the number of AUs for 10 CFR 35.300.

1. Is there a shortage in the number of AUs for medical uses under 10 CFR 35.300? If so, is the shortage associated with the use of a specific radiopharmaceutical? Explain how.
2. Are there certain geographic areas with an inadequate number of AUs? Identify these areas.
3. Do current NRC regulations on AU T&E requirements unnecessarily limit patient access to procedures involving radiopharmaceuticals? Explain how.
4. Do current NRC regulations on AU T&E requirements unnecessarily limit research and development in nuclear medicine? Explain how.

D. Other Suggested Changes to the T&E Regulations

In 2002, the NRC revised its regulatory framework for medical use. The goal was to focus the NRC's regulations on those medical procedures that pose the highest risk to workers, the general public, patients, and human research subjects and to structure the regulations to be more risk-informed and more performance-based. The 2002 rule reduced the unnecessary regulatory burden by either reducing or eliminating the prescriptiveness of some regulations. Instead, the rule provided for a performance-based approach that relied on the training and experience of the AUs, authorized nuclear pharmacists, and radiation safety officers. The NRC is requesting comments on whether there are any other changes to the T&E regulations in 10 CFR part 35 that should be considered. Please discuss your suggested changes.

1. Should the NRC regulate the T&E of physicians for medical uses?
2. Are there requirements in the NRC's T&E regulatory framework for physicians that are non-safety related?

3. How can the NRC transform its regulatory approach for T&E while still ensuring that adequate protection is maintained for workers, the general public, patients, and human research subjects?

Dated at Rockville, Maryland, this 23rd day of October 2018.

For the Nuclear Regulatory
Commission.

/RA/

Daniel S. Collins, Director,
Division of Materials Safety,
Security,
State, and Tribal Programs,
Office of Nuclear Material Safety
and Safeguards.



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

November 2, 2018

Joint Review Committee on Educational
Programs in Nuclear Medicine Technology
820 W. Danforth Rd., #B1
Edmond, OK 73003

Via e-mail to mail@jrcnmt.org

**SUBJECT: TRAINING AND EXPERIENCE REQUIREMENTS FOR DIFFERENT
CATEGORIES OF RADIOPHARMACEUTICALS**

Dear Sir or Madam,

The U.S. Nuclear Regulatory Commission (NRC) is evaluating its regulations related to the training and experience (T&E) required for a physician to become an authorized user for medical uses under Subpart E, “Unsealed Byproduct Material—Written Directive Required,” of [Title 10 of the Code of Federal Regulations \(10 CFR\) Part 35, “Medical Use of Byproduct Material.”](#)

The T&E requirements in Subpart E of 10 CFR Part 35 provide three ways that a physician can be authorized to administer unsealed byproduct materials or radiopharmaceuticals requiring a written directive:

1. A physician can be certified by a medical specialty board, whose certification process is recognized by the NRC or an Agreement State.
2. A physician can complete a structured educational program and supervised work experience under an alternate pathway. This alternate pathway includes a requirement for 700 hours of training and experience, which consists of a minimum of 200 hours of classroom and laboratory training and 500 hours of supervised work experience.
3. A physician can be authorized if previously identified as an authorized user on an NRC or Agreement State license or permit (i.e., grandfathered).

In its evaluation of the T&E requirements, the NRC staff is considering whether an additional pathway should be created or if the alternate pathway should be revised. Specifically, the staff is evaluating: (1) whether it makes sense to establish tailored T&E requirements for different categories of radiopharmaceuticals; (2) how those categories should be determined; (3) what the appropriate T&E requirements would be for each category; and (4) whether those requirements should be based on hours of training and experience, or focused more on competency.

On October 29, 2018, the NRC published a series of questions on T&E in the *Federal Register* (83 FR 54380). The *Federal Register* notice is enclosed with this letter and can also be accessed at: <https://www.gpo.gov/fdsys/pkg/FR-2018-10-29/pdf/2018-23521.pdf>. The NRC will carefully consider responses to these questions and would appreciate your feedback on whether changes to the current T&E regulations are warranted. The comment period for the T&E evaluation will end on January 29, 2019. Please follow the directions in the notice on how to submit written comments. The NRC is using the Federal rulemaking Web site, [Regulations.gov](#), to accept written comments on the docket (NRC-2018-0230).

The NRC will also conduct four public meetings scheduled for November 14 and December 11, 2018, and January 10 and January 22, 2019, and will accept oral comments provided during the meetings. The meetings on December 11 and January 10 will be held at NRC Headquarters in Rockville, MD, and all four meetings will be accessible for remote participation by moderated bridge line and webinar. The NRC's public meeting page has been updated with meeting details and registration instructions for each meeting: <https://www.nrc.gov/pmns/mtg>.

Additional information on the NRC's T&E evaluation can be found at: <https://www.nrc.gov/materials/miau/med-use-toolkit/training-experience-evaluation.html>. If you have any questions on this correspondence, please contact Sarah Lopas of my staff at (301) 415-6360 or Sarah.Lopas@nrc.gov.

A handwritten signature in black ink, appearing to read "C Einberg".

Christian Einberg, Chief
Medical Safety and Events Assessment Branch
Division of Materials Safety, Security, State
and Tribal Programs
Office of Nuclear Material Safety
and Safeguards

Enclosure:
Training and Experience
Federal Register notice

NUCLEAR REGULATORY COMMISSION

[NRC-2018-0230]

**Training and Experience Requirements for Different Categories of
Radiopharmaceuticals**

AGENCY: Nuclear Regulatory Commission.

ACTION: Training and experience requirements; request for comment.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is requesting comments on its training and experience (T&E) requirements. Specifically, the NRC would like input on whether it should establish tailored T&E requirements for different categories of radiopharmaceuticals for which a written directive is required in accordance with its regulations. The input will be used to determine whether significant regulatory changes to the NRC's T&E requirements for authorized users (AUs) are warranted.

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Dated at Rockville, Maryland, this 23rd day of October 2018.

For the Nuclear Regulatory
Commission.

/RA/

Daniel S. Collins, Director,
Division of Materials Safety,
Security,
State, and Tribal Programs,
Office of Nuclear Material Safety
and Safeguards.



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

November 2, 2018

Dr. Gerald H. Jordan, MD
Executive Secretary, American Board of Urology
600 Peter Jefferson Parkway, Suite 150
Charlottesville, VA 22911

Via e-mail to info@abu.org

SUBJECT: TRAINING AND EXPERIENCE REQUIREMENTS FOR DIFFERENT CATEGORIES OF RADIOPHARMACEUTICALS

Dear Dr. Jordan,

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On October 29, 2018, the NRC published a series of questions on T&E in the *Federal Register* (83 FR 54380). The *Federal Register* notice is enclosed with this letter and can also be accessed at: <https://www.gpo.gov/fdsys/pkg/FR-2018-10-29/pdf/2018-23521.pdf>. The NRC will carefully consider responses to these questions and would appreciate your feedback on whether changes to the current T&E regulations are warranted. The comment period for the T&E evaluation will end on January 29, 2019. Please follow the directions in the notice on how to submit written comments. The NRC is using the Federal rulemaking Web site, [Regulations.gov](#), to accept written comments on the docket (NRC-2018-0230).

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Additional information on the NRC's T&E evaluation can be found at: <https://www.nrc.gov/materials/miau/med-use-toolkit/training-experience-evaluation.html>. If you have any questions on this correspondence, please contact Sarah Lopas of my staff at (301) 415-6360 or Sarah.Lopas@nrc.gov.

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Christian Einberg, 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:
Training and Experience
Federal Register notice

NUCLEAR REGULATORY COMMISSION

[NRC-2018-0230]

**Training and Experience Requirements for Different Categories of
Radiopharmaceuticals**

AGENCY: Nuclear Regulatory Commission.

ACTION: Training and experience requirements; request for comment.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is requesting comments on its training and experience (T&E) requirements. Specifically, the NRC would like input on whether it should establish tailored T&E requirements for different categories of radiopharmaceuticals for which a written directive is required in accordance with its regulations. The input will be used to determine whether significant regulatory changes to the NRC's T&E requirements for authorized users (AUs) are warranted.

DATES: Submit comments by January 29, 2019. Comments received after this date will be considered if it is practical to do so, but the NRC is only able to ensure consideration for comments received on or before this date.

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The NRC is interested in obtaining input from as many stakeholders as possible, including members of the Advisory Committee on the Medical Uses of Isotopes, professional organizations, physicians, patients, patient advocacy groups, licensees, Agreement States, and other interested individuals. The focus of this request is to gather information that will permit the NRC staff to determine whether changes to the T&E requirements are warranted for different categories of radiopharmaceuticals for physicians seeking AU status for the medical use of specific categories of radiopharmaceuticals requiring a written directive under 10 CFR 35.300.

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III. Specific Requests for Comments

A. Tailored Training & Experience Requirements

The NRC is requesting comments on whether it should establish tailored T&E requirements for different categories of radiopharmaceuticals for physicians seeking AU status for the medical use of specific categories of radiopharmaceuticals requiring a written directive under 10 CFR 35.300 (i.e., a limited AU status). This would be for physicians seeking AU status via the alternate non-board certified pathway, and for physicians certified by a medical

specialty board that is not currently recognized by the NRC under 10 CFR 35.390, 35.392, 35.394, or 35.396 (Unsealed Byproduct Material—Written Directive Required).

1. Are the current pathways for obtaining AU status reasonable and accessible? Provide a rationale for your answer.
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3. Should the NRC develop a new tailored T&E pathway for these physicians? If so, what would be the appropriate way to categorize radiopharmaceuticals for tailored T&E requirements? If not, explain why the regulations should remain unchanged. [Some options to categorize radiopharmaceuticals include radiopharmaceuticals with similar delivery methods (oral, parenteral); same type of radiation characteristics or emission (alpha, beta, gamma, low-energy photon); similar preparation method (patient-ready doses); or a combination thereof (e.g., radiopharmaceuticals containing alpha- and beta-emitting radioisotopes that are administered intravenously and are prepared as patient-ready doses).]
4. Should the fundamental T&E required of physicians seeking limited AU status need to have the same fundamental T&E required of physicians seeking full AU status for all oral and parenteral administrations under 10 CFR 35.300?
5. How should the requirements for this fundamental T&E be structured for a specific category of radiopharmaceuticals?
 - a. Describe what the requirements should include:

- i. Classroom and laboratory training – What topics need to be covered in this training requirement? How many hours of classroom and laboratory training should be required? Provide the basis for the number of hours. If not hours, explain how this training should be quantified. [Note: The topics currently required in the regulations to be included in the classroom and laboratory training and work experience are listed in 10 CFR 35.390, 35.392, 35.394, and 35.396.]
 - ii. Work experience - What should the work experience requirement involve? How many hours of work experience should be required and what is the minimum number of patient or human research subject administrations that an individual must perform? Provide the basis for the number of hours and administrations. What should be the qualifications of the supervising individual?
 - iii. Competency - How should competency be evaluated? Should a written and/or practical examination by an independent examining committee be administered? Provide a rationale for your answer.
- b. Should a preceptor attestation be required for the fundamental T&E? Provide a rationale for your answer.
- c. Should the radiopharmaceutical manufacturer be able to provide the preceptor attestation? Provide a rational for your answer.

- d. Who should establish and administer the curriculum and examination? Provide specific group(s). [Some options are: NRC, medical specialty boards, medical professional societies, educational professional groups, and NRC in collaboration with any or more of the aforementioned groups.]
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The NRC is requesting comments on its recognition of medical specialty boards. The NRC's procedures for recognizing medical specialty boards are located on the Medical Uses Licensee Toolkit Web site (<https://www.nrc.gov/materials/miau/med-use-toolkit/certif-process-boards.html>). The NRC staff periodically reviews information to determine a board's continued eligibility for recognition.

- 1. What boards other than those already recognized by the NRC (American Board of Nuclear Medicine [ABNM], American Board of Radiology [ABR], American Osteopathic Board of Radiology [AOBR], Certification Board of Nuclear Endocrinology [CBNE]) could be considered for recognition for medical uses under 10 CFR 35.300?
- 2. Are the current NRC medical specialty board recognition criteria sufficient? If not, what additional criteria should the NRC use?

C. Patient Access

The NRC is requesting comments on whether there is a shortage in the number of AUs for 10 CFR 35.300.

1. Is there a shortage in the number of AUs for medical uses under 10 CFR 35.300? If so, is the shortage associated with the use of a specific radiopharmaceutical? Explain how.
2. Are there certain geographic areas with an inadequate number of AUs? Identify these areas.
3. Do current NRC regulations on AU T&E requirements unnecessarily limit patient access to procedures involving radiopharmaceuticals? Explain how.
4. Do current NRC regulations on AU T&E requirements unnecessarily limit research and development in nuclear medicine? Explain how.

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In 2002, the NRC revised its regulatory framework for medical use. The goal was to focus the NRC's regulations on those medical procedures that pose the highest risk to workers, the general public, patients, and human research subjects and to structure the regulations to be more risk-informed and more performance-based. The 2002 rule reduced the unnecessary regulatory burden by either reducing or eliminating the prescriptiveness of some regulations. Instead, the rule provided for a performance-based approach that relied on the training and experience of the AUs, authorized nuclear pharmacists, and radiation safety officers. The NRC is requesting comments on whether there are any other changes to the T&E regulations in 10 CFR part 35 that should be considered. Please discuss your suggested changes.

1. Should the NRC regulate the T&E of physicians for medical uses?
2. Are there requirements in the NRC's T&E regulatory framework for physicians that are non-safety related?

3. How can the NRC transform its regulatory approach for T&E while still ensuring that adequate protection is maintained for workers, the general public, patients, and human research subjects?

Dated at Rockville, Maryland, this 23rd day of October 2018.

For the Nuclear Regulatory
Commission.

/RA/

Daniel S. Collins, Director,
Division of Materials Safety,
Security,
State, and Tribal Programs,
Office of Nuclear Material Safety
and Safeguards.



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

November 2, 2018

Ms. Kathleen Cantwell
Director, Office of Strategic Operations
and Regulatory Affairs
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Via e-mail to Kathleen.Cantwell@cms.hhs.gov

SUBJECT: TRAINING AND EXPERIENCE REQUIREMENTS FOR DIFFERENT CATEGORIES OF RADIOPHARMACEUTICALS

Dear Ms. Cantwell,

The U.S. Nuclear Regulatory Commission (NRC) is evaluating its regulations related to the training and experience (T&E) required for a physician to become an authorized user for medical uses under Subpart E, “Unsealed Byproduct Material—Written Directive Required,” of [Title 10 of the Code of Federal Regulations \(10 CFR\) Part 35, “Medical Use of Byproduct Material.”](#)

The T&E requirements in Subpart E of 10 CFR Part 35 provide three ways that a physician can be authorized to administer unsealed byproduct materials or radiopharmaceuticals requiring a written directive:

1. A physician can be certified by a medical specialty board, whose certification process is recognized by the NRC or an Agreement State.
2. A physician can complete a structured educational program and supervised work experience under an alternate pathway. This alternate pathway includes a requirement for 700 hours of training and experience, which consists of a minimum of 200 hours of classroom and laboratory training and 500 hours of supervised work experience.
3. A physician can be authorized if previously identified as an authorized user on an NRC or Agreement State license or permit (i.e., grandfathered).

In its evaluation of the T&E requirements, the NRC staff is considering whether an additional pathway should be created or if the alternate pathway should be revised. Specifically, the staff is evaluating: (1) whether it makes sense to establish tailored T&E requirements for different categories of radiopharmaceuticals; (2) how those categories should be determined; (3) what the appropriate T&E requirements would be for each category; and (4) whether those requirements should be based on hours of training and experience, or focused more on competency.

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Christian Einberg, Chief
Medical Safety and Events Assessment Branch
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Enclosure:
Training and Experience
Federal Register notice

NUCLEAR REGULATORY COMMISSION

[NRC-2018-0230]

**Training and Experience Requirements for Different Categories of
Radiopharmaceuticals**

AGENCY: Nuclear Regulatory Commission.

ACTION: Training and experience requirements; request for comment.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is requesting comments on its training and experience (T&E) requirements. Specifically, the NRC would like input on whether it should establish tailored T&E requirements for different categories of radiopharmaceuticals for which a written directive is required in accordance with its regulations. The input will be used to determine whether significant regulatory changes to the NRC's T&E requirements for authorized users (AUs) are warranted.

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2. Are there requirements in the NRC's T&E regulatory framework for physicians that are non-safety related?

3. How can the NRC transform its regulatory approach for T&E while still ensuring that adequate protection is maintained for workers, the general public, patients, and human research subjects?

Dated at Rockville, Maryland, this 23rd day of October 2018.

For the Nuclear Regulatory
Commission.

/RA/

Daniel S. Collins, Director,
Division of Materials Safety,
Security,
State, and Tribal Programs,
Office of Nuclear Material Safety
and Safeguards.



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

November 2, 2018

Kidney Cancer Association
9450 SW Gemini Dr. #38269
Beaverton, OR 97008-7105

Via e-mail to office@kidneycancer.org

SUBJECT: TRAINING AND EXPERIENCE REQUIREMENTS FOR DIFFERENT CATEGORIES OF RADIOPHARMACEUTICALS

Dear Sir or Madam,

The U.S. Nuclear Regulatory Commission (NRC) is evaluating its regulations related to the training and experience (T&E) required for a physician to become an authorized user for medical uses under Subpart E, “Unsealed Byproduct Material—Written Directive Required,” of [Title 10 of the Code of Federal Regulations \(10 CFR\) Part 35, “Medical Use of Byproduct Material.”](#)

The T&E requirements in Subpart E of 10 CFR Part 35 provide three ways that a physician can be authorized to administer unsealed byproduct materials or radiopharmaceuticals requiring a written directive:

1. A physician can be certified by a medical specialty board, whose certification process is recognized by the NRC or an Agreement State.
2. A physician can complete a structured educational program and supervised work experience under an alternate pathway. This alternate pathway includes a requirement for 700 hours of training and experience, which consists of a minimum of 200 hours of classroom and laboratory training and 500 hours of supervised work experience.
3. A physician can be authorized if previously identified as an authorized user on an NRC or Agreement State license or permit (i.e., grandfathered).

In its evaluation of the T&E requirements, the NRC staff is considering whether an additional pathway should be created or if the alternate pathway should be revised. Specifically, the staff is evaluating: (1) whether it makes sense to establish tailored T&E requirements for different categories of radiopharmaceuticals; (2) how those categories should be determined; (3) what the appropriate T&E requirements would be for each category; and (4) whether those requirements should be based on hours of training and experience, or focused more on competency.

On October 29, 2018, the NRC published a series of questions on T&E in the *Federal Register* (83 FR 54380). The *Federal Register* notice is enclosed with this letter and can also be accessed at: <https://www.gpo.gov/fdsys/pkg/FR-2018-10-29/pdf/2018-23521.pdf>. The NRC will carefully consider responses to these questions and would appreciate your feedback on whether changes to the current T&E regulations are warranted. The comment period for the T&E evaluation will end on January 29, 2019. Please follow the directions in the notice on how to submit written comments. The NRC is using the Federal rulemaking Web site, [Regulations.gov](#), to accept written comments on the docket (NRC-2018-0230).

The NRC will also conduct four public meetings scheduled for November 14 and December 11, 2018, and January 10 and January 22, 2019, and will accept oral comments provided during the meetings. The meetings on December 11 and January 10 will be held at NRC Headquarters in Rockville, MD, and all four meetings will be accessible for remote participation by moderated bridge line and webinar. The NRC's public meeting page has been updated with meeting details and registration instructions for each meeting: <https://www.nrc.gov/pmns/mtg>.

Additional information on the NRC's T&E evaluation can be found at: <https://www.nrc.gov/materials/miau/med-use-toolkit/training-experience-evaluation.html>. If you have any questions on this correspondence, please contact Sarah Lopas of my staff at (301) 415-6360 or Sarah.Lopas@nrc.gov.

A handwritten signature in black ink, appearing to read "C Einberg".

Christian Einberg, Chief
Medical Safety and Events Assessment Branch
Division of Materials Safety, Security, State
and Tribal Programs
Office of Nuclear Material Safety
and Safeguards

Enclosure:
Training and Experience
Federal Register notice

NUCLEAR REGULATORY COMMISSION

[NRC-2018-0230]

**Training and Experience Requirements for Different Categories of
Radiopharmaceuticals**

AGENCY: Nuclear Regulatory Commission.

ACTION: Training and experience requirements; request for comment.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is requesting comments on its training and experience (T&E) requirements. Specifically, the NRC would like input on whether it should establish tailored T&E requirements for different categories of radiopharmaceuticals for which a written directive is required in accordance with its regulations. The input will be used to determine whether significant regulatory changes to the NRC's T&E requirements for authorized users (AUs) are warranted.

DATES: Submit comments by January 29, 2019. Comments received after this date will be considered if it is practical to do so, but the NRC is only able to ensure consideration for comments received on or before this date.

ADDRESSES: You may submit comments by any of the following methods:

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FOR FURTHER INFORMATION CONTACT: Sarah Lopas, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001; telephone: 301-415-6360, e-mail: Sarah.Lopas@nrc.gov.

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B. Submitting Comments

Please include Docket ID **NRC-2018-0230** in your comment submission.

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radionuclides or by delivery method), (3) what the appropriate T&E requirements would be for each category, and (4) whether those requirements should be based on hours of T&E or focused more on competency. In response to the SRM, the NRC staff documented its initial results, status, and next steps related to this evaluation in SECY-18-0084, "Staff Evaluation of Training and Experience Requirements for Administering Different Categories of Radiopharmaceuticals in Response to SRM-M170817" (ADAMS Accession No. ML18135A276). In SECY-18-0084, the staff concluded that additional outreach with the medical community is needed to determine whether and how to tailor the T&E requirements to establish a limited AU status, the specific T&E requirements that should apply, how the T&E requirements should be met (e.g., hours of training, demonstration of competency), and whether a competency-based approach makes sense for the T&E requirements for all the medical uses authorized under 10 CFR 35.300, "Use of unsealed byproduct material for which a written directive is required."

The NRC is interested in obtaining input from as many stakeholders as possible, including members of the Advisory Committee on the Medical Uses of Isotopes, professional organizations, physicians, patients, patient advocacy groups, licensees, Agreement States, and other interested individuals. The focus of this request is to gather information that will permit the NRC staff to determine whether changes to the T&E requirements are warranted for different categories of radiopharmaceuticals for physicians seeking AU status for the medical use of specific categories of radiopharmaceuticals requiring a written directive under 10 CFR 35.300.

During the comment period between October 29, 2018 and January 29, 2019, the NRC will hold four public meetings that will discuss the information being requested and to accept comments on the docket. All four public meetings

will be available for remote participation by moderated bridge line and webinar, and two of the four meetings will be open for in-person attendance at NRC's headquarters in Rockville, Maryland.

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III. Specific Requests for Comments

A. Tailored Training & Experience Requirements

The NRC is requesting comments on whether it should establish tailored T&E requirements for different categories of radiopharmaceuticals for physicians seeking AU status for the medical use of specific categories of radiopharmaceuticals requiring a written directive under 10 CFR 35.300 (i.e., a limited AU status). This would be for physicians seeking AU status via the alternate non-board certified pathway, and for physicians certified by a medical

specialty board that is not currently recognized by the NRC under 10 CFR 35.390, 35.392, 35.394, or 35.396 (Unsealed Byproduct Material—Written Directive Required).

1. Are the current pathways for obtaining AU status reasonable and accessible? Provide a rationale for your answer.
2. Are the current pathways for obtaining AU status adequate for protecting public health and safety? Provide a rationale for your answer.
3. Should the NRC develop a new tailored T&E pathway for these physicians? If so, what would be the appropriate way to categorize radiopharmaceuticals for tailored T&E requirements? If not, explain why the regulations should remain unchanged. [Some options to categorize radiopharmaceuticals include radiopharmaceuticals with similar delivery methods (oral, parenteral); same type of radiation characteristics or emission (alpha, beta, gamma, low-energy photon); similar preparation method (patient-ready doses); or a combination thereof (e.g., radiopharmaceuticals containing alpha- and beta-emitting radioisotopes that are administered intravenously and are prepared as patient-ready doses).]
4. Should the fundamental T&E required of physicians seeking limited AU status need to have the same fundamental T&E required of physicians seeking full AU status for all oral and parenteral administrations under 10 CFR 35.300?
5. How should the requirements for this fundamental T&E be structured for a specific category of radiopharmaceuticals?
 - a. Describe what the requirements should include:

- i. Classroom and laboratory training – What topics need to be covered in this training requirement? How many hours of classroom and laboratory training should be required? Provide the basis for the number of hours. If not hours, explain how this training should be quantified. [Note: The topics currently required in the regulations to be included in the classroom and laboratory training and work experience are listed in 10 CFR 35.390, 35.392, 35.394, and 35.396.]
 - ii. Work experience - What should the work experience requirement involve? How many hours of work experience should be required and what is the minimum number of patient or human research subject administrations that an individual must perform? Provide the basis for the number of hours and administrations. What should be the qualifications of the supervising individual?
 - iii. Competency - How should competency be evaluated? Should a written and/or practical examination by an independent examining committee be administered? Provide a rationale for your answer.
- b. Should a preceptor attestation be required for the fundamental T&E? Provide a rationale for your answer.
- c. Should the radiopharmaceutical manufacturer be able to provide the preceptor attestation? Provide a rational for your answer.

- d. Who should establish and administer the curriculum and examination? Provide specific group(s). [Some options are: NRC, medical specialty boards, medical professional societies, educational professional groups, and NRC in collaboration with any or more of the aforementioned groups.]
- e. Should AU competency be periodically assessed? If so, how should it be assessed, how often, and by whom?

B. NRC's Recognition of Medical Specialty Boards

The NRC is requesting comments on its recognition of medical specialty boards. The NRC's procedures for recognizing medical specialty boards are located on the Medical Uses Licensee Toolkit Web site (<https://www.nrc.gov/materials/miau/med-use-toolkit/certif-process-boards.html>). The NRC staff periodically reviews information to determine a board's continued eligibility for recognition.

- 1. What boards other than those already recognized by the NRC (American Board of Nuclear Medicine [ABNM], American Board of Radiology [ABR], American Osteopathic Board of Radiology [AOBR], Certification Board of Nuclear Endocrinology [CBNE]) could be considered for recognition for medical uses under 10 CFR 35.300?
- 2. Are the current NRC medical specialty board recognition criteria sufficient? If not, what additional criteria should the NRC use?

C. Patient Access

The NRC is requesting comments on whether there is a shortage in the number of AUs for 10 CFR 35.300.

1. Is there a shortage in the number of AUs for medical uses under 10 CFR 35.300? If so, is the shortage associated with the use of a specific radiopharmaceutical? Explain how.
2. Are there certain geographic areas with an inadequate number of AUs? Identify these areas.
3. Do current NRC regulations on AU T&E requirements unnecessarily limit patient access to procedures involving radiopharmaceuticals? Explain how.
4. Do current NRC regulations on AU T&E requirements unnecessarily limit research and development in nuclear medicine? Explain how.

D. Other Suggested Changes to the T&E Regulations

In 2002, the NRC revised its regulatory framework for medical use. The goal was to focus the NRC's regulations on those medical procedures that pose the highest risk to workers, the general public, patients, and human research subjects and to structure the regulations to be more risk-informed and more performance-based. The 2002 rule reduced the unnecessary regulatory burden by either reducing or eliminating the prescriptiveness of some regulations. Instead, the rule provided for a performance-based approach that relied on the training and experience of the AUs, authorized nuclear pharmacists, and radiation safety officers. The NRC is requesting comments on whether there are any other changes to the T&E regulations in 10 CFR part 35 that should be considered. Please discuss your suggested changes.

1. Should the NRC regulate the T&E of physicians for medical uses?
2. Are there requirements in the NRC's T&E regulatory framework for physicians that are non-safety related?

3. How can the NRC transform its regulatory approach for T&E while still ensuring that adequate protection is maintained for workers, the general public, patients, and human research subjects?

Dated at Rockville, Maryland, this 23rd day of October 2018.

For the Nuclear Regulatory
Commission.

/RA/

Daniel S. Collins, Director,
Division of Materials Safety,
Security,
State, and Tribal Programs,
Office of Nuclear Material Safety
and Safeguards.



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

November 2, 2018

Dr. Richard M. Kliman
Cedar Crest College, Chair, Department of Biological Sciences
c/o Nuclear Medicine Technology
100 College Drive
Allentown, PA 18104

Via e-mail to rmkliman@cedarcrest.edu

SUBJECT: TRAINING AND EXPERIENCE REQUIREMENTS FOR DIFFERENT CATEGORIES OF RADIOPHARMACEUTICALS

Dear Dr. Kliman,

The U.S. Nuclear Regulatory Commission (NRC) is evaluating its regulations related to the training and experience (T&E) required for a physician to become an authorized user for medical uses under Subpart E, “Unsealed Byproduct Material—Written Directive Required,” of [Title 10 of the Code of Federal Regulations \(10 CFR\) Part 35, “Medical Use of Byproduct Material.”](#)

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In its evaluation of the T&E requirements, the NRC staff is considering whether an additional pathway should be created or if the alternate pathway should be revised. Specifically, the staff is evaluating: (1) whether it makes sense to establish tailored T&E requirements for different categories of radiopharmaceuticals; (2) how those categories should be determined; (3) what the appropriate T&E requirements would be for each category; and (4) whether those requirements should be based on hours of training and experience, or focused more on competency.

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Christian Einberg, Chief
Medical Safety and Events Assessment Branch
Division of Materials Safety, Security, State
and Tribal Programs
Office of Nuclear Material Safety
and Safeguards

Enclosure:
Training and Experience
Federal Register notice

NUCLEAR REGULATORY COMMISSION

[NRC-2018-0230]

**Training and Experience Requirements for Different Categories of
Radiopharmaceuticals**

AGENCY: Nuclear Regulatory Commission.

ACTION: Training and experience requirements; request for comment.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is requesting comments on its training and experience (T&E) requirements. Specifically, the NRC would like input on whether it should establish tailored T&E requirements for different categories of radiopharmaceuticals for which a written directive is required in accordance with its regulations. The input will be used to determine whether significant regulatory changes to the NRC's T&E requirements for authorized users (AUs) are warranted.

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- b. Should a preceptor attestation be required for the fundamental T&E? Provide a rationale for your answer.
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- d. Who should establish and administer the curriculum and examination? Provide specific group(s). [Some options are: NRC, medical specialty boards, medical professional societies, educational professional groups, and NRC in collaboration with any or more of the aforementioned groups.]
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B. NRC's Recognition of Medical Specialty Boards

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- 1. What boards other than those already recognized by the NRC (American Board of Nuclear Medicine [ABNM], American Board of Radiology [ABR], American Osteopathic Board of Radiology [AOBR], Certification Board of Nuclear Endocrinology [CBNE]) could be considered for recognition for medical uses under 10 CFR 35.300?
- 2. Are the current NRC medical specialty board recognition criteria sufficient? If not, what additional criteria should the NRC use?

C. Patient Access

The NRC is requesting comments on whether there is a shortage in the number of AUs for 10 CFR 35.300.

1. Is there a shortage in the number of AUs for medical uses under 10 CFR 35.300? If so, is the shortage associated with the use of a specific radiopharmaceutical? Explain how.
2. Are there certain geographic areas with an inadequate number of AUs? Identify these areas.
3. Do current NRC regulations on AU T&E requirements unnecessarily limit patient access to procedures involving radiopharmaceuticals? Explain how.
4. Do current NRC regulations on AU T&E requirements unnecessarily limit research and development in nuclear medicine? Explain how.

D. Other Suggested Changes to the T&E Regulations

In 2002, the NRC revised its regulatory framework for medical use. The goal was to focus the NRC's regulations on those medical procedures that pose the highest risk to workers, the general public, patients, and human research subjects and to structure the regulations to be more risk-informed and more performance-based. The 2002 rule reduced the unnecessary regulatory burden by either reducing or eliminating the prescriptiveness of some regulations. Instead, the rule provided for a performance-based approach that relied on the training and experience of the AUs, authorized nuclear pharmacists, and radiation safety officers. The NRC is requesting comments on whether there are any other changes to the T&E regulations in 10 CFR part 35 that should be considered. Please discuss your suggested changes.

1. Should the NRC regulate the T&E of physicians for medical uses?
2. Are there requirements in the NRC's T&E regulatory framework for physicians that are non-safety related?

3. How can the NRC transform its regulatory approach for T&E while still ensuring that adequate protection is maintained for workers, the general public, patients, and human research subjects?

Dated at Rockville, Maryland, this 23rd day of October 2018.

For the Nuclear Regulatory
Commission.

/RA/

Daniel S. Collins, Director,
Division of Materials Safety,
Security,
State, and Tribal Programs,
Office of Nuclear Material Safety
and Safeguards.



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

November 2, 2018

Ms. Caitlin B. Kubler, MS
Associate Director, Health Policy
and Regulatory Affairs
Society of Nuclear Medicine and Molecular Imaging
1850 Samuel Morse Drive
Reston, VA 20190

Via e-mail to ckubler@snmmi.org

SUBJECT: TRAINING AND EXPERIENCE REQUIREMENTS FOR DIFFERENT CATEGORIES OF RADIOPHARMACEUTICALS

Dear Ms. Kubler,

The U.S. Nuclear Regulatory Commission (NRC) is evaluating its regulations related to the training and experience (T&E) required for a physician to become an authorized user for medical uses under Subpart E, “Unsealed Byproduct Material—Written Directive Required,” of [Title 10 of the Code of Federal Regulations \(10 CFR\) Part 35, “Medical Use of Byproduct Material.”](#)

The T&E requirements in Subpart E of 10 CFR Part 35 provide three ways that a physician can be authorized to administer unsealed byproduct materials or radiopharmaceuticals requiring a written directive:

1. A physician can be certified by a medical specialty board, whose certification process is recognized by the NRC or an Agreement State.
2. A physician can complete a structured educational program and supervised work experience under an alternate pathway. This alternate pathway includes a requirement for 700 hours of training and experience, which consists of a minimum of 200 hours of classroom and laboratory training and 500 hours of supervised work experience.
3. A physician can be authorized if previously identified as an authorized user on an NRC or Agreement State license or permit (i.e., grandfathered).

In its evaluation of the T&E requirements, the NRC staff is considering whether an additional pathway should be created or if the alternate pathway should be revised. Specifically, the staff is evaluating: (1) whether it makes sense to establish tailored T&E requirements for different categories of radiopharmaceuticals; (2) how those categories should be determined; (3) what the appropriate T&E requirements would be for each category; and (4) whether those requirements should be based on hours of training and experience, or focused more on competency.

On October 29, 2018, the NRC published a series of questions on T&E in the *Federal Register* (83 FR 54380). The *Federal Register* notice is enclosed with this letter and can also be accessed at: <https://www.gpo.gov/fdsys/pkg/FR-2018-10-29/pdf/2018-23521.pdf>. The NRC will carefully consider responses to these questions and would appreciate your feedback on whether changes to the current T&E regulations are warranted. The comment period for the T&E evaluation will end on January 29, 2019. Please follow the directions in the notice on how to submit written comments. The NRC is using the Federal rulemaking Web site, [Regulations.gov](#), to accept written comments on the docket (NRC-2018-0230).

The NRC will also conduct four public meetings scheduled for November 14 and December 11, 2018, and January 10 and January 22, 2019, and will accept oral comments provided during the meetings. The meetings on December 11 and January 10 will be held at NRC Headquarters in Rockville, MD, and all four meetings will be accessible for remote participation by moderated bridge line and webinar. The NRC's public meeting page has been updated with meeting details and registration instructions for each meeting: <https://www.nrc.gov/pmns/mtg>.

Additional information on the NRC's T&E evaluation can be found at: <https://www.nrc.gov/materials/miau/med-use-toolkit/training-experience-evaluation.html>. If you have any questions on this correspondence, please contact Sarah Lopas of my staff at (301) 415-6360 or Sarah.Lopas@nrc.gov.

A handwritten signature in black ink, appearing to read "C. Einberg".

Christian Einberg, Chief
Medical Safety and Events Assessment Branch
Division of Materials Safety, Security, State
and Tribal Programs
Office of Nuclear Material Safety
and Safeguards

Enclosure:
Training and Experience
Federal Register notice

NUCLEAR REGULATORY COMMISSION

[NRC-2018-0230]

**Training and Experience Requirements for Different Categories of
Radiopharmaceuticals**

AGENCY: Nuclear Regulatory Commission.

ACTION: Training and experience requirements; request for comment.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is requesting comments on its training and experience (T&E) requirements. Specifically, the NRC would like input on whether it should establish tailored T&E requirements for different categories of radiopharmaceuticals for which a written directive is required in accordance with its regulations. The input will be used to determine whether significant regulatory changes to the NRC's T&E requirements for authorized users (AUs) are warranted.

DATES: Submit comments by January 29, 2019. Comments received after this date will be considered if it is practical to do so, but the NRC is only able to ensure consideration for comments received on or before this date.

ADDRESSES: You may submit comments by any of the following methods:

- **Federal Rulemaking Web Site:** Go to <http://www.regulations.gov>

and search for Docket ID **NRC-2018-0230**. Address questions about Docket IDs in Regulations.gov to Jennifer Borges; telephone: 301-287-9127; e-mail: Jennifer.Borges@nrc.gov. For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.

- **Mail comments to:** May Ma, Office of Administration, Mail Stop: TWFN-7-A60M, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001.

For additional direction on obtaining information and submitting comments, see “Obtaining Information and Submitting Comments” in the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: Sarah Lopas, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001; telephone: 301-415-6360, e-mail: Sarah.Lopas@nrc.gov.

SUPPLEMENTARY INFORMATION:

I. Obtaining Information and Submitting Comments

A. Obtaining Information

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B. Submitting Comments

Please include Docket ID **NRC-2018-0230** in your comment submission.

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II. Background

On August 17, 2017, the Commission issued a staff requirements memorandum (SRM), SRM-M170817 (ADAMS Accession No. ML17229B284), approving the final rule revising parts 30, 32, and 35 of title 10 of the *Code of Federal Regulations* (10 CFR), "Medical Use of Byproduct Material – Medical Event Definitions, Training and Experience, and Clarifying Amendments," and directing the staff to evaluate (1) whether it makes sense to establish tailored T&E requirements for different categories of radiopharmaceuticals, (2) how those categories should be determined (such as by risks posed by groups of

radionuclides or by delivery method), (3) what the appropriate T&E requirements would be for each category, and (4) whether those requirements should be based on hours of T&E or focused more on competency. In response to the SRM, the NRC staff documented its initial results, status, and next steps related to this evaluation in SECY-18-0084, "Staff Evaluation of Training and Experience Requirements for Administering Different Categories of Radiopharmaceuticals in Response to SRM-M170817" (ADAMS Accession No. ML18135A276). In SECY-18-0084, the staff concluded that additional outreach with the medical community is needed to determine whether and how to tailor the T&E requirements to establish a limited AU status, the specific T&E requirements that should apply, how the T&E requirements should be met (e.g., hours of training, demonstration of competency), and whether a competency-based approach makes sense for the T&E requirements for all the medical uses authorized under 10 CFR 35.300, "Use of unsealed byproduct material for which a written directive is required."

The NRC is interested in obtaining input from as many stakeholders as possible, including members of the Advisory Committee on the Medical Uses of Isotopes, professional organizations, physicians, patients, patient advocacy groups, licensees, Agreement States, and other interested individuals. The focus of this request is to gather information that will permit the NRC staff to determine whether changes to the T&E requirements are warranted for different categories of radiopharmaceuticals for physicians seeking AU status for the medical use of specific categories of radiopharmaceuticals requiring a written directive under 10 CFR 35.300.

During the comment period between October 29, 2018 and January 29, 2019, the NRC will hold four public meetings that will discuss the information being requested and to accept comments on the docket. All four public meetings

will be available for remote participation by moderated bridge line and webinar, and two of the four meetings will be open for in-person attendance at NRC's headquarters in Rockville, Maryland.

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The NRC may post additional materials related to this document, including public comments, on the Federal Rulemaking Web site. The Federal Rulemaking Web site allows you to receive alerts when changes or additions occur in a docket folder. To subscribe: (1) Navigate to the docket folder **NRC-2018-0230**; (2) click the “Sign up for E-mail Alerts” link; and (3) enter your email address and select how frequently you would like to receive emails (daily, weekly, or monthly).

III. Specific Requests for Comments

A. Tailored Training & Experience Requirements

The NRC is requesting comments on whether it should establish tailored T&E requirements for different categories of radiopharmaceuticals for physicians seeking AU status for the medical use of specific categories of radiopharmaceuticals requiring a written directive under 10 CFR 35.300 (i.e., a limited AU status). This would be for physicians seeking AU status via the alternate non-board certified pathway, and for physicians certified by a medical

specialty board that is not currently recognized by the NRC under 10 CFR 35.390, 35.392, 35.394, or 35.396 (Unsealed Byproduct Material—Written Directive Required).

1. Are the current pathways for obtaining AU status reasonable and accessible? Provide a rationale for your answer.
2. Are the current pathways for obtaining AU status adequate for protecting public health and safety? Provide a rationale for your answer.
3. Should the NRC develop a new tailored T&E pathway for these physicians? If so, what would be the appropriate way to categorize radiopharmaceuticals for tailored T&E requirements? If not, explain why the regulations should remain unchanged. [Some options to categorize radiopharmaceuticals include radiopharmaceuticals with similar delivery methods (oral, parenteral); same type of radiation characteristics or emission (alpha, beta, gamma, low-energy photon); similar preparation method (patient-ready doses); or a combination thereof (e.g., radiopharmaceuticals containing alpha- and beta-emitting radioisotopes that are administered intravenously and are prepared as patient-ready doses).]
4. Should the fundamental T&E required of physicians seeking limited AU status need to have the same fundamental T&E required of physicians seeking full AU status for all oral and parenteral administrations under 10 CFR 35.300?
5. How should the requirements for this fundamental T&E be structured for a specific category of radiopharmaceuticals?
 - a. Describe what the requirements should include:

- i. Classroom and laboratory training – What topics need to be covered in this training requirement? How many hours of classroom and laboratory training should be required? Provide the basis for the number of hours. If not hours, explain how this training should be quantified. [Note: The topics currently required in the regulations to be included in the classroom and laboratory training and work experience are listed in 10 CFR 35.390, 35.392, 35.394, and 35.396.]
 - ii. Work experience - What should the work experience requirement involve? How many hours of work experience should be required and what is the minimum number of patient or human research subject administrations that an individual must perform? Provide the basis for the number of hours and administrations. What should be the qualifications of the supervising individual?
 - iii. Competency - How should competency be evaluated? Should a written and/or practical examination by an independent examining committee be administered? Provide a rationale for your answer.
- b. Should a preceptor attestation be required for the fundamental T&E? Provide a rationale for your answer.
- c. Should the radiopharmaceutical manufacturer be able to provide the preceptor attestation? Provide a rational for your answer.

- d. Who should establish and administer the curriculum and examination? Provide specific group(s). [Some options are: NRC, medical specialty boards, medical professional societies, educational professional groups, and NRC in collaboration with any or more of the aforementioned groups.]
- e. Should AU competency be periodically assessed? If so, how should it be assessed, how often, and by whom?

B. NRC's Recognition of Medical Specialty Boards

The NRC is requesting comments on its recognition of medical specialty boards. The NRC's procedures for recognizing medical specialty boards are located on the Medical Uses Licensee Toolkit Web site (<https://www.nrc.gov/materials/miau/med-use-toolkit/certif-process-boards.html>). The NRC staff periodically reviews information to determine a board's continued eligibility for recognition.

- 1. What boards other than those already recognized by the NRC (American Board of Nuclear Medicine [ABNM], American Board of Radiology [ABR], American Osteopathic Board of Radiology [AOBR], Certification Board of Nuclear Endocrinology [CBNE]) could be considered for recognition for medical uses under 10 CFR 35.300?
- 2. Are the current NRC medical specialty board recognition criteria sufficient? If not, what additional criteria should the NRC use?

C. Patient Access

The NRC is requesting comments on whether there is a shortage in the number of AUs for 10 CFR 35.300.

1. Is there a shortage in the number of AUs for medical uses under 10 CFR 35.300? If so, is the shortage associated with the use of a specific radiopharmaceutical? Explain how.
2. Are there certain geographic areas with an inadequate number of AUs? Identify these areas.
3. Do current NRC regulations on AU T&E requirements unnecessarily limit patient access to procedures involving radiopharmaceuticals? Explain how.
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D. Other Suggested Changes to the T&E Regulations

In 2002, the NRC revised its regulatory framework for medical use. The goal was to focus the NRC's regulations on those medical procedures that pose the highest risk to workers, the general public, patients, and human research subjects and to structure the regulations to be more risk-informed and more performance-based. The 2002 rule reduced the unnecessary regulatory burden by either reducing or eliminating the prescriptiveness of some regulations. Instead, the rule provided for a performance-based approach that relied on the training and experience of the AUs, authorized nuclear pharmacists, and radiation safety officers. The NRC is requesting comments on whether there are any other changes to the T&E regulations in 10 CFR part 35 that should be considered. Please discuss your suggested changes.

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Dated at Rockville, Maryland, this 23rd day of October 2018.

For the Nuclear Regulatory
Commission.

/RA/

Daniel S. Collins, Director,
Division of Materials Safety,
Security,
State, and Tribal Programs,
Office of Nuclear Material Safety
and Safeguards.



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

November 2, 2018

Dr. Cheryl Heaton
Board Chair
Lung Cancer Alliance
1700 K St. NW, Suite 660
Washington, DC 20006

Via e-mail to info@lungcanceralliance.org

SUBJECT: TRAINING AND EXPERIENCE REQUIREMENTS FOR DIFFERENT CATEGORIES OF RADIOPHARMACEUTICALS

Dear Dr. Heaton,

The U.S. Nuclear Regulatory Commission (NRC) is evaluating its regulations related to the training and experience (T&E) required for a physician to become an authorized user for medical uses under Subpart E, “Unsealed Byproduct Material—Written Directive Required,” of [Title 10 of the Code of Federal Regulations \(10 CFR\) Part 35, “Medical Use of Byproduct Material.”](#)

The T&E requirements in Subpart E of 10 CFR Part 35 provide three ways that a physician can be authorized to administer unsealed byproduct materials or radiopharmaceuticals requiring a written directive:

1. A physician can be certified by a medical specialty board, whose certification process is recognized by the NRC or an Agreement State.
2. A physician can complete a structured educational program and supervised work experience under an alternate pathway. This alternate pathway includes a requirement for 700 hours of training and experience, which consists of a minimum of 200 hours of classroom and laboratory training and 500 hours of supervised work experience.
3. A physician can be authorized if previously identified as an authorized user on an NRC or Agreement State license or permit (i.e., grandfathered).

In its evaluation of the T&E requirements, the NRC staff is considering whether an additional pathway should be created or if the alternate pathway should be revised. Specifically, the staff is evaluating: (1) whether it makes sense to establish tailored T&E requirements for different categories of radiopharmaceuticals; (2) how those categories should be determined; (3) what the appropriate T&E requirements would be for each category; and (4) whether those requirements should be based on hours of training and experience, or focused more on competency.

On October 29, 2018, the NRC published a series of questions on T&E in the *Federal Register* (83 FR 54380). The *Federal Register* notice is enclosed with this letter and can also be accessed at: <https://www.gpo.gov/fdsys/pkg/FR-2018-10-29/pdf/2018-23521.pdf>. The NRC will carefully consider responses to these questions and would appreciate your feedback on whether changes to the current T&E regulations are warranted. The comment period for the T&E evaluation will end on January 29, 2019. Please follow the directions in the notice on how to submit written comments. The NRC is using the Federal rulemaking Web site, [Regulations.gov](#), to accept written comments on the docket (NRC-2018-0230).

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Additional information on the NRC's T&E evaluation can be found at: <https://www.nrc.gov/materials/miau/med-use-toolkit/training-experience-evaluation.html>. If you have any questions on this correspondence, please contact Sarah Lopas of my staff at (301) 415-6360 or Sarah.Lopas@nrc.gov.

A handwritten signature in black ink, appearing to read "C. Einberg".

Christian Einberg, Chief
Medical Safety and Events Assessment Branch
Division of Materials Safety, Security, State
and Tribal Programs
Office of Nuclear Material Safety
and Safeguards

Enclosure:
Training and Experience
Federal Register notice

NUCLEAR REGULATORY COMMISSION

[NRC-2018-0230]

**Training and Experience Requirements for Different Categories of
Radiopharmaceuticals**

AGENCY: Nuclear Regulatory Commission.

ACTION: Training and experience requirements; request for comment.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is requesting comments on its training and experience (T&E) requirements. Specifically, the NRC would like input on whether it should establish tailored T&E requirements for different categories of radiopharmaceuticals for which a written directive is required in accordance with its regulations. The input will be used to determine whether significant regulatory changes to the NRC's T&E requirements for authorized users (AUs) are warranted.

DATES: Submit comments by January 29, 2019. Comments received after this date will be considered if it is practical to do so, but the NRC is only able to ensure consideration for comments received on or before this date.

ADDRESSES: You may submit comments by any of the following methods:

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III. Specific Requests for Comments

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specialty board that is not currently recognized by the NRC under 10 CFR 35.390, 35.392, 35.394, or 35.396 (Unsealed Byproduct Material—Written Directive Required).

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2. Are the current pathways for obtaining AU status adequate for protecting public health and safety? Provide a rationale for your answer.
3. Should the NRC develop a new tailored T&E pathway for these physicians? If so, what would be the appropriate way to categorize radiopharmaceuticals for tailored T&E requirements? If not, explain why the regulations should remain unchanged. [Some options to categorize radiopharmaceuticals include radiopharmaceuticals with similar delivery methods (oral, parenteral); same type of radiation characteristics or emission (alpha, beta, gamma, low-energy photon); similar preparation method (patient-ready doses); or a combination thereof (e.g., radiopharmaceuticals containing alpha- and beta-emitting radioisotopes that are administered intravenously and are prepared as patient-ready doses).]
4. Should the fundamental T&E required of physicians seeking limited AU status need to have the same fundamental T&E required of physicians seeking full AU status for all oral and parenteral administrations under 10 CFR 35.300?
5. How should the requirements for this fundamental T&E be structured for a specific category of radiopharmaceuticals?
 - a. Describe what the requirements should include:

- i. Classroom and laboratory training – What topics need to be covered in this training requirement? How many hours of classroom and laboratory training should be required? Provide the basis for the number of hours. If not hours, explain how this training should be quantified. [Note: The topics currently required in the regulations to be included in the classroom and laboratory training and work experience are listed in 10 CFR 35.390, 35.392, 35.394, and 35.396.]
 - ii. Work experience - What should the work experience requirement involve? How many hours of work experience should be required and what is the minimum number of patient or human research subject administrations that an individual must perform? Provide the basis for the number of hours and administrations. What should be the qualifications of the supervising individual?
 - iii. Competency - How should competency be evaluated? Should a written and/or practical examination by an independent examining committee be administered? Provide a rationale for your answer.
- b. Should a preceptor attestation be required for the fundamental T&E? Provide a rationale for your answer.
- c. Should the radiopharmaceutical manufacturer be able to provide the preceptor attestation? Provide a rational for your answer.

- d. Who should establish and administer the curriculum and examination? Provide specific group(s). [Some options are: NRC, medical specialty boards, medical professional societies, educational professional groups, and NRC in collaboration with any or more of the aforementioned groups.]
- e. Should AU competency be periodically assessed? If so, how should it be assessed, how often, and by whom?

B. NRC's Recognition of Medical Specialty Boards

The NRC is requesting comments on its recognition of medical specialty boards. The NRC's procedures for recognizing medical specialty boards are located on the Medical Uses Licensee Toolkit Web site (<https://www.nrc.gov/materials/miau/med-use-toolkit/certif-process-boards.html>). The NRC staff periodically reviews information to determine a board's continued eligibility for recognition.

- 1. What boards other than those already recognized by the NRC (American Board of Nuclear Medicine [ABNM], American Board of Radiology [ABR], American Osteopathic Board of Radiology [AOBR], Certification Board of Nuclear Endocrinology [CBNE]) could be considered for recognition for medical uses under 10 CFR 35.300?
- 2. Are the current NRC medical specialty board recognition criteria sufficient? If not, what additional criteria should the NRC use?

C. Patient Access

The NRC is requesting comments on whether there is a shortage in the number of AUs for 10 CFR 35.300.

1. Is there a shortage in the number of AUs for medical uses under 10 CFR 35.300? If so, is the shortage associated with the use of a specific radiopharmaceutical? Explain how.
2. Are there certain geographic areas with an inadequate number of AUs? Identify these areas.
3. Do current NRC regulations on AU T&E requirements unnecessarily limit patient access to procedures involving radiopharmaceuticals? Explain how.
4. Do current NRC regulations on AU T&E requirements unnecessarily limit research and development in nuclear medicine? Explain how.

D. Other Suggested Changes to the T&E Regulations

In 2002, the NRC revised its regulatory framework for medical use. The goal was to focus the NRC's regulations on those medical procedures that pose the highest risk to workers, the general public, patients, and human research subjects and to structure the regulations to be more risk-informed and more performance-based. The 2002 rule reduced the unnecessary regulatory burden by either reducing or eliminating the prescriptiveness of some regulations. Instead, the rule provided for a performance-based approach that relied on the training and experience of the AUs, authorized nuclear pharmacists, and radiation safety officers. The NRC is requesting comments on whether there are any other changes to the T&E regulations in 10 CFR part 35 that should be considered. Please discuss your suggested changes.

1. Should the NRC regulate the T&E of physicians for medical uses?
2. Are there requirements in the NRC's T&E regulatory framework for physicians that are non-safety related?

3. How can the NRC transform its regulatory approach for T&E while still ensuring that adequate protection is maintained for workers, the general public, patients, and human research subjects?

Dated at Rockville, Maryland, this 23rd day of October 2018.

For the Nuclear Regulatory
Commission.

/RA/

Daniel S. Collins, Director,
Division of Materials Safety,
Security,
State, and Tribal Programs,
Office of Nuclear Material Safety
and Safeguards.



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

November 2, 2018

The Lymphoma Research Foundation
Wall Street Plaza
88 Pine St., Suite 2400
New York, NY 10005

Via e-mail to LRF@lymphoma.org

SUBJECT: TRAINING AND EXPERIENCE REQUIREMENTS FOR DIFFERENT CATEGORIES OF RADIOPHARMACEUTICALS

Dear Sir or Madam,

The U.S. Nuclear Regulatory Commission (NRC) is evaluating its regulations related to the training and experience (T&E) required for a physician to become an authorized user for medical uses under Subpart E, “Unsealed Byproduct Material—Written Directive Required,” of [Title 10 of the Code of Federal Regulations \(10 CFR\) Part 35, “Medical Use of Byproduct Material.”](#)

The T&E requirements in Subpart E of 10 CFR Part 35 provide three ways that a physician can be authorized to administer unsealed byproduct materials or radiopharmaceuticals requiring a written directive:

1. A physician can be certified by a medical specialty board, whose certification process is recognized by the NRC or an Agreement State.
2. A physician can complete a structured educational program and supervised work experience under an alternate pathway. This alternate pathway includes a requirement for 700 hours of training and experience, which consists of a minimum of 200 hours of classroom and laboratory training and 500 hours of supervised work experience.
3. A physician can be authorized if previously identified as an authorized user on an NRC or Agreement State license or permit (i.e., grandfathered).

In its evaluation of the T&E requirements, the NRC staff is considering whether an additional pathway should be created or if the alternate pathway should be revised. Specifically, the staff is evaluating: (1) whether it makes sense to establish tailored T&E requirements for different categories of radiopharmaceuticals; (2) how those categories should be determined; (3) what the appropriate T&E requirements would be for each category; and (4) whether those requirements should be based on hours of training and experience, or focused more on competency.

On October 29, 2018, the NRC published a series of questions on T&E in the *Federal Register* (83 FR 54380). The *Federal Register* notice is enclosed with this letter and can also be accessed at: <https://www.gpo.gov/fdsys/pkg/FR-2018-10-29/pdf/2018-23521.pdf>. The NRC will carefully consider responses to these questions and would appreciate your feedback on whether changes to the current T&E regulations are warranted. The comment period for the T&E evaluation will end on January 29, 2019. Please follow the directions in the notice on how to submit written comments. The NRC is using the Federal rulemaking Web site, [Regulations.gov](#), to accept written comments on the docket (NRC-2018-0230).

The NRC will also conduct four public meetings scheduled for November 14 and December 11, 2018, and January 10 and January 22, 2019, and will accept oral comments provided during the meetings. The meetings on December 11 and January 10 will be held at NRC Headquarters in Rockville, MD, and all four meetings will be accessible for remote participation by moderated bridge line and webinar. The NRC's public meeting page has been updated with meeting details and registration instructions for each meeting: <https://www.nrc.gov/pmns/mtg>.

Additional information on the NRC's T&E evaluation can be found at: <https://www.nrc.gov/materials/miau/med-use-toolkit/training-experience-evaluation.html>. If you have any questions on this correspondence, please contact Sarah Lopas of my staff at (301) 415-6360 or Sarah.Lopas@nrc.gov.

A handwritten signature in black ink, appearing to read "C Einberg".

Christian Einberg, Chief
Medical Safety and Events Assessment Branch
Division of Materials Safety, Security, State
and Tribal Programs
Office of Nuclear Material Safety
and Safeguards

Enclosure:
Training and Experience
Federal Register notice

NUCLEAR REGULATORY COMMISSION

[NRC-2018-0230]

**Training and Experience Requirements for Different Categories of
Radiopharmaceuticals**

AGENCY: Nuclear Regulatory Commission.

ACTION: Training and experience requirements; request for comment.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is requesting comments on its training and experience (T&E) requirements. Specifically, the NRC would like input on whether it should establish tailored T&E requirements for different categories of radiopharmaceuticals for which a written directive is required in accordance with its regulations. The input will be used to determine whether significant regulatory changes to the NRC's T&E requirements for authorized users (AUs) are warranted.

DATES: Submit comments by January 29, 2019. Comments received after this date will be considered if it is practical to do so, but the NRC is only able to ensure consideration for comments received on or before this date.

ADDRESSES: You may submit comments by any of the following methods:

- **Federal Rulemaking Web Site:** Go to <http://www.regulations.gov>

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- **Mail comments to:** May Ma, Office of Administration, Mail Stop: TWFN-7-A60M, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001.

For additional direction on obtaining information and submitting comments, see “Obtaining Information and Submitting Comments” in the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: Sarah Lopas, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001; telephone: 301-415-6360, e-mail: Sarah.Lopas@nrc.gov.

SUPPLEMENTARY INFORMATION:

I. Obtaining Information and Submitting Comments

A. Obtaining Information

Please refer to Docket ID **NRC-2018-0230** when contacting the NRC about the availability of information for this action. You may obtain publicly-available information related to this action by any of the following methods:

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- **NRC's PDR:** You may examine and purchase copies of public documents at the NRC's PDR, Room O1-F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.

B. Submitting Comments

Please include Docket ID **NRC-2018-0230** in your comment submission.

The NRC cautions you not to include identifying or contact information in comment submissions that you do not want to be publicly disclosed in your comment submission. All comment submissions are posted at <http://www.regulations.gov> and entered into ADAMS. Comment submissions are not routinely edited to remove identifying or contact information.

If you are requesting or aggregating comments from other persons for submission to the NRC, then you should inform those persons not to include identifying or contact information that they do not want to be publicly disclosed in their comment submission. Your request should state that the NRC does not routinely edit comment submissions to remove such information before making the comment submissions available to the public or entering the comment into ADAMS.

II. Background

On August 17, 2017, the Commission issued a staff requirements memorandum (SRM), SRM-M170817 (ADAMS Accession No. ML17229B284), approving the final rule revising parts 30, 32, and 35 of title 10 of the *Code of Federal Regulations* (10 CFR), "Medical Use of Byproduct Material – Medical Event Definitions, Training and Experience, and Clarifying Amendments," and directing the staff to evaluate (1) whether it makes sense to establish tailored T&E requirements for different categories of radiopharmaceuticals, (2) how those categories should be determined (such as by risks posed by groups of

radionuclides or by delivery method), (3) what the appropriate T&E requirements would be for each category, and (4) whether those requirements should be based on hours of T&E or focused more on competency. In response to the SRM, the NRC staff documented its initial results, status, and next steps related to this evaluation in SECY-18-0084, "Staff Evaluation of Training and Experience Requirements for Administering Different Categories of Radiopharmaceuticals in Response to SRM-M170817" (ADAMS Accession No. ML18135A276). In SECY-18-0084, the staff concluded that additional outreach with the medical community is needed to determine whether and how to tailor the T&E requirements to establish a limited AU status, the specific T&E requirements that should apply, how the T&E requirements should be met (e.g., hours of training, demonstration of competency), and whether a competency-based approach makes sense for the T&E requirements for all the medical uses authorized under 10 CFR 35.300, "Use of unsealed byproduct material for which a written directive is required."

The NRC is interested in obtaining input from as many stakeholders as possible, including members of the Advisory Committee on the Medical Uses of Isotopes, professional organizations, physicians, patients, patient advocacy groups, licensees, Agreement States, and other interested individuals. The focus of this request is to gather information that will permit the NRC staff to determine whether changes to the T&E requirements are warranted for different categories of radiopharmaceuticals for physicians seeking AU status for the medical use of specific categories of radiopharmaceuticals requiring a written directive under 10 CFR 35.300.

During the comment period between October 29, 2018 and January 29, 2019, the NRC will hold four public meetings that will discuss the information being requested and to accept comments on the docket. All four public meetings

will be available for remote participation by moderated bridge line and webinar, and two of the four meetings will be open for in-person attendance at NRC's headquarters in Rockville, Maryland.

The public meetings are scheduled for November 14, 2018 (webinar-only); December 11, 2018 (webinar and in-person attendance); January 10, 2019 (webinar and in-person attendance); and January 22, 2019 (webinar-only). The public meetings will be noticed on the NRC's public meeting Web site at least 10 calendar days before the meeting. Members of the public should monitor the NRC's public meeting Web site at <https://www.nrc.gov/pmns/mtg>. The NRC will also post the meeting notices on the Federal Rulemaking Web site at <https://www.regulations.gov/> under Docket ID **NRC-2018-0230**.

The NRC may post additional materials related to this document, including public comments, on the Federal Rulemaking Web site. The Federal Rulemaking Web site allows you to receive alerts when changes or additions occur in a docket folder. To subscribe: (1) Navigate to the docket folder **NRC-2018-0230**; (2) click the “Sign up for E-mail Alerts” link; and (3) enter your email address and select how frequently you would like to receive emails (daily, weekly, or monthly).

III. Specific Requests for Comments

A. Tailored Training & Experience Requirements

The NRC is requesting comments on whether it should establish tailored T&E requirements for different categories of radiopharmaceuticals for physicians seeking AU status for the medical use of specific categories of radiopharmaceuticals requiring a written directive under 10 CFR 35.300 (i.e., a limited AU status). This would be for physicians seeking AU status via the alternate non-board certified pathway, and for physicians certified by a medical

specialty board that is not currently recognized by the NRC under 10 CFR 35.390, 35.392, 35.394, or 35.396 (Unsealed Byproduct Material—Written Directive Required).

1. Are the current pathways for obtaining AU status reasonable and accessible? Provide a rationale for your answer.
2. Are the current pathways for obtaining AU status adequate for protecting public health and safety? Provide a rationale for your answer.
3. Should the NRC develop a new tailored T&E pathway for these physicians? If so, what would be the appropriate way to categorize radiopharmaceuticals for tailored T&E requirements? If not, explain why the regulations should remain unchanged. [Some options to categorize radiopharmaceuticals include radiopharmaceuticals with similar delivery methods (oral, parenteral); same type of radiation characteristics or emission (alpha, beta, gamma, low-energy photon); similar preparation method (patient-ready doses); or a combination thereof (e.g., radiopharmaceuticals containing alpha- and beta-emitting radioisotopes that are administered intravenously and are prepared as patient-ready doses).]
4. Should the fundamental T&E required of physicians seeking limited AU status need to have the same fundamental T&E required of physicians seeking full AU status for all oral and parenteral administrations under 10 CFR 35.300?
5. How should the requirements for this fundamental T&E be structured for a specific category of radiopharmaceuticals?
 - a. Describe what the requirements should include:

- i. Classroom and laboratory training – What topics need to be covered in this training requirement? How many hours of classroom and laboratory training should be required? Provide the basis for the number of hours. If not hours, explain how this training should be quantified. [Note: The topics currently required in the regulations to be included in the classroom and laboratory training and work experience are listed in 10 CFR 35.390, 35.392, 35.394, and 35.396.]
 - ii. Work experience - What should the work experience requirement involve? How many hours of work experience should be required and what is the minimum number of patient or human research subject administrations that an individual must perform? Provide the basis for the number of hours and administrations. What should be the qualifications of the supervising individual?
 - iii. Competency - How should competency be evaluated? Should a written and/or practical examination by an independent examining committee be administered? Provide a rationale for your answer.
- b. Should a preceptor attestation be required for the fundamental T&E? Provide a rationale for your answer.
- c. Should the radiopharmaceutical manufacturer be able to provide the preceptor attestation? Provide a rational for your answer.

- d. Who should establish and administer the curriculum and examination? Provide specific group(s). [Some options are: NRC, medical specialty boards, medical professional societies, educational professional groups, and NRC in collaboration with any or more of the aforementioned groups.]
- e. Should AU competency be periodically assessed? If so, how should it be assessed, how often, and by whom?

B. NRC's Recognition of Medical Specialty Boards

The NRC is requesting comments on its recognition of medical specialty boards. The NRC's procedures for recognizing medical specialty boards are located on the Medical Uses Licensee Toolkit Web site (<https://www.nrc.gov/materials/miau/med-use-toolkit/certif-process-boards.html>). The NRC staff periodically reviews information to determine a board's continued eligibility for recognition.

- 1. What boards other than those already recognized by the NRC (American Board of Nuclear Medicine [ABNM], American Board of Radiology [ABR], American Osteopathic Board of Radiology [AOBR], Certification Board of Nuclear Endocrinology [CBNE]) could be considered for recognition for medical uses under 10 CFR 35.300?
- 2. Are the current NRC medical specialty board recognition criteria sufficient? If not, what additional criteria should the NRC use?

C. Patient Access

The NRC is requesting comments on whether there is a shortage in the number of AUs for 10 CFR 35.300.

1. Is there a shortage in the number of AUs for medical uses under 10 CFR 35.300? If so, is the shortage associated with the use of a specific radiopharmaceutical? Explain how.
2. Are there certain geographic areas with an inadequate number of AUs? Identify these areas.
3. Do current NRC regulations on AU T&E requirements unnecessarily limit patient access to procedures involving radiopharmaceuticals? Explain how.
4. Do current NRC regulations on AU T&E requirements unnecessarily limit research and development in nuclear medicine? Explain how.

D. Other Suggested Changes to the T&E Regulations

In 2002, the NRC revised its regulatory framework for medical use. The goal was to focus the NRC's regulations on those medical procedures that pose the highest risk to workers, the general public, patients, and human research subjects and to structure the regulations to be more risk-informed and more performance-based. The 2002 rule reduced the unnecessary regulatory burden by either reducing or eliminating the prescriptiveness of some regulations. Instead, the rule provided for a performance-based approach that relied on the training and experience of the AUs, authorized nuclear pharmacists, and radiation safety officers. The NRC is requesting comments on whether there are any other changes to the T&E regulations in 10 CFR part 35 that should be considered. Please discuss your suggested changes.

1. Should the NRC regulate the T&E of physicians for medical uses?
2. Are there requirements in the NRC's T&E regulatory framework for physicians that are non-safety related?

3. How can the NRC transform its regulatory approach for T&E while still ensuring that adequate protection is maintained for workers, the general public, patients, and human research subjects?

Dated at Rockville, Maryland, this 23rd day of October 2018.

For the Nuclear Regulatory
Commission.

/RA/

Daniel S. Collins, Director,
Division of Materials Safety,
Security,
State, and Tribal Programs,
Office of Nuclear Material Safety
and Safeguards.



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

November 2, 2018

Dr. Elias R. Melhem, MD
Chair, Dept. of Diagnostic and
Radiology & Nuclear Medicine
University of Maryland School of Medicine
655 W. Baltimore St.
Baltimore, MD 21201

Via e-mail to emelhem@umm.edu

SUBJECT: TRAINING AND EXPERIENCE REQUIREMENTS FOR DIFFERENT CATEGORIES OF RADIOPHARMACEUTICALS

Dear Dr. Melhem,

The U.S. Nuclear Regulatory Commission (NRC) is evaluating its regulations related to the training and experience (T&E) required for a physician to become an authorized user for medical uses under Subpart E, “Unsealed Byproduct Material—Written Directive Required,” of [Title 10 of the Code of Federal Regulations \(10 CFR\) Part 35, “Medical Use of Byproduct Material.”](#)

The T&E requirements in Subpart E of 10 CFR Part 35 provide three ways that a physician can be authorized to administer unsealed byproduct materials or radiopharmaceuticals requiring a written directive:

1. A physician can be certified by a medical specialty board, whose certification process is recognized by the NRC or an Agreement State.
2. A physician can complete a structured educational program and supervised work experience under an alternate pathway. This alternate pathway includes a requirement for 700 hours of training and experience, which consists of a minimum of 200 hours of classroom and laboratory training and 500 hours of supervised work experience.
3. A physician can be authorized if previously identified as an authorized user on an NRC or Agreement State license or permit (i.e., grandfathered).

In its evaluation of the T&E requirements, the NRC staff is considering whether an additional pathway should be created or if the alternate pathway should be revised. Specifically, the staff is evaluating: (1) whether it makes sense to establish tailored T&E requirements for different categories of radiopharmaceuticals; (2) how those categories should be determined; (3) what the appropriate T&E requirements would be for each category; and (4) whether those requirements should be based on hours of training and experience, or focused more on competency.

On October 29, 2018, the NRC published a series of questions on T&E in the *Federal Register* (83 FR 54380). The *Federal Register* notice is enclosed with this letter and can also be accessed at: <https://www.gpo.gov/fdsys/pkg/FR-2018-10-29/pdf/2018-23521.pdf>. The NRC will carefully consider responses to these questions and would appreciate your feedback on whether changes to the current T&E regulations are warranted. The comment period for the T&E evaluation will end on January 29, 2019. Please follow the directions in the notice on how to submit written comments. The NRC is using the Federal rulemaking Web site, [Regulations.gov](#), to accept written comments on the docket (NRC-2018-0230).

The NRC will also conduct four public meetings scheduled for November 14 and December 11, 2018, and January 10 and January 22, 2019, and will accept oral comments provided during the meetings. The meetings on December 11 and January 10 will be held at NRC Headquarters in Rockville, MD, and all four meetings will be accessible for remote participation by moderated bridge line and webinar. The NRC's public meeting page has been updated with meeting details and registration instructions for each meeting: <https://www.nrc.gov/pmns/mtg>.

Additional information on the NRC's T&E evaluation can be found at: <https://www.nrc.gov/materials/miau/med-use-toolkit/training-experience-evaluation.html>. If you have any questions on this correspondence, please contact Sarah Lopas of my staff at (301) 415-6360 or Sarah.Lopas@nrc.gov.

A handwritten signature in black ink, appearing to read "C Einberg".

Christian Einberg, Chief
Medical Safety and Events Assessment Branch
Division of Materials Safety, Security, State
and Tribal Programs
Office of Nuclear Material Safety
and Safeguards

Enclosure:
Training and Experience
Federal Register notice

NUCLEAR REGULATORY COMMISSION

[NRC-2018-0230]

**Training and Experience Requirements for Different Categories of
Radiopharmaceuticals**

AGENCY: Nuclear Regulatory Commission.

ACTION: Training and experience requirements; request for comment.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is requesting comments on its training and experience (T&E) requirements. Specifically, the NRC would like input on whether it should establish tailored T&E requirements for different categories of radiopharmaceuticals for which a written directive is required in accordance with its regulations. The input will be used to determine whether significant regulatory changes to the NRC's T&E requirements for authorized users (AUs) are warranted.

DATES: Submit comments by January 29, 2019. Comments received after this date will be considered if it is practical to do so, but the NRC is only able to ensure consideration for comments received on or before this date.

ADDRESSES: You may submit comments by any of the following methods:

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For additional direction on obtaining information and submitting comments, see “Obtaining Information and Submitting Comments” in the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: Sarah Lopas, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001; telephone: 301-415-6360, e-mail: Sarah.Lopas@nrc.gov.

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III. Specific Requests for Comments

A. Tailored Training & Experience Requirements

The NRC is requesting comments on whether it should establish tailored T&E requirements for different categories of radiopharmaceuticals for physicians seeking AU status for the medical use of specific categories of radiopharmaceuticals requiring a written directive under 10 CFR 35.300 (i.e., a limited AU status). This would be for physicians seeking AU status via the alternate non-board certified pathway, and for physicians certified by a medical

specialty board that is not currently recognized by the NRC under 10 CFR 35.390, 35.392, 35.394, or 35.396 (Unsealed Byproduct Material—Written Directive Required).

1. Are the current pathways for obtaining AU status reasonable and accessible? Provide a rationale for your answer.
2. Are the current pathways for obtaining AU status adequate for protecting public health and safety? Provide a rationale for your answer.
3. Should the NRC develop a new tailored T&E pathway for these physicians? If so, what would be the appropriate way to categorize radiopharmaceuticals for tailored T&E requirements? If not, explain why the regulations should remain unchanged. [Some options to categorize radiopharmaceuticals include radiopharmaceuticals with similar delivery methods (oral, parenteral); same type of radiation characteristics or emission (alpha, beta, gamma, low-energy photon); similar preparation method (patient-ready doses); or a combination thereof (e.g., radiopharmaceuticals containing alpha- and beta-emitting radioisotopes that are administered intravenously and are prepared as patient-ready doses).]
4. Should the fundamental T&E required of physicians seeking limited AU status need to have the same fundamental T&E required of physicians seeking full AU status for all oral and parenteral administrations under 10 CFR 35.300?
5. How should the requirements for this fundamental T&E be structured for a specific category of radiopharmaceuticals?
 - a. Describe what the requirements should include:

- i. Classroom and laboratory training – What topics need to be covered in this training requirement? How many hours of classroom and laboratory training should be required? Provide the basis for the number of hours. If not hours, explain how this training should be quantified. [Note: The topics currently required in the regulations to be included in the classroom and laboratory training and work experience are listed in 10 CFR 35.390, 35.392, 35.394, and 35.396.]
 - ii. Work experience - What should the work experience requirement involve? How many hours of work experience should be required and what is the minimum number of patient or human research subject administrations that an individual must perform? Provide the basis for the number of hours and administrations. What should be the qualifications of the supervising individual?
 - iii. Competency - How should competency be evaluated? Should a written and/or practical examination by an independent examining committee be administered? Provide a rationale for your answer.
- b. Should a preceptor attestation be required for the fundamental T&E? Provide a rationale for your answer.
- c. Should the radiopharmaceutical manufacturer be able to provide the preceptor attestation? Provide a rational for your answer.

- d. Who should establish and administer the curriculum and examination? Provide specific group(s). [Some options are: NRC, medical specialty boards, medical professional societies, educational professional groups, and NRC in collaboration with any or more of the aforementioned groups.]
- e. Should AU competency be periodically assessed? If so, how should it be assessed, how often, and by whom?

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The NRC is requesting comments on its recognition of medical specialty boards. The NRC's procedures for recognizing medical specialty boards are located on the Medical Uses Licensee Toolkit Web site (<https://www.nrc.gov/materials/miau/med-use-toolkit/certif-process-boards.html>). The NRC staff periodically reviews information to determine a board's continued eligibility for recognition.

- 1. What boards other than those already recognized by the NRC (American Board of Nuclear Medicine [ABNM], American Board of Radiology [ABR], American Osteopathic Board of Radiology [AOBR], Certification Board of Nuclear Endocrinology [CBNE]) could be considered for recognition for medical uses under 10 CFR 35.300?
- 2. Are the current NRC medical specialty board recognition criteria sufficient? If not, what additional criteria should the NRC use?

C. Patient Access

The NRC is requesting comments on whether there is a shortage in the number of AUs for 10 CFR 35.300.

1. Is there a shortage in the number of AUs for medical uses under 10 CFR 35.300? If so, is the shortage associated with the use of a specific radiopharmaceutical? Explain how.
2. Are there certain geographic areas with an inadequate number of AUs? Identify these areas.
3. Do current NRC regulations on AU T&E requirements unnecessarily limit patient access to procedures involving radiopharmaceuticals? Explain how.
4. Do current NRC regulations on AU T&E requirements unnecessarily limit research and development in nuclear medicine? Explain how.

D. Other Suggested Changes to the T&E Regulations

In 2002, the NRC revised its regulatory framework for medical use. The goal was to focus the NRC's regulations on those medical procedures that pose the highest risk to workers, the general public, patients, and human research subjects and to structure the regulations to be more risk-informed and more performance-based. The 2002 rule reduced the unnecessary regulatory burden by either reducing or eliminating the prescriptiveness of some regulations. Instead, the rule provided for a performance-based approach that relied on the training and experience of the AUs, authorized nuclear pharmacists, and radiation safety officers. The NRC is requesting comments on whether there are any other changes to the T&E regulations in 10 CFR part 35 that should be considered. Please discuss your suggested changes.

1. Should the NRC regulate the T&E of physicians for medical uses?
2. Are there requirements in the NRC's T&E regulatory framework for physicians that are non-safety related?

3. How can the NRC transform its regulatory approach for T&E while still ensuring that adequate protection is maintained for workers, the general public, patients, and human research subjects?

Dated at Rockville, Maryland, this 23rd day of October 2018.

For the Nuclear Regulatory
Commission.

/RA/

Daniel S. Collins, Director,
Division of Materials Safety,
Security,
State, and Tribal Programs,
Office of Nuclear Material Safety
and Safeguards.



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

November 2, 2018

Dr. Robert Miletich, MD, PhD
Interim Chair and Professor
University at Buffalo, Department of Nuclear Medicine
105 Parker Hall, 3435 Main St.
Buffalo, NY 14214

Via e-mail to miletich@buffalo.edu

SUBJECT: TRAINING AND EXPERIENCE REQUIREMENTS FOR DIFFERENT CATEGORIES OF RADIOPHARMACEUTICALS

Dear Dr. Miletich,

The U.S. Nuclear Regulatory Commission (NRC) is evaluating its regulations related to the training and experience (T&E) required for a physician to become an authorized user for medical uses under Subpart E, “Unsealed Byproduct Material—Written Directive Required,” of [Title 10 of the Code of Federal Regulations \(10 CFR\) Part 35, “Medical Use of Byproduct Material.”](#)

The T&E requirements in Subpart E of 10 CFR Part 35 provide three ways that a physician can be authorized to administer unsealed byproduct materials or radiopharmaceuticals requiring a written directive:

1. A physician can be certified by a medical specialty board, whose certification process is recognized by the NRC or an Agreement State.
2. A physician can complete a structured educational program and supervised work experience under an alternate pathway. This alternate pathway includes a requirement for 700 hours of training and experience, which consists of a minimum of 200 hours of classroom and laboratory training and 500 hours of supervised work experience.
3. A physician can be authorized if previously identified as an authorized user on an NRC or Agreement State license or permit (i.e., grandfathered).

In its evaluation of the T&E requirements, the NRC staff is considering whether an additional pathway should be created or if the alternate pathway should be revised. Specifically, the staff is evaluating: (1) whether it makes sense to establish tailored T&E requirements for different categories of radiopharmaceuticals; (2) how those categories should be determined; (3) what the appropriate T&E requirements would be for each category; and (4) whether those requirements should be based on hours of training and experience, or focused more on competency.

On October 29, 2018, the NRC published a series of questions on T&E in the *Federal Register* (83 FR 54380). The *Federal Register* notice is enclosed with this letter and can also be accessed at: <https://www.gpo.gov/fdsys/pkg/FR-2018-10-29/pdf/2018-23521.pdf>. The NRC will carefully consider responses to these questions and would appreciate your feedback on whether changes to the current T&E regulations are warranted. The comment period for the T&E evaluation will end on January 29, 2019. Please follow the directions in the notice on how to submit written comments. The NRC is using the Federal rulemaking Web site, [Regulations.gov](#), to accept written comments on the docket (NRC-2018-0230).

The NRC will also conduct four public meetings scheduled for November 14 and December 11, 2018, and January 10 and January 22, 2019, and will accept oral comments provided during the meetings. The meetings on December 11 and January 10 will be held at NRC Headquarters in Rockville, MD, and all four meetings will be accessible for remote participation by moderated bridge line and webinar. The NRC's public meeting page has been updated with meeting details and registration instructions for each meeting: <https://www.nrc.gov/pmns/mtg>.

Additional information on the NRC's T&E evaluation can be found at: <https://www.nrc.gov/materials/miau/med-use-toolkit/training-experience-evaluation.html>. If you have any questions on this correspondence, please contact Sarah Lopas of my staff at (301) 415-6360 or Sarah.Lopas@nrc.gov.

A handwritten signature in black ink, appearing to read "C Einberg".

Christian Einberg, Chief
Medical Safety and Events Assessment Branch
Division of Materials Safety, Security, State
and Tribal Programs
Office of Nuclear Material Safety
and Safeguards

Enclosure:
Training and Experience
Federal Register notice

NUCLEAR REGULATORY COMMISSION

[NRC-2018-0230]

**Training and Experience Requirements for Different Categories of
Radiopharmaceuticals**

AGENCY: Nuclear Regulatory Commission.

ACTION: Training and experience requirements; request for comment.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is requesting comments on its training and experience (T&E) requirements. Specifically, the NRC would like input on whether it should establish tailored T&E requirements for different categories of radiopharmaceuticals for which a written directive is required in accordance with its regulations. The input will be used to determine whether significant regulatory changes to the NRC's T&E requirements for authorized users (AUs) are warranted.

DATES: Submit comments by January 29, 2019. Comments received after this date will be considered if it is practical to do so, but the NRC is only able to ensure consideration for comments received on or before this date.

ADDRESSES: You may submit comments by any of the following methods:

- **Federal Rulemaking Web Site:** Go to <http://www.regulations.gov>

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- **Mail comments to:** May Ma, Office of Administration, Mail Stop: TWFN-7-A60M, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001.

For additional direction on obtaining information and submitting comments, see “Obtaining Information and Submitting Comments” in the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: Sarah Lopas, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001; telephone: 301-415-6360, e-mail: Sarah.Lopas@nrc.gov.

SUPPLEMENTARY INFORMATION:

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Please include Docket ID **NRC-2018-0230** in your comment submission.

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II. Background

On August 17, 2017, the Commission issued a staff requirements memorandum (SRM), SRM-M170817 (ADAMS Accession No. ML17229B284), approving the final rule revising parts 30, 32, and 35 of title 10 of the *Code of Federal Regulations* (10 CFR), "Medical Use of Byproduct Material – Medical Event Definitions, Training and Experience, and Clarifying Amendments," and directing the staff to evaluate (1) whether it makes sense to establish tailored T&E requirements for different categories of radiopharmaceuticals, (2) how those categories should be determined (such as by risks posed by groups of

radionuclides or by delivery method), (3) what the appropriate T&E requirements would be for each category, and (4) whether those requirements should be based on hours of T&E or focused more on competency. In response to the SRM, the NRC staff documented its initial results, status, and next steps related to this evaluation in SECY-18-0084, "Staff Evaluation of Training and Experience Requirements for Administering Different Categories of Radiopharmaceuticals in Response to SRM-M170817" (ADAMS Accession No. ML18135A276). In SECY-18-0084, the staff concluded that additional outreach with the medical community is needed to determine whether and how to tailor the T&E requirements to establish a limited AU status, the specific T&E requirements that should apply, how the T&E requirements should be met (e.g., hours of training, demonstration of competency), and whether a competency-based approach makes sense for the T&E requirements for all the medical uses authorized under 10 CFR 35.300, "Use of unsealed byproduct material for which a written directive is required."

The NRC is interested in obtaining input from as many stakeholders as possible, including members of the Advisory Committee on the Medical Uses of Isotopes, professional organizations, physicians, patients, patient advocacy groups, licensees, Agreement States, and other interested individuals. The focus of this request is to gather information that will permit the NRC staff to determine whether changes to the T&E requirements are warranted for different categories of radiopharmaceuticals for physicians seeking AU status for the medical use of specific categories of radiopharmaceuticals requiring a written directive under 10 CFR 35.300.

During the comment period between October 29, 2018 and January 29, 2019, the NRC will hold four public meetings that will discuss the information being requested and to accept comments on the docket. All four public meetings

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specialty board that is not currently recognized by the NRC under 10 CFR 35.390, 35.392, 35.394, or 35.396 (Unsealed Byproduct Material—Written Directive Required).

1. Are the current pathways for obtaining AU status reasonable and accessible? Provide a rationale for your answer.
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- d. Who should establish and administer the curriculum and examination? Provide specific group(s). [Some options are: NRC, medical specialty boards, medical professional societies, educational professional groups, and NRC in collaboration with any or more of the aforementioned groups.]
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Dated at Rockville, Maryland, this 23rd day of October 2018.

For the Nuclear Regulatory
Commission.

/RA/

Daniel S. Collins, Director,
Division of Materials Safety,
Security,
State, and Tribal Programs,
Office of Nuclear Material Safety
and Safeguards.



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

November 2, 2018

Dr. Marc Fischer
Nuclear Medicine Technology
Dept. of Allied Health Sciences
Molloy College
1000 Hempstead Ave., Casey Building Room 10A
Rockville Centre, NY 11571-5002

Via e-mail to mfischer@molloy.edu

SUBJECT: TRAINING AND EXPERIENCE REQUIREMENTS FOR DIFFERENT CATEGORIES OF RADIOPHARMACEUTICALS

Dear Dr. Fischer,

The U.S. Nuclear Regulatory Commission (NRC) is evaluating its regulations related to the training and experience (T&E) required for a physician to become an authorized user for medical uses under Subpart E, “Unsealed Byproduct Material—Written Directive Required,” of [Title 10 of the Code of Federal Regulations \(10 CFR\) Part 35, “Medical Use of Byproduct Material.”](#)

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Christian Einberg, Chief
Medical Safety and Events Assessment Branch
Division of Materials Safety, Security, State
and Tribal Programs
Office of Nuclear Material Safety
and Safeguards

Enclosure:
Training and Experience
Federal Register notice

NUCLEAR REGULATORY COMMISSION

[NRC-2018-0230]

**Training and Experience Requirements for Different Categories of
Radiopharmaceuticals**

AGENCY: Nuclear Regulatory Commission.

ACTION: Training and experience requirements; request for comment.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is requesting comments on its training and experience (T&E) requirements. Specifically, the NRC would like input on whether it should establish tailored T&E requirements for different categories of radiopharmaceuticals for which a written directive is required in accordance with its regulations. The input will be used to determine whether significant regulatory changes to the NRC's T&E requirements for authorized users (AUs) are warranted.

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II. Background

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radionuclides or by delivery method), (3) what the appropriate T&E requirements would be for each category, and (4) whether those requirements should be based on hours of T&E or focused more on competency. In response to the SRM, the NRC staff documented its initial results, status, and next steps related to this evaluation in SECY-18-0084, "Staff Evaluation of Training and Experience Requirements for Administering Different Categories of Radiopharmaceuticals in Response to SRM-M170817" (ADAMS Accession No. ML18135A276). In SECY-18-0084, the staff concluded that additional outreach with the medical community is needed to determine whether and how to tailor the T&E requirements to establish a limited AU status, the specific T&E requirements that should apply, how the T&E requirements should be met (e.g., hours of training, demonstration of competency), and whether a competency-based approach makes sense for the T&E requirements for all the medical uses authorized under 10 CFR 35.300, "Use of unsealed byproduct material for which a written directive is required."

The NRC is interested in obtaining input from as many stakeholders as possible, including members of the Advisory Committee on the Medical Uses of Isotopes, professional organizations, physicians, patients, patient advocacy groups, licensees, Agreement States, and other interested individuals. The focus of this request is to gather information that will permit the NRC staff to determine whether changes to the T&E requirements are warranted for different categories of radiopharmaceuticals for physicians seeking AU status for the medical use of specific categories of radiopharmaceuticals requiring a written directive under 10 CFR 35.300.

During the comment period between October 29, 2018 and January 29, 2019, the NRC will hold four public meetings that will discuss the information being requested and to accept comments on the docket. All four public meetings

will be available for remote participation by moderated bridge line and webinar, and two of the four meetings will be open for in-person attendance at NRC's headquarters in Rockville, Maryland.

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III. Specific Requests for Comments

A. Tailored Training & Experience Requirements

The NRC is requesting comments on whether it should establish tailored T&E requirements for different categories of radiopharmaceuticals for physicians seeking AU status for the medical use of specific categories of radiopharmaceuticals requiring a written directive under 10 CFR 35.300 (i.e., a limited AU status). This would be for physicians seeking AU status via the alternate non-board certified pathway, and for physicians certified by a medical

specialty board that is not currently recognized by the NRC under 10 CFR 35.390, 35.392, 35.394, or 35.396 (Unsealed Byproduct Material—Written Directive Required).

1. Are the current pathways for obtaining AU status reasonable and accessible? Provide a rationale for your answer.
2. Are the current pathways for obtaining AU status adequate for protecting public health and safety? Provide a rationale for your answer.
3. Should the NRC develop a new tailored T&E pathway for these physicians? If so, what would be the appropriate way to categorize radiopharmaceuticals for tailored T&E requirements? If not, explain why the regulations should remain unchanged. [Some options to categorize radiopharmaceuticals include radiopharmaceuticals with similar delivery methods (oral, parenteral); same type of radiation characteristics or emission (alpha, beta, gamma, low-energy photon); similar preparation method (patient-ready doses); or a combination thereof (e.g., radiopharmaceuticals containing alpha- and beta-emitting radioisotopes that are administered intravenously and are prepared as patient-ready doses).]
4. Should the fundamental T&E required of physicians seeking limited AU status need to have the same fundamental T&E required of physicians seeking full AU status for all oral and parenteral administrations under 10 CFR 35.300?
5. How should the requirements for this fundamental T&E be structured for a specific category of radiopharmaceuticals?
 - a. Describe what the requirements should include:

- i. Classroom and laboratory training – What topics need to be covered in this training requirement? How many hours of classroom and laboratory training should be required? Provide the basis for the number of hours. If not hours, explain how this training should be quantified. [Note: The topics currently required in the regulations to be included in the classroom and laboratory training and work experience are listed in 10 CFR 35.390, 35.392, 35.394, and 35.396.]
 - ii. Work experience - What should the work experience requirement involve? How many hours of work experience should be required and what is the minimum number of patient or human research subject administrations that an individual must perform? Provide the basis for the number of hours and administrations. What should be the qualifications of the supervising individual?
 - iii. Competency - How should competency be evaluated? Should a written and/or practical examination by an independent examining committee be administered? Provide a rationale for your answer.
- b. Should a preceptor attestation be required for the fundamental T&E? Provide a rationale for your answer.
- c. Should the radiopharmaceutical manufacturer be able to provide the preceptor attestation? Provide a rational for your answer.

- d. Who should establish and administer the curriculum and examination? Provide specific group(s). [Some options are: NRC, medical specialty boards, medical professional societies, educational professional groups, and NRC in collaboration with any or more of the aforementioned groups.]
- e. Should AU competency be periodically assessed? If so, how should it be assessed, how often, and by whom?

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The NRC is requesting comments on its recognition of medical specialty boards. The NRC's procedures for recognizing medical specialty boards are located on the Medical Uses Licensee Toolkit Web site (<https://www.nrc.gov/materials/miau/med-use-toolkit/certif-process-boards.html>). The NRC staff periodically reviews information to determine a board's continued eligibility for recognition.

- 1. What boards other than those already recognized by the NRC (American Board of Nuclear Medicine [ABNM], American Board of Radiology [ABR], American Osteopathic Board of Radiology [AOBR], Certification Board of Nuclear Endocrinology [CBNE]) could be considered for recognition for medical uses under 10 CFR 35.300?
- 2. Are the current NRC medical specialty board recognition criteria sufficient? If not, what additional criteria should the NRC use?

C. Patient Access

The NRC is requesting comments on whether there is a shortage in the number of AUs for 10 CFR 35.300.

1. Is there a shortage in the number of AUs for medical uses under 10 CFR 35.300? If so, is the shortage associated with the use of a specific radiopharmaceutical? Explain how.
2. Are there certain geographic areas with an inadequate number of AUs? Identify these areas.
3. Do current NRC regulations on AU T&E requirements unnecessarily limit patient access to procedures involving radiopharmaceuticals? Explain how.
4. Do current NRC regulations on AU T&E requirements unnecessarily limit research and development in nuclear medicine? Explain how.

D. Other Suggested Changes to the T&E Regulations

In 2002, the NRC revised its regulatory framework for medical use. The goal was to focus the NRC's regulations on those medical procedures that pose the highest risk to workers, the general public, patients, and human research subjects and to structure the regulations to be more risk-informed and more performance-based. The 2002 rule reduced the unnecessary regulatory burden by either reducing or eliminating the prescriptiveness of some regulations. Instead, the rule provided for a performance-based approach that relied on the training and experience of the AUs, authorized nuclear pharmacists, and radiation safety officers. The NRC is requesting comments on whether there are any other changes to the T&E regulations in 10 CFR part 35 that should be considered. Please discuss your suggested changes.

1. Should the NRC regulate the T&E of physicians for medical uses?
2. Are there requirements in the NRC's T&E regulatory framework for physicians that are non-safety related?

3. How can the NRC transform its regulatory approach for T&E while still ensuring that adequate protection is maintained for workers, the general public, patients, and human research subjects?

Dated at Rockville, Maryland, this 23rd day of October 2018.

For the Nuclear Regulatory
Commission.

/RA/

Daniel S. Collins, Director,
Division of Materials Safety,
Security,
State, and Tribal Programs,
Office of Nuclear Material Safety
and Safeguards.



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

November 2, 2018

Ms. Terri Mosley, MA
Program Coordinator and Advisor
Department of Radiation and Technology
Loma Linda University,
School of Allied Health Professions
Nichol Hall A829
Loma Linda, CA 92350

Via e-mail to tmosley@llu.edu

**SUBJECT: TRAINING AND EXPERIENCE REQUIREMENTS FOR DIFFERENT
CATEGORIES OF RADIOPHARMACEUTICALS**

Dear Ms. Mosley,

The U.S. Nuclear Regulatory Commission (NRC) is evaluating its regulations related to the training and experience (T&E) required for a physician to become an authorized user for medical uses under Subpart E, “Unsealed Byproduct Material—Written Directive Required,” of [Title 10 of the Code of Federal Regulations \(10 CFR\) Part 35, “Medical Use of Byproduct Material.”](#)

The T&E requirements in Subpart E of 10 CFR Part 35 provide three ways that a physician can be authorized to administer unsealed byproduct materials or radiopharmaceuticals requiring a written directive:

1. A physician can be certified by a medical specialty board, whose certification process is recognized by the NRC or an Agreement State.
2. A physician can complete a structured educational program and supervised work experience under an alternate pathway. This alternate pathway includes a requirement for 700 hours of training and experience, which consists of a minimum of 200 hours of classroom and laboratory training and 500 hours of supervised work experience.
3. A physician can be authorized if previously identified as an authorized user on an NRC or Agreement State license or permit (i.e., grandfathered).

In its evaluation of the T&E requirements, the NRC staff is considering whether an additional pathway should be created or if the alternate pathway should be revised. Specifically, the staff is evaluating: (1) whether it makes sense to establish tailored T&E requirements for different categories of radiopharmaceuticals; (2) how those categories should be determined; (3) what the appropriate T&E requirements would be for each category; and (4) whether those requirements should be based on hours of training and experience, or focused more on competency.

On October 29, 2018, the NRC published a series of questions on T&E in the *Federal Register* (83 FR 54380). The *Federal Register* notice is enclosed with this letter and can also be accessed at: <https://www.gpo.gov/fdsys/pkg/FR-2018-10-29/pdf/2018-23521.pdf>. The NRC will carefully consider responses to these questions and would appreciate your feedback on whether changes to the current T&E regulations are warranted. The comment period for the T&E evaluation will end on January 29, 2019. Please follow the directions in the notice on how to submit written comments. The NRC is using the Federal rulemaking Web site, [Regulations.gov](#), to accept written comments on the docket (NRC-2018-0230).

The NRC will also conduct four public meetings scheduled for November 14 and December 11, 2018, and January 10 and January 22, 2019, and will accept oral comments provided during the meetings. The meetings on December 11 and January 10 will be held at NRC Headquarters in Rockville, MD, and all four meetings will be accessible for remote participation by moderated bridge line and webinar. The NRC's public meeting page has been updated with meeting details and registration instructions for each meeting: <https://www.nrc.gov/pmns/mtg>.

Additional information on the NRC's T&E evaluation can be found at: <https://www.nrc.gov/materials/miau/med-use-toolkit/training-experience-evaluation.html>. If you have any questions on this correspondence, please contact Sarah Lopas of my staff at (301) 415-6360 or Sarah.Lopas@nrc.gov.

A handwritten signature in black ink, appearing to read "C Einberg".

Christian Einberg, Chief
Medical Safety and Events Assessment Branch
Division of Materials Safety, Security, State
and Tribal Programs
Office of Nuclear Material Safety
and Safeguards

Enclosure:
Training and Experience
Federal Register notice

NUCLEAR REGULATORY COMMISSION

[NRC-2018-0230]

**Training and Experience Requirements for Different Categories of
Radiopharmaceuticals**

AGENCY: Nuclear Regulatory Commission.

ACTION: Training and experience requirements; request for comment.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is requesting comments on its training and experience (T&E) requirements. Specifically, the NRC would like input on whether it should establish tailored T&E requirements for different categories of radiopharmaceuticals for which a written directive is required in accordance with its regulations. The input will be used to determine whether significant regulatory changes to the NRC's T&E requirements for authorized users (AUs) are warranted.

DATES: Submit comments by January 29, 2019. Comments received after this date will be considered if it is practical to do so, but the NRC is only able to ensure consideration for comments received on or before this date.

ADDRESSES: You may submit comments by any of the following methods:

- **Federal Rulemaking Web Site:** Go to <http://www.regulations.gov>

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- **Mail comments to:** May Ma, Office of Administration, Mail Stop: TWFN-7-A60M, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001.

For additional direction on obtaining information and submitting comments, see “Obtaining Information and Submitting Comments” in the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: Sarah Lopas, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001; telephone: 301-415-6360, e-mail: Sarah.Lopas@nrc.gov.

SUPPLEMENTARY INFORMATION:

I. Obtaining Information and Submitting Comments

A. Obtaining Information

Please refer to Docket ID **NRC-2018-0230** when contacting the NRC about the availability of information for this action. You may obtain publicly-available information related to this action by any of the following methods:

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- **NRC's PDR:** You may examine and purchase copies of public documents at the NRC's PDR, Room O1-F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.

B. Submitting Comments

Please include Docket ID **NRC-2018-0230** in your comment submission.

The NRC cautions you not to include identifying or contact information in comment submissions that you do not want to be publicly disclosed in your comment submission. All comment submissions are posted at <http://www.regulations.gov> and entered into ADAMS. Comment submissions are not routinely edited to remove identifying or contact information.

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specialty board that is not currently recognized by the NRC under 10 CFR 35.390, 35.392, 35.394, or 35.396 (Unsealed Byproduct Material—Written Directive Required).

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 - iii. Competency - How should competency be evaluated? Should a written and/or practical examination by an independent examining committee be administered? Provide a rationale for your answer.
- b. Should a preceptor attestation be required for the fundamental T&E? Provide a rationale for your answer.
- c. Should the radiopharmaceutical manufacturer be able to provide the preceptor attestation? Provide a rational for your answer.

- d. Who should establish and administer the curriculum and examination? Provide specific group(s). [Some options are: NRC, medical specialty boards, medical professional societies, educational professional groups, and NRC in collaboration with any or more of the aforementioned groups.]
- e. Should AU competency be periodically assessed? If so, how should it be assessed, how often, and by whom?

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- 2. Are the current NRC medical specialty board recognition criteria sufficient? If not, what additional criteria should the NRC use?

C. Patient Access

The NRC is requesting comments on whether there is a shortage in the number of AUs for 10 CFR 35.300.

1. Is there a shortage in the number of AUs for medical uses under 10 CFR 35.300? If so, is the shortage associated with the use of a specific radiopharmaceutical? Explain how.
2. Are there certain geographic areas with an inadequate number of AUs? Identify these areas.
3. Do current NRC regulations on AU T&E requirements unnecessarily limit patient access to procedures involving radiopharmaceuticals? Explain how.
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1. Should the NRC regulate the T&E of physicians for medical uses?
2. Are there requirements in the NRC's T&E regulatory framework for physicians that are non-safety related?

3. How can the NRC transform its regulatory approach for T&E while still ensuring that adequate protection is maintained for workers, the general public, patients, and human research subjects?

Dated at Rockville, Maryland, this 23rd day of October 2018.

For the Nuclear Regulatory
Commission.

/RA/

Daniel S. Collins, Director,
Division of Materials Safety,
Security,
State, and Tribal Programs,
Office of Nuclear Material Safety
and Safeguards.



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

November 2, 2018

National Patient Advocate Foundation

Via e-mail to action@npaf.org

SUBJECT: TRAINING AND EXPERIENCE REQUIREMENTS FOR DIFFERENT CATEGORIES OF RADIOPHARMACEUTICALS

Dear Sir or Madam,

The U.S. Nuclear Regulatory Commission (NRC) is evaluating its regulations related to the training and experience (T&E) required for a physician to become an authorized user for medical uses under Subpart E, “Unsealed Byproduct Material—Written Directive Required,” of [Title 10 of the Code of Federal Regulations \(10 CFR\) Part 35, “Medical Use of Byproduct Material.”](#)

The T&E requirements in Subpart E of 10 CFR Part 35 provide three ways that a physician can be authorized to administer unsealed byproduct materials or radiopharmaceuticals requiring a written directive:

1. A physician can be certified by a medical specialty board, whose certification process is recognized by the NRC or an Agreement State.
2. A physician can complete a structured educational program and supervised work experience under an alternate pathway. This alternate pathway includes a requirement for 700 hours of training and experience, which consists of a minimum of 200 hours of classroom and laboratory training and 500 hours of supervised work experience.
3. A physician can be authorized if previously identified as an authorized user on an NRC or Agreement State license or permit (i.e., grandfathered).

In its evaluation of the T&E requirements, the NRC staff is considering whether an additional pathway should be created or if the alternate pathway should be revised. Specifically, the staff is evaluating: (1) whether it makes sense to establish tailored T&E requirements for different categories of radiopharmaceuticals; (2) how those categories should be determined; (3) what the appropriate T&E requirements would be for each category; and (4) whether those requirements should be based on hours of training and experience, or focused more on competency.

On October 29, 2018, the NRC published a series of questions on T&E in the *Federal Register* (83 FR 54380). The *Federal Register* notice is enclosed with this letter and can also be accessed at: <https://www.gpo.gov/fdsys/pkg/FR-2018-10-29/pdf/2018-23521.pdf>. The NRC will carefully consider responses to these questions and would appreciate your feedback on whether changes to the current T&E regulations are warranted. The comment period for the T&E evaluation will end on January 29, 2019. Please follow the directions in the notice on how to submit written comments. The NRC is using the Federal rulemaking Web site, [Regulations.gov](#), to accept written comments on the docket (NRC-2018-0230).

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Additional information on the NRC's T&E evaluation can be found at: <https://www.nrc.gov/materials/miau/med-use-toolkit/training-experience-evaluation.html>. If you have any questions on this correspondence, please contact Sarah Lopas of my staff at (301) 415-6360 or Sarah.Lopas@nrc.gov.



Christian Einberg, Chief
Medical Safety and Events Assessment Branch
Division of Materials Safety, Security, State
and Tribal Programs
Office of Nuclear Material Safety
and Safeguards

Enclosure:
Training and Experience
Federal Register notice

NUCLEAR REGULATORY COMMISSION

[NRC-2018-0230]

**Training and Experience Requirements for Different Categories of
Radiopharmaceuticals**

AGENCY: Nuclear Regulatory Commission.

ACTION: Training and experience requirements; request for comment.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is requesting comments on its training and experience (T&E) requirements. Specifically, the NRC would like input on whether it should establish tailored T&E requirements for different categories of radiopharmaceuticals for which a written directive is required in accordance with its regulations. The input will be used to determine whether significant regulatory changes to the NRC's T&E requirements for authorized users (AUs) are warranted.

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ADDRESSES: You may submit comments by any of the following methods:

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and search for Docket ID **NRC-2018-0230**. Address questions about Docket IDs in Regulations.gov to Jennifer Borges; telephone: 301-287-9127; e-mail: Jennifer.Borges@nrc.gov. For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.

- **Mail comments to:** May Ma, Office of Administration, Mail Stop: TWFN-7-A60M, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001.

For additional direction on obtaining information and submitting comments, see “Obtaining Information and Submitting Comments” in the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: Sarah Lopas, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001; telephone: 301-415-6360, e-mail: Sarah.Lopas@nrc.gov.

SUPPLEMENTARY INFORMATION:

I. Obtaining Information and Submitting Comments

A. Obtaining Information

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radionuclides or by delivery method), (3) what the appropriate T&E requirements would be for each category, and (4) whether those requirements should be based on hours of T&E or focused more on competency. In response to the SRM, the NRC staff documented its initial results, status, and next steps related to this evaluation in SECY-18-0084, "Staff Evaluation of Training and Experience Requirements for Administering Different Categories of Radiopharmaceuticals in Response to SRM-M170817" (ADAMS Accession No. ML18135A276). In SECY-18-0084, the staff concluded that additional outreach with the medical community is needed to determine whether and how to tailor the T&E requirements to establish a limited AU status, the specific T&E requirements that should apply, how the T&E requirements should be met (e.g., hours of training, demonstration of competency), and whether a competency-based approach makes sense for the T&E requirements for all the medical uses authorized under 10 CFR 35.300, "Use of unsealed byproduct material for which a written directive is required."

The NRC is interested in obtaining input from as many stakeholders as possible, including members of the Advisory Committee on the Medical Uses of Isotopes, professional organizations, physicians, patients, patient advocacy groups, licensees, Agreement States, and other interested individuals. The focus of this request is to gather information that will permit the NRC staff to determine whether changes to the T&E requirements are warranted for different categories of radiopharmaceuticals for physicians seeking AU status for the medical use of specific categories of radiopharmaceuticals requiring a written directive under 10 CFR 35.300.

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III. Specific Requests for Comments

A. Tailored Training & Experience Requirements

The NRC is requesting comments on whether it should establish tailored T&E requirements for different categories of radiopharmaceuticals for physicians seeking AU status for the medical use of specific categories of radiopharmaceuticals requiring a written directive under 10 CFR 35.300 (i.e., a limited AU status). This would be for physicians seeking AU status via the alternate non-board certified pathway, and for physicians certified by a medical

specialty board that is not currently recognized by the NRC under 10 CFR 35.390, 35.392, 35.394, or 35.396 (Unsealed Byproduct Material—Written Directive Required).

1. Are the current pathways for obtaining AU status reasonable and accessible? Provide a rationale for your answer.
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3. Should the NRC develop a new tailored T&E pathway for these physicians? If so, what would be the appropriate way to categorize radiopharmaceuticals for tailored T&E requirements? If not, explain why the regulations should remain unchanged. [Some options to categorize radiopharmaceuticals include radiopharmaceuticals with similar delivery methods (oral, parenteral); same type of radiation characteristics or emission (alpha, beta, gamma, low-energy photon); similar preparation method (patient-ready doses); or a combination thereof (e.g., radiopharmaceuticals containing alpha- and beta-emitting radioisotopes that are administered intravenously and are prepared as patient-ready doses).]
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- b. Should a preceptor attestation be required for the fundamental T&E? Provide a rationale for your answer.
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- d. Who should establish and administer the curriculum and examination? Provide specific group(s). [Some options are: NRC, medical specialty boards, medical professional societies, educational professional groups, and NRC in collaboration with any or more of the aforementioned groups.]
- e. Should AU competency be periodically assessed? If so, how should it be assessed, how often, and by whom?

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The NRC is requesting comments on its recognition of medical specialty boards. The NRC's procedures for recognizing medical specialty boards are located on the Medical Uses Licensee Toolkit Web site (<https://www.nrc.gov/materials/miau/med-use-toolkit/certif-process-boards.html>). The NRC staff periodically reviews information to determine a board's continued eligibility for recognition.

- 1. What boards other than those already recognized by the NRC (American Board of Nuclear Medicine [ABNM], American Board of Radiology [ABR], American Osteopathic Board of Radiology [AOBR], Certification Board of Nuclear Endocrinology [CBNE]) could be considered for recognition for medical uses under 10 CFR 35.300?
- 2. Are the current NRC medical specialty board recognition criteria sufficient? If not, what additional criteria should the NRC use?

C. Patient Access

The NRC is requesting comments on whether there is a shortage in the number of AUs for 10 CFR 35.300.

1. Is there a shortage in the number of AUs for medical uses under 10 CFR 35.300? If so, is the shortage associated with the use of a specific radiopharmaceutical? Explain how.
2. Are there certain geographic areas with an inadequate number of AUs? Identify these areas.
3. Do current NRC regulations on AU T&E requirements unnecessarily limit patient access to procedures involving radiopharmaceuticals? Explain how.
4. Do current NRC regulations on AU T&E requirements unnecessarily limit research and development in nuclear medicine? Explain how.

D. Other Suggested Changes to the T&E Regulations

In 2002, the NRC revised its regulatory framework for medical use. The goal was to focus the NRC's regulations on those medical procedures that pose the highest risk to workers, the general public, patients, and human research subjects and to structure the regulations to be more risk-informed and more performance-based. The 2002 rule reduced the unnecessary regulatory burden by either reducing or eliminating the prescriptiveness of some regulations. Instead, the rule provided for a performance-based approach that relied on the training and experience of the AUs, authorized nuclear pharmacists, and radiation safety officers. The NRC is requesting comments on whether there are any other changes to the T&E regulations in 10 CFR part 35 that should be considered. Please discuss your suggested changes.

1. Should the NRC regulate the T&E of physicians for medical uses?
2. Are there requirements in the NRC's T&E regulatory framework for physicians that are non-safety related?

3. How can the NRC transform its regulatory approach for T&E while still ensuring that adequate protection is maintained for workers, the general public, patients, and human research subjects?

Dated at Rockville, Maryland, this 23rd day of October 2018.

For the Nuclear Regulatory
Commission.

/RA/

Daniel S. Collins, Director,
Division of Materials Safety,
Security,
State, and Tribal Programs,
Office of Nuclear Material Safety
and Safeguards.



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

November 2, 2018

Nuclear Medicine Technology Certification Board
3558 Habersham at Northlake Rd.
Tucker, GA 30084-4009

Via e-mail to board@nmtcb.org

**SUBJECT: TRAINING AND EXPERIENCE REQUIREMENTS FOR DIFFERENT
CATEGORIES OF RADIOPHARMACEUTICALS**

Dear Sir or Madam,

The U.S. Nuclear Regulatory Commission (NRC) is evaluating its regulations related to the training and experience (T&E) required for a physician to become an authorized user for medical uses under Subpart E, “Unsealed Byproduct Material—Written Directive Required,” of [Title 10 of the Code of Federal Regulations \(10 CFR\) Part 35, “Medical Use of Byproduct Material.”](#)

The T&E requirements in Subpart E of 10 CFR Part 35 provide three ways that a physician can be authorized to administer unsealed byproduct materials or radiopharmaceuticals requiring a written directive:

1. A physician can be certified by a medical specialty board, whose certification process is recognized by the NRC or an Agreement State.
2. A physician can complete a structured educational program and supervised work experience under an alternate pathway. This alternate pathway includes a requirement for 700 hours of training and experience, which consists of a minimum of 200 hours of classroom and laboratory training and 500 hours of supervised work experience.
3. A physician can be authorized if previously identified as an authorized user on an NRC or Agreement State license or permit (i.e., grandfathered).

In its evaluation of the T&E requirements, the NRC staff is considering whether an additional pathway should be created or if the alternate pathway should be revised. Specifically, the staff is evaluating: (1) whether it makes sense to establish tailored T&E requirements for different categories of radiopharmaceuticals; (2) how those categories should be determined; (3) what the appropriate T&E requirements would be for each category; and (4) whether those requirements should be based on hours of training and experience, or focused more on competency.

On October 29, 2018, the NRC published a series of questions on T&E in the *Federal Register* (83 FR 54380). The *Federal Register* notice is enclosed with this letter and can also be accessed at: <https://www.gpo.gov/fdsys/pkg/FR-2018-10-29/pdf/2018-23521.pdf>. The NRC will carefully consider responses to these questions and would appreciate your feedback on whether changes to the current T&E regulations are warranted. The comment period for the T&E evaluation will end on January 29, 2019. Please follow the directions in the notice on how to submit written comments. The NRC is using the Federal rulemaking Web site, [Regulations.gov](#), to accept written comments on the docket (NRC-2018-0230).

The NRC will also conduct four public meetings scheduled for November 14 and December 11, 2018, and January 10 and January 22, 2019, and will accept oral comments provided during the meetings. The meetings on December 11 and January 10 will be held at NRC Headquarters in Rockville, MD, and all four meetings will be accessible for remote participation by moderated bridge line and webinar. The NRC's public meeting page has been updated with meeting details and registration instructions for each meeting: <https://www.nrc.gov/pmns/mtg>.

Additional information on the NRC's T&E evaluation can be found at: <https://www.nrc.gov/materials/miau/med-use-toolkit/training-experience-evaluation.html>. If you have any questions on this correspondence, please contact Sarah Lopas of my staff at (301) 415-6360 or Sarah.Lopas@nrc.gov.



Christian Einberg, Chief
Medical Safety and Events Assessment Branch
Division of Materials Safety, Security, State
and Tribal Programs
Office of Nuclear Material Safety
and Safeguards

Enclosure:
Training and Experience
Federal Register notice

NUCLEAR REGULATORY COMMISSION

[NRC-2018-0230]

**Training and Experience Requirements for Different Categories of
Radiopharmaceuticals**

AGENCY: Nuclear Regulatory Commission.

ACTION: Training and experience requirements; request for comment.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is requesting comments on its training and experience (T&E) requirements. Specifically, the NRC would like input on whether it should establish tailored T&E requirements for different categories of radiopharmaceuticals for which a written directive is required in accordance with its regulations. The input will be used to determine whether significant regulatory changes to the NRC's T&E requirements for authorized users (AUs) are warranted.

DATES: Submit comments by January 29, 2019. Comments received after this date will be considered if it is practical to do so, but the NRC is only able to ensure consideration for comments received on or before this date.

ADDRESSES: You may submit comments by any of the following methods:

- **Federal Rulemaking Web Site:** Go to <http://www.regulations.gov>

and search for Docket ID **NRC-2018-0230**. Address questions about Docket IDs in Regulations.gov to Jennifer Borges; telephone: 301-287-9127; e-mail: Jennifer.Borges@nrc.gov. For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.

- **Mail comments to:** May Ma, Office of Administration, Mail Stop: TWFN-7-A60M, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001.

For additional direction on obtaining information and submitting comments, see “Obtaining Information and Submitting Comments” in the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: Sarah Lopas, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001; telephone: 301-415-6360, e-mail: Sarah.Lopas@nrc.gov.

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Dated at Rockville, Maryland, this 23rd day of October 2018.

For the Nuclear Regulatory
Commission.

/RA/

Daniel S. Collins, Director,
Division of Materials Safety,
Security,
State, and Tribal Programs,
Office of Nuclear Material Safety
and Safeguards.



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

November 2, 2018

Dr. Mitchell B. Pace, DO, FAOCR
Chair, American Osteopathic Board of Radiology
142 E. Ontario St.
Chicago, IL 60611-2864

Via e-mail to aobr@osteopathic.org

SUBJECT: TRAINING AND EXPERIENCE REQUIREMENTS FOR DIFFERENT CATEGORIES OF RADIOPHARMACEUTICALS

Dear Dr. Pace,

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Christian Einberg, 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:
Training and Experience
Federal Register notice

NUCLEAR REGULATORY COMMISSION

[NRC-2018-0230]

**Training and Experience Requirements for Different Categories of
Radiopharmaceuticals**

AGENCY: Nuclear Regulatory Commission.

ACTION: Training and experience requirements; request for comment.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is requesting comments on its training and experience (T&E) requirements. Specifically, the NRC would like input on whether it should establish tailored T&E requirements for different categories of radiopharmaceuticals for which a written directive is required in accordance with its regulations. The input will be used to determine whether significant regulatory changes to the NRC's T&E requirements for authorized users (AUs) are warranted.

DATES: Submit comments by January 29, 2019. Comments received after this date will be considered if it is practical to do so, but the NRC is only able to ensure consideration for comments received on or before this date.

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and search for Docket ID **NRC-2018-0230**. Address questions about Docket IDs in Regulations.gov to Jennifer Borges; telephone: 301-287-9127; e-mail: Jennifer.Borges@nrc.gov. For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.

- **Mail comments to:** May Ma, Office of Administration, Mail Stop: TWFN-7-A60M, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001.

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FOR FURTHER INFORMATION CONTACT: Sarah Lopas, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001; telephone: 301-415-6360, e-mail: Sarah.Lopas@nrc.gov.

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radionuclides or by delivery method), (3) what the appropriate T&E requirements would be for each category, and (4) whether those requirements should be based on hours of T&E or focused more on competency. In response to the SRM, the NRC staff documented its initial results, status, and next steps related to this evaluation in SECY-18-0084, "Staff Evaluation of Training and Experience Requirements for Administering Different Categories of Radiopharmaceuticals in Response to SRM-M170817" (ADAMS Accession No. ML18135A276). In SECY-18-0084, the staff concluded that additional outreach with the medical community is needed to determine whether and how to tailor the T&E requirements to establish a limited AU status, the specific T&E requirements that should apply, how the T&E requirements should be met (e.g., hours of training, demonstration of competency), and whether a competency-based approach makes sense for the T&E requirements for all the medical uses authorized under 10 CFR 35.300, "Use of unsealed byproduct material for which a written directive is required."

The NRC is interested in obtaining input from as many stakeholders as possible, including members of the Advisory Committee on the Medical Uses of Isotopes, professional organizations, physicians, patients, patient advocacy groups, licensees, Agreement States, and other interested individuals. The focus of this request is to gather information that will permit the NRC staff to determine whether changes to the T&E requirements are warranted for different categories of radiopharmaceuticals for physicians seeking AU status for the medical use of specific categories of radiopharmaceuticals requiring a written directive under 10 CFR 35.300.

During the comment period between October 29, 2018 and January 29, 2019, the NRC will hold four public meetings that will discuss the information being requested and to accept comments on the docket. All four public meetings

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III. Specific Requests for Comments

A. Tailored Training & Experience Requirements

The NRC is requesting comments on whether it should establish tailored T&E requirements for different categories of radiopharmaceuticals for physicians seeking AU status for the medical use of specific categories of radiopharmaceuticals requiring a written directive under 10 CFR 35.300 (i.e., a limited AU status). This would be for physicians seeking AU status via the alternate non-board certified pathway, and for physicians certified by a medical

specialty board that is not currently recognized by the NRC under 10 CFR 35.390, 35.392, 35.394, or 35.396 (Unsealed Byproduct Material—Written Directive Required).

1. Are the current pathways for obtaining AU status reasonable and accessible? Provide a rationale for your answer.
2. Are the current pathways for obtaining AU status adequate for protecting public health and safety? Provide a rationale for your answer.
3. Should the NRC develop a new tailored T&E pathway for these physicians? If so, what would be the appropriate way to categorize radiopharmaceuticals for tailored T&E requirements? If not, explain why the regulations should remain unchanged. [Some options to categorize radiopharmaceuticals include radiopharmaceuticals with similar delivery methods (oral, parenteral); same type of radiation characteristics or emission (alpha, beta, gamma, low-energy photon); similar preparation method (patient-ready doses); or a combination thereof (e.g., radiopharmaceuticals containing alpha- and beta-emitting radioisotopes that are administered intravenously and are prepared as patient-ready doses).]
4. Should the fundamental T&E required of physicians seeking limited AU status need to have the same fundamental T&E required of physicians seeking full AU status for all oral and parenteral administrations under 10 CFR 35.300?
5. How should the requirements for this fundamental T&E be structured for a specific category of radiopharmaceuticals?
 - a. Describe what the requirements should include:

- i. Classroom and laboratory training – What topics need to be covered in this training requirement? How many hours of classroom and laboratory training should be required? Provide the basis for the number of hours. If not hours, explain how this training should be quantified. [Note: The topics currently required in the regulations to be included in the classroom and laboratory training and work experience are listed in 10 CFR 35.390, 35.392, 35.394, and 35.396.]
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 - iii. Competency - How should competency be evaluated? Should a written and/or practical examination by an independent examining committee be administered? Provide a rationale for your answer.
- b. Should a preceptor attestation be required for the fundamental T&E? Provide a rationale for your answer.
- c. Should the radiopharmaceutical manufacturer be able to provide the preceptor attestation? Provide a rational for your answer.

- d. Who should establish and administer the curriculum and examination? Provide specific group(s). [Some options are: NRC, medical specialty boards, medical professional societies, educational professional groups, and NRC in collaboration with any or more of the aforementioned groups.]
- e. Should AU competency be periodically assessed? If so, how should it be assessed, how often, and by whom?

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The NRC is requesting comments on its recognition of medical specialty boards. The NRC's procedures for recognizing medical specialty boards are located on the Medical Uses Licensee Toolkit Web site (<https://www.nrc.gov/materials/miau/med-use-toolkit/certif-process-boards.html>). The NRC staff periodically reviews information to determine a board's continued eligibility for recognition.

- 1. What boards other than those already recognized by the NRC (American Board of Nuclear Medicine [ABNM], American Board of Radiology [ABR], American Osteopathic Board of Radiology [AOBR], Certification Board of Nuclear Endocrinology [CBNE]) could be considered for recognition for medical uses under 10 CFR 35.300?
- 2. Are the current NRC medical specialty board recognition criteria sufficient? If not, what additional criteria should the NRC use?

C. Patient Access

The NRC is requesting comments on whether there is a shortage in the number of AUs for 10 CFR 35.300.

1. Is there a shortage in the number of AUs for medical uses under 10 CFR 35.300? If so, is the shortage associated with the use of a specific radiopharmaceutical? Explain how.
2. Are there certain geographic areas with an inadequate number of AUs? Identify these areas.
3. Do current NRC regulations on AU T&E requirements unnecessarily limit patient access to procedures involving radiopharmaceuticals? Explain how.
4. Do current NRC regulations on AU T&E requirements unnecessarily limit research and development in nuclear medicine? Explain how.

D. Other Suggested Changes to the T&E Regulations

In 2002, the NRC revised its regulatory framework for medical use. The goal was to focus the NRC's regulations on those medical procedures that pose the highest risk to workers, the general public, patients, and human research subjects and to structure the regulations to be more risk-informed and more performance-based. The 2002 rule reduced the unnecessary regulatory burden by either reducing or eliminating the prescriptiveness of some regulations. Instead, the rule provided for a performance-based approach that relied on the training and experience of the AUs, authorized nuclear pharmacists, and radiation safety officers. The NRC is requesting comments on whether there are any other changes to the T&E regulations in 10 CFR part 35 that should be considered. Please discuss your suggested changes.

1. Should the NRC regulate the T&E of physicians for medical uses?
2. Are there requirements in the NRC's T&E regulatory framework for physicians that are non-safety related?

3. How can the NRC transform its regulatory approach for T&E while still ensuring that adequate protection is maintained for workers, the general public, patients, and human research subjects?

Dated at Rockville, Maryland, this 23rd day of October 2018.

For the Nuclear Regulatory
Commission.

/RA/

Daniel S. Collins, Director,
Division of Materials Safety,
Security,
State, and Tribal Programs,
Office of Nuclear Material Safety
and Safeguards.



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

November 2, 2018

Dr. Gerhild Packert, Ph.D.
Department of Medical Technology
College of Nursing and Health Sciences, Barry University
11300 NE 2nd Ave.
Miami Shores, FL 33161-6695

Via e-mail to alliedhealth@barry.edu

SUBJECT: TRAINING AND EXPERIENCE REQUIREMENTS FOR DIFFERENT CATEGORIES OF RADIOPHARMACEUTICALS

Dear Dr. Packert,

The U.S. Nuclear Regulatory Commission (NRC) is evaluating its regulations related to the training and experience (T&E) required for a physician to become an authorized user for medical uses under Subpart E, “Unsealed Byproduct Material—Written Directive Required,” of [Title 10 of the Code of Federal Regulations \(10 CFR\) Part 35, “Medical Use of Byproduct Material.”](#)

The T&E requirements in Subpart E of 10 CFR Part 35 provide three ways that a physician can be authorized to administer unsealed byproduct materials or radiopharmaceuticals requiring a written directive:

1. A physician can be certified by a medical specialty board, whose certification process is recognized by the NRC or an Agreement State.
2. A physician can complete a structured educational program and supervised work experience under an alternate pathway. This alternate pathway includes a requirement for 700 hours of training and experience, which consists of a minimum of 200 hours of classroom and laboratory training and 500 hours of supervised work experience.
3. A physician can be authorized if previously identified as an authorized user on an NRC or Agreement State license or permit (i.e., grandfathered).

In its evaluation of the T&E requirements, the NRC staff is considering whether an additional pathway should be created or if the alternate pathway should be revised. Specifically, the staff is evaluating: (1) whether it makes sense to establish tailored T&E requirements for different categories of radiopharmaceuticals; (2) how those categories should be determined; (3) what the appropriate T&E requirements would be for each category; and (4) whether those requirements should be based on hours of training and experience, or focused more on competency.

On October 29, 2018, the NRC published a series of questions on T&E in the *Federal Register* (83 FR 54380). The *Federal Register* notice is enclosed with this letter and can also be accessed at: <https://www.gpo.gov/fdsys/pkg/FR-2018-10-29/pdf/2018-23521.pdf>. The NRC will carefully consider responses to these questions and would appreciate your feedback on whether changes to the current T&E regulations are warranted. The comment period for the T&E evaluation will end on January 29, 2019. Please follow the directions in the notice on how to submit written comments. The NRC is using the Federal rulemaking Web site, [Regulations.gov](#), to accept written comments on the docket (NRC-2018-0230).

The NRC will also conduct four public meetings scheduled for November 14 and December 11, 2018, and January 10 and January 22, 2019, and will accept oral comments provided during the meetings. The meetings on December 11 and January 10 will be held at NRC Headquarters in Rockville, MD, and all four meetings will be accessible for remote participation by moderated bridge line and webinar. The NRC's public meeting page has been updated with meeting details and registration instructions for each meeting: <https://www.nrc.gov/pmns/mtg>.

Additional information on the NRC's T&E evaluation can be found at: <https://www.nrc.gov/materials/miau/med-use-toolkit/training-experience-evaluation.html>. If you have any questions on this correspondence, please contact Sarah Lopas of my staff at (301) 415-6360 or Sarah.Lopas@nrc.gov.

A handwritten signature in black ink, appearing to read "C Einberg".

Christian Einberg, Chief
Medical Safety and Events Assessment Branch
Division of Materials Safety, Security, State
and Tribal Programs
Office of Nuclear Material Safety
and Safeguards

Enclosure:
Training and Experience
Federal Register notice

NUCLEAR REGULATORY COMMISSION

[NRC-2018-0230]

**Training and Experience Requirements for Different Categories of
Radiopharmaceuticals**

AGENCY: Nuclear Regulatory Commission.

ACTION: Training and experience requirements; request for comment.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is requesting comments on its training and experience (T&E) requirements. Specifically, the NRC would like input on whether it should establish tailored T&E requirements for different categories of radiopharmaceuticals for which a written directive is required in accordance with its regulations. The input will be used to determine whether significant regulatory changes to the NRC's T&E requirements for authorized users (AUs) are warranted.

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Dated at Rockville, Maryland, this 23rd day of October 2018.

For the Nuclear Regulatory
Commission.

/RA/

Daniel S. Collins, Director,
Division of Materials Safety,
Security,
State, and Tribal Programs,
Office of Nuclear Material Safety
and Safeguards.



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

November 2, 2018

Dr. Miguel Hernandez Pampaloni, MD
Associate Professor,
Chief of Nuclear Medicine
Director, Nuclear Medicine Residency
& Fellowship Programs
University of California San Francisco
505 Parnassus Ave.
San Francisco, CA 94117

Via e-mail to Miguel.Pampaloni@ucsf.edu

**SUBJECT: TRAINING AND EXPERIENCE REQUIREMENTS FOR DIFFERENT
CATEGORIES OF RADIOPHARMACEUTICALS**

Dear Dr. Pampaloni,

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On October 29, 2018, the NRC published a series of questions on T&E in the *Federal Register* (83 FR 54380). The *Federal Register* notice is enclosed with this letter and can also be accessed at: <https://www.gpo.gov/fdsys/pkg/FR-2018-10-29/pdf/2018-23521.pdf>. The NRC will carefully consider responses to these questions and would appreciate your feedback on whether changes to the current T&E regulations are warranted. The comment period for the T&E evaluation will end on January 29, 2019. Please follow the directions in the notice on how to submit written comments. The NRC is using the Federal rulemaking Web site, [Regulations.gov](#), to accept written comments on the docket (NRC-2018-0230).

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Christian Einberg, Chief
Medical Safety and Events Assessment Branch
Division of Materials Safety, Security, State
and Tribal Programs
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Enclosure:
Training and Experience
Federal Register notice

NUCLEAR REGULATORY COMMISSION

[NRC-2018-0230]

**Training and Experience Requirements for Different Categories of
Radiopharmaceuticals**

AGENCY: Nuclear Regulatory Commission.

ACTION: Training and experience requirements; request for comment.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is requesting comments on its training and experience (T&E) requirements. Specifically, the NRC would like input on whether it should establish tailored T&E requirements for different categories of radiopharmaceuticals for which a written directive is required in accordance with its regulations. The input will be used to determine whether significant regulatory changes to the NRC's T&E requirements for authorized users (AUs) are warranted.

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The NRC is interested in obtaining input from as many stakeholders as possible, including members of the Advisory Committee on the Medical Uses of Isotopes, professional organizations, physicians, patients, patient advocacy groups, licensees, Agreement States, and other interested individuals. The focus of this request is to gather information that will permit the NRC staff to determine whether changes to the T&E requirements are warranted for different categories of radiopharmaceuticals for physicians seeking AU status for the medical use of specific categories of radiopharmaceuticals requiring a written directive under 10 CFR 35.300.

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III. Specific Requests for Comments

A. Tailored Training & Experience Requirements

The NRC is requesting comments on whether it should establish tailored T&E requirements for different categories of radiopharmaceuticals for physicians seeking AU status for the medical use of specific categories of radiopharmaceuticals requiring a written directive under 10 CFR 35.300 (i.e., a limited AU status). This would be for physicians seeking AU status via the alternate non-board certified pathway, and for physicians certified by a medical

specialty board that is not currently recognized by the NRC under 10 CFR 35.390, 35.392, 35.394, or 35.396 (Unsealed Byproduct Material—Written Directive Required).

1. Are the current pathways for obtaining AU status reasonable and accessible? Provide a rationale for your answer.
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3. Should the NRC develop a new tailored T&E pathway for these physicians? If so, what would be the appropriate way to categorize radiopharmaceuticals for tailored T&E requirements? If not, explain why the regulations should remain unchanged. [Some options to categorize radiopharmaceuticals include radiopharmaceuticals with similar delivery methods (oral, parenteral); same type of radiation characteristics or emission (alpha, beta, gamma, low-energy photon); similar preparation method (patient-ready doses); or a combination thereof (e.g., radiopharmaceuticals containing alpha- and beta-emitting radioisotopes that are administered intravenously and are prepared as patient-ready doses).]
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5. How should the requirements for this fundamental T&E be structured for a specific category of radiopharmaceuticals?
 - a. Describe what the requirements should include:

- i. Classroom and laboratory training – What topics need to be covered in this training requirement? How many hours of classroom and laboratory training should be required? Provide the basis for the number of hours. If not hours, explain how this training should be quantified. [Note: The topics currently required in the regulations to be included in the classroom and laboratory training and work experience are listed in 10 CFR 35.390, 35.392, 35.394, and 35.396.]
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 - iii. Competency - How should competency be evaluated? Should a written and/or practical examination by an independent examining committee be administered? Provide a rationale for your answer.
- b. Should a preceptor attestation be required for the fundamental T&E? Provide a rationale for your answer.
- c. Should the radiopharmaceutical manufacturer be able to provide the preceptor attestation? Provide a rational for your answer.

- d. Who should establish and administer the curriculum and examination? Provide specific group(s). [Some options are: NRC, medical specialty boards, medical professional societies, educational professional groups, and NRC in collaboration with any or more of the aforementioned groups.]
- e. Should AU competency be periodically assessed? If so, how should it be assessed, how often, and by whom?

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The NRC is requesting comments on its recognition of medical specialty boards. The NRC's procedures for recognizing medical specialty boards are located on the Medical Uses Licensee Toolkit Web site (<https://www.nrc.gov/materials/miau/med-use-toolkit/certif-process-boards.html>). The NRC staff periodically reviews information to determine a board's continued eligibility for recognition.

- 1. What boards other than those already recognized by the NRC (American Board of Nuclear Medicine [ABNM], American Board of Radiology [ABR], American Osteopathic Board of Radiology [AOBR], Certification Board of Nuclear Endocrinology [CBNE]) could be considered for recognition for medical uses under 10 CFR 35.300?
- 2. Are the current NRC medical specialty board recognition criteria sufficient? If not, what additional criteria should the NRC use?

C. Patient Access

The NRC is requesting comments on whether there is a shortage in the number of AUs for 10 CFR 35.300.

1. Is there a shortage in the number of AUs for medical uses under 10 CFR 35.300? If so, is the shortage associated with the use of a specific radiopharmaceutical? Explain how.
2. Are there certain geographic areas with an inadequate number of AUs? Identify these areas.
3. Do current NRC regulations on AU T&E requirements unnecessarily limit patient access to procedures involving radiopharmaceuticals? Explain how.
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D. Other Suggested Changes to the T&E Regulations

In 2002, the NRC revised its regulatory framework for medical use. The goal was to focus the NRC's regulations on those medical procedures that pose the highest risk to workers, the general public, patients, and human research subjects and to structure the regulations to be more risk-informed and more performance-based. The 2002 rule reduced the unnecessary regulatory burden by either reducing or eliminating the prescriptiveness of some regulations. Instead, the rule provided for a performance-based approach that relied on the training and experience of the AUs, authorized nuclear pharmacists, and radiation safety officers. The NRC is requesting comments on whether there are any other changes to the T&E regulations in 10 CFR part 35 that should be considered. Please discuss your suggested changes.

1. Should the NRC regulate the T&E of physicians for medical uses?
2. Are there requirements in the NRC's T&E regulatory framework for physicians that are non-safety related?

3. How can the NRC transform its regulatory approach for T&E while still ensuring that adequate protection is maintained for workers, the general public, patients, and human research subjects?

Dated at Rockville, Maryland, this 23rd day of October 2018.

For the Nuclear Regulatory
Commission.

/RA/

Daniel S. Collins, Director,
Division of Materials Safety,
Security,
State, and Tribal Programs,
Office of Nuclear Material Safety
and Safeguards.



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

November 2, 2018

Pancreatic Cancer Action Network
1050 Connecticut Ave. NW, Suite 500
Washington, DC 20036

Via e-mail to info@pancan.org

SUBJECT: TRAINING AND EXPERIENCE REQUIREMENTS FOR DIFFERENT CATEGORIES OF RADIOPHARMACEUTICALS

Dear Sir or Madam,

The U.S. Nuclear Regulatory Commission (NRC) is evaluating its regulations related to the training and experience (T&E) required for a physician to become an authorized user for medical uses under Subpart E, “Unsealed Byproduct Material—Written Directive Required,” of [Title 10 of the Code of Federal Regulations \(10 CFR\) Part 35, “Medical Use of Byproduct Material.”](#)

The T&E requirements in Subpart E of 10 CFR Part 35 provide three ways that a physician can be authorized to administer unsealed byproduct materials or radiopharmaceuticals requiring a written directive:

1. A physician can be certified by a medical specialty board, whose certification process is recognized by the NRC or an Agreement State.
2. A physician can complete a structured educational program and supervised work experience under an alternate pathway. This alternate pathway includes a requirement for 700 hours of training and experience, which consists of a minimum of 200 hours of classroom and laboratory training and 500 hours of supervised work experience.
3. A physician can be authorized if previously identified as an authorized user on an NRC or Agreement State license or permit (i.e., grandfathered).

In its evaluation of the T&E requirements, the NRC staff is considering whether an additional pathway should be created or if the alternate pathway should be revised. Specifically, the staff is evaluating: (1) whether it makes sense to establish tailored T&E requirements for different categories of radiopharmaceuticals; (2) how those categories should be determined; (3) what the appropriate T&E requirements would be for each category; and (4) whether those requirements should be based on hours of training and experience, or focused more on competency.

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Christian Einberg, Chief
Medical Safety and Events Assessment Branch
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Enclosure:
Training and Experience
Federal Register notice

NUCLEAR REGULATORY COMMISSION

[NRC-2018-0230]

**Training and Experience Requirements for Different Categories of
Radiopharmaceuticals**

AGENCY: Nuclear Regulatory Commission.

ACTION: Training and experience requirements; request for comment.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is requesting comments on its training and experience (T&E) requirements. Specifically, the NRC would like input on whether it should establish tailored T&E requirements for different categories of radiopharmaceuticals for which a written directive is required in accordance with its regulations. The input will be used to determine whether significant regulatory changes to the NRC's T&E requirements for authorized users (AUs) are warranted.

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Dated at Rockville, Maryland, this 23rd day of October 2018.

For the Nuclear Regulatory
Commission.

/RA/

Daniel S. Collins, Director,
Division of Materials Safety,
Security,
State, and Tribal Programs,
Office of Nuclear Material Safety
and Safeguards.



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

November 2, 2018

Baptist Health College Little Rock
School of Nuclear Medicine Technology
11900 Colonel Glenn Road
Little Rock, AR 72210-2820

SUBJECT: TRAINING AND EXPERIENCE REQUIREMENTS FOR DIFFERENT CATEGORIES OF RADIOPHARMACEUTICALS

Dear Sir or Madam,

The U.S. Nuclear Regulatory Commission (NRC) is evaluating its regulations related to the training and experience (T&E) required for a physician to become an authorized user for medical uses under Subpart E, “Unsealed Byproduct Material—Written Directive Required,” of [Title 10 of the Code of Federal Regulations \(10 CFR\) Part 35, “Medical Use of Byproduct Material.”](#)

The T&E requirements in Subpart E of 10 CFR Part 35 provide three ways that a physician can be authorized to administer unsealed byproduct materials or radiopharmaceuticals requiring a written directive:

1. A physician can be certified by a medical specialty board, whose certification process is recognized by the NRC or an Agreement State.
2. A physician can complete a structured educational program and supervised work experience under an alternate pathway. This alternate pathway includes a requirement for 700 hours of training and experience, which consists of a minimum of 200 hours of classroom and laboratory training and 500 hours of supervised work experience.
3. A physician can be authorized if previously identified as an authorized user on an NRC or Agreement State license or permit (i.e., grandfathered).

In its evaluation of the T&E requirements, the NRC staff is considering whether an additional pathway should be created or if the alternate pathway should be revised. Specifically, the staff is evaluating: (1) whether it makes sense to establish tailored T&E requirements for different categories of radiopharmaceuticals; (2) how those categories should be determined; (3) what the appropriate T&E requirements would be for each category; and (4) whether those requirements should be based on hours of training and experience, or focused more on competency.

On October 29, 2018, the NRC published a series of questions on T&E in the *Federal Register* (83 FR 54380). The *Federal Register* notice is enclosed with this letter and can also be accessed at: <https://www.gpo.gov/fdsys/pkg/FR-2018-10-29/pdf/2018-23521.pdf>. The NRC will carefully consider responses to these questions and would appreciate your feedback on whether changes to the current T&E regulations are warranted. The comment period for the T&E evaluation will end on January 29, 2019. Please follow the directions in the notice on how to submit written comments. The NRC is using the Federal rulemaking Web site, [Regulations.gov](#), to accept written comments on the docket (NRC-2018-0230).

The NRC will also conduct four public meetings scheduled for November 14 and December 11, 2018, and January 10 and January 22, 2019, and will accept oral comments provided during the meetings. The meetings on December 11 and January 10 will be held at NRC Headquarters in Rockville, MD, and all four meetings will be accessible for remote participation by moderated bridge line and webinar. The NRC's public meeting page has been updated with meeting details and registration instructions for each meeting: <https://www.nrc.gov/pmns/mtg>.

Additional information on the NRC's T&E evaluation can be found at: <https://www.nrc.gov/materials/miau/med-use-toolkit/training-experience-evaluation.html>. If you have any questions on this correspondence, please contact Sarah Lopas of my staff at (301) 415-6360 or Sarah.Lopas@nrc.gov.

A handwritten signature in black ink, appearing to read "C Einberg".

Christian Einberg, Chief
Medical Safety and Events Assessment Branch
Division of Materials Safety, Security, State
and Tribal Programs
Office of Nuclear Material Safety
and Safeguards

Enclosure:
Training and Experience
Federal Register notice

NUCLEAR REGULATORY COMMISSION

[NRC-2018-0230]

**Training and Experience Requirements for Different Categories of
Radiopharmaceuticals**

AGENCY: Nuclear Regulatory Commission.

ACTION: Training and experience requirements; request for comment.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is requesting comments on its training and experience (T&E) requirements. Specifically, the NRC would like input on whether it should establish tailored T&E requirements for different categories of radiopharmaceuticals for which a written directive is required in accordance with its regulations. The input will be used to determine whether significant regulatory changes to the NRC's T&E requirements for authorized users (AUs) are warranted.

DATES: Submit comments by January 29, 2019. Comments received after this date will be considered if it is practical to do so, but the NRC is only able to ensure consideration for comments received on or before this date.

ADDRESSES: You may submit comments by any of the following methods:

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B. Submitting Comments

Please include Docket ID **NRC-2018-0230** in your comment submission.

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The NRC is interested in obtaining input from as many stakeholders as possible, including members of the Advisory Committee on the Medical Uses of Isotopes, professional organizations, physicians, patients, patient advocacy groups, licensees, Agreement States, and other interested individuals. The focus of this request is to gather information that will permit the NRC staff to determine whether changes to the T&E requirements are warranted for different categories of radiopharmaceuticals for physicians seeking AU status for the medical use of specific categories of radiopharmaceuticals requiring a written directive under 10 CFR 35.300.

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III. Specific Requests for Comments

A. Tailored Training & Experience Requirements

The NRC is requesting comments on whether it should establish tailored T&E requirements for different categories of radiopharmaceuticals for physicians seeking AU status for the medical use of specific categories of radiopharmaceuticals requiring a written directive under 10 CFR 35.300 (i.e., a limited AU status). This would be for physicians seeking AU status via the alternate non-board certified pathway, and for physicians certified by a medical

specialty board that is not currently recognized by the NRC under 10 CFR 35.390, 35.392, 35.394, or 35.396 (Unsealed Byproduct Material—Written Directive Required).

1. Are the current pathways for obtaining AU status reasonable and accessible? Provide a rationale for your answer.
2. Are the current pathways for obtaining AU status adequate for protecting public health and safety? Provide a rationale for your answer.
3. Should the NRC develop a new tailored T&E pathway for these physicians? If so, what would be the appropriate way to categorize radiopharmaceuticals for tailored T&E requirements? If not, explain why the regulations should remain unchanged. [Some options to categorize radiopharmaceuticals include radiopharmaceuticals with similar delivery methods (oral, parenteral); same type of radiation characteristics or emission (alpha, beta, gamma, low-energy photon); similar preparation method (patient-ready doses); or a combination thereof (e.g., radiopharmaceuticals containing alpha- and beta-emitting radioisotopes that are administered intravenously and are prepared as patient-ready doses).]
4. Should the fundamental T&E required of physicians seeking limited AU status need to have the same fundamental T&E required of physicians seeking full AU status for all oral and parenteral administrations under 10 CFR 35.300?
5. How should the requirements for this fundamental T&E be structured for a specific category of radiopharmaceuticals?
 - a. Describe what the requirements should include:

- i. Classroom and laboratory training – What topics need to be covered in this training requirement? How many hours of classroom and laboratory training should be required? Provide the basis for the number of hours. If not hours, explain how this training should be quantified. [Note: The topics currently required in the regulations to be included in the classroom and laboratory training and work experience are listed in 10 CFR 35.390, 35.392, 35.394, and 35.396.]
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 - iii. Competency - How should competency be evaluated? Should a written and/or practical examination by an independent examining committee be administered? Provide a rationale for your answer.
- b. Should a preceptor attestation be required for the fundamental T&E? Provide a rationale for your answer.
- c. Should the radiopharmaceutical manufacturer be able to provide the preceptor attestation? Provide a rational for your answer.

- d. Who should establish and administer the curriculum and examination? Provide specific group(s). [Some options are: NRC, medical specialty boards, medical professional societies, educational professional groups, and NRC in collaboration with any or more of the aforementioned groups.]
- e. Should AU competency be periodically assessed? If so, how should it be assessed, how often, and by whom?

B. NRC's Recognition of Medical Specialty Boards

The NRC is requesting comments on its recognition of medical specialty boards. The NRC's procedures for recognizing medical specialty boards are located on the Medical Uses Licensee Toolkit Web site (<https://www.nrc.gov/materials/miau/med-use-toolkit/certif-process-boards.html>). The NRC staff periodically reviews information to determine a board's continued eligibility for recognition.

- 1. What boards other than those already recognized by the NRC (American Board of Nuclear Medicine [ABNM], American Board of Radiology [ABR], American Osteopathic Board of Radiology [AOBR], Certification Board of Nuclear Endocrinology [CBNE]) could be considered for recognition for medical uses under 10 CFR 35.300?
- 2. Are the current NRC medical specialty board recognition criteria sufficient? If not, what additional criteria should the NRC use?

C. Patient Access

The NRC is requesting comments on whether there is a shortage in the number of AUs for 10 CFR 35.300.

1. Is there a shortage in the number of AUs for medical uses under 10 CFR 35.300? If so, is the shortage associated with the use of a specific radiopharmaceutical? Explain how.
2. Are there certain geographic areas with an inadequate number of AUs? Identify these areas.
3. Do current NRC regulations on AU T&E requirements unnecessarily limit patient access to procedures involving radiopharmaceuticals? Explain how.
4. Do current NRC regulations on AU T&E requirements unnecessarily limit research and development in nuclear medicine? Explain how.

D. Other Suggested Changes to the T&E Regulations

In 2002, the NRC revised its regulatory framework for medical use. The goal was to focus the NRC's regulations on those medical procedures that pose the highest risk to workers, the general public, patients, and human research subjects and to structure the regulations to be more risk-informed and more performance-based. The 2002 rule reduced the unnecessary regulatory burden by either reducing or eliminating the prescriptiveness of some regulations. Instead, the rule provided for a performance-based approach that relied on the training and experience of the AUs, authorized nuclear pharmacists, and radiation safety officers. The NRC is requesting comments on whether there are any other changes to the T&E regulations in 10 CFR part 35 that should be considered. Please discuss your suggested changes.

1. Should the NRC regulate the T&E of physicians for medical uses?
2. Are there requirements in the NRC's T&E regulatory framework for physicians that are non-safety related?

3. How can the NRC transform its regulatory approach for T&E while still ensuring that adequate protection is maintained for workers, the general public, patients, and human research subjects?

Dated at Rockville, Maryland, this 23rd day of October 2018.

For the Nuclear Regulatory
Commission.

/RA/

Daniel S. Collins, Director,
Division of Materials Safety,
Security,
State, and Tribal Programs,
Office of Nuclear Material Safety
and Safeguards.



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

November 2, 2018

Dr. Eric A. Orzeck, MD, FACP, FACE
Chair, Certification Board of Nuclear Endocrinology
245 Riverside Ave., Suite 200
Jacksonville, FL 32202

**SUBJECT: TRAINING AND EXPERIENCE REQUIREMENTS FOR DIFFERENT
CATEGORIES OF RADIOPHARMACEUTICALS**

Dear Dr. Orzeck,

The U.S. Nuclear Regulatory Commission (NRC) is evaluating its regulations related to the training and experience (T&E) required for a physician to become an authorized user for medical uses under Subpart E, “Unsealed Byproduct Material—Written Directive Required,” of [Title 10 of the Code of Federal Regulations \(10 CFR\) Part 35, “Medical Use of Byproduct Material.”](#)

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Christian Einberg, Chief
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Enclosure:
Training and Experience
Federal Register notice

NUCLEAR REGULATORY COMMISSION

[NRC-2018-0230]

**Training and Experience Requirements for Different Categories of
Radiopharmaceuticals**

AGENCY: Nuclear Regulatory Commission.

ACTION: Training and experience requirements; request for comment.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is requesting comments on its training and experience (T&E) requirements. Specifically, the NRC would like input on whether it should establish tailored T&E requirements for different categories of radiopharmaceuticals for which a written directive is required in accordance with its regulations. The input will be used to determine whether significant regulatory changes to the NRC's T&E requirements for authorized users (AUs) are warranted.

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C. Patient Access

The NRC is requesting comments on whether there is a shortage in the number of AUs for 10 CFR 35.300.

1. Is there a shortage in the number of AUs for medical uses under 10 CFR 35.300? If so, is the shortage associated with the use of a specific radiopharmaceutical? Explain how.
2. Are there certain geographic areas with an inadequate number of AUs? Identify these areas.
3. Do current NRC regulations on AU T&E requirements unnecessarily limit patient access to procedures involving radiopharmaceuticals? Explain how.
4. Do current NRC regulations on AU T&E requirements unnecessarily limit research and development in nuclear medicine? Explain how.

D. Other Suggested Changes to the T&E Regulations

In 2002, the NRC revised its regulatory framework for medical use. The goal was to focus the NRC's regulations on those medical procedures that pose the highest risk to workers, the general public, patients, and human research subjects and to structure the regulations to be more risk-informed and more performance-based. The 2002 rule reduced the unnecessary regulatory burden by either reducing or eliminating the prescriptiveness of some regulations. Instead, the rule provided for a performance-based approach that relied on the training and experience of the AUs, authorized nuclear pharmacists, and radiation safety officers. The NRC is requesting comments on whether there are any other changes to the T&E regulations in 10 CFR part 35 that should be considered. Please discuss your suggested changes.

1. Should the NRC regulate the T&E of physicians for medical uses?
2. Are there requirements in the NRC's T&E regulatory framework for physicians that are non-safety related?

3. How can the NRC transform its regulatory approach for T&E while still ensuring that adequate protection is maintained for workers, the general public, patients, and human research subjects?

Dated at Rockville, Maryland, this 23rd day of October 2018.

For the Nuclear Regulatory
Commission.

/RA/

Daniel S. Collins, Director,
Division of Materials Safety,
Security,
State, and Tribal Programs,
Office of Nuclear Material Safety
and Safeguards.



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

November 2, 2018

American Association of Nurse Practitioners
Office of Government Affairs
1400 Crystal Drive, Suite 540
Alexandria, VA 22202

SUBJECT: TRAINING AND EXPERIENCE REQUIREMENTS FOR DIFFERENT CATEGORIES OF RADIOPHARMACEUTICALS

Dear Sir or Madam,

The U.S. Nuclear Regulatory Commission (NRC) is evaluating its regulations related to the training and experience (T&E) required for a physician to become an authorized user for medical uses under Subpart E, “Unsealed Byproduct Material—Written Directive Required,” of [Title 10 of the Code of Federal Regulations \(10 CFR\) Part 35, “Medical Use of Byproduct Material.”](#)

The T&E requirements in Subpart E of 10 CFR Part 35 provide three ways that a physician can be authorized to administer unsealed byproduct materials or radiopharmaceuticals requiring a written directive:

1. A physician can be certified by a medical specialty board, whose certification process is recognized by the NRC or an Agreement State.
2. A physician can complete a structured educational program and supervised work experience under an alternate pathway. This alternate pathway includes a requirement for 700 hours of training and experience, which consists of a minimum of 200 hours of classroom and laboratory training and 500 hours of supervised work experience.
3. A physician can be authorized if previously identified as an authorized user on an NRC or Agreement State license or permit (i.e., grandfathered).

In its evaluation of the T&E requirements, the NRC staff is considering whether an additional pathway should be created or if the alternate pathway should be revised. Specifically, the staff is evaluating: (1) whether it makes sense to establish tailored T&E requirements for different categories of radiopharmaceuticals; (2) how those categories should be determined; (3) what the appropriate T&E requirements would be for each category; and (4) whether those requirements should be based on hours of training and experience, or focused more on competency.

On October 29, 2018, the NRC published a series of questions on T&E in the *Federal Register* (83 FR 54380). The *Federal Register* notice is enclosed with this letter and can also be accessed at: <https://www.gpo.gov/fdsys/pkg/FR-2018-10-29/pdf/2018-23521.pdf>. The NRC will carefully consider responses to these questions and would appreciate your feedback on whether changes to the current T&E regulations are warranted. The comment period for the T&E evaluation will end on January 29, 2019. Please follow the directions in the notice on how to submit written comments. The NRC is using the Federal rulemaking Web site, [Regulations.gov](#), to accept written comments on the docket (NRC-2018-0230).

The NRC will also conduct four public meetings scheduled for November 14 and December 11, 2018, and January 10 and January 22, 2019, and will accept oral comments provided during the meetings. The meetings on December 11 and January 10 will be held at NRC Headquarters in Rockville, MD, and all four meetings will be accessible for remote participation by moderated bridge line and webinar. The NRC's public meeting page has been updated with meeting details and registration instructions for each meeting: <https://www.nrc.gov/pmns/mtg>.

Additional information on the NRC's T&E evaluation can be found at: <https://www.nrc.gov/materials/miau/med-use-toolkit/training-experience-evaluation.html>. If you have any questions on this correspondence, please contact Sarah Lopas of my staff at (301) 415-6360 or Sarah.Lopas@nrc.gov.



Christian Einberg, Chief
Medical Safety and Events Assessment Branch
Division of Materials Safety, Security, State
and Tribal Programs
Office of Nuclear Material Safety
and Safeguards

Enclosure:
Training and Experience
Federal Register notice

NUCLEAR REGULATORY COMMISSION

[NRC-2018-0230]

**Training and Experience Requirements for Different Categories of
Radiopharmaceuticals**

AGENCY: Nuclear Regulatory Commission.

ACTION: Training and experience requirements; request for comment.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is requesting comments on its training and experience (T&E) requirements. Specifically, the NRC would like input on whether it should establish tailored T&E requirements for different categories of radiopharmaceuticals for which a written directive is required in accordance with its regulations. The input will be used to determine whether significant regulatory changes to the NRC's T&E requirements for authorized users (AUs) are warranted.

DATES: Submit comments by January 29, 2019. Comments received after this date will be considered if it is practical to do so, but the NRC is only able to ensure consideration for comments received on or before this date.

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FOR FURTHER INFORMATION CONTACT: Sarah Lopas, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001; telephone: 301-415-6360, e-mail: Sarah.Lopas@nrc.gov.

SUPPLEMENTARY INFORMATION:

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B. Submitting Comments

Please include Docket ID **NRC-2018-0230** in your comment submission.

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radionuclides or by delivery method), (3) what the appropriate T&E requirements would be for each category, and (4) whether those requirements should be based on hours of T&E or focused more on competency. In response to the SRM, the NRC staff documented its initial results, status, and next steps related to this evaluation in SECY-18-0084, "Staff Evaluation of Training and Experience Requirements for Administering Different Categories of Radiopharmaceuticals in Response to SRM-M170817" (ADAMS Accession No. ML18135A276). In SECY-18-0084, the staff concluded that additional outreach with the medical community is needed to determine whether and how to tailor the T&E requirements to establish a limited AU status, the specific T&E requirements that should apply, how the T&E requirements should be met (e.g., hours of training, demonstration of competency), and whether a competency-based approach makes sense for the T&E requirements for all the medical uses authorized under 10 CFR 35.300, "Use of unsealed byproduct material for which a written directive is required."

The NRC is interested in obtaining input from as many stakeholders as possible, including members of the Advisory Committee on the Medical Uses of Isotopes, professional organizations, physicians, patients, patient advocacy groups, licensees, Agreement States, and other interested individuals. The focus of this request is to gather information that will permit the NRC staff to determine whether changes to the T&E requirements are warranted for different categories of radiopharmaceuticals for physicians seeking AU status for the medical use of specific categories of radiopharmaceuticals requiring a written directive under 10 CFR 35.300.

During the comment period between October 29, 2018 and January 29, 2019, the NRC will hold four public meetings that will discuss the information being requested and to accept comments on the docket. All four public meetings

will be available for remote participation by moderated bridge line and webinar, and two of the four meetings will be open for in-person attendance at NRC's headquarters in Rockville, Maryland.

The public meetings are scheduled for November 14, 2018 (webinar-only); December 11, 2018 (webinar and in-person attendance); January 10, 2019 (webinar and in-person attendance); and January 22, 2019 (webinar-only). The public meetings will be noticed on the NRC's public meeting Web site at least 10 calendar days before the meeting. Members of the public should monitor the NRC's public meeting Web site at <https://www.nrc.gov/pmns/mtg>. The NRC will also post the meeting notices on the Federal Rulemaking Web site at <https://www.regulations.gov/> under Docket ID **NRC-2018-0230**.

The NRC may post additional materials related to this document, including public comments, on the Federal Rulemaking Web site. The Federal Rulemaking Web site allows you to receive alerts when changes or additions occur in a docket folder. To subscribe: (1) Navigate to the docket folder **NRC-2018-0230**; (2) click the “Sign up for E-mail Alerts” link; and (3) enter your email address and select how frequently you would like to receive emails (daily, weekly, or monthly).

III. Specific Requests for Comments

A. Tailored Training & Experience Requirements

The NRC is requesting comments on whether it should establish tailored T&E requirements for different categories of radiopharmaceuticals for physicians seeking AU status for the medical use of specific categories of radiopharmaceuticals requiring a written directive under 10 CFR 35.300 (i.e., a limited AU status). This would be for physicians seeking AU status via the alternate non-board certified pathway, and for physicians certified by a medical

specialty board that is not currently recognized by the NRC under 10 CFR 35.390, 35.392, 35.394, or 35.396 (Unsealed Byproduct Material—Written Directive Required).

1. Are the current pathways for obtaining AU status reasonable and accessible? Provide a rationale for your answer.
2. Are the current pathways for obtaining AU status adequate for protecting public health and safety? Provide a rationale for your answer.
3. Should the NRC develop a new tailored T&E pathway for these physicians? If so, what would be the appropriate way to categorize radiopharmaceuticals for tailored T&E requirements? If not, explain why the regulations should remain unchanged. [Some options to categorize radiopharmaceuticals include radiopharmaceuticals with similar delivery methods (oral, parenteral); same type of radiation characteristics or emission (alpha, beta, gamma, low-energy photon); similar preparation method (patient-ready doses); or a combination thereof (e.g., radiopharmaceuticals containing alpha- and beta-emitting radioisotopes that are administered intravenously and are prepared as patient-ready doses).]
4. Should the fundamental T&E required of physicians seeking limited AU status need to have the same fundamental T&E required of physicians seeking full AU status for all oral and parenteral administrations under 10 CFR 35.300?
5. How should the requirements for this fundamental T&E be structured for a specific category of radiopharmaceuticals?
 - a. Describe what the requirements should include:

- i. Classroom and laboratory training – What topics need to be covered in this training requirement? How many hours of classroom and laboratory training should be required? Provide the basis for the number of hours. If not hours, explain how this training should be quantified. [Note: The topics currently required in the regulations to be included in the classroom and laboratory training and work experience are listed in 10 CFR 35.390, 35.392, 35.394, and 35.396.]
 - ii. Work experience - What should the work experience requirement involve? How many hours of work experience should be required and what is the minimum number of patient or human research subject administrations that an individual must perform? Provide the basis for the number of hours and administrations. What should be the qualifications of the supervising individual?
 - iii. Competency - How should competency be evaluated? Should a written and/or practical examination by an independent examining committee be administered? Provide a rationale for your answer.
- b. Should a preceptor attestation be required for the fundamental T&E? Provide a rationale for your answer.
- c. Should the radiopharmaceutical manufacturer be able to provide the preceptor attestation? Provide a rational for your answer.

- d. Who should establish and administer the curriculum and examination? Provide specific group(s). [Some options are: NRC, medical specialty boards, medical professional societies, educational professional groups, and NRC in collaboration with any or more of the aforementioned groups.]
- e. Should AU competency be periodically assessed? If so, how should it be assessed, how often, and by whom?

B. NRC's Recognition of Medical Specialty Boards

The NRC is requesting comments on its recognition of medical specialty boards. The NRC's procedures for recognizing medical specialty boards are located on the Medical Uses Licensee Toolkit Web site (<https://www.nrc.gov/materials/miau/med-use-toolkit/certif-process-boards.html>). The NRC staff periodically reviews information to determine a board's continued eligibility for recognition.

- 1. What boards other than those already recognized by the NRC (American Board of Nuclear Medicine [ABNM], American Board of Radiology [ABR], American Osteopathic Board of Radiology [AOBR], Certification Board of Nuclear Endocrinology [CBNE]) could be considered for recognition for medical uses under 10 CFR 35.300?
- 2. Are the current NRC medical specialty board recognition criteria sufficient? If not, what additional criteria should the NRC use?

C. Patient Access

The NRC is requesting comments on whether there is a shortage in the number of AUs for 10 CFR 35.300.

1. Is there a shortage in the number of AUs for medical uses under 10 CFR 35.300? If so, is the shortage associated with the use of a specific radiopharmaceutical? Explain how.
2. Are there certain geographic areas with an inadequate number of AUs? Identify these areas.
3. Do current NRC regulations on AU T&E requirements unnecessarily limit patient access to procedures involving radiopharmaceuticals? Explain how.
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D. Other Suggested Changes to the T&E Regulations

In 2002, the NRC revised its regulatory framework for medical use. The goal was to focus the NRC's regulations on those medical procedures that pose the highest risk to workers, the general public, patients, and human research subjects and to structure the regulations to be more risk-informed and more performance-based. The 2002 rule reduced the unnecessary regulatory burden by either reducing or eliminating the prescriptiveness of some regulations. Instead, the rule provided for a performance-based approach that relied on the training and experience of the AUs, authorized nuclear pharmacists, and radiation safety officers. The NRC is requesting comments on whether there are any other changes to the T&E regulations in 10 CFR part 35 that should be considered. Please discuss your suggested changes.

1. Should the NRC regulate the T&E of physicians for medical uses?
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Dated at Rockville, Maryland, this 23rd day of October 2018.

For the Nuclear Regulatory
Commission.

/RA/

Daniel S. Collins, Director,
Division of Materials Safety,
Security,
State, and Tribal Programs,
Office of Nuclear Material Safety
and Safeguards.



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

November 2, 2018

Advanced Accelerator Applications (Novartis)
The Empire State Building
350 Fifth Ave., Suite 6902
New York, NY 10118

SUBJECT: TRAINING AND EXPERIENCE REQUIREMENTS FOR DIFFERENT CATEGORIES OF RADIOPHARMACEUTICALS

Dear Sir or Madam,

The U.S. Nuclear Regulatory Commission (NRC) is evaluating its regulations related to the training and experience (T&E) required for a physician to become an authorized user for medical uses under Subpart E, "Unsealed Byproduct Material—Written Directive Required," of [Title 10 of the Code of Federal Regulations \(10 CFR\) Part 35, "Medical Use of Byproduct Material."](#)

The T&E requirements in Subpart E of 10 CFR Part 35 provide three ways that a physician can be authorized to administer unsealed byproduct materials or radiopharmaceuticals requiring a written directive:

1. A physician can be certified by a medical specialty board, whose certification process is recognized by the NRC or an Agreement State.
2. A physician can complete a structured educational program and supervised work experience under an alternate pathway. This alternate pathway includes a requirement for 700 hours of training and experience, which consists of a minimum of 200 hours of classroom and laboratory training and 500 hours of supervised work experience.
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In its evaluation of the T&E requirements, the NRC staff is considering whether an additional pathway should be created or if the alternate pathway should be revised. Specifically, the staff is evaluating: (1) whether it makes sense to establish tailored T&E requirements for different categories of radiopharmaceuticals; (2) how those categories should be determined; (3) what the appropriate T&E requirements would be for each category; and (4) whether those requirements should be based on hours of training and experience, or focused more on competency.

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A handwritten signature in black ink, appearing to read "C Einberg".

Christian Einberg, Chief
Medical Safety and Events Assessment Branch
Division of Materials Safety, Security, State
and Tribal Programs
Office of Nuclear Material Safety
and Safeguards

Enclosure:
Training and Experience
Federal Register notice

NUCLEAR REGULATORY COMMISSION

[NRC-2018-0230]

**Training and Experience Requirements for Different Categories of
Radiopharmaceuticals**

AGENCY: Nuclear Regulatory Commission.

ACTION: Training and experience requirements; request for comment.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is requesting comments on its training and experience (T&E) requirements. Specifically, the NRC would like input on whether it should establish tailored T&E requirements for different categories of radiopharmaceuticals for which a written directive is required in accordance with its regulations. The input will be used to determine whether significant regulatory changes to the NRC's T&E requirements for authorized users (AUs) are warranted.

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- i. Classroom and laboratory training – What topics need to be covered in this training requirement? How many hours of classroom and laboratory training should be required? Provide the basis for the number of hours. If not hours, explain how this training should be quantified. [Note: The topics currently required in the regulations to be included in the classroom and laboratory training and work experience are listed in 10 CFR 35.390, 35.392, 35.394, and 35.396.]
 - ii. Work experience - What should the work experience requirement involve? How many hours of work experience should be required and what is the minimum number of patient or human research subject administrations that an individual must perform? Provide the basis for the number of hours and administrations. What should be the qualifications of the supervising individual?
 - iii. Competency - How should competency be evaluated? Should a written and/or practical examination by an independent examining committee be administered? Provide a rationale for your answer.
- b. Should a preceptor attestation be required for the fundamental T&E? Provide a rationale for your answer.
- c. Should the radiopharmaceutical manufacturer be able to provide the preceptor attestation? Provide a rational for your answer.

- d. Who should establish and administer the curriculum and examination? Provide specific group(s). [Some options are: NRC, medical specialty boards, medical professional societies, educational professional groups, and NRC in collaboration with any or more of the aforementioned groups.]
- e. Should AU competency be periodically assessed? If so, how should it be assessed, how often, and by whom?

B. NRC's Recognition of Medical Specialty Boards

The NRC is requesting comments on its recognition of medical specialty boards. The NRC's procedures for recognizing medical specialty boards are located on the Medical Uses Licensee Toolkit Web site (<https://www.nrc.gov/materials/miau/med-use-toolkit/certif-process-boards.html>). The NRC staff periodically reviews information to determine a board's continued eligibility for recognition.

- 1. What boards other than those already recognized by the NRC (American Board of Nuclear Medicine [ABNM], American Board of Radiology [ABR], American Osteopathic Board of Radiology [AOBR], Certification Board of Nuclear Endocrinology [CBNE]) could be considered for recognition for medical uses under 10 CFR 35.300?
- 2. Are the current NRC medical specialty board recognition criteria sufficient? If not, what additional criteria should the NRC use?

C. Patient Access

The NRC is requesting comments on whether there is a shortage in the number of AUs for 10 CFR 35.300.

1. Is there a shortage in the number of AUs for medical uses under 10 CFR 35.300? If so, is the shortage associated with the use of a specific radiopharmaceutical? Explain how.
2. Are there certain geographic areas with an inadequate number of AUs? Identify these areas.
3. Do current NRC regulations on AU T&E requirements unnecessarily limit patient access to procedures involving radiopharmaceuticals? Explain how.
4. Do current NRC regulations on AU T&E requirements unnecessarily limit research and development in nuclear medicine? Explain how.

D. Other Suggested Changes to the T&E Regulations

In 2002, the NRC revised its regulatory framework for medical use. The goal was to focus the NRC's regulations on those medical procedures that pose the highest risk to workers, the general public, patients, and human research subjects and to structure the regulations to be more risk-informed and more performance-based. The 2002 rule reduced the unnecessary regulatory burden by either reducing or eliminating the prescriptiveness of some regulations. Instead, the rule provided for a performance-based approach that relied on the training and experience of the AUs, authorized nuclear pharmacists, and radiation safety officers. The NRC is requesting comments on whether there are any other changes to the T&E regulations in 10 CFR part 35 that should be considered. Please discuss your suggested changes.

1. Should the NRC regulate the T&E of physicians for medical uses?
2. Are there requirements in the NRC's T&E regulatory framework for physicians that are non-safety related?

3. How can the NRC transform its regulatory approach for T&E while still ensuring that adequate protection is maintained for workers, the general public, patients, and human research subjects?

Dated at Rockville, Maryland, this 23rd day of October 2018.

For the Nuclear Regulatory
Commission.

/RA/

Daniel S. Collins, Director,
Division of Materials Safety,
Security,
State, and Tribal Programs,
Office of Nuclear Material Safety
and Safeguards.



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

November 2, 2018

American College of Nuclear Medicine
1850 Samuel Morse Drive
Reston, VA 20190

**SUBJECT: TRAINING AND EXPERIENCE REQUIREMENTS FOR DIFFERENT
CATEGORIES OF RADIOPHARMACEUTICALS**

Dear Sir or Madam,

The U.S. Nuclear Regulatory Commission (NRC) is evaluating its regulations related to the training and experience (T&E) required for a physician to become an authorized user for medical uses under Subpart E, “Unsealed Byproduct Material—Written Directive Required,” of [Title 10 of the Code of Federal Regulations \(10 CFR\) Part 35, “Medical Use of Byproduct Material.”](#)

The T&E requirements in Subpart E of 10 CFR Part 35 provide three ways that a physician can be authorized to administer unsealed byproduct materials or radiopharmaceuticals requiring a written directive:

1. A physician can be certified by a medical specialty board, whose certification process is recognized by the NRC or an Agreement State.
2. A physician can complete a structured educational program and supervised work experience under an alternate pathway. This alternate pathway includes a requirement for 700 hours of training and experience, which consists of a minimum of 200 hours of classroom and laboratory training and 500 hours of supervised work experience.
3. A physician can be authorized if previously identified as an authorized user on an NRC or Agreement State license or permit (i.e., grandfathered).

In its evaluation of the T&E requirements, the NRC staff is considering whether an additional pathway should be created or if the alternate pathway should be revised. Specifically, the staff is evaluating: (1) whether it makes sense to establish tailored T&E requirements for different categories of radiopharmaceuticals; (2) how those categories should be determined; (3) what the appropriate T&E requirements would be for each category; and (4) whether those requirements should be based on hours of training and experience, or focused more on competency.

On October 29, 2018, the NRC published a series of questions on T&E in the *Federal Register* (83 FR 54380). The *Federal Register* notice is enclosed with this letter and can also be accessed at: <https://www.gpo.gov/fdsys/pkg/FR-2018-10-29/pdf/2018-23521.pdf>. The NRC will carefully consider responses to these questions and would appreciate your feedback on whether changes to the current T&E regulations are warranted. The comment period for the T&E evaluation will end on January 29, 2019. Please follow the directions in the notice on how to submit written comments. The NRC is using the Federal rulemaking Web site, [Regulations.gov](#), to accept written comments on the docket (NRC-2018-0230).

The NRC will also conduct four public meetings scheduled for November 14 and December 11, 2018, and January 10 and January 22, 2019, and will accept oral comments provided during the meetings. The meetings on December 11 and January 10 will be held at NRC Headquarters in Rockville, MD, and all four meetings will be accessible for remote participation by moderated bridge line and webinar. The NRC's public meeting page has been updated with meeting details and registration instructions for each meeting: <https://www.nrc.gov/pmns/mtg>.

Additional information on the NRC's T&E evaluation can be found at: <https://www.nrc.gov/materials/miau/med-use-toolkit/training-experience-evaluation.html>. If you have any questions on this correspondence, please contact Sarah Lopas of my staff at (301) 415-6360 or Sarah.Lopas@nrc.gov.



Christian Einberg, Chief
Medical Safety and Events Assessment Branch
Division of Materials Safety, Security, State
and Tribal Programs
Office of Nuclear Material Safety
and Safeguards

Enclosure:
Training and Experience
Federal Register notice

NUCLEAR REGULATORY COMMISSION

[NRC-2018-0230]

**Training and Experience Requirements for Different Categories of
Radiopharmaceuticals**

AGENCY: Nuclear Regulatory Commission.

ACTION: Training and experience requirements; request for comment.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is requesting comments on its training and experience (T&E) requirements. Specifically, the NRC would like input on whether it should establish tailored T&E requirements for different categories of radiopharmaceuticals for which a written directive is required in accordance with its regulations. The input will be used to determine whether significant regulatory changes to the NRC's T&E requirements for authorized users (AUs) are warranted.

DATES: Submit comments by January 29, 2019. Comments received after this date will be considered if it is practical to do so, but the NRC is only able to ensure consideration for comments received on or before this date.

ADDRESSES: You may submit comments by any of the following methods:

- **Federal Rulemaking Web Site:** Go to <http://www.regulations.gov>

and search for Docket ID **NRC-2018-0230**. Address questions about Docket IDs in Regulations.gov to Jennifer Borges; telephone: 301-287-9127; e-mail: Jennifer.Borges@nrc.gov. For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.

- **Mail comments to:** May Ma, Office of Administration, Mail Stop: TWFN-7-A60M, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001.

For additional direction on obtaining information and submitting comments, see “Obtaining Information and Submitting Comments” in the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: Sarah Lopas, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001; telephone: 301-415-6360, e-mail: Sarah.Lopas@nrc.gov.

SUPPLEMENTARY INFORMATION:

I. Obtaining Information and Submitting Comments

A. Obtaining Information

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B. Submitting Comments

Please include Docket ID **NRC-2018-0230** in your comment submission.

The NRC cautions you not to include identifying or contact information in comment submissions that you do not want to be publicly disclosed in your comment submission. All comment submissions are posted at <http://www.regulations.gov> and entered into ADAMS. Comment submissions are not routinely edited to remove identifying or contact information.

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II. Background

On August 17, 2017, the Commission issued a staff requirements memorandum (SRM), SRM-M170817 (ADAMS Accession No. ML17229B284), approving the final rule revising parts 30, 32, and 35 of title 10 of the *Code of Federal Regulations* (10 CFR), "Medical Use of Byproduct Material – Medical Event Definitions, Training and Experience, and Clarifying Amendments," and directing the staff to evaluate (1) whether it makes sense to establish tailored T&E requirements for different categories of radiopharmaceuticals, (2) how those categories should be determined (such as by risks posed by groups of

radionuclides or by delivery method), (3) what the appropriate T&E requirements would be for each category, and (4) whether those requirements should be based on hours of T&E or focused more on competency. In response to the SRM, the NRC staff documented its initial results, status, and next steps related to this evaluation in SECY-18-0084, "Staff Evaluation of Training and Experience Requirements for Administering Different Categories of Radiopharmaceuticals in Response to SRM-M170817" (ADAMS Accession No. ML18135A276). In SECY-18-0084, the staff concluded that additional outreach with the medical community is needed to determine whether and how to tailor the T&E requirements to establish a limited AU status, the specific T&E requirements that should apply, how the T&E requirements should be met (e.g., hours of training, demonstration of competency), and whether a competency-based approach makes sense for the T&E requirements for all the medical uses authorized under 10 CFR 35.300, "Use of unsealed byproduct material for which a written directive is required."

The NRC is interested in obtaining input from as many stakeholders as possible, including members of the Advisory Committee on the Medical Uses of Isotopes, professional organizations, physicians, patients, patient advocacy groups, licensees, Agreement States, and other interested individuals. The focus of this request is to gather information that will permit the NRC staff to determine whether changes to the T&E requirements are warranted for different categories of radiopharmaceuticals for physicians seeking AU status for the medical use of specific categories of radiopharmaceuticals requiring a written directive under 10 CFR 35.300.

During the comment period between October 29, 2018 and January 29, 2019, the NRC will hold four public meetings that will discuss the information being requested and to accept comments on the docket. All four public meetings

will be available for remote participation by moderated bridge line and webinar, and two of the four meetings will be open for in-person attendance at NRC's headquarters in Rockville, Maryland.

The public meetings are scheduled for November 14, 2018 (webinar-only); December 11, 2018 (webinar and in-person attendance); January 10, 2019 (webinar and in-person attendance); and January 22, 2019 (webinar-only). The public meetings will be noticed on the NRC's public meeting Web site at least 10 calendar days before the meeting. Members of the public should monitor the NRC's public meeting Web site at <https://www.nrc.gov/pmns/mtg>. The NRC will also post the meeting notices on the Federal Rulemaking Web site at <https://www.regulations.gov/> under Docket ID **NRC-2018-0230**.

The NRC may post additional materials related to this document, including public comments, on the Federal Rulemaking Web site. The Federal Rulemaking Web site allows you to receive alerts when changes or additions occur in a docket folder. To subscribe: (1) Navigate to the docket folder **NRC-2018-0230**; (2) click the “Sign up for E-mail Alerts” link; and (3) enter your email address and select how frequently you would like to receive emails (daily, weekly, or monthly).

III. Specific Requests for Comments

A. Tailored Training & Experience Requirements

The NRC is requesting comments on whether it should establish tailored T&E requirements for different categories of radiopharmaceuticals for physicians seeking AU status for the medical use of specific categories of radiopharmaceuticals requiring a written directive under 10 CFR 35.300 (i.e., a limited AU status). This would be for physicians seeking AU status via the alternate non-board certified pathway, and for physicians certified by a medical

specialty board that is not currently recognized by the NRC under 10 CFR 35.390, 35.392, 35.394, or 35.396 (Unsealed Byproduct Material—Written Directive Required).

1. Are the current pathways for obtaining AU status reasonable and accessible? Provide a rationale for your answer.
2. Are the current pathways for obtaining AU status adequate for protecting public health and safety? Provide a rationale for your answer.
3. Should the NRC develop a new tailored T&E pathway for these physicians? If so, what would be the appropriate way to categorize radiopharmaceuticals for tailored T&E requirements? If not, explain why the regulations should remain unchanged. [Some options to categorize radiopharmaceuticals include radiopharmaceuticals with similar delivery methods (oral, parenteral); same type of radiation characteristics or emission (alpha, beta, gamma, low-energy photon); similar preparation method (patient-ready doses); or a combination thereof (e.g., radiopharmaceuticals containing alpha- and beta-emitting radioisotopes that are administered intravenously and are prepared as patient-ready doses).]
4. Should the fundamental T&E required of physicians seeking limited AU status need to have the same fundamental T&E required of physicians seeking full AU status for all oral and parenteral administrations under 10 CFR 35.300?
5. How should the requirements for this fundamental T&E be structured for a specific category of radiopharmaceuticals?
 - a. Describe what the requirements should include:

- i. Classroom and laboratory training – What topics need to be covered in this training requirement? How many hours of classroom and laboratory training should be required? Provide the basis for the number of hours. If not hours, explain how this training should be quantified. [Note: The topics currently required in the regulations to be included in the classroom and laboratory training and work experience are listed in 10 CFR 35.390, 35.392, 35.394, and 35.396.]
 - ii. Work experience - What should the work experience requirement involve? How many hours of work experience should be required and what is the minimum number of patient or human research subject administrations that an individual must perform? Provide the basis for the number of hours and administrations. What should be the qualifications of the supervising individual?
 - iii. Competency - How should competency be evaluated? Should a written and/or practical examination by an independent examining committee be administered? Provide a rationale for your answer.
- b. Should a preceptor attestation be required for the fundamental T&E? Provide a rationale for your answer.
- c. Should the radiopharmaceutical manufacturer be able to provide the preceptor attestation? Provide a rational for your answer.

- d. Who should establish and administer the curriculum and examination? Provide specific group(s). [Some options are: NRC, medical specialty boards, medical professional societies, educational professional groups, and NRC in collaboration with any or more of the aforementioned groups.]
- e. Should AU competency be periodically assessed? If so, how should it be assessed, how often, and by whom?

B. NRC's Recognition of Medical Specialty Boards

The NRC is requesting comments on its recognition of medical specialty boards. The NRC's procedures for recognizing medical specialty boards are located on the Medical Uses Licensee Toolkit Web site (<https://www.nrc.gov/materials/miau/med-use-toolkit/certif-process-boards.html>). The NRC staff periodically reviews information to determine a board's continued eligibility for recognition.

- 1. What boards other than those already recognized by the NRC (American Board of Nuclear Medicine [ABNM], American Board of Radiology [ABR], American Osteopathic Board of Radiology [AOBR], Certification Board of Nuclear Endocrinology [CBNE]) could be considered for recognition for medical uses under 10 CFR 35.300?
- 2. Are the current NRC medical specialty board recognition criteria sufficient? If not, what additional criteria should the NRC use?

C. Patient Access

The NRC is requesting comments on whether there is a shortage in the number of AUs for 10 CFR 35.300.

1. Is there a shortage in the number of AUs for medical uses under 10 CFR 35.300? If so, is the shortage associated with the use of a specific radiopharmaceutical? Explain how.
2. Are there certain geographic areas with an inadequate number of AUs? Identify these areas.
3. Do current NRC regulations on AU T&E requirements unnecessarily limit patient access to procedures involving radiopharmaceuticals? Explain how.
4. Do current NRC regulations on AU T&E requirements unnecessarily limit research and development in nuclear medicine? Explain how.

D. Other Suggested Changes to the T&E Regulations

In 2002, the NRC revised its regulatory framework for medical use. The goal was to focus the NRC's regulations on those medical procedures that pose the highest risk to workers, the general public, patients, and human research subjects and to structure the regulations to be more risk-informed and more performance-based. The 2002 rule reduced the unnecessary regulatory burden by either reducing or eliminating the prescriptiveness of some regulations. Instead, the rule provided for a performance-based approach that relied on the training and experience of the AUs, authorized nuclear pharmacists, and radiation safety officers. The NRC is requesting comments on whether there are any other changes to the T&E regulations in 10 CFR part 35 that should be considered. Please discuss your suggested changes.

1. Should the NRC regulate the T&E of physicians for medical uses?
2. Are there requirements in the NRC's T&E regulatory framework for physicians that are non-safety related?

3. How can the NRC transform its regulatory approach for T&E while still ensuring that adequate protection is maintained for workers, the general public, patients, and human research subjects?

Dated at Rockville, Maryland, this 23rd day of October 2018.

For the Nuclear Regulatory
Commission.

/RA/

Daniel S. Collins, Director,
Division of Materials Safety,
Security,
State, and Tribal Programs,
Office of Nuclear Material Safety
and Safeguards.



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

November 2, 2018

University of Arkansas College of Pharmacy
College of Pharmacy, Dean's Office
University of Arkansas of Medical Sciences
4301 W. Markham St.
Little Rock, AR 72205

**SUBJECT: TRAINING AND EXPERIENCE REQUIREMENTS FOR DIFFERENT
CATEGORIES OF RADIOPHARMACEUTICALS**

Dear Sir or Madam,

The U.S. Nuclear Regulatory Commission (NRC) is evaluating its regulations related to the training and experience (T&E) required for a physician to become an authorized user for medical uses under Subpart E, "Unsealed Byproduct Material—Written Directive Required," of [Title 10 of the Code of Federal Regulations \(10 CFR\) Part 35, "Medical Use of Byproduct Material."](#)

The T&E requirements in Subpart E of 10 CFR Part 35 provide three ways that a physician can be authorized to administer unsealed byproduct materials or radiopharmaceuticals requiring a written directive:

1. A physician can be certified by a medical specialty board, whose certification process is recognized by the NRC or an Agreement State.
2. A physician can complete a structured educational program and supervised work experience under an alternate pathway. This alternate pathway includes a requirement for 700 hours of training and experience, which consists of a minimum of 200 hours of classroom and laboratory training and 500 hours of supervised work experience.
3. A physician can be authorized if previously identified as an authorized user on an NRC or Agreement State license or permit (i.e., grandfathered).

In its evaluation of the T&E requirements, the NRC staff is considering whether an additional pathway should be created or if the alternate pathway should be revised. Specifically, the staff is evaluating: (1) whether it makes sense to establish tailored T&E requirements for different categories of radiopharmaceuticals; (2) how those categories should be determined; (3) what the appropriate T&E requirements would be for each category; and (4) whether those requirements should be based on hours of training and experience, or focused more on competency.

On October 29, 2018, the NRC published a series of questions on T&E in the *Federal Register* (83 FR 54380). The *Federal Register* notice is enclosed with this letter and can also be accessed at: <https://www.gpo.gov/fdsys/pkg/FR-2018-10-29/pdf/2018-23521.pdf>. The NRC will carefully consider responses to these questions and would appreciate your feedback on whether changes to the current T&E regulations are warranted. The comment period for the T&E evaluation will end on January 29, 2019. Please follow the directions in the notice on how to submit written comments. The NRC is using the Federal rulemaking Web site, [Regulations.gov](#), to accept written comments on the docket (NRC-2018-0230).

The NRC will also conduct four public meetings scheduled for November 14 and December 11, 2018, and January 10 and January 22, 2019, and will accept oral comments provided during the meetings. The meetings on December 11 and January 10 will be held at NRC Headquarters in Rockville, MD, and all four meetings will be accessible for remote participation by moderated bridge line and webinar. The NRC's public meeting page has been updated with meeting details and registration instructions for each meeting: <https://www.nrc.gov/pmns/mtg>.

Additional information on the NRC's T&E evaluation can be found at: <https://www.nrc.gov/materials/miau/med-use-toolkit/training-experience-evaluation.html>. If you have any questions on this correspondence, please contact Sarah Lopas of my staff at (301) 415-6360 or Sarah.Lopas@nrc.gov.

A handwritten signature in black ink, appearing to read "C Einberg".

Christian Einberg, Chief
Medical Safety and Events Assessment Branch
Division of Materials Safety, Security, State
and Tribal Programs
Office of Nuclear Material Safety
and Safeguards

Enclosure:
Training and Experience
Federal Register notice

NUCLEAR REGULATORY COMMISSION

[NRC-2018-0230]

**Training and Experience Requirements for Different Categories of
Radiopharmaceuticals**

AGENCY: Nuclear Regulatory Commission.

ACTION: Training and experience requirements; request for comment.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is requesting comments on its training and experience (T&E) requirements. Specifically, the NRC would like input on whether it should establish tailored T&E requirements for different categories of radiopharmaceuticals for which a written directive is required in accordance with its regulations. The input will be used to determine whether significant regulatory changes to the NRC's T&E requirements for authorized users (AUs) are warranted.

DATES: Submit comments by January 29, 2019. Comments received after this date will be considered if it is practical to do so, but the NRC is only able to ensure consideration for comments received on or before this date.

ADDRESSES: You may submit comments by any of the following methods:

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For additional direction on obtaining information and submitting comments, see “Obtaining Information and Submitting Comments” in the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: Sarah Lopas, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001; telephone: 301-415-6360, e-mail: Sarah.Lopas@nrc.gov.

SUPPLEMENTARY INFORMATION:

I. Obtaining Information and Submitting Comments

A. Obtaining Information

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B. Submitting Comments

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radionuclides or by delivery method), (3) what the appropriate T&E requirements would be for each category, and (4) whether those requirements should be based on hours of T&E or focused more on competency. In response to the SRM, the NRC staff documented its initial results, status, and next steps related to this evaluation in SECY-18-0084, "Staff Evaluation of Training and Experience Requirements for Administering Different Categories of Radiopharmaceuticals in Response to SRM-M170817" (ADAMS Accession No. ML18135A276). In SECY-18-0084, the staff concluded that additional outreach with the medical community is needed to determine whether and how to tailor the T&E requirements to establish a limited AU status, the specific T&E requirements that should apply, how the T&E requirements should be met (e.g., hours of training, demonstration of competency), and whether a competency-based approach makes sense for the T&E requirements for all the medical uses authorized under 10 CFR 35.300, "Use of unsealed byproduct material for which a written directive is required."

The NRC is interested in obtaining input from as many stakeholders as possible, including members of the Advisory Committee on the Medical Uses of Isotopes, professional organizations, physicians, patients, patient advocacy groups, licensees, Agreement States, and other interested individuals. The focus of this request is to gather information that will permit the NRC staff to determine whether changes to the T&E requirements are warranted for different categories of radiopharmaceuticals for physicians seeking AU status for the medical use of specific categories of radiopharmaceuticals requiring a written directive under 10 CFR 35.300.

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III. Specific Requests for Comments

A. Tailored Training & Experience Requirements

The NRC is requesting comments on whether it should establish tailored T&E requirements for different categories of radiopharmaceuticals for physicians seeking AU status for the medical use of specific categories of radiopharmaceuticals requiring a written directive under 10 CFR 35.300 (i.e., a limited AU status). This would be for physicians seeking AU status via the alternate non-board certified pathway, and for physicians certified by a medical

specialty board that is not currently recognized by the NRC under 10 CFR 35.390, 35.392, 35.394, or 35.396 (Unsealed Byproduct Material—Written Directive Required).

1. Are the current pathways for obtaining AU status reasonable and accessible? Provide a rationale for your answer.
2. Are the current pathways for obtaining AU status adequate for protecting public health and safety? Provide a rationale for your answer.
3. Should the NRC develop a new tailored T&E pathway for these physicians? If so, what would be the appropriate way to categorize radiopharmaceuticals for tailored T&E requirements? If not, explain why the regulations should remain unchanged. [Some options to categorize radiopharmaceuticals include radiopharmaceuticals with similar delivery methods (oral, parenteral); same type of radiation characteristics or emission (alpha, beta, gamma, low-energy photon); similar preparation method (patient-ready doses); or a combination thereof (e.g., radiopharmaceuticals containing alpha- and beta-emitting radioisotopes that are administered intravenously and are prepared as patient-ready doses).]
4. Should the fundamental T&E required of physicians seeking limited AU status need to have the same fundamental T&E required of physicians seeking full AU status for all oral and parenteral administrations under 10 CFR 35.300?
5. How should the requirements for this fundamental T&E be structured for a specific category of radiopharmaceuticals?
 - a. Describe what the requirements should include:

- i. Classroom and laboratory training – What topics need to be covered in this training requirement? How many hours of classroom and laboratory training should be required? Provide the basis for the number of hours. If not hours, explain how this training should be quantified. [Note: The topics currently required in the regulations to be included in the classroom and laboratory training and work experience are listed in 10 CFR 35.390, 35.392, 35.394, and 35.396.]
 - ii. Work experience - What should the work experience requirement involve? How many hours of work experience should be required and what is the minimum number of patient or human research subject administrations that an individual must perform? Provide the basis for the number of hours and administrations. What should be the qualifications of the supervising individual?
 - iii. Competency - How should competency be evaluated? Should a written and/or practical examination by an independent examining committee be administered? Provide a rationale for your answer.
- b. Should a preceptor attestation be required for the fundamental T&E? Provide a rationale for your answer.
- c. Should the radiopharmaceutical manufacturer be able to provide the preceptor attestation? Provide a rational for your answer.

- d. Who should establish and administer the curriculum and examination? Provide specific group(s). [Some options are: NRC, medical specialty boards, medical professional societies, educational professional groups, and NRC in collaboration with any or more of the aforementioned groups.]
- e. Should AU competency be periodically assessed? If so, how should it be assessed, how often, and by whom?

B. NRC's Recognition of Medical Specialty Boards

The NRC is requesting comments on its recognition of medical specialty boards. The NRC's procedures for recognizing medical specialty boards are located on the Medical Uses Licensee Toolkit Web site (<https://www.nrc.gov/materials/miau/med-use-toolkit/certif-process-boards.html>). The NRC staff periodically reviews information to determine a board's continued eligibility for recognition.

- 1. What boards other than those already recognized by the NRC (American Board of Nuclear Medicine [ABNM], American Board of Radiology [ABR], American Osteopathic Board of Radiology [AOBR], Certification Board of Nuclear Endocrinology [CBNE]) could be considered for recognition for medical uses under 10 CFR 35.300?
- 2. Are the current NRC medical specialty board recognition criteria sufficient? If not, what additional criteria should the NRC use?

C. Patient Access

The NRC is requesting comments on whether there is a shortage in the number of AUs for 10 CFR 35.300.

1. Is there a shortage in the number of AUs for medical uses under 10 CFR 35.300? If so, is the shortage associated with the use of a specific radiopharmaceutical? Explain how.
2. Are there certain geographic areas with an inadequate number of AUs? Identify these areas.
3. Do current NRC regulations on AU T&E requirements unnecessarily limit patient access to procedures involving radiopharmaceuticals? Explain how.
4. Do current NRC regulations on AU T&E requirements unnecessarily limit research and development in nuclear medicine? Explain how.

D. Other Suggested Changes to the T&E Regulations

In 2002, the NRC revised its regulatory framework for medical use. The goal was to focus the NRC's regulations on those medical procedures that pose the highest risk to workers, the general public, patients, and human research subjects and to structure the regulations to be more risk-informed and more performance-based. The 2002 rule reduced the unnecessary regulatory burden by either reducing or eliminating the prescriptiveness of some regulations. Instead, the rule provided for a performance-based approach that relied on the training and experience of the AUs, authorized nuclear pharmacists, and radiation safety officers. The NRC is requesting comments on whether there are any other changes to the T&E regulations in 10 CFR part 35 that should be considered. Please discuss your suggested changes.

1. Should the NRC regulate the T&E of physicians for medical uses?
2. Are there requirements in the NRC's T&E regulatory framework for physicians that are non-safety related?

3. How can the NRC transform its regulatory approach for T&E while still ensuring that adequate protection is maintained for workers, the general public, patients, and human research subjects?

Dated at Rockville, Maryland, this 23rd day of October 2018.

For the Nuclear Regulatory
Commission.

/RA/

Daniel S. Collins, Director,
Division of Materials Safety,
Security,
State, and Tribal Programs,
Office of Nuclear Material Safety
and Safeguards.



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

November 2, 2018

American Society of Hematology
2021 L St. NW, Suite 900
Washington, DC 20036

**SUBJECT: TRAINING AND EXPERIENCE REQUIREMENTS FOR DIFFERENT
CATEGORIES OF RADIOPHARMACEUTICALS**

Dear Sir or Madam,

The U.S. Nuclear Regulatory Commission (NRC) is evaluating its regulations related to the training and experience (T&E) required for a physician to become an authorized user for medical uses under Subpart E, “Unsealed Byproduct Material—Written Directive Required,” of [Title 10 of the Code of Federal Regulations \(10 CFR\) Part 35, “Medical Use of Byproduct Material.”](#)

The T&E requirements in Subpart E of 10 CFR Part 35 provide three ways that a physician can be authorized to administer unsealed byproduct materials or radiopharmaceuticals requiring a written directive:

1. A physician can be certified by a medical specialty board, whose certification process is recognized by the NRC or an Agreement State.
2. A physician can complete a structured educational program and supervised work experience under an alternate pathway. This alternate pathway includes a requirement for 700 hours of training and experience, which consists of a minimum of 200 hours of classroom and laboratory training and 500 hours of supervised work experience.
3. A physician can be authorized if previously identified as an authorized user on an NRC or Agreement State license or permit (i.e., grandfathered).

In its evaluation of the T&E requirements, the NRC staff is considering whether an additional pathway should be created or if the alternate pathway should be revised. Specifically, the staff is evaluating: (1) whether it makes sense to establish tailored T&E requirements for different categories of radiopharmaceuticals; (2) how those categories should be determined; (3) what the appropriate T&E requirements would be for each category; and (4) whether those requirements should be based on hours of training and experience, or focused more on competency.

On October 29, 2018, the NRC published a series of questions on T&E in the *Federal Register* (83 FR 54380). The *Federal Register* notice is enclosed with this letter and can also be accessed at: <https://www.gpo.gov/fdsys/pkg/FR-2018-10-29/pdf/2018-23521.pdf>. The NRC will carefully consider responses to these questions and would appreciate your feedback on whether changes to the current T&E regulations are warranted. The comment period for the T&E evaluation will end on January 29, 2019. Please follow the directions in the notice on how to submit written comments. The NRC is using the Federal rulemaking Web site, [Regulations.gov](#), to accept written comments on the docket (NRC-2018-0230).

The NRC will also conduct four public meetings scheduled for November 14 and December 11, 2018, and January 10 and January 22, 2019, and will accept oral comments provided during the meetings. The meetings on December 11 and January 10 will be held at NRC Headquarters in Rockville, MD, and all four meetings will be accessible for remote participation by moderated bridge line and webinar. The NRC's public meeting page has been updated with meeting details and registration instructions for each meeting: <https://www.nrc.gov/pmns/mtg>.

Additional information on the NRC's T&E evaluation can be found at: <https://www.nrc.gov/materials/miau/med-use-toolkit/training-experience-evaluation.html>. If you have any questions on this correspondence, please contact Sarah Lopas of my staff at (301) 415-6360 or Sarah.Lopas@nrc.gov.



Christian Einberg, Chief
Medical Safety and Events Assessment Branch
Division of Materials Safety, Security, State
and Tribal Programs
Office of Nuclear Material Safety
and Safeguards

Enclosure:
Training and Experience
Federal Register notice

NUCLEAR REGULATORY COMMISSION

[NRC-2018-0230]

**Training and Experience Requirements for Different Categories of
Radiopharmaceuticals**

AGENCY: Nuclear Regulatory Commission.

ACTION: Training and experience requirements; request for comment.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is requesting comments on its training and experience (T&E) requirements. Specifically, the NRC would like input on whether it should establish tailored T&E requirements for different categories of radiopharmaceuticals for which a written directive is required in accordance with its regulations. The input will be used to determine whether significant regulatory changes to the NRC's T&E requirements for authorized users (AUs) are warranted.

DATES: Submit comments by January 29, 2019. Comments received after this date will be considered if it is practical to do so, but the NRC is only able to ensure consideration for comments received on or before this date.

ADDRESSES: You may submit comments by any of the following methods:

- **Federal Rulemaking Web Site:** Go to <http://www.regulations.gov>

and search for Docket ID **NRC-2018-0230**. Address questions about Docket IDs in Regulations.gov to Jennifer Borges; telephone: 301-287-9127; e-mail: Jennifer.Borges@nrc.gov. For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.

- **Mail comments to:** May Ma, Office of Administration, Mail Stop: TWFN-7-A60M, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001.

For additional direction on obtaining information and submitting comments, see “Obtaining Information and Submitting Comments” in the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: Sarah Lopas, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001; telephone: 301-415-6360, e-mail: Sarah.Lopas@nrc.gov.

SUPPLEMENTARY INFORMATION:

I. Obtaining Information and Submitting Comments

A. Obtaining Information

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- **NRC's PDR:** You may examine and purchase copies of public documents at the NRC's PDR, Room O1-F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.

B. Submitting Comments

Please include Docket ID **NRC-2018-0230** in your comment submission.

The NRC cautions you not to include identifying or contact information in comment submissions that you do not want to be publicly disclosed in your comment submission. All comment submissions are posted at <http://www.regulations.gov> and entered into ADAMS. Comment submissions are not routinely edited to remove identifying or contact information.

If you are requesting or aggregating comments from other persons for submission to the NRC, then you should inform those persons not to include identifying or contact information that they do not want to be publicly disclosed in their comment submission. Your request should state that the NRC does not routinely edit comment submissions to remove such information before making the comment submissions available to the public or entering the comment into ADAMS.

II. Background

On August 17, 2017, the Commission issued a staff requirements memorandum (SRM), SRM-M170817 (ADAMS Accession No. ML17229B284), approving the final rule revising parts 30, 32, and 35 of title 10 of the *Code of Federal Regulations* (10 CFR), "Medical Use of Byproduct Material – Medical Event Definitions, Training and Experience, and Clarifying Amendments," and directing the staff to evaluate (1) whether it makes sense to establish tailored T&E requirements for different categories of radiopharmaceuticals, (2) how those categories should be determined (such as by risks posed by groups of

radionuclides or by delivery method), (3) what the appropriate T&E requirements would be for each category, and (4) whether those requirements should be based on hours of T&E or focused more on competency. In response to the SRM, the NRC staff documented its initial results, status, and next steps related to this evaluation in SECY-18-0084, "Staff Evaluation of Training and Experience Requirements for Administering Different Categories of Radiopharmaceuticals in Response to SRM-M170817" (ADAMS Accession No. ML18135A276). In SECY-18-0084, the staff concluded that additional outreach with the medical community is needed to determine whether and how to tailor the T&E requirements to establish a limited AU status, the specific T&E requirements that should apply, how the T&E requirements should be met (e.g., hours of training, demonstration of competency), and whether a competency-based approach makes sense for the T&E requirements for all the medical uses authorized under 10 CFR 35.300, "Use of unsealed byproduct material for which a written directive is required."

The NRC is interested in obtaining input from as many stakeholders as possible, including members of the Advisory Committee on the Medical Uses of Isotopes, professional organizations, physicians, patients, patient advocacy groups, licensees, Agreement States, and other interested individuals. The focus of this request is to gather information that will permit the NRC staff to determine whether changes to the T&E requirements are warranted for different categories of radiopharmaceuticals for physicians seeking AU status for the medical use of specific categories of radiopharmaceuticals requiring a written directive under 10 CFR 35.300.

During the comment period between October 29, 2018 and January 29, 2019, the NRC will hold four public meetings that will discuss the information being requested and to accept comments on the docket. All four public meetings

will be available for remote participation by moderated bridge line and webinar, and two of the four meetings will be open for in-person attendance at NRC's headquarters in Rockville, Maryland.

The public meetings are scheduled for November 14, 2018 (webinar-only); December 11, 2018 (webinar and in-person attendance); January 10, 2019 (webinar and in-person attendance); and January 22, 2019 (webinar-only). The public meetings will be noticed on the NRC's public meeting Web site at least 10 calendar days before the meeting. Members of the public should monitor the NRC's public meeting Web site at <https://www.nrc.gov/pmns/mtg>. The NRC will also post the meeting notices on the Federal Rulemaking Web site at <https://www.regulations.gov/> under Docket ID **NRC-2018-0230**.

The NRC may post additional materials related to this document, including public comments, on the Federal Rulemaking Web site. The Federal Rulemaking Web site allows you to receive alerts when changes or additions occur in a docket folder. To subscribe: (1) Navigate to the docket folder **NRC-2018-0230**; (2) click the “Sign up for E-mail Alerts” link; and (3) enter your email address and select how frequently you would like to receive emails (daily, weekly, or monthly).

III. Specific Requests for Comments

A. Tailored Training & Experience Requirements

The NRC is requesting comments on whether it should establish tailored T&E requirements for different categories of radiopharmaceuticals for physicians seeking AU status for the medical use of specific categories of radiopharmaceuticals requiring a written directive under 10 CFR 35.300 (i.e., a limited AU status). This would be for physicians seeking AU status via the alternate non-board certified pathway, and for physicians certified by a medical

specialty board that is not currently recognized by the NRC under 10 CFR 35.390, 35.392, 35.394, or 35.396 (Unsealed Byproduct Material—Written Directive Required).

1. Are the current pathways for obtaining AU status reasonable and accessible? Provide a rationale for your answer.
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3. Should the NRC develop a new tailored T&E pathway for these physicians? If so, what would be the appropriate way to categorize radiopharmaceuticals for tailored T&E requirements? If not, explain why the regulations should remain unchanged. [Some options to categorize radiopharmaceuticals include radiopharmaceuticals with similar delivery methods (oral, parenteral); same type of radiation characteristics or emission (alpha, beta, gamma, low-energy photon); similar preparation method (patient-ready doses); or a combination thereof (e.g., radiopharmaceuticals containing alpha- and beta-emitting radioisotopes that are administered intravenously and are prepared as patient-ready doses).]
4. Should the fundamental T&E required of physicians seeking limited AU status need to have the same fundamental T&E required of physicians seeking full AU status for all oral and parenteral administrations under 10 CFR 35.300?
5. How should the requirements for this fundamental T&E be structured for a specific category of radiopharmaceuticals?
 - a. Describe what the requirements should include:

- i. Classroom and laboratory training – What topics need to be covered in this training requirement? How many hours of classroom and laboratory training should be required? Provide the basis for the number of hours. If not hours, explain how this training should be quantified. [Note: The topics currently required in the regulations to be included in the classroom and laboratory training and work experience are listed in 10 CFR 35.390, 35.392, 35.394, and 35.396.]
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 - iii. Competency - How should competency be evaluated? Should a written and/or practical examination by an independent examining committee be administered? Provide a rationale for your answer.
- b. Should a preceptor attestation be required for the fundamental T&E? Provide a rationale for your answer.
- c. Should the radiopharmaceutical manufacturer be able to provide the preceptor attestation? Provide a rational for your answer.

- d. Who should establish and administer the curriculum and examination? Provide specific group(s). [Some options are: NRC, medical specialty boards, medical professional societies, educational professional groups, and NRC in collaboration with any or more of the aforementioned groups.]
- e. Should AU competency be periodically assessed? If so, how should it be assessed, how often, and by whom?

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The NRC is requesting comments on its recognition of medical specialty boards. The NRC's procedures for recognizing medical specialty boards are located on the Medical Uses Licensee Toolkit Web site (<https://www.nrc.gov/materials/miau/med-use-toolkit/certif-process-boards.html>). The NRC staff periodically reviews information to determine a board's continued eligibility for recognition.

- 1. What boards other than those already recognized by the NRC (American Board of Nuclear Medicine [ABNM], American Board of Radiology [ABR], American Osteopathic Board of Radiology [AOBR], Certification Board of Nuclear Endocrinology [CBNE]) could be considered for recognition for medical uses under 10 CFR 35.300?
- 2. Are the current NRC medical specialty board recognition criteria sufficient? If not, what additional criteria should the NRC use?

C. Patient Access

The NRC is requesting comments on whether there is a shortage in the number of AUs for 10 CFR 35.300.

1. Is there a shortage in the number of AUs for medical uses under 10 CFR 35.300? If so, is the shortage associated with the use of a specific radiopharmaceutical? Explain how.
2. Are there certain geographic areas with an inadequate number of AUs? Identify these areas.
3. Do current NRC regulations on AU T&E requirements unnecessarily limit patient access to procedures involving radiopharmaceuticals? Explain how.
4. Do current NRC regulations on AU T&E requirements unnecessarily limit research and development in nuclear medicine? Explain how.

D. Other Suggested Changes to the T&E Regulations

In 2002, the NRC revised its regulatory framework for medical use. The goal was to focus the NRC's regulations on those medical procedures that pose the highest risk to workers, the general public, patients, and human research subjects and to structure the regulations to be more risk-informed and more performance-based. The 2002 rule reduced the unnecessary regulatory burden by either reducing or eliminating the prescriptiveness of some regulations. Instead, the rule provided for a performance-based approach that relied on the training and experience of the AUs, authorized nuclear pharmacists, and radiation safety officers. The NRC is requesting comments on whether there are any other changes to the T&E regulations in 10 CFR part 35 that should be considered. Please discuss your suggested changes.

1. Should the NRC regulate the T&E of physicians for medical uses?
2. Are there requirements in the NRC's T&E regulatory framework for physicians that are non-safety related?

3. How can the NRC transform its regulatory approach for T&E while still ensuring that adequate protection is maintained for workers, the general public, patients, and human research subjects?

Dated at Rockville, Maryland, this 23rd day of October 2018.

For the Nuclear Regulatory
Commission.

/RA/

Daniel S. Collins, Director,
Division of Materials Safety,
Security,
State, and Tribal Programs,
Office of Nuclear Material Safety
and Safeguards.



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

November 2, 2018

Baptist Health College Little Rock
School of Nuclear Medicine Technolgy
11900 Colonel Glenn Road
Little Rock, AR 72210-2820

**SUBJECT: TRAINING AND EXPERIENCE REQUIREMENTS FOR DIFFERENT
CATEGORIES OF RADIOPHARMACEUTICALS**

Dear Sir or Madam,

The U.S. Nuclear Regulatory Commission (NRC) is evaluating its regulations related to the training and experience (T&E) required for a physician to become an authorized user for medical uses under Subpart E, “Unsealed Byproduct Material—Written Directive Required,” of [Title 10 of the Code of Federal Regulations \(10 CFR\) Part 35, “Medical Use of Byproduct Material.”](#)

The T&E requirements in Subpart E of 10 CFR Part 35 provide three ways that a physician can be authorized to administer unsealed byproduct materials or radiopharmaceuticals requiring a written directive:

1. A physician can be certified by a medical specialty board, whose certification process is recognized by the NRC or an Agreement State.
2. A physician can complete a structured educational program and supervised work experience under an alternate pathway. This alternate pathway includes a requirement for 700 hours of training and experience, which consists of a minimum of 200 hours of classroom and laboratory training and 500 hours of supervised work experience.
3. A physician can be authorized if previously identified as an authorized user on an NRC or Agreement State license or permit (i.e., grandfathered).

In its evaluation of the T&E requirements, the NRC staff is considering whether an additional pathway should be created or if the alternate pathway should be revised. Specifically, the staff is evaluating: (1) whether it makes sense to establish tailored T&E requirements for different categories of radiopharmaceuticals; (2) how those categories should be determined; (3) what the appropriate T&E requirements would be for each category; and (4) whether those requirements should be based on hours of training and experience, or focused more on competency.

On October 29, 2018, the NRC published a series of questions on T&E in the *Federal Register* (83 FR 54380). The *Federal Register* notice is enclosed with this letter and can also be accessed at: <https://www.gpo.gov/fdsys/pkg/FR-2018-10-29/pdf/2018-23521.pdf>. The NRC will carefully consider responses to these questions and would appreciate your feedback on whether changes to the current T&E regulations are warranted. The comment period for the T&E evaluation will end on January 29, 2019. Please follow the directions in the notice on how to submit written comments. The NRC is using the Federal rulemaking Web site, [Regulations.gov](#), to accept written comments on the docket (NRC-2018-0230).

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Additional information on the NRC's T&E evaluation can be found at: <https://www.nrc.gov/materials/miau/med-use-toolkit/training-experience-evaluation.html>. If you have any questions on this correspondence, please contact Sarah Lopas of my staff at (301) 415-6360 or Sarah.Lopas@nrc.gov.

A handwritten signature in black ink, appearing to read "C Einberg".

Christian Einberg, Chief
Medical Safety and Events Assessment Branch
Division of Materials Safety, Security, State
and Tribal Programs
Office of Nuclear Material Safety
and Safeguards

Enclosure:
Training and Experience
Federal Register notice

NUCLEAR REGULATORY COMMISSION

[NRC-2018-0230]

**Training and Experience Requirements for Different Categories of
Radiopharmaceuticals**

AGENCY: Nuclear Regulatory Commission.

ACTION: Training and experience requirements; request for comment.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is requesting comments on its training and experience (T&E) requirements. Specifically, the NRC would like input on whether it should establish tailored T&E requirements for different categories of radiopharmaceuticals for which a written directive is required in accordance with its regulations. The input will be used to determine whether significant regulatory changes to the NRC's T&E requirements for authorized users (AUs) are warranted.

DATES: Submit comments by January 29, 2019. Comments received after this date will be considered if it is practical to do so, but the NRC is only able to ensure consideration for comments received on or before this date.

ADDRESSES: You may submit comments by any of the following methods:

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FOR FURTHER INFORMATION CONTACT: Sarah Lopas, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001; telephone: 301-415-6360, e-mail: Sarah.Lopas@nrc.gov.

SUPPLEMENTARY INFORMATION:

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B. Submitting Comments

Please include Docket ID **NRC-2018-0230** in your comment submission.

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radionuclides or by delivery method), (3) what the appropriate T&E requirements would be for each category, and (4) whether those requirements should be based on hours of T&E or focused more on competency. In response to the SRM, the NRC staff documented its initial results, status, and next steps related to this evaluation in SECY-18-0084, "Staff Evaluation of Training and Experience Requirements for Administering Different Categories of Radiopharmaceuticals in Response to SRM-M170817" (ADAMS Accession No. ML18135A276). In SECY-18-0084, the staff concluded that additional outreach with the medical community is needed to determine whether and how to tailor the T&E requirements to establish a limited AU status, the specific T&E requirements that should apply, how the T&E requirements should be met (e.g., hours of training, demonstration of competency), and whether a competency-based approach makes sense for the T&E requirements for all the medical uses authorized under 10 CFR 35.300, "Use of unsealed byproduct material for which a written directive is required."

The NRC is interested in obtaining input from as many stakeholders as possible, including members of the Advisory Committee on the Medical Uses of Isotopes, professional organizations, physicians, patients, patient advocacy groups, licensees, Agreement States, and other interested individuals. The focus of this request is to gather information that will permit the NRC staff to determine whether changes to the T&E requirements are warranted for different categories of radiopharmaceuticals for physicians seeking AU status for the medical use of specific categories of radiopharmaceuticals requiring a written directive under 10 CFR 35.300.

During the comment period between October 29, 2018 and January 29, 2019, the NRC will hold four public meetings that will discuss the information being requested and to accept comments on the docket. All four public meetings

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III. Specific Requests for Comments

A. Tailored Training & Experience Requirements

The NRC is requesting comments on whether it should establish tailored T&E requirements for different categories of radiopharmaceuticals for physicians seeking AU status for the medical use of specific categories of radiopharmaceuticals requiring a written directive under 10 CFR 35.300 (i.e., a limited AU status). This would be for physicians seeking AU status via the alternate non-board certified pathway, and for physicians certified by a medical

specialty board that is not currently recognized by the NRC under 10 CFR 35.390, 35.392, 35.394, or 35.396 (Unsealed Byproduct Material—Written Directive Required).

1. Are the current pathways for obtaining AU status reasonable and accessible? Provide a rationale for your answer.
2. Are the current pathways for obtaining AU status adequate for protecting public health and safety? Provide a rationale for your answer.
3. Should the NRC develop a new tailored T&E pathway for these physicians? If so, what would be the appropriate way to categorize radiopharmaceuticals for tailored T&E requirements? If not, explain why the regulations should remain unchanged. [Some options to categorize radiopharmaceuticals include radiopharmaceuticals with similar delivery methods (oral, parenteral); same type of radiation characteristics or emission (alpha, beta, gamma, low-energy photon); similar preparation method (patient-ready doses); or a combination thereof (e.g., radiopharmaceuticals containing alpha- and beta-emitting radioisotopes that are administered intravenously and are prepared as patient-ready doses).]
4. Should the fundamental T&E required of physicians seeking limited AU status need to have the same fundamental T&E required of physicians seeking full AU status for all oral and parenteral administrations under 10 CFR 35.300?
5. How should the requirements for this fundamental T&E be structured for a specific category of radiopharmaceuticals?
 - a. Describe what the requirements should include:

- i. Classroom and laboratory training – What topics need to be covered in this training requirement? How many hours of classroom and laboratory training should be required? Provide the basis for the number of hours. If not hours, explain how this training should be quantified. [Note: The topics currently required in the regulations to be included in the classroom and laboratory training and work experience are listed in 10 CFR 35.390, 35.392, 35.394, and 35.396.]
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 - iii. Competency - How should competency be evaluated? Should a written and/or practical examination by an independent examining committee be administered? Provide a rationale for your answer.
- b. Should a preceptor attestation be required for the fundamental T&E? Provide a rationale for your answer.
- c. Should the radiopharmaceutical manufacturer be able to provide the preceptor attestation? Provide a rational for your answer.

- d. Who should establish and administer the curriculum and examination? Provide specific group(s). [Some options are: NRC, medical specialty boards, medical professional societies, educational professional groups, and NRC in collaboration with any or more of the aforementioned groups.]
- e. Should AU competency be periodically assessed? If so, how should it be assessed, how often, and by whom?

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The NRC is requesting comments on its recognition of medical specialty boards. The NRC's procedures for recognizing medical specialty boards are located on the Medical Uses Licensee Toolkit Web site (<https://www.nrc.gov/materials/miau/med-use-toolkit/certif-process-boards.html>). The NRC staff periodically reviews information to determine a board's continued eligibility for recognition.

- 1. What boards other than those already recognized by the NRC (American Board of Nuclear Medicine [ABNM], American Board of Radiology [ABR], American Osteopathic Board of Radiology [AOBR], Certification Board of Nuclear Endocrinology [CBNE]) could be considered for recognition for medical uses under 10 CFR 35.300?
- 2. Are the current NRC medical specialty board recognition criteria sufficient? If not, what additional criteria should the NRC use?

C. Patient Access

The NRC is requesting comments on whether there is a shortage in the number of AUs for 10 CFR 35.300.

1. Is there a shortage in the number of AUs for medical uses under 10 CFR 35.300? If so, is the shortage associated with the use of a specific radiopharmaceutical? Explain how.
2. Are there certain geographic areas with an inadequate number of AUs? Identify these areas.
3. Do current NRC regulations on AU T&E requirements unnecessarily limit patient access to procedures involving radiopharmaceuticals? Explain how.
4. Do current NRC regulations on AU T&E requirements unnecessarily limit research and development in nuclear medicine? Explain how.

D. Other Suggested Changes to the T&E Regulations

In 2002, the NRC revised its regulatory framework for medical use. The goal was to focus the NRC's regulations on those medical procedures that pose the highest risk to workers, the general public, patients, and human research subjects and to structure the regulations to be more risk-informed and more performance-based. The 2002 rule reduced the unnecessary regulatory burden by either reducing or eliminating the prescriptiveness of some regulations. Instead, the rule provided for a performance-based approach that relied on the training and experience of the AUs, authorized nuclear pharmacists, and radiation safety officers. The NRC is requesting comments on whether there are any other changes to the T&E regulations in 10 CFR part 35 that should be considered. Please discuss your suggested changes.

1. Should the NRC regulate the T&E of physicians for medical uses?
2. Are there requirements in the NRC's T&E regulatory framework for physicians that are non-safety related?

3. How can the NRC transform its regulatory approach for T&E while still ensuring that adequate protection is maintained for workers, the general public, patients, and human research subjects?

Dated at Rockville, Maryland, this 23rd day of October 2018.

For the Nuclear Regulatory
Commission.

/RA/

Daniel S. Collins, Director,
Division of Materials Safety,
Security,
State, and Tribal Programs,
Office of Nuclear Material Safety
and Safeguards.



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

November 2, 2018

Baptist College of Health Sciences
Department of Nuclear Technology Medicine
1003 Monroe Avenue
Memphis, TN 38104

**SUBJECT: TRAINING AND EXPERIENCE REQUIREMENTS FOR DIFFERENT
CATEGORIES OF RADIOPHARMACEUTICALS**

Dear Sir or Madam,

The U.S. Nuclear Regulatory Commission (NRC) is evaluating its regulations related to the training and experience (T&E) required for a physician to become an authorized user for medical uses under Subpart E, “Unsealed Byproduct Material—Written Directive Required,” of [Title 10 of the Code of Federal Regulations \(10 CFR\) Part 35, “Medical Use of Byproduct Material.”](#)

The T&E requirements in Subpart E of 10 CFR Part 35 provide three ways that a physician can be authorized to administer unsealed byproduct materials or radiopharmaceuticals requiring a written directive:

1. A physician can be certified by a medical specialty board, whose certification process is recognized by the NRC or an Agreement State.
2. A physician can complete a structured educational program and supervised work experience under an alternate pathway. This alternate pathway includes a requirement for 700 hours of training and experience, which consists of a minimum of 200 hours of classroom and laboratory training and 500 hours of supervised work experience.
3. A physician can be authorized if previously identified as an authorized user on an NRC or Agreement State license or permit (i.e., grandfathered).

In its evaluation of the T&E requirements, the NRC staff is considering whether an additional pathway should be created or if the alternate pathway should be revised. Specifically, the staff is evaluating: (1) whether it makes sense to establish tailored T&E requirements for different categories of radiopharmaceuticals; (2) how those categories should be determined; (3) what the appropriate T&E requirements would be for each category; and (4) whether those requirements should be based on hours of training and experience, or focused more on competency.

On October 29, 2018, the NRC published a series of questions on T&E in the *Federal Register* (83 FR 54380). The *Federal Register* notice is enclosed with this letter and can also be accessed at: <https://www.gpo.gov/fdsys/pkg/FR-2018-10-29/pdf/2018-23521.pdf>. The NRC will carefully consider responses to these questions and would appreciate your feedback on whether changes to the current T&E regulations are warranted. The comment period for the T&E evaluation will end on January 29, 2019. Please follow the directions in the notice on how to submit written comments. The NRC is using the Federal rulemaking Web site, [Regulations.gov](#), to accept written comments on the docket (NRC-2018-0230).

The NRC will also conduct four public meetings scheduled for November 14 and December 11, 2018, and January 10 and January 22, 2019, and will accept oral comments provided during the meetings. The meetings on December 11 and January 10 will be held at NRC Headquarters in Rockville, MD, and all four meetings will be accessible for remote participation by moderated bridge line and webinar. The NRC's public meeting page has been updated with meeting details and registration instructions for each meeting: <https://www.nrc.gov/pmns/mtg>.

Additional information on the NRC's T&E evaluation can be found at: <https://www.nrc.gov/materials/miau/med-use-toolkit/training-experience-evaluation.html>. If you have any questions on this correspondence, please contact Sarah Lopas of my staff at (301) 415-6360 or Sarah.Lopas@nrc.gov.

A handwritten signature in black ink, appearing to read "C Einberg".

Christian Einberg, Chief
Medical Safety and Events Assessment Branch
Division of Materials Safety, Security, State
and Tribal Programs
Office of Nuclear Material Safety
and Safeguards

Enclosure:
Training and Experience
Federal Register notice

NUCLEAR REGULATORY COMMISSION

[NRC-2018-0230]

**Training and Experience Requirements for Different Categories of
Radiopharmaceuticals**

AGENCY: Nuclear Regulatory Commission.

ACTION: Training and experience requirements; request for comment.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is requesting comments on its training and experience (T&E) requirements. Specifically, the NRC would like input on whether it should establish tailored T&E requirements for different categories of radiopharmaceuticals for which a written directive is required in accordance with its regulations. The input will be used to determine whether significant regulatory changes to the NRC's T&E requirements for authorized users (AUs) are warranted.

DATES: Submit comments by January 29, 2019. Comments received after this date will be considered if it is practical to do so, but the NRC is only able to ensure consideration for comments received on or before this date.

ADDRESSES: You may submit comments by any of the following methods:

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- **Mail comments to:** May Ma, Office of Administration, Mail Stop: TWFN-7-A60M, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001.

For additional direction on obtaining information and submitting comments, see “Obtaining Information and Submitting Comments” in the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: Sarah Lopas, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001; telephone: 301-415-6360, e-mail: Sarah.Lopas@nrc.gov.

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- **NRC's PDR:** You may examine and purchase copies of public documents at the NRC's PDR, Room O1-F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.

B. Submitting Comments

Please include Docket ID **NRC-2018-0230** in your comment submission.

The NRC cautions you not to include identifying or contact information in comment submissions that you do not want to be publicly disclosed in your comment submission. All comment submissions are posted at <http://www.regulations.gov> and entered into ADAMS. Comment submissions are not routinely edited to remove identifying or contact information.

If you are requesting or aggregating comments from other persons for submission to the NRC, then you should inform those persons not to include identifying or contact information that they do not want to be publicly disclosed in their comment submission. Your request should state that the NRC does not routinely edit comment submissions to remove such information before making the comment submissions available to the public or entering the comment into ADAMS.

II. Background

On August 17, 2017, the Commission issued a staff requirements memorandum (SRM), SRM-M170817 (ADAMS Accession No. ML17229B284), approving the final rule revising parts 30, 32, and 35 of title 10 of the *Code of Federal Regulations* (10 CFR), "Medical Use of Byproduct Material – Medical Event Definitions, Training and Experience, and Clarifying Amendments," and directing the staff to evaluate (1) whether it makes sense to establish tailored T&E requirements for different categories of radiopharmaceuticals, (2) how those categories should be determined (such as by risks posed by groups of

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- 2. Are the current NRC medical specialty board recognition criteria sufficient? If not, what additional criteria should the NRC use?

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1. Should the NRC regulate the T&E of physicians for medical uses?
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Dated at Rockville, Maryland, this 23rd day of October 2018.

For the Nuclear Regulatory
Commission.

/RA/

Daniel S. Collins, Director,
Division of Materials Safety,
Security,
State, and Tribal Programs,
Office of Nuclear Material Safety
and Safeguards.



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

November 2, 2018

Bayer HealthCare Pharmaceuticals, Inc.
Bayer AG
51368 Leverkusen
Germany

SUBJECT: TRAINING AND EXPERIENCE REQUIREMENTS FOR DIFFERENT
CATEGORIES OF RADIOPHARMACEUTICALS

Dear Sir or Madam,

The U.S. Nuclear Regulatory Commission (NRC) is evaluating its regulations related to the training and experience (T&E) required for a physician to become an authorized user for medical uses under Subpart E, “Unsealed Byproduct Material—Written Directive Required,” of [Title 10 of the Code of Federal Regulations \(10 CFR\) Part 35, “Medical Use of Byproduct Material.”](#)

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Additional information on the NRC's T&E evaluation can be found at: <https://www.nrc.gov/materials/miau/med-use-toolkit/training-experience-evaluation.html>. If you have any questions on this correspondence, please contact Sarah Lopas of my staff at (301) 415-6360 or Sarah.Lopas@nrc.gov.

A handwritten signature in black ink, appearing to read "C Einberg".

Christian Einberg, Chief
Medical Safety and Events Assessment Branch
Division of Materials Safety, Security, State
and Tribal Programs
Office of Nuclear Material Safety
and Safeguards

Enclosure:
Training and Experience
Federal Register notice

NUCLEAR REGULATORY COMMISSION

[NRC-2018-0230]

**Training and Experience Requirements for Different Categories of
Radiopharmaceuticals**

AGENCY: Nuclear Regulatory Commission.

ACTION: Training and experience requirements; request for comment.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is requesting comments on its training and experience (T&E) requirements. Specifically, the NRC would like input on whether it should establish tailored T&E requirements for different categories of radiopharmaceuticals for which a written directive is required in accordance with its regulations. The input will be used to determine whether significant regulatory changes to the NRC's T&E requirements for authorized users (AUs) are warranted.

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ADDRESSES: You may submit comments by any of the following methods:

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FOR FURTHER INFORMATION CONTACT: Sarah Lopas, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001; telephone: 301-415-6360, e-mail: Sarah.Lopas@nrc.gov.

SUPPLEMENTARY INFORMATION:

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radionuclides or by delivery method), (3) what the appropriate T&E requirements would be for each category, and (4) whether those requirements should be based on hours of T&E or focused more on competency. In response to the SRM, the NRC staff documented its initial results, status, and next steps related to this evaluation in SECY-18-0084, "Staff Evaluation of Training and Experience Requirements for Administering Different Categories of Radiopharmaceuticals in Response to SRM-M170817" (ADAMS Accession No. ML18135A276). In SECY-18-0084, the staff concluded that additional outreach with the medical community is needed to determine whether and how to tailor the T&E requirements to establish a limited AU status, the specific T&E requirements that should apply, how the T&E requirements should be met (e.g., hours of training, demonstration of competency), and whether a competency-based approach makes sense for the T&E requirements for all the medical uses authorized under 10 CFR 35.300, "Use of unsealed byproduct material for which a written directive is required."

The NRC is interested in obtaining input from as many stakeholders as possible, including members of the Advisory Committee on the Medical Uses of Isotopes, professional organizations, physicians, patients, patient advocacy groups, licensees, Agreement States, and other interested individuals. The focus of this request is to gather information that will permit the NRC staff to determine whether changes to the T&E requirements are warranted for different categories of radiopharmaceuticals for physicians seeking AU status for the medical use of specific categories of radiopharmaceuticals requiring a written directive under 10 CFR 35.300.

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III. Specific Requests for Comments

A. Tailored Training & Experience Requirements

The NRC is requesting comments on whether it should establish tailored T&E requirements for different categories of radiopharmaceuticals for physicians seeking AU status for the medical use of specific categories of radiopharmaceuticals requiring a written directive under 10 CFR 35.300 (i.e., a limited AU status). This would be for physicians seeking AU status via the alternate non-board certified pathway, and for physicians certified by a medical

specialty board that is not currently recognized by the NRC under 10 CFR 35.390, 35.392, 35.394, or 35.396 (Unsealed Byproduct Material—Written Directive Required).

1. Are the current pathways for obtaining AU status reasonable and accessible? Provide a rationale for your answer.
2. Are the current pathways for obtaining AU status adequate for protecting public health and safety? Provide a rationale for your answer.
3. Should the NRC develop a new tailored T&E pathway for these physicians? If so, what would be the appropriate way to categorize radiopharmaceuticals for tailored T&E requirements? If not, explain why the regulations should remain unchanged. [Some options to categorize radiopharmaceuticals include radiopharmaceuticals with similar delivery methods (oral, parenteral); same type of radiation characteristics or emission (alpha, beta, gamma, low-energy photon); similar preparation method (patient-ready doses); or a combination thereof (e.g., radiopharmaceuticals containing alpha- and beta-emitting radioisotopes that are administered intravenously and are prepared as patient-ready doses).]
4. Should the fundamental T&E required of physicians seeking limited AU status need to have the same fundamental T&E required of physicians seeking full AU status for all oral and parenteral administrations under 10 CFR 35.300?
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 - iii. Competency - How should competency be evaluated? Should a written and/or practical examination by an independent examining committee be administered? Provide a rationale for your answer.
- b. Should a preceptor attestation be required for the fundamental T&E? Provide a rationale for your answer.
- c. Should the radiopharmaceutical manufacturer be able to provide the preceptor attestation? Provide a rational for your answer.

- d. Who should establish and administer the curriculum and examination? Provide specific group(s). [Some options are: NRC, medical specialty boards, medical professional societies, educational professional groups, and NRC in collaboration with any or more of the aforementioned groups.]
- e. Should AU competency be periodically assessed? If so, how should it be assessed, how often, and by whom?

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- 1. What boards other than those already recognized by the NRC (American Board of Nuclear Medicine [ABNM], American Board of Radiology [ABR], American Osteopathic Board of Radiology [AOBR], Certification Board of Nuclear Endocrinology [CBNE]) could be considered for recognition for medical uses under 10 CFR 35.300?
- 2. Are the current NRC medical specialty board recognition criteria sufficient? If not, what additional criteria should the NRC use?

C. Patient Access

The NRC is requesting comments on whether there is a shortage in the number of AUs for 10 CFR 35.300.

1. Is there a shortage in the number of AUs for medical uses under 10 CFR 35.300? If so, is the shortage associated with the use of a specific radiopharmaceutical? Explain how.
2. Are there certain geographic areas with an inadequate number of AUs? Identify these areas.
3. Do current NRC regulations on AU T&E requirements unnecessarily limit patient access to procedures involving radiopharmaceuticals? Explain how.
4. Do current NRC regulations on AU T&E requirements unnecessarily limit research and development in nuclear medicine? Explain how.

D. Other Suggested Changes to the T&E Regulations

In 2002, the NRC revised its regulatory framework for medical use. The goal was to focus the NRC's regulations on those medical procedures that pose the highest risk to workers, the general public, patients, and human research subjects and to structure the regulations to be more risk-informed and more performance-based. The 2002 rule reduced the unnecessary regulatory burden by either reducing or eliminating the prescriptiveness of some regulations. Instead, the rule provided for a performance-based approach that relied on the training and experience of the AUs, authorized nuclear pharmacists, and radiation safety officers. The NRC is requesting comments on whether there are any other changes to the T&E regulations in 10 CFR part 35 that should be considered. Please discuss your suggested changes.

1. Should the NRC regulate the T&E of physicians for medical uses?
2. Are there requirements in the NRC's T&E regulatory framework for physicians that are non-safety related?

3. How can the NRC transform its regulatory approach for T&E while still ensuring that adequate protection is maintained for workers, the general public, patients, and human research subjects?

Dated at Rockville, Maryland, this 23rd day of October 2018.

For the Nuclear Regulatory
Commission.

/RA/

Daniel S. Collins, Director,
Division of Materials Safety,
Security,
State, and Tribal Programs,
Office of Nuclear Material Safety
and Safeguards.



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

November 2, 2018

Dr. Lilja Bjork Solnes
Program Director, Diagnostic Radiology Residency
Assistant Professor of Radiology and Radiological Science
Johns Hopkins Medicine - White Marsh
4924 Campbell Boulevard
Nottingham, MD 21236

**SUBJECT: TRAINING AND EXPERIENCE REQUIREMENTS FOR DIFFERENT
CATEGORIES OF RADIOPHARMACEUTICALS**

Dear Dr. Bjork Solnes,

The U.S. Nuclear Regulatory Commission (NRC) is evaluating its regulations related to the training and experience (T&E) required for a physician to become an authorized user for medical uses under Subpart E, “Unsealed Byproduct Material—Written Directive Required,” of [Title 10 of the Code of Federal Regulations \(10 CFR\) Part 35, “Medical Use of Byproduct Material.”](#)

The T&E requirements in Subpart E of 10 CFR Part 35 provide three ways that a physician can be authorized to administer unsealed byproduct materials or radiopharmaceuticals requiring a written directive:

1. A physician can be certified by a medical specialty board, whose certification process is recognized by the NRC or an Agreement State.
2. A physician can complete a structured educational program and supervised work experience under an alternate pathway. This alternate pathway includes a requirement for 700 hours of training and experience, which consists of a minimum of 200 hours of classroom and laboratory training and 500 hours of supervised work experience.
3. A physician can be authorized if previously identified as an authorized user on an NRC or Agreement State license or permit (i.e., grandfathered).

In its evaluation of the T&E requirements, the NRC staff is considering whether an additional pathway should be created or if the alternate pathway should be revised. Specifically, the staff is evaluating: (1) whether it makes sense to establish tailored T&E requirements for different categories of radiopharmaceuticals; (2) how those categories should be determined; (3) what the appropriate T&E requirements would be for each category; and (4) whether those requirements should be based on hours of training and experience, or focused more on competency.

On October 29, 2018, the NRC published a series of questions on T&E in the *Federal Register* (83 FR 54380). The *Federal Register* notice is enclosed with this letter and can also be accessed at: <https://www.gpo.gov/fdsys/pkg/FR-2018-10-29/pdf/2018-23521.pdf>. The NRC will carefully consider responses to these questions and would appreciate your feedback on whether changes to the current T&E regulations are warranted. The comment period for the T&E evaluation will end on January 29, 2019. Please follow the directions in the notice on how to submit written comments. The NRC is using the Federal rulemaking Web site, [Regulations.gov](#), to accept written comments on the docket (NRC-2018-0230).

The NRC will also conduct four public meetings scheduled for November 14 and December 11, 2018, and January 10 and January 22, 2019, and will accept oral comments provided during the meetings. The meetings on December 11 and January 10 will be held at NRC Headquarters in Rockville, MD, and all four meetings will be accessible for remote participation by moderated bridge line and webinar. The NRC's public meeting page has been updated with meeting details and registration instructions for each meeting: <https://www.nrc.gov/pmns/mtg>.

Additional information on the NRC's T&E evaluation can be found at: <https://www.nrc.gov/materials/miau/med-use-toolkit/training-experience-evaluation.html>. If you have any questions on this correspondence, please contact Sarah Lopas of my staff at (301) 415-6360 or Sarah.Lopas@nrc.gov.

A handwritten signature in black ink, appearing to read "C Einberg".

Christian Einberg, Chief
Medical Safety and Events Assessment Branch
Division of Materials Safety, Security, State
and Tribal Programs
Office of Nuclear Material Safety
and Safeguards

Enclosure:
Training and Experience
Federal Register notice

NUCLEAR REGULATORY COMMISSION

[NRC-2018-0230]

**Training and Experience Requirements for Different Categories of
Radiopharmaceuticals**

AGENCY: Nuclear Regulatory Commission.

ACTION: Training and experience requirements; request for comment.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is requesting comments on its training and experience (T&E) requirements. Specifically, the NRC would like input on whether it should establish tailored T&E requirements for different categories of radiopharmaceuticals for which a written directive is required in accordance with its regulations. The input will be used to determine whether significant regulatory changes to the NRC's T&E requirements for authorized users (AUs) are warranted.

DATES: Submit comments by January 29, 2019. Comments received after this date will be considered if it is practical to do so, but the NRC is only able to ensure consideration for comments received on or before this date.

ADDRESSES: You may submit comments by any of the following methods:

- **Federal Rulemaking Web Site:** Go to <http://www.regulations.gov>

and search for Docket ID **NRC-2018-0230**. Address questions about Docket IDs in Regulations.gov to Jennifer Borges; telephone: 301-287-9127; e-mail: Jennifer.Borges@nrc.gov. For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.

- **Mail comments to:** May Ma, Office of Administration, Mail Stop: TWFN-7-A60M, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001.

For additional direction on obtaining information and submitting comments, see “Obtaining Information and Submitting Comments” in the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: Sarah Lopas, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001; telephone: 301-415-6360, e-mail: Sarah.Lopas@nrc.gov.

SUPPLEMENTARY INFORMATION:

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- d. Who should establish and administer the curriculum and examination? Provide specific group(s). [Some options are: NRC, medical specialty boards, medical professional societies, educational professional groups, and NRC in collaboration with any or more of the aforementioned groups.]
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Dated at Rockville, Maryland, this 23rd day of October 2018.

For the Nuclear Regulatory
Commission.

/RA/

Daniel S. Collins, Director,
Division of Materials Safety,
Security,
State, and Tribal Programs,
Office of Nuclear Material Safety
and Safeguards.



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

November 2, 2018

Cardinal Health
7000 Cardinal Place
Dublin, OH 43017

SUBJECT: TRAINING AND EXPERIENCE REQUIREMENTS FOR DIFFERENT CATEGORIES OF RADIOPHARMACEUTICALS

Dear Sir or Madam,

The U.S. Nuclear Regulatory Commission (NRC) is evaluating its regulations related to the training and experience (T&E) required for a physician to become an authorized user for medical uses under Subpart E, “Unsealed Byproduct Material—Written Directive Required,” of [Title 10 of the Code of Federal Regulations \(10 CFR\) Part 35, “Medical Use of Byproduct Material.”](#)

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Christian Einberg, Chief
Medical Safety and Events Assessment Branch
Division of Materials Safety, Security, State
and Tribal Programs
Office of Nuclear Material Safety
and Safeguards

Enclosure:
Training and Experience
Federal Register notice

NUCLEAR REGULATORY COMMISSION

[NRC-2018-0230]

**Training and Experience Requirements for Different Categories of
Radiopharmaceuticals**

AGENCY: Nuclear Regulatory Commission.

ACTION: Training and experience requirements; request for comment.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is requesting comments on its training and experience (T&E) requirements. Specifically, the NRC would like input on whether it should establish tailored T&E requirements for different categories of radiopharmaceuticals for which a written directive is required in accordance with its regulations. The input will be used to determine whether significant regulatory changes to the NRC's T&E requirements for authorized users (AUs) are warranted.

DATES: Submit comments by January 29, 2019. Comments received after this date will be considered if it is practical to do so, but the NRC is only able to ensure consideration for comments received on or before this date.

ADDRESSES: You may submit comments by any of the following methods:

- **Federal Rulemaking Web Site:** Go to <http://www.regulations.gov>

and search for Docket ID **NRC-2018-0230**. Address questions about Docket IDs in Regulations.gov to Jennifer Borges; telephone: 301-287-9127; e-mail: Jennifer.Borges@nrc.gov. For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.

- **Mail comments to:** May Ma, Office of Administration, Mail Stop: TWFN-7-A60M, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001.

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FOR FURTHER INFORMATION CONTACT: Sarah Lopas, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001; telephone: 301-415-6360, e-mail: Sarah.Lopas@nrc.gov.

SUPPLEMENTARY INFORMATION:

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radionuclides or by delivery method), (3) what the appropriate T&E requirements would be for each category, and (4) whether those requirements should be based on hours of T&E or focused more on competency. In response to the SRM, the NRC staff documented its initial results, status, and next steps related to this evaluation in SECY-18-0084, "Staff Evaluation of Training and Experience Requirements for Administering Different Categories of Radiopharmaceuticals in Response to SRM-M170817" (ADAMS Accession No. ML18135A276). In SECY-18-0084, the staff concluded that additional outreach with the medical community is needed to determine whether and how to tailor the T&E requirements to establish a limited AU status, the specific T&E requirements that should apply, how the T&E requirements should be met (e.g., hours of training, demonstration of competency), and whether a competency-based approach makes sense for the T&E requirements for all the medical uses authorized under 10 CFR 35.300, "Use of unsealed byproduct material for which a written directive is required."

The NRC is interested in obtaining input from as many stakeholders as possible, including members of the Advisory Committee on the Medical Uses of Isotopes, professional organizations, physicians, patients, patient advocacy groups, licensees, Agreement States, and other interested individuals. The focus of this request is to gather information that will permit the NRC staff to determine whether changes to the T&E requirements are warranted for different categories of radiopharmaceuticals for physicians seeking AU status for the medical use of specific categories of radiopharmaceuticals requiring a written directive under 10 CFR 35.300.

During the comment period between October 29, 2018 and January 29, 2019, the NRC will hold four public meetings that will discuss the information being requested and to accept comments on the docket. All four public meetings

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III. Specific Requests for Comments

A. Tailored Training & Experience Requirements

The NRC is requesting comments on whether it should establish tailored T&E requirements for different categories of radiopharmaceuticals for physicians seeking AU status for the medical use of specific categories of radiopharmaceuticals requiring a written directive under 10 CFR 35.300 (i.e., a limited AU status). This would be for physicians seeking AU status via the alternate non-board certified pathway, and for physicians certified by a medical

specialty board that is not currently recognized by the NRC under 10 CFR 35.390, 35.392, 35.394, or 35.396 (Unsealed Byproduct Material—Written Directive Required).

1. Are the current pathways for obtaining AU status reasonable and accessible? Provide a rationale for your answer.
2. Are the current pathways for obtaining AU status adequate for protecting public health and safety? Provide a rationale for your answer.
3. Should the NRC develop a new tailored T&E pathway for these physicians? If so, what would be the appropriate way to categorize radiopharmaceuticals for tailored T&E requirements? If not, explain why the regulations should remain unchanged. [Some options to categorize radiopharmaceuticals include radiopharmaceuticals with similar delivery methods (oral, parenteral); same type of radiation characteristics or emission (alpha, beta, gamma, low-energy photon); similar preparation method (patient-ready doses); or a combination thereof (e.g., radiopharmaceuticals containing alpha- and beta-emitting radioisotopes that are administered intravenously and are prepared as patient-ready doses).]
4. Should the fundamental T&E required of physicians seeking limited AU status need to have the same fundamental T&E required of physicians seeking full AU status for all oral and parenteral administrations under 10 CFR 35.300?
5. How should the requirements for this fundamental T&E be structured for a specific category of radiopharmaceuticals?
 - a. Describe what the requirements should include:

- i. Classroom and laboratory training – What topics need to be covered in this training requirement? How many hours of classroom and laboratory training should be required? Provide the basis for the number of hours. If not hours, explain how this training should be quantified. [Note: The topics currently required in the regulations to be included in the classroom and laboratory training and work experience are listed in 10 CFR 35.390, 35.392, 35.394, and 35.396.]
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 - iii. Competency - How should competency be evaluated? Should a written and/or practical examination by an independent examining committee be administered? Provide a rationale for your answer.
- b. Should a preceptor attestation be required for the fundamental T&E? Provide a rationale for your answer.
- c. Should the radiopharmaceutical manufacturer be able to provide the preceptor attestation? Provide a rational for your answer.

- d. Who should establish and administer the curriculum and examination? Provide specific group(s). [Some options are: NRC, medical specialty boards, medical professional societies, educational professional groups, and NRC in collaboration with any or more of the aforementioned groups.]
- e. Should AU competency be periodically assessed? If so, how should it be assessed, how often, and by whom?

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The NRC is requesting comments on its recognition of medical specialty boards. The NRC's procedures for recognizing medical specialty boards are located on the Medical Uses Licensee Toolkit Web site (<https://www.nrc.gov/materials/miau/med-use-toolkit/certif-process-boards.html>). The NRC staff periodically reviews information to determine a board's continued eligibility for recognition.

- 1. What boards other than those already recognized by the NRC (American Board of Nuclear Medicine [ABNM], American Board of Radiology [ABR], American Osteopathic Board of Radiology [AOBR], Certification Board of Nuclear Endocrinology [CBNE]) could be considered for recognition for medical uses under 10 CFR 35.300?
- 2. Are the current NRC medical specialty board recognition criteria sufficient? If not, what additional criteria should the NRC use?

C. Patient Access

The NRC is requesting comments on whether there is a shortage in the number of AUs for 10 CFR 35.300.

1. Is there a shortage in the number of AUs for medical uses under 10 CFR 35.300? If so, is the shortage associated with the use of a specific radiopharmaceutical? Explain how.
2. Are there certain geographic areas with an inadequate number of AUs? Identify these areas.
3. Do current NRC regulations on AU T&E requirements unnecessarily limit patient access to procedures involving radiopharmaceuticals? Explain how.
4. Do current NRC regulations on AU T&E requirements unnecessarily limit research and development in nuclear medicine? Explain how.

D. Other Suggested Changes to the T&E Regulations

In 2002, the NRC revised its regulatory framework for medical use. The goal was to focus the NRC's regulations on those medical procedures that pose the highest risk to workers, the general public, patients, and human research subjects and to structure the regulations to be more risk-informed and more performance-based. The 2002 rule reduced the unnecessary regulatory burden by either reducing or eliminating the prescriptiveness of some regulations. Instead, the rule provided for a performance-based approach that relied on the training and experience of the AUs, authorized nuclear pharmacists, and radiation safety officers. The NRC is requesting comments on whether there are any other changes to the T&E regulations in 10 CFR part 35 that should be considered. Please discuss your suggested changes.

1. Should the NRC regulate the T&E of physicians for medical uses?
2. Are there requirements in the NRC's T&E regulatory framework for physicians that are non-safety related?

3. How can the NRC transform its regulatory approach for T&E while still ensuring that adequate protection is maintained for workers, the general public, patients, and human research subjects?

Dated at Rockville, Maryland, this 23rd day of October 2018.

For the Nuclear Regulatory
Commission.

/RA/

Daniel S. Collins, Director,
Division of Materials Safety,
Security,
State, and Tribal Programs,
Office of Nuclear Material Safety
and Safeguards.



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

November 2, 2018

Dana-Farber Cancer Institute
Radiation Oncology Training and Fellowship Program
450 Brookline Avenue
Boston, MA 02215-5450

SUBJECT: TRAINING AND EXPERIENCE REQUIREMENTS FOR DIFFERENT CATEGORIES OF RADIOPHARMACEUTICALS

Dear Sir or Madam,

The U.S. Nuclear Regulatory Commission (NRC) is evaluating its regulations related to the training and experience (T&E) required for a physician to become an authorized user for medical uses under Subpart E, “Unsealed Byproduct Material—Written Directive Required,” of [Title 10 of the Code of Federal Regulations \(10 CFR\) Part 35, “Medical Use of Byproduct Material.”](#)

The T&E requirements in Subpart E of 10 CFR Part 35 provide three ways that a physician can be authorized to administer unsealed byproduct materials or radiopharmaceuticals requiring a written directive:

1. A physician can be certified by a medical specialty board, whose certification process is recognized by the NRC or an Agreement State.
2. A physician can complete a structured educational program and supervised work experience under an alternate pathway. This alternate pathway includes a requirement for 700 hours of training and experience, which consists of a minimum of 200 hours of classroom and laboratory training and 500 hours of supervised work experience.
3. A physician can be authorized if previously identified as an authorized user on an NRC or Agreement State license or permit (i.e., grandfathered).

In its evaluation of the T&E requirements, the NRC staff is considering whether an additional pathway should be created or if the alternate pathway should be revised. Specifically, the staff is evaluating: (1) whether it makes sense to establish tailored T&E requirements for different categories of radiopharmaceuticals; (2) how those categories should be determined; (3) what the appropriate T&E requirements would be for each category; and (4) whether those requirements should be based on hours of training and experience, or focused more on competency.

On October 29, 2018, the NRC published a series of questions on T&E in the *Federal Register* (83 FR 54380). The *Federal Register* notice is enclosed with this letter and can also be accessed at: <https://www.gpo.gov/fdsys/pkg/FR-2018-10-29/pdf/2018-23521.pdf>. The NRC will carefully consider responses to these questions and would appreciate your feedback on whether changes to the current T&E regulations are warranted. The comment period for the T&E evaluation will end on January 29, 2019. Please follow the directions in the notice on how to submit written comments. The NRC is using the Federal rulemaking Web site, [Regulations.gov](#), to accept written comments on the docket (NRC-2018-0230).

The NRC will also conduct four public meetings scheduled for November 14 and December 11, 2018, and January 10 and January 22, 2019, and will accept oral comments provided during the meetings. The meetings on December 11 and January 10 will be held at NRC Headquarters in Rockville, MD, and all four meetings will be accessible for remote participation by moderated bridge line and webinar. The NRC's public meeting page has been updated with meeting details and registration instructions for each meeting: <https://www.nrc.gov/pmns/mtg>.

Additional information on the NRC's T&E evaluation can be found at: <https://www.nrc.gov/materials/miau/med-use-toolkit/training-experience-evaluation.html>. If you have any questions on this correspondence, please contact Sarah Lopas of my staff at (301) 415-6360 or Sarah.Lopas@nrc.gov.

A handwritten signature in black ink, appearing to read "C Einberg".

Christian Einberg, Chief
Medical Safety and Events Assessment Branch
Division of Materials Safety, Security, State
and Tribal Programs
Office of Nuclear Material Safety
and Safeguards

Enclosure:
Training and Experience
Federal Register notice

NUCLEAR REGULATORY COMMISSION

[NRC-2018-0230]

**Training and Experience Requirements for Different Categories of
Radiopharmaceuticals**

AGENCY: Nuclear Regulatory Commission.

ACTION: Training and experience requirements; request for comment.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is requesting comments on its training and experience (T&E) requirements. Specifically, the NRC would like input on whether it should establish tailored T&E requirements for different categories of radiopharmaceuticals for which a written directive is required in accordance with its regulations. The input will be used to determine whether significant regulatory changes to the NRC's T&E requirements for authorized users (AUs) are warranted.

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Dated at Rockville, Maryland, this 23rd day of October 2018.

For the Nuclear Regulatory
Commission.

/RA/

Daniel S. Collins, Director,
Division of Materials Safety,
Security,
State, and Tribal Programs,
Office of Nuclear Material Safety
and Safeguards.



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

November 2, 2018

DuPont Merck
Dupont Government Affairs
601 Pennsylvania Ave. NW, #325
Washington, DC 20004

**SUBJECT: TRAINING AND EXPERIENCE REQUIREMENTS FOR DIFFERENT
CATEGORIES OF RADIOPHARMACEUTICALS**

Dear Sir or Madam,

The U.S. Nuclear Regulatory Commission (NRC) is evaluating its regulations related to the training and experience (T&E) required for a physician to become an authorized user for medical uses under Subpart E, “Unsealed Byproduct Material—Written Directive Required,” of [Title 10 of the Code of Federal Regulations \(10 CFR\) Part 35, “Medical Use of Byproduct Material.”](#)

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On October 29, 2018, the NRC published a series of questions on T&E in the *Federal Register* (83 FR 54380). The *Federal Register* notice is enclosed with this letter and can also be accessed at: <https://www.gpo.gov/fdsys/pkg/FR-2018-10-29/pdf/2018-23521.pdf>. The NRC will carefully consider responses to these questions and would appreciate your feedback on whether changes to the current T&E regulations are warranted. The comment period for the T&E evaluation will end on January 29, 2019. Please follow the directions in the notice on how to submit written comments. The NRC is using the Federal rulemaking Web site, [Regulations.gov](#), to accept written comments on the docket (NRC-2018-0230).

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Christian Einberg, Chief
Medical Safety and Events Assessment Branch
Division of Materials Safety, Security, State
and Tribal Programs
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Enclosure:
Training and Experience
Federal Register notice

NUCLEAR REGULATORY COMMISSION

[NRC-2018-0230]

**Training and Experience Requirements for Different Categories of
Radiopharmaceuticals**

AGENCY: Nuclear Regulatory Commission.

ACTION: Training and experience requirements; request for comment.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is requesting comments on its training and experience (T&E) requirements. Specifically, the NRC would like input on whether it should establish tailored T&E requirements for different categories of radiopharmaceuticals for which a written directive is required in accordance with its regulations. The input will be used to determine whether significant regulatory changes to the NRC's T&E requirements for authorized users (AUs) are warranted.

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The NRC is interested in obtaining input from as many stakeholders as possible, including members of the Advisory Committee on the Medical Uses of Isotopes, professional organizations, physicians, patients, patient advocacy groups, licensees, Agreement States, and other interested individuals. The focus of this request is to gather information that will permit the NRC staff to determine whether changes to the T&E requirements are warranted for different categories of radiopharmaceuticals for physicians seeking AU status for the medical use of specific categories of radiopharmaceuticals requiring a written directive under 10 CFR 35.300.

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III. Specific Requests for Comments

A. Tailored Training & Experience Requirements

The NRC is requesting comments on whether it should establish tailored T&E requirements for different categories of radiopharmaceuticals for physicians seeking AU status for the medical use of specific categories of radiopharmaceuticals requiring a written directive under 10 CFR 35.300 (i.e., a limited AU status). This would be for physicians seeking AU status via the alternate non-board certified pathway, and for physicians certified by a medical

specialty board that is not currently recognized by the NRC under 10 CFR 35.390, 35.392, 35.394, or 35.396 (Unsealed Byproduct Material—Written Directive Required).

1. Are the current pathways for obtaining AU status reasonable and accessible? Provide a rationale for your answer.
2. Are the current pathways for obtaining AU status adequate for protecting public health and safety? Provide a rationale for your answer.
3. Should the NRC develop a new tailored T&E pathway for these physicians? If so, what would be the appropriate way to categorize radiopharmaceuticals for tailored T&E requirements? If not, explain why the regulations should remain unchanged. [Some options to categorize radiopharmaceuticals include radiopharmaceuticals with similar delivery methods (oral, parenteral); same type of radiation characteristics or emission (alpha, beta, gamma, low-energy photon); similar preparation method (patient-ready doses); or a combination thereof (e.g., radiopharmaceuticals containing alpha- and beta-emitting radioisotopes that are administered intravenously and are prepared as patient-ready doses).]
4. Should the fundamental T&E required of physicians seeking limited AU status need to have the same fundamental T&E required of physicians seeking full AU status for all oral and parenteral administrations under 10 CFR 35.300?
5. How should the requirements for this fundamental T&E be structured for a specific category of radiopharmaceuticals?
 - a. Describe what the requirements should include:

- i. Classroom and laboratory training – What topics need to be covered in this training requirement? How many hours of classroom and laboratory training should be required? Provide the basis for the number of hours. If not hours, explain how this training should be quantified. [Note: The topics currently required in the regulations to be included in the classroom and laboratory training and work experience are listed in 10 CFR 35.390, 35.392, 35.394, and 35.396.]
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 - iii. Competency - How should competency be evaluated? Should a written and/or practical examination by an independent examining committee be administered? Provide a rationale for your answer.
- b. Should a preceptor attestation be required for the fundamental T&E? Provide a rationale for your answer.
- c. Should the radiopharmaceutical manufacturer be able to provide the preceptor attestation? Provide a rational for your answer.

- d. Who should establish and administer the curriculum and examination? Provide specific group(s). [Some options are: NRC, medical specialty boards, medical professional societies, educational professional groups, and NRC in collaboration with any or more of the aforementioned groups.]
- e. Should AU competency be periodically assessed? If so, how should it be assessed, how often, and by whom?

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The NRC is requesting comments on its recognition of medical specialty boards. The NRC's procedures for recognizing medical specialty boards are located on the Medical Uses Licensee Toolkit Web site (<https://www.nrc.gov/materials/miau/med-use-toolkit/certif-process-boards.html>). The NRC staff periodically reviews information to determine a board's continued eligibility for recognition.

- 1. What boards other than those already recognized by the NRC (American Board of Nuclear Medicine [ABNM], American Board of Radiology [ABR], American Osteopathic Board of Radiology [AOBR], Certification Board of Nuclear Endocrinology [CBNE]) could be considered for recognition for medical uses under 10 CFR 35.300?
- 2. Are the current NRC medical specialty board recognition criteria sufficient? If not, what additional criteria should the NRC use?

C. Patient Access

The NRC is requesting comments on whether there is a shortage in the number of AUs for 10 CFR 35.300.

1. Is there a shortage in the number of AUs for medical uses under 10 CFR 35.300? If so, is the shortage associated with the use of a specific radiopharmaceutical? Explain how.
2. Are there certain geographic areas with an inadequate number of AUs? Identify these areas.
3. Do current NRC regulations on AU T&E requirements unnecessarily limit patient access to procedures involving radiopharmaceuticals? Explain how.
4. Do current NRC regulations on AU T&E requirements unnecessarily limit research and development in nuclear medicine? Explain how.

D. Other Suggested Changes to the T&E Regulations

In 2002, the NRC revised its regulatory framework for medical use. The goal was to focus the NRC's regulations on those medical procedures that pose the highest risk to workers, the general public, patients, and human research subjects and to structure the regulations to be more risk-informed and more performance-based. The 2002 rule reduced the unnecessary regulatory burden by either reducing or eliminating the prescriptiveness of some regulations. Instead, the rule provided for a performance-based approach that relied on the training and experience of the AUs, authorized nuclear pharmacists, and radiation safety officers. The NRC is requesting comments on whether there are any other changes to the T&E regulations in 10 CFR part 35 that should be considered. Please discuss your suggested changes.

1. Should the NRC regulate the T&E of physicians for medical uses?
2. Are there requirements in the NRC's T&E regulatory framework for physicians that are non-safety related?

3. How can the NRC transform its regulatory approach for T&E while still ensuring that adequate protection is maintained for workers, the general public, patients, and human research subjects?

Dated at Rockville, Maryland, this 23rd day of October 2018.

For the Nuclear Regulatory
Commission.

/RA/

Daniel S. Collins, Director,
Division of Materials Safety,
Security,
State, and Tribal Programs,
Office of Nuclear Material Safety
and Safeguards.



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

November 2, 2018

Mr. William M. Ellis, MS, RPh
Board of Pharmacy Specialities
2215 Constitution Ave. NW
Washington, DC 20037-2985

**SUBJECT: TRAINING AND EXPERIENCE REQUIREMENTS FOR DIFFERENT
CATEGORIES OF RADIOPHARMACEUTICALS**

Dear Mr. Ellis,

The U.S. Nuclear Regulatory Commission (NRC) is evaluating its regulations related to the training and experience (T&E) required for a physician to become an authorized user for medical uses under Subpart E, “Unsealed Byproduct Material—Written Directive Required,” of [Title 10 of the Code of Federal Regulations \(10 CFR\) Part 35, “Medical Use of Byproduct Material.”](#)

The T&E requirements in Subpart E of 10 CFR Part 35 provide three ways that a physician can be authorized to administer unsealed byproduct materials or radiopharmaceuticals requiring a written directive:

1. A physician can be certified by a medical specialty board, whose certification process is recognized by the NRC or an Agreement State.
2. A physician can complete a structured educational program and supervised work experience under an alternate pathway. This alternate pathway includes a requirement for 700 hours of training and experience, which consists of a minimum of 200 hours of classroom and laboratory training and 500 hours of supervised work experience.
3. A physician can be authorized if previously identified as an authorized user on an NRC or Agreement State license or permit (i.e., grandfathered).

In its evaluation of the T&E requirements, the NRC staff is considering whether an additional pathway should be created or if the alternate pathway should be revised. Specifically, the staff is evaluating: (1) whether it makes sense to establish tailored T&E requirements for different categories of radiopharmaceuticals; (2) how those categories should be determined; (3) what the appropriate T&E requirements would be for each category; and (4) whether those requirements should be based on hours of training and experience, or focused more on competency.

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Christian Einberg, Chief
Medical Safety and Events Assessment Branch
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Enclosure:
Training and Experience
Federal Register notice

NUCLEAR REGULATORY COMMISSION

[NRC-2018-0230]

**Training and Experience Requirements for Different Categories of
Radiopharmaceuticals**

AGENCY: Nuclear Regulatory Commission.

ACTION: Training and experience requirements; request for comment.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is requesting comments on its training and experience (T&E) requirements. Specifically, the NRC would like input on whether it should establish tailored T&E requirements for different categories of radiopharmaceuticals for which a written directive is required in accordance with its regulations. The input will be used to determine whether significant regulatory changes to the NRC's T&E requirements for authorized users (AUs) are warranted.

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Dated at Rockville, Maryland, this 23rd day of October 2018.

For the Nuclear Regulatory
Commission.

/RA/

Daniel S. Collins, Director,
Division of Materials Safety,
Security,
State, and Tribal Programs,
Office of Nuclear Material Safety
and Safeguards.



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

November 2, 2018

University of Findlay, Nuclear Medicine Institute
1000 N. Main St.
Findlay, OH 45840

**SUBJECT: TRAINING AND EXPERIENCE REQUIREMENTS FOR DIFFERENT
CATEGORIES OF RADIOPHARMACEUTICALS**

Dear Sir or Madam,

The U.S. Nuclear Regulatory Commission (NRC) is evaluating its regulations related to the training and experience (T&E) required for a physician to become an authorized user for medical uses under Subpart E, “Unsealed Byproduct Material—Written Directive Required,” of [Title 10 of the Code of Federal Regulations \(10 CFR\) Part 35, “Medical Use of Byproduct Material.”](#)

The T&E requirements in Subpart E of 10 CFR Part 35 provide three ways that a physician can be authorized to administer unsealed byproduct materials or radiopharmaceuticals requiring a written directive:

1. A physician can be certified by a medical specialty board, whose certification process is recognized by the NRC or an Agreement State.
2. A physician can complete a structured educational program and supervised work experience under an alternate pathway. This alternate pathway includes a requirement for 700 hours of training and experience, which consists of a minimum of 200 hours of classroom and laboratory training and 500 hours of supervised work experience.
3. A physician can be authorized if previously identified as an authorized user on an NRC or Agreement State license or permit (i.e., grandfathered).

In its evaluation of the T&E requirements, the NRC staff is considering whether an additional pathway should be created or if the alternate pathway should be revised. Specifically, the staff is evaluating: (1) whether it makes sense to establish tailored T&E requirements for different categories of radiopharmaceuticals; (2) how those categories should be determined; (3) what the appropriate T&E requirements would be for each category; and (4) whether those requirements should be based on hours of training and experience, or focused more on competency.

On October 29, 2018, the NRC published a series of questions on T&E in the *Federal Register* (83 FR 54380). The *Federal Register* notice is enclosed with this letter and can also be accessed at: <https://www.gpo.gov/fdsys/pkg/FR-2018-10-29/pdf/2018-23521.pdf>. The NRC will carefully consider responses to these questions and would appreciate your feedback on whether changes to the current T&E regulations are warranted. The comment period for the T&E evaluation will end on January 29, 2019. Please follow the directions in the notice on how to submit written comments. The NRC is using the Federal rulemaking Web site, [Regulations.gov](#), to accept written comments on the docket (NRC-2018-0230).

The NRC will also conduct four public meetings scheduled for November 14 and December 11, 2018, and January 10 and January 22, 2019, and will accept oral comments provided during the meetings. The meetings on December 11 and January 10 will be held at NRC Headquarters in Rockville, MD, and all four meetings will be accessible for remote participation by moderated bridge line and webinar. The NRC's public meeting page has been updated with meeting details and registration instructions for each meeting: <https://www.nrc.gov/pmns/mtg>.

Additional information on the NRC's T&E evaluation can be found at: <https://www.nrc.gov/materials/miau/med-use-toolkit/training-experience-evaluation.html>. If you have any questions on this correspondence, please contact Sarah Lopas of my staff at (301) 415-6360 or Sarah.Lopas@nrc.gov.

A handwritten signature in black ink, appearing to read "C Einberg".

Christian Einberg, Chief
Medical Safety and Events Assessment Branch
Division of Materials Safety, Security, State
and Tribal Programs
Office of Nuclear Material Safety
and Safeguards

Enclosure:
Training and Experience
Federal Register notice

NUCLEAR REGULATORY COMMISSION

[NRC-2018-0230]

**Training and Experience Requirements for Different Categories of
Radiopharmaceuticals**

AGENCY: Nuclear Regulatory Commission.

ACTION: Training and experience requirements; request for comment.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is requesting comments on its training and experience (T&E) requirements. Specifically, the NRC would like input on whether it should establish tailored T&E requirements for different categories of radiopharmaceuticals for which a written directive is required in accordance with its regulations. The input will be used to determine whether significant regulatory changes to the NRC's T&E requirements for authorized users (AUs) are warranted.

DATES: Submit comments by January 29, 2019. Comments received after this date will be considered if it is practical to do so, but the NRC is only able to ensure consideration for comments received on or before this date.

ADDRESSES: You may submit comments by any of the following methods:

- **Federal Rulemaking Web Site:** Go to <http://www.regulations.gov>

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- **Mail comments to:** May Ma, Office of Administration, Mail Stop: TWFN-7-A60M, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001.

For additional direction on obtaining information and submitting comments, see “Obtaining Information and Submitting Comments” in the **SUPPLEMENTARY INFORMATION** section of this document.

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B. Submitting Comments

Please include Docket ID **NRC-2018-0230** in your comment submission.

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radionuclides or by delivery method), (3) what the appropriate T&E requirements would be for each category, and (4) whether those requirements should be based on hours of T&E or focused more on competency. In response to the SRM, the NRC staff documented its initial results, status, and next steps related to this evaluation in SECY-18-0084, "Staff Evaluation of Training and Experience Requirements for Administering Different Categories of Radiopharmaceuticals in Response to SRM-M170817" (ADAMS Accession No. ML18135A276). In SECY-18-0084, the staff concluded that additional outreach with the medical community is needed to determine whether and how to tailor the T&E requirements to establish a limited AU status, the specific T&E requirements that should apply, how the T&E requirements should be met (e.g., hours of training, demonstration of competency), and whether a competency-based approach makes sense for the T&E requirements for all the medical uses authorized under 10 CFR 35.300, "Use of unsealed byproduct material for which a written directive is required."

The NRC is interested in obtaining input from as many stakeholders as possible, including members of the Advisory Committee on the Medical Uses of Isotopes, professional organizations, physicians, patients, patient advocacy groups, licensees, Agreement States, and other interested individuals. The focus of this request is to gather information that will permit the NRC staff to determine whether changes to the T&E requirements are warranted for different categories of radiopharmaceuticals for physicians seeking AU status for the medical use of specific categories of radiopharmaceuticals requiring a written directive under 10 CFR 35.300.

During the comment period between October 29, 2018 and January 29, 2019, the NRC will hold four public meetings that will discuss the information being requested and to accept comments on the docket. All four public meetings

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III. Specific Requests for Comments

A. Tailored Training & Experience Requirements

The NRC is requesting comments on whether it should establish tailored T&E requirements for different categories of radiopharmaceuticals for physicians seeking AU status for the medical use of specific categories of radiopharmaceuticals requiring a written directive under 10 CFR 35.300 (i.e., a limited AU status). This would be for physicians seeking AU status via the alternate non-board certified pathway, and for physicians certified by a medical

specialty board that is not currently recognized by the NRC under 10 CFR 35.390, 35.392, 35.394, or 35.396 (Unsealed Byproduct Material—Written Directive Required).

1. Are the current pathways for obtaining AU status reasonable and accessible? Provide a rationale for your answer.
2. Are the current pathways for obtaining AU status adequate for protecting public health and safety? Provide a rationale for your answer.
3. Should the NRC develop a new tailored T&E pathway for these physicians? If so, what would be the appropriate way to categorize radiopharmaceuticals for tailored T&E requirements? If not, explain why the regulations should remain unchanged. [Some options to categorize radiopharmaceuticals include radiopharmaceuticals with similar delivery methods (oral, parenteral); same type of radiation characteristics or emission (alpha, beta, gamma, low-energy photon); similar preparation method (patient-ready doses); or a combination thereof (e.g., radiopharmaceuticals containing alpha- and beta-emitting radioisotopes that are administered intravenously and are prepared as patient-ready doses).]
4. Should the fundamental T&E required of physicians seeking limited AU status need to have the same fundamental T&E required of physicians seeking full AU status for all oral and parenteral administrations under 10 CFR 35.300?
5. How should the requirements for this fundamental T&E be structured for a specific category of radiopharmaceuticals?
 - a. Describe what the requirements should include:

- i. Classroom and laboratory training – What topics need to be covered in this training requirement? How many hours of classroom and laboratory training should be required? Provide the basis for the number of hours. If not hours, explain how this training should be quantified. [Note: The topics currently required in the regulations to be included in the classroom and laboratory training and work experience are listed in 10 CFR 35.390, 35.392, 35.394, and 35.396.]
 - ii. Work experience - What should the work experience requirement involve? How many hours of work experience should be required and what is the minimum number of patient or human research subject administrations that an individual must perform? Provide the basis for the number of hours and administrations. What should be the qualifications of the supervising individual?
 - iii. Competency - How should competency be evaluated? Should a written and/or practical examination by an independent examining committee be administered? Provide a rationale for your answer.
- b. Should a preceptor attestation be required for the fundamental T&E? Provide a rationale for your answer.
- c. Should the radiopharmaceutical manufacturer be able to provide the preceptor attestation? Provide a rational for your answer.

- d. Who should establish and administer the curriculum and examination? Provide specific group(s). [Some options are: NRC, medical specialty boards, medical professional societies, educational professional groups, and NRC in collaboration with any or more of the aforementioned groups.]
- e. Should AU competency be periodically assessed? If so, how should it be assessed, how often, and by whom?

B. NRC's Recognition of Medical Specialty Boards

The NRC is requesting comments on its recognition of medical specialty boards. The NRC's procedures for recognizing medical specialty boards are located on the Medical Uses Licensee Toolkit Web site (<https://www.nrc.gov/materials/miau/med-use-toolkit/certif-process-boards.html>). The NRC staff periodically reviews information to determine a board's continued eligibility for recognition.

- 1. What boards other than those already recognized by the NRC (American Board of Nuclear Medicine [ABNM], American Board of Radiology [ABR], American Osteopathic Board of Radiology [AOBR], Certification Board of Nuclear Endocrinology [CBNE]) could be considered for recognition for medical uses under 10 CFR 35.300?
- 2. Are the current NRC medical specialty board recognition criteria sufficient? If not, what additional criteria should the NRC use?

C. Patient Access

The NRC is requesting comments on whether there is a shortage in the number of AUs for 10 CFR 35.300.

1. Is there a shortage in the number of AUs for medical uses under 10 CFR 35.300? If so, is the shortage associated with the use of a specific radiopharmaceutical? Explain how.
2. Are there certain geographic areas with an inadequate number of AUs? Identify these areas.
3. Do current NRC regulations on AU T&E requirements unnecessarily limit patient access to procedures involving radiopharmaceuticals? Explain how.
4. Do current NRC regulations on AU T&E requirements unnecessarily limit research and development in nuclear medicine? Explain how.

D. Other Suggested Changes to the T&E Regulations

In 2002, the NRC revised its regulatory framework for medical use. The goal was to focus the NRC's regulations on those medical procedures that pose the highest risk to workers, the general public, patients, and human research subjects and to structure the regulations to be more risk-informed and more performance-based. The 2002 rule reduced the unnecessary regulatory burden by either reducing or eliminating the prescriptiveness of some regulations. Instead, the rule provided for a performance-based approach that relied on the training and experience of the AUs, authorized nuclear pharmacists, and radiation safety officers. The NRC is requesting comments on whether there are any other changes to the T&E regulations in 10 CFR part 35 that should be considered. Please discuss your suggested changes.

1. Should the NRC regulate the T&E of physicians for medical uses?
2. Are there requirements in the NRC's T&E regulatory framework for physicians that are non-safety related?

3. How can the NRC transform its regulatory approach for T&E while still ensuring that adequate protection is maintained for workers, the general public, patients, and human research subjects?

Dated at Rockville, Maryland, this 23rd day of October 2018.

For the Nuclear Regulatory
Commission.

/RA/

Daniel S. Collins, Director,
Division of Materials Safety,
Security,
State, and Tribal Programs,
Office of Nuclear Material Safety
and Safeguards.



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

November 2, 2018

Dr. Ryan Fisher
Chair, Department of Biology
Nuclear Medicine Technology Concentration
Salem State University
352 Lafayette St.
Salem, MA 01970

SUBJECT: TRAINING AND EXPERIENCE REQUIREMENTS FOR DIFFERENT CATEGORIES OF RADIOPHARMACEUTICALS

Dear Dr. Fisher,

The U.S. Nuclear Regulatory Commission (NRC) is evaluating its regulations related to the training and experience (T&E) required for a physician to become an authorized user for medical uses under Subpart E, “Unsealed Byproduct Material—Written Directive Required,” of [Title 10 of the Code of Federal Regulations \(10 CFR\) Part 35, “Medical Use of Byproduct Material.”](#)

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Christian Einberg, Chief
Medical Safety and Events Assessment Branch
Division of Materials Safety, Security, State
and Tribal Programs
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Enclosure:
Training and Experience
Federal Register notice

NUCLEAR REGULATORY COMMISSION

[NRC-2018-0230]

**Training and Experience Requirements for Different Categories of
Radiopharmaceuticals**

AGENCY: Nuclear Regulatory Commission.

ACTION: Training and experience requirements; request for comment.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is requesting comments on its training and experience (T&E) requirements. Specifically, the NRC would like input on whether it should establish tailored T&E requirements for different categories of radiopharmaceuticals for which a written directive is required in accordance with its regulations. The input will be used to determine whether significant regulatory changes to the NRC's T&E requirements for authorized users (AUs) are warranted.

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The NRC is requesting comments on whether there is a shortage in the number of AUs for 10 CFR 35.300.

1. Is there a shortage in the number of AUs for medical uses under 10 CFR 35.300? If so, is the shortage associated with the use of a specific radiopharmaceutical? Explain how.
2. Are there certain geographic areas with an inadequate number of AUs? Identify these areas.
3. Do current NRC regulations on AU T&E requirements unnecessarily limit patient access to procedures involving radiopharmaceuticals? Explain how.
4. Do current NRC regulations on AU T&E requirements unnecessarily limit research and development in nuclear medicine? Explain how.

D. Other Suggested Changes to the T&E Regulations

In 2002, the NRC revised its regulatory framework for medical use. The goal was to focus the NRC's regulations on those medical procedures that pose the highest risk to workers, the general public, patients, and human research subjects and to structure the regulations to be more risk-informed and more performance-based. The 2002 rule reduced the unnecessary regulatory burden by either reducing or eliminating the prescriptiveness of some regulations. Instead, the rule provided for a performance-based approach that relied on the training and experience of the AUs, authorized nuclear pharmacists, and radiation safety officers. The NRC is requesting comments on whether there are any other changes to the T&E regulations in 10 CFR part 35 that should be considered. Please discuss your suggested changes.

1. Should the NRC regulate the T&E of physicians for medical uses?
2. Are there requirements in the NRC's T&E regulatory framework for physicians that are non-safety related?

3. How can the NRC transform its regulatory approach for T&E while still ensuring that adequate protection is maintained for workers, the general public, patients, and human research subjects?

Dated at Rockville, Maryland, this 23rd day of October 2018.

For the Nuclear Regulatory
Commission.

/RA/

Daniel S. Collins, Director,
Division of Materials Safety,
Security,
State, and Tribal Programs,
Office of Nuclear Material Safety
and Safeguards.



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

November 2, 2018

Roosevelt University
Nuclear Medicine Technology, College of Arts and Sciences
430 S. Michigan Ave.
Chicago, IL 60605

**SUBJECT: TRAINING AND EXPERIENCE REQUIREMENTS FOR DIFFERENT
CATEGORIES OF RADIOPHARMACEUTICALS**

Dear Sir or Madam,

The U.S. Nuclear Regulatory Commission (NRC) is evaluating its regulations related to the training and experience (T&E) required for a physician to become an authorized user for medical uses under Subpart E, “Unsealed Byproduct Material—Written Directive Required,” of [Title 10 of the Code of Federal Regulations \(10 CFR\) Part 35, “Medical Use of Byproduct Material.”](#)

The T&E requirements in Subpart E of 10 CFR Part 35 provide three ways that a physician can be authorized to administer unsealed byproduct materials or radiopharmaceuticals requiring a written directive:

1. A physician can be certified by a medical specialty board, whose certification process is recognized by the NRC or an Agreement State.
2. A physician can complete a structured educational program and supervised work experience under an alternate pathway. This alternate pathway includes a requirement for 700 hours of training and experience, which consists of a minimum of 200 hours of classroom and laboratory training and 500 hours of supervised work experience.
3. A physician can be authorized if previously identified as an authorized user on an NRC or Agreement State license or permit (i.e., grandfathered).

In its evaluation of the T&E requirements, the NRC staff is considering whether an additional pathway should be created or if the alternate pathway should be revised. Specifically, the staff is evaluating: (1) whether it makes sense to establish tailored T&E requirements for different categories of radiopharmaceuticals; (2) how those categories should be determined; (3) what the appropriate T&E requirements would be for each category; and (4) whether those requirements should be based on hours of training and experience, or focused more on competency.

On October 29, 2018, the NRC published a series of questions on T&E in the *Federal Register* (83 FR 54380). The *Federal Register* notice is enclosed with this letter and can also be accessed at: <https://www.gpo.gov/fdsys/pkg/FR-2018-10-29/pdf/2018-23521.pdf>. The NRC will carefully consider responses to these questions and would appreciate your feedback on whether changes to the current T&E regulations are warranted. The comment period for the T&E evaluation will end on January 29, 2019. Please follow the directions in the notice on how to submit written comments. The NRC is using the Federal rulemaking Web site, [Regulations.gov](#), to accept written comments on the docket (NRC-2018-0230).

The NRC will also conduct four public meetings scheduled for November 14 and December 11, 2018, and January 10 and January 22, 2019, and will accept oral comments provided during the meetings. The meetings on December 11 and January 10 will be held at NRC Headquarters in Rockville, MD, and all four meetings will be accessible for remote participation by moderated bridge line and webinar. The NRC's public meeting page has been updated with meeting details and registration instructions for each meeting: <https://www.nrc.gov/pmns/mtg>.

Additional information on the NRC's T&E evaluation can be found at: <https://www.nrc.gov/materials/miau/med-use-toolkit/training-experience-evaluation.html>. If you have any questions on this correspondence, please contact Sarah Lopas of my staff at (301) 415-6360 or Sarah.Lopas@nrc.gov.

A handwritten signature in black ink, appearing to read "C Einberg".

Christian Einberg, Chief
Medical Safety and Events Assessment Branch
Division of Materials Safety, Security, State
and Tribal Programs
Office of Nuclear Material Safety
and Safeguards

Enclosure:
Training and Experience
Federal Register notice

NUCLEAR REGULATORY COMMISSION

[NRC-2018-0230]

**Training and Experience Requirements for Different Categories of
Radiopharmaceuticals**

AGENCY: Nuclear Regulatory Commission.

ACTION: Training and experience requirements; request for comment.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is requesting comments on its training and experience (T&E) requirements. Specifically, the NRC would like input on whether it should establish tailored T&E requirements for different categories of radiopharmaceuticals for which a written directive is required in accordance with its regulations. The input will be used to determine whether significant regulatory changes to the NRC's T&E requirements for authorized users (AUs) are warranted.

DATES: Submit comments by January 29, 2019. Comments received after this date will be considered if it is practical to do so, but the NRC is only able to ensure consideration for comments received on or before this date.

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Please include Docket ID **NRC-2018-0230** in your comment submission.

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radionuclides or by delivery method), (3) what the appropriate T&E requirements would be for each category, and (4) whether those requirements should be based on hours of T&E or focused more on competency. In response to the SRM, the NRC staff documented its initial results, status, and next steps related to this evaluation in SECY-18-0084, "Staff Evaluation of Training and Experience Requirements for Administering Different Categories of Radiopharmaceuticals in Response to SRM-M170817" (ADAMS Accession No. ML18135A276). In SECY-18-0084, the staff concluded that additional outreach with the medical community is needed to determine whether and how to tailor the T&E requirements to establish a limited AU status, the specific T&E requirements that should apply, how the T&E requirements should be met (e.g., hours of training, demonstration of competency), and whether a competency-based approach makes sense for the T&E requirements for all the medical uses authorized under 10 CFR 35.300, "Use of unsealed byproduct material for which a written directive is required."

The NRC is interested in obtaining input from as many stakeholders as possible, including members of the Advisory Committee on the Medical Uses of Isotopes, professional organizations, physicians, patients, patient advocacy groups, licensees, Agreement States, and other interested individuals. The focus of this request is to gather information that will permit the NRC staff to determine whether changes to the T&E requirements are warranted for different categories of radiopharmaceuticals for physicians seeking AU status for the medical use of specific categories of radiopharmaceuticals requiring a written directive under 10 CFR 35.300.

During the comment period between October 29, 2018 and January 29, 2019, the NRC will hold four public meetings that will discuss the information being requested and to accept comments on the docket. All four public meetings

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III. Specific Requests for Comments

A. Tailored Training & Experience Requirements

The NRC is requesting comments on whether it should establish tailored T&E requirements for different categories of radiopharmaceuticals for physicians seeking AU status for the medical use of specific categories of radiopharmaceuticals requiring a written directive under 10 CFR 35.300 (i.e., a limited AU status). This would be for physicians seeking AU status via the alternate non-board certified pathway, and for physicians certified by a medical

specialty board that is not currently recognized by the NRC under 10 CFR 35.390, 35.392, 35.394, or 35.396 (Unsealed Byproduct Material—Written Directive Required).

1. Are the current pathways for obtaining AU status reasonable and accessible? Provide a rationale for your answer.
2. Are the current pathways for obtaining AU status adequate for protecting public health and safety? Provide a rationale for your answer.
3. Should the NRC develop a new tailored T&E pathway for these physicians? If so, what would be the appropriate way to categorize radiopharmaceuticals for tailored T&E requirements? If not, explain why the regulations should remain unchanged. [Some options to categorize radiopharmaceuticals include radiopharmaceuticals with similar delivery methods (oral, parenteral); same type of radiation characteristics or emission (alpha, beta, gamma, low-energy photon); similar preparation method (patient-ready doses); or a combination thereof (e.g., radiopharmaceuticals containing alpha- and beta-emitting radioisotopes that are administered intravenously and are prepared as patient-ready doses).]
4. Should the fundamental T&E required of physicians seeking limited AU status need to have the same fundamental T&E required of physicians seeking full AU status for all oral and parenteral administrations under 10 CFR 35.300?
5. How should the requirements for this fundamental T&E be structured for a specific category of radiopharmaceuticals?
 - a. Describe what the requirements should include:

- i. Classroom and laboratory training – What topics need to be covered in this training requirement? How many hours of classroom and laboratory training should be required? Provide the basis for the number of hours. If not hours, explain how this training should be quantified. [Note: The topics currently required in the regulations to be included in the classroom and laboratory training and work experience are listed in 10 CFR 35.390, 35.392, 35.394, and 35.396.]
 - ii. Work experience - What should the work experience requirement involve? How many hours of work experience should be required and what is the minimum number of patient or human research subject administrations that an individual must perform? Provide the basis for the number of hours and administrations. What should be the qualifications of the supervising individual?
 - iii. Competency - How should competency be evaluated? Should a written and/or practical examination by an independent examining committee be administered? Provide a rationale for your answer.
- b. Should a preceptor attestation be required for the fundamental T&E? Provide a rationale for your answer.
- c. Should the radiopharmaceutical manufacturer be able to provide the preceptor attestation? Provide a rational for your answer.

- d. Who should establish and administer the curriculum and examination? Provide specific group(s). [Some options are: NRC, medical specialty boards, medical professional societies, educational professional groups, and NRC in collaboration with any or more of the aforementioned groups.]
- e. Should AU competency be periodically assessed? If so, how should it be assessed, how often, and by whom?

B. NRC's Recognition of Medical Specialty Boards

The NRC is requesting comments on its recognition of medical specialty boards. The NRC's procedures for recognizing medical specialty boards are located on the Medical Uses Licensee Toolkit Web site (<https://www.nrc.gov/materials/miau/med-use-toolkit/certif-process-boards.html>). The NRC staff periodically reviews information to determine a board's continued eligibility for recognition.

- 1. What boards other than those already recognized by the NRC (American Board of Nuclear Medicine [ABNM], American Board of Radiology [ABR], American Osteopathic Board of Radiology [AOBR], Certification Board of Nuclear Endocrinology [CBNE]) could be considered for recognition for medical uses under 10 CFR 35.300?
- 2. Are the current NRC medical specialty board recognition criteria sufficient? If not, what additional criteria should the NRC use?

C. Patient Access

The NRC is requesting comments on whether there is a shortage in the number of AUs for 10 CFR 35.300.

1. Is there a shortage in the number of AUs for medical uses under 10 CFR 35.300? If so, is the shortage associated with the use of a specific radiopharmaceutical? Explain how.
2. Are there certain geographic areas with an inadequate number of AUs? Identify these areas.
3. Do current NRC regulations on AU T&E requirements unnecessarily limit patient access to procedures involving radiopharmaceuticals? Explain how.
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D. Other Suggested Changes to the T&E Regulations

In 2002, the NRC revised its regulatory framework for medical use. The goal was to focus the NRC's regulations on those medical procedures that pose the highest risk to workers, the general public, patients, and human research subjects and to structure the regulations to be more risk-informed and more performance-based. The 2002 rule reduced the unnecessary regulatory burden by either reducing or eliminating the prescriptiveness of some regulations. Instead, the rule provided for a performance-based approach that relied on the training and experience of the AUs, authorized nuclear pharmacists, and radiation safety officers. The NRC is requesting comments on whether there are any other changes to the T&E regulations in 10 CFR part 35 that should be considered. Please discuss your suggested changes.

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Dated at Rockville, Maryland, this 23rd day of October 2018.

For the Nuclear Regulatory
Commission.

/RA/

Daniel S. Collins, Director,
Division of Materials Safety,
Security,
State, and Tribal Programs,
Office of Nuclear Material Safety
and Safeguards.



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

November 2, 2018

GE Healthcare
945 N. Edgewood Ave., #A1
Wood Dale, IL 60191

**SUBJECT: TRAINING AND EXPERIENCE REQUIREMENTS FOR DIFFERENT
CATEGORIES OF RADIOPHARMACEUTICALS**

Dear Sir or Madam,

The U.S. Nuclear Regulatory Commission (NRC) is evaluating its regulations related to the training and experience (T&E) required for a physician to become an authorized user for medical uses under Subpart E, “Unsealed Byproduct Material—Written Directive Required,” of [Title 10 of the Code of Federal Regulations \(10 CFR\) Part 35, “Medical Use of Byproduct Material.”](#)

The T&E requirements in Subpart E of 10 CFR Part 35 provide three ways that a physician can be authorized to administer unsealed byproduct materials or radiopharmaceuticals requiring a written directive:

1. A physician can be certified by a medical specialty board, whose certification process is recognized by the NRC or an Agreement State.
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In its evaluation of the T&E requirements, the NRC staff is considering whether an additional pathway should be created or if the alternate pathway should be revised. Specifically, the staff is evaluating: (1) whether it makes sense to establish tailored T&E requirements for different categories of radiopharmaceuticals; (2) how those categories should be determined; (3) what the appropriate T&E requirements would be for each category; and (4) whether those requirements should be based on hours of training and experience, or focused more on competency.

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Christian Einberg, 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:
Training and Experience
Federal Register notice

NUCLEAR REGULATORY COMMISSION

[NRC-2018-0230]

**Training and Experience Requirements for Different Categories of
Radiopharmaceuticals**

AGENCY: Nuclear Regulatory Commission.

ACTION: Training and experience requirements; request for comment.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is requesting comments on its training and experience (T&E) requirements. Specifically, the NRC would like input on whether it should establish tailored T&E requirements for different categories of radiopharmaceuticals for which a written directive is required in accordance with its regulations. The input will be used to determine whether significant regulatory changes to the NRC's T&E requirements for authorized users (AUs) are warranted.

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 - ii. Work experience - What should the work experience requirement involve? How many hours of work experience should be required and what is the minimum number of patient or human research subject administrations that an individual must perform? Provide the basis for the number of hours and administrations. What should be the qualifications of the supervising individual?
 - iii. Competency - How should competency be evaluated? Should a written and/or practical examination by an independent examining committee be administered? Provide a rationale for your answer.
- b. Should a preceptor attestation be required for the fundamental T&E? Provide a rationale for your answer.
- c. Should the radiopharmaceutical manufacturer be able to provide the preceptor attestation? Provide a rational for your answer.

- d. Who should establish and administer the curriculum and examination? Provide specific group(s). [Some options are: NRC, medical specialty boards, medical professional societies, educational professional groups, and NRC in collaboration with any or more of the aforementioned groups.]
- e. Should AU competency be periodically assessed? If so, how should it be assessed, how often, and by whom?

B. NRC's Recognition of Medical Specialty Boards

The NRC is requesting comments on its recognition of medical specialty boards. The NRC's procedures for recognizing medical specialty boards are located on the Medical Uses Licensee Toolkit Web site (<https://www.nrc.gov/materials/miau/med-use-toolkit/certif-process-boards.html>). The NRC staff periodically reviews information to determine a board's continued eligibility for recognition.

- 1. What boards other than those already recognized by the NRC (American Board of Nuclear Medicine [ABNM], American Board of Radiology [ABR], American Osteopathic Board of Radiology [AOBR], Certification Board of Nuclear Endocrinology [CBNE]) could be considered for recognition for medical uses under 10 CFR 35.300?
- 2. Are the current NRC medical specialty board recognition criteria sufficient? If not, what additional criteria should the NRC use?

C. Patient Access

The NRC is requesting comments on whether there is a shortage in the number of AUs for 10 CFR 35.300.

1. Is there a shortage in the number of AUs for medical uses under 10 CFR 35.300? If so, is the shortage associated with the use of a specific radiopharmaceutical? Explain how.
2. Are there certain geographic areas with an inadequate number of AUs? Identify these areas.
3. Do current NRC regulations on AU T&E requirements unnecessarily limit patient access to procedures involving radiopharmaceuticals? Explain how.
4. Do current NRC regulations on AU T&E requirements unnecessarily limit research and development in nuclear medicine? Explain how.

D. Other Suggested Changes to the T&E Regulations

In 2002, the NRC revised its regulatory framework for medical use. The goal was to focus the NRC's regulations on those medical procedures that pose the highest risk to workers, the general public, patients, and human research subjects and to structure the regulations to be more risk-informed and more performance-based. The 2002 rule reduced the unnecessary regulatory burden by either reducing or eliminating the prescriptiveness of some regulations. Instead, the rule provided for a performance-based approach that relied on the training and experience of the AUs, authorized nuclear pharmacists, and radiation safety officers. The NRC is requesting comments on whether there are any other changes to the T&E regulations in 10 CFR part 35 that should be considered. Please discuss your suggested changes.

1. Should the NRC regulate the T&E of physicians for medical uses?
2. Are there requirements in the NRC's T&E regulatory framework for physicians that are non-safety related?

3. How can the NRC transform its regulatory approach for T&E while still ensuring that adequate protection is maintained for workers, the general public, patients, and human research subjects?

Dated at Rockville, Maryland, this 23rd day of October 2018.

For the Nuclear Regulatory
Commission.

/RA/

Daniel S. Collins, Director,
Division of Materials Safety,
Security,
State, and Tribal Programs,
Office of Nuclear Material Safety
and Safeguards.



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

November 2, 2018

Dr. Richard Hoylman
Program Director, Nuclear Medicine and Molecular Imaging Technology
Oregon Institute of Technology
3201 Campus Drive
Klamath Falls, OR 97601

**SUBJECT: TRAINING AND EXPERIENCE REQUIREMENTS FOR DIFFERENT
CATEGORIES OF RADIOPHARMACEUTICALS**

Dear Dr. Hoylman,

The U.S. Nuclear Regulatory Commission (NRC) is evaluating its regulations related to the training and experience (T&E) required for a physician to become an authorized user for medical uses under Subpart E, “Unsealed Byproduct Material—Written Directive Required,” of [Title 10 of the Code of Federal Regulations \(10 CFR\) Part 35, “Medical Use of Byproduct Material.”](#)

The T&E requirements in Subpart E of 10 CFR Part 35 provide three ways that a physician can be authorized to administer unsealed byproduct materials or radiopharmaceuticals requiring a written directive:

1. A physician can be certified by a medical specialty board, whose certification process is recognized by the NRC or an Agreement State.
2. A physician can complete a structured educational program and supervised work experience under an alternate pathway. This alternate pathway includes a requirement for 700 hours of training and experience, which consists of a minimum of 200 hours of classroom and laboratory training and 500 hours of supervised work experience.
3. A physician can be authorized if previously identified as an authorized user on an NRC or Agreement State license or permit (i.e., grandfathered).

In its evaluation of the T&E requirements, the NRC staff is considering whether an additional pathway should be created or if the alternate pathway should be revised. Specifically, the staff is evaluating: (1) whether it makes sense to establish tailored T&E requirements for different categories of radiopharmaceuticals; (2) how those categories should be determined; (3) what the appropriate T&E requirements would be for each category; and (4) whether those requirements should be based on hours of training and experience, or focused more on competency.

On October 29, 2018, the NRC published a series of questions on T&E in the *Federal Register* (83 FR 54380). The *Federal Register* notice is enclosed with this letter and can also be accessed at: <https://www.gpo.gov/fdsys/pkg/FR-2018-10-29/pdf/2018-23521.pdf>. The NRC will carefully consider responses to these questions and would appreciate your feedback on whether changes to the current T&E regulations are warranted. The comment period for the T&E evaluation will end on January 29, 2019. Please follow the directions in the notice on how to submit written comments. The NRC is using the Federal rulemaking Web site, [Regulations.gov](#), to accept written comments on the docket (NRC-2018-0230).

The NRC will also conduct four public meetings scheduled for November 14 and December 11, 2018, and January 10 and January 22, 2019, and will accept oral comments provided during the meetings. The meetings on December 11 and January 10 will be held at NRC Headquarters in Rockville, MD, and all four meetings will be accessible for remote participation by moderated bridge line and webinar. The NRC's public meeting page has been updated with meeting details and registration instructions for each meeting: <https://www.nrc.gov/pmns/mtg>.

Additional information on the NRC's T&E evaluation can be found at: <https://www.nrc.gov/materials/miau/med-use-toolkit/training-experience-evaluation.html>. If you have any questions on this correspondence, please contact Sarah Lopas of my staff at (301) 415-6360 or Sarah.Lopas@nrc.gov.

A handwritten signature in black ink, appearing to read "C Einberg".

Christian Einberg, Chief
Medical Safety and Events Assessment Branch
Division of Materials Safety, Security, State
and Tribal Programs
Office of Nuclear Material Safety
and Safeguards

Enclosure:
Training and Experience
Federal Register notice

NUCLEAR REGULATORY COMMISSION

[NRC-2018-0230]

**Training and Experience Requirements for Different Categories of
Radiopharmaceuticals**

AGENCY: Nuclear Regulatory Commission.

ACTION: Training and experience requirements; request for comment.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is requesting comments on its training and experience (T&E) requirements. Specifically, the NRC would like input on whether it should establish tailored T&E requirements for different categories of radiopharmaceuticals for which a written directive is required in accordance with its regulations. The input will be used to determine whether significant regulatory changes to the NRC's T&E requirements for authorized users (AUs) are warranted.

DATES: Submit comments by January 29, 2019. Comments received after this date will be considered if it is practical to do so, but the NRC is only able to ensure consideration for comments received on or before this date.

ADDRESSES: You may submit comments by any of the following methods:

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FOR FURTHER INFORMATION CONTACT: Sarah Lopas, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001; telephone: 301-415-6360, e-mail: Sarah.Lopas@nrc.gov.

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Please include Docket ID **NRC-2018-0230** in your comment submission.

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radionuclides or by delivery method), (3) what the appropriate T&E requirements would be for each category, and (4) whether those requirements should be based on hours of T&E or focused more on competency. In response to the SRM, the NRC staff documented its initial results, status, and next steps related to this evaluation in SECY-18-0084, "Staff Evaluation of Training and Experience Requirements for Administering Different Categories of Radiopharmaceuticals in Response to SRM-M170817" (ADAMS Accession No. ML18135A276). In SECY-18-0084, the staff concluded that additional outreach with the medical community is needed to determine whether and how to tailor the T&E requirements to establish a limited AU status, the specific T&E requirements that should apply, how the T&E requirements should be met (e.g., hours of training, demonstration of competency), and whether a competency-based approach makes sense for the T&E requirements for all the medical uses authorized under 10 CFR 35.300, "Use of unsealed byproduct material for which a written directive is required."

The NRC is interested in obtaining input from as many stakeholders as possible, including members of the Advisory Committee on the Medical Uses of Isotopes, professional organizations, physicians, patients, patient advocacy groups, licensees, Agreement States, and other interested individuals. The focus of this request is to gather information that will permit the NRC staff to determine whether changes to the T&E requirements are warranted for different categories of radiopharmaceuticals for physicians seeking AU status for the medical use of specific categories of radiopharmaceuticals requiring a written directive under 10 CFR 35.300.

During the comment period between October 29, 2018 and January 29, 2019, the NRC will hold four public meetings that will discuss the information being requested and to accept comments on the docket. All four public meetings

will be available for remote participation by moderated bridge line and webinar, and two of the four meetings will be open for in-person attendance at NRC's headquarters in Rockville, Maryland.

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The NRC may post additional materials related to this document, including public comments, on the Federal Rulemaking Web site. The Federal Rulemaking Web site allows you to receive alerts when changes or additions occur in a docket folder. To subscribe: (1) Navigate to the docket folder **NRC-2018-0230**; (2) click the “Sign up for E-mail Alerts” link; and (3) enter your email address and select how frequently you would like to receive emails (daily, weekly, or monthly).

III. Specific Requests for Comments

A. Tailored Training & Experience Requirements

The NRC is requesting comments on whether it should establish tailored T&E requirements for different categories of radiopharmaceuticals for physicians seeking AU status for the medical use of specific categories of radiopharmaceuticals requiring a written directive under 10 CFR 35.300 (i.e., a limited AU status). This would be for physicians seeking AU status via the alternate non-board certified pathway, and for physicians certified by a medical

specialty board that is not currently recognized by the NRC under 10 CFR 35.390, 35.392, 35.394, or 35.396 (Unsealed Byproduct Material—Written Directive Required).

1. Are the current pathways for obtaining AU status reasonable and accessible? Provide a rationale for your answer.
2. Are the current pathways for obtaining AU status adequate for protecting public health and safety? Provide a rationale for your answer.
3. Should the NRC develop a new tailored T&E pathway for these physicians? If so, what would be the appropriate way to categorize radiopharmaceuticals for tailored T&E requirements? If not, explain why the regulations should remain unchanged. [Some options to categorize radiopharmaceuticals include radiopharmaceuticals with similar delivery methods (oral, parenteral); same type of radiation characteristics or emission (alpha, beta, gamma, low-energy photon); similar preparation method (patient-ready doses); or a combination thereof (e.g., radiopharmaceuticals containing alpha- and beta-emitting radioisotopes that are administered intravenously and are prepared as patient-ready doses).]
4. Should the fundamental T&E required of physicians seeking limited AU status need to have the same fundamental T&E required of physicians seeking full AU status for all oral and parenteral administrations under 10 CFR 35.300?
5. How should the requirements for this fundamental T&E be structured for a specific category of radiopharmaceuticals?
 - a. Describe what the requirements should include:

- i. Classroom and laboratory training – What topics need to be covered in this training requirement? How many hours of classroom and laboratory training should be required? Provide the basis for the number of hours. If not hours, explain how this training should be quantified. [Note: The topics currently required in the regulations to be included in the classroom and laboratory training and work experience are listed in 10 CFR 35.390, 35.392, 35.394, and 35.396.]
 - ii. Work experience - What should the work experience requirement involve? How many hours of work experience should be required and what is the minimum number of patient or human research subject administrations that an individual must perform? Provide the basis for the number of hours and administrations. What should be the qualifications of the supervising individual?
 - iii. Competency - How should competency be evaluated? Should a written and/or practical examination by an independent examining committee be administered? Provide a rationale for your answer.
- b. Should a preceptor attestation be required for the fundamental T&E? Provide a rationale for your answer.
- c. Should the radiopharmaceutical manufacturer be able to provide the preceptor attestation? Provide a rational for your answer.

- d. Who should establish and administer the curriculum and examination? Provide specific group(s). [Some options are: NRC, medical specialty boards, medical professional societies, educational professional groups, and NRC in collaboration with any or more of the aforementioned groups.]
- e. Should AU competency be periodically assessed? If so, how should it be assessed, how often, and by whom?

B. NRC's Recognition of Medical Specialty Boards

The NRC is requesting comments on its recognition of medical specialty boards. The NRC's procedures for recognizing medical specialty boards are located on the Medical Uses Licensee Toolkit Web site (<https://www.nrc.gov/materials/miau/med-use-toolkit/certif-process-boards.html>). The NRC staff periodically reviews information to determine a board's continued eligibility for recognition.

- 1. What boards other than those already recognized by the NRC (American Board of Nuclear Medicine [ABNM], American Board of Radiology [ABR], American Osteopathic Board of Radiology [AOBR], Certification Board of Nuclear Endocrinology [CBNE]) could be considered for recognition for medical uses under 10 CFR 35.300?
- 2. Are the current NRC medical specialty board recognition criteria sufficient? If not, what additional criteria should the NRC use?

C. Patient Access

The NRC is requesting comments on whether there is a shortage in the number of AUs for 10 CFR 35.300.

1. Is there a shortage in the number of AUs for medical uses under 10 CFR 35.300? If so, is the shortage associated with the use of a specific radiopharmaceutical? Explain how.
2. Are there certain geographic areas with an inadequate number of AUs? Identify these areas.
3. Do current NRC regulations on AU T&E requirements unnecessarily limit patient access to procedures involving radiopharmaceuticals? Explain how.
4. Do current NRC regulations on AU T&E requirements unnecessarily limit research and development in nuclear medicine? Explain how.

D. Other Suggested Changes to the T&E Regulations

In 2002, the NRC revised its regulatory framework for medical use. The goal was to focus the NRC's regulations on those medical procedures that pose the highest risk to workers, the general public, patients, and human research subjects and to structure the regulations to be more risk-informed and more performance-based. The 2002 rule reduced the unnecessary regulatory burden by either reducing or eliminating the prescriptiveness of some regulations. Instead, the rule provided for a performance-based approach that relied on the training and experience of the AUs, authorized nuclear pharmacists, and radiation safety officers. The NRC is requesting comments on whether there are any other changes to the T&E regulations in 10 CFR part 35 that should be considered. Please discuss your suggested changes.

1. Should the NRC regulate the T&E of physicians for medical uses?
2. Are there requirements in the NRC's T&E regulatory framework for physicians that are non-safety related?

3. How can the NRC transform its regulatory approach for T&E while still ensuring that adequate protection is maintained for workers, the general public, patients, and human research subjects?

Dated at Rockville, Maryland, this 23rd day of October 2018.

For the Nuclear Regulatory
Commission.

/RA/

Daniel S. Collins, Director,
Division of Materials Safety,
Security,
State, and Tribal Programs,
Office of Nuclear Material Safety
and Safeguards.



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

November 2, 2018

Dr. Mark King, MD
Associate Professor of Radiology
Diagnostic Radiology Program Director
Associate Program Director,
Interventional Radiology
The Ohio State University Wexner Medical Center
410 W. 10th Ave.
Columbus, OH 43210

**SUBJECT: TRAINING AND EXPERIENCE REQUIREMENTS FOR DIFFERENT
CATEGORIES OF RADIOPHARMACEUTICALS**

Dear Dr. King,

The U.S. Nuclear Regulatory Commission (NRC) is evaluating its regulations related to the training and experience (T&E) required for a physician to become an authorized user for medical uses under Subpart E, “Unsealed Byproduct Material—Written Directive Required,” of [Title 10 of the Code of Federal Regulations \(10 CFR\) Part 35, “Medical Use of Byproduct Material.”](#)

The T&E requirements in Subpart E of 10 CFR Part 35 provide three ways that a physician can be authorized to administer unsealed byproduct materials or radiopharmaceuticals requiring a written directive:

1. A physician can be certified by a medical specialty board, whose certification process is recognized by the NRC or an Agreement State.
2. A physician can complete a structured educational program and supervised work experience under an alternate pathway. This alternate pathway includes a requirement for 700 hours of training and experience, which consists of a minimum of 200 hours of classroom and laboratory training and 500 hours of supervised work experience.
3. A physician can be authorized if previously identified as an authorized user on an NRC or Agreement State license or permit (i.e., grandfathered).

In its evaluation of the T&E requirements, the NRC staff is considering whether an additional pathway should be created or if the alternate pathway should be revised. Specifically, the staff is evaluating: (1) whether it makes sense to establish tailored T&E requirements for different categories of radiopharmaceuticals; (2) how those categories should be determined; (3) what the appropriate T&E requirements would be for each category; and (4) whether those requirements should be based on hours of training and experience, or focused more on competency.

On October 29, 2018, the NRC published a series of questions on T&E in the *Federal Register* (83 FR 54380). The *Federal Register* notice is enclosed with this letter and can also be accessed at: <https://www.gpo.gov/fdsys/pkg/FR-2018-10-29/pdf/2018-23521.pdf>. The NRC will carefully consider responses to these questions and would appreciate your feedback on whether changes to the current T&E regulations are warranted. The comment period for the T&E evaluation will end on January 29, 2019. Please follow the directions in the notice on how to submit written comments. The NRC is using the Federal rulemaking Web site, [Regulations.gov](#), to accept written comments on the docket (NRC-2018-0230).

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Additional information on the NRC's T&E evaluation can be found at: <https://www.nrc.gov/materials/miau/med-use-toolkit/training-experience-evaluation.html>. If you have any questions on this correspondence, please contact Sarah Lopas of my staff at (301) 415-6360 or Sarah.Lopas@nrc.gov.

A handwritten signature in black ink, appearing to read "C Einberg".

Christian Einberg, Chief
Medical Safety and Events Assessment Branch
Division of Materials Safety, Security, State
and Tribal Programs
Office of Nuclear Material Safety
and Safeguards

Enclosure:
Training and Experience
Federal Register notice

NUCLEAR REGULATORY COMMISSION

[NRC-2018-0230]

**Training and Experience Requirements for Different Categories of
Radiopharmaceuticals**

AGENCY: Nuclear Regulatory Commission.

ACTION: Training and experience requirements; request for comment.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is requesting comments on its training and experience (T&E) requirements. Specifically, the NRC would like input on whether it should establish tailored T&E requirements for different categories of radiopharmaceuticals for which a written directive is required in accordance with its regulations. The input will be used to determine whether significant regulatory changes to the NRC's T&E requirements for authorized users (AUs) are warranted.

DATES: Submit comments by January 29, 2019. Comments received after this date will be considered if it is practical to do so, but the NRC is only able to ensure consideration for comments received on or before this date.

ADDRESSES: You may submit comments by any of the following methods:

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A. Tailored Training & Experience Requirements

The NRC is requesting comments on whether it should establish tailored T&E requirements for different categories of radiopharmaceuticals for physicians seeking AU status for the medical use of specific categories of radiopharmaceuticals requiring a written directive under 10 CFR 35.300 (i.e., a limited AU status). This would be for physicians seeking AU status via the alternate non-board certified pathway, and for physicians certified by a medical

specialty board that is not currently recognized by the NRC under 10 CFR 35.390, 35.392, 35.394, or 35.396 (Unsealed Byproduct Material—Written Directive Required).

1. Are the current pathways for obtaining AU status reasonable and accessible? Provide a rationale for your answer.
2. Are the current pathways for obtaining AU status adequate for protecting public health and safety? Provide a rationale for your answer.
3. Should the NRC develop a new tailored T&E pathway for these physicians? If so, what would be the appropriate way to categorize radiopharmaceuticals for tailored T&E requirements? If not, explain why the regulations should remain unchanged. [Some options to categorize radiopharmaceuticals include radiopharmaceuticals with similar delivery methods (oral, parenteral); same type of radiation characteristics or emission (alpha, beta, gamma, low-energy photon); similar preparation method (patient-ready doses); or a combination thereof (e.g., radiopharmaceuticals containing alpha- and beta-emitting radioisotopes that are administered intravenously and are prepared as patient-ready doses).]
4. Should the fundamental T&E required of physicians seeking limited AU status need to have the same fundamental T&E required of physicians seeking full AU status for all oral and parenteral administrations under 10 CFR 35.300?
5. How should the requirements for this fundamental T&E be structured for a specific category of radiopharmaceuticals?
 - a. Describe what the requirements should include:

- i. Classroom and laboratory training – What topics need to be covered in this training requirement? How many hours of classroom and laboratory training should be required? Provide the basis for the number of hours. If not hours, explain how this training should be quantified. [Note: The topics currently required in the regulations to be included in the classroom and laboratory training and work experience are listed in 10 CFR 35.390, 35.392, 35.394, and 35.396.]
 - ii. Work experience - What should the work experience requirement involve? How many hours of work experience should be required and what is the minimum number of patient or human research subject administrations that an individual must perform? Provide the basis for the number of hours and administrations. What should be the qualifications of the supervising individual?
 - iii. Competency - How should competency be evaluated? Should a written and/or practical examination by an independent examining committee be administered? Provide a rationale for your answer.
- b. Should a preceptor attestation be required for the fundamental T&E? Provide a rationale for your answer.
- c. Should the radiopharmaceutical manufacturer be able to provide the preceptor attestation? Provide a rational for your answer.

- d. Who should establish and administer the curriculum and examination? Provide specific group(s). [Some options are: NRC, medical specialty boards, medical professional societies, educational professional groups, and NRC in collaboration with any or more of the aforementioned groups.]
- e. Should AU competency be periodically assessed? If so, how should it be assessed, how often, and by whom?

B. NRC's Recognition of Medical Specialty Boards

The NRC is requesting comments on its recognition of medical specialty boards. The NRC's procedures for recognizing medical specialty boards are located on the Medical Uses Licensee Toolkit Web site (<https://www.nrc.gov/materials/miau/med-use-toolkit/certif-process-boards.html>). The NRC staff periodically reviews information to determine a board's continued eligibility for recognition.

- 1. What boards other than those already recognized by the NRC (American Board of Nuclear Medicine [ABNM], American Board of Radiology [ABR], American Osteopathic Board of Radiology [AOBR], Certification Board of Nuclear Endocrinology [CBNE]) could be considered for recognition for medical uses under 10 CFR 35.300?
- 2. Are the current NRC medical specialty board recognition criteria sufficient? If not, what additional criteria should the NRC use?

C. Patient Access

The NRC is requesting comments on whether there is a shortage in the number of AUs for 10 CFR 35.300.

1. Is there a shortage in the number of AUs for medical uses under 10 CFR 35.300? If so, is the shortage associated with the use of a specific radiopharmaceutical? Explain how.
2. Are there certain geographic areas with an inadequate number of AUs? Identify these areas.
3. Do current NRC regulations on AU T&E requirements unnecessarily limit patient access to procedures involving radiopharmaceuticals? Explain how.
4. Do current NRC regulations on AU T&E requirements unnecessarily limit research and development in nuclear medicine? Explain how.

D. Other Suggested Changes to the T&E Regulations

In 2002, the NRC revised its regulatory framework for medical use. The goal was to focus the NRC's regulations on those medical procedures that pose the highest risk to workers, the general public, patients, and human research subjects and to structure the regulations to be more risk-informed and more performance-based. The 2002 rule reduced the unnecessary regulatory burden by either reducing or eliminating the prescriptiveness of some regulations. Instead, the rule provided for a performance-based approach that relied on the training and experience of the AUs, authorized nuclear pharmacists, and radiation safety officers. The NRC is requesting comments on whether there are any other changes to the T&E regulations in 10 CFR part 35 that should be considered. Please discuss your suggested changes.

1. Should the NRC regulate the T&E of physicians for medical uses?
2. Are there requirements in the NRC's T&E regulatory framework for physicians that are non-safety related?

3. How can the NRC transform its regulatory approach for T&E while still ensuring that adequate protection is maintained for workers, the general public, patients, and human research subjects?

Dated at Rockville, Maryland, this 23rd day of October 2018.

For the Nuclear Regulatory
Commission.

/RA/

Daniel S. Collins, Director,
Division of Materials Safety,
Security,
State, and Tribal Programs,
Office of Nuclear Material Safety
and Safeguards.



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

November 2, 2018

Lantheus Medical Imaging, Inc.
331 Treble Cove Rd.
North Billerica, MA 01862

**SUBJECT: TRAINING AND EXPERIENCE REQUIREMENTS FOR DIFFERENT
CATEGORIES OF RADIOPHARMACEUTICALS**

Dear Sir or Madam,

The U.S. Nuclear Regulatory Commission (NRC) is evaluating its regulations related to the training and experience (T&E) required for a physician to become an authorized user for medical uses under Subpart E, "Unsealed Byproduct Material—Written Directive Required," of [Title 10 of the Code of Federal Regulations \(10 CFR\) Part 35, "Medical Use of Byproduct Material."](#)

The T&E requirements in Subpart E of 10 CFR Part 35 provide three ways that a physician can be authorized to administer unsealed byproduct materials or radiopharmaceuticals requiring a written directive:

1. A physician can be certified by a medical specialty board, whose certification process is recognized by the NRC or an Agreement State.
2. A physician can complete a structured educational program and supervised work experience under an alternate pathway. This alternate pathway includes a requirement for 700 hours of training and experience, which consists of a minimum of 200 hours of classroom and laboratory training and 500 hours of supervised work experience.
3. A physician can be authorized if previously identified as an authorized user on an NRC or Agreement State license or permit (i.e., grandfathered).

In its evaluation of the T&E requirements, the NRC staff is considering whether an additional pathway should be created or if the alternate pathway should be revised. Specifically, the staff is evaluating: (1) whether it makes sense to establish tailored T&E requirements for different categories of radiopharmaceuticals; (2) how those categories should be determined; (3) what the appropriate T&E requirements would be for each category; and (4) whether those requirements should be based on hours of training and experience, or focused more on competency.

On October 29, 2018, the NRC published a series of questions on T&E in the *Federal Register* (83 FR 54380). The *Federal Register* notice is enclosed with this letter and can also be accessed at: <https://www.gpo.gov/fdsys/pkg/FR-2018-10-29/pdf/2018-23521.pdf>. The NRC will carefully consider responses to these questions and would appreciate your feedback on whether changes to the current T&E regulations are warranted. The comment period for the T&E evaluation will end on January 29, 2019. Please follow the directions in the notice on how to submit written comments. The NRC is using the Federal rulemaking Web site, [Regulations.gov](#), to accept written comments on the docket (NRC-2018-0230).

The NRC will also conduct four public meetings scheduled for November 14 and December 11, 2018, and January 10 and January 22, 2019, and will accept oral comments provided during the meetings. The meetings on December 11 and January 10 will be held at NRC Headquarters in Rockville, MD, and all four meetings will be accessible for remote participation by moderated bridge line and webinar. The NRC's public meeting page has been updated with meeting details and registration instructions for each meeting: <https://www.nrc.gov/pmns/mtg>.

Additional information on the NRC's T&E evaluation can be found at: <https://www.nrc.gov/materials/miau/med-use-toolkit/training-experience-evaluation.html>. If you have any questions on this correspondence, please contact Sarah Lopas of my staff at (301) 415-6360 or Sarah.Lopas@nrc.gov.

A handwritten signature in black ink, appearing to read "C Einberg".

Christian Einberg, Chief
Medical Safety and Events Assessment Branch
Division of Materials Safety, Security, State
and Tribal Programs
Office of Nuclear Material Safety
and Safeguards

Enclosure:
Training and Experience
Federal Register notice

NUCLEAR REGULATORY COMMISSION

[NRC-2018-0230]

**Training and Experience Requirements for Different Categories of
Radiopharmaceuticals**

AGENCY: Nuclear Regulatory Commission.

ACTION: Training and experience requirements; request for comment.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is requesting comments on its training and experience (T&E) requirements. Specifically, the NRC would like input on whether it should establish tailored T&E requirements for different categories of radiopharmaceuticals for which a written directive is required in accordance with its regulations. The input will be used to determine whether significant regulatory changes to the NRC's T&E requirements for authorized users (AUs) are warranted.

DATES: Submit comments by January 29, 2019. Comments received after this date will be considered if it is practical to do so, but the NRC is only able to ensure consideration for comments received on or before this date.

ADDRESSES: You may submit comments by any of the following methods:

- **Federal Rulemaking Web Site:** Go to <http://www.regulations.gov>

and search for Docket ID **NRC-2018-0230**. Address questions about Docket IDs in Regulations.gov to Jennifer Borges; telephone: 301-287-9127; e-mail: Jennifer.Borges@nrc.gov. For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.

- **Mail comments to:** May Ma, Office of Administration, Mail Stop: TWFN-7-A60M, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001.

For additional direction on obtaining information and submitting comments, see “Obtaining Information and Submitting Comments” in the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: Sarah Lopas, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001; telephone: 301-415-6360, e-mail: Sarah.Lopas@nrc.gov.

SUPPLEMENTARY INFORMATION:

I. Obtaining Information and Submitting Comments

A. Obtaining Information

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- **NRC's PDR:** You may examine and purchase copies of public documents at the NRC's PDR, Room O1-F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.

B. Submitting Comments

Please include Docket ID **NRC-2018-0230** in your comment submission.

The NRC cautions you not to include identifying or contact information in comment submissions that you do not want to be publicly disclosed in your comment submission. All comment submissions are posted at <http://www.regulations.gov> and entered into ADAMS. Comment submissions are not routinely edited to remove identifying or contact information.

If you are requesting or aggregating comments from other persons for submission to the NRC, then you should inform those persons not to include identifying or contact information that they do not want to be publicly disclosed in their comment submission. Your request should state that the NRC does not routinely edit comment submissions to remove such information before making the comment submissions available to the public or entering the comment into ADAMS.

II. Background

On August 17, 2017, the Commission issued a staff requirements memorandum (SRM), SRM-M170817 (ADAMS Accession No. ML17229B284), approving the final rule revising parts 30, 32, and 35 of title 10 of the *Code of Federal Regulations* (10 CFR), "Medical Use of Byproduct Material – Medical Event Definitions, Training and Experience, and Clarifying Amendments," and directing the staff to evaluate (1) whether it makes sense to establish tailored T&E requirements for different categories of radiopharmaceuticals, (2) how those categories should be determined (such as by risks posed by groups of

radionuclides or by delivery method), (3) what the appropriate T&E requirements would be for each category, and (4) whether those requirements should be based on hours of T&E or focused more on competency. In response to the SRM, the NRC staff documented its initial results, status, and next steps related to this evaluation in SECY-18-0084, "Staff Evaluation of Training and Experience Requirements for Administering Different Categories of Radiopharmaceuticals in Response to SRM-M170817" (ADAMS Accession No. ML18135A276). In SECY-18-0084, the staff concluded that additional outreach with the medical community is needed to determine whether and how to tailor the T&E requirements to establish a limited AU status, the specific T&E requirements that should apply, how the T&E requirements should be met (e.g., hours of training, demonstration of competency), and whether a competency-based approach makes sense for the T&E requirements for all the medical uses authorized under 10 CFR 35.300, "Use of unsealed byproduct material for which a written directive is required."

The NRC is interested in obtaining input from as many stakeholders as possible, including members of the Advisory Committee on the Medical Uses of Isotopes, professional organizations, physicians, patients, patient advocacy groups, licensees, Agreement States, and other interested individuals. The focus of this request is to gather information that will permit the NRC staff to determine whether changes to the T&E requirements are warranted for different categories of radiopharmaceuticals for physicians seeking AU status for the medical use of specific categories of radiopharmaceuticals requiring a written directive under 10 CFR 35.300.

During the comment period between October 29, 2018 and January 29, 2019, the NRC will hold four public meetings that will discuss the information being requested and to accept comments on the docket. All four public meetings

will be available for remote participation by moderated bridge line and webinar, and two of the four meetings will be open for in-person attendance at NRC's headquarters in Rockville, Maryland.

The public meetings are scheduled for November 14, 2018 (webinar-only); December 11, 2018 (webinar and in-person attendance); January 10, 2019 (webinar and in-person attendance); and January 22, 2019 (webinar-only). The public meetings will be noticed on the NRC's public meeting Web site at least 10 calendar days before the meeting. Members of the public should monitor the NRC's public meeting Web site at <https://www.nrc.gov/pmns/mtg>. The NRC will also post the meeting notices on the Federal Rulemaking Web site at <https://www.regulations.gov/> under Docket ID **NRC-2018-0230**.

The NRC may post additional materials related to this document, including public comments, on the Federal Rulemaking Web site. The Federal Rulemaking Web site allows you to receive alerts when changes or additions occur in a docket folder. To subscribe: (1) Navigate to the docket folder **NRC-2018-0230**; (2) click the “Sign up for E-mail Alerts” link; and (3) enter your email address and select how frequently you would like to receive emails (daily, weekly, or monthly).

III. Specific Requests for Comments

A. Tailored Training & Experience Requirements

The NRC is requesting comments on whether it should establish tailored T&E requirements for different categories of radiopharmaceuticals for physicians seeking AU status for the medical use of specific categories of radiopharmaceuticals requiring a written directive under 10 CFR 35.300 (i.e., a limited AU status). This would be for physicians seeking AU status via the alternate non-board certified pathway, and for physicians certified by a medical

specialty board that is not currently recognized by the NRC under 10 CFR 35.390, 35.392, 35.394, or 35.396 (Unsealed Byproduct Material—Written Directive Required).

1. Are the current pathways for obtaining AU status reasonable and accessible? Provide a rationale for your answer.
2. Are the current pathways for obtaining AU status adequate for protecting public health and safety? Provide a rationale for your answer.
3. Should the NRC develop a new tailored T&E pathway for these physicians? If so, what would be the appropriate way to categorize radiopharmaceuticals for tailored T&E requirements? If not, explain why the regulations should remain unchanged. [Some options to categorize radiopharmaceuticals include radiopharmaceuticals with similar delivery methods (oral, parenteral); same type of radiation characteristics or emission (alpha, beta, gamma, low-energy photon); similar preparation method (patient-ready doses); or a combination thereof (e.g., radiopharmaceuticals containing alpha- and beta-emitting radioisotopes that are administered intravenously and are prepared as patient-ready doses).]
4. Should the fundamental T&E required of physicians seeking limited AU status need to have the same fundamental T&E required of physicians seeking full AU status for all oral and parenteral administrations under 10 CFR 35.300?
5. How should the requirements for this fundamental T&E be structured for a specific category of radiopharmaceuticals?
 - a. Describe what the requirements should include:

- i. Classroom and laboratory training – What topics need to be covered in this training requirement? How many hours of classroom and laboratory training should be required? Provide the basis for the number of hours. If not hours, explain how this training should be quantified. [Note: The topics currently required in the regulations to be included in the classroom and laboratory training and work experience are listed in 10 CFR 35.390, 35.392, 35.394, and 35.396.]
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 - iii. Competency - How should competency be evaluated? Should a written and/or practical examination by an independent examining committee be administered? Provide a rationale for your answer.
- b. Should a preceptor attestation be required for the fundamental T&E? Provide a rationale for your answer.
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- d. Who should establish and administer the curriculum and examination? Provide specific group(s). [Some options are: NRC, medical specialty boards, medical professional societies, educational professional groups, and NRC in collaboration with any or more of the aforementioned groups.]
- e. Should AU competency be periodically assessed? If so, how should it be assessed, how often, and by whom?

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The NRC is requesting comments on its recognition of medical specialty boards. The NRC's procedures for recognizing medical specialty boards are located on the Medical Uses Licensee Toolkit Web site (<https://www.nrc.gov/materials/miau/med-use-toolkit/certif-process-boards.html>). The NRC staff periodically reviews information to determine a board's continued eligibility for recognition.

- 1. What boards other than those already recognized by the NRC (American Board of Nuclear Medicine [ABNM], American Board of Radiology [ABR], American Osteopathic Board of Radiology [AOBR], Certification Board of Nuclear Endocrinology [CBNE]) could be considered for recognition for medical uses under 10 CFR 35.300?
- 2. Are the current NRC medical specialty board recognition criteria sufficient? If not, what additional criteria should the NRC use?

C. Patient Access

The NRC is requesting comments on whether there is a shortage in the number of AUs for 10 CFR 35.300.

1. Is there a shortage in the number of AUs for medical uses under 10 CFR 35.300? If so, is the shortage associated with the use of a specific radiopharmaceutical? Explain how.
2. Are there certain geographic areas with an inadequate number of AUs? Identify these areas.
3. Do current NRC regulations on AU T&E requirements unnecessarily limit patient access to procedures involving radiopharmaceuticals? Explain how.
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D. Other Suggested Changes to the T&E Regulations

In 2002, the NRC revised its regulatory framework for medical use. The goal was to focus the NRC's regulations on those medical procedures that pose the highest risk to workers, the general public, patients, and human research subjects and to structure the regulations to be more risk-informed and more performance-based. The 2002 rule reduced the unnecessary regulatory burden by either reducing or eliminating the prescriptiveness of some regulations. Instead, the rule provided for a performance-based approach that relied on the training and experience of the AUs, authorized nuclear pharmacists, and radiation safety officers. The NRC is requesting comments on whether there are any other changes to the T&E regulations in 10 CFR part 35 that should be considered. Please discuss your suggested changes.

1. Should the NRC regulate the T&E of physicians for medical uses?
2. Are there requirements in the NRC's T&E regulatory framework for physicians that are non-safety related?

3. How can the NRC transform its regulatory approach for T&E while still ensuring that adequate protection is maintained for workers, the general public, patients, and human research subjects?

Dated at Rockville, Maryland, this 23rd day of October 2018.

For the Nuclear Regulatory
Commission.

/RA/

Daniel S. Collins, Director,
Division of Materials Safety,
Security,
State, and Tribal Programs,
Office of Nuclear Material Safety
and Safeguards.



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

November 2, 2018

Dr. William R. Law
Dean, College of Science
c/o Nuclear Medicine Disciplines
Benedictine University
5700 College Road
Lisle, IL 60532

SUBJECT: TRAINING AND EXPERIENCE REQUIREMENTS FOR DIFFERENT CATEGORIES OF RADIOPHARMACEUTICALS

Dear Dr. Law,

The U.S. Nuclear Regulatory Commission (NRC) is evaluating its regulations related to the training and experience (T&E) required for a physician to become an authorized user for medical uses under Subpart E, “Unsealed Byproduct Material—Written Directive Required,” of [Title 10 of the Code of Federal Regulations \(10 CFR\) Part 35, “Medical Use of Byproduct Material.”](#)

The T&E requirements in Subpart E of 10 CFR Part 35 provide three ways that a physician can be authorized to administer unsealed byproduct materials or radiopharmaceuticals requiring a written directive:

1. A physician can be certified by a medical specialty board, whose certification process is recognized by the NRC or an Agreement State.
2. A physician can complete a structured educational program and supervised work experience under an alternate pathway. This alternate pathway includes a requirement for 700 hours of training and experience, which consists of a minimum of 200 hours of classroom and laboratory training and 500 hours of supervised work experience.
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In its evaluation of the T&E requirements, the NRC staff is considering whether an additional pathway should be created or if the alternate pathway should be revised. Specifically, the staff is evaluating: (1) whether it makes sense to establish tailored T&E requirements for different categories of radiopharmaceuticals; (2) how those categories should be determined; (3) what the appropriate T&E requirements would be for each category; and (4) whether those requirements should be based on hours of training and experience, or focused more on competency.

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Additional information on the NRC's T&E evaluation can be found at: <https://www.nrc.gov/materials/miau/med-use-toolkit/training-experience-evaluation.html>. If you have any questions on this correspondence, please contact Sarah Lopas of my staff at (301) 415-6360 or Sarah.Lopas@nrc.gov.

A handwritten signature in black ink, appearing to read "C Einberg".

Christian Einberg, Chief
Medical Safety and Events Assessment Branch
Division of Materials Safety, Security, State
and Tribal Programs
Office of Nuclear Material Safety
and Safeguards

Enclosure:
Training and Experience
Federal Register notice

NUCLEAR REGULATORY COMMISSION

[NRC-2018-0230]

**Training and Experience Requirements for Different Categories of
Radiopharmaceuticals**

AGENCY: Nuclear Regulatory Commission.

ACTION: Training and experience requirements; request for comment.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is requesting comments on its training and experience (T&E) requirements. Specifically, the NRC would like input on whether it should establish tailored T&E requirements for different categories of radiopharmaceuticals for which a written directive is required in accordance with its regulations. The input will be used to determine whether significant regulatory changes to the NRC's T&E requirements for authorized users (AUs) are warranted.

DATES: Submit comments by January 29, 2019. Comments received after this date will be considered if it is practical to do so, but the NRC is only able to ensure consideration for comments received on or before this date.

ADDRESSES: You may submit comments by any of the following methods:

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FOR FURTHER INFORMATION CONTACT: Sarah Lopas, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001; telephone: 301-415-6360, e-mail: Sarah.Lopas@nrc.gov.

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B. Submitting Comments

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radionuclides or by delivery method), (3) what the appropriate T&E requirements would be for each category, and (4) whether those requirements should be based on hours of T&E or focused more on competency. In response to the SRM, the NRC staff documented its initial results, status, and next steps related to this evaluation in SECY-18-0084, "Staff Evaluation of Training and Experience Requirements for Administering Different Categories of Radiopharmaceuticals in Response to SRM-M170817" (ADAMS Accession No. ML18135A276). In SECY-18-0084, the staff concluded that additional outreach with the medical community is needed to determine whether and how to tailor the T&E requirements to establish a limited AU status, the specific T&E requirements that should apply, how the T&E requirements should be met (e.g., hours of training, demonstration of competency), and whether a competency-based approach makes sense for the T&E requirements for all the medical uses authorized under 10 CFR 35.300, "Use of unsealed byproduct material for which a written directive is required."

The NRC is interested in obtaining input from as many stakeholders as possible, including members of the Advisory Committee on the Medical Uses of Isotopes, professional organizations, physicians, patients, patient advocacy groups, licensees, Agreement States, and other interested individuals. The focus of this request is to gather information that will permit the NRC staff to determine whether changes to the T&E requirements are warranted for different categories of radiopharmaceuticals for physicians seeking AU status for the medical use of specific categories of radiopharmaceuticals requiring a written directive under 10 CFR 35.300.

During the comment period between October 29, 2018 and January 29, 2019, the NRC will hold four public meetings that will discuss the information being requested and to accept comments on the docket. All four public meetings

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III. Specific Requests for Comments

A. Tailored Training & Experience Requirements

The NRC is requesting comments on whether it should establish tailored T&E requirements for different categories of radiopharmaceuticals for physicians seeking AU status for the medical use of specific categories of radiopharmaceuticals requiring a written directive under 10 CFR 35.300 (i.e., a limited AU status). This would be for physicians seeking AU status via the alternate non-board certified pathway, and for physicians certified by a medical

specialty board that is not currently recognized by the NRC under 10 CFR 35.390, 35.392, 35.394, or 35.396 (Unsealed Byproduct Material—Written Directive Required).

1. Are the current pathways for obtaining AU status reasonable and accessible? Provide a rationale for your answer.
2. Are the current pathways for obtaining AU status adequate for protecting public health and safety? Provide a rationale for your answer.
3. Should the NRC develop a new tailored T&E pathway for these physicians? If so, what would be the appropriate way to categorize radiopharmaceuticals for tailored T&E requirements? If not, explain why the regulations should remain unchanged. [Some options to categorize radiopharmaceuticals include radiopharmaceuticals with similar delivery methods (oral, parenteral); same type of radiation characteristics or emission (alpha, beta, gamma, low-energy photon); similar preparation method (patient-ready doses); or a combination thereof (e.g., radiopharmaceuticals containing alpha- and beta-emitting radioisotopes that are administered intravenously and are prepared as patient-ready doses).]
4. Should the fundamental T&E required of physicians seeking limited AU status need to have the same fundamental T&E required of physicians seeking full AU status for all oral and parenteral administrations under 10 CFR 35.300?
5. How should the requirements for this fundamental T&E be structured for a specific category of radiopharmaceuticals?
 - a. Describe what the requirements should include:

- i. Classroom and laboratory training – What topics need to be covered in this training requirement? How many hours of classroom and laboratory training should be required? Provide the basis for the number of hours. If not hours, explain how this training should be quantified. [Note: The topics currently required in the regulations to be included in the classroom and laboratory training and work experience are listed in 10 CFR 35.390, 35.392, 35.394, and 35.396.]
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 - iii. Competency - How should competency be evaluated? Should a written and/or practical examination by an independent examining committee be administered? Provide a rationale for your answer.
- b. Should a preceptor attestation be required for the fundamental T&E? Provide a rationale for your answer.
- c. Should the radiopharmaceutical manufacturer be able to provide the preceptor attestation? Provide a rational for your answer.

- d. Who should establish and administer the curriculum and examination? Provide specific group(s). [Some options are: NRC, medical specialty boards, medical professional societies, educational professional groups, and NRC in collaboration with any or more of the aforementioned groups.]
- e. Should AU competency be periodically assessed? If so, how should it be assessed, how often, and by whom?

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The NRC is requesting comments on its recognition of medical specialty boards. The NRC's procedures for recognizing medical specialty boards are located on the Medical Uses Licensee Toolkit Web site (<https://www.nrc.gov/materials/miau/med-use-toolkit/certif-process-boards.html>). The NRC staff periodically reviews information to determine a board's continued eligibility for recognition.

- 1. What boards other than those already recognized by the NRC (American Board of Nuclear Medicine [ABNM], American Board of Radiology [ABR], American Osteopathic Board of Radiology [AOBR], Certification Board of Nuclear Endocrinology [CBNE]) could be considered for recognition for medical uses under 10 CFR 35.300?
- 2. Are the current NRC medical specialty board recognition criteria sufficient? If not, what additional criteria should the NRC use?

C. Patient Access

The NRC is requesting comments on whether there is a shortage in the number of AUs for 10 CFR 35.300.

1. Is there a shortage in the number of AUs for medical uses under 10 CFR 35.300? If so, is the shortage associated with the use of a specific radiopharmaceutical? Explain how.
2. Are there certain geographic areas with an inadequate number of AUs? Identify these areas.
3. Do current NRC regulations on AU T&E requirements unnecessarily limit patient access to procedures involving radiopharmaceuticals? Explain how.
4. Do current NRC regulations on AU T&E requirements unnecessarily limit research and development in nuclear medicine? Explain how.

D. Other Suggested Changes to the T&E Regulations

In 2002, the NRC revised its regulatory framework for medical use. The goal was to focus the NRC's regulations on those medical procedures that pose the highest risk to workers, the general public, patients, and human research subjects and to structure the regulations to be more risk-informed and more performance-based. The 2002 rule reduced the unnecessary regulatory burden by either reducing or eliminating the prescriptiveness of some regulations. Instead, the rule provided for a performance-based approach that relied on the training and experience of the AUs, authorized nuclear pharmacists, and radiation safety officers. The NRC is requesting comments on whether there are any other changes to the T&E regulations in 10 CFR part 35 that should be considered. Please discuss your suggested changes.

1. Should the NRC regulate the T&E of physicians for medical uses?
2. Are there requirements in the NRC's T&E regulatory framework for physicians that are non-safety related?

3. How can the NRC transform its regulatory approach for T&E while still ensuring that adequate protection is maintained for workers, the general public, patients, and human research subjects?

Dated at Rockville, Maryland, this 23rd day of October 2018.

For the Nuclear Regulatory
Commission.

/RA/

Daniel S. Collins, Director,
Division of Materials Safety,
Security,
State, and Tribal Programs,
Office of Nuclear Material Safety
and Safeguards.



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

November 2, 2018

The Leukemia & Lymphoma Society
3 International Dr., Suite 200
Rye Brook, NY 10573

**SUBJECT: TRAINING AND EXPERIENCE REQUIREMENTS FOR DIFFERENT
CATEGORIES OF RADIOPHARMACEUTICALS**

Dear Sir or Madam,

The U.S. Nuclear Regulatory Commission (NRC) is evaluating its regulations related to the training and experience (T&E) required for a physician to become an authorized user for medical uses under Subpart E, "Unsealed Byproduct Material—Written Directive Required," of [Title 10 of the Code of Federal Regulations \(10 CFR\) Part 35, "Medical Use of Byproduct Material."](#)

The T&E requirements in Subpart E of 10 CFR Part 35 provide three ways that a physician can be authorized to administer unsealed byproduct materials or radiopharmaceuticals requiring a written directive:

1. A physician can be certified by a medical specialty board, whose certification process is recognized by the NRC or an Agreement State.
2. A physician can complete a structured educational program and supervised work experience under an alternate pathway. This alternate pathway includes a requirement for 700 hours of training and experience, which consists of a minimum of 200 hours of classroom and laboratory training and 500 hours of supervised work experience.
3. A physician can be authorized if previously identified as an authorized user on an NRC or Agreement State license or permit (i.e., grandfathered).

In its evaluation of the T&E requirements, the NRC staff is considering whether an additional pathway should be created or if the alternate pathway should be revised. Specifically, the staff is evaluating: (1) whether it makes sense to establish tailored T&E requirements for different categories of radiopharmaceuticals; (2) how those categories should be determined; (3) what the appropriate T&E requirements would be for each category; and (4) whether those requirements should be based on hours of training and experience, or focused more on competency.

On October 29, 2018, the NRC published a series of questions on T&E in the *Federal Register* (83 FR 54380). The *Federal Register* notice is enclosed with this letter and can also be accessed at: <https://www.gpo.gov/fdsys/pkg/FR-2018-10-29/pdf/2018-23521.pdf>. The NRC will carefully consider responses to these questions and would appreciate your feedback on whether changes to the current T&E regulations are warranted. The comment period for the T&E evaluation will end on January 29, 2019. Please follow the directions in the notice on how to submit written comments. The NRC is using the Federal rulemaking Web site, [Regulations.gov](#), to accept written comments on the docket (NRC-2018-0230).

The NRC will also conduct four public meetings scheduled for November 14 and December 11, 2018, and January 10 and January 22, 2019, and will accept oral comments provided during the meetings. The meetings on December 11 and January 10 will be held at NRC Headquarters in Rockville, MD, and all four meetings will be accessible for remote participation by moderated bridge line and webinar. The NRC's public meeting page has been updated with meeting details and registration instructions for each meeting: <https://www.nrc.gov/pmns/mtg>.

Additional information on the NRC's T&E evaluation can be found at: <https://www.nrc.gov/materials/miau/med-use-toolkit/training-experience-evaluation.html>. If you have any questions on this correspondence, please contact Sarah Lopas of my staff at (301) 415-6360 or Sarah.Lopas@nrc.gov.

A handwritten signature in black ink, appearing to read "C Einberg".

Christian Einberg, Chief
Medical Safety and Events Assessment Branch
Division of Materials Safety, Security, State
and Tribal Programs
Office of Nuclear Material Safety
and Safeguards

Enclosure:
Training and Experience
Federal Register notice

NUCLEAR REGULATORY COMMISSION

[NRC-2018-0230]

**Training and Experience Requirements for Different Categories of
Radiopharmaceuticals**

AGENCY: Nuclear Regulatory Commission.

ACTION: Training and experience requirements; request for comment.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is requesting comments on its training and experience (T&E) requirements. Specifically, the NRC would like input on whether it should establish tailored T&E requirements for different categories of radiopharmaceuticals for which a written directive is required in accordance with its regulations. The input will be used to determine whether significant regulatory changes to the NRC's T&E requirements for authorized users (AUs) are warranted.

DATES: Submit comments by January 29, 2019. Comments received after this date will be considered if it is practical to do so, but the NRC is only able to ensure consideration for comments received on or before this date.

ADDRESSES: You may submit comments by any of the following methods:

- **Federal Rulemaking Web Site:** Go to <http://www.regulations.gov>

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- **Mail comments to:** May Ma, Office of Administration, Mail Stop: TWFN-7-A60M, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001.

For additional direction on obtaining information and submitting comments, see “Obtaining Information and Submitting Comments” in the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: Sarah Lopas, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001; telephone: 301-415-6360, e-mail: Sarah.Lopas@nrc.gov.

SUPPLEMENTARY INFORMATION:

I. Obtaining Information and Submitting Comments

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- **NRC's PDR:** You may examine and purchase copies of public documents at the NRC's PDR, Room O1-F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.

B. Submitting Comments

Please include Docket ID **NRC-2018-0230** in your comment submission.

The NRC cautions you not to include identifying or contact information in comment submissions that you do not want to be publicly disclosed in your comment submission. All comment submissions are posted at <http://www.regulations.gov> and entered into ADAMS. Comment submissions are not routinely edited to remove identifying or contact information.

If you are requesting or aggregating comments from other persons for submission to the NRC, then you should inform those persons not to include identifying or contact information that they do not want to be publicly disclosed in their comment submission. Your request should state that the NRC does not routinely edit comment submissions to remove such information before making the comment submissions available to the public or entering the comment into ADAMS.

II. Background

On August 17, 2017, the Commission issued a staff requirements memorandum (SRM), SRM-M170817 (ADAMS Accession No. ML17229B284), approving the final rule revising parts 30, 32, and 35 of title 10 of the *Code of Federal Regulations* (10 CFR), "Medical Use of Byproduct Material – Medical Event Definitions, Training and Experience, and Clarifying Amendments," and directing the staff to evaluate (1) whether it makes sense to establish tailored T&E requirements for different categories of radiopharmaceuticals, (2) how those categories should be determined (such as by risks posed by groups of

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- 2. Are the current NRC medical specialty board recognition criteria sufficient? If not, what additional criteria should the NRC use?

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1. Should the NRC regulate the T&E of physicians for medical uses?
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Dated at Rockville, Maryland, this 23rd day of October 2018.

For the Nuclear Regulatory
Commission.

/RA/

Daniel S. Collins, Director,
Division of Materials Safety,
Security,
State, and Tribal Programs,
Office of Nuclear Material Safety
and Safeguards.



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

November 2, 2018

Lewis University
Nuclear Medicine Technology, College of Arts and Sciences
1 University Parkway
Romeoville, IL 60446

**SUBJECT: TRAINING AND EXPERIENCE REQUIREMENTS FOR DIFFERENT
CATEGORIES OF RADIOPHARMACEUTICALS**

Dear Sir or Madam,

The U.S. Nuclear Regulatory Commission (NRC) is evaluating its regulations related to the training and experience (T&E) required for a physician to become an authorized user for medical uses under Subpart E, “Unsealed Byproduct Material—Written Directive Required,” of [Title 10 of the Code of Federal Regulations \(10 CFR\) Part 35, “Medical Use of Byproduct Material.”](#)

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Additional information on the NRC's T&E evaluation can be found at: <https://www.nrc.gov/materials/miau/med-use-toolkit/training-experience-evaluation.html>. If you have any questions on this correspondence, please contact Sarah Lopas of my staff at (301) 415-6360 or Sarah.Lopas@nrc.gov.

A handwritten signature in black ink, appearing to read "C Einberg".

Christian Einberg, Chief
Medical Safety and Events Assessment Branch
Division of Materials Safety, Security, State
and Tribal Programs
Office of Nuclear Material Safety
and Safeguards

Enclosure:
Training and Experience
Federal Register notice

NUCLEAR REGULATORY COMMISSION

[NRC-2018-0230]

**Training and Experience Requirements for Different Categories of
Radiopharmaceuticals**

AGENCY: Nuclear Regulatory Commission.

ACTION: Training and experience requirements; request for comment.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is requesting comments on its training and experience (T&E) requirements. Specifically, the NRC would like input on whether it should establish tailored T&E requirements for different categories of radiopharmaceuticals for which a written directive is required in accordance with its regulations. The input will be used to determine whether significant regulatory changes to the NRC's T&E requirements for authorized users (AUs) are warranted.

DATES: Submit comments by January 29, 2019. Comments received after this date will be considered if it is practical to do so, but the NRC is only able to ensure consideration for comments received on or before this date.

ADDRESSES: You may submit comments by any of the following methods:

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and search for Docket ID **NRC-2018-0230**. Address questions about Docket IDs in Regulations.gov to Jennifer Borges; telephone: 301-287-9127; e-mail: Jennifer.Borges@nrc.gov. For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.

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FOR FURTHER INFORMATION CONTACT: Sarah Lopas, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001; telephone: 301-415-6360, e-mail: Sarah.Lopas@nrc.gov.

SUPPLEMENTARY INFORMATION:

I. Obtaining Information and Submitting Comments

A. Obtaining Information

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radionuclides or by delivery method), (3) what the appropriate T&E requirements would be for each category, and (4) whether those requirements should be based on hours of T&E or focused more on competency. In response to the SRM, the NRC staff documented its initial results, status, and next steps related to this evaluation in SECY-18-0084, "Staff Evaluation of Training and Experience Requirements for Administering Different Categories of Radiopharmaceuticals in Response to SRM-M170817" (ADAMS Accession No. ML18135A276). In SECY-18-0084, the staff concluded that additional outreach with the medical community is needed to determine whether and how to tailor the T&E requirements to establish a limited AU status, the specific T&E requirements that should apply, how the T&E requirements should be met (e.g., hours of training, demonstration of competency), and whether a competency-based approach makes sense for the T&E requirements for all the medical uses authorized under 10 CFR 35.300, "Use of unsealed byproduct material for which a written directive is required."

The NRC is interested in obtaining input from as many stakeholders as possible, including members of the Advisory Committee on the Medical Uses of Isotopes, professional organizations, physicians, patients, patient advocacy groups, licensees, Agreement States, and other interested individuals. The focus of this request is to gather information that will permit the NRC staff to determine whether changes to the T&E requirements are warranted for different categories of radiopharmaceuticals for physicians seeking AU status for the medical use of specific categories of radiopharmaceuticals requiring a written directive under 10 CFR 35.300.

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III. Specific Requests for Comments

A. Tailored Training & Experience Requirements

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specialty board that is not currently recognized by the NRC under 10 CFR 35.390, 35.392, 35.394, or 35.396 (Unsealed Byproduct Material—Written Directive Required).

1. Are the current pathways for obtaining AU status reasonable and accessible? Provide a rationale for your answer.
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3. Should the NRC develop a new tailored T&E pathway for these physicians? If so, what would be the appropriate way to categorize radiopharmaceuticals for tailored T&E requirements? If not, explain why the regulations should remain unchanged. [Some options to categorize radiopharmaceuticals include radiopharmaceuticals with similar delivery methods (oral, parenteral); same type of radiation characteristics or emission (alpha, beta, gamma, low-energy photon); similar preparation method (patient-ready doses); or a combination thereof (e.g., radiopharmaceuticals containing alpha- and beta-emitting radioisotopes that are administered intravenously and are prepared as patient-ready doses).]
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- b. Should a preceptor attestation be required for the fundamental T&E? Provide a rationale for your answer.
- c. Should the radiopharmaceutical manufacturer be able to provide the preceptor attestation? Provide a rational for your answer.

- d. Who should establish and administer the curriculum and examination? Provide specific group(s). [Some options are: NRC, medical specialty boards, medical professional societies, educational professional groups, and NRC in collaboration with any or more of the aforementioned groups.]
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- 1. What boards other than those already recognized by the NRC (American Board of Nuclear Medicine [ABNM], American Board of Radiology [ABR], American Osteopathic Board of Radiology [AOBR], Certification Board of Nuclear Endocrinology [CBNE]) could be considered for recognition for medical uses under 10 CFR 35.300?
- 2. Are the current NRC medical specialty board recognition criteria sufficient? If not, what additional criteria should the NRC use?

C. Patient Access

The NRC is requesting comments on whether there is a shortage in the number of AUs for 10 CFR 35.300.

1. Is there a shortage in the number of AUs for medical uses under 10 CFR 35.300? If so, is the shortage associated with the use of a specific radiopharmaceutical? Explain how.
2. Are there certain geographic areas with an inadequate number of AUs? Identify these areas.
3. Do current NRC regulations on AU T&E requirements unnecessarily limit patient access to procedures involving radiopharmaceuticals? Explain how.
4. Do current NRC regulations on AU T&E requirements unnecessarily limit research and development in nuclear medicine? Explain how.

D. Other Suggested Changes to the T&E Regulations

In 2002, the NRC revised its regulatory framework for medical use. The goal was to focus the NRC's regulations on those medical procedures that pose the highest risk to workers, the general public, patients, and human research subjects and to structure the regulations to be more risk-informed and more performance-based. The 2002 rule reduced the unnecessary regulatory burden by either reducing or eliminating the prescriptiveness of some regulations. Instead, the rule provided for a performance-based approach that relied on the training and experience of the AUs, authorized nuclear pharmacists, and radiation safety officers. The NRC is requesting comments on whether there are any other changes to the T&E regulations in 10 CFR part 35 that should be considered. Please discuss your suggested changes.

1. Should the NRC regulate the T&E of physicians for medical uses?
2. Are there requirements in the NRC's T&E regulatory framework for physicians that are non-safety related?

3. How can the NRC transform its regulatory approach for T&E while still ensuring that adequate protection is maintained for workers, the general public, patients, and human research subjects?

Dated at Rockville, Maryland, this 23rd day of October 2018.

For the Nuclear Regulatory
Commission.

/RA/

Daniel S. Collins, Director,
Division of Materials Safety,
Security,
State, and Tribal Programs,
Office of Nuclear Material Safety
and Safeguards.



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

November 2, 2018

Dr. Gary Marano, MD
Nuclear Medicine Preceptor
West Virginia University, Ruby Memorial Hospital
1 Medical Center Drive
Morgantown, WV 26505

**SUBJECT: TRAINING AND EXPERIENCE REQUIREMENTS FOR DIFFERENT
CATEGORIES OF RADIOPHARMACEUTICALS**

Dear Dr. Marano,

The U.S. Nuclear Regulatory Commission (NRC) is evaluating its regulations related to the training and experience (T&E) required for a physician to become an authorized user for medical uses under Subpart E, “Unsealed Byproduct Material—Written Directive Required,” of [Title 10 of the Code of Federal Regulations \(10 CFR\) Part 35, “Medical Use of Byproduct Material.”](#)

The T&E requirements in Subpart E of 10 CFR Part 35 provide three ways that a physician can be authorized to administer unsealed byproduct materials or radiopharmaceuticals requiring a written directive:

1. A physician can be certified by a medical specialty board, whose certification process is recognized by the NRC or an Agreement State.
2. A physician can complete a structured educational program and supervised work experience under an alternate pathway. This alternate pathway includes a requirement for 700 hours of training and experience, which consists of a minimum of 200 hours of classroom and laboratory training and 500 hours of supervised work experience.
3. A physician can be authorized if previously identified as an authorized user on an NRC or Agreement State license or permit (i.e., grandfathered).

In its evaluation of the T&E requirements, the NRC staff is considering whether an additional pathway should be created or if the alternate pathway should be revised. Specifically, the staff is evaluating: (1) whether it makes sense to establish tailored T&E requirements for different categories of radiopharmaceuticals; (2) how those categories should be determined; (3) what the appropriate T&E requirements would be for each category; and (4) whether those requirements should be based on hours of training and experience, or focused more on competency.

On October 29, 2018, the NRC published a series of questions on T&E in the *Federal Register* (83 FR 54380). The *Federal Register* notice is enclosed with this letter and can also be accessed at: <https://www.gpo.gov/fdsys/pkg/FR-2018-10-29/pdf/2018-23521.pdf>. The NRC will carefully consider responses to these questions and would appreciate your feedback on whether changes to the current T&E regulations are warranted. The comment period for the T&E evaluation will end on January 29, 2019. Please follow the directions in the notice on how to submit written comments. The NRC is using the Federal rulemaking Web site, [Regulations.gov](#), to accept written comments on the docket (NRC-2018-0230).

The NRC will also conduct four public meetings scheduled for November 14 and December 11, 2018, and January 10 and January 22, 2019, and will accept oral comments provided during the meetings. The meetings on December 11 and January 10 will be held at NRC Headquarters in Rockville, MD, and all four meetings will be accessible for remote participation by moderated bridge line and webinar. The NRC's public meeting page has been updated with meeting details and registration instructions for each meeting: <https://www.nrc.gov/pmns/mtg>.

Additional information on the NRC's T&E evaluation can be found at: <https://www.nrc.gov/materials/miau/med-use-toolkit/training-experience-evaluation.html>. If you have any questions on this correspondence, please contact Sarah Lopas of my staff at (301) 415-6360 or Sarah.Lopas@nrc.gov.

A handwritten signature in black ink, appearing to read "C Einberg".

Christian Einberg, Chief
Medical Safety and Events Assessment Branch
Division of Materials Safety, Security, State
and Tribal Programs
Office of Nuclear Material Safety
and Safeguards

Enclosure:
Training and Experience
Federal Register notice

NUCLEAR REGULATORY COMMISSION

[NRC-2018-0230]

**Training and Experience Requirements for Different Categories of
Radiopharmaceuticals**

AGENCY: Nuclear Regulatory Commission.

ACTION: Training and experience requirements; request for comment.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is requesting comments on its training and experience (T&E) requirements. Specifically, the NRC would like input on whether it should establish tailored T&E requirements for different categories of radiopharmaceuticals for which a written directive is required in accordance with its regulations. The input will be used to determine whether significant regulatory changes to the NRC's T&E requirements for authorized users (AUs) are warranted.

DATES: Submit comments by January 29, 2019. Comments received after this date will be considered if it is practical to do so, but the NRC is only able to ensure consideration for comments received on or before this date.

ADDRESSES: You may submit comments by any of the following methods:

- **Federal Rulemaking Web Site:** Go to <http://www.regulations.gov>

and search for Docket ID **NRC-2018-0230**. Address questions about Docket IDs in Regulations.gov to Jennifer Borges; telephone: 301-287-9127; e-mail: Jennifer.Borges@nrc.gov. For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.

- **Mail comments to:** May Ma, Office of Administration, Mail Stop: TWFN-7-A60M, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001.

For additional direction on obtaining information and submitting comments, see “Obtaining Information and Submitting Comments” in the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: Sarah Lopas, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001; telephone: 301-415-6360, e-mail: Sarah.Lopas@nrc.gov.

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- d. Who should establish and administer the curriculum and examination? Provide specific group(s). [Some options are: NRC, medical specialty boards, medical professional societies, educational professional groups, and NRC in collaboration with any or more of the aforementioned groups.]
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Dated at Rockville, Maryland, this 23rd day of October 2018.

For the Nuclear Regulatory
Commission.

/RA/

Daniel S. Collins, Director,
Division of Materials Safety,
Security,
State, and Tribal Programs,
Office of Nuclear Material Safety
and Safeguards.



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

November 2, 2018

Dr. Kyle P. Meyer
Dean, College of Allied Health Professions
University of Nebraska Medical Center
42nd and Emile
Omaha, NE 68198

**SUBJECT: TRAINING AND EXPERIENCE REQUIREMENTS FOR DIFFERENT
CATEGORIES OF RADIOPHARMACEUTICALS**

Dear Dr. Meyer,

The U.S. Nuclear Regulatory Commission (NRC) is evaluating its regulations related to the training and experience (T&E) required for a physician to become an authorized user for medical uses under Subpart E, “Unsealed Byproduct Material—Written Directive Required,” of [Title 10 of the Code of Federal Regulations \(10 CFR\) Part 35, “Medical Use of Byproduct Material.”](#)

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Christian Einberg, Chief
Medical Safety and Events Assessment Branch
Division of Materials Safety, Security, State
and Tribal Programs
Office of Nuclear Material Safety
and Safeguards

Enclosure:
Training and Experience
Federal Register notice

NUCLEAR REGULATORY COMMISSION

[NRC-2018-0230]

**Training and Experience Requirements for Different Categories of
Radiopharmaceuticals**

AGENCY: Nuclear Regulatory Commission.

ACTION: Training and experience requirements; request for comment.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is requesting comments on its training and experience (T&E) requirements. Specifically, the NRC would like input on whether it should establish tailored T&E requirements for different categories of radiopharmaceuticals for which a written directive is required in accordance with its regulations. The input will be used to determine whether significant regulatory changes to the NRC's T&E requirements for authorized users (AUs) are warranted.

DATES: Submit comments by January 29, 2019. Comments received after this date will be considered if it is practical to do so, but the NRC is only able to ensure consideration for comments received on or before this date.

ADDRESSES: You may submit comments by any of the following methods:

- **Federal Rulemaking Web Site:** Go to <http://www.regulations.gov>

and search for Docket ID **NRC-2018-0230**. Address questions about Docket IDs in Regulations.gov to Jennifer Borges; telephone: 301-287-9127; e-mail: Jennifer.Borges@nrc.gov. For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.

- **Mail comments to:** May Ma, Office of Administration, Mail Stop: TWFN-7-A60M, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001.

For additional direction on obtaining information and submitting comments, see “Obtaining Information and Submitting Comments” in the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: Sarah Lopas, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001; telephone: 301-415-6360, e-mail: Sarah.Lopas@nrc.gov.

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Please include Docket ID **NRC-2018-0230** in your comment submission.

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radionuclides or by delivery method), (3) what the appropriate T&E requirements would be for each category, and (4) whether those requirements should be based on hours of T&E or focused more on competency. In response to the SRM, the NRC staff documented its initial results, status, and next steps related to this evaluation in SECY-18-0084, "Staff Evaluation of Training and Experience Requirements for Administering Different Categories of Radiopharmaceuticals in Response to SRM-M170817" (ADAMS Accession No. ML18135A276). In SECY-18-0084, the staff concluded that additional outreach with the medical community is needed to determine whether and how to tailor the T&E requirements to establish a limited AU status, the specific T&E requirements that should apply, how the T&E requirements should be met (e.g., hours of training, demonstration of competency), and whether a competency-based approach makes sense for the T&E requirements for all the medical uses authorized under 10 CFR 35.300, "Use of unsealed byproduct material for which a written directive is required."

The NRC is interested in obtaining input from as many stakeholders as possible, including members of the Advisory Committee on the Medical Uses of Isotopes, professional organizations, physicians, patients, patient advocacy groups, licensees, Agreement States, and other interested individuals. The focus of this request is to gather information that will permit the NRC staff to determine whether changes to the T&E requirements are warranted for different categories of radiopharmaceuticals for physicians seeking AU status for the medical use of specific categories of radiopharmaceuticals requiring a written directive under 10 CFR 35.300.

During the comment period between October 29, 2018 and January 29, 2019, the NRC will hold four public meetings that will discuss the information being requested and to accept comments on the docket. All four public meetings

will be available for remote participation by moderated bridge line and webinar, and two of the four meetings will be open for in-person attendance at NRC's headquarters in Rockville, Maryland.

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III. Specific Requests for Comments

A. Tailored Training & Experience Requirements

The NRC is requesting comments on whether it should establish tailored T&E requirements for different categories of radiopharmaceuticals for physicians seeking AU status for the medical use of specific categories of radiopharmaceuticals requiring a written directive under 10 CFR 35.300 (i.e., a limited AU status). This would be for physicians seeking AU status via the alternate non-board certified pathway, and for physicians certified by a medical

specialty board that is not currently recognized by the NRC under 10 CFR 35.390, 35.392, 35.394, or 35.396 (Unsealed Byproduct Material—Written Directive Required).

1. Are the current pathways for obtaining AU status reasonable and accessible? Provide a rationale for your answer.
2. Are the current pathways for obtaining AU status adequate for protecting public health and safety? Provide a rationale for your answer.
3. Should the NRC develop a new tailored T&E pathway for these physicians? If so, what would be the appropriate way to categorize radiopharmaceuticals for tailored T&E requirements? If not, explain why the regulations should remain unchanged. [Some options to categorize radiopharmaceuticals include radiopharmaceuticals with similar delivery methods (oral, parenteral); same type of radiation characteristics or emission (alpha, beta, gamma, low-energy photon); similar preparation method (patient-ready doses); or a combination thereof (e.g., radiopharmaceuticals containing alpha- and beta-emitting radioisotopes that are administered intravenously and are prepared as patient-ready doses).]
4. Should the fundamental T&E required of physicians seeking limited AU status need to have the same fundamental T&E required of physicians seeking full AU status for all oral and parenteral administrations under 10 CFR 35.300?
5. How should the requirements for this fundamental T&E be structured for a specific category of radiopharmaceuticals?
 - a. Describe what the requirements should include:

- i. Classroom and laboratory training – What topics need to be covered in this training requirement? How many hours of classroom and laboratory training should be required? Provide the basis for the number of hours. If not hours, explain how this training should be quantified. [Note: The topics currently required in the regulations to be included in the classroom and laboratory training and work experience are listed in 10 CFR 35.390, 35.392, 35.394, and 35.396.]
 - ii. Work experience - What should the work experience requirement involve? How many hours of work experience should be required and what is the minimum number of patient or human research subject administrations that an individual must perform? Provide the basis for the number of hours and administrations. What should be the qualifications of the supervising individual?
 - iii. Competency - How should competency be evaluated? Should a written and/or practical examination by an independent examining committee be administered? Provide a rationale for your answer.
- b. Should a preceptor attestation be required for the fundamental T&E? Provide a rationale for your answer.
- c. Should the radiopharmaceutical manufacturer be able to provide the preceptor attestation? Provide a rational for your answer.

- d. Who should establish and administer the curriculum and examination? Provide specific group(s). [Some options are: NRC, medical specialty boards, medical professional societies, educational professional groups, and NRC in collaboration with any or more of the aforementioned groups.]
- e. Should AU competency be periodically assessed? If so, how should it be assessed, how often, and by whom?

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The NRC is requesting comments on its recognition of medical specialty boards. The NRC's procedures for recognizing medical specialty boards are located on the Medical Uses Licensee Toolkit Web site (<https://www.nrc.gov/materials/miau/med-use-toolkit/certif-process-boards.html>). The NRC staff periodically reviews information to determine a board's continued eligibility for recognition.

- 1. What boards other than those already recognized by the NRC (American Board of Nuclear Medicine [ABNM], American Board of Radiology [ABR], American Osteopathic Board of Radiology [AOBR], Certification Board of Nuclear Endocrinology [CBNE]) could be considered for recognition for medical uses under 10 CFR 35.300?
- 2. Are the current NRC medical specialty board recognition criteria sufficient? If not, what additional criteria should the NRC use?

C. Patient Access

The NRC is requesting comments on whether there is a shortage in the number of AUs for 10 CFR 35.300.

1. Is there a shortage in the number of AUs for medical uses under 10 CFR 35.300? If so, is the shortage associated with the use of a specific radiopharmaceutical? Explain how.
2. Are there certain geographic areas with an inadequate number of AUs? Identify these areas.
3. Do current NRC regulations on AU T&E requirements unnecessarily limit patient access to procedures involving radiopharmaceuticals? Explain how.
4. Do current NRC regulations on AU T&E requirements unnecessarily limit research and development in nuclear medicine? Explain how.

D. Other Suggested Changes to the T&E Regulations

In 2002, the NRC revised its regulatory framework for medical use. The goal was to focus the NRC's regulations on those medical procedures that pose the highest risk to workers, the general public, patients, and human research subjects and to structure the regulations to be more risk-informed and more performance-based. The 2002 rule reduced the unnecessary regulatory burden by either reducing or eliminating the prescriptiveness of some regulations. Instead, the rule provided for a performance-based approach that relied on the training and experience of the AUs, authorized nuclear pharmacists, and radiation safety officers. The NRC is requesting comments on whether there are any other changes to the T&E regulations in 10 CFR part 35 that should be considered. Please discuss your suggested changes.

1. Should the NRC regulate the T&E of physicians for medical uses?
2. Are there requirements in the NRC's T&E regulatory framework for physicians that are non-safety related?

3. How can the NRC transform its regulatory approach for T&E while still ensuring that adequate protection is maintained for workers, the general public, patients, and human research subjects?

Dated at Rockville, Maryland, this 23rd day of October 2018.

For the Nuclear Regulatory
Commission.

/RA/

Daniel S. Collins, Director,
Division of Materials Safety,
Security,
State, and Tribal Programs,
Office of Nuclear Material Safety
and Safeguards.



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

November 2, 2018

Prof. Miriam Espada Caro
University of Puerto Rico, Medical
Sciences Campus
School of Health Professions Main Building
7th Fl., Office #723
Monacillo Area, Rio Piedras, PR

**SUBJECT: TRAINING AND EXPERIENCE REQUIREMENTS FOR DIFFERENT
CATEGORIES OF RADIOPHARMACEUTICALS**

Dear Prof. Espada Caro,

The U.S. Nuclear Regulatory Commission (NRC) is evaluating its regulations related to the training and experience (T&E) required for a physician to become an authorized user for medical uses under Subpart E, “Unsealed Byproduct Material—Written Directive Required,” of [Title 10 of the Code of Federal Regulations \(10 CFR\) Part 35, “Medical Use of Byproduct Material.”](#)

The T&E requirements in Subpart E of 10 CFR Part 35 provide three ways that a physician can be authorized to administer unsealed byproduct materials or radiopharmaceuticals requiring a written directive:

1. A physician can be certified by a medical specialty board, whose certification process is recognized by the NRC or an Agreement State.
2. A physician can complete a structured educational program and supervised work experience under an alternate pathway. This alternate pathway includes a requirement for 700 hours of training and experience, which consists of a minimum of 200 hours of classroom and laboratory training and 500 hours of supervised work experience.
3. A physician can be authorized if previously identified as an authorized user on an NRC or Agreement State license or permit (i.e., grandfathered).

In its evaluation of the T&E requirements, the NRC staff is considering whether an additional pathway should be created or if the alternate pathway should be revised. Specifically, the staff is evaluating: (1) whether it makes sense to establish tailored T&E requirements for different categories of radiopharmaceuticals; (2) how those categories should be determined; (3) what the appropriate T&E requirements would be for each category; and (4) whether those requirements should be based on hours of training and experience, or focused more on competency.

On October 29, 2018, the NRC published a series of questions on T&E in the *Federal Register* (83 FR 54380). The *Federal Register* notice is enclosed with this letter and can also be accessed at: <https://www.gpo.gov/fdsys/pkg/FR-2018-10-29/pdf/2018-23521.pdf>. The NRC will carefully consider responses to these questions and would appreciate your feedback on whether changes to the current T&E regulations are warranted. The comment period for the T&E evaluation will end on January 29, 2019. Please follow the directions in the notice on how to submit written comments. The NRC is using the Federal rulemaking Web site, [Regulations.gov](#), to accept written comments on the docket (NRC-2018-0230).

The NRC will also conduct four public meetings scheduled for November 14 and December 11, 2018, and January 10 and January 22, 2019, and will accept oral comments provided during the meetings. The meetings on December 11 and January 10 will be held at NRC Headquarters in Rockville, MD, and all four meetings will be accessible for remote participation by moderated bridge line and webinar. The NRC's public meeting page has been updated with meeting details and registration instructions for each meeting: <https://www.nrc.gov/pmns/mtg>.

Additional information on the NRC's T&E evaluation can be found at: <https://www.nrc.gov/materials/miau/med-use-toolkit/training-experience-evaluation.html>. If you have any questions on this correspondence, please contact Sarah Lopas of my staff at (301) 415-6360 or Sarah.Lopas@nrc.gov.

A handwritten signature in black ink, appearing to read "C Einberg".

Christian Einberg, Chief
Medical Safety and Events Assessment Branch
Division of Materials Safety, Security, State
and Tribal Programs
Office of Nuclear Material Safety
and Safeguards

Enclosure:
Training and Experience
Federal Register notice

NUCLEAR REGULATORY COMMISSION

[NRC-2018-0230]

**Training and Experience Requirements for Different Categories of
Radiopharmaceuticals**

AGENCY: Nuclear Regulatory Commission.

ACTION: Training and experience requirements; request for comment.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is requesting comments on its training and experience (T&E) requirements. Specifically, the NRC would like input on whether it should establish tailored T&E requirements for different categories of radiopharmaceuticals for which a written directive is required in accordance with its regulations. The input will be used to determine whether significant regulatory changes to the NRC's T&E requirements for authorized users (AUs) are warranted.

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Dated at Rockville, Maryland, this 23rd day of October 2018.

For the Nuclear Regulatory
Commission.

/RA/

Daniel S. Collins, Director,
Division of Materials Safety,
Security,
State, and Tribal Programs,
Office of Nuclear Material Safety
and Safeguards.



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

November 2, 2018

South College
School of Health and Therapy
3904 Lonas Drive
Knoxville, TN 37909

SUBJECT: TRAINING AND EXPERIENCE REQUIREMENTS FOR DIFFERENT CATEGORIES OF RADIOPHARMACEUTICALS

Dear Sir or Madam,

The U.S. Nuclear Regulatory Commission (NRC) is evaluating its regulations related to the training and experience (T&E) required for a physician to become an authorized user for medical uses under Subpart E, “Unsealed Byproduct Material—Written Directive Required,” of [Title 10 of the Code of Federal Regulations \(10 CFR\) Part 35, “Medical Use of Byproduct Material.”](#)

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On October 29, 2018, the NRC published a series of questions on T&E in the *Federal Register* (83 FR 54380). The *Federal Register* notice is enclosed with this letter and can also be accessed at: <https://www.gpo.gov/fdsys/pkg/FR-2018-10-29/pdf/2018-23521.pdf>. The NRC will carefully consider responses to these questions and would appreciate your feedback on whether changes to the current T&E regulations are warranted. The comment period for the T&E evaluation will end on January 29, 2019. Please follow the directions in the notice on how to submit written comments. The NRC is using the Federal rulemaking Web site, [Regulations.gov](#), to accept written comments on the docket (NRC-2018-0230).

The NRC will also conduct four public meetings scheduled for November 14 and December 11, 2018, and January 10 and January 22, 2019, and will accept oral comments provided during the meetings. The meetings on December 11 and January 10 will be held at NRC Headquarters in Rockville, MD, and all four meetings will be accessible for remote participation by moderated bridge line and webinar. The NRC's public meeting page has been updated with meeting details and registration instructions for each meeting: <https://www.nrc.gov/pmns/mtg>.

Additional information on the NRC's T&E evaluation can be found at: <https://www.nrc.gov/materials/miau/med-use-toolkit/training-experience-evaluation.html>. If you have any questions on this correspondence, please contact Sarah Lopas of my staff at (301) 415-6360 or Sarah.Lopas@nrc.gov.

A handwritten signature in black ink, appearing to read "C Einberg".

Christian Einberg, Chief
Medical Safety and Events Assessment Branch
Division of Materials Safety, Security, State
and Tribal Programs
Office of Nuclear Material Safety
and Safeguards

Enclosure:
Training and Experience
Federal Register notice

NUCLEAR REGULATORY COMMISSION

[NRC-2018-0230]

**Training and Experience Requirements for Different Categories of
Radiopharmaceuticals**

AGENCY: Nuclear Regulatory Commission.

ACTION: Training and experience requirements; request for comment.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is requesting comments on its training and experience (T&E) requirements. Specifically, the NRC would like input on whether it should establish tailored T&E requirements for different categories of radiopharmaceuticals for which a written directive is required in accordance with its regulations. The input will be used to determine whether significant regulatory changes to the NRC's T&E requirements for authorized users (AUs) are warranted.

DATES: Submit comments by January 29, 2019. Comments received after this date will be considered if it is practical to do so, but the NRC is only able to ensure consideration for comments received on or before this date.

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FOR FURTHER INFORMATION CONTACT: Sarah Lopas, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001; telephone: 301-415-6360, e-mail: Sarah.Lopas@nrc.gov.

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radionuclides or by delivery method), (3) what the appropriate T&E requirements would be for each category, and (4) whether those requirements should be based on hours of T&E or focused more on competency. In response to the SRM, the NRC staff documented its initial results, status, and next steps related to this evaluation in SECY-18-0084, "Staff Evaluation of Training and Experience Requirements for Administering Different Categories of Radiopharmaceuticals in Response to SRM-M170817" (ADAMS Accession No. ML18135A276). In SECY-18-0084, the staff concluded that additional outreach with the medical community is needed to determine whether and how to tailor the T&E requirements to establish a limited AU status, the specific T&E requirements that should apply, how the T&E requirements should be met (e.g., hours of training, demonstration of competency), and whether a competency-based approach makes sense for the T&E requirements for all the medical uses authorized under 10 CFR 35.300, "Use of unsealed byproduct material for which a written directive is required."

The NRC is interested in obtaining input from as many stakeholders as possible, including members of the Advisory Committee on the Medical Uses of Isotopes, professional organizations, physicians, patients, patient advocacy groups, licensees, Agreement States, and other interested individuals. The focus of this request is to gather information that will permit the NRC staff to determine whether changes to the T&E requirements are warranted for different categories of radiopharmaceuticals for physicians seeking AU status for the medical use of specific categories of radiopharmaceuticals requiring a written directive under 10 CFR 35.300.

During the comment period between October 29, 2018 and January 29, 2019, the NRC will hold four public meetings that will discuss the information being requested and to accept comments on the docket. All four public meetings

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III. Specific Requests for Comments

A. Tailored Training & Experience Requirements

The NRC is requesting comments on whether it should establish tailored T&E requirements for different categories of radiopharmaceuticals for physicians seeking AU status for the medical use of specific categories of radiopharmaceuticals requiring a written directive under 10 CFR 35.300 (i.e., a limited AU status). This would be for physicians seeking AU status via the alternate non-board certified pathway, and for physicians certified by a medical

specialty board that is not currently recognized by the NRC under 10 CFR 35.390, 35.392, 35.394, or 35.396 (Unsealed Byproduct Material—Written Directive Required).

1. Are the current pathways for obtaining AU status reasonable and accessible? Provide a rationale for your answer.
2. Are the current pathways for obtaining AU status adequate for protecting public health and safety? Provide a rationale for your answer.
3. Should the NRC develop a new tailored T&E pathway for these physicians? If so, what would be the appropriate way to categorize radiopharmaceuticals for tailored T&E requirements? If not, explain why the regulations should remain unchanged. [Some options to categorize radiopharmaceuticals include radiopharmaceuticals with similar delivery methods (oral, parenteral); same type of radiation characteristics or emission (alpha, beta, gamma, low-energy photon); similar preparation method (patient-ready doses); or a combination thereof (e.g., radiopharmaceuticals containing alpha- and beta-emitting radioisotopes that are administered intravenously and are prepared as patient-ready doses).]
4. Should the fundamental T&E required of physicians seeking limited AU status need to have the same fundamental T&E required of physicians seeking full AU status for all oral and parenteral administrations under 10 CFR 35.300?
5. How should the requirements for this fundamental T&E be structured for a specific category of radiopharmaceuticals?
 - a. Describe what the requirements should include:

- i. Classroom and laboratory training – What topics need to be covered in this training requirement? How many hours of classroom and laboratory training should be required? Provide the basis for the number of hours. If not hours, explain how this training should be quantified. [Note: The topics currently required in the regulations to be included in the classroom and laboratory training and work experience are listed in 10 CFR 35.390, 35.392, 35.394, and 35.396.]
 - ii. Work experience - What should the work experience requirement involve? How many hours of work experience should be required and what is the minimum number of patient or human research subject administrations that an individual must perform? Provide the basis for the number of hours and administrations. What should be the qualifications of the supervising individual?
 - iii. Competency - How should competency be evaluated? Should a written and/or practical examination by an independent examining committee be administered? Provide a rationale for your answer.
- b. Should a preceptor attestation be required for the fundamental T&E? Provide a rationale for your answer.
- c. Should the radiopharmaceutical manufacturer be able to provide the preceptor attestation? Provide a rational for your answer.

- d. Who should establish and administer the curriculum and examination? Provide specific group(s). [Some options are: NRC, medical specialty boards, medical professional societies, educational professional groups, and NRC in collaboration with any or more of the aforementioned groups.]
- e. Should AU competency be periodically assessed? If so, how should it be assessed, how often, and by whom?

B. NRC's Recognition of Medical Specialty Boards

The NRC is requesting comments on its recognition of medical specialty boards. The NRC's procedures for recognizing medical specialty boards are located on the Medical Uses Licensee Toolkit Web site (<https://www.nrc.gov/materials/miau/med-use-toolkit/certif-process-boards.html>). The NRC staff periodically reviews information to determine a board's continued eligibility for recognition.

- 1. What boards other than those already recognized by the NRC (American Board of Nuclear Medicine [ABNM], American Board of Radiology [ABR], American Osteopathic Board of Radiology [AOBR], Certification Board of Nuclear Endocrinology [CBNE]) could be considered for recognition for medical uses under 10 CFR 35.300?
- 2. Are the current NRC medical specialty board recognition criteria sufficient? If not, what additional criteria should the NRC use?

C. Patient Access

The NRC is requesting comments on whether there is a shortage in the number of AUs for 10 CFR 35.300.

1. Is there a shortage in the number of AUs for medical uses under 10 CFR 35.300? If so, is the shortage associated with the use of a specific radiopharmaceutical? Explain how.
2. Are there certain geographic areas with an inadequate number of AUs? Identify these areas.
3. Do current NRC regulations on AU T&E requirements unnecessarily limit patient access to procedures involving radiopharmaceuticals? Explain how.
4. Do current NRC regulations on AU T&E requirements unnecessarily limit research and development in nuclear medicine? Explain how.

D. Other Suggested Changes to the T&E Regulations

In 2002, the NRC revised its regulatory framework for medical use. The goal was to focus the NRC's regulations on those medical procedures that pose the highest risk to workers, the general public, patients, and human research subjects and to structure the regulations to be more risk-informed and more performance-based. The 2002 rule reduced the unnecessary regulatory burden by either reducing or eliminating the prescriptiveness of some regulations. Instead, the rule provided for a performance-based approach that relied on the training and experience of the AUs, authorized nuclear pharmacists, and radiation safety officers. The NRC is requesting comments on whether there are any other changes to the T&E regulations in 10 CFR part 35 that should be considered. Please discuss your suggested changes.

1. Should the NRC regulate the T&E of physicians for medical uses?
2. Are there requirements in the NRC's T&E regulatory framework for physicians that are non-safety related?

3. How can the NRC transform its regulatory approach for T&E while still ensuring that adequate protection is maintained for workers, the general public, patients, and human research subjects?

Dated at Rockville, Maryland, this 23rd day of October 2018.

For the Nuclear Regulatory
Commission.

/RA/

Daniel S. Collins, Director,
Division of Materials Safety,
Security,
State, and Tribal Programs,
Office of Nuclear Material Safety
and Safeguards.



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

November 2, 2018

Mr. Joseph W. Turgeon
President and CEO
Spectrum Pharmaceuticals
11500 S. Eastern Ave., #240
Henderson, NV 89052

SUBJECT: TRAINING AND EXPERIENCE REQUIREMENTS FOR DIFFERENT CATEGORIES OF RADIOPHARMACEUTICALS

Dear Mr. Turgeon,

The U.S. Nuclear Regulatory Commission (NRC) is evaluating its regulations related to the training and experience (T&E) required for a physician to become an authorized user for medical uses under Subpart E, “Unsealed Byproduct Material—Written Directive Required,” of [Title 10 of the Code of Federal Regulations \(10 CFR\) Part 35, “Medical Use of Byproduct Material.”](#)

The T&E requirements in Subpart E of 10 CFR Part 35 provide three ways that a physician can be authorized to administer unsealed byproduct materials or radiopharmaceuticals requiring a written directive:

1. A physician can be certified by a medical specialty board, whose certification process is recognized by the NRC or an Agreement State.
2. A physician can complete a structured educational program and supervised work experience under an alternate pathway. This alternate pathway includes a requirement for 700 hours of training and experience, which consists of a minimum of 200 hours of classroom and laboratory training and 500 hours of supervised work experience.
3. A physician can be authorized if previously identified as an authorized user on an NRC or Agreement State license or permit (i.e., grandfathered).

In its evaluation of the T&E requirements, the NRC staff is considering whether an additional pathway should be created or if the alternate pathway should be revised. Specifically, the staff is evaluating: (1) whether it makes sense to establish tailored T&E requirements for different categories of radiopharmaceuticals; (2) how those categories should be determined; (3) what the appropriate T&E requirements would be for each category; and (4) whether those requirements should be based on hours of training and experience, or focused more on competency.

On October 29, 2018, the NRC published a series of questions on T&E in the *Federal Register* (83 FR 54380). The *Federal Register* notice is enclosed with this letter and can also be accessed at: <https://www.gpo.gov/fdsys/pkg/FR-2018-10-29/pdf/2018-23521.pdf>. The NRC will carefully consider responses to these questions and would appreciate your feedback on whether changes to the current T&E regulations are warranted. The comment period for the T&E evaluation will end on January 29, 2019. Please follow the directions in the notice on how to submit written comments. The NRC is using the Federal rulemaking Web site, [Regulations.gov](#), to accept written comments on the docket (NRC-2018-0230).

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Christian Einberg, Chief
Medical Safety and Events Assessment Branch
Division of Materials Safety, Security, State
and Tribal Programs
Office of Nuclear Material Safety
and Safeguards

Enclosure:
Training and Experience
Federal Register notice

NUCLEAR REGULATORY COMMISSION

[NRC-2018-0230]

**Training and Experience Requirements for Different Categories of
Radiopharmaceuticals**

AGENCY: Nuclear Regulatory Commission.

ACTION: Training and experience requirements; request for comment.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is requesting comments on its training and experience (T&E) requirements. Specifically, the NRC would like input on whether it should establish tailored T&E requirements for different categories of radiopharmaceuticals for which a written directive is required in accordance with its regulations. The input will be used to determine whether significant regulatory changes to the NRC's T&E requirements for authorized users (AUs) are warranted.

DATES: Submit comments by January 29, 2019. Comments received after this date will be considered if it is practical to do so, but the NRC is only able to ensure consideration for comments received on or before this date.

ADDRESSES: You may submit comments by any of the following methods:

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 - a. Describe what the requirements should include:

- i. Classroom and laboratory training – What topics need to be covered in this training requirement? How many hours of classroom and laboratory training should be required? Provide the basis for the number of hours. If not hours, explain how this training should be quantified. [Note: The topics currently required in the regulations to be included in the classroom and laboratory training and work experience are listed in 10 CFR 35.390, 35.392, 35.394, and 35.396.]
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- 2. Are the current NRC medical specialty board recognition criteria sufficient? If not, what additional criteria should the NRC use?

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1. Is there a shortage in the number of AUs for medical uses under 10 CFR 35.300? If so, is the shortage associated with the use of a specific radiopharmaceutical? Explain how.
2. Are there certain geographic areas with an inadequate number of AUs? Identify these areas.
3. Do current NRC regulations on AU T&E requirements unnecessarily limit patient access to procedures involving radiopharmaceuticals? Explain how.
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D. Other Suggested Changes to the T&E Regulations

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1. Should the NRC regulate the T&E of physicians for medical uses?
2. Are there requirements in the NRC's T&E regulatory framework for physicians that are non-safety related?

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Dated at Rockville, Maryland, this 23rd day of October 2018.

For the Nuclear Regulatory
Commission.

/RA/

Daniel S. Collins, Director,
Division of Materials Safety,
Security,
State, and Tribal Programs,
Office of Nuclear Material Safety
and Safeguards.



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

November 2, 2018

Dr. Dinko Franceschi, MD
Division Chief, Nuclear Medicine
Stony Brook University Hospital
101 Nicolls Road
Stony Brook, NY 11794

SUBJECT: TRAINING AND EXPERIENCE REQUIREMENTS FOR DIFFERENT CATEGORIES OF RADIOPHARMACEUTICALS

Dear Dr. Franceschi,

The U.S. Nuclear Regulatory Commission (NRC) is evaluating its regulations related to the training and experience (T&E) required for a physician to become an authorized user for medical uses under Subpart E, “Unsealed Byproduct Material—Written Directive Required,” of [Title 10 of the Code of Federal Regulations \(10 CFR\) Part 35, “Medical Use of Byproduct Material.”](#)

The T&E requirements in Subpart E of 10 CFR Part 35 provide three ways that a physician can be authorized to administer unsealed byproduct materials or radiopharmaceuticals requiring a written directive:

1. A physician can be certified by a medical specialty board, whose certification process is recognized by the NRC or an Agreement State.
2. A physician can complete a structured educational program and supervised work experience under an alternate pathway. This alternate pathway includes a requirement for 700 hours of training and experience, which consists of a minimum of 200 hours of classroom and laboratory training and 500 hours of supervised work experience.
3. A physician can be authorized if previously identified as an authorized user on an NRC or Agreement State license or permit (i.e., grandfathered).

In its evaluation of the T&E requirements, the NRC staff is considering whether an additional pathway should be created or if the alternate pathway should be revised. Specifically, the staff is evaluating: (1) whether it makes sense to establish tailored T&E requirements for different categories of radiopharmaceuticals; (2) how those categories should be determined; (3) what the appropriate T&E requirements would be for each category; and (4) whether those requirements should be based on hours of training and experience, or focused more on competency.

On October 29, 2018, the NRC published a series of questions on T&E in the *Federal Register* (83 FR 54380). The *Federal Register* notice is enclosed with this letter and can also be accessed at: <https://www.gpo.gov/fdsys/pkg/FR-2018-10-29/pdf/2018-23521.pdf>. The NRC will carefully consider responses to these questions and would appreciate your feedback on whether changes to the current T&E regulations are warranted. The comment period for the T&E evaluation will end on January 29, 2019. Please follow the directions in the notice on how to submit written comments. The NRC is using the Federal rulemaking Web site, [Regulations.gov](#), to accept written comments on the docket (NRC-2018-0230).

The NRC will also conduct four public meetings scheduled for November 14 and December 11, 2018, and January 10 and January 22, 2019, and will accept oral comments provided during the meetings. The meetings on December 11 and January 10 will be held at NRC Headquarters in Rockville, MD, and all four meetings will be accessible for remote participation by moderated bridge line and webinar. The NRC's public meeting page has been updated with meeting details and registration instructions for each meeting: <https://www.nrc.gov/pmns/mtg>.

Additional information on the NRC's T&E evaluation can be found at: <https://www.nrc.gov/materials/miau/med-use-toolkit/training-experience-evaluation.html>. If you have any questions on this correspondence, please contact Sarah Lopas of my staff at (301) 415-6360 or Sarah.Lopas@nrc.gov.



Christian Einberg, Chief
Medical Safety and Events Assessment Branch
Division of Materials Safety, Security, State
and Tribal Programs
Office of Nuclear Material Safety
and Safeguards

Enclosure:
Training and Experience
Federal Register notice

NUCLEAR REGULATORY COMMISSION

[NRC-2018-0230]

**Training and Experience Requirements for Different Categories of
Radiopharmaceuticals**

AGENCY: Nuclear Regulatory Commission.

ACTION: Training and experience requirements; request for comment.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is requesting comments on its training and experience (T&E) requirements. Specifically, the NRC would like input on whether it should establish tailored T&E requirements for different categories of radiopharmaceuticals for which a written directive is required in accordance with its regulations. The input will be used to determine whether significant regulatory changes to the NRC's T&E requirements for authorized users (AUs) are warranted.

DATES: Submit comments by January 29, 2019. Comments received after this date will be considered if it is practical to do so, but the NRC is only able to ensure consideration for comments received on or before this date.

ADDRESSES: You may submit comments by any of the following methods:

- **Federal Rulemaking Web Site:** Go to <http://www.regulations.gov>

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- **Mail comments to:** May Ma, Office of Administration, Mail Stop: TWFN-7-A60M, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001.

For additional direction on obtaining information and submitting comments, see “Obtaining Information and Submitting Comments” in the **SUPPLEMENTARY INFORMATION** section of this document.

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B. Submitting Comments

Please include Docket ID **NRC-2018-0230** in your comment submission.

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radionuclides or by delivery method), (3) what the appropriate T&E requirements would be for each category, and (4) whether those requirements should be based on hours of T&E or focused more on competency. In response to the SRM, the NRC staff documented its initial results, status, and next steps related to this evaluation in SECY-18-0084, "Staff Evaluation of Training and Experience Requirements for Administering Different Categories of Radiopharmaceuticals in Response to SRM-M170817" (ADAMS Accession No. ML18135A276). In SECY-18-0084, the staff concluded that additional outreach with the medical community is needed to determine whether and how to tailor the T&E requirements to establish a limited AU status, the specific T&E requirements that should apply, how the T&E requirements should be met (e.g., hours of training, demonstration of competency), and whether a competency-based approach makes sense for the T&E requirements for all the medical uses authorized under 10 CFR 35.300, "Use of unsealed byproduct material for which a written directive is required."

The NRC is interested in obtaining input from as many stakeholders as possible, including members of the Advisory Committee on the Medical Uses of Isotopes, professional organizations, physicians, patients, patient advocacy groups, licensees, Agreement States, and other interested individuals. The focus of this request is to gather information that will permit the NRC staff to determine whether changes to the T&E requirements are warranted for different categories of radiopharmaceuticals for physicians seeking AU status for the medical use of specific categories of radiopharmaceuticals requiring a written directive under 10 CFR 35.300.

During the comment period between October 29, 2018 and January 29, 2019, the NRC will hold four public meetings that will discuss the information being requested and to accept comments on the docket. All four public meetings

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III. Specific Requests for Comments

A. Tailored Training & Experience Requirements

The NRC is requesting comments on whether it should establish tailored T&E requirements for different categories of radiopharmaceuticals for physicians seeking AU status for the medical use of specific categories of radiopharmaceuticals requiring a written directive under 10 CFR 35.300 (i.e., a limited AU status). This would be for physicians seeking AU status via the alternate non-board certified pathway, and for physicians certified by a medical

specialty board that is not currently recognized by the NRC under 10 CFR 35.390, 35.392, 35.394, or 35.396 (Unsealed Byproduct Material—Written Directive Required).

1. Are the current pathways for obtaining AU status reasonable and accessible? Provide a rationale for your answer.
2. Are the current pathways for obtaining AU status adequate for protecting public health and safety? Provide a rationale for your answer.
3. Should the NRC develop a new tailored T&E pathway for these physicians? If so, what would be the appropriate way to categorize radiopharmaceuticals for tailored T&E requirements? If not, explain why the regulations should remain unchanged. [Some options to categorize radiopharmaceuticals include radiopharmaceuticals with similar delivery methods (oral, parenteral); same type of radiation characteristics or emission (alpha, beta, gamma, low-energy photon); similar preparation method (patient-ready doses); or a combination thereof (e.g., radiopharmaceuticals containing alpha- and beta-emitting radioisotopes that are administered intravenously and are prepared as patient-ready doses).]
4. Should the fundamental T&E required of physicians seeking limited AU status need to have the same fundamental T&E required of physicians seeking full AU status for all oral and parenteral administrations under 10 CFR 35.300?
5. How should the requirements for this fundamental T&E be structured for a specific category of radiopharmaceuticals?
 - a. Describe what the requirements should include:

- i. Classroom and laboratory training – What topics need to be covered in this training requirement? How many hours of classroom and laboratory training should be required? Provide the basis for the number of hours. If not hours, explain how this training should be quantified. [Note: The topics currently required in the regulations to be included in the classroom and laboratory training and work experience are listed in 10 CFR 35.390, 35.392, 35.394, and 35.396.]
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 - iii. Competency - How should competency be evaluated? Should a written and/or practical examination by an independent examining committee be administered? Provide a rationale for your answer.
- b. Should a preceptor attestation be required for the fundamental T&E? Provide a rationale for your answer.
- c. Should the radiopharmaceutical manufacturer be able to provide the preceptor attestation? Provide a rational for your answer.

- d. Who should establish and administer the curriculum and examination? Provide specific group(s). [Some options are: NRC, medical specialty boards, medical professional societies, educational professional groups, and NRC in collaboration with any or more of the aforementioned groups.]
- e. Should AU competency be periodically assessed? If so, how should it be assessed, how often, and by whom?

B. NRC's Recognition of Medical Specialty Boards

The NRC is requesting comments on its recognition of medical specialty boards. The NRC's procedures for recognizing medical specialty boards are located on the Medical Uses Licensee Toolkit Web site (<https://www.nrc.gov/materials/miau/med-use-toolkit/certif-process-boards.html>). The NRC staff periodically reviews information to determine a board's continued eligibility for recognition.

- 1. What boards other than those already recognized by the NRC (American Board of Nuclear Medicine [ABNM], American Board of Radiology [ABR], American Osteopathic Board of Radiology [AOBR], Certification Board of Nuclear Endocrinology [CBNE]) could be considered for recognition for medical uses under 10 CFR 35.300?
- 2. Are the current NRC medical specialty board recognition criteria sufficient? If not, what additional criteria should the NRC use?

C. Patient Access

The NRC is requesting comments on whether there is a shortage in the number of AUs for 10 CFR 35.300.

1. Is there a shortage in the number of AUs for medical uses under 10 CFR 35.300? If so, is the shortage associated with the use of a specific radiopharmaceutical? Explain how.
2. Are there certain geographic areas with an inadequate number of AUs? Identify these areas.
3. Do current NRC regulations on AU T&E requirements unnecessarily limit patient access to procedures involving radiopharmaceuticals? Explain how.
4. Do current NRC regulations on AU T&E requirements unnecessarily limit research and development in nuclear medicine? Explain how.

D. Other Suggested Changes to the T&E Regulations

In 2002, the NRC revised its regulatory framework for medical use. The goal was to focus the NRC's regulations on those medical procedures that pose the highest risk to workers, the general public, patients, and human research subjects and to structure the regulations to be more risk-informed and more performance-based. The 2002 rule reduced the unnecessary regulatory burden by either reducing or eliminating the prescriptiveness of some regulations. Instead, the rule provided for a performance-based approach that relied on the training and experience of the AUs, authorized nuclear pharmacists, and radiation safety officers. The NRC is requesting comments on whether there are any other changes to the T&E regulations in 10 CFR part 35 that should be considered. Please discuss your suggested changes.

1. Should the NRC regulate the T&E of physicians for medical uses?
2. Are there requirements in the NRC's T&E regulatory framework for physicians that are non-safety related?

3. How can the NRC transform its regulatory approach for T&E while still ensuring that adequate protection is maintained for workers, the general public, patients, and human research subjects?

Dated at Rockville, Maryland, this 23rd day of October 2018.

For the Nuclear Regulatory
Commission.

/RA/

Daniel S. Collins, Director,
Division of Materials Safety,
Security,
State, and Tribal Programs,
Office of Nuclear Material Safety
and Safeguards.



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

November 2, 2018

Thomas Jefferson University
Jefferson College of Health Professions
Edison Building, 130 S. Ninth St., Suite 100
Philadelphia, PA 19107

**SUBJECT: TRAINING AND EXPERIENCE REQUIREMENTS FOR DIFFERENT
CATEGORIES OF RADIOPHARMACEUTICALS**

Dear Sir or Madam,

The U.S. Nuclear Regulatory Commission (NRC) is evaluating its regulations related to the training and experience (T&E) required for a physician to become an authorized user for medical uses under Subpart E, "Unsealed Byproduct Material—Written Directive Required," of [Title 10 of the Code of Federal Regulations \(10 CFR\) Part 35, "Medical Use of Byproduct Material."](#)

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Christian Einberg, 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:
Training and Experience
Federal Register notice

NUCLEAR REGULATORY COMMISSION

[NRC-2018-0230]

**Training and Experience Requirements for Different Categories of
Radiopharmaceuticals**

AGENCY: Nuclear Regulatory Commission.

ACTION: Training and experience requirements; request for comment.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is requesting comments on its training and experience (T&E) requirements. Specifically, the NRC would like input on whether it should establish tailored T&E requirements for different categories of radiopharmaceuticals for which a written directive is required in accordance with its regulations. The input will be used to determine whether significant regulatory changes to the NRC's T&E requirements for authorized users (AUs) are warranted.

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1. Is there a shortage in the number of AUs for medical uses under 10 CFR 35.300? If so, is the shortage associated with the use of a specific radiopharmaceutical? Explain how.
2. Are there certain geographic areas with an inadequate number of AUs? Identify these areas.
3. Do current NRC regulations on AU T&E requirements unnecessarily limit patient access to procedures involving radiopharmaceuticals? Explain how.
4. Do current NRC regulations on AU T&E requirements unnecessarily limit research and development in nuclear medicine? Explain how.

D. Other Suggested Changes to the T&E Regulations

In 2002, the NRC revised its regulatory framework for medical use. The goal was to focus the NRC's regulations on those medical procedures that pose the highest risk to workers, the general public, patients, and human research subjects and to structure the regulations to be more risk-informed and more performance-based. The 2002 rule reduced the unnecessary regulatory burden by either reducing or eliminating the prescriptiveness of some regulations. Instead, the rule provided for a performance-based approach that relied on the training and experience of the AUs, authorized nuclear pharmacists, and radiation safety officers. The NRC is requesting comments on whether there are any other changes to the T&E regulations in 10 CFR part 35 that should be considered. Please discuss your suggested changes.

1. Should the NRC regulate the T&E of physicians for medical uses?
2. Are there requirements in the NRC's T&E regulatory framework for physicians that are non-safety related?

3. How can the NRC transform its regulatory approach for T&E while still ensuring that adequate protection is maintained for workers, the general public, patients, and human research subjects?

Dated at Rockville, Maryland, this 23rd day of October 2018.

For the Nuclear Regulatory
Commission.

/RA/

Daniel S. Collins, Director,
Division of Materials Safety,
Security,
State, and Tribal Programs,
Office of Nuclear Material Safety
and Safeguards.



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

November 2, 2018

Ms. Kellee George, M.S., CNMT, RT(R)(N)
Program Director, KU Nuclear
Medicine Technology
Department of Respiratory Care and
Diagnostic Science
University of Kansas
3901 Rainbow Blvd.
Kansas City, KS 66160

**SUBJECT: TRAINING AND EXPERIENCE REQUIREMENTS FOR DIFFERENT
CATEGORIES OF RADIOPHARMACEUTICALS**

Dear Ms. George,

The U.S. Nuclear Regulatory Commission (NRC) is evaluating its regulations related to the training and experience (T&E) required for a physician to become an authorized user for medical uses under Subpart E, “Unsealed Byproduct Material—Written Directive Required,” of [Title 10 of the Code of Federal Regulations \(10 CFR\) Part 35, “Medical Use of Byproduct Material.”](#)

The T&E requirements in Subpart E of 10 CFR Part 35 provide three ways that a physician can be authorized to administer unsealed byproduct materials or radiopharmaceuticals requiring a written directive:

1. A physician can be certified by a medical specialty board, whose certification process is recognized by the NRC or an Agreement State.
2. A physician can complete a structured educational program and supervised work experience under an alternate pathway. This alternate pathway includes a requirement for 700 hours of training and experience, which consists of a minimum of 200 hours of classroom and laboratory training and 500 hours of supervised work experience.
3. A physician can be authorized if previously identified as an authorized user on an NRC or Agreement State license or permit (i.e., grandfathered).

In its evaluation of the T&E requirements, the NRC staff is considering whether an additional pathway should be created or if the alternate pathway should be revised. Specifically, the staff is evaluating: (1) whether it makes sense to establish tailored T&E requirements for different categories of radiopharmaceuticals; (2) how those categories should be determined; (3) what the appropriate T&E requirements would be for each category; and (4) whether those requirements should be based on hours of training and experience, or focused more on competency.

On October 29, 2018, the NRC published a series of questions on T&E in the *Federal Register* (83 FR 54380). The *Federal Register* notice is enclosed with this letter and can also be accessed at: <https://www.gpo.gov/fdsys/pkg/FR-2018-10-29/pdf/2018-23521.pdf>. The NRC will carefully consider responses to these questions and would appreciate your feedback on whether changes to the current T&E regulations are warranted. The comment period for the T&E evaluation will end on January 29, 2019. Please follow the directions in the notice on how to submit written comments. The NRC is using the Federal rulemaking Web site, [Regulations.gov](#), to accept written comments on the docket (NRC-2018-0230).

The NRC will also conduct four public meetings scheduled for November 14 and December 11, 2018, and January 10 and January 22, 2019, and will accept oral comments provided during the meetings. The meetings on December 11 and January 10 will be held at NRC Headquarters in Rockville, MD, and all four meetings will be accessible for remote participation by moderated bridge line and webinar. The NRC's public meeting page has been updated with meeting details and registration instructions for each meeting: <https://www.nrc.gov/pmns/mtg>.

Additional information on the NRC's T&E evaluation can be found at: <https://www.nrc.gov/materials/miau/med-use-toolkit/training-experience-evaluation.html>. If you have any questions on this correspondence, please contact Sarah Lopas of my staff at (301) 415-6360 or Sarah.Lopas@nrc.gov.

A handwritten signature in black ink, appearing to read "C Einberg".

Christian Einberg, Chief
Medical Safety and Events Assessment Branch
Division of Materials Safety, Security, State
and Tribal Programs
Office of Nuclear Material Safety
and Safeguards

Enclosure:
Training and Experience
Federal Register notice

NUCLEAR REGULATORY COMMISSION

[NRC-2018-0230]

**Training and Experience Requirements for Different Categories of
Radiopharmaceuticals**

AGENCY: Nuclear Regulatory Commission.

ACTION: Training and experience requirements; request for comment.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is requesting comments on its training and experience (T&E) requirements. Specifically, the NRC would like input on whether it should establish tailored T&E requirements for different categories of radiopharmaceuticals for which a written directive is required in accordance with its regulations. The input will be used to determine whether significant regulatory changes to the NRC's T&E requirements for authorized users (AUs) are warranted.

DATES: Submit comments by January 29, 2019. Comments received after this date will be considered if it is practical to do so, but the NRC is only able to ensure consideration for comments received on or before this date.

ADDRESSES: You may submit comments by any of the following methods:

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FOR FURTHER INFORMATION CONTACT: Sarah Lopas, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001; telephone: 301-415-6360, e-mail: Sarah.Lopas@nrc.gov.

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Please include Docket ID **NRC-2018-0230** in your comment submission.

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radionuclides or by delivery method), (3) what the appropriate T&E requirements would be for each category, and (4) whether those requirements should be based on hours of T&E or focused more on competency. In response to the SRM, the NRC staff documented its initial results, status, and next steps related to this evaluation in SECY-18-0084, "Staff Evaluation of Training and Experience Requirements for Administering Different Categories of Radiopharmaceuticals in Response to SRM-M170817" (ADAMS Accession No. ML18135A276). In SECY-18-0084, the staff concluded that additional outreach with the medical community is needed to determine whether and how to tailor the T&E requirements to establish a limited AU status, the specific T&E requirements that should apply, how the T&E requirements should be met (e.g., hours of training, demonstration of competency), and whether a competency-based approach makes sense for the T&E requirements for all the medical uses authorized under 10 CFR 35.300, "Use of unsealed byproduct material for which a written directive is required."

The NRC is interested in obtaining input from as many stakeholders as possible, including members of the Advisory Committee on the Medical Uses of Isotopes, professional organizations, physicians, patients, patient advocacy groups, licensees, Agreement States, and other interested individuals. The focus of this request is to gather information that will permit the NRC staff to determine whether changes to the T&E requirements are warranted for different categories of radiopharmaceuticals for physicians seeking AU status for the medical use of specific categories of radiopharmaceuticals requiring a written directive under 10 CFR 35.300.

During the comment period between October 29, 2018 and January 29, 2019, the NRC will hold four public meetings that will discuss the information being requested and to accept comments on the docket. All four public meetings

will be available for remote participation by moderated bridge line and webinar, and two of the four meetings will be open for in-person attendance at NRC's headquarters in Rockville, Maryland.

The public meetings are scheduled for November 14, 2018 (webinar-only); December 11, 2018 (webinar and in-person attendance); January 10, 2019 (webinar and in-person attendance); and January 22, 2019 (webinar-only). The public meetings will be noticed on the NRC's public meeting Web site at least 10 calendar days before the meeting. Members of the public should monitor the NRC's public meeting Web site at <https://www.nrc.gov/pmns/mtg>. The NRC will also post the meeting notices on the Federal Rulemaking Web site at <https://www.regulations.gov/> under Docket ID **NRC-2018-0230**.

The NRC may post additional materials related to this document, including public comments, on the Federal Rulemaking Web site. The Federal Rulemaking Web site allows you to receive alerts when changes or additions occur in a docket folder. To subscribe: (1) Navigate to the docket folder **NRC-2018-0230**; (2) click the “Sign up for E-mail Alerts” link; and (3) enter your email address and select how frequently you would like to receive emails (daily, weekly, or monthly).

III. Specific Requests for Comments

A. Tailored Training & Experience Requirements

The NRC is requesting comments on whether it should establish tailored T&E requirements for different categories of radiopharmaceuticals for physicians seeking AU status for the medical use of specific categories of radiopharmaceuticals requiring a written directive under 10 CFR 35.300 (i.e., a limited AU status). This would be for physicians seeking AU status via the alternate non-board certified pathway, and for physicians certified by a medical

specialty board that is not currently recognized by the NRC under 10 CFR 35.390, 35.392, 35.394, or 35.396 (Unsealed Byproduct Material—Written Directive Required).

1. Are the current pathways for obtaining AU status reasonable and accessible? Provide a rationale for your answer.
2. Are the current pathways for obtaining AU status adequate for protecting public health and safety? Provide a rationale for your answer.
3. Should the NRC develop a new tailored T&E pathway for these physicians? If so, what would be the appropriate way to categorize radiopharmaceuticals for tailored T&E requirements? If not, explain why the regulations should remain unchanged. [Some options to categorize radiopharmaceuticals include radiopharmaceuticals with similar delivery methods (oral, parenteral); same type of radiation characteristics or emission (alpha, beta, gamma, low-energy photon); similar preparation method (patient-ready doses); or a combination thereof (e.g., radiopharmaceuticals containing alpha- and beta-emitting radioisotopes that are administered intravenously and are prepared as patient-ready doses).]
4. Should the fundamental T&E required of physicians seeking limited AU status need to have the same fundamental T&E required of physicians seeking full AU status for all oral and parenteral administrations under 10 CFR 35.300?
5. How should the requirements for this fundamental T&E be structured for a specific category of radiopharmaceuticals?
 - a. Describe what the requirements should include:

- i. Classroom and laboratory training – What topics need to be covered in this training requirement? How many hours of classroom and laboratory training should be required? Provide the basis for the number of hours. If not hours, explain how this training should be quantified. [Note: The topics currently required in the regulations to be included in the classroom and laboratory training and work experience are listed in 10 CFR 35.390, 35.392, 35.394, and 35.396.]
 - ii. Work experience - What should the work experience requirement involve? How many hours of work experience should be required and what is the minimum number of patient or human research subject administrations that an individual must perform? Provide the basis for the number of hours and administrations. What should be the qualifications of the supervising individual?
 - iii. Competency - How should competency be evaluated? Should a written and/or practical examination by an independent examining committee be administered? Provide a rationale for your answer.
- b. Should a preceptor attestation be required for the fundamental T&E? Provide a rationale for your answer.
- c. Should the radiopharmaceutical manufacturer be able to provide the preceptor attestation? Provide a rational for your answer.

- d. Who should establish and administer the curriculum and examination? Provide specific group(s). [Some options are: NRC, medical specialty boards, medical professional societies, educational professional groups, and NRC in collaboration with any or more of the aforementioned groups.]
- e. Should AU competency be periodically assessed? If so, how should it be assessed, how often, and by whom?

B. NRC's Recognition of Medical Specialty Boards

The NRC is requesting comments on its recognition of medical specialty boards. The NRC's procedures for recognizing medical specialty boards are located on the Medical Uses Licensee Toolkit Web site (<https://www.nrc.gov/materials/miau/med-use-toolkit/certif-process-boards.html>). The NRC staff periodically reviews information to determine a board's continued eligibility for recognition.

- 1. What boards other than those already recognized by the NRC (American Board of Nuclear Medicine [ABNM], American Board of Radiology [ABR], American Osteopathic Board of Radiology [AOBR], Certification Board of Nuclear Endocrinology [CBNE]) could be considered for recognition for medical uses under 10 CFR 35.300?
- 2. Are the current NRC medical specialty board recognition criteria sufficient? If not, what additional criteria should the NRC use?

C. Patient Access

The NRC is requesting comments on whether there is a shortage in the number of AUs for 10 CFR 35.300.

1. Is there a shortage in the number of AUs for medical uses under 10 CFR 35.300? If so, is the shortage associated with the use of a specific radiopharmaceutical? Explain how.
2. Are there certain geographic areas with an inadequate number of AUs? Identify these areas.
3. Do current NRC regulations on AU T&E requirements unnecessarily limit patient access to procedures involving radiopharmaceuticals? Explain how.
4. Do current NRC regulations on AU T&E requirements unnecessarily limit research and development in nuclear medicine? Explain how.

D. Other Suggested Changes to the T&E Regulations

In 2002, the NRC revised its regulatory framework for medical use. The goal was to focus the NRC's regulations on those medical procedures that pose the highest risk to workers, the general public, patients, and human research subjects and to structure the regulations to be more risk-informed and more performance-based. The 2002 rule reduced the unnecessary regulatory burden by either reducing or eliminating the prescriptiveness of some regulations. Instead, the rule provided for a performance-based approach that relied on the training and experience of the AUs, authorized nuclear pharmacists, and radiation safety officers. The NRC is requesting comments on whether there are any other changes to the T&E regulations in 10 CFR part 35 that should be considered. Please discuss your suggested changes.

1. Should the NRC regulate the T&E of physicians for medical uses?
2. Are there requirements in the NRC's T&E regulatory framework for physicians that are non-safety related?

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Dated at Rockville, Maryland, this 23rd day of October 2018.

For the Nuclear Regulatory
Commission.

/RA/

Daniel S. Collins, Director,
Division of Materials Safety,
Security,
State, and Tribal Programs,
Office of Nuclear Material Safety
and Safeguards.



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

November 2, 2018

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

Via e-mail to abnm@abnm.org

SUBJECT: TRAINING AND EXPERIENCE REQUIREMENTS FOR DIFFERENT CATEGORIES OF RADIOPHARMACEUTICALS

Dear Dr. Pryma,

The U.S. Nuclear Regulatory Commission (NRC) is evaluating its regulations related to the training and experience (T&E) required for a physician to become an authorized user for medical uses under Subpart E, “Unsealed Byproduct Material—Written Directive Required,” of [Title 10 of the Code of Federal Regulations \(10 CFR\) Part 35, “Medical Use of Byproduct Material.”](#)

The T&E requirements in Subpart E of 10 CFR Part 35 provide three ways that a physician can be authorized to administer unsealed byproduct materials or radiopharmaceuticals requiring a written directive:

1. A physician can be certified by a medical specialty board, whose certification process is recognized by the NRC or an Agreement State.
2. A physician can complete a structured educational program and supervised work experience under an alternate pathway. This alternate pathway includes a requirement for 700 hours of training and experience, which consists of a minimum of 200 hours of classroom and laboratory training and 500 hours of supervised work experience.
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In its evaluation of the T&E requirements, the NRC staff is considering whether an additional pathway should be created or if the alternate pathway should be revised. Specifically, the staff is evaluating: (1) whether it makes sense to establish tailored T&E requirements for different categories of radiopharmaceuticals; (2) how those categories should be determined; (3) what the appropriate T&E requirements would be for each category; and (4) whether those requirements should be based on hours of training and experience, or focused more on competency.

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Christian Einberg, Chief
Medical Safety and Events Assessment Branch
Division of Materials Safety, Security, State
and Tribal Programs
Office of Nuclear Material Safety
and Safeguards

Enclosure:
Training and Experience
Federal Register notice

NUCLEAR REGULATORY COMMISSION

[NRC-2018-0230]

**Training and Experience Requirements for Different Categories of
Radiopharmaceuticals**

AGENCY: Nuclear Regulatory Commission.

ACTION: Training and experience requirements; request for comment.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is requesting comments on its training and experience (T&E) requirements. Specifically, the NRC would like input on whether it should establish tailored T&E requirements for different categories of radiopharmaceuticals for which a written directive is required in accordance with its regulations. The input will be used to determine whether significant regulatory changes to the NRC's T&E requirements for authorized users (AUs) are warranted.

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5. How should the requirements for this fundamental T&E be structured for a specific category of radiopharmaceuticals?
 - a. Describe what the requirements should include:

- i. Classroom and laboratory training – What topics need to be covered in this training requirement? How many hours of classroom and laboratory training should be required? Provide the basis for the number of hours. If not hours, explain how this training should be quantified. [Note: The topics currently required in the regulations to be included in the classroom and laboratory training and work experience are listed in 10 CFR 35.390, 35.392, 35.394, and 35.396.]
 - ii. Work experience - What should the work experience requirement involve? How many hours of work experience should be required and what is the minimum number of patient or human research subject administrations that an individual must perform? Provide the basis for the number of hours and administrations. What should be the qualifications of the supervising individual?
 - iii. Competency - How should competency be evaluated? Should a written and/or practical examination by an independent examining committee be administered? Provide a rationale for your answer.
- b. Should a preceptor attestation be required for the fundamental T&E? Provide a rationale for your answer.
- c. Should the radiopharmaceutical manufacturer be able to provide the preceptor attestation? Provide a rational for your answer.

- d. Who should establish and administer the curriculum and examination? Provide specific group(s). [Some options are: NRC, medical specialty boards, medical professional societies, educational professional groups, and NRC in collaboration with any or more of the aforementioned groups.]
- e. Should AU competency be periodically assessed? If so, how should it be assessed, how often, and by whom?

B. NRC's Recognition of Medical Specialty Boards

The NRC is requesting comments on its recognition of medical specialty boards. The NRC's procedures for recognizing medical specialty boards are located on the Medical Uses Licensee Toolkit Web site (<https://www.nrc.gov/materials/miau/med-use-toolkit/certif-process-boards.html>). The NRC staff periodically reviews information to determine a board's continued eligibility for recognition.

- 1. What boards other than those already recognized by the NRC (American Board of Nuclear Medicine [ABNM], American Board of Radiology [ABR], American Osteopathic Board of Radiology [AOBR], Certification Board of Nuclear Endocrinology [CBNE]) could be considered for recognition for medical uses under 10 CFR 35.300?
- 2. Are the current NRC medical specialty board recognition criteria sufficient? If not, what additional criteria should the NRC use?

C. Patient Access

The NRC is requesting comments on whether there is a shortage in the number of AUs for 10 CFR 35.300.

1. Is there a shortage in the number of AUs for medical uses under 10 CFR 35.300? If so, is the shortage associated with the use of a specific radiopharmaceutical? Explain how.
2. Are there certain geographic areas with an inadequate number of AUs? Identify these areas.
3. Do current NRC regulations on AU T&E requirements unnecessarily limit patient access to procedures involving radiopharmaceuticals? Explain how.
4. Do current NRC regulations on AU T&E requirements unnecessarily limit research and development in nuclear medicine? Explain how.

D. Other Suggested Changes to the T&E Regulations

In 2002, the NRC revised its regulatory framework for medical use. The goal was to focus the NRC's regulations on those medical procedures that pose the highest risk to workers, the general public, patients, and human research subjects and to structure the regulations to be more risk-informed and more performance-based. The 2002 rule reduced the unnecessary regulatory burden by either reducing or eliminating the prescriptiveness of some regulations. Instead, the rule provided for a performance-based approach that relied on the training and experience of the AUs, authorized nuclear pharmacists, and radiation safety officers. The NRC is requesting comments on whether there are any other changes to the T&E regulations in 10 CFR part 35 that should be considered. Please discuss your suggested changes.

1. Should the NRC regulate the T&E of physicians for medical uses?
2. Are there requirements in the NRC's T&E regulatory framework for physicians that are non-safety related?

3. How can the NRC transform its regulatory approach for T&E while still ensuring that adequate protection is maintained for workers, the general public, patients, and human research subjects?

Dated at Rockville, Maryland, this 23rd day of October 2018.

For the Nuclear Regulatory
Commission.

/RA/

Daniel S. Collins, Director,
Division of Materials Safety,
Security,
State, and Tribal Programs,
Office of Nuclear Material Safety
and Safeguards.



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

November 2, 2018

Dr. Aria Razmaria, MD

Via e-mail to arazmaria@mednet.ucla.edu

SUBJECT: TRAINING AND EXPERIENCE REQUIREMENTS FOR DIFFERENT CATEGORIES OF RADIOPHARMACEUTICALS

Dear Dr. Razmaria,

The U.S. Nuclear Regulatory Commission (NRC) is evaluating its regulations related to the training and experience (T&E) required for a physician to become an authorized user for medical uses under Subpart E, “Unsealed Byproduct Material—Written Directive Required,” of [Title 10 of the Code of Federal Regulations \(10 CFR\) Part 35, “Medical Use of Byproduct Material.”](#)

The T&E requirements in Subpart E of 10 CFR Part 35 provide three ways that a physician can be authorized to administer unsealed byproduct materials or radiopharmaceuticals requiring a written directive:

1. A physician can be certified by a medical specialty board, whose certification process is recognized by the NRC or an Agreement State.
2. A physician can complete a structured educational program and supervised work experience under an alternate pathway. This alternate pathway includes a requirement for 700 hours of training and experience, which consists of a minimum of 200 hours of classroom and laboratory training and 500 hours of supervised work experience.
3. A physician can be authorized if previously identified as an authorized user on an NRC or Agreement State license or permit (i.e., grandfathered).

In its evaluation of the T&E requirements, the NRC staff is considering whether an additional pathway should be created or if the alternate pathway should be revised. Specifically, the staff is evaluating: (1) whether it makes sense to establish tailored T&E requirements for different categories of radiopharmaceuticals; (2) how those categories should be determined; (3) what the appropriate T&E requirements would be for each category; and (4) whether those requirements should be based on hours of training and experience, or focused more on competency.

On October 29, 2018, the NRC published a series of questions on T&E in the *Federal Register* (83 FR 54380). The *Federal Register* notice is enclosed with this letter and can also be accessed at: <https://www.gpo.gov/fdsys/pkg/FR-2018-10-29/pdf/2018-23521.pdf>. The NRC will carefully consider responses to these questions and would appreciate your feedback on whether changes to the current T&E regulations are warranted. The comment period for the T&E evaluation will end on January 29, 2019. Please follow the directions in the notice on how to submit written comments. The NRC is using the Federal rulemaking Web site, [Regulations.gov](#), to accept written comments on the docket (NRC-2018-0230).

The NRC will also conduct four public meetings scheduled for November 14 and December 11, 2018, and January 10 and January 22, 2019, and will accept oral comments provided during the meetings. The meetings on December 11 and January 10 will be held at NRC Headquarters in Rockville, MD, and all four meetings will be accessible for remote participation by moderated bridge line and webinar. The NRC's public meeting page has been updated with meeting details and registration instructions for each meeting: <https://www.nrc.gov/pmns/mtg>.

Additional information on the NRC's T&E evaluation can be found at: <https://www.nrc.gov/materials/miau/med-use-toolkit/training-experience-evaluation.html>. If you have any questions on this correspondence, please contact Sarah Lopas of my staff at (301) 415-6360 or Sarah.Lopas@nrc.gov.



Christian Einberg, Chief
Medical Safety and Events Assessment Branch
Division of Materials Safety, Security, State
and Tribal Programs
Office of Nuclear Material Safety
and Safeguards

Enclosure:
Training and Experience
Federal Register notice

NUCLEAR REGULATORY COMMISSION

[NRC-2018-0230]

**Training and Experience Requirements for Different Categories of
Radiopharmaceuticals**

AGENCY: Nuclear Regulatory Commission.

ACTION: Training and experience requirements; request for comment.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is requesting comments on its training and experience (T&E) requirements. Specifically, the NRC would like input on whether it should establish tailored T&E requirements for different categories of radiopharmaceuticals for which a written directive is required in accordance with its regulations. The input will be used to determine whether significant regulatory changes to the NRC's T&E requirements for authorized users (AUs) are warranted.

DATES: Submit comments by January 29, 2019. Comments received after this date will be considered if it is practical to do so, but the NRC is only able to ensure consideration for comments received on or before this date.

ADDRESSES: You may submit comments by any of the following methods:

- **Federal Rulemaking Web Site:** Go to <http://www.regulations.gov>

and search for Docket ID **NRC-2018-0230**. Address questions about Docket IDs in Regulations.gov to Jennifer Borges; telephone: 301-287-9127; e-mail: Jennifer.Borges@nrc.gov. For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.

- **Mail comments to:** May Ma, Office of Administration, Mail Stop: TWFN-7-A60M, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001.

For additional direction on obtaining information and submitting comments, see “Obtaining Information and Submitting Comments” in the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: Sarah Lopas, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001; telephone: 301-415-6360, e-mail: Sarah.Lopas@nrc.gov.

SUPPLEMENTARY INFORMATION:

I. Obtaining Information and Submitting Comments

A. Obtaining Information

Please refer to Docket ID **NRC-2018-0230** when contacting the NRC about the availability of information for this action. You may obtain publicly-available information related to this action by any of the following methods:

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- **NRC's PDR:** You may examine and purchase copies of public documents at the NRC's PDR, Room O1-F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.

B. Submitting Comments

Please include Docket ID **NRC-2018-0230** in your comment submission.

The NRC cautions you not to include identifying or contact information in comment submissions that you do not want to be publicly disclosed in your comment submission. All comment submissions are posted at <http://www.regulations.gov> and entered into ADAMS. Comment submissions are not routinely edited to remove identifying or contact information.

If you are requesting or aggregating comments from other persons for submission to the NRC, then you should inform those persons not to include identifying or contact information that they do not want to be publicly disclosed in their comment submission. Your request should state that the NRC does not routinely edit comment submissions to remove such information before making the comment submissions available to the public or entering the comment into ADAMS.

II. Background

On August 17, 2017, the Commission issued a staff requirements memorandum (SRM), SRM-M170817 (ADAMS Accession No. ML17229B284), approving the final rule revising parts 30, 32, and 35 of title 10 of the *Code of Federal Regulations* (10 CFR), "Medical Use of Byproduct Material – Medical Event Definitions, Training and Experience, and Clarifying Amendments," and directing the staff to evaluate (1) whether it makes sense to establish tailored T&E requirements for different categories of radiopharmaceuticals, (2) how those categories should be determined (such as by risks posed by groups of

radionuclides or by delivery method), (3) what the appropriate T&E requirements would be for each category, and (4) whether those requirements should be based on hours of T&E or focused more on competency. In response to the SRM, the NRC staff documented its initial results, status, and next steps related to this evaluation in SECY-18-0084, "Staff Evaluation of Training and Experience Requirements for Administering Different Categories of Radiopharmaceuticals in Response to SRM-M170817" (ADAMS Accession No. ML18135A276). In SECY-18-0084, the staff concluded that additional outreach with the medical community is needed to determine whether and how to tailor the T&E requirements to establish a limited AU status, the specific T&E requirements that should apply, how the T&E requirements should be met (e.g., hours of training, demonstration of competency), and whether a competency-based approach makes sense for the T&E requirements for all the medical uses authorized under 10 CFR 35.300, "Use of unsealed byproduct material for which a written directive is required."

The NRC is interested in obtaining input from as many stakeholders as possible, including members of the Advisory Committee on the Medical Uses of Isotopes, professional organizations, physicians, patients, patient advocacy groups, licensees, Agreement States, and other interested individuals. The focus of this request is to gather information that will permit the NRC staff to determine whether changes to the T&E requirements are warranted for different categories of radiopharmaceuticals for physicians seeking AU status for the medical use of specific categories of radiopharmaceuticals requiring a written directive under 10 CFR 35.300.

During the comment period between October 29, 2018 and January 29, 2019, the NRC will hold four public meetings that will discuss the information being requested and to accept comments on the docket. All four public meetings

will be available for remote participation by moderated bridge line and webinar, and two of the four meetings will be open for in-person attendance at NRC's headquarters in Rockville, Maryland.

The public meetings are scheduled for November 14, 2018 (webinar-only); December 11, 2018 (webinar and in-person attendance); January 10, 2019 (webinar and in-person attendance); and January 22, 2019 (webinar-only). The public meetings will be noticed on the NRC's public meeting Web site at least 10 calendar days before the meeting. Members of the public should monitor the NRC's public meeting Web site at <https://www.nrc.gov/pmns/mtg>. The NRC will also post the meeting notices on the Federal Rulemaking Web site at <https://www.regulations.gov/> under Docket ID **NRC-2018-0230**.

The NRC may post additional materials related to this document, including public comments, on the Federal Rulemaking Web site. The Federal Rulemaking Web site allows you to receive alerts when changes or additions occur in a docket folder. To subscribe: (1) Navigate to the docket folder **NRC-2018-0230**; (2) click the “Sign up for E-mail Alerts” link; and (3) enter your email address and select how frequently you would like to receive emails (daily, weekly, or monthly).

III. Specific Requests for Comments

A. Tailored Training & Experience Requirements

The NRC is requesting comments on whether it should establish tailored T&E requirements for different categories of radiopharmaceuticals for physicians seeking AU status for the medical use of specific categories of radiopharmaceuticals requiring a written directive under 10 CFR 35.300 (i.e., a limited AU status). This would be for physicians seeking AU status via the alternate non-board certified pathway, and for physicians certified by a medical

specialty board that is not currently recognized by the NRC under 10 CFR 35.390, 35.392, 35.394, or 35.396 (Unsealed Byproduct Material—Written Directive Required).

1. Are the current pathways for obtaining AU status reasonable and accessible? Provide a rationale for your answer.
2. Are the current pathways for obtaining AU status adequate for protecting public health and safety? Provide a rationale for your answer.
3. Should the NRC develop a new tailored T&E pathway for these physicians? If so, what would be the appropriate way to categorize radiopharmaceuticals for tailored T&E requirements? If not, explain why the regulations should remain unchanged. [Some options to categorize radiopharmaceuticals include radiopharmaceuticals with similar delivery methods (oral, parenteral); same type of radiation characteristics or emission (alpha, beta, gamma, low-energy photon); similar preparation method (patient-ready doses); or a combination thereof (e.g., radiopharmaceuticals containing alpha- and beta-emitting radioisotopes that are administered intravenously and are prepared as patient-ready doses).]
4. Should the fundamental T&E required of physicians seeking limited AU status need to have the same fundamental T&E required of physicians seeking full AU status for all oral and parenteral administrations under 10 CFR 35.300?
5. How should the requirements for this fundamental T&E be structured for a specific category of radiopharmaceuticals?
 - a. Describe what the requirements should include:

- i. Classroom and laboratory training – What topics need to be covered in this training requirement? How many hours of classroom and laboratory training should be required? Provide the basis for the number of hours. If not hours, explain how this training should be quantified. [Note: The topics currently required in the regulations to be included in the classroom and laboratory training and work experience are listed in 10 CFR 35.390, 35.392, 35.394, and 35.396.]
 - ii. Work experience - What should the work experience requirement involve? How many hours of work experience should be required and what is the minimum number of patient or human research subject administrations that an individual must perform? Provide the basis for the number of hours and administrations. What should be the qualifications of the supervising individual?
 - iii. Competency - How should competency be evaluated? Should a written and/or practical examination by an independent examining committee be administered? Provide a rationale for your answer.
- b. Should a preceptor attestation be required for the fundamental T&E? Provide a rationale for your answer.
- c. Should the radiopharmaceutical manufacturer be able to provide the preceptor attestation? Provide a rational for your answer.

- d. Who should establish and administer the curriculum and examination? Provide specific group(s). [Some options are: NRC, medical specialty boards, medical professional societies, educational professional groups, and NRC in collaboration with any or more of the aforementioned groups.]
- e. Should AU competency be periodically assessed? If so, how should it be assessed, how often, and by whom?

B. NRC's Recognition of Medical Specialty Boards

The NRC is requesting comments on its recognition of medical specialty boards. The NRC's procedures for recognizing medical specialty boards are located on the Medical Uses Licensee Toolkit Web site (<https://www.nrc.gov/materials/miau/med-use-toolkit/certif-process-boards.html>). The NRC staff periodically reviews information to determine a board's continued eligibility for recognition.

- 1. What boards other than those already recognized by the NRC (American Board of Nuclear Medicine [ABNM], American Board of Radiology [ABR], American Osteopathic Board of Radiology [AOBR], Certification Board of Nuclear Endocrinology [CBNE]) could be considered for recognition for medical uses under 10 CFR 35.300?
- 2. Are the current NRC medical specialty board recognition criteria sufficient? If not, what additional criteria should the NRC use?

C. Patient Access

The NRC is requesting comments on whether there is a shortage in the number of AUs for 10 CFR 35.300.

1. Is there a shortage in the number of AUs for medical uses under 10 CFR 35.300? If so, is the shortage associated with the use of a specific radiopharmaceutical? Explain how.
2. Are there certain geographic areas with an inadequate number of AUs? Identify these areas.
3. Do current NRC regulations on AU T&E requirements unnecessarily limit patient access to procedures involving radiopharmaceuticals? Explain how.
4. Do current NRC regulations on AU T&E requirements unnecessarily limit research and development in nuclear medicine? Explain how.

D. Other Suggested Changes to the T&E Regulations

In 2002, the NRC revised its regulatory framework for medical use. The goal was to focus the NRC's regulations on those medical procedures that pose the highest risk to workers, the general public, patients, and human research subjects and to structure the regulations to be more risk-informed and more performance-based. The 2002 rule reduced the unnecessary regulatory burden by either reducing or eliminating the prescriptiveness of some regulations. Instead, the rule provided for a performance-based approach that relied on the training and experience of the AUs, authorized nuclear pharmacists, and radiation safety officers. The NRC is requesting comments on whether there are any other changes to the T&E regulations in 10 CFR part 35 that should be considered. Please discuss your suggested changes.

1. Should the NRC regulate the T&E of physicians for medical uses?
2. Are there requirements in the NRC's T&E regulatory framework for physicians that are non-safety related?

3. How can the NRC transform its regulatory approach for T&E while still ensuring that adequate protection is maintained for workers, the general public, patients, and human research subjects?

Dated at Rockville, Maryland, this 23rd day of October 2018.

For the Nuclear Regulatory
Commission.

/RA/

Daniel S. Collins, Director,
Division of Materials Safety,
Security,
State, and Tribal Programs,
Office of Nuclear Material Safety
and Safeguards.



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

November 2, 2018

Dr. Gary R. L'Abbe
Regis College
Medical Imaging, Nuclear Medicine
Technology Concentration
235 Wellesley St.
Weston, MA 02493

Via e-mail to gary.labbe@regiscollege.edu

SUBJECT: TRAINING AND EXPERIENCE REQUIREMENTS FOR DIFFERENT CATEGORIES OF RADIOPHARMACEUTICALS

Dear Dr. L'Abbe,

The U.S. Nuclear Regulatory Commission (NRC) is evaluating its regulations related to the training and experience (T&E) required for a physician to become an authorized user for medical uses under Subpart E, “Unsealed Byproduct Material—Written Directive Required,” of [Title 10 of the Code of Federal Regulations \(10 CFR\) Part 35, “Medical Use of Byproduct Material.”](#)

The T&E requirements in Subpart E of 10 CFR Part 35 provide three ways that a physician can be authorized to administer unsealed byproduct materials or radiopharmaceuticals requiring a written directive:

1. A physician can be certified by a medical specialty board, whose certification process is recognized by the NRC or an Agreement State.
2. A physician can complete a structured educational program and supervised work experience under an alternate pathway. This alternate pathway includes a requirement for 700 hours of training and experience, which consists of a minimum of 200 hours of classroom and laboratory training and 500 hours of supervised work experience.
3. A physician can be authorized if previously identified as an authorized user on an NRC or Agreement State license or permit (i.e., grandfathered).

In its evaluation of the T&E requirements, the NRC staff is considering whether an additional pathway should be created or if the alternate pathway should be revised. Specifically, the staff is evaluating: (1) whether it makes sense to establish tailored T&E requirements for different categories of radiopharmaceuticals; (2) how those categories should be determined; (3) what the appropriate T&E requirements would be for each category; and (4) whether those requirements should be based on hours of training and experience, or focused more on competency.

On October 29, 2018, the NRC published a series of questions on T&E in the *Federal Register* (83 FR 54380). The *Federal Register* notice is enclosed with this letter and can also be accessed at: <https://www.gpo.gov/fdsys/pkg/FR-2018-10-29/pdf/2018-23521.pdf>. The NRC will carefully consider responses to these questions and would appreciate your feedback on whether changes to the current T&E regulations are warranted. The comment period for the T&E evaluation will end on January 29, 2019. Please follow the directions in the notice on how to submit written comments. The NRC is using the Federal rulemaking Web site, [Regulations.gov](#), to accept written comments on the docket (NRC-2018-0230).

The NRC will also conduct four public meetings scheduled for November 14 and December 11, 2018, and January 10 and January 22, 2019, and will accept oral comments provided during the meetings. The meetings on December 11 and January 10 will be held at NRC Headquarters in Rockville, MD, and all four meetings will be accessible for remote participation by moderated bridge line and webinar. The NRC's public meeting page has been updated with meeting details and registration instructions for each meeting: <https://www.nrc.gov/pmns/mtg>.

Additional information on the NRC's T&E evaluation can be found at: <https://www.nrc.gov/materials/miau/med-use-toolkit/training-experience-evaluation.html>. If you have any questions on this correspondence, please contact Sarah Lopas of my staff at (301) 415-6360 or Sarah.Lopas@nrc.gov.

A handwritten signature in black ink, appearing to read "C Einberg".

Christian Einberg, Chief
Medical Safety and Events Assessment Branch
Division of Materials Safety, Security, State
and Tribal Programs
Office of Nuclear Material Safety
and Safeguards

Enclosure:
Training and Experience
Federal Register notice

NUCLEAR REGULATORY COMMISSION

[NRC-2018-0230]

**Training and Experience Requirements for Different Categories of
Radiopharmaceuticals**

AGENCY: Nuclear Regulatory Commission.

ACTION: Training and experience requirements; request for comment.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is requesting comments on its training and experience (T&E) requirements. Specifically, the NRC would like input on whether it should establish tailored T&E requirements for different categories of radiopharmaceuticals for which a written directive is required in accordance with its regulations. The input will be used to determine whether significant regulatory changes to the NRC's T&E requirements for authorized users (AUs) are warranted.

DATES: Submit comments by January 29, 2019. Comments received after this date will be considered if it is practical to do so, but the NRC is only able to ensure consideration for comments received on or before this date.

ADDRESSES: You may submit comments by any of the following methods:

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For additional direction on obtaining information and submitting comments, see “Obtaining Information and Submitting Comments” in the **SUPPLEMENTARY INFORMATION** section of this document.

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B. Submitting Comments

Please include Docket ID **NRC-2018-0230** in your comment submission.

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radionuclides or by delivery method), (3) what the appropriate T&E requirements would be for each category, and (4) whether those requirements should be based on hours of T&E or focused more on competency. In response to the SRM, the NRC staff documented its initial results, status, and next steps related to this evaluation in SECY-18-0084, "Staff Evaluation of Training and Experience Requirements for Administering Different Categories of Radiopharmaceuticals in Response to SRM-M170817" (ADAMS Accession No. ML18135A276). In SECY-18-0084, the staff concluded that additional outreach with the medical community is needed to determine whether and how to tailor the T&E requirements to establish a limited AU status, the specific T&E requirements that should apply, how the T&E requirements should be met (e.g., hours of training, demonstration of competency), and whether a competency-based approach makes sense for the T&E requirements for all the medical uses authorized under 10 CFR 35.300, "Use of unsealed byproduct material for which a written directive is required."

The NRC is interested in obtaining input from as many stakeholders as possible, including members of the Advisory Committee on the Medical Uses of Isotopes, professional organizations, physicians, patients, patient advocacy groups, licensees, Agreement States, and other interested individuals. The focus of this request is to gather information that will permit the NRC staff to determine whether changes to the T&E requirements are warranted for different categories of radiopharmaceuticals for physicians seeking AU status for the medical use of specific categories of radiopharmaceuticals requiring a written directive under 10 CFR 35.300.

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III. Specific Requests for Comments

A. Tailored Training & Experience Requirements

The NRC is requesting comments on whether it should establish tailored T&E requirements for different categories of radiopharmaceuticals for physicians seeking AU status for the medical use of specific categories of radiopharmaceuticals requiring a written directive under 10 CFR 35.300 (i.e., a limited AU status). This would be for physicians seeking AU status via the alternate non-board certified pathway, and for physicians certified by a medical

specialty board that is not currently recognized by the NRC under 10 CFR 35.390, 35.392, 35.394, or 35.396 (Unsealed Byproduct Material—Written Directive Required).

1. Are the current pathways for obtaining AU status reasonable and accessible? Provide a rationale for your answer.
2. Are the current pathways for obtaining AU status adequate for protecting public health and safety? Provide a rationale for your answer.
3. Should the NRC develop a new tailored T&E pathway for these physicians? If so, what would be the appropriate way to categorize radiopharmaceuticals for tailored T&E requirements? If not, explain why the regulations should remain unchanged. [Some options to categorize radiopharmaceuticals include radiopharmaceuticals with similar delivery methods (oral, parenteral); same type of radiation characteristics or emission (alpha, beta, gamma, low-energy photon); similar preparation method (patient-ready doses); or a combination thereof (e.g., radiopharmaceuticals containing alpha- and beta-emitting radioisotopes that are administered intravenously and are prepared as patient-ready doses).]
4. Should the fundamental T&E required of physicians seeking limited AU status need to have the same fundamental T&E required of physicians seeking full AU status for all oral and parenteral administrations under 10 CFR 35.300?
5. How should the requirements for this fundamental T&E be structured for a specific category of radiopharmaceuticals?
 - a. Describe what the requirements should include:

- i. Classroom and laboratory training – What topics need to be covered in this training requirement? How many hours of classroom and laboratory training should be required? Provide the basis for the number of hours. If not hours, explain how this training should be quantified. [Note: The topics currently required in the regulations to be included in the classroom and laboratory training and work experience are listed in 10 CFR 35.390, 35.392, 35.394, and 35.396.]
 - ii. Work experience - What should the work experience requirement involve? How many hours of work experience should be required and what is the minimum number of patient or human research subject administrations that an individual must perform? Provide the basis for the number of hours and administrations. What should be the qualifications of the supervising individual?
 - iii. Competency - How should competency be evaluated? Should a written and/or practical examination by an independent examining committee be administered? Provide a rationale for your answer.
- b. Should a preceptor attestation be required for the fundamental T&E? Provide a rationale for your answer.
- c. Should the radiopharmaceutical manufacturer be able to provide the preceptor attestation? Provide a rational for your answer.

- d. Who should establish and administer the curriculum and examination? Provide specific group(s). [Some options are: NRC, medical specialty boards, medical professional societies, educational professional groups, and NRC in collaboration with any or more of the aforementioned groups.]
- e. Should AU competency be periodically assessed? If so, how should it be assessed, how often, and by whom?

B. NRC's Recognition of Medical Specialty Boards

The NRC is requesting comments on its recognition of medical specialty boards. The NRC's procedures for recognizing medical specialty boards are located on the Medical Uses Licensee Toolkit Web site (<https://www.nrc.gov/materials/miau/med-use-toolkit/certif-process-boards.html>). The NRC staff periodically reviews information to determine a board's continued eligibility for recognition.

- 1. What boards other than those already recognized by the NRC (American Board of Nuclear Medicine [ABNM], American Board of Radiology [ABR], American Osteopathic Board of Radiology [AOBR], Certification Board of Nuclear Endocrinology [CBNE]) could be considered for recognition for medical uses under 10 CFR 35.300?
- 2. Are the current NRC medical specialty board recognition criteria sufficient? If not, what additional criteria should the NRC use?

C. Patient Access

The NRC is requesting comments on whether there is a shortage in the number of AUs for 10 CFR 35.300.

1. Is there a shortage in the number of AUs for medical uses under 10 CFR 35.300? If so, is the shortage associated with the use of a specific radiopharmaceutical? Explain how.
2. Are there certain geographic areas with an inadequate number of AUs? Identify these areas.
3. Do current NRC regulations on AU T&E requirements unnecessarily limit patient access to procedures involving radiopharmaceuticals? Explain how.
4. Do current NRC regulations on AU T&E requirements unnecessarily limit research and development in nuclear medicine? Explain how.

D. Other Suggested Changes to the T&E Regulations

In 2002, the NRC revised its regulatory framework for medical use. The goal was to focus the NRC's regulations on those medical procedures that pose the highest risk to workers, the general public, patients, and human research subjects and to structure the regulations to be more risk-informed and more performance-based. The 2002 rule reduced the unnecessary regulatory burden by either reducing or eliminating the prescriptiveness of some regulations. Instead, the rule provided for a performance-based approach that relied on the training and experience of the AUs, authorized nuclear pharmacists, and radiation safety officers. The NRC is requesting comments on whether there are any other changes to the T&E regulations in 10 CFR part 35 that should be considered. Please discuss your suggested changes.

1. Should the NRC regulate the T&E of physicians for medical uses?
2. Are there requirements in the NRC's T&E regulatory framework for physicians that are non-safety related?

3. How can the NRC transform its regulatory approach for T&E while still ensuring that adequate protection is maintained for workers, the general public, patients, and human research subjects?

Dated at Rockville, Maryland, this 23rd day of October 2018.

For the Nuclear Regulatory
Commission.

/RA/

Daniel S. Collins, Director,
Division of Materials Safety,
Security,
State, and Tribal Programs,
Office of Nuclear Material Safety
and Safeguards.



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

November 2, 2018

Sarcoma Alliance
775 Blithedale Ave., #334
Mill Valley, CA 94941

Via e-mail to info@sarcomaalliance.org

SUBJECT: TRAINING AND EXPERIENCE REQUIREMENTS FOR DIFFERENT CATEGORIES OF RADIOPHARMACEUTICALS

Dear Sir or Madam,

The U.S. Nuclear Regulatory Commission (NRC) is evaluating its regulations related to the training and experience (T&E) required for a physician to become an authorized user for medical uses under Subpart E, “Unsealed Byproduct Material—Written Directive Required,” of [Title 10 of the Code of Federal Regulations \(10 CFR\) Part 35, “Medical Use of Byproduct Material.”](#)

The T&E requirements in Subpart E of 10 CFR Part 35 provide three ways that a physician can be authorized to administer unsealed byproduct materials or radiopharmaceuticals requiring a written directive:

1. A physician can be certified by a medical specialty board, whose certification process is recognized by the NRC or an Agreement State.
2. A physician can complete a structured educational program and supervised work experience under an alternate pathway. This alternate pathway includes a requirement for 700 hours of training and experience, which consists of a minimum of 200 hours of classroom and laboratory training and 500 hours of supervised work experience.
3. A physician can be authorized if previously identified as an authorized user on an NRC or Agreement State license or permit (i.e., grandfathered).

In its evaluation of the T&E requirements, the NRC staff is considering whether an additional pathway should be created or if the alternate pathway should be revised. Specifically, the staff is evaluating: (1) whether it makes sense to establish tailored T&E requirements for different categories of radiopharmaceuticals; (2) how those categories should be determined; (3) what the appropriate T&E requirements would be for each category; and (4) whether those requirements should be based on hours of training and experience, or focused more on competency.

On October 29, 2018, the NRC published a series of questions on T&E in the *Federal Register* (83 FR 54380). The *Federal Register* notice is enclosed with this letter and can also be accessed at: <https://www.gpo.gov/fdsys/pkg/FR-2018-10-29/pdf/2018-23521.pdf>. The NRC will carefully consider responses to these questions and would appreciate your feedback on whether changes to the current T&E regulations are warranted. The comment period for the T&E evaluation will end on January 29, 2019. Please follow the directions in the notice on how to submit written comments. The NRC is using the Federal rulemaking Web site, [Regulations.gov](#), to accept written comments on the docket (NRC-2018-0230).

The NRC will also conduct four public meetings scheduled for November 14 and December 11, 2018, and January 10 and January 22, 2019, and will accept oral comments provided during the meetings. The meetings on December 11 and January 10 will be held at NRC Headquarters in Rockville, MD, and all four meetings will be accessible for remote participation by moderated bridge line and webinar. The NRC's public meeting page has been updated with meeting details and registration instructions for each meeting: <https://www.nrc.gov/pmns/mtg>.

Additional information on the NRC's T&E evaluation can be found at: <https://www.nrc.gov/materials/miau/med-use-toolkit/training-experience-evaluation.html>. If you have any questions on this correspondence, please contact Sarah Lopas of my staff at (301) 415-6360 or Sarah.Lopas@nrc.gov.



Christian Einberg, Chief
Medical Safety and Events Assessment Branch
Division of Materials Safety, Security, State
and Tribal Programs
Office of Nuclear Material Safety
and Safeguards

Enclosure:
Training and Experience
Federal Register notice

NUCLEAR REGULATORY COMMISSION

[NRC-2018-0230]

**Training and Experience Requirements for Different Categories of
Radiopharmaceuticals**

AGENCY: Nuclear Regulatory Commission.

ACTION: Training and experience requirements; request for comment.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is requesting comments on its training and experience (T&E) requirements. Specifically, the NRC would like input on whether it should establish tailored T&E requirements for different categories of radiopharmaceuticals for which a written directive is required in accordance with its regulations. The input will be used to determine whether significant regulatory changes to the NRC's T&E requirements for authorized users (AUs) are warranted.

DATES: Submit comments by January 29, 2019. Comments received after this date will be considered if it is practical to do so, but the NRC is only able to ensure consideration for comments received on or before this date.

ADDRESSES: You may submit comments by any of the following methods:

- **Federal Rulemaking Web Site:** Go to <http://www.regulations.gov>

and search for Docket ID **NRC-2018-0230**. Address questions about Docket IDs in Regulations.gov to Jennifer Borges; telephone: 301-287-9127; e-mail: Jennifer.Borges@nrc.gov. For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.

- **Mail comments to:** May Ma, Office of Administration, Mail Stop: TWFN-7-A60M, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001.

For additional direction on obtaining information and submitting comments, see “Obtaining Information and Submitting Comments” in the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: Sarah Lopas, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001; telephone: 301-415-6360, e-mail: Sarah.Lopas@nrc.gov.

SUPPLEMENTARY INFORMATION:

I. Obtaining Information and Submitting Comments

A. Obtaining Information

Please refer to Docket ID **NRC-2018-0230** when contacting the NRC about the availability of information for this action. You may obtain publicly-available information related to this action by any of the following methods:

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- **NRC’s Agencywide Documents Access and Management System (ADAMS):** You may obtain publicly-available documents online in the ADAMS Public Documents collection at <http://www.nrc.gov/reading-rm/adams.html>. To begin the search, select “[Begin Web-based ADAMS Search](#).” For problems with ADAMS, please contact the NRC’s Public Document Room (PDR) reference staff at 1-800-397-4209, 301-415-4737, or by e-mail to pdr.resource@nrc.gov. The ADAMS accession number for each document referenced is provided the first time that it is mentioned in the **SUPPLEMENTARY INFORMATION** section.

- **NRC's PDR:** You may examine and purchase copies of public documents at the NRC's PDR, Room O1-F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.

B. Submitting Comments

Please include Docket ID **NRC-2018-0230** in your comment submission.

The NRC cautions you not to include identifying or contact information in comment submissions that you do not want to be publicly disclosed in your comment submission. All comment submissions are posted at <http://www.regulations.gov> and entered into ADAMS. Comment submissions are not routinely edited to remove identifying or contact information.

If you are requesting or aggregating comments from other persons for submission to the NRC, then you should inform those persons not to include identifying or contact information that they do not want to be publicly disclosed in their comment submission. Your request should state that the NRC does not routinely edit comment submissions to remove such information before making the comment submissions available to the public or entering the comment into ADAMS.

II. Background

On August 17, 2017, the Commission issued a staff requirements memorandum (SRM), SRM-M170817 (ADAMS Accession No. ML17229B284), approving the final rule revising parts 30, 32, and 35 of title 10 of the *Code of Federal Regulations* (10 CFR), "Medical Use of Byproduct Material – Medical Event Definitions, Training and Experience, and Clarifying Amendments," and directing the staff to evaluate (1) whether it makes sense to establish tailored T&E requirements for different categories of radiopharmaceuticals, (2) how those categories should be determined (such as by risks posed by groups of

radionuclides or by delivery method), (3) what the appropriate T&E requirements would be for each category, and (4) whether those requirements should be based on hours of T&E or focused more on competency. In response to the SRM, the NRC staff documented its initial results, status, and next steps related to this evaluation in SECY-18-0084, "Staff Evaluation of Training and Experience Requirements for Administering Different Categories of Radiopharmaceuticals in Response to SRM-M170817" (ADAMS Accession No. ML18135A276). In SECY-18-0084, the staff concluded that additional outreach with the medical community is needed to determine whether and how to tailor the T&E requirements to establish a limited AU status, the specific T&E requirements that should apply, how the T&E requirements should be met (e.g., hours of training, demonstration of competency), and whether a competency-based approach makes sense for the T&E requirements for all the medical uses authorized under 10 CFR 35.300, "Use of unsealed byproduct material for which a written directive is required."

The NRC is interested in obtaining input from as many stakeholders as possible, including members of the Advisory Committee on the Medical Uses of Isotopes, professional organizations, physicians, patients, patient advocacy groups, licensees, Agreement States, and other interested individuals. The focus of this request is to gather information that will permit the NRC staff to determine whether changes to the T&E requirements are warranted for different categories of radiopharmaceuticals for physicians seeking AU status for the medical use of specific categories of radiopharmaceuticals requiring a written directive under 10 CFR 35.300.

During the comment period between October 29, 2018 and January 29, 2019, the NRC will hold four public meetings that will discuss the information being requested and to accept comments on the docket. All four public meetings

will be available for remote participation by moderated bridge line and webinar, and two of the four meetings will be open for in-person attendance at NRC's headquarters in Rockville, Maryland.

The public meetings are scheduled for November 14, 2018 (webinar-only); December 11, 2018 (webinar and in-person attendance); January 10, 2019 (webinar and in-person attendance); and January 22, 2019 (webinar-only). The public meetings will be noticed on the NRC's public meeting Web site at least 10 calendar days before the meeting. Members of the public should monitor the NRC's public meeting Web site at <https://www.nrc.gov/pmns/mtg>. The NRC will also post the meeting notices on the Federal Rulemaking Web site at <https://www.regulations.gov/> under Docket ID **NRC-2018-0230**.

The NRC may post additional materials related to this document, including public comments, on the Federal Rulemaking Web site. The Federal Rulemaking Web site allows you to receive alerts when changes or additions occur in a docket folder. To subscribe: (1) Navigate to the docket folder **NRC-2018-0230**; (2) click the “Sign up for E-mail Alerts” link; and (3) enter your email address and select how frequently you would like to receive emails (daily, weekly, or monthly).

III. Specific Requests for Comments

A. Tailored Training & Experience Requirements

The NRC is requesting comments on whether it should establish tailored T&E requirements for different categories of radiopharmaceuticals for physicians seeking AU status for the medical use of specific categories of radiopharmaceuticals requiring a written directive under 10 CFR 35.300 (i.e., a limited AU status). This would be for physicians seeking AU status via the alternate non-board certified pathway, and for physicians certified by a medical

specialty board that is not currently recognized by the NRC under 10 CFR 35.390, 35.392, 35.394, or 35.396 (Unsealed Byproduct Material—Written Directive Required).

1. Are the current pathways for obtaining AU status reasonable and accessible? Provide a rationale for your answer.
2. Are the current pathways for obtaining AU status adequate for protecting public health and safety? Provide a rationale for your answer.
3. Should the NRC develop a new tailored T&E pathway for these physicians? If so, what would be the appropriate way to categorize radiopharmaceuticals for tailored T&E requirements? If not, explain why the regulations should remain unchanged. [Some options to categorize radiopharmaceuticals include radiopharmaceuticals with similar delivery methods (oral, parenteral); same type of radiation characteristics or emission (alpha, beta, gamma, low-energy photon); similar preparation method (patient-ready doses); or a combination thereof (e.g., radiopharmaceuticals containing alpha- and beta-emitting radioisotopes that are administered intravenously and are prepared as patient-ready doses).]
4. Should the fundamental T&E required of physicians seeking limited AU status need to have the same fundamental T&E required of physicians seeking full AU status for all oral and parenteral administrations under 10 CFR 35.300?
5. How should the requirements for this fundamental T&E be structured for a specific category of radiopharmaceuticals?
 - a. Describe what the requirements should include:

- i. Classroom and laboratory training – What topics need to be covered in this training requirement? How many hours of classroom and laboratory training should be required? Provide the basis for the number of hours. If not hours, explain how this training should be quantified. [Note: The topics currently required in the regulations to be included in the classroom and laboratory training and work experience are listed in 10 CFR 35.390, 35.392, 35.394, and 35.396.]
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 - iii. Competency - How should competency be evaluated? Should a written and/or practical examination by an independent examining committee be administered? Provide a rationale for your answer.
- b. Should a preceptor attestation be required for the fundamental T&E? Provide a rationale for your answer.
- c. Should the radiopharmaceutical manufacturer be able to provide the preceptor attestation? Provide a rational for your answer.

- d. Who should establish and administer the curriculum and examination? Provide specific group(s). [Some options are: NRC, medical specialty boards, medical professional societies, educational professional groups, and NRC in collaboration with any or more of the aforementioned groups.]
- e. Should AU competency be periodically assessed? If so, how should it be assessed, how often, and by whom?

B. NRC's Recognition of Medical Specialty Boards

The NRC is requesting comments on its recognition of medical specialty boards. The NRC's procedures for recognizing medical specialty boards are located on the Medical Uses Licensee Toolkit Web site (<https://www.nrc.gov/materials/miau/med-use-toolkit/certif-process-boards.html>). The NRC staff periodically reviews information to determine a board's continued eligibility for recognition.

- 1. What boards other than those already recognized by the NRC (American Board of Nuclear Medicine [ABNM], American Board of Radiology [ABR], American Osteopathic Board of Radiology [AOBR], Certification Board of Nuclear Endocrinology [CBNE]) could be considered for recognition for medical uses under 10 CFR 35.300?
- 2. Are the current NRC medical specialty board recognition criteria sufficient? If not, what additional criteria should the NRC use?

C. Patient Access

The NRC is requesting comments on whether there is a shortage in the number of AUs for 10 CFR 35.300.

1. Is there a shortage in the number of AUs for medical uses under 10 CFR 35.300? If so, is the shortage associated with the use of a specific radiopharmaceutical? Explain how.
2. Are there certain geographic areas with an inadequate number of AUs? Identify these areas.
3. Do current NRC regulations on AU T&E requirements unnecessarily limit patient access to procedures involving radiopharmaceuticals? Explain how.
4. Do current NRC regulations on AU T&E requirements unnecessarily limit research and development in nuclear medicine? Explain how.

D. Other Suggested Changes to the T&E Regulations

In 2002, the NRC revised its regulatory framework for medical use. The goal was to focus the NRC's regulations on those medical procedures that pose the highest risk to workers, the general public, patients, and human research subjects and to structure the regulations to be more risk-informed and more performance-based. The 2002 rule reduced the unnecessary regulatory burden by either reducing or eliminating the prescriptiveness of some regulations. Instead, the rule provided for a performance-based approach that relied on the training and experience of the AUs, authorized nuclear pharmacists, and radiation safety officers. The NRC is requesting comments on whether there are any other changes to the T&E regulations in 10 CFR part 35 that should be considered. Please discuss your suggested changes.

1. Should the NRC regulate the T&E of physicians for medical uses?
2. Are there requirements in the NRC's T&E regulatory framework for physicians that are non-safety related?

3. How can the NRC transform its regulatory approach for T&E while still ensuring that adequate protection is maintained for workers, the general public, patients, and human research subjects?

Dated at Rockville, Maryland, this 23rd day of October 2018.

For the Nuclear Regulatory
Commission.

/RA/

Daniel S. Collins, Director,
Division of Materials Safety,
Security,
State, and Tribal Programs,
Office of Nuclear Material Safety
and Safeguards.



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

November 2, 2018

Sarcoma Foundation of America
9899 Main St., Suite 204
Damascus, MD 20872

Via e-mail to info@curesarcoma.org

SUBJECT: TRAINING AND EXPERIENCE REQUIREMENTS FOR DIFFERENT CATEGORIES OF RADIOPHARMACEUTICALS

Dear Sir or Madam,

The U.S. Nuclear Regulatory Commission (NRC) is evaluating its regulations related to the training and experience (T&E) required for a physician to become an authorized user for medical uses under Subpart E, “Unsealed Byproduct Material—Written Directive Required,” of [Title 10 of the Code of Federal Regulations \(10 CFR\) Part 35, “Medical Use of Byproduct Material.”](#)

The T&E requirements in Subpart E of 10 CFR Part 35 provide three ways that a physician can be authorized to administer unsealed byproduct materials or radiopharmaceuticals requiring a written directive:

1. A physician can be certified by a medical specialty board, whose certification process is recognized by the NRC or an Agreement State.
2. A physician can complete a structured educational program and supervised work experience under an alternate pathway. This alternate pathway includes a requirement for 700 hours of training and experience, which consists of a minimum of 200 hours of classroom and laboratory training and 500 hours of supervised work experience.
3. A physician can be authorized if previously identified as an authorized user on an NRC or Agreement State license or permit (i.e., grandfathered).

In its evaluation of the T&E requirements, the NRC staff is considering whether an additional pathway should be created or if the alternate pathway should be revised. Specifically, the staff is evaluating: (1) whether it makes sense to establish tailored T&E requirements for different categories of radiopharmaceuticals; (2) how those categories should be determined; (3) what the appropriate T&E requirements would be for each category; and (4) whether those requirements should be based on hours of training and experience, or focused more on competency.

On October 29, 2018, the NRC published a series of questions on T&E in the *Federal Register* (83 FR 54380). The *Federal Register* notice is enclosed with this letter and can also be accessed at: <https://www.gpo.gov/fdsys/pkg/FR-2018-10-29/pdf/2018-23521.pdf>. The NRC will carefully consider responses to these questions and would appreciate your feedback on whether changes to the current T&E regulations are warranted. The comment period for the T&E evaluation will end on January 29, 2019. Please follow the directions in the notice on how to submit written comments. The NRC is using the Federal rulemaking Web site, [Regulations.gov](#), to accept written comments on the docket (NRC-2018-0230).

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Additional information on the NRC's T&E evaluation can be found at: <https://www.nrc.gov/materials/miau/med-use-toolkit/training-experience-evaluation.html>. If you have any questions on this correspondence, please contact Sarah Lopas of my staff at (301) 415-6360 or Sarah.Lopas@nrc.gov.

A handwritten signature in black ink, appearing to read "C Einberg".

Christian Einberg, Chief
Medical Safety and Events Assessment Branch
Division of Materials Safety, Security, State
and Tribal Programs
Office of Nuclear Material Safety
and Safeguards

Enclosure:
Training and Experience
Federal Register notice

NUCLEAR REGULATORY COMMISSION

[NRC-2018-0230]

**Training and Experience Requirements for Different Categories of
Radiopharmaceuticals**

AGENCY: Nuclear Regulatory Commission.

ACTION: Training and experience requirements; request for comment.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is requesting comments on its training and experience (T&E) requirements. Specifically, the NRC would like input on whether it should establish tailored T&E requirements for different categories of radiopharmaceuticals for which a written directive is required in accordance with its regulations. The input will be used to determine whether significant regulatory changes to the NRC's T&E requirements for authorized users (AUs) are warranted.

DATES: Submit comments by January 29, 2019. Comments received after this date will be considered if it is practical to do so, but the NRC is only able to ensure consideration for comments received on or before this date.

ADDRESSES: You may submit comments by any of the following methods:

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FOR FURTHER INFORMATION CONTACT: Sarah Lopas, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001; telephone: 301-415-6360, e-mail: Sarah.Lopas@nrc.gov.

SUPPLEMENTARY INFORMATION:

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B. Submitting Comments

Please include Docket ID **NRC-2018-0230** in your comment submission.

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radionuclides or by delivery method), (3) what the appropriate T&E requirements would be for each category, and (4) whether those requirements should be based on hours of T&E or focused more on competency. In response to the SRM, the NRC staff documented its initial results, status, and next steps related to this evaluation in SECY-18-0084, "Staff Evaluation of Training and Experience Requirements for Administering Different Categories of Radiopharmaceuticals in Response to SRM-M170817" (ADAMS Accession No. ML18135A276). In SECY-18-0084, the staff concluded that additional outreach with the medical community is needed to determine whether and how to tailor the T&E requirements to establish a limited AU status, the specific T&E requirements that should apply, how the T&E requirements should be met (e.g., hours of training, demonstration of competency), and whether a competency-based approach makes sense for the T&E requirements for all the medical uses authorized under 10 CFR 35.300, "Use of unsealed byproduct material for which a written directive is required."

The NRC is interested in obtaining input from as many stakeholders as possible, including members of the Advisory Committee on the Medical Uses of Isotopes, professional organizations, physicians, patients, patient advocacy groups, licensees, Agreement States, and other interested individuals. The focus of this request is to gather information that will permit the NRC staff to determine whether changes to the T&E requirements are warranted for different categories of radiopharmaceuticals for physicians seeking AU status for the medical use of specific categories of radiopharmaceuticals requiring a written directive under 10 CFR 35.300.

During the comment period between October 29, 2018 and January 29, 2019, the NRC will hold four public meetings that will discuss the information being requested and to accept comments on the docket. All four public meetings

will be available for remote participation by moderated bridge line and webinar, and two of the four meetings will be open for in-person attendance at NRC's headquarters in Rockville, Maryland.

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III. Specific Requests for Comments

A. Tailored Training & Experience Requirements

The NRC is requesting comments on whether it should establish tailored T&E requirements for different categories of radiopharmaceuticals for physicians seeking AU status for the medical use of specific categories of radiopharmaceuticals requiring a written directive under 10 CFR 35.300 (i.e., a limited AU status). This would be for physicians seeking AU status via the alternate non-board certified pathway, and for physicians certified by a medical

specialty board that is not currently recognized by the NRC under 10 CFR 35.390, 35.392, 35.394, or 35.396 (Unsealed Byproduct Material—Written Directive Required).

1. Are the current pathways for obtaining AU status reasonable and accessible? Provide a rationale for your answer.
2. Are the current pathways for obtaining AU status adequate for protecting public health and safety? Provide a rationale for your answer.
3. Should the NRC develop a new tailored T&E pathway for these physicians? If so, what would be the appropriate way to categorize radiopharmaceuticals for tailored T&E requirements? If not, explain why the regulations should remain unchanged. [Some options to categorize radiopharmaceuticals include radiopharmaceuticals with similar delivery methods (oral, parenteral); same type of radiation characteristics or emission (alpha, beta, gamma, low-energy photon); similar preparation method (patient-ready doses); or a combination thereof (e.g., radiopharmaceuticals containing alpha- and beta-emitting radioisotopes that are administered intravenously and are prepared as patient-ready doses).]
4. Should the fundamental T&E required of physicians seeking limited AU status need to have the same fundamental T&E required of physicians seeking full AU status for all oral and parenteral administrations under 10 CFR 35.300?
5. How should the requirements for this fundamental T&E be structured for a specific category of radiopharmaceuticals?
 - a. Describe what the requirements should include:

- i. Classroom and laboratory training – What topics need to be covered in this training requirement? How many hours of classroom and laboratory training should be required? Provide the basis for the number of hours. If not hours, explain how this training should be quantified. [Note: The topics currently required in the regulations to be included in the classroom and laboratory training and work experience are listed in 10 CFR 35.390, 35.392, 35.394, and 35.396.]
 - ii. Work experience - What should the work experience requirement involve? How many hours of work experience should be required and what is the minimum number of patient or human research subject administrations that an individual must perform? Provide the basis for the number of hours and administrations. What should be the qualifications of the supervising individual?
 - iii. Competency - How should competency be evaluated? Should a written and/or practical examination by an independent examining committee be administered? Provide a rationale for your answer.
- b. Should a preceptor attestation be required for the fundamental T&E? Provide a rationale for your answer.
- c. Should the radiopharmaceutical manufacturer be able to provide the preceptor attestation? Provide a rational for your answer.

- d. Who should establish and administer the curriculum and examination? Provide specific group(s). [Some options are: NRC, medical specialty boards, medical professional societies, educational professional groups, and NRC in collaboration with any or more of the aforementioned groups.]
- e. Should AU competency be periodically assessed? If so, how should it be assessed, how often, and by whom?

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The NRC is requesting comments on its recognition of medical specialty boards. The NRC's procedures for recognizing medical specialty boards are located on the Medical Uses Licensee Toolkit Web site (<https://www.nrc.gov/materials/miau/med-use-toolkit/certif-process-boards.html>). The NRC staff periodically reviews information to determine a board's continued eligibility for recognition.

- 1. What boards other than those already recognized by the NRC (American Board of Nuclear Medicine [ABNM], American Board of Radiology [ABR], American Osteopathic Board of Radiology [AOBR], Certification Board of Nuclear Endocrinology [CBNE]) could be considered for recognition for medical uses under 10 CFR 35.300?
- 2. Are the current NRC medical specialty board recognition criteria sufficient? If not, what additional criteria should the NRC use?

C. Patient Access

The NRC is requesting comments on whether there is a shortage in the number of AUs for 10 CFR 35.300.

1. Is there a shortage in the number of AUs for medical uses under 10 CFR 35.300? If so, is the shortage associated with the use of a specific radiopharmaceutical? Explain how.
2. Are there certain geographic areas with an inadequate number of AUs? Identify these areas.
3. Do current NRC regulations on AU T&E requirements unnecessarily limit patient access to procedures involving radiopharmaceuticals? Explain how.
4. Do current NRC regulations on AU T&E requirements unnecessarily limit research and development in nuclear medicine? Explain how.

D. Other Suggested Changes to the T&E Regulations

In 2002, the NRC revised its regulatory framework for medical use. The goal was to focus the NRC's regulations on those medical procedures that pose the highest risk to workers, the general public, patients, and human research subjects and to structure the regulations to be more risk-informed and more performance-based. The 2002 rule reduced the unnecessary regulatory burden by either reducing or eliminating the prescriptiveness of some regulations. Instead, the rule provided for a performance-based approach that relied on the training and experience of the AUs, authorized nuclear pharmacists, and radiation safety officers. The NRC is requesting comments on whether there are any other changes to the T&E regulations in 10 CFR part 35 that should be considered. Please discuss your suggested changes.

1. Should the NRC regulate the T&E of physicians for medical uses?
2. Are there requirements in the NRC's T&E regulatory framework for physicians that are non-safety related?

3. How can the NRC transform its regulatory approach for T&E while still ensuring that adequate protection is maintained for workers, the general public, patients, and human research subjects?

Dated at Rockville, Maryland, this 23rd day of October 2018.

For the Nuclear Regulatory
Commission.

/RA/

Daniel S. Collins, Director,
Division of Materials Safety,
Security,
State, and Tribal Programs,
Office of Nuclear Material Safety
and Safeguards.



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

November 2, 2018

Dr. Jennifer Scheler, MD
Assistant Professor of Radiology
Department of Radiology
University of Cincinnati Medical Center
234 Goodman St.
Cincinnati, OH 45219

Via e-mail to jennifer.scheler@uchealth.com

SUBJECT: TRAINING AND EXPERIENCE REQUIREMENTS FOR DIFFERENT CATEGORIES OF RADIOPHARMACEUTICALS

Dear Dr. Scheler,

The U.S. Nuclear Regulatory Commission (NRC) is evaluating its regulations related to the training and experience (T&E) required for a physician to become an authorized user for medical uses under Subpart E, “Unsealed Byproduct Material—Written Directive Required,” of [Title 10 of the Code of Federal Regulations \(10 CFR\) Part 35, “Medical Use of Byproduct Material.”](#)

The T&E requirements in Subpart E of 10 CFR Part 35 provide three ways that a physician can be authorized to administer unsealed byproduct materials or radiopharmaceuticals requiring a written directive:

1. A physician can be certified by a medical specialty board, whose certification process is recognized by the NRC or an Agreement State.
2. A physician can complete a structured educational program and supervised work experience under an alternate pathway. This alternate pathway includes a requirement for 700 hours of training and experience, which consists of a minimum of 200 hours of classroom and laboratory training and 500 hours of supervised work experience.
3. A physician can be authorized if previously identified as an authorized user on an NRC or Agreement State license or permit (i.e., grandfathered).

In its evaluation of the T&E requirements, the NRC staff is considering whether an additional pathway should be created or if the alternate pathway should be revised. Specifically, the staff is evaluating: (1) whether it makes sense to establish tailored T&E requirements for different categories of radiopharmaceuticals; (2) how those categories should be determined; (3) what the appropriate T&E requirements would be for each category; and (4) whether those requirements should be based on hours of training and experience, or focused more on competency.

On October 29, 2018, the NRC published a series of questions on T&E in the *Federal Register* (83 FR 54380). The *Federal Register* notice is enclosed with this letter and can also be accessed at: <https://www.gpo.gov/fdsys/pkg/FR-2018-10-29/pdf/2018-23521.pdf>. The NRC will carefully consider responses to these questions and would appreciate your feedback on whether changes to the current T&E regulations are warranted. The comment period for the T&E evaluation will end on January 29, 2019. Please follow the directions in the notice on how to submit written comments. The NRC is using the Federal rulemaking Web site, [Regulations.gov](#), to accept written comments on the docket (NRC-2018-0230).

The NRC will also conduct four public meetings scheduled for November 14 and December 11, 2018, and January 10 and January 22, 2019, and will accept oral comments provided during the meetings. The meetings on December 11 and January 10 will be held at NRC Headquarters in Rockville, MD, and all four meetings will be accessible for remote participation by moderated bridge line and webinar. The NRC's public meeting page has been updated with meeting details and registration instructions for each meeting: <https://www.nrc.gov/pmns/mtg>.

Additional information on the NRC's T&E evaluation can be found at: <https://www.nrc.gov/materials/miau/med-use-toolkit/training-experience-evaluation.html>. If you have any questions on this correspondence, please contact Sarah Lopas of my staff at (301) 415-6360 or Sarah.Lopas@nrc.gov.



Christian Einberg, Chief
Medical Safety and Events Assessment Branch
Division of Materials Safety, Security, State
and Tribal Programs
Office of Nuclear Material Safety
and Safeguards

Enclosure:
Training and Experience
Federal Register notice

NUCLEAR REGULATORY COMMISSION

[NRC-2018-0230]

**Training and Experience Requirements for Different Categories of
Radiopharmaceuticals**

AGENCY: Nuclear Regulatory Commission.

ACTION: Training and experience requirements; request for comment.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is requesting comments on its training and experience (T&E) requirements. Specifically, the NRC would like input on whether it should establish tailored T&E requirements for different categories of radiopharmaceuticals for which a written directive is required in accordance with its regulations. The input will be used to determine whether significant regulatory changes to the NRC's T&E requirements for authorized users (AUs) are warranted.

DATES: Submit comments by January 29, 2019. Comments received after this date will be considered if it is practical to do so, but the NRC is only able to ensure consideration for comments received on or before this date.

ADDRESSES: You may submit comments by any of the following methods:

- **Federal Rulemaking Web Site:** Go to <http://www.regulations.gov>

and search for Docket ID **NRC-2018-0230**. Address questions about Docket IDs in Regulations.gov to Jennifer Borges; telephone: 301-287-9127; e-mail: Jennifer.Borges@nrc.gov. For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.

- **Mail comments to:** May Ma, Office of Administration, Mail Stop: TWFN-7-A60M, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001.

For additional direction on obtaining information and submitting comments, see “Obtaining Information and Submitting Comments” in the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: Sarah Lopas, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001; telephone: 301-415-6360, e-mail: Sarah.Lopas@nrc.gov.

SUPPLEMENTARY INFORMATION:

I. Obtaining Information and Submitting Comments

A. Obtaining Information

Please refer to Docket ID **NRC-2018-0230** when contacting the NRC about the availability of information for this action. You may obtain publicly-available information related to this action by any of the following methods:

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- **NRC’s Agencywide Documents Access and Management System (ADAMS):** You may obtain publicly-available documents online in the ADAMS Public Documents collection at <http://www.nrc.gov/reading-rm/adams.html>. To begin the search, select “[Begin Web-based ADAMS Search](#).” For problems with ADAMS, please contact the NRC’s Public Document Room (PDR) reference staff at 1-800-397-4209, 301-415-4737, or by e-mail to pdr.resource@nrc.gov. The ADAMS accession number for each document referenced is provided the first time that it is mentioned in the **SUPPLEMENTARY INFORMATION** section.

- **NRC's PDR:** You may examine and purchase copies of public documents at the NRC's PDR, Room O1-F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.

B. Submitting Comments

Please include Docket ID **NRC-2018-0230** in your comment submission.

The NRC cautions you not to include identifying or contact information in comment submissions that you do not want to be publicly disclosed in your comment submission. All comment submissions are posted at <http://www.regulations.gov> and entered into ADAMS. Comment submissions are not routinely edited to remove identifying or contact information.

If you are requesting or aggregating comments from other persons for submission to the NRC, then you should inform those persons not to include identifying or contact information that they do not want to be publicly disclosed in their comment submission. Your request should state that the NRC does not routinely edit comment submissions to remove such information before making the comment submissions available to the public or entering the comment into ADAMS.

II. Background

On August 17, 2017, the Commission issued a staff requirements memorandum (SRM), SRM-M170817 (ADAMS Accession No. ML17229B284), approving the final rule revising parts 30, 32, and 35 of title 10 of the *Code of Federal Regulations* (10 CFR), "Medical Use of Byproduct Material – Medical Event Definitions, Training and Experience, and Clarifying Amendments," and directing the staff to evaluate (1) whether it makes sense to establish tailored T&E requirements for different categories of radiopharmaceuticals, (2) how those categories should be determined (such as by risks posed by groups of

radionuclides or by delivery method), (3) what the appropriate T&E requirements would be for each category, and (4) whether those requirements should be based on hours of T&E or focused more on competency. In response to the SRM, the NRC staff documented its initial results, status, and next steps related to this evaluation in SECY-18-0084, "Staff Evaluation of Training and Experience Requirements for Administering Different Categories of Radiopharmaceuticals in Response to SRM-M170817" (ADAMS Accession No. ML18135A276). In SECY-18-0084, the staff concluded that additional outreach with the medical community is needed to determine whether and how to tailor the T&E requirements to establish a limited AU status, the specific T&E requirements that should apply, how the T&E requirements should be met (e.g., hours of training, demonstration of competency), and whether a competency-based approach makes sense for the T&E requirements for all the medical uses authorized under 10 CFR 35.300, "Use of unsealed byproduct material for which a written directive is required."

The NRC is interested in obtaining input from as many stakeholders as possible, including members of the Advisory Committee on the Medical Uses of Isotopes, professional organizations, physicians, patients, patient advocacy groups, licensees, Agreement States, and other interested individuals. The focus of this request is to gather information that will permit the NRC staff to determine whether changes to the T&E requirements are warranted for different categories of radiopharmaceuticals for physicians seeking AU status for the medical use of specific categories of radiopharmaceuticals requiring a written directive under 10 CFR 35.300.

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specialty board that is not currently recognized by the NRC under 10 CFR 35.390, 35.392, 35.394, or 35.396 (Unsealed Byproduct Material—Written Directive Required).

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 - iii. Competency - How should competency be evaluated? Should a written and/or practical examination by an independent examining committee be administered? Provide a rationale for your answer.
- b. Should a preceptor attestation be required for the fundamental T&E? Provide a rationale for your answer.
- c. Should the radiopharmaceutical manufacturer be able to provide the preceptor attestation? Provide a rational for your answer.

- d. Who should establish and administer the curriculum and examination? Provide specific group(s). [Some options are: NRC, medical specialty boards, medical professional societies, educational professional groups, and NRC in collaboration with any or more of the aforementioned groups.]
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The NRC is requesting comments on its recognition of medical specialty boards. The NRC's procedures for recognizing medical specialty boards are located on the Medical Uses Licensee Toolkit Web site (<https://www.nrc.gov/materials/miau/med-use-toolkit/certif-process-boards.html>). The NRC staff periodically reviews information to determine a board's continued eligibility for recognition.

- 1. What boards other than those already recognized by the NRC (American Board of Nuclear Medicine [ABNM], American Board of Radiology [ABR], American Osteopathic Board of Radiology [AOBR], Certification Board of Nuclear Endocrinology [CBNE]) could be considered for recognition for medical uses under 10 CFR 35.300?
- 2. Are the current NRC medical specialty board recognition criteria sufficient? If not, what additional criteria should the NRC use?

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1. Is there a shortage in the number of AUs for medical uses under 10 CFR 35.300? If so, is the shortage associated with the use of a specific radiopharmaceutical? Explain how.
2. Are there certain geographic areas with an inadequate number of AUs? Identify these areas.
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1. Should the NRC regulate the T&E of physicians for medical uses?
2. Are there requirements in the NRC's T&E regulatory framework for physicians that are non-safety related?

3. How can the NRC transform its regulatory approach for T&E while still ensuring that adequate protection is maintained for workers, the general public, patients, and human research subjects?

Dated at Rockville, Maryland, this 23rd day of October 2018.

For the Nuclear Regulatory
Commission.

/RA/

Daniel S. Collins, Director,
Division of Materials Safety,
Security,
State, and Tribal Programs,
Office of Nuclear Material Safety
and Safeguards.



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

November 2, 2018

Dr. Scott R. Sechrist
Associate Professor, Medical Diagnostic & Translational Sciences
Old Dominion University
2128 Health Sciences Building
Norfolk, VA 23529

Via e-mail to ssechris@odu.edu

SUBJECT: TRAINING AND EXPERIENCE REQUIREMENTS FOR DIFFERENT CATEGORIES OF RADIOPHARMACEUTICALS

Dear Dr. Sechrist,

The U.S. Nuclear Regulatory Commission (NRC) is evaluating its regulations related to the training and experience (T&E) required for a physician to become an authorized user for medical uses under Subpart E, “Unsealed Byproduct Material—Written Directive Required,” of [Title 10 of the Code of Federal Regulations \(10 CFR\) Part 35, “Medical Use of Byproduct Material.”](#)

The T&E requirements in Subpart E of 10 CFR Part 35 provide three ways that a physician can be authorized to administer unsealed byproduct materials or radiopharmaceuticals requiring a written directive:

1. A physician can be certified by a medical specialty board, whose certification process is recognized by the NRC or an Agreement State.
2. A physician can complete a structured educational program and supervised work experience under an alternate pathway. This alternate pathway includes a requirement for 700 hours of training and experience, which consists of a minimum of 200 hours of classroom and laboratory training and 500 hours of supervised work experience.
3. A physician can be authorized if previously identified as an authorized user on an NRC or Agreement State license or permit (i.e., grandfathered).

In its evaluation of the T&E requirements, the NRC staff is considering whether an additional pathway should be created or if the alternate pathway should be revised. Specifically, the staff is evaluating: (1) whether it makes sense to establish tailored T&E requirements for different categories of radiopharmaceuticals; (2) how those categories should be determined; (3) what the appropriate T&E requirements would be for each category; and (4) whether those requirements should be based on hours of training and experience, or focused more on competency.

On October 29, 2018, the NRC published a series of questions on T&E in the *Federal Register* (83 FR 54380). The *Federal Register* notice is enclosed with this letter and can also be accessed at: <https://www.gpo.gov/fdsys/pkg/FR-2018-10-29/pdf/2018-23521.pdf>. The NRC will carefully consider responses to these questions and would appreciate your feedback on whether changes to the current T&E regulations are warranted. The comment period for the T&E evaluation will end on January 29, 2019. Please follow the directions in the notice on how to submit written comments. The NRC is using the Federal rulemaking Web site, [Regulations.gov](#), to accept written comments on the docket (NRC-2018-0230).

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Additional information on the NRC's T&E evaluation can be found at: <https://www.nrc.gov/materials/miau/med-use-toolkit/training-experience-evaluation.html>. If you have any questions on this correspondence, please contact Sarah Lopas of my staff at (301) 415-6360 or Sarah.Lopas@nrc.gov.

A handwritten signature in black ink, appearing to read "C Einberg".

Christian Einberg, Chief
Medical Safety and Events Assessment Branch
Division of Materials Safety, Security, State
and Tribal Programs
Office of Nuclear Material Safety
and Safeguards

Enclosure:
Training and Experience
Federal Register notice

NUCLEAR REGULATORY COMMISSION

[NRC-2018-0230]

**Training and Experience Requirements for Different Categories of
Radiopharmaceuticals**

AGENCY: Nuclear Regulatory Commission.

ACTION: Training and experience requirements; request for comment.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is requesting comments on its training and experience (T&E) requirements. Specifically, the NRC would like input on whether it should establish tailored T&E requirements for different categories of radiopharmaceuticals for which a written directive is required in accordance with its regulations. The input will be used to determine whether significant regulatory changes to the NRC's T&E requirements for authorized users (AUs) are warranted.

DATES: Submit comments by January 29, 2019. Comments received after this date will be considered if it is practical to do so, but the NRC is only able to ensure consideration for comments received on or before this date.

ADDRESSES: You may submit comments by any of the following methods:

- **Federal Rulemaking Web Site:** Go to <http://www.regulations.gov>

and search for Docket ID **NRC-2018-0230**. Address questions about Docket IDs in Regulations.gov to Jennifer Borges; telephone: 301-287-9127; e-mail: Jennifer.Borges@nrc.gov. For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.

- **Mail comments to:** May Ma, Office of Administration, Mail Stop: TWFN-7-A60M, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001.

For additional direction on obtaining information and submitting comments, see “Obtaining Information and Submitting Comments” in the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: Sarah Lopas, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001; telephone: 301-415-6360, e-mail: Sarah.Lopas@nrc.gov.

SUPPLEMENTARY INFORMATION:

I. Obtaining Information and Submitting Comments

A. Obtaining Information

Please refer to Docket ID **NRC-2018-0230** when contacting the NRC about the availability of information for this action. You may obtain publicly-available information related to this action by any of the following methods:

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radionuclides or by delivery method), (3) what the appropriate T&E requirements would be for each category, and (4) whether those requirements should be based on hours of T&E or focused more on competency. In response to the SRM, the NRC staff documented its initial results, status, and next steps related to this evaluation in SECY-18-0084, "Staff Evaluation of Training and Experience Requirements for Administering Different Categories of Radiopharmaceuticals in Response to SRM-M170817" (ADAMS Accession No. ML18135A276). In SECY-18-0084, the staff concluded that additional outreach with the medical community is needed to determine whether and how to tailor the T&E requirements to establish a limited AU status, the specific T&E requirements that should apply, how the T&E requirements should be met (e.g., hours of training, demonstration of competency), and whether a competency-based approach makes sense for the T&E requirements for all the medical uses authorized under 10 CFR 35.300, "Use of unsealed byproduct material for which a written directive is required."

The NRC is interested in obtaining input from as many stakeholders as possible, including members of the Advisory Committee on the Medical Uses of Isotopes, professional organizations, physicians, patients, patient advocacy groups, licensees, Agreement States, and other interested individuals. The focus of this request is to gather information that will permit the NRC staff to determine whether changes to the T&E requirements are warranted for different categories of radiopharmaceuticals for physicians seeking AU status for the medical use of specific categories of radiopharmaceuticals requiring a written directive under 10 CFR 35.300.

During the comment period between October 29, 2018 and January 29, 2019, the NRC will hold four public meetings that will discuss the information being requested and to accept comments on the docket. All four public meetings

will be available for remote participation by moderated bridge line and webinar, and two of the four meetings will be open for in-person attendance at NRC's headquarters in Rockville, Maryland.

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III. Specific Requests for Comments

A. Tailored Training & Experience Requirements

The NRC is requesting comments on whether it should establish tailored T&E requirements for different categories of radiopharmaceuticals for physicians seeking AU status for the medical use of specific categories of radiopharmaceuticals requiring a written directive under 10 CFR 35.300 (i.e., a limited AU status). This would be for physicians seeking AU status via the alternate non-board certified pathway, and for physicians certified by a medical

specialty board that is not currently recognized by the NRC under 10 CFR 35.390, 35.392, 35.394, or 35.396 (Unsealed Byproduct Material—Written Directive Required).

1. Are the current pathways for obtaining AU status reasonable and accessible? Provide a rationale for your answer.
2. Are the current pathways for obtaining AU status adequate for protecting public health and safety? Provide a rationale for your answer.
3. Should the NRC develop a new tailored T&E pathway for these physicians? If so, what would be the appropriate way to categorize radiopharmaceuticals for tailored T&E requirements? If not, explain why the regulations should remain unchanged. [Some options to categorize radiopharmaceuticals include radiopharmaceuticals with similar delivery methods (oral, parenteral); same type of radiation characteristics or emission (alpha, beta, gamma, low-energy photon); similar preparation method (patient-ready doses); or a combination thereof (e.g., radiopharmaceuticals containing alpha- and beta-emitting radioisotopes that are administered intravenously and are prepared as patient-ready doses).]
4. Should the fundamental T&E required of physicians seeking limited AU status need to have the same fundamental T&E required of physicians seeking full AU status for all oral and parenteral administrations under 10 CFR 35.300?
5. How should the requirements for this fundamental T&E be structured for a specific category of radiopharmaceuticals?
 - a. Describe what the requirements should include:

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 - iii. Competency - How should competency be evaluated? Should a written and/or practical examination by an independent examining committee be administered? Provide a rationale for your answer.
- b. Should a preceptor attestation be required for the fundamental T&E? Provide a rationale for your answer.
- c. Should the radiopharmaceutical manufacturer be able to provide the preceptor attestation? Provide a rational for your answer.

- d. Who should establish and administer the curriculum and examination? Provide specific group(s). [Some options are: NRC, medical specialty boards, medical professional societies, educational professional groups, and NRC in collaboration with any or more of the aforementioned groups.]
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The NRC is requesting comments on its recognition of medical specialty boards. The NRC's procedures for recognizing medical specialty boards are located on the Medical Uses Licensee Toolkit Web site (<https://www.nrc.gov/materials/miau/med-use-toolkit/certif-process-boards.html>). The NRC staff periodically reviews information to determine a board's continued eligibility for recognition.

- 1. What boards other than those already recognized by the NRC (American Board of Nuclear Medicine [ABNM], American Board of Radiology [ABR], American Osteopathic Board of Radiology [AOBR], Certification Board of Nuclear Endocrinology [CBNE]) could be considered for recognition for medical uses under 10 CFR 35.300?
- 2. Are the current NRC medical specialty board recognition criteria sufficient? If not, what additional criteria should the NRC use?

C. Patient Access

The NRC is requesting comments on whether there is a shortage in the number of AUs for 10 CFR 35.300.

1. Is there a shortage in the number of AUs for medical uses under 10 CFR 35.300? If so, is the shortage associated with the use of a specific radiopharmaceutical? Explain how.
2. Are there certain geographic areas with an inadequate number of AUs? Identify these areas.
3. Do current NRC regulations on AU T&E requirements unnecessarily limit patient access to procedures involving radiopharmaceuticals? Explain how.
4. Do current NRC regulations on AU T&E requirements unnecessarily limit research and development in nuclear medicine? Explain how.

D. Other Suggested Changes to the T&E Regulations

In 2002, the NRC revised its regulatory framework for medical use. The goal was to focus the NRC's regulations on those medical procedures that pose the highest risk to workers, the general public, patients, and human research subjects and to structure the regulations to be more risk-informed and more performance-based. The 2002 rule reduced the unnecessary regulatory burden by either reducing or eliminating the prescriptiveness of some regulations. Instead, the rule provided for a performance-based approach that relied on the training and experience of the AUs, authorized nuclear pharmacists, and radiation safety officers. The NRC is requesting comments on whether there are any other changes to the T&E regulations in 10 CFR part 35 that should be considered. Please discuss your suggested changes.

1. Should the NRC regulate the T&E of physicians for medical uses?
2. Are there requirements in the NRC's T&E regulatory framework for physicians that are non-safety related?

3. How can the NRC transform its regulatory approach for T&E while still ensuring that adequate protection is maintained for workers, the general public, patients, and human research subjects?

Dated at Rockville, Maryland, this 23rd day of October 2018.

For the Nuclear Regulatory
Commission.

/RA/

Daniel S. Collins, Director,
Division of Materials Safety,
Security,
State, and Tribal Programs,
Office of Nuclear Material Safety
and Safeguards.



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

November 2, 2018

Dr. George Sledge, Jr., MD
Chief Scientific Advisor
Susan G. Komen
5005 LBJ Freeway, Suite 526
Dallas, TX 75244

Via e-mail to mcarrasco84@stanford.edu

SUBJECT: TRAINING AND EXPERIENCE REQUIREMENTS FOR DIFFERENT CATEGORIES OF RADIOPHARMACEUTICALS

Dear Dr. Sledge,

The U.S. Nuclear Regulatory Commission (NRC) is evaluating its regulations related to the training and experience (T&E) required for a physician to become an authorized user for medical uses under Subpart E, “Unsealed Byproduct Material—Written Directive Required,” of [Title 10 of the Code of Federal Regulations \(10 CFR\) Part 35, “Medical Use of Byproduct Material.”](#)

The T&E requirements in Subpart E of 10 CFR Part 35 provide three ways that a physician can be authorized to administer unsealed byproduct materials or radiopharmaceuticals requiring a written directive:

1. A physician can be certified by a medical specialty board, whose certification process is recognized by the NRC or an Agreement State.
2. A physician can complete a structured educational program and supervised work experience under an alternate pathway. This alternate pathway includes a requirement for 700 hours of training and experience, which consists of a minimum of 200 hours of classroom and laboratory training and 500 hours of supervised work experience.
3. A physician can be authorized if previously identified as an authorized user on an NRC or Agreement State license or permit (i.e., grandfathered).

In its evaluation of the T&E requirements, the NRC staff is considering whether an additional pathway should be created or if the alternate pathway should be revised. Specifically, the staff is evaluating: (1) whether it makes sense to establish tailored T&E requirements for different categories of radiopharmaceuticals; (2) how those categories should be determined; (3) what the appropriate T&E requirements would be for each category; and (4) whether those requirements should be based on hours of training and experience, or focused more on competency.

On October 29, 2018, the NRC published a series of questions on T&E in the *Federal Register* (83 FR 54380). The *Federal Register* notice is enclosed with this letter and can also be accessed at: <https://www.gpo.gov/fdsys/pkg/FR-2018-10-29/pdf/2018-23521.pdf>. The NRC will carefully consider responses to these questions and would appreciate your feedback on whether changes to the current T&E regulations are warranted. The comment period for the T&E evaluation will end on January 29, 2019. Please follow the directions in the notice on how to submit written comments. The NRC is using the Federal rulemaking Web site, [Regulations.gov](#), to accept written comments on the docket (NRC-2018-0230).

The NRC will also conduct four public meetings scheduled for November 14 and December 11, 2018, and January 10 and January 22, 2019, and will accept oral comments provided during the meetings. The meetings on December 11 and January 10 will be held at NRC Headquarters in Rockville, MD, and all four meetings will be accessible for remote participation by moderated bridge line and webinar. The NRC's public meeting page has been updated with meeting details and registration instructions for each meeting: <https://www.nrc.gov/pmns/mtg>.

Additional information on the NRC's T&E evaluation can be found at: <https://www.nrc.gov/materials/miau/med-use-toolkit/training-experience-evaluation.html>. If you have any questions on this correspondence, please contact Sarah Lopas of my staff at (301) 415-6360 or Sarah.Lopas@nrc.gov.

A handwritten signature in black ink, appearing to read "C Einberg".

Christian Einberg, Chief
Medical Safety and Events Assessment Branch
Division of Materials Safety, Security, State
and Tribal Programs
Office of Nuclear Material Safety
and Safeguards

Enclosure:
Training and Experience
Federal Register notice

NUCLEAR REGULATORY COMMISSION

[NRC-2018-0230]

**Training and Experience Requirements for Different Categories of
Radiopharmaceuticals**

AGENCY: Nuclear Regulatory Commission.

ACTION: Training and experience requirements; request for comment.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is requesting comments on its training and experience (T&E) requirements. Specifically, the NRC would like input on whether it should establish tailored T&E requirements for different categories of radiopharmaceuticals for which a written directive is required in accordance with its regulations. The input will be used to determine whether significant regulatory changes to the NRC's T&E requirements for authorized users (AUs) are warranted.

DATES: Submit comments by January 29, 2019. Comments received after this date will be considered if it is practical to do so, but the NRC is only able to ensure consideration for comments received on or before this date.

ADDRESSES: You may submit comments by any of the following methods:

- **Federal Rulemaking Web Site:** Go to <http://www.regulations.gov>

and search for Docket ID **NRC-2018-0230**. Address questions about Docket IDs in Regulations.gov to Jennifer Borges; telephone: 301-287-9127; e-mail: Jennifer.Borges@nrc.gov. For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.

- **Mail comments to:** May Ma, Office of Administration, Mail Stop: TWFN-7-A60M, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001.

For additional direction on obtaining information and submitting comments, see “Obtaining Information and Submitting Comments” in the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: Sarah Lopas, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001; telephone: 301-415-6360, e-mail: Sarah.Lopas@nrc.gov.

SUPPLEMENTARY INFORMATION:

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- d. Who should establish and administer the curriculum and examination? Provide specific group(s). [Some options are: NRC, medical specialty boards, medical professional societies, educational professional groups, and NRC in collaboration with any or more of the aforementioned groups.]
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Dated at Rockville, Maryland, this 23rd day of October 2018.

For the Nuclear Regulatory
Commission.

/RA/

Daniel S. Collins, Director,
Division of Materials Safety,
Security,
State, and Tribal Programs,
Office of Nuclear Material Safety
and Safeguards.



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

November 2, 2018

Dr. T. Bryson Struse, DO
Chair, American Osteopathic Board of Nuclear Medicine
142 E. Ontario St., Fl. 4
Chicago, IL 60611

Via e-mail to aobnm@osteopathic.org

SUBJECT: TRAINING AND EXPERIENCE REQUIREMENTS FOR DIFFERENT CATEGORIES OF RADIOPHARMACEUTICALS

Dear Dr. Struse,

The U.S. Nuclear Regulatory Commission (NRC) is evaluating its regulations related to the training and experience (T&E) required for a physician to become an authorized user for medical uses under Subpart E, “Unsealed Byproduct Material—Written Directive Required,” of [Title 10 of the Code of Federal Regulations \(10 CFR\) Part 35, “Medical Use of Byproduct Material.”](#)

The T&E requirements in Subpart E of 10 CFR Part 35 provide three ways that a physician can be authorized to administer unsealed byproduct materials or radiopharmaceuticals requiring a written directive:

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Additional information on the NRC's T&E evaluation can be found at: <https://www.nrc.gov/materials/miau/med-use-toolkit/training-experience-evaluation.html>. If you have any questions on this correspondence, please contact Sarah Lopas of my staff at (301) 415-6360 or Sarah.Lopas@nrc.gov.

A handwritten signature in black ink, appearing to read "C Einberg".

Christian Einberg, Chief
Medical Safety and Events Assessment Branch
Division of Materials Safety, Security, State
and Tribal Programs
Office of Nuclear Material Safety
and Safeguards

Enclosure:
Training and Experience
Federal Register notice

NUCLEAR REGULATORY COMMISSION

[NRC-2018-0230]

**Training and Experience Requirements for Different Categories of
Radiopharmaceuticals**

AGENCY: Nuclear Regulatory Commission.

ACTION: Training and experience requirements; request for comment.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is requesting comments on its training and experience (T&E) requirements. Specifically, the NRC would like input on whether it should establish tailored T&E requirements for different categories of radiopharmaceuticals for which a written directive is required in accordance with its regulations. The input will be used to determine whether significant regulatory changes to the NRC's T&E requirements for authorized users (AUs) are warranted.

DATES: Submit comments by January 29, 2019. Comments received after this date will be considered if it is practical to do so, but the NRC is only able to ensure consideration for comments received on or before this date.

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and search for Docket ID **NRC-2018-0230**. Address questions about Docket IDs in Regulations.gov to Jennifer Borges; telephone: 301-287-9127; e-mail: Jennifer.Borges@nrc.gov. For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.

- **Mail comments to:** May Ma, Office of Administration, Mail Stop: TWFN-7-A60M, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001.

For additional direction on obtaining information and submitting comments, see “Obtaining Information and Submitting Comments” in the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: Sarah Lopas, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001; telephone: 301-415-6360, e-mail: Sarah.Lopas@nrc.gov.

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radionuclides or by delivery method), (3) what the appropriate T&E requirements would be for each category, and (4) whether those requirements should be based on hours of T&E or focused more on competency. In response to the SRM, the NRC staff documented its initial results, status, and next steps related to this evaluation in SECY-18-0084, "Staff Evaluation of Training and Experience Requirements for Administering Different Categories of Radiopharmaceuticals in Response to SRM-M170817" (ADAMS Accession No. ML18135A276). In SECY-18-0084, the staff concluded that additional outreach with the medical community is needed to determine whether and how to tailor the T&E requirements to establish a limited AU status, the specific T&E requirements that should apply, how the T&E requirements should be met (e.g., hours of training, demonstration of competency), and whether a competency-based approach makes sense for the T&E requirements for all the medical uses authorized under 10 CFR 35.300, "Use of unsealed byproduct material for which a written directive is required."

The NRC is interested in obtaining input from as many stakeholders as possible, including members of the Advisory Committee on the Medical Uses of Isotopes, professional organizations, physicians, patients, patient advocacy groups, licensees, Agreement States, and other interested individuals. The focus of this request is to gather information that will permit the NRC staff to determine whether changes to the T&E requirements are warranted for different categories of radiopharmaceuticals for physicians seeking AU status for the medical use of specific categories of radiopharmaceuticals requiring a written directive under 10 CFR 35.300.

During the comment period between October 29, 2018 and January 29, 2019, the NRC will hold four public meetings that will discuss the information being requested and to accept comments on the docket. All four public meetings

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III. Specific Requests for Comments

A. Tailored Training & Experience Requirements

The NRC is requesting comments on whether it should establish tailored T&E requirements for different categories of radiopharmaceuticals for physicians seeking AU status for the medical use of specific categories of radiopharmaceuticals requiring a written directive under 10 CFR 35.300 (i.e., a limited AU status). This would be for physicians seeking AU status via the alternate non-board certified pathway, and for physicians certified by a medical

specialty board that is not currently recognized by the NRC under 10 CFR 35.390, 35.392, 35.394, or 35.396 (Unsealed Byproduct Material—Written Directive Required).

1. Are the current pathways for obtaining AU status reasonable and accessible? Provide a rationale for your answer.
2. Are the current pathways for obtaining AU status adequate for protecting public health and safety? Provide a rationale for your answer.
3. Should the NRC develop a new tailored T&E pathway for these physicians? If so, what would be the appropriate way to categorize radiopharmaceuticals for tailored T&E requirements? If not, explain why the regulations should remain unchanged. [Some options to categorize radiopharmaceuticals include radiopharmaceuticals with similar delivery methods (oral, parenteral); same type of radiation characteristics or emission (alpha, beta, gamma, low-energy photon); similar preparation method (patient-ready doses); or a combination thereof (e.g., radiopharmaceuticals containing alpha- and beta-emitting radioisotopes that are administered intravenously and are prepared as patient-ready doses).]
4. Should the fundamental T&E required of physicians seeking limited AU status need to have the same fundamental T&E required of physicians seeking full AU status for all oral and parenteral administrations under 10 CFR 35.300?
5. How should the requirements for this fundamental T&E be structured for a specific category of radiopharmaceuticals?
 - a. Describe what the requirements should include:

- i. Classroom and laboratory training – What topics need to be covered in this training requirement? How many hours of classroom and laboratory training should be required? Provide the basis for the number of hours. If not hours, explain how this training should be quantified. [Note: The topics currently required in the regulations to be included in the classroom and laboratory training and work experience are listed in 10 CFR 35.390, 35.392, 35.394, and 35.396.]
 - ii. Work experience - What should the work experience requirement involve? How many hours of work experience should be required and what is the minimum number of patient or human research subject administrations that an individual must perform? Provide the basis for the number of hours and administrations. What should be the qualifications of the supervising individual?
 - iii. Competency - How should competency be evaluated? Should a written and/or practical examination by an independent examining committee be administered? Provide a rationale for your answer.
- b. Should a preceptor attestation be required for the fundamental T&E? Provide a rationale for your answer.
- c. Should the radiopharmaceutical manufacturer be able to provide the preceptor attestation? Provide a rational for your answer.

- d. Who should establish and administer the curriculum and examination? Provide specific group(s). [Some options are: NRC, medical specialty boards, medical professional societies, educational professional groups, and NRC in collaboration with any or more of the aforementioned groups.]
- e. Should AU competency be periodically assessed? If so, how should it be assessed, how often, and by whom?

B. NRC's Recognition of Medical Specialty Boards

The NRC is requesting comments on its recognition of medical specialty boards. The NRC's procedures for recognizing medical specialty boards are located on the Medical Uses Licensee Toolkit Web site (<https://www.nrc.gov/materials/miau/med-use-toolkit/certif-process-boards.html>). The NRC staff periodically reviews information to determine a board's continued eligibility for recognition.

- 1. What boards other than those already recognized by the NRC (American Board of Nuclear Medicine [ABNM], American Board of Radiology [ABR], American Osteopathic Board of Radiology [AOBR], Certification Board of Nuclear Endocrinology [CBNE]) could be considered for recognition for medical uses under 10 CFR 35.300?
- 2. Are the current NRC medical specialty board recognition criteria sufficient? If not, what additional criteria should the NRC use?

C. Patient Access

The NRC is requesting comments on whether there is a shortage in the number of AUs for 10 CFR 35.300.

1. Is there a shortage in the number of AUs for medical uses under 10 CFR 35.300? If so, is the shortage associated with the use of a specific radiopharmaceutical? Explain how.
2. Are there certain geographic areas with an inadequate number of AUs? Identify these areas.
3. Do current NRC regulations on AU T&E requirements unnecessarily limit patient access to procedures involving radiopharmaceuticals? Explain how.
4. Do current NRC regulations on AU T&E requirements unnecessarily limit research and development in nuclear medicine? Explain how.

D. Other Suggested Changes to the T&E Regulations

In 2002, the NRC revised its regulatory framework for medical use. The goal was to focus the NRC's regulations on those medical procedures that pose the highest risk to workers, the general public, patients, and human research subjects and to structure the regulations to be more risk-informed and more performance-based. The 2002 rule reduced the unnecessary regulatory burden by either reducing or eliminating the prescriptiveness of some regulations. Instead, the rule provided for a performance-based approach that relied on the training and experience of the AUs, authorized nuclear pharmacists, and radiation safety officers. The NRC is requesting comments on whether there are any other changes to the T&E regulations in 10 CFR part 35 that should be considered. Please discuss your suggested changes.

1. Should the NRC regulate the T&E of physicians for medical uses?
2. Are there requirements in the NRC's T&E regulatory framework for physicians that are non-safety related?

3. How can the NRC transform its regulatory approach for T&E while still ensuring that adequate protection is maintained for workers, the general public, patients, and human research subjects?

Dated at Rockville, Maryland, this 23rd day of October 2018.

For the Nuclear Regulatory
Commission.

/RA/

Daniel S. Collins, Director,
Division of Materials Safety,
Security,
State, and Tribal Programs,
Office of Nuclear Material Safety
and Safeguards.



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

November 2, 2018

Ms. Leah Eshraghi
Dr. Susan Love Research Foundation
16133 Ventura Boulevard
Suite 1000
Encino, CA 91436

Via e-mail to info@DrSusanLoveResearch.org

SUBJECT: TRAINING AND EXPERIENCE REQUIREMENTS FOR DIFFERENT CATEGORIES OF RADIOPHARMACEUTICALS

Dear Ms. Eshraghi,

The U.S. Nuclear Regulatory Commission (NRC) is evaluating its regulations related to the training and experience (T&E) required for a physician to become an authorized user for medical uses under Subpart E, “Unsealed Byproduct Material—Written Directive Required,” of [Title 10 of the Code of Federal Regulations \(10 CFR\) Part 35, “Medical Use of Byproduct Material.”](#)

The T&E requirements in Subpart E of 10 CFR Part 35 provide three ways that a physician can be authorized to administer unsealed byproduct materials or radiopharmaceuticals requiring a written directive:

1. A physician can be certified by a medical specialty board, whose certification process is recognized by the NRC or an Agreement State.
2. A physician can complete a structured educational program and supervised work experience under an alternate pathway. This alternate pathway includes a requirement for 700 hours of training and experience, which consists of a minimum of 200 hours of classroom and laboratory training and 500 hours of supervised work experience.
3. A physician can be authorized if previously identified as an authorized user on an NRC or Agreement State license or permit (i.e., grandfathered).

In its evaluation of the T&E requirements, the NRC staff is considering whether an additional pathway should be created or if the alternate pathway should be revised. Specifically, the staff is evaluating: (1) whether it makes sense to establish tailored T&E requirements for different categories of radiopharmaceuticals; (2) how those categories should be determined; (3) what the appropriate T&E requirements would be for each category; and (4) whether those requirements should be based on hours of training and experience, or focused more on competency.

On October 29, 2018, the NRC published a series of questions on T&E in the *Federal Register* (83 FR 54380). The *Federal Register* notice is enclosed with this letter and can also be accessed at: <https://www.gpo.gov/fdsys/pkg/FR-2018-10-29/pdf/2018-23521.pdf>. The NRC will carefully consider responses to these questions and would appreciate your feedback on whether changes to the current T&E regulations are warranted. The comment period for the T&E evaluation will end on January 29, 2019. Please follow the directions in the notice on how to submit written comments. The NRC is using the Federal rulemaking Web site, [Regulations.gov](#), to accept written comments on the docket (NRC-2018-0230).

The NRC will also conduct four public meetings scheduled for November 14 and December 11, 2018, and January 10 and January 22, 2019, and will accept oral comments provided during the meetings. The meetings on December 11 and January 10 will be held at NRC Headquarters in Rockville, MD, and all four meetings will be accessible for remote participation by moderated bridge line and webinar. The NRC's public meeting page has been updated with meeting details and registration instructions for each meeting: <https://www.nrc.gov/pmns/mtg>.

Additional information on the NRC's T&E evaluation can be found at: <https://www.nrc.gov/materials/miau/med-use-toolkit/training-experience-evaluation.html>. If you have any questions on this correspondence, please contact Sarah Lopas of my staff at (301) 415-6360 or Sarah.Lopas@nrc.gov.

A handwritten signature in black ink, appearing to read "C Einberg".

Christian Einberg, Chief
Medical Safety and Events Assessment Branch
Division of Materials Safety, Security, State
and Tribal Programs
Office of Nuclear Material Safety
and Safeguards

Enclosure:
Training and Experience
Federal Register notice

NUCLEAR REGULATORY COMMISSION

[NRC-2018-0230]

**Training and Experience Requirements for Different Categories of
Radiopharmaceuticals**

AGENCY: Nuclear Regulatory Commission.

ACTION: Training and experience requirements; request for comment.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is requesting comments on its training and experience (T&E) requirements. Specifically, the NRC would like input on whether it should establish tailored T&E requirements for different categories of radiopharmaceuticals for which a written directive is required in accordance with its regulations. The input will be used to determine whether significant regulatory changes to the NRC's T&E requirements for authorized users (AUs) are warranted.

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Dated at Rockville, Maryland, this 23rd day of October 2018.

For the Nuclear Regulatory
Commission.

/RA/

Daniel S. Collins, Director,
Division of Materials Safety,
Security,
State, and Tribal Programs,
Office of Nuclear Material Safety
and Safeguards.



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

November 2, 2018

Thyroid Cancer Survivors' Association, Inc.
P.O. Box 1102
Olney, MD 20830-1102

Via e-mail to thyca@thyca.org

SUBJECT: TRAINING AND EXPERIENCE REQUIREMENTS FOR DIFFERENT CATEGORIES OF RADIOPHARMACEUTICALS

Dear Sir or Madam,

The U.S. Nuclear Regulatory Commission (NRC) is evaluating its regulations related to the training and experience (T&E) required for a physician to become an authorized user for medical uses under Subpart E, "Unsealed Byproduct Material—Written Directive Required," of [Title 10 of the Code of Federal Regulations \(10 CFR\) Part 35, "Medical Use of Byproduct Material."](#)

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3. A physician can be authorized if previously identified as an authorized user on an NRC or Agreement State license or permit (i.e., grandfathered).

In its evaluation of the T&E requirements, the NRC staff is considering whether an additional pathway should be created or if the alternate pathway should be revised. Specifically, the staff is evaluating: (1) whether it makes sense to establish tailored T&E requirements for different categories of radiopharmaceuticals; (2) how those categories should be determined; (3) what the appropriate T&E requirements would be for each category; and (4) whether those requirements should be based on hours of training and experience, or focused more on competency.

On October 29, 2018, the NRC published a series of questions on T&E in the *Federal Register* (83 FR 54380). The *Federal Register* notice is enclosed with this letter and can also be accessed at: <https://www.gpo.gov/fdsys/pkg/FR-2018-10-29/pdf/2018-23521.pdf>. The NRC will carefully consider responses to these questions and would appreciate your feedback on whether changes to the current T&E regulations are warranted. The comment period for the T&E evaluation will end on January 29, 2019. Please follow the directions in the notice on how to submit written comments. The NRC is using the Federal rulemaking Web site, [Regulations.gov](#), to accept written comments on the docket (NRC-2018-0230).

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Additional information on the NRC's T&E evaluation can be found at: <https://www.nrc.gov/materials/miau/med-use-toolkit/training-experience-evaluation.html>. If you have any questions on this correspondence, please contact Sarah Lopas of my staff at (301) 415-6360 or Sarah.Lopas@nrc.gov.



Christian Einberg, Chief
Medical Safety and Events Assessment Branch
Division of Materials Safety, Security, State
and Tribal Programs
Office of Nuclear Material Safety
and Safeguards

Enclosure:
Training and Experience
Federal Register notice

NUCLEAR REGULATORY COMMISSION

[NRC-2018-0230]

**Training and Experience Requirements for Different Categories of
Radiopharmaceuticals**

AGENCY: Nuclear Regulatory Commission.

ACTION: Training and experience requirements; request for comment.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is requesting comments on its training and experience (T&E) requirements. Specifically, the NRC would like input on whether it should establish tailored T&E requirements for different categories of radiopharmaceuticals for which a written directive is required in accordance with its regulations. The input will be used to determine whether significant regulatory changes to the NRC's T&E requirements for authorized users (AUs) are warranted.

DATES: Submit comments by January 29, 2019. Comments received after this date will be considered if it is practical to do so, but the NRC is only able to ensure consideration for comments received on or before this date.

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The NRC is interested in obtaining input from as many stakeholders as possible, including members of the Advisory Committee on the Medical Uses of Isotopes, professional organizations, physicians, patients, patient advocacy groups, licensees, Agreement States, and other interested individuals. The focus of this request is to gather information that will permit the NRC staff to determine whether changes to the T&E requirements are warranted for different categories of radiopharmaceuticals for physicians seeking AU status for the medical use of specific categories of radiopharmaceuticals requiring a written directive under 10 CFR 35.300.

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III. Specific Requests for Comments

A. Tailored Training & Experience Requirements

The NRC is requesting comments on whether it should establish tailored T&E requirements for different categories of radiopharmaceuticals for physicians seeking AU status for the medical use of specific categories of radiopharmaceuticals requiring a written directive under 10 CFR 35.300 (i.e., a limited AU status). This would be for physicians seeking AU status via the alternate non-board certified pathway, and for physicians certified by a medical

specialty board that is not currently recognized by the NRC under 10 CFR 35.390, 35.392, 35.394, or 35.396 (Unsealed Byproduct Material—Written Directive Required).

1. Are the current pathways for obtaining AU status reasonable and accessible? Provide a rationale for your answer.
2. Are the current pathways for obtaining AU status adequate for protecting public health and safety? Provide a rationale for your answer.
3. Should the NRC develop a new tailored T&E pathway for these physicians? If so, what would be the appropriate way to categorize radiopharmaceuticals for tailored T&E requirements? If not, explain why the regulations should remain unchanged. [Some options to categorize radiopharmaceuticals include radiopharmaceuticals with similar delivery methods (oral, parenteral); same type of radiation characteristics or emission (alpha, beta, gamma, low-energy photon); similar preparation method (patient-ready doses); or a combination thereof (e.g., radiopharmaceuticals containing alpha- and beta-emitting radioisotopes that are administered intravenously and are prepared as patient-ready doses).]
4. Should the fundamental T&E required of physicians seeking limited AU status need to have the same fundamental T&E required of physicians seeking full AU status for all oral and parenteral administrations under 10 CFR 35.300?
5. How should the requirements for this fundamental T&E be structured for a specific category of radiopharmaceuticals?
 - a. Describe what the requirements should include:

- i. Classroom and laboratory training – What topics need to be covered in this training requirement? How many hours of classroom and laboratory training should be required? Provide the basis for the number of hours. If not hours, explain how this training should be quantified. [Note: The topics currently required in the regulations to be included in the classroom and laboratory training and work experience are listed in 10 CFR 35.390, 35.392, 35.394, and 35.396.]
 - ii. Work experience - What should the work experience requirement involve? How many hours of work experience should be required and what is the minimum number of patient or human research subject administrations that an individual must perform? Provide the basis for the number of hours and administrations. What should be the qualifications of the supervising individual?
 - iii. Competency - How should competency be evaluated? Should a written and/or practical examination by an independent examining committee be administered? Provide a rationale for your answer.
- b. Should a preceptor attestation be required for the fundamental T&E? Provide a rationale for your answer.
- c. Should the radiopharmaceutical manufacturer be able to provide the preceptor attestation? Provide a rational for your answer.

- d. Who should establish and administer the curriculum and examination? Provide specific group(s). [Some options are: NRC, medical specialty boards, medical professional societies, educational professional groups, and NRC in collaboration with any or more of the aforementioned groups.]
- e. Should AU competency be periodically assessed? If so, how should it be assessed, how often, and by whom?

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The NRC is requesting comments on its recognition of medical specialty boards. The NRC's procedures for recognizing medical specialty boards are located on the Medical Uses Licensee Toolkit Web site (<https://www.nrc.gov/materials/miau/med-use-toolkit/certif-process-boards.html>). The NRC staff periodically reviews information to determine a board's continued eligibility for recognition.

- 1. What boards other than those already recognized by the NRC (American Board of Nuclear Medicine [ABNM], American Board of Radiology [ABR], American Osteopathic Board of Radiology [AOBR], Certification Board of Nuclear Endocrinology [CBNE]) could be considered for recognition for medical uses under 10 CFR 35.300?
- 2. Are the current NRC medical specialty board recognition criteria sufficient? If not, what additional criteria should the NRC use?

C. Patient Access

The NRC is requesting comments on whether there is a shortage in the number of AUs for 10 CFR 35.300.

1. Is there a shortage in the number of AUs for medical uses under 10 CFR 35.300? If so, is the shortage associated with the use of a specific radiopharmaceutical? Explain how.
2. Are there certain geographic areas with an inadequate number of AUs? Identify these areas.
3. Do current NRC regulations on AU T&E requirements unnecessarily limit patient access to procedures involving radiopharmaceuticals? Explain how.
4. Do current NRC regulations on AU T&E requirements unnecessarily limit research and development in nuclear medicine? Explain how.

D. Other Suggested Changes to the T&E Regulations

In 2002, the NRC revised its regulatory framework for medical use. The goal was to focus the NRC's regulations on those medical procedures that pose the highest risk to workers, the general public, patients, and human research subjects and to structure the regulations to be more risk-informed and more performance-based. The 2002 rule reduced the unnecessary regulatory burden by either reducing or eliminating the prescriptiveness of some regulations. Instead, the rule provided for a performance-based approach that relied on the training and experience of the AUs, authorized nuclear pharmacists, and radiation safety officers. The NRC is requesting comments on whether there are any other changes to the T&E regulations in 10 CFR part 35 that should be considered. Please discuss your suggested changes.

1. Should the NRC regulate the T&E of physicians for medical uses?
2. Are there requirements in the NRC's T&E regulatory framework for physicians that are non-safety related?

3. How can the NRC transform its regulatory approach for T&E while still ensuring that adequate protection is maintained for workers, the general public, patients, and human research subjects?

Dated at Rockville, Maryland, this 23rd day of October 2018.

For the Nuclear Regulatory
Commission.

/RA/

Daniel S. Collins, Director,
Division of Materials Safety,
Security,
State, and Tribal Programs,
Office of Nuclear Material Safety
and Safeguards.



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

November 2, 2018

Dr. Timothy Stenzel
Director, Office of In Vitro Diagnostics
and Radiological Health
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Via e-mail to Timothy.Stenzel@fda.hhs.gov

SUBJECT: TRAINING AND EXPERIENCE REQUIREMENTS FOR DIFFERENT CATEGORIES OF RADIOPHARMACEUTICALS

Dear Dr. Stenzel,

The U.S. Nuclear Regulatory Commission (NRC) is evaluating its regulations related to the training and experience (T&E) required for a physician to become an authorized user for medical uses under Subpart E, “Unsealed Byproduct Material—Written Directive Required,” of [Title 10 of the Code of Federal Regulations \(10 CFR\) Part 35, “Medical Use of Byproduct Material.”](#)

The T&E requirements in Subpart E of 10 CFR Part 35 provide three ways that a physician can be authorized to administer unsealed byproduct materials or radiopharmaceuticals requiring a written directive:

1. A physician can be certified by a medical specialty board, whose certification process is recognized by the NRC or an Agreement State.
2. A physician can complete a structured educational program and supervised work experience under an alternate pathway. This alternate pathway includes a requirement for 700 hours of training and experience, which consists of a minimum of 200 hours of classroom and laboratory training and 500 hours of supervised work experience.
3. A physician can be authorized if previously identified as an authorized user on an NRC or Agreement State license or permit (i.e., grandfathered).

In its evaluation of the T&E requirements, the NRC staff is considering whether an additional pathway should be created or if the alternate pathway should be revised. Specifically, the staff is evaluating: (1) whether it makes sense to establish tailored T&E requirements for different categories of radiopharmaceuticals; (2) how those categories should be determined; (3) what the appropriate T&E requirements would be for each category; and (4) whether those requirements should be based on hours of training and experience, or focused more on competency.

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Christian Einberg, 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:
Training and Experience
Federal Register notice

NUCLEAR REGULATORY COMMISSION

[NRC-2018-0230]

**Training and Experience Requirements for Different Categories of
Radiopharmaceuticals**

AGENCY: Nuclear Regulatory Commission.

ACTION: Training and experience requirements; request for comment.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is requesting comments on its training and experience (T&E) requirements. Specifically, the NRC would like input on whether it should establish tailored T&E requirements for different categories of radiopharmaceuticals for which a written directive is required in accordance with its regulations. The input will be used to determine whether significant regulatory changes to the NRC's T&E requirements for authorized users (AUs) are warranted.

DATES: Submit comments by January 29, 2019. Comments received after this date will be considered if it is practical to do so, but the NRC is only able to ensure consideration for comments received on or before this date.

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Dated at Rockville, Maryland, this 23rd day of October 2018.

For the Nuclear Regulatory
Commission.

/RA/

Daniel S. Collins, Director,
Division of Materials Safety,
Security,
State, and Tribal Programs,
Office of Nuclear Material Safety
and Safeguards.



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

November 2, 2018

Ms. Tomi Papanikolaou
Executive Director, American Board
of Medical Physics
P.O. Box 780518
San Antonio, TX 78278

Via e-mail to info@abmpexam.com

**SUBJECT: TRAINING AND EXPERIENCE REQUIREMENTS FOR DIFFERENT
CATEGORIES OF RADIOPHARMACEUTICALS**

Dear Ms. Papanikolaou,

The U.S. Nuclear Regulatory Commission (NRC) is evaluating its regulations related to the training and experience (T&E) required for a physician to become an authorized user for medical uses under Subpart E, “Unsealed Byproduct Material—Written Directive Required,” of [Title 10 of the Code of Federal Regulations \(10 CFR\) Part 35, “Medical Use of Byproduct Material.”](#)

The T&E requirements in Subpart E of 10 CFR Part 35 provide three ways that a physician can be authorized to administer unsealed byproduct materials or radiopharmaceuticals requiring a written directive:

1. A physician can be certified by a medical specialty board, whose certification process is recognized by the NRC or an Agreement State.
2. A physician can complete a structured educational program and supervised work experience under an alternate pathway. This alternate pathway includes a requirement for 700 hours of training and experience, which consists of a minimum of 200 hours of classroom and laboratory training and 500 hours of supervised work experience.
3. A physician can be authorized if previously identified as an authorized user on an NRC or Agreement State license or permit (i.e., grandfathered).

In its evaluation of the T&E requirements, the NRC staff is considering whether an additional pathway should be created or if the alternate pathway should be revised. Specifically, the staff is evaluating: (1) whether it makes sense to establish tailored T&E requirements for different categories of radiopharmaceuticals; (2) how those categories should be determined; (3) what the appropriate T&E requirements would be for each category; and (4) whether those requirements should be based on hours of training and experience, or focused more on competency.

On October 29, 2018, the NRC published a series of questions on T&E in the *Federal Register* (83 FR 54380). The *Federal Register* notice is enclosed with this letter and can also be accessed at: <https://www.gpo.gov/fdsys/pkg/FR-2018-10-29/pdf/2018-23521.pdf>. The NRC will carefully consider responses to these questions and would appreciate your feedback on whether changes to the current T&E regulations are warranted. The comment period for the T&E evaluation will end on January 29, 2019. Please follow the directions in the notice on how to submit written comments. The NRC is using the Federal rulemaking Web site, [Regulations.gov](#), to accept written comments on the docket (NRC-2018-0230).

The NRC will also conduct four public meetings scheduled for November 14 and December 11, 2018, and January 10 and January 22, 2019, and will accept oral comments provided during the meetings. The meetings on December 11 and January 10 will be held at NRC Headquarters in Rockville, MD, and all four meetings will be accessible for remote participation by moderated bridge line and webinar. The NRC's public meeting page has been updated with meeting details and registration instructions for each meeting: <https://www.nrc.gov/pmns/mtg>.

Additional information on the NRC's T&E evaluation can be found at: <https://www.nrc.gov/materials/miau/med-use-toolkit/training-experience-evaluation.html>. If you have any questions on this correspondence, please contact Sarah Lopas of my staff at (301) 415-6360 or Sarah.Lopas@nrc.gov.

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Christian Einberg, Chief
Medical Safety and Events Assessment Branch
Division of Materials Safety, Security, State
and Tribal Programs
Office of Nuclear Material Safety
and Safeguards

Enclosure:
Training and Experience
Federal Register notice

NUCLEAR REGULATORY COMMISSION

[NRC-2018-0230]

**Training and Experience Requirements for Different Categories of
Radiopharmaceuticals**

AGENCY: Nuclear Regulatory Commission.

ACTION: Training and experience requirements; request for comment.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is requesting comments on its training and experience (T&E) requirements. Specifically, the NRC would like input on whether it should establish tailored T&E requirements for different categories of radiopharmaceuticals for which a written directive is required in accordance with its regulations. The input will be used to determine whether significant regulatory changes to the NRC's T&E requirements for authorized users (AUs) are warranted.

DATES: Submit comments by January 29, 2019. Comments received after this date will be considered if it is practical to do so, but the NRC is only able to ensure consideration for comments received on or before this date.

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B. Submitting Comments

Please include Docket ID **NRC-2018-0230** in your comment submission.

The NRC cautions you not to include identifying or contact information in comment submissions that you do not want to be publicly disclosed in your comment submission. All comment submissions are posted at <http://www.regulations.gov> and entered into ADAMS. Comment submissions are not routinely edited to remove identifying or contact information.

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II. Background

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The NRC is interested in obtaining input from as many stakeholders as possible, including members of the Advisory Committee on the Medical Uses of Isotopes, professional organizations, physicians, patients, patient advocacy groups, licensees, Agreement States, and other interested individuals. The focus of this request is to gather information that will permit the NRC staff to determine whether changes to the T&E requirements are warranted for different categories of radiopharmaceuticals for physicians seeking AU status for the medical use of specific categories of radiopharmaceuticals requiring a written directive under 10 CFR 35.300.

During the comment period between October 29, 2018 and January 29, 2019, the NRC will hold four public meetings that will discuss the information being requested and to accept comments on the docket. All four public meetings

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III. Specific Requests for Comments

A. Tailored Training & Experience Requirements

The NRC is requesting comments on whether it should establish tailored T&E requirements for different categories of radiopharmaceuticals for physicians seeking AU status for the medical use of specific categories of radiopharmaceuticals requiring a written directive under 10 CFR 35.300 (i.e., a limited AU status). This would be for physicians seeking AU status via the alternate non-board certified pathway, and for physicians certified by a medical

specialty board that is not currently recognized by the NRC under 10 CFR 35.390, 35.392, 35.394, or 35.396 (Unsealed Byproduct Material—Written Directive Required).

1. Are the current pathways for obtaining AU status reasonable and accessible? Provide a rationale for your answer.
2. Are the current pathways for obtaining AU status adequate for protecting public health and safety? Provide a rationale for your answer.
3. Should the NRC develop a new tailored T&E pathway for these physicians? If so, what would be the appropriate way to categorize radiopharmaceuticals for tailored T&E requirements? If not, explain why the regulations should remain unchanged. [Some options to categorize radiopharmaceuticals include radiopharmaceuticals with similar delivery methods (oral, parenteral); same type of radiation characteristics or emission (alpha, beta, gamma, low-energy photon); similar preparation method (patient-ready doses); or a combination thereof (e.g., radiopharmaceuticals containing alpha- and beta-emitting radioisotopes that are administered intravenously and are prepared as patient-ready doses).]
4. Should the fundamental T&E required of physicians seeking limited AU status need to have the same fundamental T&E required of physicians seeking full AU status for all oral and parenteral administrations under 10 CFR 35.300?
5. How should the requirements for this fundamental T&E be structured for a specific category of radiopharmaceuticals?
 - a. Describe what the requirements should include:

- i. Classroom and laboratory training – What topics need to be covered in this training requirement? How many hours of classroom and laboratory training should be required? Provide the basis for the number of hours. If not hours, explain how this training should be quantified. [Note: The topics currently required in the regulations to be included in the classroom and laboratory training and work experience are listed in 10 CFR 35.390, 35.392, 35.394, and 35.396.]
 - ii. Work experience - What should the work experience requirement involve? How many hours of work experience should be required and what is the minimum number of patient or human research subject administrations that an individual must perform? Provide the basis for the number of hours and administrations. What should be the qualifications of the supervising individual?
 - iii. Competency - How should competency be evaluated? Should a written and/or practical examination by an independent examining committee be administered? Provide a rationale for your answer.
- b. Should a preceptor attestation be required for the fundamental T&E? Provide a rationale for your answer.
- c. Should the radiopharmaceutical manufacturer be able to provide the preceptor attestation? Provide a rational for your answer.

- d. Who should establish and administer the curriculum and examination? Provide specific group(s). [Some options are: NRC, medical specialty boards, medical professional societies, educational professional groups, and NRC in collaboration with any or more of the aforementioned groups.]
- e. Should AU competency be periodically assessed? If so, how should it be assessed, how often, and by whom?

B. NRC's Recognition of Medical Specialty Boards

The NRC is requesting comments on its recognition of medical specialty boards. The NRC's procedures for recognizing medical specialty boards are located on the Medical Uses Licensee Toolkit Web site (<https://www.nrc.gov/materials/miau/med-use-toolkit/certif-process-boards.html>). The NRC staff periodically reviews information to determine a board's continued eligibility for recognition.

- 1. What boards other than those already recognized by the NRC (American Board of Nuclear Medicine [ABNM], American Board of Radiology [ABR], American Osteopathic Board of Radiology [AOBR], Certification Board of Nuclear Endocrinology [CBNE]) could be considered for recognition for medical uses under 10 CFR 35.300?
- 2. Are the current NRC medical specialty board recognition criteria sufficient? If not, what additional criteria should the NRC use?

C. Patient Access

The NRC is requesting comments on whether there is a shortage in the number of AUs for 10 CFR 35.300.

1. Is there a shortage in the number of AUs for medical uses under 10 CFR 35.300? If so, is the shortage associated with the use of a specific radiopharmaceutical? Explain how.
2. Are there certain geographic areas with an inadequate number of AUs? Identify these areas.
3. Do current NRC regulations on AU T&E requirements unnecessarily limit patient access to procedures involving radiopharmaceuticals? Explain how.
4. Do current NRC regulations on AU T&E requirements unnecessarily limit research and development in nuclear medicine? Explain how.

D. Other Suggested Changes to the T&E Regulations

In 2002, the NRC revised its regulatory framework for medical use. The goal was to focus the NRC's regulations on those medical procedures that pose the highest risk to workers, the general public, patients, and human research subjects and to structure the regulations to be more risk-informed and more performance-based. The 2002 rule reduced the unnecessary regulatory burden by either reducing or eliminating the prescriptiveness of some regulations. Instead, the rule provided for a performance-based approach that relied on the training and experience of the AUs, authorized nuclear pharmacists, and radiation safety officers. The NRC is requesting comments on whether there are any other changes to the T&E regulations in 10 CFR part 35 that should be considered. Please discuss your suggested changes.

1. Should the NRC regulate the T&E of physicians for medical uses?
2. Are there requirements in the NRC's T&E regulatory framework for physicians that are non-safety related?

3. How can the NRC transform its regulatory approach for T&E while still ensuring that adequate protection is maintained for workers, the general public, patients, and human research subjects?

Dated at Rockville, Maryland, this 23rd day of October 2018.

For the Nuclear Regulatory
Commission.

/RA/

Daniel S. Collins, Director,
Division of Materials Safety,
Security,
State, and Tribal Programs,
Office of Nuclear Material Safety
and Safeguards.



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

November 2, 2018

Dr. Timothy Stenzel
Director, Office of In Vitro Diagnostics and Radiological Health
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Via e-mail to Timothy.Stenzel@fda.hhs.gov

SUBJECT: TRAINING AND EXPERIENCE REQUIREMENTS FOR DIFFERENT CATEGORIES OF RADIOPHARMACEUTICALS

Dear Dr. Stenzel,

The U.S. Nuclear Regulatory Commission (NRC) is evaluating its regulations related to the training and experience (T&E) required for a physician to become an authorized user for medical uses under Subpart E, “Unsealed Byproduct Material—Written Directive Required,” of [Title 10 of the Code of Federal Regulations \(10 CFR\) Part 35, “Medical Use of Byproduct Material.”](#)

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Christian Einberg, Chief
Medical Safety and Events Assessment Branch
Division of Materials Safety, Security, State
and Tribal Programs
Office of Nuclear Material Safety
and Safeguards

Enclosure:
Training and Experience
Federal Register notice

SUBJECT: TRAINING AND EXPERIENCE REQUIREMENTS FOR DIFFERENT
CATEGORIES OF RADIOPHARMACEUTICALS

Enclosure:
Training and Experience
Federal Register notice

IDENTICAL LETTERS SENT TO: See Attached

ML18306A926

OFC	NMSS/MSST	NMSS/MSST	NMSS/MSST	NMSS/MSST
NAME	SLopas	LDimmick (via e-mail)	SAttack (via e-mail)	CEinberg
DATE	10/25/18	10/31/18	11/1/18	11/2/18

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NUCLEAR REGULATORY COMMISSION

[NRC-2018-0230]

**Training and Experience Requirements for Different Categories of
Radiopharmaceuticals**

AGENCY: Nuclear Regulatory Commission.

ACTION: Training and experience requirements; request for comment.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is requesting comments on its training and experience (T&E) requirements. Specifically, the NRC would like input on whether it should establish tailored T&E requirements for different categories of radiopharmaceuticals for which a written directive is required in accordance with its regulations. The input will be used to determine whether significant regulatory changes to the NRC's T&E requirements for authorized users (AUs) are warranted.

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 - a. Describe what the requirements should include:

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- e. Should AU competency be periodically assessed? If so, how should it be assessed, how often, and by whom?

B. NRC's Recognition of Medical Specialty Boards

The NRC is requesting comments on its recognition of medical specialty boards. The NRC's procedures for recognizing medical specialty boards are located on the Medical Uses Licensee Toolkit Web site (<https://www.nrc.gov/materials/miau/med-use-toolkit/certif-process-boards.html>). The NRC staff periodically reviews information to determine a board's continued eligibility for recognition.

- 1. What boards other than those already recognized by the NRC (American Board of Nuclear Medicine [ABNM], American Board of Radiology [ABR], American Osteopathic Board of Radiology [AOBR], Certification Board of Nuclear Endocrinology [CBNE]) could be considered for recognition for medical uses under 10 CFR 35.300?
- 2. Are the current NRC medical specialty board recognition criteria sufficient? If not, what additional criteria should the NRC use?

C. Patient Access

The NRC is requesting comments on whether there is a shortage in the number of AUs for 10 CFR 35.300.

1. Is there a shortage in the number of AUs for medical uses under 10 CFR 35.300? If so, is the shortage associated with the use of a specific radiopharmaceutical? Explain how.
2. Are there certain geographic areas with an inadequate number of AUs? Identify these areas.
3. Do current NRC regulations on AU T&E requirements unnecessarily limit patient access to procedures involving radiopharmaceuticals? Explain how.
4. Do current NRC regulations on AU T&E requirements unnecessarily limit research and development in nuclear medicine? Explain how.

D. Other Suggested Changes to the T&E Regulations

In 2002, the NRC revised its regulatory framework for medical use. The goal was to focus the NRC's regulations on those medical procedures that pose the highest risk to workers, the general public, patients, and human research subjects and to structure the regulations to be more risk-informed and more performance-based. The 2002 rule reduced the unnecessary regulatory burden by either reducing or eliminating the prescriptiveness of some regulations. Instead, the rule provided for a performance-based approach that relied on the training and experience of the AUs, authorized nuclear pharmacists, and radiation safety officers. The NRC is requesting comments on whether there are any other changes to the T&E regulations in 10 CFR part 35 that should be considered. Please discuss your suggested changes.

1. Should the NRC regulate the T&E of physicians for medical uses?
2. Are there requirements in the NRC's T&E regulatory framework for physicians that are non-safety related?

3. How can the NRC transform its regulatory approach for T&E while still ensuring that adequate protection is maintained for workers, the general public, patients, and human research subjects?

Dated at Rockville, Maryland, this 23rd day of October 2018.

For the Nuclear Regulatory
Commission.

/RA/

Daniel S. Collins, Director,
Division of Materials Safety,
Security,
State, and Tribal Programs,
Office of Nuclear Material Safety
and Safeguards.



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

November 2, 2018

Mr. John Witkowski
United Pharmacy Partners
5400 Laurel Springs Parkway
Suwanee, GA 30024

Via e-mail to john.witkowski@uppi.org

SUBJECT: TRAINING AND EXPERIENCE REQUIREMENTS FOR DIFFERENT CATEGORIES OF RADIOPHARMACEUTICALS

Dear Mr. Witkowski,

The U.S. Nuclear Regulatory Commission (NRC) is evaluating its regulations related to the training and experience (T&E) required for a physician to become an authorized user for medical uses under Subpart E, “Unsealed Byproduct Material—Written Directive Required,” of [Title 10 of the Code of Federal Regulations \(10 CFR\) Part 35, “Medical Use of Byproduct Material.”](#)

The T&E requirements in Subpart E of 10 CFR Part 35 provide three ways that a physician can be authorized to administer unsealed byproduct materials or radiopharmaceuticals requiring a written directive:

1. A physician can be certified by a medical specialty board, whose certification process is recognized by the NRC or an Agreement State.
2. A physician can complete a structured educational program and supervised work experience under an alternate pathway. This alternate pathway includes a requirement for 700 hours of training and experience, which consists of a minimum of 200 hours of classroom and laboratory training and 500 hours of supervised work experience.
3. A physician can be authorized if previously identified as an authorized user on an NRC or Agreement State license or permit (i.e., grandfathered).

In its evaluation of the T&E requirements, the NRC staff is considering whether an additional pathway should be created or if the alternate pathway should be revised. Specifically, the staff is evaluating: (1) whether it makes sense to establish tailored T&E requirements for different categories of radiopharmaceuticals; (2) how those categories should be determined; (3) what the appropriate T&E requirements would be for each category; and (4) whether those requirements should be based on hours of training and experience, or focused more on competency.

On October 29, 2018, the NRC published a series of questions on T&E in the *Federal Register* (83 FR 54380). The *Federal Register* notice is enclosed with this letter and can also be accessed at: <https://www.gpo.gov/fdsys/pkg/FR-2018-10-29/pdf/2018-23521.pdf>. The NRC will carefully consider responses to these questions and would appreciate your feedback on whether changes to the current T&E regulations are warranted. The comment period for the T&E evaluation will end on January 29, 2019. Please follow the directions in the notice on how to submit written comments. The NRC is using the Federal rulemaking Web site, [Regulations.gov](#), to accept written comments on the docket (NRC-2018-0230).

The NRC will also conduct four public meetings scheduled for November 14 and December 11, 2018, and January 10 and January 22, 2019, and will accept oral comments provided during the meetings. The meetings on December 11 and January 10 will be held at NRC Headquarters in Rockville, MD, and all four meetings will be accessible for remote participation by moderated bridge line and webinar. The NRC's public meeting page has been updated with meeting details and registration instructions for each meeting: <https://www.nrc.gov/pmns/mtg>.

Additional information on the NRC's T&E evaluation can be found at: <https://www.nrc.gov/materials/miau/med-use-toolkit/training-experience-evaluation.html>. If you have any questions on this correspondence, please contact Sarah Lopas of my staff at (301) 415-6360 or Sarah.Lopas@nrc.gov.

A handwritten signature in black ink, appearing to read "C Einberg".

Christian Einberg, Chief
Medical Safety and Events Assessment Branch
Division of Materials Safety, Security, State
and Tribal Programs
Office of Nuclear Material Safety
and Safeguards

Enclosure:
Training and Experience
Federal Register notice

NUCLEAR REGULATORY COMMISSION

[NRC-2018-0230]

**Training and Experience Requirements for Different Categories of
Radiopharmaceuticals**

AGENCY: Nuclear Regulatory Commission.

ACTION: Training and experience requirements; request for comment.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is requesting comments on its training and experience (T&E) requirements. Specifically, the NRC would like input on whether it should establish tailored T&E requirements for different categories of radiopharmaceuticals for which a written directive is required in accordance with its regulations. The input will be used to determine whether significant regulatory changes to the NRC's T&E requirements for authorized users (AUs) are warranted.

DATES: Submit comments by January 29, 2019. Comments received after this date will be considered if it is practical to do so, but the NRC is only able to ensure consideration for comments received on or before this date.

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FOR FURTHER INFORMATION CONTACT: Sarah Lopas, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001; telephone: 301-415-6360, e-mail: Sarah.Lopas@nrc.gov.

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Please include Docket ID **NRC-2018-0230** in your comment submission.

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radionuclides or by delivery method), (3) what the appropriate T&E requirements would be for each category, and (4) whether those requirements should be based on hours of T&E or focused more on competency. In response to the SRM, the NRC staff documented its initial results, status, and next steps related to this evaluation in SECY-18-0084, "Staff Evaluation of Training and Experience Requirements for Administering Different Categories of Radiopharmaceuticals in Response to SRM-M170817" (ADAMS Accession No. ML18135A276). In SECY-18-0084, the staff concluded that additional outreach with the medical community is needed to determine whether and how to tailor the T&E requirements to establish a limited AU status, the specific T&E requirements that should apply, how the T&E requirements should be met (e.g., hours of training, demonstration of competency), and whether a competency-based approach makes sense for the T&E requirements for all the medical uses authorized under 10 CFR 35.300, "Use of unsealed byproduct material for which a written directive is required."

The NRC is interested in obtaining input from as many stakeholders as possible, including members of the Advisory Committee on the Medical Uses of Isotopes, professional organizations, physicians, patients, patient advocacy groups, licensees, Agreement States, and other interested individuals. The focus of this request is to gather information that will permit the NRC staff to determine whether changes to the T&E requirements are warranted for different categories of radiopharmaceuticals for physicians seeking AU status for the medical use of specific categories of radiopharmaceuticals requiring a written directive under 10 CFR 35.300.

During the comment period between October 29, 2018 and January 29, 2019, the NRC will hold four public meetings that will discuss the information being requested and to accept comments on the docket. All four public meetings

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The NRC may post additional materials related to this document, including public comments, on the Federal Rulemaking Web site. The Federal Rulemaking Web site allows you to receive alerts when changes or additions occur in a docket folder. To subscribe: (1) Navigate to the docket folder **NRC-2018-0230**; (2) click the “Sign up for E-mail Alerts” link; and (3) enter your email address and select how frequently you would like to receive emails (daily, weekly, or monthly).

III. Specific Requests for Comments

A. Tailored Training & Experience Requirements

The NRC is requesting comments on whether it should establish tailored T&E requirements for different categories of radiopharmaceuticals for physicians seeking AU status for the medical use of specific categories of radiopharmaceuticals requiring a written directive under 10 CFR 35.300 (i.e., a limited AU status). This would be for physicians seeking AU status via the alternate non-board certified pathway, and for physicians certified by a medical

specialty board that is not currently recognized by the NRC under 10 CFR 35.390, 35.392, 35.394, or 35.396 (Unsealed Byproduct Material—Written Directive Required).

1. Are the current pathways for obtaining AU status reasonable and accessible? Provide a rationale for your answer.
2. Are the current pathways for obtaining AU status adequate for protecting public health and safety? Provide a rationale for your answer.
3. Should the NRC develop a new tailored T&E pathway for these physicians? If so, what would be the appropriate way to categorize radiopharmaceuticals for tailored T&E requirements? If not, explain why the regulations should remain unchanged. [Some options to categorize radiopharmaceuticals include radiopharmaceuticals with similar delivery methods (oral, parenteral); same type of radiation characteristics or emission (alpha, beta, gamma, low-energy photon); similar preparation method (patient-ready doses); or a combination thereof (e.g., radiopharmaceuticals containing alpha- and beta-emitting radioisotopes that are administered intravenously and are prepared as patient-ready doses).]
4. Should the fundamental T&E required of physicians seeking limited AU status need to have the same fundamental T&E required of physicians seeking full AU status for all oral and parenteral administrations under 10 CFR 35.300?
5. How should the requirements for this fundamental T&E be structured for a specific category of radiopharmaceuticals?
 - a. Describe what the requirements should include:

- i. Classroom and laboratory training – What topics need to be covered in this training requirement? How many hours of classroom and laboratory training should be required? Provide the basis for the number of hours. If not hours, explain how this training should be quantified. [Note: The topics currently required in the regulations to be included in the classroom and laboratory training and work experience are listed in 10 CFR 35.390, 35.392, 35.394, and 35.396.]
 - ii. Work experience - What should the work experience requirement involve? How many hours of work experience should be required and what is the minimum number of patient or human research subject administrations that an individual must perform? Provide the basis for the number of hours and administrations. What should be the qualifications of the supervising individual?
 - iii. Competency - How should competency be evaluated? Should a written and/or practical examination by an independent examining committee be administered? Provide a rationale for your answer.
- b. Should a preceptor attestation be required for the fundamental T&E? Provide a rationale for your answer.
- c. Should the radiopharmaceutical manufacturer be able to provide the preceptor attestation? Provide a rational for your answer.

- d. Who should establish and administer the curriculum and examination? Provide specific group(s). [Some options are: NRC, medical specialty boards, medical professional societies, educational professional groups, and NRC in collaboration with any or more of the aforementioned groups.]
- e. Should AU competency be periodically assessed? If so, how should it be assessed, how often, and by whom?

B. NRC's Recognition of Medical Specialty Boards

The NRC is requesting comments on its recognition of medical specialty boards. The NRC's procedures for recognizing medical specialty boards are located on the Medical Uses Licensee Toolkit Web site (<https://www.nrc.gov/materials/miau/med-use-toolkit/certif-process-boards.html>). The NRC staff periodically reviews information to determine a board's continued eligibility for recognition.

- 1. What boards other than those already recognized by the NRC (American Board of Nuclear Medicine [ABNM], American Board of Radiology [ABR], American Osteopathic Board of Radiology [AOBR], Certification Board of Nuclear Endocrinology [CBNE]) could be considered for recognition for medical uses under 10 CFR 35.300?
- 2. Are the current NRC medical specialty board recognition criteria sufficient? If not, what additional criteria should the NRC use?

C. Patient Access

The NRC is requesting comments on whether there is a shortage in the number of AUs for 10 CFR 35.300.

1. Is there a shortage in the number of AUs for medical uses under 10 CFR 35.300? If so, is the shortage associated with the use of a specific radiopharmaceutical? Explain how.
2. Are there certain geographic areas with an inadequate number of AUs? Identify these areas.
3. Do current NRC regulations on AU T&E requirements unnecessarily limit patient access to procedures involving radiopharmaceuticals? Explain how.
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D. Other Suggested Changes to the T&E Regulations

In 2002, the NRC revised its regulatory framework for medical use. The goal was to focus the NRC's regulations on those medical procedures that pose the highest risk to workers, the general public, patients, and human research subjects and to structure the regulations to be more risk-informed and more performance-based. The 2002 rule reduced the unnecessary regulatory burden by either reducing or eliminating the prescriptiveness of some regulations. Instead, the rule provided for a performance-based approach that relied on the training and experience of the AUs, authorized nuclear pharmacists, and radiation safety officers. The NRC is requesting comments on whether there are any other changes to the T&E regulations in 10 CFR part 35 that should be considered. Please discuss your suggested changes.

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Dated at Rockville, Maryland, this 23rd day of October 2018.

For the Nuclear Regulatory
Commission.

/RA/

Daniel S. Collins, Director,
Division of Materials Safety,
Security,
State, and Tribal Programs,
Office of Nuclear Material Safety
and Safeguards.



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

November 2, 2018

Dr. Stevee McIntyre
Program Coordinator,
Radiologic Sciences Program
University of New Mexico
1 University of New Mexico
Albuquerque, NM 87131-0001

Via e-mail to raddpt@unm.edu

SUBJECT: TRAINING AND EXPERIENCE REQUIREMENTS FOR DIFFERENT CATEGORIES OF RADIOPHARMACEUTICALS

Dear Dr. McIntyre,

The U.S. Nuclear Regulatory Commission (NRC) is evaluating its regulations related to the training and experience (T&E) required for a physician to become an authorized user for medical uses under Subpart E, “Unsealed Byproduct Material—Written Directive Required,” of [Title 10 of the Code of Federal Regulations \(10 CFR\) Part 35, “Medical Use of Byproduct Material.”](#)

The T&E requirements in Subpart E of 10 CFR Part 35 provide three ways that a physician can be authorized to administer unsealed byproduct materials or radiopharmaceuticals requiring a written directive:

1. A physician can be certified by a medical specialty board, whose certification process is recognized by the NRC or an Agreement State.
2. A physician can complete a structured educational program and supervised work experience under an alternate pathway. This alternate pathway includes a requirement for 700 hours of training and experience, which consists of a minimum of 200 hours of classroom and laboratory training and 500 hours of supervised work experience.
3. A physician can be authorized if previously identified as an authorized user on an NRC or Agreement State license or permit (i.e., grandfathered).

In its evaluation of the T&E requirements, the NRC staff is considering whether an additional pathway should be created or if the alternate pathway should be revised. Specifically, the staff is evaluating: (1) whether it makes sense to establish tailored T&E requirements for different categories of radiopharmaceuticals; (2) how those categories should be determined; (3) what the appropriate T&E requirements would be for each category; and (4) whether those requirements should be based on hours of training and experience, or focused more on competency.

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Additional information on the NRC's T&E evaluation can be found at: <https://www.nrc.gov/materials/miau/med-use-toolkit/training-experience-evaluation.html>. If you have any questions on this correspondence, please contact Sarah Lopas of my staff at (301) 415-6360 or Sarah.Lopas@nrc.gov.

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Christian Einberg, 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:
Training and Experience
Federal Register notice

NUCLEAR REGULATORY COMMISSION

[NRC-2018-0230]

**Training and Experience Requirements for Different Categories of
Radiopharmaceuticals**

AGENCY: Nuclear Regulatory Commission.

ACTION: Training and experience requirements; request for comment.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is requesting comments on its training and experience (T&E) requirements. Specifically, the NRC would like input on whether it should establish tailored T&E requirements for different categories of radiopharmaceuticals for which a written directive is required in accordance with its regulations. The input will be used to determine whether significant regulatory changes to the NRC's T&E requirements for authorized users (AUs) are warranted.

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1. Are the current pathways for obtaining AU status reasonable and accessible? Provide a rationale for your answer.
2. Are the current pathways for obtaining AU status adequate for protecting public health and safety? Provide a rationale for your answer.
3. Should the NRC develop a new tailored T&E pathway for these physicians? If so, what would be the appropriate way to categorize radiopharmaceuticals for tailored T&E requirements? If not, explain why the regulations should remain unchanged. [Some options to categorize radiopharmaceuticals include radiopharmaceuticals with similar delivery methods (oral, parenteral); same type of radiation characteristics or emission (alpha, beta, gamma, low-energy photon); similar preparation method (patient-ready doses); or a combination thereof (e.g., radiopharmaceuticals containing alpha- and beta-emitting radioisotopes that are administered intravenously and are prepared as patient-ready doses).]
4. Should the fundamental T&E required of physicians seeking limited AU status need to have the same fundamental T&E required of physicians seeking full AU status for all oral and parenteral administrations under 10 CFR 35.300?
5. How should the requirements for this fundamental T&E be structured for a specific category of radiopharmaceuticals?
 - a. Describe what the requirements should include:

- i. Classroom and laboratory training – What topics need to be covered in this training requirement? How many hours of classroom and laboratory training should be required? Provide the basis for the number of hours. If not hours, explain how this training should be quantified. [Note: The topics currently required in the regulations to be included in the classroom and laboratory training and work experience are listed in 10 CFR 35.390, 35.392, 35.394, and 35.396.]
 - ii. Work experience - What should the work experience requirement involve? How many hours of work experience should be required and what is the minimum number of patient or human research subject administrations that an individual must perform? Provide the basis for the number of hours and administrations. What should be the qualifications of the supervising individual?
 - iii. Competency - How should competency be evaluated? Should a written and/or practical examination by an independent examining committee be administered? Provide a rationale for your answer.
- b. Should a preceptor attestation be required for the fundamental T&E? Provide a rationale for your answer.
- c. Should the radiopharmaceutical manufacturer be able to provide the preceptor attestation? Provide a rational for your answer.

- d. Who should establish and administer the curriculum and examination? Provide specific group(s). [Some options are: NRC, medical specialty boards, medical professional societies, educational professional groups, and NRC in collaboration with any or more of the aforementioned groups.]
- e. Should AU competency be periodically assessed? If so, how should it be assessed, how often, and by whom?

B. NRC's Recognition of Medical Specialty Boards

The NRC is requesting comments on its recognition of medical specialty boards. The NRC's procedures for recognizing medical specialty boards are located on the Medical Uses Licensee Toolkit Web site (<https://www.nrc.gov/materials/miau/med-use-toolkit/certif-process-boards.html>). The NRC staff periodically reviews information to determine a board's continued eligibility for recognition.

- 1. What boards other than those already recognized by the NRC (American Board of Nuclear Medicine [ABNM], American Board of Radiology [ABR], American Osteopathic Board of Radiology [AOBR], Certification Board of Nuclear Endocrinology [CBNE]) could be considered for recognition for medical uses under 10 CFR 35.300?
- 2. Are the current NRC medical specialty board recognition criteria sufficient? If not, what additional criteria should the NRC use?

C. Patient Access

The NRC is requesting comments on whether there is a shortage in the number of AUs for 10 CFR 35.300.

1. Is there a shortage in the number of AUs for medical uses under 10 CFR 35.300? If so, is the shortage associated with the use of a specific radiopharmaceutical? Explain how.
2. Are there certain geographic areas with an inadequate number of AUs? Identify these areas.
3. Do current NRC regulations on AU T&E requirements unnecessarily limit patient access to procedures involving radiopharmaceuticals? Explain how.
4. Do current NRC regulations on AU T&E requirements unnecessarily limit research and development in nuclear medicine? Explain how.

D. Other Suggested Changes to the T&E Regulations

In 2002, the NRC revised its regulatory framework for medical use. The goal was to focus the NRC's regulations on those medical procedures that pose the highest risk to workers, the general public, patients, and human research subjects and to structure the regulations to be more risk-informed and more performance-based. The 2002 rule reduced the unnecessary regulatory burden by either reducing or eliminating the prescriptiveness of some regulations. Instead, the rule provided for a performance-based approach that relied on the training and experience of the AUs, authorized nuclear pharmacists, and radiation safety officers. The NRC is requesting comments on whether there are any other changes to the T&E regulations in 10 CFR part 35 that should be considered. Please discuss your suggested changes.

1. Should the NRC regulate the T&E of physicians for medical uses?
2. Are there requirements in the NRC's T&E regulatory framework for physicians that are non-safety related?

3. How can the NRC transform its regulatory approach for T&E while still ensuring that adequate protection is maintained for workers, the general public, patients, and human research subjects?

Dated at Rockville, Maryland, this 23rd day of October 2018.

For the Nuclear Regulatory
Commission.

/RA/

Daniel S. Collins, Director,
Division of Materials Safety,
Security,
State, and Tribal Programs,
Office of Nuclear Material Safety
and Safeguards.



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

November 2, 2018

Ms. Valerie P. Jackson
Executive Director,
American Board of Radiology
5441 E. Williams Circle
Tucson, AZ 85711-7412

Via e-mail to information@theabr.org

SUBJECT: TRAINING AND EXPERIENCE REQUIREMENTS FOR DIFFERENT CATEGORIES OF RADIOPHARMACEUTICALS

Dear Ms. Jackson,

The U.S. Nuclear Regulatory Commission (NRC) is evaluating its regulations related to the training and experience (T&E) required for a physician to become an authorized user for medical uses under Subpart E, “Unsealed Byproduct Material—Written Directive Required,” of [Title 10 of the Code of Federal Regulations \(10 CFR\) Part 35, “Medical Use of Byproduct Material.”](#)

The T&E requirements in Subpart E of 10 CFR Part 35 provide three ways that a physician can be authorized to administer unsealed byproduct materials or radiopharmaceuticals requiring a written directive:

1. A physician can be certified by a medical specialty board, whose certification process is recognized by the NRC or an Agreement State.
2. A physician can complete a structured educational program and supervised work experience under an alternate pathway. This alternate pathway includes a requirement for 700 hours of training and experience, which consists of a minimum of 200 hours of classroom and laboratory training and 500 hours of supervised work experience.
3. A physician can be authorized if previously identified as an authorized user on an NRC or Agreement State license or permit (i.e., grandfathered).

In its evaluation of the T&E requirements, the NRC staff is considering whether an additional pathway should be created or if the alternate pathway should be revised. Specifically, the staff is evaluating: (1) whether it makes sense to establish tailored T&E requirements for different categories of radiopharmaceuticals; (2) how those categories should be determined; (3) what the appropriate T&E requirements would be for each category; and (4) whether those requirements should be based on hours of training and experience, or focused more on competency.

On October 29, 2018, the NRC published a series of questions on T&E in the *Federal Register* (83 FR 54380). The *Federal Register* notice is enclosed with this letter and can also be accessed at: <https://www.gpo.gov/fdsys/pkg/FR-2018-10-29/pdf/2018-23521.pdf>. The NRC will carefully consider responses to these questions and would appreciate your feedback on whether changes to the current T&E regulations are warranted. The comment period for the T&E evaluation will end on January 29, 2019. Please follow the directions in the notice on how to submit written comments. The NRC is using the Federal rulemaking Web site, [Regulations.gov](#), to accept written comments on the docket (NRC-2018-0230).

The NRC will also conduct four public meetings scheduled for November 14 and December 11, 2018, and January 10 and January 22, 2019, and will accept oral comments provided during the meetings. The meetings on December 11 and January 10 will be held at NRC Headquarters in Rockville, MD, and all four meetings will be accessible for remote participation by moderated bridge line and webinar. The NRC's public meeting page has been updated with meeting details and registration instructions for each meeting: <https://www.nrc.gov/pmns/mtg>.

Additional information on the NRC's T&E evaluation can be found at: <https://www.nrc.gov/materials/miau/med-use-toolkit/training-experience-evaluation.html>. If you have any questions on this correspondence, please contact Sarah Lopas of my staff at (301) 415-6360 or Sarah.Lopas@nrc.gov.

A handwritten signature in black ink, appearing to read "C Einberg".

Christian Einberg, Chief
Medical Safety and Events Assessment Branch
Division of Materials Safety, Security, State
and Tribal Programs
Office of Nuclear Material Safety
and Safeguards

Enclosure:
Training and Experience
Federal Register notice

NUCLEAR REGULATORY COMMISSION

[NRC-2018-0230]

**Training and Experience Requirements for Different Categories of
Radiopharmaceuticals**

AGENCY: Nuclear Regulatory Commission.

ACTION: Training and experience requirements; request for comment.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is requesting comments on its training and experience (T&E) requirements. Specifically, the NRC would like input on whether it should establish tailored T&E requirements for different categories of radiopharmaceuticals for which a written directive is required in accordance with its regulations. The input will be used to determine whether significant regulatory changes to the NRC's T&E requirements for authorized users (AUs) are warranted.

DATES: Submit comments by January 29, 2019. Comments received after this date will be considered if it is practical to do so, but the NRC is only able to ensure consideration for comments received on or before this date.

ADDRESSES: You may submit comments by any of the following methods:

- **Federal Rulemaking Web Site:** Go to <http://www.regulations.gov>

and search for Docket ID **NRC-2018-0230**. Address questions about Docket IDs in Regulations.gov to Jennifer Borges; telephone: 301-287-9127; e-mail: Jennifer.Borges@nrc.gov. For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.

- **Mail comments to:** May Ma, Office of Administration, Mail Stop: TWFN-7-A60M, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001.

For additional direction on obtaining information and submitting comments, see “Obtaining Information and Submitting Comments” in the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: Sarah Lopas, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001; telephone: 301-415-6360, e-mail: Sarah.Lopas@nrc.gov.

SUPPLEMENTARY INFORMATION:

I. Obtaining Information and Submitting Comments

A. Obtaining Information

Please refer to Docket ID **NRC-2018-0230** when contacting the NRC about the availability of information for this action. You may obtain publicly-available information related to this action by any of the following methods:

- **Federal Rulemaking Web Site:** Go to <http://www.regulations.gov> and search for Docket ID **NRC-2018-0230**.
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- **NRC's PDR:** You may examine and purchase copies of public documents at the NRC's PDR, Room O1-F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.

B. Submitting Comments

Please include Docket ID **NRC-2018-0230** in your comment submission.

The NRC cautions you not to include identifying or contact information in comment submissions that you do not want to be publicly disclosed in your comment submission. All comment submissions are posted at <http://www.regulations.gov> and entered into ADAMS. Comment submissions are not routinely edited to remove identifying or contact information.

If you are requesting or aggregating comments from other persons for submission to the NRC, then you should inform those persons not to include identifying or contact information that they do not want to be publicly disclosed in their comment submission. Your request should state that the NRC does not routinely edit comment submissions to remove such information before making the comment submissions available to the public or entering the comment into ADAMS.

II. Background

On August 17, 2017, the Commission issued a staff requirements memorandum (SRM), SRM-M170817 (ADAMS Accession No. ML17229B284), approving the final rule revising parts 30, 32, and 35 of title 10 of the *Code of Federal Regulations* (10 CFR), "Medical Use of Byproduct Material – Medical Event Definitions, Training and Experience, and Clarifying Amendments," and directing the staff to evaluate (1) whether it makes sense to establish tailored T&E requirements for different categories of radiopharmaceuticals, (2) how those categories should be determined (such as by risks posed by groups of

radionuclides or by delivery method), (3) what the appropriate T&E requirements would be for each category, and (4) whether those requirements should be based on hours of T&E or focused more on competency. In response to the SRM, the NRC staff documented its initial results, status, and next steps related to this evaluation in SECY-18-0084, "Staff Evaluation of Training and Experience Requirements for Administering Different Categories of Radiopharmaceuticals in Response to SRM-M170817" (ADAMS Accession No. ML18135A276). In SECY-18-0084, the staff concluded that additional outreach with the medical community is needed to determine whether and how to tailor the T&E requirements to establish a limited AU status, the specific T&E requirements that should apply, how the T&E requirements should be met (e.g., hours of training, demonstration of competency), and whether a competency-based approach makes sense for the T&E requirements for all the medical uses authorized under 10 CFR 35.300, "Use of unsealed byproduct material for which a written directive is required."

The NRC is interested in obtaining input from as many stakeholders as possible, including members of the Advisory Committee on the Medical Uses of Isotopes, professional organizations, physicians, patients, patient advocacy groups, licensees, Agreement States, and other interested individuals. The focus of this request is to gather information that will permit the NRC staff to determine whether changes to the T&E requirements are warranted for different categories of radiopharmaceuticals for physicians seeking AU status for the medical use of specific categories of radiopharmaceuticals requiring a written directive under 10 CFR 35.300.

During the comment period between October 29, 2018 and January 29, 2019, the NRC will hold four public meetings that will discuss the information being requested and to accept comments on the docket. All four public meetings

will be available for remote participation by moderated bridge line and webinar, and two of the four meetings will be open for in-person attendance at NRC's headquarters in Rockville, Maryland.

The public meetings are scheduled for November 14, 2018 (webinar-only); December 11, 2018 (webinar and in-person attendance); January 10, 2019 (webinar and in-person attendance); and January 22, 2019 (webinar-only). The public meetings will be noticed on the NRC's public meeting Web site at least 10 calendar days before the meeting. Members of the public should monitor the NRC's public meeting Web site at <https://www.nrc.gov/pmns/mtg>. The NRC will also post the meeting notices on the Federal Rulemaking Web site at <https://www.regulations.gov/> under Docket ID **NRC-2018-0230**.

The NRC may post additional materials related to this document, including public comments, on the Federal Rulemaking Web site. The Federal Rulemaking Web site allows you to receive alerts when changes or additions occur in a docket folder. To subscribe: (1) Navigate to the docket folder **NRC-2018-0230**; (2) click the “Sign up for E-mail Alerts” link; and (3) enter your email address and select how frequently you would like to receive emails (daily, weekly, or monthly).

III. Specific Requests for Comments

A. Tailored Training & Experience Requirements

The NRC is requesting comments on whether it should establish tailored T&E requirements for different categories of radiopharmaceuticals for physicians seeking AU status for the medical use of specific categories of radiopharmaceuticals requiring a written directive under 10 CFR 35.300 (i.e., a limited AU status). This would be for physicians seeking AU status via the alternate non-board certified pathway, and for physicians certified by a medical

specialty board that is not currently recognized by the NRC under 10 CFR 35.390, 35.392, 35.394, or 35.396 (Unsealed Byproduct Material—Written Directive Required).

1. Are the current pathways for obtaining AU status reasonable and accessible? Provide a rationale for your answer.
2. Are the current pathways for obtaining AU status adequate for protecting public health and safety? Provide a rationale for your answer.
3. Should the NRC develop a new tailored T&E pathway for these physicians? If so, what would be the appropriate way to categorize radiopharmaceuticals for tailored T&E requirements? If not, explain why the regulations should remain unchanged. [Some options to categorize radiopharmaceuticals include radiopharmaceuticals with similar delivery methods (oral, parenteral); same type of radiation characteristics or emission (alpha, beta, gamma, low-energy photon); similar preparation method (patient-ready doses); or a combination thereof (e.g., radiopharmaceuticals containing alpha- and beta-emitting radioisotopes that are administered intravenously and are prepared as patient-ready doses).]
4. Should the fundamental T&E required of physicians seeking limited AU status need to have the same fundamental T&E required of physicians seeking full AU status for all oral and parenteral administrations under 10 CFR 35.300?
5. How should the requirements for this fundamental T&E be structured for a specific category of radiopharmaceuticals?
 - a. Describe what the requirements should include:

- i. Classroom and laboratory training – What topics need to be covered in this training requirement? How many hours of classroom and laboratory training should be required? Provide the basis for the number of hours. If not hours, explain how this training should be quantified. [Note: The topics currently required in the regulations to be included in the classroom and laboratory training and work experience are listed in 10 CFR 35.390, 35.392, 35.394, and 35.396.]
 - ii. Work experience - What should the work experience requirement involve? How many hours of work experience should be required and what is the minimum number of patient or human research subject administrations that an individual must perform? Provide the basis for the number of hours and administrations. What should be the qualifications of the supervising individual?
 - iii. Competency - How should competency be evaluated? Should a written and/or practical examination by an independent examining committee be administered? Provide a rationale for your answer.
- b. Should a preceptor attestation be required for the fundamental T&E? Provide a rationale for your answer.
- c. Should the radiopharmaceutical manufacturer be able to provide the preceptor attestation? Provide a rational for your answer.

- d. Who should establish and administer the curriculum and examination? Provide specific group(s). [Some options are: NRC, medical specialty boards, medical professional societies, educational professional groups, and NRC in collaboration with any or more of the aforementioned groups.]
- e. Should AU competency be periodically assessed? If so, how should it be assessed, how often, and by whom?

B. NRC's Recognition of Medical Specialty Boards

The NRC is requesting comments on its recognition of medical specialty boards. The NRC's procedures for recognizing medical specialty boards are located on the Medical Uses Licensee Toolkit Web site (<https://www.nrc.gov/materials/miau/med-use-toolkit/certif-process-boards.html>). The NRC staff periodically reviews information to determine a board's continued eligibility for recognition.

- 1. What boards other than those already recognized by the NRC (American Board of Nuclear Medicine [ABNM], American Board of Radiology [ABR], American Osteopathic Board of Radiology [AOBR], Certification Board of Nuclear Endocrinology [CBNE]) could be considered for recognition for medical uses under 10 CFR 35.300?
- 2. Are the current NRC medical specialty board recognition criteria sufficient? If not, what additional criteria should the NRC use?

C. Patient Access

The NRC is requesting comments on whether there is a shortage in the number of AUs for 10 CFR 35.300.

1. Is there a shortage in the number of AUs for medical uses under 10 CFR 35.300? If so, is the shortage associated with the use of a specific radiopharmaceutical? Explain how.
2. Are there certain geographic areas with an inadequate number of AUs? Identify these areas.
3. Do current NRC regulations on AU T&E requirements unnecessarily limit patient access to procedures involving radiopharmaceuticals? Explain how.
4. Do current NRC regulations on AU T&E requirements unnecessarily limit research and development in nuclear medicine? Explain how.

D. Other Suggested Changes to the T&E Regulations

In 2002, the NRC revised its regulatory framework for medical use. The goal was to focus the NRC's regulations on those medical procedures that pose the highest risk to workers, the general public, patients, and human research subjects and to structure the regulations to be more risk-informed and more performance-based. The 2002 rule reduced the unnecessary regulatory burden by either reducing or eliminating the prescriptiveness of some regulations. Instead, the rule provided for a performance-based approach that relied on the training and experience of the AUs, authorized nuclear pharmacists, and radiation safety officers. The NRC is requesting comments on whether there are any other changes to the T&E regulations in 10 CFR part 35 that should be considered. Please discuss your suggested changes.

1. Should the NRC regulate the T&E of physicians for medical uses?
2. Are there requirements in the NRC's T&E regulatory framework for physicians that are non-safety related?

3. How can the NRC transform its regulatory approach for T&E while still ensuring that adequate protection is maintained for workers, the general public, patients, and human research subjects?

Dated at Rockville, Maryland, this 23rd day of October 2018.

For the Nuclear Regulatory
Commission.

/RA/

Daniel S. Collins, Director,
Division of Materials Safety,
Security,
State, and Tribal Programs,
Office of Nuclear Material Safety
and Safeguards.



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

November 2, 2018

Dr. Kayla Valentino
Chair, Radiological & Health Professions
Manhattan College
4513 Manhattan College Parkway
Riverdale, NY 10471

Via e-mail to kayla.valentino@manhattan.edu

SUBJECT: TRAINING AND EXPERIENCE REQUIREMENTS FOR DIFFERENT CATEGORIES OF RADIOPHARMACEUTICALS

Dear Dr. Valentino,

The U.S. Nuclear Regulatory Commission (NRC) is evaluating its regulations related to the training and experience (T&E) required for a physician to become an authorized user for medical uses under Subpart E, “Unsealed Byproduct Material—Written Directive Required,” of [Title 10 of the Code of Federal Regulations \(10 CFR\) Part 35, “Medical Use of Byproduct Material.”](#)

The T&E requirements in Subpart E of 10 CFR Part 35 provide three ways that a physician can be authorized to administer unsealed byproduct materials or radiopharmaceuticals requiring a written directive:

1. A physician can be certified by a medical specialty board, whose certification process is recognized by the NRC or an Agreement State.
2. A physician can complete a structured educational program and supervised work experience under an alternate pathway. This alternate pathway includes a requirement for 700 hours of training and experience, which consists of a minimum of 200 hours of classroom and laboratory training and 500 hours of supervised work experience.
3. A physician can be authorized if previously identified as an authorized user on an NRC or Agreement State license or permit (i.e., grandfathered).

In its evaluation of the T&E requirements, the NRC staff is considering whether an additional pathway should be created or if the alternate pathway should be revised. Specifically, the staff is evaluating: (1) whether it makes sense to establish tailored T&E requirements for different categories of radiopharmaceuticals; (2) how those categories should be determined; (3) what the appropriate T&E requirements would be for each category; and (4) whether those requirements should be based on hours of training and experience, or focused more on competency.

On October 29, 2018, the NRC published a series of questions on T&E in the *Federal Register* (83 FR 54380). The *Federal Register* notice is enclosed with this letter and can also be accessed at: <https://www.gpo.gov/fdsys/pkg/FR-2018-10-29/pdf/2018-23521.pdf>. The NRC will carefully consider responses to these questions and would appreciate your feedback on whether changes to the current T&E regulations are warranted. The comment period for the T&E evaluation will end on January 29, 2019. Please follow the directions in the notice on how to submit written comments. The NRC is using the Federal rulemaking Web site, [Regulations.gov](#), to accept written comments on the docket (NRC-2018-0230).

The NRC will also conduct four public meetings scheduled for November 14 and December 11, 2018, and January 10 and January 22, 2019, and will accept oral comments provided during the meetings. The meetings on December 11 and January 10 will be held at NRC Headquarters in Rockville, MD, and all four meetings will be accessible for remote participation by moderated bridge line and webinar. The NRC's public meeting page has been updated with meeting details and registration instructions for each meeting: <https://www.nrc.gov/pmns/mtg>.

Additional information on the NRC's T&E evaluation can be found at: <https://www.nrc.gov/materials/miau/med-use-toolkit/training-experience-evaluation.html>. If you have any questions on this correspondence, please contact Sarah Lopas of my staff at (301) 415-6360 or Sarah.Lopas@nrc.gov.

A handwritten signature in black ink, appearing to read "C Einberg".

Christian Einberg, Chief
Medical Safety and Events Assessment Branch
Division of Materials Safety, Security, State
and Tribal Programs
Office of Nuclear Material Safety
and Safeguards

Enclosure:
Training and Experience
Federal Register notice

NUCLEAR REGULATORY COMMISSION

[NRC-2018-0230]

**Training and Experience Requirements for Different Categories of
Radiopharmaceuticals**

AGENCY: Nuclear Regulatory Commission.

ACTION: Training and experience requirements; request for comment.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is requesting comments on its training and experience (T&E) requirements. Specifically, the NRC would like input on whether it should establish tailored T&E requirements for different categories of radiopharmaceuticals for which a written directive is required in accordance with its regulations. The input will be used to determine whether significant regulatory changes to the NRC's T&E requirements for authorized users (AUs) are warranted.

DATES: Submit comments by January 29, 2019. Comments received after this date will be considered if it is practical to do so, but the NRC is only able to ensure consideration for comments received on or before this date.

ADDRESSES: You may submit comments by any of the following methods:

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and search for Docket ID **NRC-2018-0230**. Address questions about Docket IDs in Regulations.gov to Jennifer Borges; telephone: 301-287-9127; e-mail: Jennifer.Borges@nrc.gov. For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.

- **Mail comments to:** May Ma, Office of Administration, Mail Stop: TWFN-7-A60M, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001.

For additional direction on obtaining information and submitting comments, see “Obtaining Information and Submitting Comments” in the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: Sarah Lopas, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001; telephone: 301-415-6360, e-mail: Sarah.Lopas@nrc.gov.

SUPPLEMENTARY INFORMATION:

I. Obtaining Information and Submitting Comments

A. Obtaining Information

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B. Submitting Comments

Please include Docket ID **NRC-2018-0230** in your comment submission.

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radionuclides or by delivery method), (3) what the appropriate T&E requirements would be for each category, and (4) whether those requirements should be based on hours of T&E or focused more on competency. In response to the SRM, the NRC staff documented its initial results, status, and next steps related to this evaluation in SECY-18-0084, "Staff Evaluation of Training and Experience Requirements for Administering Different Categories of Radiopharmaceuticals in Response to SRM-M170817" (ADAMS Accession No. ML18135A276). In SECY-18-0084, the staff concluded that additional outreach with the medical community is needed to determine whether and how to tailor the T&E requirements to establish a limited AU status, the specific T&E requirements that should apply, how the T&E requirements should be met (e.g., hours of training, demonstration of competency), and whether a competency-based approach makes sense for the T&E requirements for all the medical uses authorized under 10 CFR 35.300, "Use of unsealed byproduct material for which a written directive is required."

The NRC is interested in obtaining input from as many stakeholders as possible, including members of the Advisory Committee on the Medical Uses of Isotopes, professional organizations, physicians, patients, patient advocacy groups, licensees, Agreement States, and other interested individuals. The focus of this request is to gather information that will permit the NRC staff to determine whether changes to the T&E requirements are warranted for different categories of radiopharmaceuticals for physicians seeking AU status for the medical use of specific categories of radiopharmaceuticals requiring a written directive under 10 CFR 35.300.

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III. Specific Requests for Comments

A. Tailored Training & Experience Requirements

The NRC is requesting comments on whether it should establish tailored T&E requirements for different categories of radiopharmaceuticals for physicians seeking AU status for the medical use of specific categories of radiopharmaceuticals requiring a written directive under 10 CFR 35.300 (i.e., a limited AU status). This would be for physicians seeking AU status via the alternate non-board certified pathway, and for physicians certified by a medical

specialty board that is not currently recognized by the NRC under 10 CFR 35.390, 35.392, 35.394, or 35.396 (Unsealed Byproduct Material—Written Directive Required).

1. Are the current pathways for obtaining AU status reasonable and accessible? Provide a rationale for your answer.
2. Are the current pathways for obtaining AU status adequate for protecting public health and safety? Provide a rationale for your answer.
3. Should the NRC develop a new tailored T&E pathway for these physicians? If so, what would be the appropriate way to categorize radiopharmaceuticals for tailored T&E requirements? If not, explain why the regulations should remain unchanged. [Some options to categorize radiopharmaceuticals include radiopharmaceuticals with similar delivery methods (oral, parenteral); same type of radiation characteristics or emission (alpha, beta, gamma, low-energy photon); similar preparation method (patient-ready doses); or a combination thereof (e.g., radiopharmaceuticals containing alpha- and beta-emitting radioisotopes that are administered intravenously and are prepared as patient-ready doses).]
4. Should the fundamental T&E required of physicians seeking limited AU status need to have the same fundamental T&E required of physicians seeking full AU status for all oral and parenteral administrations under 10 CFR 35.300?
5. How should the requirements for this fundamental T&E be structured for a specific category of radiopharmaceuticals?
 - a. Describe what the requirements should include:

- i. Classroom and laboratory training – What topics need to be covered in this training requirement? How many hours of classroom and laboratory training should be required? Provide the basis for the number of hours. If not hours, explain how this training should be quantified. [Note: The topics currently required in the regulations to be included in the classroom and laboratory training and work experience are listed in 10 CFR 35.390, 35.392, 35.394, and 35.396.]
 - ii. Work experience - What should the work experience requirement involve? How many hours of work experience should be required and what is the minimum number of patient or human research subject administrations that an individual must perform? Provide the basis for the number of hours and administrations. What should be the qualifications of the supervising individual?
 - iii. Competency - How should competency be evaluated? Should a written and/or practical examination by an independent examining committee be administered? Provide a rationale for your answer.
- b. Should a preceptor attestation be required for the fundamental T&E? Provide a rationale for your answer.
- c. Should the radiopharmaceutical manufacturer be able to provide the preceptor attestation? Provide a rational for your answer.

- d. Who should establish and administer the curriculum and examination? Provide specific group(s). [Some options are: NRC, medical specialty boards, medical professional societies, educational professional groups, and NRC in collaboration with any or more of the aforementioned groups.]
- e. Should AU competency be periodically assessed? If so, how should it be assessed, how often, and by whom?

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The NRC is requesting comments on its recognition of medical specialty boards. The NRC's procedures for recognizing medical specialty boards are located on the Medical Uses Licensee Toolkit Web site (<https://www.nrc.gov/materials/miau/med-use-toolkit/certif-process-boards.html>). The NRC staff periodically reviews information to determine a board's continued eligibility for recognition.

- 1. What boards other than those already recognized by the NRC (American Board of Nuclear Medicine [ABNM], American Board of Radiology [ABR], American Osteopathic Board of Radiology [AOBR], Certification Board of Nuclear Endocrinology [CBNE]) could be considered for recognition for medical uses under 10 CFR 35.300?
- 2. Are the current NRC medical specialty board recognition criteria sufficient? If not, what additional criteria should the NRC use?

C. Patient Access

The NRC is requesting comments on whether there is a shortage in the number of AUs for 10 CFR 35.300.

1. Is there a shortage in the number of AUs for medical uses under 10 CFR 35.300? If so, is the shortage associated with the use of a specific radiopharmaceutical? Explain how.
2. Are there certain geographic areas with an inadequate number of AUs? Identify these areas.
3. Do current NRC regulations on AU T&E requirements unnecessarily limit patient access to procedures involving radiopharmaceuticals? Explain how.
4. Do current NRC regulations on AU T&E requirements unnecessarily limit research and development in nuclear medicine? Explain how.

D. Other Suggested Changes to the T&E Regulations

In 2002, the NRC revised its regulatory framework for medical use. The goal was to focus the NRC's regulations on those medical procedures that pose the highest risk to workers, the general public, patients, and human research subjects and to structure the regulations to be more risk-informed and more performance-based. The 2002 rule reduced the unnecessary regulatory burden by either reducing or eliminating the prescriptiveness of some regulations. Instead, the rule provided for a performance-based approach that relied on the training and experience of the AUs, authorized nuclear pharmacists, and radiation safety officers. The NRC is requesting comments on whether there are any other changes to the T&E regulations in 10 CFR part 35 that should be considered. Please discuss your suggested changes.

1. Should the NRC regulate the T&E of physicians for medical uses?
2. Are there requirements in the NRC's T&E regulatory framework for physicians that are non-safety related?

3. How can the NRC transform its regulatory approach for T&E while still ensuring that adequate protection is maintained for workers, the general public, patients, and human research subjects?

Dated at Rockville, Maryland, this 23rd day of October 2018.

For the Nuclear Regulatory
Commission.

/RA/

Daniel S. Collins, Director,
Division of Materials Safety,
Security,
State, and Tribal Programs,
Office of Nuclear Material Safety
and Safeguards.



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

November 2, 2018

Dr. Robert J. Walker, PhD
Dumke Endowed Chair and Professor
Department of Health Sciences
Weber State University
Marriott Health Sciences Building, Room 363F
3875 Stadium Way, Dept. 3909
Ogden, UT 84408-3909

Via e-mail to rwalker2@weber.edu

**SUBJECT: TRAINING AND EXPERIENCE REQUIREMENTS FOR DIFFERENT
CATEGORIES OF RADIOPHARMACEUTICALS**

Dear Dr. Walker,

The U.S. Nuclear Regulatory Commission (NRC) is evaluating its regulations related to the training and experience (T&E) required for a physician to become an authorized user for medical uses under Subpart E, “Unsealed Byproduct Material—Written Directive Required,” of [Title 10 of the Code of Federal Regulations \(10 CFR\) Part 35, “Medical Use of Byproduct Material.”](#)

The T&E requirements in Subpart E of 10 CFR Part 35 provide three ways that a physician can be authorized to administer unsealed byproduct materials or radiopharmaceuticals requiring a written directive:

1. A physician can be certified by a medical specialty board, whose certification process is recognized by the NRC or an Agreement State.
2. A physician can complete a structured educational program and supervised work experience under an alternate pathway. This alternate pathway includes a requirement for 700 hours of training and experience, which consists of a minimum of 200 hours of classroom and laboratory training and 500 hours of supervised work experience.
3. A physician can be authorized if previously identified as an authorized user on an NRC or Agreement State license or permit (i.e., grandfathered).

In its evaluation of the T&E requirements, the NRC staff is considering whether an additional pathway should be created or if the alternate pathway should be revised. Specifically, the staff is evaluating: (1) whether it makes sense to establish tailored T&E requirements for different categories of radiopharmaceuticals; (2) how those categories should be determined; (3) what the appropriate T&E requirements would be for each category; and (4) whether those requirements should be based on hours of training and experience, or focused more on competency.

On October 29, 2018, the NRC published a series of questions on T&E in the *Federal Register* (83 FR 54380). The *Federal Register* notice is enclosed with this letter and can also be accessed at: <https://www.gpo.gov/fdsys/pkg/FR-2018-10-29/pdf/2018-23521.pdf>. The NRC will carefully consider responses to these questions and would appreciate your feedback on whether changes to the current T&E regulations are warranted. The comment period for the T&E evaluation will end on January 29, 2019. Please follow the directions in the notice on how to submit written comments. The NRC is using the Federal rulemaking Web site, [Regulations.gov](#), to accept written comments on the docket (NRC-2018-0230).

The NRC will also conduct four public meetings scheduled for November 14 and December 11, 2018, and January 10 and January 22, 2019, and will accept oral comments provided during the meetings. The meetings on December 11 and January 10 will be held at NRC Headquarters in Rockville, MD, and all four meetings will be accessible for remote participation by moderated bridge line and webinar. The NRC's public meeting page has been updated with meeting details and registration instructions for each meeting: <https://www.nrc.gov/pmns/mtg>.

Additional information on the NRC's T&E evaluation can be found at: <https://www.nrc.gov/materials/miau/med-use-toolkit/training-experience-evaluation.html>. If you have any questions on this correspondence, please contact Sarah Lopas of my staff at (301) 415-6360 or Sarah.Lopas@nrc.gov.

A handwritten signature in black ink, appearing to read "C Einberg".

Christian Einberg, Chief
Medical Safety and Events Assessment Branch
Division of Materials Safety, Security, State
and Tribal Programs
Office of Nuclear Material Safety
and Safeguards

Enclosure:
Training and Experience
Federal Register notice

NUCLEAR REGULATORY COMMISSION

[NRC-2018-0230]

**Training and Experience Requirements for Different Categories of
Radiopharmaceuticals**

AGENCY: Nuclear Regulatory Commission.

ACTION: Training and experience requirements; request for comment.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is requesting comments on its training and experience (T&E) requirements. Specifically, the NRC would like input on whether it should establish tailored T&E requirements for different categories of radiopharmaceuticals for which a written directive is required in accordance with its regulations. The input will be used to determine whether significant regulatory changes to the NRC's T&E requirements for authorized users (AUs) are warranted.

DATES: Submit comments by January 29, 2019. Comments received after this date will be considered if it is practical to do so, but the NRC is only able to ensure consideration for comments received on or before this date.

ADDRESSES: You may submit comments by any of the following methods:

- **Federal Rulemaking Web Site:** Go to <http://www.regulations.gov>

and search for Docket ID **NRC-2018-0230**. Address questions about Docket IDs in Regulations.gov to Jennifer Borges; telephone: 301-287-9127; e-mail: Jennifer.Borges@nrc.gov. For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.

- **Mail comments to:** May Ma, Office of Administration, Mail Stop: TWFN-7-A60M, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001.

For additional direction on obtaining information and submitting comments, see “Obtaining Information and Submitting Comments” in the **SUPPLEMENTARY INFORMATION** section of this document.

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SUPPLEMENTARY INFORMATION:

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B. Submitting Comments

Please include Docket ID **NRC-2018-0230** in your comment submission.

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II. Background

On August 17, 2017, the Commission issued a staff requirements memorandum (SRM), SRM-M170817 (ADAMS Accession No. ML17229B284), approving the final rule revising parts 30, 32, and 35 of title 10 of the *Code of Federal Regulations* (10 CFR), "Medical Use of Byproduct Material – Medical Event Definitions, Training and Experience, and Clarifying Amendments," and directing the staff to evaluate (1) whether it makes sense to establish tailored T&E requirements for different categories of radiopharmaceuticals, (2) how those categories should be determined (such as by risks posed by groups of

radionuclides or by delivery method), (3) what the appropriate T&E requirements would be for each category, and (4) whether those requirements should be based on hours of T&E or focused more on competency. In response to the SRM, the NRC staff documented its initial results, status, and next steps related to this evaluation in SECY-18-0084, "Staff Evaluation of Training and Experience Requirements for Administering Different Categories of Radiopharmaceuticals in Response to SRM-M170817" (ADAMS Accession No. ML18135A276). In SECY-18-0084, the staff concluded that additional outreach with the medical community is needed to determine whether and how to tailor the T&E requirements to establish a limited AU status, the specific T&E requirements that should apply, how the T&E requirements should be met (e.g., hours of training, demonstration of competency), and whether a competency-based approach makes sense for the T&E requirements for all the medical uses authorized under 10 CFR 35.300, "Use of unsealed byproduct material for which a written directive is required."

The NRC is interested in obtaining input from as many stakeholders as possible, including members of the Advisory Committee on the Medical Uses of Isotopes, professional organizations, physicians, patients, patient advocacy groups, licensees, Agreement States, and other interested individuals. The focus of this request is to gather information that will permit the NRC staff to determine whether changes to the T&E requirements are warranted for different categories of radiopharmaceuticals for physicians seeking AU status for the medical use of specific categories of radiopharmaceuticals requiring a written directive under 10 CFR 35.300.

During the comment period between October 29, 2018 and January 29, 2019, the NRC will hold four public meetings that will discuss the information being requested and to accept comments on the docket. All four public meetings

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1. Are the current pathways for obtaining AU status reasonable and accessible? Provide a rationale for your answer.
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- d. Who should establish and administer the curriculum and examination? Provide specific group(s). [Some options are: NRC, medical specialty boards, medical professional societies, educational professional groups, and NRC in collaboration with any or more of the aforementioned groups.]
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1. Is there a shortage in the number of AUs for medical uses under 10 CFR 35.300? If so, is the shortage associated with the use of a specific radiopharmaceutical? Explain how.
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1. Should the NRC regulate the T&E of physicians for medical uses?
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Dated at Rockville, Maryland, this 23rd day of October 2018.

For the Nuclear Regulatory
Commission.

/RA/

Daniel S. Collins, Director,
Division of Materials Safety,
Security,
State, and Tribal Programs,
Office of Nuclear Material Safety
and Safeguards.



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

November 2, 2018

Dr. J. Lynne Williams
Nuclear Medicine Technology
Department of Clinical and Diagnostic Sciences
Oakland University
433 Meadow Brook Rd.
Rochester, MI 48309-4452

Via e-mail to jwillia@oakland.edu

SUBJECT: TRAINING AND EXPERIENCE REQUIREMENTS FOR DIFFERENT CATEGORIES OF RADIOPHARMACEUTICALS

Dear Dr. Williams,

The U.S. Nuclear Regulatory Commission (NRC) is evaluating its regulations related to the training and experience (T&E) required for a physician to become an authorized user for medical uses under Subpart E, “Unsealed Byproduct Material—Written Directive Required,” of [Title 10 of the Code of Federal Regulations \(10 CFR\) Part 35, “Medical Use of Byproduct Material.”](#)

The T&E requirements in Subpart E of 10 CFR Part 35 provide three ways that a physician can be authorized to administer unsealed byproduct materials or radiopharmaceuticals requiring a written directive:

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In its evaluation of the T&E requirements, the NRC staff is considering whether an additional pathway should be created or if the alternate pathway should be revised. Specifically, the staff is evaluating: (1) whether it makes sense to establish tailored T&E requirements for different categories of radiopharmaceuticals; (2) how those categories should be determined; (3) what the appropriate T&E requirements would be for each category; and (4) whether those requirements should be based on hours of training and experience, or focused more on competency.

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Additional information on the NRC's T&E evaluation can be found at: <https://www.nrc.gov/materials/miau/med-use-toolkit/training-experience-evaluation.html>. If you have any questions on this correspondence, please contact Sarah Lopas of my staff at (301) 415-6360 or Sarah.Lopas@nrc.gov.

A handwritten signature in black ink, appearing to read "C Einberg".

Christian Einberg, Chief
Medical Safety and Events Assessment Branch
Division of Materials Safety, Security, State
and Tribal Programs
Office of Nuclear Material Safety
and Safeguards

Enclosure:
Training and Experience
Federal Register notice

NUCLEAR REGULATORY COMMISSION

[NRC-2018-0230]

**Training and Experience Requirements for Different Categories of
Radiopharmaceuticals**

AGENCY: Nuclear Regulatory Commission.

ACTION: Training and experience requirements; request for comment.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is requesting comments on its training and experience (T&E) requirements. Specifically, the NRC would like input on whether it should establish tailored T&E requirements for different categories of radiopharmaceuticals for which a written directive is required in accordance with its regulations. The input will be used to determine whether significant regulatory changes to the NRC's T&E requirements for authorized users (AUs) are warranted.

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specialty board that is not currently recognized by the NRC under 10 CFR 35.390, 35.392, 35.394, or 35.396 (Unsealed Byproduct Material—Written Directive Required).

1. Are the current pathways for obtaining AU status reasonable and accessible? Provide a rationale for your answer.
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3. Should the NRC develop a new tailored T&E pathway for these physicians? If so, what would be the appropriate way to categorize radiopharmaceuticals for tailored T&E requirements? If not, explain why the regulations should remain unchanged. [Some options to categorize radiopharmaceuticals include radiopharmaceuticals with similar delivery methods (oral, parenteral); same type of radiation characteristics or emission (alpha, beta, gamma, low-energy photon); similar preparation method (patient-ready doses); or a combination thereof (e.g., radiopharmaceuticals containing alpha- and beta-emitting radioisotopes that are administered intravenously and are prepared as patient-ready doses).]
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 - iii. Competency - How should competency be evaluated? Should a written and/or practical examination by an independent examining committee be administered? Provide a rationale for your answer.
- b. Should a preceptor attestation be required for the fundamental T&E? Provide a rationale for your answer.
- c. Should the radiopharmaceutical manufacturer be able to provide the preceptor attestation? Provide a rational for your answer.

- d. Who should establish and administer the curriculum and examination? Provide specific group(s). [Some options are: NRC, medical specialty boards, medical professional societies, educational professional groups, and NRC in collaboration with any or more of the aforementioned groups.]
- e. Should AU competency be periodically assessed? If so, how should it be assessed, how often, and by whom?

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The NRC is requesting comments on its recognition of medical specialty boards. The NRC's procedures for recognizing medical specialty boards are located on the Medical Uses Licensee Toolkit Web site (<https://www.nrc.gov/materials/miau/med-use-toolkit/certif-process-boards.html>). The NRC staff periodically reviews information to determine a board's continued eligibility for recognition.

- 1. What boards other than those already recognized by the NRC (American Board of Nuclear Medicine [ABNM], American Board of Radiology [ABR], American Osteopathic Board of Radiology [AOBR], Certification Board of Nuclear Endocrinology [CBNE]) could be considered for recognition for medical uses under 10 CFR 35.300?
- 2. Are the current NRC medical specialty board recognition criteria sufficient? If not, what additional criteria should the NRC use?

C. Patient Access

The NRC is requesting comments on whether there is a shortage in the number of AUs for 10 CFR 35.300.

1. Is there a shortage in the number of AUs for medical uses under 10 CFR 35.300? If so, is the shortage associated with the use of a specific radiopharmaceutical? Explain how.
2. Are there certain geographic areas with an inadequate number of AUs? Identify these areas.
3. Do current NRC regulations on AU T&E requirements unnecessarily limit patient access to procedures involving radiopharmaceuticals? Explain how.
4. Do current NRC regulations on AU T&E requirements unnecessarily limit research and development in nuclear medicine? Explain how.

D. Other Suggested Changes to the T&E Regulations

In 2002, the NRC revised its regulatory framework for medical use. The goal was to focus the NRC's regulations on those medical procedures that pose the highest risk to workers, the general public, patients, and human research subjects and to structure the regulations to be more risk-informed and more performance-based. The 2002 rule reduced the unnecessary regulatory burden by either reducing or eliminating the prescriptiveness of some regulations. Instead, the rule provided for a performance-based approach that relied on the training and experience of the AUs, authorized nuclear pharmacists, and radiation safety officers. The NRC is requesting comments on whether there are any other changes to the T&E regulations in 10 CFR part 35 that should be considered. Please discuss your suggested changes.

1. Should the NRC regulate the T&E of physicians for medical uses?
2. Are there requirements in the NRC's T&E regulatory framework for physicians that are non-safety related?

3. How can the NRC transform its regulatory approach for T&E while still ensuring that adequate protection is maintained for workers, the general public, patients, and human research subjects?

Dated at Rockville, Maryland, this 23rd day of October 2018.

For the Nuclear Regulatory
Commission.

/RA/

Daniel S. Collins, Director,
Division of Materials Safety,
Security,
State, and Tribal Programs,
Office of Nuclear Material Safety
and Safeguards.



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

November 2, 2018

Ms. Amy Wride-Graney
American Board of Health Physics
1313 Dolley Madison Blvd., Suite 402
McLean , VA 22101

Via e-mail to awride-graney@burkinc.com

SUBJECT: TRAINING AND EXPERIENCE REQUIREMENTS FOR DIFFERENT CATEGORIES OF RADIOPHARMACEUTICALS

Dear Ms. Wride-Graney,

The U.S. Nuclear Regulatory Commission (NRC) is evaluating its regulations related to the training and experience (T&E) required for a physician to become an authorized user for medical uses under Subpart E, “Unsealed Byproduct Material—Written Directive Required,” of [Title 10 of the Code of Federal Regulations \(10 CFR\) Part 35, “Medical Use of Byproduct Material.”](#)

The T&E requirements in Subpart E of 10 CFR Part 35 provide three ways that a physician can be authorized to administer unsealed byproduct materials or radiopharmaceuticals requiring a written directive:

1. A physician can be certified by a medical specialty board, whose certification process is recognized by the NRC or an Agreement State.
2. A physician can complete a structured educational program and supervised work experience under an alternate pathway. This alternate pathway includes a requirement for 700 hours of training and experience, which consists of a minimum of 200 hours of classroom and laboratory training and 500 hours of supervised work experience.
3. A physician can be authorized if previously identified as an authorized user on an NRC or Agreement State license or permit (i.e., grandfathered).

In its evaluation of the T&E requirements, the NRC staff is considering whether an additional pathway should be created or if the alternate pathway should be revised. Specifically, the staff is evaluating: (1) whether it makes sense to establish tailored T&E requirements for different categories of radiopharmaceuticals; (2) how those categories should be determined; (3) what the appropriate T&E requirements would be for each category; and (4) whether those requirements should be based on hours of training and experience, or focused more on competency.

On October 29, 2018, the NRC published a series of questions on T&E in the *Federal Register* (83 FR 54380). The *Federal Register* notice is enclosed with this letter and can also be accessed at: <https://www.gpo.gov/fdsys/pkg/FR-2018-10-29/pdf/2018-23521.pdf>. The NRC will carefully consider responses to these questions and would appreciate your feedback on whether changes to the current T&E regulations are warranted. The comment period for the T&E evaluation will end on January 29, 2019. Please follow the directions in the notice on how to submit written comments. The NRC is using the Federal rulemaking Web site, [Regulations.gov](#), to accept written comments on the docket (NRC-2018-0230).

The NRC will also conduct four public meetings scheduled for November 14 and December 11, 2018, and January 10 and January 22, 2019, and will accept oral comments provided during the meetings. The meetings on December 11 and January 10 will be held at NRC Headquarters in Rockville, MD, and all four meetings will be accessible for remote participation by moderated bridge line and webinar. The NRC's public meeting page has been updated with meeting details and registration instructions for each meeting: <https://www.nrc.gov/pmns/mtg>.

Additional information on the NRC's T&E evaluation can be found at: <https://www.nrc.gov/materials/miau/med-use-toolkit/training-experience-evaluation.html>. If you have any questions on this correspondence, please contact Sarah Lopas of my staff at (301) 415-6360 or Sarah.Lopas@nrc.gov.

A handwritten signature in black ink, appearing to read "C Einberg".

Christian Einberg, Chief
Medical Safety and Events Assessment Branch
Division of Materials Safety, Security, State
and Tribal Programs
Office of Nuclear Material Safety
and Safeguards

Enclosure:
Training and Experience
Federal Register notice

NUCLEAR REGULATORY COMMISSION

[NRC-2018-0230]

**Training and Experience Requirements for Different Categories of
Radiopharmaceuticals**

AGENCY: Nuclear Regulatory Commission.

ACTION: Training and experience requirements; request for comment.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is requesting comments on its training and experience (T&E) requirements. Specifically, the NRC would like input on whether it should establish tailored T&E requirements for different categories of radiopharmaceuticals for which a written directive is required in accordance with its regulations. The input will be used to determine whether significant regulatory changes to the NRC's T&E requirements for authorized users (AUs) are warranted.

DATES: Submit comments by January 29, 2019. Comments received after this date will be considered if it is practical to do so, but the NRC is only able to ensure consideration for comments received on or before this date.

ADDRESSES: You may submit comments by any of the following methods:

- **Federal Rulemaking Web Site:** Go to <http://www.regulations.gov>

and search for Docket ID **NRC-2018-0230**. Address questions about Docket IDs in Regulations.gov to Jennifer Borges; telephone: 301-287-9127; e-mail: Jennifer.Borges@nrc.gov. For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.

- **Mail comments to:** May Ma, Office of Administration, Mail Stop: TWFN-7-A60M, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001.

For additional direction on obtaining information and submitting comments, see “Obtaining Information and Submitting Comments” in the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: Sarah Lopas, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001; telephone: 301-415-6360, e-mail: Sarah.Lopas@nrc.gov.

SUPPLEMENTARY INFORMATION:

I. Obtaining Information and Submitting Comments

A. Obtaining Information

Please refer to Docket ID **NRC-2018-0230** when contacting the NRC about the availability of information for this action. You may obtain publicly-available information related to this action by any of the following methods:

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- **NRC’s Agencywide Documents Access and Management System (ADAMS):** You may obtain publicly-available documents online in the ADAMS Public Documents collection at <http://www.nrc.gov/reading-rm/adams.html>. To begin the search, select “[Begin Web-based ADAMS Search](#).” For problems with ADAMS, please contact the NRC’s Public Document Room (PDR) reference staff at 1-800-397-4209, 301-415-4737, or by e-mail to pdr.resource@nrc.gov. The ADAMS accession number for each document referenced is provided the first time that it is mentioned in the **SUPPLEMENTARY INFORMATION** section.

- **NRC's PDR:** You may examine and purchase copies of public documents at the NRC's PDR, Room O1-F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.

B. Submitting Comments

Please include Docket ID **NRC-2018-0230** in your comment submission.

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