revised to address the comments received.

III. Finding of No Significant Impact

Based on its review of the proposed action, as documented in the EA, the NRC staff concludes that the renewal of License SUC–1591 with an expanded scope of authorized activities will not have a significant effect on the quality of the human environment. Therefore, the NRC staff has determined not to prepare an EIS for the proposed action and that, pursuant to 10 CFR 51.32, a finding of no significant impact is appropriate.

Dated at Rockville, Maryland, on October 23, 2018.

For the Nuclear Regulatory Commission.

Brian W. Smith,

Acting Director, Division of Fuel Cycle Safety, Safeguards and Environmental Review, Office of Nuclear Material Safety and Safeguards.

[FR Doc. 2018–23509 Filed 10–26–18; 8:45 am]

BILLING CODE 7590–01–P

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 Website:* 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; email: *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, email: *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 Website:* Go to *http://www.regulations.gov* and search for Docket ID NRC–2018–0230.
- *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 email 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 website at least 10 calendar days before the meeting. Members of the public should monitor the NRC's public meeting website at *https://www.nrc.gov/pmns/mtg.* The NRC will also post the meeting notices on the Federal Rulemaking website 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 website. The Federal Rulemaking website 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 Email 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 website (*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.

Daniel S. Collins,

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

[FR Doc. 2018–23521 Filed 10–26–18; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[NRC–2018–0062]

Information Collection: Physical Protection of Category 1 and Category 2 Quantities of Radioactive Material

AGENCY: Nuclear Regulatory Commission.

ACTION: Renewal of existing information collection; request for comment.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) invites public comment on the renewal of Office of Management and Budget (OMB) approval for an existing collection of information. The information collection is entitled, ''Physical Protection of Category 1 and Category 2 Quantities of Radioactive Material.''

DATES: Submit comments by December 28, 2018. Comments received after this date will be considered if it is practical to do so, but the Commission is able to ensure consideration only for comments received on or before this date.

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

- *Federal Rulemaking Website:* Go to *http://www.regulations.gov* and search for Docket ID NRC–2018–0062. Address questions about Docket IDs in *Regulations.gov* to Jennifer Borges; telephone: 301–287–9127; email: *Jennifer.Borges@nrc.gov.* For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.
- *Mail comments to:* David Cullison, Office of the Chief Information Officer, Mail Stop: T–2 F43, 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: David Cullison, Office of the Chief Information Officer, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–415–2084; email: *INFOCOLLECTS.Resource@nrc.gov.*

SUPPLEMENTARY INFORMATION:

I. Obtaining Information and Submitting Comments

A. Obtaining Information

Please refer to Docket ID NRC–2018–0062 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 Website:* Go to *http://www.regulations.gov* and search for Docket ID NRC–2018–0062.
- *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 email to *pdr.resource@nrc.gov.* The supporting statement associated with the part 37 information collections, the burden table, and the NRC Form 755 are available in ADAMS under Accession Nos. ML18172A301, ML18172A300, and ML18295A594.
- *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.
- *NRC's Clearance Officer:* A copy of the collection of information and related instructions may be obtained without charge by contacting the NRC's Clearance Officer, David Cullison, Office of the Chief Information Officer, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–415–2084; email: *INFOCOLLECTS.Resource@nrc.gov.*

B. Submitting Comments

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 OMB, 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 submissions into ADAMS.

II. Background

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35), the NRC is requesting public comment on its intention to request the OMB's approval for the information collection summarized in this section.

1. *The title of the information collection:* 10 CFR part 37, Physical Protection of Category 1 and Category 2 Quantities of Radioactive Material.''

2. *OMB approval number:* 3150–0214.

3. *Type of submission:* Revision.

4. *The form number, if applicable:* NRC Form 755, ''Notification to the NRC