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

May 23, 2019

ALL AGREEMENT STATES, VERMONT

U.S. NUCLEAR REGULATORY COMMISSION *FEDERAL REGISTER* NOTICE EXTENDING THE PUBLIC COMMENT PERIOD ON DRAFT APPROACHES REGARDING TRAINING AND EXPERIENCE REQUIREMENTS FOR RADIOPHARMACEUTICALS (STC-19-029)

Purpose: To inform the Agreement States that the U.S. Nuclear Regulatory Commission (NRC), Office of Nuclear Material Safety and Safeguards: (1) published a notice in the *Federal Register* on May 23, 2019, extending the public comment period on draft approaches regarding training and experience (T&E) requirements for radiopharmaceuticals (84 FRN 23812); and (2) plans to hold a webinar on the draft approaches with the Agreement States on May 30, 2019.

Background: On May 2, 2019, the NRC published a notice in the *Federal Register* (84 FR 18874) requesting comments on draft approaches the staff developed regarding the T&E requirements for radiopharmaceuticals requiring a written directive. The NRC notified the Agreement States of this *Federal Register* notice (FRN) in a State and Tribal Communication letter dated May 3, 2019 (STC-19-023). The comment period was originally scheduled to end on June 3, 2019.

Discussion: In response to several requests from medical stakeholders, the NRC is extending the comment period to **July 3, 2019**, to allow more time for Agreement State, stakeholders, and members of the public to submit their comments. The FRN announcing the extension is enclosed with this letter and can also be accessed at https://www.federalregister.gov/documents/2019/05/23/2019-10760/draft-approaches-for-addressing-training-and-experience-requirements-for-radiopharmaceuticals.

The NRC is also planning to conduct a webinar for the Agreement States on the draft approaches outlined in the May 2, 2019 FRN. The Agreement States webinar will be held on May 30, 2019, from 2:00 p.m. to 4:00 p.m. EDT. Participation details will be provided to the Agreement States in a forthcoming RCPD letter.

If you have any questions on this correspondence, please contact me at (301) 415-3340, or the individuals named below:

POINT OF CONTACT: Sarah Lopas E-MAIL: Sarah.Lopas@nrc.gov
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/RA/

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

Enclosure:
Training and Experience
Draft Approaches *Federal Register* notice

[7590-01-P]

NUCLEAR REGULATORY COMMISSION

[NRC-2018-0230]

Draft Approaches for Addressing Training and Experience Requirements for Radiopharmaceuticals Requiring a Written Directive

AGENCY: Nuclear Regulatory Commission.

ACTION: Request for comment; extension of comment period.

SUMMARY: On May 2, 2019, the U.S. Nuclear Regulatory Commission (NRC) requested comments on draft approaches regarding the training and experience (T&E) requirements for radiopharmaceuticals requiring a written directive. The public comment period was originally scheduled to close on June 3, 2019. The NRC is extending the comment period to July 3, 2019, to allow more time for stakeholders and members of the public to submit their comments.

DATES: The due date of comments requested in the notice published on May 2, 2019 (84 FR 18874) is extended. Comments should be submitted no later than July 3, 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 NRC 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:** Office of Administration, Mail Stop: TWFN-7-A60M, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, ATTN: Program Management, Announcements and Editing Staff.

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**.

- **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. Discussion

On May 2, 2019, the NRC published a notice in the *Federal Register* (84 FR 18874) requesting comments on draft approaches the staff developed regarding the T&E requirements for radiopharmaceuticals requiring a written directive. The public comment period was originally scheduled to close on June 3, 2019. By letter dated May 13, 2019 (ADAMS Accession No. ML19136A236), the American College of Radiology, the American Society for Radiation Oncology, and the Society of Nuclear Medicine and Molecular Imaging jointly requested a 30-day extension to the public comment period. United Pharmacy Partners, Inc. also submitted a request for extension by letter dated

May 14, 2019 (ADAMS Accession No. ML19136A238). Additional requests for an extension to the public comment period were also heard during a May 14, 2019, public comment meeting. The NRC is granting this request and will extend the public comment period until July 3, 2019, to allow more time for medical and regulatory stakeholders and members of the public to submit their comments.

Dated at Rockville, Maryland, this 17th day of May 2019.

For the Nuclear Regulatory Commission.

/RA/

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