

NUCLEAR REGULATORY COMMISSION

[NRC-2017-0094]

Patient Release Program

AGENCY: Nuclear Regulatory Commission.

ACTION: Request for comment.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is requesting comment from the general public on its patient release programs. Specifically, the NRC would like input from the public on whether additional or alternate criteria are needed and whether to clarify the NRC's current patient release requirements. The information will be used to determine whether significant regulatory changes to the NRC's patient release requirements are warranted.

DATES: Submit comments by June 12, 2017. Comments received after this date will be considered if it is practical to do so, but the NRC is able to assure consideration only for comments received on or before this date.

ADDRESSES: You may submit comments by any of the following methods (unless this document describes a different method for submitting comments on a specific subject):

- **Federal Rulemaking Web Site:** Go to <http://www.regulations.gov> and search for Docket ID **NRC-2017-0094**. Address questions about NRC dockets to Carol Gallagher; telephone: 301-415-3463; e-mail: Carol.Gallagher@nrc.gov. For technical questions, contact the individual listed in the FOR FURTHER INFORMATION CONTACT section of this document.

- **Mail comments to:** Cindy Bladey, Office of Administration, Mail Stop: OWFN-12-H08, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001.

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

FOR FURTHER INFORMATION CONTACT: Donna-Beth Howe, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001; telephone: 301-415-7848; e-mail: Donna-Beth.Howe@nrc.gov.

SUPPLEMENTARY INFORMATION:

I. Obtaining Information and Submitting Comments

A. Obtaining Information

Please refer to Docket ID **NRC-2017-0094** 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-2017-0094**.

- **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 “[ADAMS Public Documents](#)” and then 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 (if it is available in ADAMS) 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-2017-0094** in your submission.

The NRC cautions you not to include identifying or contact information that you do not want to be publicly disclosed in your comment submission. The NRC posts all comment submissions at <http://www.regulations.gov> and enters the comment submissions into ADAMS. The NRC does not routinely edit comment submissions 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 submissions into ADAMS.

II. Background

In a March 10, 2014, Commission Action Memorandum (COMAMM-14-0001/COMWDM-14-0001, "Background and Proposed Direction to NRC Staff to Verify Assumptions Made Concerning Patient Release Guidance" (ADAMS Accession No. ML14072A112), then NRC Chairman MacFarlane and then Commissioner Magwood brought into question, among other things, whether significant regulatory changes to the patient release program are warranted. They asked whether different criteria should be used to determine when patients should be

released, whether the application of the current dose release standard needed to be clarified, whether all exposed members of the public should be subject to the same patient release dose limit, and whether new release requirements are needed for patients who are likely to expose young children and pregnant women.

In the Staff Requirements Memorandum (SRM) to COMAMM-14-0001/COMWDM-14-0001 (ADAMS Accession No. ML14118A387), the Commission, among other things, directed the NRC staff to evaluate whether regulatory changes are necessary to clarify the NRC's current release criteria and whether additional or alternate criteria are needed. As a result of earlier public comments on other elements of the SRM (November 16, 2015; 80 FR 70843), the staff identified two additional questions to consider. These are whether a requirement is needed to ensure the discussion between the licensee and patient concerning patient isolation occurs in sufficient time for licensees or patients to make necessary arrangements for holding or releasing the patient and whether patients required to receive instructions on minimizing dose to others should be provided with these instructions before the administration.

The NRC is interested in obtaining input from as many stakeholders as possible, including the NRC's Advisory Committee on the Medical Use 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 significant regulatory changes to the patient release program are warranted.

During the comment period on April 25, 2017 and May 23, 2017, the NRC will have two public meetings at the NRC's Headquarters that will explain and clarify the information requested with members of the public. These meetings will be webcast.

The NRC does not intend to provide any responses to comments received during the public meeting(s). The public meeting(s) 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 <http://www.nrc.gov/public-involve/public-meetings/index.cfm>.

The NRC will also post the meeting notices on the Federal rulemaking Web site at <http://www.regulations.gov> under Docket ID **NRC-2017-0094**. 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-2017-0094**); 2) click the "Sign up for E-mail Alerts" link; and 3) enter your e-mail address and select how frequently you would like to receive e-mails (daily, weekly, or monthly).

III. Requested Information and Comments

A. Development of an activity-based patient release threshold

The NRC is asking the public to comment on whether the NRC should develop an activity-based patient release threshold under which patients would be required to be maintained in a clinic-sponsored facility (e.g., a medical facility or facility under the licensee's control) until the standard for release is met.

Question: Should the NRC develop an activity-based patient release threshold?

1. If so, explain why and provide a potential activity-based criterion.
2. If not, explain why the regulations should remain as is.
3. In either case, describe the resulting health and safety benefits, or lack of benefits, to the individual being released and to individual members of the public.

B. Clarification of the time covered by the current dose limit in 10 CFR 35.75(a) for releasing Individuals

Currently, under section 35.75(a) of title 10 of the *Code of Federal Regulations* (10 CFR), allows a licensee to release a patient if the dose to any other individual is not likely to

exceed 5 milliSieverts (mSv) (0.5 rem). The NRC staff determined in the NRC' Regulatory Issue Summary 2008-07, "Dose Limit for Patient Release Under 10 CFR 35.75" (ADAMS Accession No. ML063030572) that, as written the regulation is ambiguous and the dose to any other individual from the released individual does not reflect the NRC's intent of a per-year limit and that this limit has been interpreted by others to be per release. The NRC staff explained that a "per release" interpretation does not consider the cumulative dose received in a year from the same released individual or repeated exposure to different released individuals. The Commission has asked the NRC staff to clarify this issue.

Question: Should the NRC amend the regulations to clarify the time frame for the current dose limit in 10 CFR 35.75(a) for releasing Individuals? For example, should the regulations explicitly state that the criterion is a per year limit? If not, is there a different criterion that the NRC should consider? In either case, describe the resulting health and safety benefits, or lack of benefit, to the individual being released and to individual members of the public as a result of the proposed clarification.

C. Appropriateness of applying the same limit on dose from patient exposure to all members of the general public

In the current NRC patient release dose criterion, the NRC does not distinguish between family members, young children, pregnant women, caregivers, hotel workers, and other members of the public. Further, the NRC patient release dose criterion is above the 10 CFR part 20 public dose limit.

Question: Should the NRC continue to apply the same dose criteria of 5 mSv (0.5 rem), to all members of the general public, including family members, young children, pregnant women, caregivers, hotel workers, and other members of the public when considering the release of patients?

1. If so, explain why.
2. If not, what criterion should the NRC use for an individual group or groups? Specify the group (e.g., family members, young children, pregnant women, caregivers, hotel workers, or others) for each criterion.
3. In either case, describe the resulting health and safety benefits, or lack of benefits, to the individual being released and to individual members of the public.

D. Requirements for releasing individuals who are likely to expose young children and pregnant women

The current NRC patient release program requires the licensee to provide the released individual with instructions if the dose to any individual is likely to exceed 1 mSv (0.1 rem). The NRC does not have specific requirements for releasing patients who are likely to expose young children or pregnant women to doses above the public dose limit.

Question: Should the NRC include a specific requirement for the release of a patient who is likely to expose young children or pregnant women to doses above the public dose limit?

1. If so, explain why and describe what the requirement should include.
2. If not, explain why the requirement is not needed.
3. In either case, describe the resulting health and safety benefits, or lack of benefits, to the individual being released and to a young child or to pregnant woman.

E. Requirement for timely discussion with the patient about patient isolation to provide time for licensee and patient planning

The current NRC patient release program permits the licensee to authorize the release from its control of any individual who has been administered unsealed byproduct material or implants containing byproduct material if the total effective dose equivalent to any other individual from exposure to the released individual is not likely to exceed 5 mSv (0.5 rem). In

some common procedures (e.g. Iodine-131 procedures), the patients must isolate themselves for the licensee to meet this dose release requirement. In other cases, the patient cannot be released and the licensee must make arrangements to isolate the patient. The requirements are silent on when the licensee should discuss patient isolation with the patient. As a result, both patients and licensees may not have time to make appropriate isolation arrangements prior to the planned administration. Some patients reported that they were unaware of a need to isolate themselves from others prior to the administration.

Question: Should the NRC have a specific requirement for the licensee to have a patient isolation discussion with patients in sufficient time prior to the administration to provide the patient time to make isolation arrangements or the licensee to make plans to hold the patient, if the patient cannot be immediately released?

1. If so, explain why and describe what the requirement should include.
2. If not, explain why the requirement is not needed.
3. In either case, describe the resulting health and safety benefits, or lack of benefits, to individual being released, the licensee, and to the public.

F. Requirement to ensure patients are given instructions prior to the procedure

The current NRC patient release regulations require the licensee to provide the released individual with instructions if the dose to any individual is likely to exceed 1 mSv (0.1 rem). The requirements are silent on when the required instructions should be given to the patient. Some patients are given instructions along with other medical release paperwork and may not be aware of the instructions.

Question: Should the NRC explicitly include the time frame for providing instructions in the regulations (e.g., the instructions should be given prior to the procedure)?

1. If so, explain why and provide a recommended time period for the instructions to be provided.
2. If not, explain why the requirement is not needed.
3. In either case, describe the resulting health and safety benefits, or lack of benefits, to the individual being released, the licensee, and to the public.

Dated at Rockville, Maryland, this 3rd day of April, 2017.

For the Nuclear Regulatory Commission.

/RA/

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