

Proposed Rules

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This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

NUCLEAR REGULATORY COMMISSION

10 CFR Part 35

[Docket No. PRM-35-21; NRC-2020-0037]

Patient Release Criteria for Radioactive Iodine

AGENCY: Nuclear Regulatory Commission.

ACTION: Petition for rulemaking; notice of docketing.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) has received a petition for rulemaking from Peter Crane, on behalf of the organization, Sensible Controls on Administrations of Radioactive Iodine, dated November 15, 2019. The petitioner requests that the NRC revise its regulations regarding the criteria for patient release after the administration of radioactive iodine. The petition was docketed by the NRC on January 24, 2020 and has been assigned Docket No. PRM-35-21. The NRC is examining the issues raised by the petition to determine whether they should be considered in rulemaking. The NRC is not seeking public comment on this petition at this time.

DATES: The NRC received PRM-35-21 on November 15, 2019 and docketed it on January 24, 2020.

ADDRESSES: Please refer to Docket ID NRC-2020-0037 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 <https://www.regulations.gov> and search for Docket ID NRC-2020-0037. Address questions about NRC dockets to Carol Gallagher; telephone: 301-415-3463; email: Carol.Gallagher@nrc.gov. For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.

- *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly-available documents online in the ADAMS Public Documents collection at <https://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 (if it is available in ADAMS) is provided the first time that it is mentioned in this document.

- *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.

FOR FURTHER INFORMATION CONTACT: Pamela Noto, Office of Nuclear Material Security and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001; telephone: 301-415-6795, email: Pamela.Noto@nrc.gov.

SUPPLEMENTARY INFORMATION:

I. The Petitioner

Peter Crane is the Acting Secretary for Sensible Controls on Administrations of Radioactive Iodine (SCAR). Most of the members of SCAR have been treated with radioactive iodine. The petitioner requests that the NRC amend part 35 of title 10 of the *Code of Federal Regulations* (10 CFR) to revise the criteria for patient release after the administration of radioactive iodine. The petition can be found in ADAMS at Accession No. ML20024F779.

II. The Petition

The petitioner requests that the NRC revise the patient release criteria in § 35.75 to ensure the availability of inpatient treatment when required. The petitioner summarized the history of the NRC's patient release regulations before, and after, the 1997 rulemaking that amended the criteria for the release of patients following medical treatments involving radioactive isotopes. The petitioner states that the current NRC patient release regulations neglect internal radiation dose and are based solely on the external radiation exposure from radioactive iodine. The petitioner further states that, according

to the Centers for Disease Control and other national and international authorities, internal radiation dose is critically important, particularly for children as they are far more at risk from the effects of radiation exposure than adults. The petitioner also states that the NRC's patient release regulations have been interpreted to permit newly treated patients to be released, resulting in five times the radioactive iodine exposure to the patient's family and the public than is allowed by national and international standards. The petitioner asserts that the responsibility to protect the public has shifted from medical providers to individual patients, who may not be adequately informed of the risks to the public. The petitioner asserts that the NRC's patient release regulations allow insurance companies to dictate whether patients and their families receive adequate radiation protection. The petitioner states that the patient release regulations need to be amended, and that this can be accomplished in different ways. The petitioner suggests that the NRC could reinstate an activity cap at 10 or 15 millicuries of radioactive iodine or reduce the current dose limit from 500 millirem to 100 millirem, which the petitioner says is consistent with national and international standards. The petitioner observes that guidance on patient release is non-binding; therefore, to enforce new requirements, the petitioner requests that the NRC conduct rulemaking.

III. Docketing

The NRC has determined that the petition satisfies the requirements for docketing a petition for rulemaking in § 2.802(c). The NRC is reviewing the merits of the petition. The NRC has sufficient information to understand and evaluate the merits of the petition; therefore, NRC is not seeking public comment at this time.

Dated at Rockville, Maryland, this 3rd day of April, 2020.

For the Nuclear Regulatory Commission.

Annette L. Vietti-Cook,

Secretary of the Commission.

[FR Doc. 2020-07383 Filed 4-10-20; 8:45 am]

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