



This document is scheduled to be published in the Federal Register on 11/16/2015 and available online at <http://federalregister.gov/a/2015-29027>, and on FDsys.gov

[7590-01-P]

NUCLEAR REGULATORY COMMISSION

[NRC-2015-0020]

SODIUM IODIDE-131 PATIENT RELEASE INFORMATION COLLECTION

AGENCY: Nuclear Regulatory Commission.

ACTION: Request for information.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is requesting information from the general public on a number of issues associated with medical treatment of patients with sodium iodide I-131 (hereafter referred to as I-131). Specifically, the NRC would like input on patient concerns about medical treatment involving the use of I-131, information that physicians use to make decisions on when it is safe to release I-131 patients based on radiation exposure concerns, radiation safety information used by I-131 patients after their release, and the availability of a radiation safety informational guidance brochure for I-131 patients that can be distributed nationwide. The information collected will be used to develop a Web site to provide patients with clear and consistent information about radioactive iodine treatments and to revise NRC patient release guidance.

DATES: Submit information and comments by **[INSERT DATE 90 DAYS FROM DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**. Information and 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 information and comments received on or before this date.

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

- **Federal Rulemaking Web Site:** Go to <http://www.regulations.gov> and search for Docket ID NRC-2015-0020. 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 information and 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 information and comments, see “Obtaining and Submitting Information and Comments” in the SUPPLEMENTARY INFORMATION section of this document.

FOR FURTHER INFORMATION CONTACT: Donna-Beth Howe, Ph.D., 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 and Submitting Information and Comments

A. Obtaining Information

Please refer to Docket ID NRC-2015-0020 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-2015-0020.

- **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 Information and Comments

Please include Docket ID NRC-2015-0020 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 submission. The NRC will post all submissions at <http://www.regulations.gov> as well as enter the submissions into ADAMS. The NRC does not routinely edit submissions to remove identifying or contact information.

If you are requesting or aggregating information 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 submission. Your request should state that the NRC does not routinely edit submissions to remove such information before making the submissions available to the public or entering the submission into ADAMS.

II. Background

In a March 10, 2014, memorandum to the Commission (COMAMM-14-0001/COMWDM-14-0001, "Background and Proposed Direction to NRC Staff to Verify Assumptions Made Concerning Patient Release Guidance" (see <http://www.nrc.gov/reading-rm/doc-collections/commission/comm-secy/2014/2014-0001comamm-0001-comwdm.pdf>)), NRC Chairman MacFarlane and Commissioner Magwood brought into question whether patients receiving I-131 treatments are given consistent and useful information from medical facilities and whether patients can correctly follow those instructions. Anecdotal data from patients and patient advocacy groups indicated that while instructions are provided, the quality of the instructions varies significantly, and that some patients are provided with instructions that the patient and the medical facility know will be impractical to follow.

In the Staff Requirements Memorandum to COMAMM-14-0001/COMWDM-14-0001 (see <http://www.nrc.gov/reading-rm/doc-collections/commission/comm-secy/2014/2014-0001comamm-0001-comwdmsrm.pdf>), the Commission, among other things, directed the NRC staff to develop a Web site that provides patients with clear and concise information and links to relevant medical and patient advocacy Web sites about I-131 treatments, to revise NRC guidance to specify guidelines for patient instructions and information including a voluntary model patient/licensee acknowledgement form documenting the patient/licensee dialog leading to the licensee's decision of when to safely release the patient from its control based on radiation exposure concerns, and to develop a standard set of guidelines that licensees can use to provide instructions to released I-131 patients. The Commission also directed the NRC staff to consider whether the guidance information provided to the patients can be made into an NRC

brochure, or whether a medical organization already has, or would produce, a brochure for nationwide distribution.

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 information gathering effort is to obtain: information that patients believe will help them understand the I-131 treatment (also referred to as Radioactive Iodine (RAI)) procedures, the physician's or licensee's best practices when making informed decisions on releasing RAI treatment patients, and information provided to patients on how to reduce radiation doses to others. The NRC is also interested in learning if patient advocacy, medical professional organizations, licensees, or other individuals have brochures that already contain the information requested.

III. Requested Information and Comments

A. Web Site Information

The NRC is considering establishing a Web site that provides potential patients with information on RAI treatment procedures so that patients will understand the reason for the procedures, the process, and how to reduce radiation exposure to others. Some of this is medical information that is outside the NRC's field of expertise. The NRC would like to be able to provide links to other sites providing this medical information. The NRC may develop the basic radiation safety information itself, but could provide links if established sites already have this information.

The NRC is also seeking input from patients, patient advocacy groups, and other interested individuals to articulate concerns that may not be included in the topics identified in this section.

If you have, or know of, a Web site that that can be used to explain the disease and treatment process, and addresses one or more of the following topics, please provide the link to the NRC.

- What is radioactivity?
- What is radioactive iodine (RAI)?
- RAI treatment:
 - Any explanation of how radiation is used in the treatment should include clear information that the patient will receive radioactive material, emit radiation, retain radioactive material, and release radioactive material.
 - Preparing for RAI treatment.
 - What to expect before and after receiving the treatment.
 - Side effects of RAI treatment.
- Basic radiation safety:
 - Appropriate venues for recovery after release.
 - Precautions to take after receiving treatment.
 - Risks to others, to include risks to young children and pregnant women.
 - Expected general behaviors after release.

When identifying a Web site, indicate the topic it addresses and provide a link to that specific information on the topic.

B. Patient/Licensee Acknowledgement Form and Best Practices in Making Informed Decisions on Releasing Patients Treated with I-131 based on Radiation Exposure Considerations

The NRC is looking for best practices used by individual physicians and licensees that focus on enhancing the ability to make informed radiation safety decisions on the release of

individual patients from their radiation safety control under the patient release criteria in the NRC's medical use regulations. The NRC expects the physician (licensee) to have a dialog with the patient that will ultimately lead to an informed decision on when the patient should be released from its radiation safety control based on radiation exposure considerations (this includes immediate or delayed release, in addition to hospitalization). The NRC is also interested in knowing whether a patient/licensee acknowledgment form documenting this dialog exists and is part of the physicians' best practices. The NRC believes this dialog would include some or all of the following:

- The patient's ability to understand the language of the physician (licensee) or need for an interpreter that understands the procedure.
- The need for a family member or another support person present to facilitate better retention of information.
- A discussion with the patient to determine suitability for release.
- Description of the patient's transportation from the medical facility to home.
- Discussion of the patient's normal daily behavior and patterns, including but not limited

to:

- The patient's normal/routine social interactions.
 - The patient's normal/routine working environment and tasks.
 - The patient's normal/routine living arrangements.
 - The planned changes to the patient's normal/routine behaviors during the treatment period (have friend or family member accompany the patient or spend time with patient, change in living arrangements, etc.).
- Financial considerations that will affect the patient's preference on early or delayed release.
 - Discussion to evaluate patient's ability to understand and follow instructions.

- Discussion to evaluate of patient's willingness to follow instructions.
- Discussion to evaluate the level of disruption to patient routine lifestyle, if released, and

the ability of the patient to make and follow the changes, if released.

If you have a policy or procedure that provides you with the confidence that you are releasing the patient at the appropriate time, please describe your policy or provide your procedure. If the policy or procedure includes a patient/licensee acknowledgement form, or if you have a stand-alone form, documenting the patient/licensee discussion, please provide it. The policy, procedure, or form could include some of the topics listed but may include others. Indicate when this type of discussion with the patients takes place (e.g., when the patient is referred for the procedure, before administration, after administration, etc.). Does the timing of this discussion allow the patient enough time to make different living, working, or transportation arrangements or for the medical facility to make delayed release (may include hospitalization) arrangements? Please describe how your best practices are used in the decision making process.

The NRC would also like input from the patient's or other interested individual's perspective of the optimal time for the discussion to take place so that both the patient and the medical facility have confidence the release decision is appropriate. How much time is needed to allow patients to make different living, working, transportation arrangements? The NRC is also seeking input from patients, patient advocacy groups, and other interested individuals to articulate other topics that should be included in the discussion.

C. Guidance for Released Patients

The Commission directed the NRC staff to develop standardized guidance for licensees to provide to their patients that would help to reduce the variability of instructions provided to patients and eliminate some of the uncertainty regarding the type of information that is provided

to the patient. While the NRC currently prefers to develop performance based guidance (articulating objectives but not telling licensees how to reach those objectives), prescriptive guidance (i.e., very detailed and specific) may be necessary to reduce uncertainty and provide confidence that regulatory requirements are met. If the standardized guidance is performance-based, it would need to provide individual patients with the “tools” needed to follow the objectives in the guidance and protect others.

If you have guidance documents that you believe provide clear instructions to released patients, please provide a copy to the NRC. If your guidance includes topics not addressed below, indicate why you think each is an important topic to include. If it does not address one of the topics and you believe that topic is not needed, describe why it is not needed.

- What “tools” (or methods/means) can the patient use to protect others once released?
- Are both oral and written information presented in the patient’s native language and presented in a manner understandable to both the patient and physician (licensee)?
- Does the medical facility/licensee have access to an interpreting service to make sure that oral and written information and instructions are understood?
- How are instructions personalized to the individual patient?
- Does the medical facility explain how to limit the exposures to others (especially to young children and pregnant women)?
 - Arrangements for protecting others once arriving at home.
 - Informed how long special care must be exercised.
- Are actions described that the patient can take to minimize the exposure of people both inside and outside the home?
- Do transportation instructions from the medical facility to home match the patient’s plans?

- Are discussions held on managing biological wastes and trash in accordance with NRC, state, and local requirements?
- Are discussions held to identify whom to contact in the event that questions arise during the recovery period?
- Are discussions held on where to go for emergency care?

The NRC is also seeking input from patients, patient advocacy groups, and other interested individuals to articulate topics that should be included in the instructions provided to released patients. Further, when do you want to be provided with these instructions? Are the instructions provided in a manner that is easy to understand and follow? What would have made the instructions better?

D. Brochure for Nationwide Use

The NRC is seeking identification of a brochure that you believe provides clear guidance on the release of patients treated with I-131. If you have or know of such a brochure please send the NRC a copy or a link to it. The intent is to identify a brochure that could be distributed nationwide.

IV. Paperwork Reduction Act Statement

This information request contains information collection requirements that are subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.). These information collections were approved by the Office of Management and Budget (OMB), OMB control number 3150-0229, expiration date of October 31, 2018.

The burden to the public for these information collections is estimated to average 0.25 to 0.50 hours per response, including time for reviewing instructions, searching existing data sources, gathering data, performing necessary analyses, and completing and reviewing the

information collection. This information collection request only information already possessed by the responder and does not request the responder develop any new data.

The NRC may not conduct or sponsor, and a person is not required to respond to, a request for information or an information collection requirement unless the requesting document displays a currently valid OMB control number.

Dated at Rockville, Maryland, this 5th day of November, 2015.

For the Nuclear Regulatory Commission.

Christian E. Einberg, Acting Deputy Director,
Division of Material Safety, State, Tribal
and Rulemaking Programs,
Office of Nuclear Material Safety
and Safeguards.

[FR Doc. 2015-29027 Filed: 11/13/2015 8:45 am; Publication Date: 11/16/2015]