UNITED STATES
NUCLEAR REGULATORY COMMISSION
OFFICE OF NUCLEAR MATERIAL SAFETY AND SAFEGUARDS
WASHINGTON, DC 20555-0001

December 14, 2015

NRC REGULATORY ISSUE SUMMARY 2015-18
SODIUM IODIDE-131 (I-131) PATIENT RELEASE INFORMATION COLLECTION

ADDRESSEES

All U.S. Nuclear Regulatory Commission (NRC) medical use licensees and NRC Master Materials License (MML) medical use permittees administering sodium iodine I-131 to patients under a written directive.

All Agreement State Radiation Control Program Directors.

INTENT

The NRC is issuing this Regulatory Issue Summary (RIS) to inform physicians, licensees, and permittees of an opportunity to voluntarily submit information requested in NRC's November 16, 2015, *Federal Register* notice (FRN) information request entitled, "Sodium Iodide-131 (I-131) Patient Release Information Collection" (80 FR 70843). No specific action or any written response is required. The RIS is provided to the NRC MMLs for their information and for distribution to their appropriate medical use permittees. The NRC is providing this RIS to the Agreement States for their information and for distribution to their licensees as appropriate.

BACKGROUND INFORMATION

In April 2014, the Commission, among other things, directed the 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;
- Revise the 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;
- Develop a standard set of guidelines that licensees can use to provide instructions to released I-131 patients; and
- Determine 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.

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SUMMARY OF THE ISSUE

The NRC is interested in obtaining input from as many stakeholders as possible, including the physicians, the NRC and Agreement State medical use licensees, and NRC MML medical use permittees that administer I-131 under the provisions of Title 10 of the *Code of Federal Regulations* Part 35 (10 CFR 35.300) or equivalent Agreement State requirements. The NRC is also interested in obtaining input from Agreement States. In addition to the recipients of this RIS, the NRC will also be seeking input from patients, patient advocacy groups, professional organizations, 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 (also referred to as Radioactive Iodine (RAI)) treatment procedures, the physician's or licensee's/permittee'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 groups, medical professional organizations, licensees, or other individuals have brochures that already contain the information requested.

The NRC published the "Sodium Iodide I-131 Patient Release Information Collection" FRN to reach as many stakeholders as possible. In the FRN, the NRC staff requested that stakeholders provide the NRC with information that they already possess concerning: (1) Web sites that provide 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; (2) patient/licensee acknowledgement forms and best practices that focus on the dialog used by physicians/licensees and patients that ultimately results in the informed decision, based on radiation exposure considerations, on when the patient should be released; (3) guidance for released patients that helps to reduce the variability of instructions provided to patients and to eliminate some of the uncertainty regarding the type of information that is provided to the patient; and (4) an existing brochure for nationwide use that licensees and Agreement States believe provides clear guidance on the release of patients treated with I-131.

To aid all stakeholders, in the FRN NRC staff provided suggested topics or questions related to the information the stakeholders will submit on the Web site, in the patient/licensee acknowledgement forms, in guidance for released patients, and in a brochure for nationwide use. Because these topics and questions are probably incomplete, the NRC staff also requested that stakeholders, based on their personnel experience, identify any additional topics and questions that they believe should be included in these lists and any that they believe should be omitted from these lists. The NRC is not requesting the development of new information or that individuals research any of the topics presented in the FRN. Greater detail on the information requested and how to submit it is provided in the FRN. The NRC is also requesting that Agreement State and NRC medical use licensees, as well as NRC MML medical use permittees, voluntarily share the FRN with their staff associated with the administration of sodium iodine I-131. As noted in the FRN, this information should be submitted by February 16, 2016. The FRN is enclosed or can be accessed on the electronic *Federal Register* page at https://www.federalregister.gov/articles/2015/11/16/2015-29027/sodium-iodide-131-patient-release-information-collection).

BACKFIT DISCUSSION

This RIS does not apply to the entities protected by the backfit rule (10 CFR 50.109, 70.76, 72.62, or 76.76) or the issue finality provisions in 10 CFR Part 52. Therefore, the backfit rule and issue finality provisions do not apply to this RIS.

FEDERAL REGISTER NOTIFICATION

A notice of opportunity for public comment on this RIS was not published in the *Federal Register* because this RIS is informational and does not represent a departure from current regulatory requirements.

CONGRESSIONAL REVIEW ACT

This RIS is not a rule as defined in the Congressional Review Act (5 U.S.C. §§ 801-808).

PAPERWORK REDUCTION ACT STATEMENT

This regulatory issue summary contains information collections 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, approval number 3150-0229, which expires October 31, 2018.

The burden to the public for these voluntary information collections is estimated to be 0.5 hours per response. Send comments regarding this burden estimate to the FOIA, Privacy and Information Collection Branch (T-5 F53), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, or by Internet electronic mail to INFOCOLLECTS.RESOURCE@NRC.GOV; and to the Desk Officer, Office of Information and Regulatory Affairs, NEOB-10202, (3150-0229), Office of Management and Budget, Washington, DC 20503.

PUBLIC PROTECTION NOTIFICATION

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.

CONTACT

This RIS requires neither specific action nor a written response. If you have any questions please contact the technical contact listed below.

/RA/

Pamela J. Henderson, Acting Director
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and Rulemaking Programs
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Enclosure:
November 16, 2015 *Federal Register*
Notice, (80 FR 70843)

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