

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.

ML15015A395

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
Division of Material Safety, State, Tribal
and Rulemaking Programs
Office of Nuclear Material Safety
and Safeguards

Technical Contact: Donna-Beth Howe, PhD, NMSS
(301) 415-7848
Email: Donna-Beth.Howe@nrc.gov

Enclosure:
November 16, 2015 *Federal Register*
Notice, (80 FR 70843)

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

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Enclosure:
November 16, 2015 *Federal Register*
Notice, (80 FR 70843)

DISTRIBUTION:
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NAME	DBHowe	AMcIntosh	MFuller	DBollock	CEinberg	EHouseman
DATE	11/18 /15	11/16/15	11/18/15	11/18/15	11/19/15	12/4/15
OFC	OIS	NMSS/MSTR				
NAME	TDonnell	PHenderson				
DATE	12/8/15	12/15/15				

OFFICIAL RECORD COPY

Dated: November 9, 2015.

Kathy Plowitz-Worden,

Panel Coordinator, National Endowment for the Arts.

[FR Doc. 2015-28852 Filed 11-13-15; 8:45 am]

BILLING CODE 7537-01-P

NATIONAL SCIENCE FOUNDATION

Proposal Review Panel for Computing and Communication Foundations; Notice of Meeting

In accordance with the Federal Advisory Committee Act (Pub., L. 92-463, as amended), the National Science Foundation announces the following meeting:

Name: Proposal Panel Review for Science and Technology Centers—Integrative Partnerships (#1192) Site Visit.

Date/Time: December 7, 2015, 6:30 p.m.–8:30 p.m.; December 8, 2015, 8:00 a.m.–8:00 p.m.; December 9, 2015, 8:30 a.m.–3:00 p.m.

Place: Purdue University, West Lafayette, IN 47907.

Type of Meeting: Part-Open.

Contact Person: John Cozzens, National Science Foundation, 4201 Wilson Boulevard, Room 1115, Arlington, VA 22230. Telephone: (703) 292-8910.

Purpose of Meeting: To assess the progress of the STC Award: 0939370 “Emerging Frontiers of Science of Information: the Science and the Technology of Intelligence”, and to provide advise and recommendations concerning further NSF support for the Center.

Agenda: CSol Purdue Site Visit

Monday, December 7, 2015, 6:30 p.m. to 8:30 p.m.: Closed; Site Team and NSF Staff meets to discuss Site Visit materials, review process and charge.

Tuesday, December 8, 2015, 8:00 a.m. to 1:00 p.m.: Open; Presentations by Awardee Institution, faculty staff and students, to Site Team and NSF Staff; Discussions, question and answer sessions.

1:00 p.m.–8:00 p.m.: Closed; Draft report on education and research activities.

Wednesday, December 9, 2015, 8:30 a.m.–noon: Open; Response presentations by Site Team and NSF Staff Awardee Institution faculty staff; Discussions, question and answer sessions.

Noon to 3:00 p.m.: Closed; Complete written site visit report with preliminary recommendations.

Reason for Closing: The proposals being reviewed include information of a proprietary or confidential nature,

including technical information; financial data, such as salaries; and personal information concerning individuals associated with the proposals. These matters are exempt under 5 U.S.C. 552b(c), (4) and (6) of the Government in the Sunshine Act.

Dated: November 10, 2015.

Crystal Robinson,

Committee Management Officer.

[FR Doc. 2015-29165 Filed 11-13-15; 8:45 am]

BILLING CODE 7555-01-P

NATIONAL SCIENCE FOUNDATION

Business and Operations Advisory Committee; Notice of Meeting

In accordance with Federal Advisory Committee Act (Pub. L. 92-463, as amended), the National Science Foundation announces the following meeting:

Name: Business and Operations Advisory Committee (9556).

Date/Time: December 8, 2015; 1:00 p.m. to 5:45 p.m. (EST).

December 9, 2015; 8:45 a.m. to 12:00 p.m. (EST).

Place: National Science Foundation, 4201 Wilson Boulevard, Arlington, Virginia 22230; Stafford I, Room 1235

Type of Meeting: PART-OPEN.

Contact Person: Joan Miller, National Science Foundation, 4201 Wilson Boulevard, Arlington, VA 22230 (703) 292-8200.

Purpose of Meeting: To provide advice concerning issues related to the oversight, integrity, development and enhancement of NSF’s business operations.

Agenda:

December 8, 2015.

1:00 p.m.–4:30 p.m., OPEN—Welcome/ Introductions; BFA/OIRM Updates; NSF Headquarters Relocation Update; Modernizing the Workforce—IT—Driven Change Management; Records Management/Digitization.

4:30 p.m.–5:45 p.m. CLOSED—Briefing on the National Academy of Public Administration Study of NSF’s Use of Cooperative Agreements to Support Large Scale Investments in Science and Technology.

December 9, 2015

8:45 a.m.–12:00 p.m. OPEN—

Preparation for discussion with NSF Director and Chief Operating Officer; Discussion with NSF Director and Chief Operating Officer; Presidential Transitions: What Agencies Can Do to Prepare; Meeting Wrap-Up.

Reason for Closing: This session of the meeting is closed to the public in accordance with the provisions of 5 U.S.C. 552b(c), (4) and (6) of the Government in the Sunshine Act.

Dated: November 10, 2015.

Crystal Robinson,

Committee Management Officer.

[FR Doc. 2015-29164 Filed 11-13-15; 8:45 am]

BILLING CODE 7555-01-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 February 16, 2016.

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; email: 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; email: *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 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 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 acknowledgment 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 11-13-15; 8:45 am]

BILLING CODE 7590-01-P

NUCLEAR REGULATORY COMMISSION

[Docket No. 40-38367, NRC-2015-0255]

Rare Element Resources, Inc.; Bear Lodge Project

AGENCY: Nuclear Regulatory Commission.

ACTION: License application; opportunity to request a hearing and petition for leave to intervene; order.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) has received an application from Rare Element Resources, Inc., for a license to possess and use source material associated with its Bear Lodge Project. The Bear Lodge Project includes a mine in the Black Hills National Forest in Crook County, Wyoming for the purpose of extracting rare earth element ores, and a rare earth element processing plant in Weston County, Wyoming. In addition, the license application contains sensitive unclassified non-safeguards information (SUNSI).

DATES: A request for a hearing or petition for leave to intervene must be filed by January 15, 2016. Any potential party as defined in § 2.4 of title 10 of the *Code of Federal Regulations* (10 CFR), who believes access to SUNSI is necessary to respond to this notice must request document access by November 27, 2015.

ADDRESSES: Please refer to Docket ID NRC-2015-0255 when contacting the NRC about the availability of information regarding this document. You may obtain publicly-available information related to this document using any of the following methods:

- Federal Rulemaking Web site: Go to <http://www.regulations.gov> and search for Docket ID NRC-2015-0255. 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 <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 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 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.

FOR FURTHER INFORMATION CONTACT: Kenneth Kalman, Office of Nuclear Material Safety and Safeguards, U.S.

Nuclear Regulatory Commission, Washington, DC 20555-0001; telephone: 301-415-6664, email: Kenneth.Kalman@nrc.gov.

SUPPLEMENTARY INFORMATION:

I. Introduction

The NRC has received, by letter dated May 4, 2015 (ADAMS Accession No. ML15132A726), an application from Rare Element Resources Inc., to possess and use up to 10 curies of unsealed, non-volatile thorium hydroxide and to possess and use unlimited quantities of unsealed, non-volatile source material in any bound form. The source material will be uranium and thorium in their natural isotopic abundance in concentrations greater than 0.05 percent by weight. The NRC staff will document its review of this license application in a safety evaluation report and an environmental assessment.

The license application is available in ADAMS under Accession No. ML15134A378. The NRC has identified the following documents as containing SUNSI and is withholding these documents from public disclosure pursuant to Section 304 of the National Historic Preservation Act of 1966, 54 U.S.C. 307103.

- "Stand Alone Report 10, A Class III Cultural Resource Inventory of the Bear Lodge Project—Upton Plant Site."
- The two Tribal reports referenced in Section 7.3, "Historic, Scenic, and Cultural Resources," of the application.

II. Opportunity to Request a Hearing and Petition for Leave To Intervene

Within 60 days after the date of publication of this notice, any person(s) whose interest may be affected by this action may file a request for a hearing and a petition to intervene with respect to issuance of the amendment to the subject facility operating license or combined license. Requests for a hearing and a petition for leave to intervene shall be filed in accordance with the Commission's "Agency Rules of Practice and Procedure" in 10 CFR part 2. Interested person(s) should consult a current copy of 10 CFR 2.309, which is available at the NRC's PDR, located in One White Flint North, Room O1-F21 (first floor), 11555 Rockville Pike, Rockville, Maryland 20852. The NRC's regulations are accessible electronically from the NRC Library on the NRC's Web site at <http://www.nrc.gov/reading-rm/doc-collections/cfr/>. If a request for a hearing or petition for leave to intervene is filed within 60 days, the Commission or a presiding officer designated by the Commission or by the Chief Administrative Judge of the Atomic