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Docket: NRC-2015-0020
Nuclear Request for Sodium Iodide I-131 Treatment and Patient Release Information

Comment On: NRC-2015-0020-0014
Sodium Iodide I-131 Patient Release Information Collection; Request for Information

Document: NRC-2015-0020-DRAFT-0024
Comment on FR Doc # 2015-29027

Submitter Information

Name: Anonymous Anonymous
Submitter's Representative: Joseph Ring
Organization: Beth Israel Deaconess Medical Center

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RULES AND DIRECTIVES
ENVIRONMENTAL
LAW

General Comment

See attached file

11/16/2015
60 FR 70843

Attachments

RS 33.16 NRC Info Request on 131I Therapy

14

SUNSI Review Complete
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Add= D-B Howe (dbh)



Beth Israel Deaconess
Medical Center



Harvard
Medical School
Teaching Affiliate

RS 33.16

February 3, 2016

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

Subject: Docket ID NRC-2015-0020

Dear Ms. Bladey,

Attached you will find comments in response to the Nuclear Regulatory Commission request for information related to release of patients treated with Sodium Iodide-131 (I-131). We appreciate the opportunity to provide comment.

If I may be of additional assistance or clarification, please contact me as listed below.

Sincerely,

A handwritten signature in cursive script that reads "Gerald M. Kolodny, M.D."

Gerald M. Kolodny, M.D.
Radiation Safety Committee, Chair

cc: Radiation Safety Committee
C. Bennett
E. McCarthy
P. McMullin

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330 Brookline Avenue

**Comments on NUCLEAR REGULATORY COMMISSION [NRC–2015–0020] Sodium Iodide–131
Patient Release Information Collection**

The following comments address the information requested by the Nuclear Regulatory Commission.

1. Patient concerns about medical treatment involving the use of ¹³¹I:

Patient concerns and questions about their medical care are the responsibility of the physician(s) treating the patient and as such should be discussed between the patient and physician. Providing generic information about typical patient questions may be of value to both the clinician and patient and should be provided with the statement that patients should discuss these issues with their physician.

Reference materials to support both patients and physicians are available from professional medical associations. These materials should be referenced as they represent the collective experience of a wide range of medical practitioners and are designed to address patient questions and concerns. Example publications and websites are:

- a. American Thyroid Association, <http://www.thyroid.org/radioactive-iodine/>
- b. American Association of Clinical Endocrinologists,
 - i. Radioiodine Therapy, <https://www.aace.com/files/radioiodine.pdf>
 - ii. www.ThyroidAwareness.com
- c. Society of Nuclear Medicine and Molecular Imaging,
 - i. Fact Sheet: Guidelines for Patients Receiving Radioiodine I-131 Treatment, <http://www.snmami.org/AboutSNMMI/Content.aspx?ItemNumber=5609>
 - ii. 131-I Radiotherapy, <http://www.snmami.org/AboutSNMMI/Content.aspx?ItemNumber=10563>
- d. Radiological Society of North America, <http://www.radiologyinfo.org/en/info.cfm?PG=radioiodine>
- e. Thyroid Cancer Survivors Network,
 - i. Main Website: <http://www.thyca.org/home/>
 - ii. Radioactive Iodine: <http://www.thyca.org/pap-foi/rai/>
- f. International Atomic Energy Agency
 - i. Information for patients with respect to nuclear medicine treatments: <https://rpop.iaea.org/RPOP/RPoP/Content/InformationFor/Patients/patient-information-nuclear-medicine/index.htm#PINMFAQ03>

- ii. Patient and Public information about medical radiation:
<https://rpop.iaea.org/RPOP/RPoP/Content/InformationFor/Patients/index.htm>
- iii. Information about therapeutic nuclear medicine treatments:
https://rpop.iaea.org/RPOP/RPoP/Content/InformationFor/HealthProfessionals/3_NuclearMedicine/TherapeuticNuclearMedicine/index.htm

2. Information that physicians use to make decisions on when it is safe to release ¹³¹I patients based on radiation exposure concerns:

The decision to release a patient after RIA treatment is a complex issue requiring the cooperative effort of physicians and health physicists. The NRC question about a safe release is flawed as there is no universally accepted definition of safe. The Health Physics Society has published a position statement¹ that the 10 CFR 35.75 patient release dose criteria poses no discernible risk to the public, thus providing ample public health and safety measures, while offering significant benefits to patients, their families, and society. In addition, there are numerous publications^{2,3,4,5,6,7,8} that have studied the radiation exposure to others incidental to a ¹³¹I therapy patient and show that doses are unlikely to exceed 1 mSv. There are readily available calculational models for the licensee community to use, such those contained in Appendix U of NUREG 1556, Vol. 9, Rev 2⁹, or the RADAR Patient Exposure Radiation Dose Calculator¹⁰, when determining when to treat a patient as an outpatient and determining the length of any radiation safety practices.

It is important for physicians and health physicists to work together to determine if the patient can be released in compliance with 10 CFR 35.75 and if it is in the patient's best

¹ Release of Patients Treated With Therapeutic Quantities of Radiopharmaceuticals and Sealed Sources. Health Physics Society Position Statement. McLean, VA: HPS; March 2012.
(http://hps.org/documents/patientrelease_ps027-0.pdf)

² Estimated dose rates to members of the public from external exposure to patients with ¹³¹I thyroid treatment, S. Dewji, Medical Physics: 42, 1851 (2015).

³ An Alternative Method for the Release Criteria and Calculation of the Total Dose Equivalent to Another Individual from a Patient Treated with a Therapeutic Dose of ¹³¹I, DeSantis, David M.; Health Physics: 81(1):15-26, July 2001.

⁴ Patient Release Report, Advisory Committee on the Medical Use of Isotopes (ACMUI), December 13, 2010.

⁵ Radiation Safety in the Treatment of Patients with Thyroid Diseases by Radioiodine ¹³¹I: Practice Recommendations of the American Thyroid Association. Thyroid: Volume 21, Number 4, 2011.

⁶ Radiation Exposure From Outpatient Radioactive Iodine (¹³¹I) Therapy for Thyroid Carcinoma, P. Grigsby, JAMA: May 3, 2000—Vol 283, No. 17.

⁷ Thyroid Cancer: Radiation Safety Precautions in ¹³¹I Therapy Based on Actual Biokinetic Measurements, Liu, Bin; Radiology: Volume 273: Number 1.

⁸ Evaluation of the Potential Absorbed Doses from Patients Based on Whole Body ¹³¹I Clearance in Thyroid Cancer Therapy, J. Willegaignon, Health Physics: August 2006 - Volume 91 - Issue 2 - pp 123-127.

⁹ NUREG-1556, Vol 9, Rev 2, Consolidated Guidance about Materials Licenses, US Nuclear Regulatory Commission, Jan 2008.

¹⁰ RADAR Patient Exposure Radiation Dose Calculator, <http://www.doseinfo-radar.com/ExposureCalculator.html>.

interest. The physician input provides insight into the patient's medical condition, living arrangements, ability to follow the recommended practices and appropriate metabolic data for the health physicist to use in determining the recommended practices. The decision to release a patient is not simply a radiation safety decision. Such a decision needs to be made with consideration for the patient's ability to follow the restrictions and living arrangements for example.

3. Radiation safety information used by ^{131}I patients after release and a radiation safety informational guidance brochure for ^{131}I patients:

While it is a laudable effort to provide information that patients can use to better prepare themselves for their post-treatment care, the patient should be encouraged to seek this information from his or her team of care providers who are better prepared to explain the intricacies of the individual's needs.

There is a wide variety of information available to the licensee community such as that from the National Council on Radiation Protection (NCRP)¹¹, Society of Nuclear Medicine¹² and The American Thyroid Association^{13,14} in addition to the existing information listed in Item 2 above for patients and physicians. This material should be used as a framework that is tailored by the patient's care team as appropriate for the individual patient.

There are also websites from professional organizations about radiation and medical treatments such as the Health Physics Society (www.hps.org/). Some of their sites related to this issue are:

- a. Health Care Personnel: <http://hps.org/physicians/>
- b. Ask the Experts: <http://hps.org/publicinformation/ate/>
- c. Nuclear Medicine and the Pregnant Patient Q&A:
http://hps.org/physicians/nuclear_medicine_pregnant_patient_qa.html
- d. Radiation Answers: <http://www.radiationanswers.org/>

4. The NRC wishes to collect information to develop a website to provide patients with clear and consistent information about radioactive iodine treatments and to revise NRC patient release guidance:

¹¹ NCRP Report No. 155, Management of Radionuclide Patients, December 11, 2006.

¹² Procedure Guideline for Therapy of Thyroid Disease with Iodine-131 (Sodium Iodide), Version 2.0; Society of Nuclear Medicine.

¹³ Radiation Safety in the Treatment of Patients with Thyroid Diseases by Radioiodine 131I: Practice Recommendations of the American Thyroid Association. THYROID: Volume 21, Number 4, 2011.

¹⁴ Comments Regarding Practice Recommendations of the American Thyroid Association for Radiation Safety in the Treatment of Thyroid Disease with Radioiodine, James V. Hennessey, THYROID: Volume 22, Number 3, 2012.

There is already an extensive amount of information available on websites from professional medical organizations and others interested in the health care of radioiodine patients. The NRC should seek a partnership with professional medical organizations, such as those in Item 1, to provide this patient information while the NRC provides information related to the regulatory aspects. An additional website by the Nuclear Regulatory Commission will likely only confuse and overburden the patient by adding to the vast amount of existing information. Patients should be referred to professional medical organizations and their physician for information in support of their care.

There is an additional concern that this information, once published on a NRC website will become de facto regulation and some recommendations may be inconsistent with a specific patient's medical needs.

5. The NRC requested specific information related to assisting the patient with the post-treatment care:

- a) *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)?*

Information related to patient treatment and care are discussed by the patient's care team including the physician and nuclear medicine and / or health physics staff before and at the time of administration.

- b) *Does the medical facility/licensee have access to an interpreting service to make sure that oral and written information and instructions are understood?*

Interpreter services are available to directly service most patients. However, if the patient's language is not supported, they will call in a contract interpreter. Written information is available in the six most common languages.

- c) *How are instructions personalized to the individual patient?*

When working with the patient's physician, the biological and social considerations are included in a plan to minimize exposures. A model can be used to predict restriction time based on the physiological parameters while the patient's living arrangements can be discussed. With the personal and medical information from the patient's care team, a program for the post-treatment care can address medical, physiological, personal needs and living arrangements. These lead to consideration for: minimizing exposures to young children, pregnant women and others, managing wastes and length of any restrictions. The treating physician and health physics / nuclear medicine staff review recommendations with the patient before the day of administration. The patients are instructed to arrange for someone to drive them home from the administration. The patients are given written instructions that document the discussion. A generic example patient instruction form is attached. It should be

noted that when the form is used, it is tailored to the individual with input from the physician, patient's physiological condition and health physics practices.

Example Patient Instructions

¹³¹Iodine Radiopharmaceutical Therapy Post Treatment Precautions and Instructions

Radiopharmaceutical therapy using ¹³¹Iodine is administered orally for the treatment of specific thyroid conditions, such as thyroid cancers and hyperthyroidism.

Please discuss any specific medical questions or concerns with your physician. If you have any questions or concerns regarding your medical condition or potential side effects of treatment (i.e. nausea, headaches, sore throat, etc.) that may arise at a later time, contact your physician directly. **Radiation Safety staff cannot assist with medical questions.**

At time of treatment, safety issues will be discussed with you by the Radiation Safety staff. After treatment, any questions about the radiation precautions indicated below can be addressed by contacting the Radiation Safety Office at XXXX weekdays or off hours by the 24-hour on-call staff at pager #####.

Date of Administration: _____

It is recommended that you:

1. Have someone assist you in the care of any small children and/or infants for a total of ____ days from time of administration.
2. Follow the precautions below for a total of ____ days from time of administration:

General Precautions:

1. Drink plenty of fluids following this treatment. This will help facilitate the removal of the excess radioactive material from your body;
2. Children or pregnant women should not accompany the patient on the day of the treatment;
3. Do not return to work if all the precautions listed below cannot be followed;
4. Discourage visits by family or friends during the precautionary period.

Precautions for Contact with Family Members and the General Public:

1. Maintain a distance of 4 feet from adults (6 feet from children and pregnant women);
2. Avoid public transportation (trains, buses, and taxis etc.) for the duration of the precaution period;
3. When traveling in a car with others, sit in the back seat as far as possible from the driver or other passengers;
4. Avoid traveling with children or pregnant women;
5. Avoid travel by airplane. If traveling by air within four weeks of the administration date, keep this signed form with you in the event that you are stopped for security reasons. This form can serve as proof of your radiopharmaceutical treatment;
6. Do not stay in hotels, motels and similar lodgings.

Form 410.3

Precautions at Home:

1. Have the sole use of a bathroom, if possible;
2. Flush the toilet twice after each use. Males should sit for urination to avoid splashing. Your urine will be radioactive. Take extra care for sanitation in the bathroom;
3. Wash hands thoroughly and routinely;
4. Sleep alone for the duration of the treatment. Wash your bed linens and clothing separately when the precautionary period ends. The mattress does not need to be washed;
5. Abstain from all forms of intimate contact for the duration of the precautionary period;
6. Do not prepare food for others;
7. Use a single set of flatware and utensils (1 plate, bowl, fork, knife, spoon, glass, etc. for the precautionary period. Wash your utensils separately after each use and rinse thoroughly;
8. Wash any clothing you wore against the skin separately from the family's at the end of the precautionary period. Jackets and shoes do not need to be washed. Clothing should not be discarded in the trash;
9. If you vomit during the precautionary period, wash any areas contaminated by vomit three times with a household cleanser. Call Radiation Safety Office for guidance.

Trash and Waste Disposal:

1. Segregate personal disposable waste from regular waste. This waste should include any material that may have come in contact with any body fluid. Examples are plastic cups, dishes, utensils, and tissues and paper towels used on your skin; or any material that has contact with your mouth;
2. Wash or rinse any trash that can be rinsed without damage (i.e. plastic plates or forks);
3. Hold the segregated waste for a minimum of 4 weeks before disposal (i.e., leaving curbside, taking to landfill, etc.). Store the trash as far away from living areas as possible, where access will be limited.

For Females Only:

1. If you are pregnant or potentially pregnant, notify your physician **before** any Nuclear Medicine testing or therapy. Procedures using radioactive material may cause harm to your unborn child;
2. Breast-feeding / pumping needs to have been discontinued well before this treatment as directed by your physician;
3. If your menstrual cycle and this treatment coincide, all disposable waste should be segregated with the personal disposable trash as described above. Any waste that is normally disposed of down the toilet should still be disposed of in that manner. Wash your hands thoroughly after handling tampons or sanitary napkins.

Your signature is required below. A signature by the Radiation Safety staff member certifies that the necessary safety precautions were discussed with you and that you were given a copy of this form.

Patient Signature

Radiation Safety Office Signature

Date

Date