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

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General Comment

The Health Physics Society submits the attached comments on Docket # 2015-0020

Attachments

Response to Questions NRC-2015-0020-I-131 Final

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HEALTH PHYSICS SOCIETY

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February 16, 2015

RE: Docket ID No. NRC-2015-0020
Comments in Response to Sodium Iodide I-131 Patient Release Information Collection; Request for Information dated November 16, 2015

To whom it may concern:

The Health Physics Society¹ (HPS) is a professional organization whose mission is to promote excellence in the science and practice of radiation safety. The HPS appreciates the opportunity to provide responses to the questions posed in Federal Register notice of November 16, 2016

The HPS considers these questions posed by the Nuclear Regulatory Commission (NRC) related to the practice of medicine and dependent upon the individual circumstances surrounding the patient-physician relationship. 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 professional societies, patient advocacy groups, or his or her team of care providers who are better prepared to explain the intricacies of the individual's needs. The attached detailed comments expand on this generalized comment.

The HPS appreciates this opportunity to provide comments.

Sincerely,

Nancy P. Kirner, CHP
President, Health Physics Society

cc: Brett Burk, HPS Executive Director
Craig Little, PhD, HPS Government Agency Liaison
Robert Cherry, HPS President-Elect
Barbara Hamrick, HPS Chair, Scientific & Public Issues Committee
Joseph Ring, CHP, Chair, Government Relations Committee

¹ The Health Physics Society is a non-profit scientific professional organization whose mission is to promote the practice of radiation safety. Since its formation in 1956, the Society has grown to include over 4,000 scientists, physicians, engineers, lawyers, and other professionals representing academia, industry, government, national laboratories, the department of defense, and other organizations. Society activities include encouraging research in radiation science, developing standards, and disseminating radiation safety information. Society members are involved in understanding, evaluating, and controlling the potential risks from radiation relative to the benefits. Official position statements are prepared and adopted in accordance with standard policies and procedures of the Society.

Health Physics Society
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.snmmi.org/AboutSNMMI/Content.aspx?ItemNumber=5609>
 - ii. 131-I Radiotherapy, <http://www.snmmi.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-fol/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](https://rpop.iaea.org/RPOP/RPoP/Content/InformationFor/HealthProfessionals/3%20NuclearMedicine/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 RAI 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 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 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.

3. *Radiation safety information used by 131I patients after release and a radiation safety informational guidance brochure for 131I 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.

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>.
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There is a wide variety of information available to the licensee community such as that from the National Council on Radiation Protection (NCRP)¹, Society of Nuclear Medicine² and The American Thyroid Association^{3,4} 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](http://hps.org/physicians/nuclear%20medicine%20pregnant%20patient%20qa.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:*

There is already an extensive amount of information available on websites from professional medical organizations and others interested in health care. 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)?*

¹ NCRP Report No. 155, Management of Radionuclide Patients, December 11, 2006.

² Procedure Guideline for Therapy of Thyroid Disease with Iodine-131 (Sodium Iodide), Version 2.0; Society of Nuclear Medicine.

³ Radiation Safety in the Treatment of Patients with Thyroid Diseases by Radioiodine I31I: Practice Recommendations of the American Thyroid Association. THYROID: Volume 21, Number 4, 2011.

⁴ 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.

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 to 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 can be 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, length of any restrictions. These are discussed by the treating physician and health physics / nuclear medicine staff before the day of administration where patients are instructed to arrange for someone to drive them home from the administration. The patients are given written instructions that are discussed with the patient. 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.

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