SOCIETY OF NUCLEAR MEDICINE AND MOLECULAR IMAGING

February 16, 2016

Chairman Stephen G. Burns
U.S. Nuclear Regulatory Commission
Washington, DC 20555-0001

ATTN: Rulemakings and Adjudications Staff

Re: Nuclear Regulatory Commission: Request for Information Concerning Patient Release Practices [NRC-2015-0020]

Dear Chairman Burns:

The Society of Nuclear Medicine and Molecular Imaging (SNMMI) appreciates the opportunity to respond to the Commission's request for information regarding patient release practices for radioiodine I-131. SNMMI's more than 17,000 members set the standard for molecular imaging and nuclear medicine practice through the creation of clinical guidelines, sharing evidence-based medicine through journals and meetings, and leading advocacy on key issues that affect molecular imaging and therapy research and practice. SNMMI is pleased to offer comments on topics detailed below.

A. Website Information

Through SNMMI's website, patients, providers, or the general public can access information on practices for radioiodine. The document, "Fact Sheet: Guidelines for Patients Receiving Radioiodine I-131 Treatment," may be accessed at http://www.snmmi.org/AboutSNMMI/Content.aspx?ItemNumber=5609.

SNMMI's web information below is also available as a printable brochure for free download.

What is radioiodine?

Radioiodine (sodium I-131) is a form of radiation therapy that has been used for many years to treat thyroid conditions. It is safe and effective but requires you to observe certain precautions to decrease the small amount of radiation that other people may receive from your body and bodily fluids.

How long does the radioiodine stay in your body?

Radioiodine stays in your body for only a short time. Most of the radioiodine that does not go to thyroid tissue will be eliminated from your body during the first few days after treatment. Radioiodine leaves your body primarily through your urine, but very small amounts can be found in your saliva, sweat, bowel movements and other bodily fluids.

Ask your doctor for more information. You also may get more information from the Society of Nuclear Medicine and Molecular Imaging at www.snmmi.org.

How can you reduce radiation exposure to others?

Radiation exposure to other people can be reduced by keeping a reasonable distance between yourself and others and keeping the time you are close to others to a minimum. Your doctor should review the following instructions with you and answer all of your questions. It is important to let your doctor know if you will not be able to follow all of these instructions.

These instructions apply if you are returning to your own home after treatment using private transportation. You should ask your doctor for additional instructions if you are planning to use public transportation or stay in a hotel or other non-private lodging.

First 8 hours:

Drink one glass of water each hour and use the bathroom as soon as possible when you need to empty your bladder. Men should sit on the toilet while urinating to decrease splashing. Use a tissue to wipe up any urine on the toilet bowl and flush twice. Wash your hands and rinse the sink.

Maintain a distance of at least 3 feet from all people. If possible, you should drive home alone. If it is not possible to drive alone, you should choose the seat that keeps as much distance as possible between you and the other passengers.

First two days:

Do not share cups, glasses, plates or eating utensils. Wash items promptly after using. Other people may use items after they are washed.

Do not share towels or washcloths.

Flush the toilet twice and rinse the sink and tub after use.

Wash your towels, bed linens, underwear, and any clothing stained with urine or sweat.

First week:

Arrangements should be made for others to provide childcare for infants and very young children.

Sleep alone for 7 days unless otherwise instructed by your doctor.

Avoid kissing and physical contact with others, and maintain a distance of at least 3 feet from women who are pregnant and children under 18 years old.

Avoid activities where you may be close to others for more than 5 minutes, for example, movie theaters, sporting events and shopping malls.

Additional instructions for women who are breastfeeding

You must stop breastfeeding before you can be treated with radioiodine. If possible, you should stop breastfeeding for 6 weeks prior to treatment. You should not resume breastfeeding after treatment for your current child, but you may safely breastfeed babies you may have in the future. Failure to follow this guidance may result in permanent damage to the thyroid gland of the nursing infant or child.

Pregnancy

Radioiodine treatment should not be given during pregnancy. Tell your doctor if you are pregnant or could be pregnant. If you are planning to become pregnant, you should wait at least 6 months after treatment to ensure your thyroid hormone level is normal and that you do not need additional treatment. Consult your doctor.

Other things you should know during the first week after treatment:

Small amounts of radiation from your body may trigger radiation monitors at airports, border crossings, government buildings, hospitals, and waste disposal sites for up to 3 months after treatment. Ask your doctor for advice if you will be in these areas. Your doctor can provide you with a letter describing your medical treatment if you cannot avoid these areas.

Discarded items that are heavily stained with urine, saliva, nasal secretions, sweat or blood may trigger alarms at waste disposal sites. Ask your doctor for advice on how to safely dispose of these items.

Many other available resources are available online and at various institutions that provide radioactive iodine therapy for hyperthyroidism as well as cancer treatment. We collected various sources of patient information, and then as a group reviewed, rated and commented on the scope of the sources. A table of these resources and websites is listed as an Addendum to this document.

A subcommittee of the SNMMI-ACNM Joint Government Relations Committee evaluated various relevant websites (Table 1), and scored them on a scale of 1-5 (1 being the least valuable and 5 the most valuable) based on the quality of information, scientific rigor and applicability to the subject at hand. Additional information regarding the perceived website audience and comments were also compiled.

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

It is of upmost importance that the treating physician has a good understanding of the patient's disease status and also be well informed on their current socioeconomic status, living arrangements, and ability to comply with the recommendations. This includes detailed communication between the practitioner and the patient, regardless of language barriers. Appropriate medical translators should be available, in person or via other approved electronic translation services. Occasionally, a family member or friend of the patient may also be a method to increase compliance and improve retention of the recommended precautions and risks.

A discussion concerning the patient's release must take place in order to alert the patient of necessary precautions after radioiodine treatment. The suitability for release must be determined by the treating physician, who should consider the patient's understanding and willingness to comply with the precautions.

It is important to provide appropriate treatment to the patient while ensuring safety for any individuals that they may come in contact with during the treatment course. Several factors should be considered, including but not limited to, socioeconomic barriers, the patient's routine contacts, willingness to abide by the recommendations and follow up, and work environment. A conversation should take place regarding who resides with the patient and what living arrangements are. This conversation should specifically include the topic of availability of bathroom and sleeping facilities.

C. Guidance for Released Patients

Many patient tools are available for patients undergoing treatment with I-131, including facility brochures, websites (as reviewed above), and Society guidelines. Guidelines and recommendations for the patient should be communicated in a manor such that the patient has understanding of treatment side effects and radiation safety concerns.

The SNMMI strongly encourages that, prior to release, a patient's individual situation is thoroughly understood and that the instructions are personalized, appropriate, clear, and easy-to-follow. These instructions should be available, both written and verbally, in the preferred language of the patient.

The patient and physician should discuss activities of daily living (from transportation to childcare, disposing of waste and more…), and be able to demonstrate willingness to comply. As these activities are variable in patients, it is vital that instructions are individualized to fit any possible special situations.

In August 2014, SNMMI requested information from all members regarding the information supplied to the patients treated with I-131.

Summary of results:

- Members from over 30 hospitals and other facilities across the United States responded
- The majority (19) had instructions in place which were more stringent than SNMMI's guidelines
- 2 facilities had instructions less stringent than SNMMI's instructions
- The remaining facilities had instructions which either aligned with SNMMI's brochure or were not specified

D. Brochure for Nationwide Use

As mentioned in Section A, SNMMI has a brochure available for free download that is available for Nationwide Use. The brochure is available for free download here - http://snmmi.files.cms-plus.com/FileDownloads/Patients/FactSheets/Radio_.pdf

SNMMI is ready to discuss any of its comments or meet with the NRC regarding the above issues. In this regard, please contact Susan Bunning, Director, Health Policy and Regulatory Affairs, by email at sbunning@snmmi.org or by phone at 703-326-1182.

Sincerely,

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Addendum

Table 1. Patient release practices for I-131: website reviews

Procedure/ standard	Website	Rating	Date	Audience	Comments
SNMMI patient instructions	http://snmmi.files.cms-plus.com/FileDownloads/DiscoverMI/FactSheets/Radio_.pdf	5	2011	Patients	Ideal for patients, families, and caregivers
SNMMI procedure standards	http://snmmi.files.cms-plus.com/docs/Scintigraphy%20for%20Differentiated%20Thyroid%20Cancer%20V3%200%20(9-25-06).pdf	5	2006	Physicians/ Professionals	Ideal for healthcare professionals, though outdated
ACR Appropriateness Criteria	https://acsearch.acr.org/docs/3082874/Narrative/	5	2013	Physicians/ Professionals	Good information, though not within the scope of information needed
Up To Date	http://www.uptodate.com/contents/differentiated-thyroid-cancer-radioiodine-treatment#H130958638	5	2015	Professionals	Excellent resource for professionals and individuals with a high degree of health literacy, could be expanded to a broader audience
ATA patient instructions	http://www.thyroid.org/radioactive-iodine/	4	2012	Patients	Beyond reasonable expectations with recent guidelines
ATA radiation safety	http://www.thyca.org/download/document/184/ataradiation.pdf	4	2011	Physicians/ Professionals	Good, though physician based
Safety practices survey	http://www.thyroidcancercanada.org/userfiles/files/I-131_Current_Safety_Practices.pdf	4	2011	Physicians/ Professionals	Good resource, but contains some degree of bias
Duke University Presentation	http://www.aapm.org/meetings/05AM/pdf/18-2638-6734-583.pdf	3	2005	Physicians/ Professionals	Not enough cross-references, not current
RADAR	http://www.doseinfo-radar.com/RADAR-INT-NM-Release.html	3	n.d.	Physicians/ Professionals	Needs updating and more specific patient information
Arkansas regulations	http://www.healthy.arkansas.gov/programsServices/hsLicensingRegulation/RadiationCo	3	2005	Professionals and patients	Needs updating, state specific , no references

	ntrol/radioactiveMaterials/Documents/references/GuidanceI131Patients.pdf				
UAB	http://www.uab.edu/ohs/images/docs/rad/Patient_Release_Criteria_2013-09-20.pdf	3	2013	Professionals	Lacking scientific information
UChicago	https://radiology.uchicago.edu/sites/radiology.uchicago.edu/files/uploads/I-131%20low%20dose%20therapy.pdf	3	2010	Patients	Good concept, but too high degree of variability in patient requirements
Duke calculator	https://www.safety.duke.edu/RadSafety/discharge_demo/default.asp	2	n.d.	Physicians/ Professionals	Not within the scope of NRC's request
UNC	http://ehs.unc.edu/radiation/docs/patient_survey.pdf	2	2014	Physicians/ Professionals	Institution specific, not sure about broad utility
MUSC	http://academicdepartments.musc.edu/vpfa/operations/Risk%20Management/radsafety/manual/APPENDIXI.pdf	2	2001	Professionals	Out of date
LSU	http://www.sh.lsuhsc.edu/raddept/pdf/sec18/Rad%20Proc%2018.8.1.19.pdf	2	2014	Professionals	Brief, not relevant to scope