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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-0034
Comment on FR Doc # 2015-29027

Submitter Information

11/16/2015

Name: Lynne Fairobent
Submitter's Representative: Lynne Fairobent
Organization: AAPM

@FR 70843

General Comment

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See attached file(s)

Attachments

2016-02-16-AAPM-comments_NRC_Patient_Release

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February 16, 2016

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

Re: Docket No. NRC-2015-0020

Dear Ms. Bladey:

The American Association of Physicists in Medicine¹ (AAPM) is pleased to provide comments on the Sodium Iodide-131 Patient Release Information Collection (NRC-2015-0020) published in the Federal Register on November 16, 2015.

1. Introduction

The U.S. Nuclear Regulatory Commission (NRC) is requesting information from stakeholders regarding medical treatment of patients with I-131 and public radiation exposure concerns related to releasing I-131 patients.

Specifically, the NRC is seeking input on:

- Patient concerns about medical treatment involving the use of I-131;
- Information that physicians use to determine when it is safe to release I-131;
- Radiation safety information used by I-131 patients after their release; and
- Availability of a radiation safety information/guidance for I-131 patients.

We address each of these subject areas in the paragraphs below.

2. Patient concerns about medical treatment involving the use of I-131

AAPM believes it is not appropriate for the NRC to request information from patients on their concerns about medical treatment involving the use of I-131 independently of their physician. A patient's concerns

¹ The American Association of Physicists in Medicine's (AAPM) is the premier organization in medical physics, a broadly-based scientific and professional discipline encompassing physics principles and applications in biology and medicine whose mission is to advance the science, education and professional practice of medical physics. Medical physicists contribute to the effectiveness of radiological imaging procedures by assuring radiation safety and helping to develop improved imaging techniques (e.g. mammography, CT, MR, ultrasound). They contribute to development of therapeutic techniques (e.g., prostate implants, stereotactic radiosurgery), collaborate with radiation oncologists to design treatment plans, and monitor equipment and procedures to insure that cancer patients receive the prescribed dose of radiation to the correct location. Medical physicists are responsible for ensuring that imaging and treatment facilities meet the rules and regulations of the U.S. Nuclear Regulatory Commission (NRC) and various state regulatory agencies. AAPM represents over 8,000 medical physicists.

about their medical treatment are best discussed with their physician as defined in the NRC's Medical Use of Byproduct Material Policy.

Additionally, while patients have expressed concerns anecdotally, demonstrated harm to others has not been shown from patients released per the restrictions identified in the I-131 patient calculation model presented in Appendix U of NUREG 1556, Vol. 9, Rev 2, or the RADAR Patient Exposure Radiation Dose Calculator².

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

Most licensees will use the release calculation model in Appendix U of NUREG 1556, Vol. 9, Rev 2, or the RADAR Patient Exposure Radiation Dose Calculator³. The Health Physics Society has published a position statement⁴ on the NRC patient release dose criteria that maintains release of patients in accordance with 10 CFR §35.75 poses no discernable risk to the public, thus providing ample public health and safety measures, while offering significant benefits to patients, their families, and society. Numerous publications have evaluated radiation exposure to others from I-131 patient therapies and report exposures to others are unlikely to exceed 1mSv. If there is concern that a particular licensee is not using appropriate patient release criteria, this will be determined during routine inspection of the radiation protection program.

A nuance of this issue that has not been discussed is that 10 CFR §35.75 states: *A licensee may authorize the release from its control of any individual who has been administered unsealed byproduct material or implants containing byproduct material if the total effective dose equivalent to any other individual from exposure to the released individual is not likely to exceed 5 mSv (0.5 rem)*. Although this section is required for the release of patients receiving I-131 treatments, it is also required for patients with diagnostically administered radiopharmaceuticals, such as Tc99m cardiac stress patient procedures.

4. Radiation safety information used by I-131 patients after their release

This information is available to licensees from the National Council on Radiation Protection and Measurements⁵, the Society of Nuclear Medicine and Molecular Imaging⁶ and the American Thyroid Association⁷ for their use as determined appropriate for the individual patient. If a licensee is not providing

² <http://www.doseinfo-radar.com/ExposureCalculator.html>

³ <http://www.doseinfo-radar.com/ExposureCalculator.html>

⁴ Health Physics Society. Release of Patients Treated with Therapeutic Quantities of Radiopharmaceuticals and Sealed Sources. HPS Position Statement. McLean, VA: HPS; March 2012.

⁵ NCRP Report No. 155, Management of Radionuclide Patients, December 11, 2006.

⁶ Society of Nuclear Medicine Procedure Guideline for Therapy of Thyroid Disease with Iodine-131 (Sodium Iodide) Version 2.0.

⁷ Radiation Safety in the Treatment of Patients with Thyroid Diseases by Radioiodine 131: Practice Recommendations of the American Thyroid Association. THROID; Volume 21, Number 4, 2011.

appropriate radiation safety instruction to patients, this will be determined during routine inspection of the radiation protection program.

5. The availability of a radiation safety informational guidance brochure for I-131 patients that can be distributed nationwide

The development of an informational guidance brochure for I-131 patients should be left to the professional societies who possess the necessary expertise in this area. The Society of Nuclear Medicine and Molecular Imaging and the American Thyroid Association are the leading organizations in addressing I-131 treatment.

6. NRC's proposed development of a web site to provide patients with clear and consistent information about radioactive iodine treatments

AAPM believes it is not appropriate for the NRC to develop a website to provide patient information on radioactive iodine treatment. We are concerned this may confuse patients, as not all information may pertain or be relevant to a respective patient's particular case. Specific instruction on I-131 therapy should be tailored to the patient and be the responsibility of the authorized user.

The Society of Nuclear Medicine and Molecular Imaging and American Thyroid Association offer informational guidance brochures for I-131 patients.

7. Conclusion

In summary, a collaboration of the NRC with the professional organizations mentioned above will help to better educate licensees and address patient specific concerns. The AAPM appreciates the opportunity to participate in this Request for Information.

Should you have any further questions, please contact Richard Martin, Government Relations Specialist at Richard@aapm.org or 571.298.1227 or Lynne Fairbent, Senior Manager for Government Relations at lynne@aapm.org or 571.298.1264.

Sincerely,



Bruce H. Curran, MEng, MS, FAAPM, FACMP, FACR
President