

United States Senate

WASHINGTON, DC 20510-4704

May 30, 2014

Amy Powell
Acting Director, Office of Congressional Affairs
Nuclear Regulatory Commission
Washington, DC 20555-0001

Dear Ms. Powell:

I received the attached communication from Mr. Peter Crane regarding his concerns with the hospital treatment of patients exposed to radioactive iodine 131. I would appreciate it if you consider this issue and would please respond directly to Mr. Crane regarding this matter.

Thank you very much for your time.

Sincerely,



Patty Murray
United States Senator

PM\ks

From: Peter Crane [<mailto:kinderhook46@yahoo.com>]

Sent: Friday, March 28, 2014 8:11 PM

To: Evans, Ariel (Murray)

Subject: Radioactive patients -- hazards to hotel housekeepers and guests

Dear Ariel,

Thank you very much for your call. Attached is the paper I submitted to the December 2012 conference on radiation safety and health of the International Atomic Energy Agency. There is going to be another IAEA conference this year, on radiation safety in the workplace, and I plan to submit a paper to it as well. If they accept it, I will go.

Please let me know if there is additional information you would like. I can supply a ton of it, including a crisp description of the issue as it relates specifically to hotel workers, but I don't want to swamp you.

Best regards,
Peter

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RADIATION PROTECTION ISSUES ASSOCIATED WITH OUTPATIENT TREATMENT OF THYROID CANCER USING HIGH DOSES OF IODINE-131: THE U.S. EXPERIENCE

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For Session "Protecting patients, carers, comforters, and the public in nuclear medicine"

ABSTRACT

The United States Nuclear Regulatory Commission (NRC) sets no maximum activity level for the release of patients treated with radioactive iodine 131 (I-131). For decades, NRC used an activity-based standard, 1110 MBq, but since 1997, it has allowed medical licensees to use a dose-based standard by which patients can be released without regard to activity level, provided that the probable dose to any other person will not exceed 5 mSv. This limit, applicable even to infants and nursing mothers, far exceeds ICRP, IAEA, and NCRP standards. Outpatient treatment has become the norm in the U.S., even for doses of 7400 MBq and above, as insurance companies refuse to pay for inpatient care. Radioactive patients are frequently released to hotels, where they are a hazard to other guests and above all to housekeepers, who are typically women of childbearing age and may be pregnant or nursing. The dose to unsuspecting hotel workers violates a cardinal principle of radiation protection, informed consent. The NRC has also failed to ensure that practitioners and patients receive appropriate guidance about limiting exposure to others. The 15-year U.S. experience with dose-based standards for I-131 suggests that a major revision of the NRC's rules on radioactive patients is overdue.

1. INTRODUCTION

United States law gives the Nuclear Regulatory Commission (NRC), the agency which oversees nuclear power plants, the incidental duty of regulating the use of radioactive materials in medicine [1]. For decades, the NRC and its predecessor, the Atomic Energy Commission (AEC), required hospitalization for all patients administered 1110 MBq or more of iodine 131 (I-131) [2]. In 1997, however, in response to requests from medical licensees, the NRC changed its rules and began allowing doctors to administer high doses of I-131 on an outpatient basis [3]. The NRC's current rules, unchanged since 1997, present safety issues with respect to therapy doses of I-131 for thyroid cancer, therapy doses for hyperthyroidism, and diagnostic doses for thyroid cancer. This paper focuses exclusively on therapy doses for thyroid cancer.

2. DISCUSSION

2.1 The NRC rule change of 1997

Under the NRC rules in place since 1997, medical licensees treating patients with I-131 can choose between using the 1110 MBq activity standard as a default value and using a dose-based standard, under which patients can be released regardless of activity level if they are found unlikely to expose any other person to 5 mSv in a year [4]. This 5 mSv dose limit applies equally to all persons, irrespective of age, pregnancy status, and relationship to the patient. Only if the external dose to others is likely to exceed 1 mSv do the NRC's rules require licensees to provide patients with guidance on precautions for reducing radiation exposure to others.

In 1985, the NRC stated, accurately, that patients treated with I-131 are "a source of external radiation and can be a source of radioactive contamination" [5]. In 1997, however, the NRC declared that internal dose from contamination was insignificant, except for babies and nursing mothers, and stated: "[I]nternal exposures will not be considered in this analysis other than for the breast-feeding infant" [6]. The NRC conceded that exposure to patients' family members could be better controlled in

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a hospital setting, but pointed out that sending patients home would mean lower radiation doses to frequent hospital visitors, such as members of the clergy, and hospital orderlies [7].

The NRC's decision that its limits on I-131 should be made less stringent came just as international and national bodies were moving in the opposite direction, toward **more** stringent controls on the isotope. ICRP 60 (1991) had reduced dose limits to the public to 1 mSv per year, and the IAEA's Basic Safety Standards (1996) prescribed hospitalization for any I-131 treatment of more than 1110 MBq [8, 9]. For many nations, moreover, the 1110 MBq activity limit of the BSS was **insufficiently** strict. As of 1998, activity limits in the EU Member States ranged from 95 to 800 MBq, with most between 400 and 600 MBq [10].

2.2 Effects of the NRC rule change

Once the new rule was in place, many physicians found that insurance companies were refusing to pay for inpatient treatment with I-131 on the grounds that it was no longer necessary. For a doctor to insist on hospitalization was, therefore, to risk not being reimbursed. At a meeting of the NRC's Advisory Committee on the Medical Uses of Isotopes in 2007, two doctors (both supporters of the current rule, it should be stressed) candidly acknowledged the dominant role of insurers in the decision whether to hospitalize patients for I-131 therapy¹ [11].

A recent survey of 311 health professionals found that 15% **never** hospitalized patients for I-131 doses below 7363 MBq; 6% **never** hospitalized for doses below 11,063 MBq; and only 22% **invariably** hospitalized for doses between 7363 and 11,063 MBq [12]. In 2002, after receiving reports that released I-131 patients were exposing members of the public to radiation, the NRC Commissioners considered and rejected a proposal to require a report to the NRC if a patient caused a dose to another person of 50 mSv or more [13]. If hard data pointing to the rule's adverse effects is sparse, it is in part because the NRC has chosen not to receive it.

2.3 Radioactive patients in hotels

In changing its rules, the NRC assumed that patients would either meet the criteria for release, in which case they would go directly home, or remain hospitalized. It had not foreseen a third possibility: that some patients, either because the criteria for home release could not be met or because they lived far away, might be sent to hotels. This presents serious risks to hotel chambermaids, who in the U.S. are typically women of childbearing age. These workers do not "knowingly and willingly" accept their exposure to radiation. Unlike hospital staff and the families of patients sent home, they are unaware of the contamination and cannot take even basic precautions. A chambermaid may receive a substantial internal dose, and if she is pregnant or nursing, her baby's thyroid may also be affected. If

¹ Dr. Douglas Eggli: "We can't get a preceptor to admit most patients to the hospital anymore from the insurance companies since the release rule went into effect. ... If I am admitting somebody [with] less than 200 millicuries [7400 MBq], the chances that I can get an insurance authorization for a hospitalization to isolate them, **even when I have family situations that require it**, it's fighting tooth and nail with the insurance companies...."

Dr. Leon Malmud: "It is not now possible to treat a patient at our hospital and many hospitals in the Philadelphia area with I-131 in high doses for thyroid cancer because in order to do that a patient has to be isolated in a room which itself is isolated from the rooms next door. Therefore, **all patients are discharged upon treatment. We whisk them out the doors as fast as possible.** They are given outpatient doses between 100 and 200 millicuries [3700 MBq and 7400 MBq] of I-131, depending upon the extent of their thyroid cancer and occasionally, even higher doses. ... There's also an impossibility of keeping the patient in the hospital since the insurer will not cover it. The insurer will not cover it, will not cover the inpatient stay. It will cover the treatment, but not the inpatient stay. ... Being in the hospital today in most situations is an absolute impossibility. The nursing staff won't care for the patient. The other personnel in the hospital don't want to be near the patient. ... Within the hospital, this patient is an unwelcome guest currently. **Uninsured, their wonderful insurance stops because it's no longer necessary for them to be an inpatient.** The health care workers are concerned and the hospital will not allow them to stay." [Emphasis added.] [Transcript at pp. 126-130.]

the hotel is near a cancer center, moreover, she may clean numerous contaminated rooms in a year. Guests in adjoining rooms may also receive external radiation doses through the walls. Current estimates are that between 4 and 5 percent of patients go to hotels after receiving therapeutic doses of I-131 [14].

In 2009, the New York City Department of Health issued a directive to medical licensees warning in forceful terms against sending radioactive patients to hotels [15]. In 2011, the NRC published a non-binding notice that "strongly discouraged" licensees from doing so [16]. The practice nevertheless continues, and even has defenders. In a March 2011 article in an online medical journal, *ASCO Post*, Dr. R. Michael Tuttle, a distinguished thyroidologist at Memorial Sloan-Kettering Cancer Center in New York, was quoted as saying that Sloan-Kettering gives outpatient doses of up to 7400 MBq of I-131 [17]. "We are absolutely comfortable that it is safe for these patients to be in a hotel," Dr. Tuttle reportedly said, adding, "Many patients don't have a choice, because they are flying in for their treatments." In context, the implication was that if they returned home to countries with stricter standards, airport radiation detectors would identify them. Currently, the chance that a radioactive patient will be identified in a hotel or motel is virtually nil, unless, as happened in Illinois in 2007, the person occupying a room just vacated by an I-131 patient happens to work in a nuclear power plant, and the contamination on his skin sets off the plant's radiation alarms [18].

2.4 The NRC reaffirms the 1997 rule

In 2005, the present writer, a retired NRC lawyer who had in the past received I-131 treatments totaling over 28,000 MBq, filed a petition asking the NRC to revisit its rules on release of radioactive patients [18]. A supplementary filing in 2006 raised the issue of radioactive patients in hotels and the resulting risk to chambermaids [19]. The NRC denied the petition in 2008, in a decision that rejected the idea of adopting a 1 mSv limit for infants and children, and made no mention of hotels [20]. (In 2009, a federal court dismissed the resulting appeal on procedural grounds, accepting the NRC's argument that because the petitioner's I-131 treatments had occurred long in the past, he was insufficiently affected by the NRC's rule to be allowed to challenge it in court [21].) At the same time that it denied the petition, the NRC issued a "Regulatory Issue Summary" [22] that drew medical licensees' attention to ICRP 94 [23] and ICRP 103 [24] and their warnings about the hazard to infants and children from I-131 patients. Acknowledging that the 1997 rule had been based on the assumption that internal dose presented insignificant risks, the NRC notice asked doctors to "consider" hospitalizing patients with children at home. It made clear, however, that the request was not binding.

2.5 The current situation

Not only is U.S. practice regarding radioactive patients unconservative by comparison with world practice, it has failed to provide appropriate safety guidance to aid licensees and patients in minimizing radiation doses to others. Although NCRP 155 [25] (a report which reaffirms earlier NCRP recommendations of a 1 mSv dose limit for children, pregnant women, and the public) includes sample precautions for thyroid patients treated with I-131, the NRC has not recommended their use. Instead, current NRC guidance suggests that licensees obtain and use a pamphlet issued in 1987, when the 1110 MBq activity standard still applied [26]. The NRC's approach to human I-131 patients contrasts with its stringent rules for cats treated with I-131 for feline hyperthyroidism. Typically administered doses of 111 to 222 MBq, they must be hospitalized for a minimum of 72 hours [27].

3. CONCLUSION

The IAEA has recently revised the BSS to eliminate the 1110 MBq activity limit on I-131, and endorsed the dose-based approach to protecting the public from treated patients [28]. In its February 23, 2010 "Position statement on release of patients after radionuclide therapy" [29], the IAEA implied that "global harmonization" had been achieved among ICRP 94, SRS 63 [30], EC publication Radiation Protection 97 [10], and the NRC's 1997 guidelines. Any such apparent harmonization is purely illusory, however, so long as the IAEA adheres to the 1 mSv dose standard for exposure to the

public, while the NRC's standard is 5 mSv, even for infants and pregnant women. The IAEA and ICRP have yet to address the pressing issue of highly radioactive patients sent to hotels. The exposure of unsuspecting and unprotected hotel chambermaids to I-131 contamination is medically and ethically unacceptable and deserves condemnation. A revision of the NRC's regulations to bring them into conformity with international norms is overdue.

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