

EDO Principal Correspondence Control

FROM: DUE: 01/22/10

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FINAL REPLY:

Representative Edward J. Markey

TO:

Chairman Jaczko

FOR SIGNATURE OF :

** PRI **

CRC NO: 10-0020

Chairman Jaczko

DESC:

ROUTING:

NRC's Regulations for the Treatment of Patients
with Radioisotopes and the Criteria for Which
These Patients are Released from Hospital Care -
Possibly Emitting Radiation
(EDATS: SECY-2010-0040)

Borchardt
Virgilio
Mallett
Ash
Mamish
Burns/Rothschild
Leeds, NRR
Caputo, OI
Collins, RI
Schmidt, OCA
Doane, OIP
Bell, IG
Rihm, OEDO

DATE: 01/14/10

ASSIGNED TO:

CONTACT:

FSME

Miller

SPECIAL INSTRUCTIONS OR REMARKS:

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Approval Level: No Approval Required

OEDO Concurrence: YES

OCM Concurrence: NO

OCA Concurrence: NO

Special Instructions: Ref. G20090597. Any contact Roger Rihm, OEDO for any additional guidance.

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Addressee: Chairman Jaczko

Date Response Requested by Originator: 2/3/2010

Incoming Task Received: Letter

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AUTHOR: *Edward J. Markey*
REP ~~Henry Waxman~~
AFFILIATION: CONG
ADDRESSEE: Gregory Jaczko
SUBJECT: NRC's regulations for the treatment of patients with radioisotopes and the criteria for which these patients are released from hospital care, while possibly still emitting radiation///
ACTION: Signature of Chairman
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LETTER DATE: 01/14/2010
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DATE DUE: 01/26/2010 **DATE SIGNED:**

EDO --G20100026

ONE HUNDRED ELEVENTH CONGRESS
Congress of the United States
House of Representatives

COMMITTEE ON ENERGY AND COMMERCE
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Majority (202) 225-2927
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January 14, 2010

The Honorable Greg Jaczko
Chairman
Nuclear Regulatory Commission
11555 Rockville Pike
Rockville, MD, 20852

Dear Chairman Jaczko:

I am writing in regard to your November 17, 2009 letter to me concerning the Nuclear Regulatory Commission's (NRC) regulations for the treatment of patients with radioisotopes and the criteria for which these patients are released from hospital care, while possibly still emitting radiation that is dangerous to those around them.

In your response, you indicated that the NRC believes that the public is sufficiently protected from this risk provided that "adequate instructions are given at discharge to patients and family members," and that these same considerations - including the need to perform an individualized analysis of a patient's living situation and the determination that the patient will not emit radiation above a threshold level - would also apply to those patients who go to hotels after their release from the hospital.

While I appreciate both your response and the time spent by your staff in providing my office with supplemental background information, I have additional questions and concerns and request your prompt reply.

In 1997, when NRC revised its regulations for how to treat patients that receive radiation treatment, it did so in a way that permits the immediate release of most cancer patients being treated with medical radioisotopes, including iodine-131 (I-131). It is my understanding that what NRC intended was for patients to be released to their homes or, in situations in which release was not possible, for these patients to remain hospitalized. However, nothing in the NRC rulemaking documents suggests that there may be prevalence of a third possibility, namely that patients would be instructed to go to a hotel, or would do so on their own initiative. In 2009, the Minnesota Department of Health issued new guidance to its licensee facilities discouraging physicians from suggesting that patients use hotels after their release; noting that this practice has

proven to cause significant concerns to hotel property, staff and guests. The health departments of Washington State and New York City have issued a similar warning to its licensees.

When NRC revised its regulations in 1997 it also issued guidance for criteria that must be met before patients treated with radioactive iodine (I-131) in excess of default limits (30 millicuries) could be released from the hospital¹. This guidance includes the need to conduct an individualized assessment of a patient's living situation to ensure that the effective dose to any other individual from exposure to the released patient would not exceed a threshold value of 0.5 rem. The release of an I-131 patient to a hotel, where there is potential for pregnant hotel workers and children of guests to be unwittingly exposed is exceptionally problematic because for patients released to hotels it would be difficult, if not impossible, to come up with credible assumptions with which to estimate the dose received by an unknown person at an unknown distance when performing the sort of individualized analysis referenced in the 1997 guidance that is based partly on a patient's proximity to others, since each hotel is differently designed.

It is my understanding that the NRC performs sampling inspections of hospitals that are licensed to use I-131 in medical treatments. These inspection records should be useful in assessing how exactly hospitals are currently advising patients, and how exactly the Commission is overseeing these efforts. Please provide the Subcommittee with responses to the following questions and requests for information

1. In your letter to me you cite the 2006 report of the National Council on Radiation Protection (NCRP), No. 155, which found that with "adequate instructions," no member of the public is likely to be exposed to more than 5 millisieverts of radiation by a released patient. However, NCRP No. 155 also says that for children and pregnant women, the acceptable dose rate is not five millisieverts, but one-fifth that: "Pregnant women and children *shall not* exceed 1 millisieverts." Later in your response, you state that "There is no distinction between the dose limits that apply to other members of the public and those that apply to pregnant women and young children", yet you also state that NRC's release requirements are consistent with NCRP. Can you please clarify the NRC position on this? Does NRC agree with the NCRP's recommendation for a lower dose limit to pregnant women and children? If not, why not? If so, then how is that recommendation factored into NRC's regulations regarding the release of patients treated with radionuclides?
2. How many I-131 licensee facilities are there in the United States?
3. How often does the NRC perform sampling inspections each of these I-131 licensee facilities?

¹ Nuclear Regulatory Commission, *Criteria for the Release of Individuals Administered Radioactive Material*, 62 Fed. Reg.4120 (January 29, 1997) Final Rule.

4. What does such an inspection entail? Please provide copies of any handbooks or inspection checklists or other similar documents that are used to conduct such inspections.
5. NCRP 155 includes "Radiation Safety Precautions for Radiopharmaceutical Therapy Patients."² For a patient receiving 175 millicuries of I-131, the patient is instructed not to hold or embrace children for more than 10 minutes a day for 21 days; to refrain from sharing a bed with one's sleeping partner for 7 days; and for the first day, to store and launder one's used clothing and bed linens separately from the rest of the household, using two rinse cycles; to wipe down the telephone with paper towels and then discard the paper towels; etc. What instructions has NRC given to its medical licensees about how to provide guidance to patients to ensure that these radiation precautions will be followed?
6. In the past ten years, how many times has NRC, as part of these inspections, requested documentation from the licensee facilities that details the individualized analysis and/or dose calculations used when determining whether to send a patient that was treated with I-131 in excess of the default limits home, or to a hotel?
7. In the past ten years, how many times has NRC, as part of these inspections, requested documentation from the licensee facilities that details the guidance provided to the patient by the licensee facility when the patient is released from licensee care?
8. In the past ten years, how many times has NRC identified problems with the individualized analysis and/or dose calculations used or guidance provided to the patient by the licensee facility? Please detail these problems.
9. In situations where an individualized analysis of dose to others is required, it would seem impossible for the authorizing physician to do so for a patient going to a hotel, since this would require a knowledge of the layout of the hotel and the proximity to the nearest other guest, who might be a child or a pregnant woman sleeping on the other side of a wall. Do you agree?
10. Has the NRC ever attempted to determine how many patients treated with I-131 are a) sent home, b) sent to a hotel or c) kept in the hospital for additional time? If so, please provide the results. If not, why not?

² National Council on Radiation Protection & Measurements, *NCRP Report No. 155 Management of Radionuclide Therapy Patients*, 2006, Appendix B, pages 166-168.

The Honorable Greg Jaczko

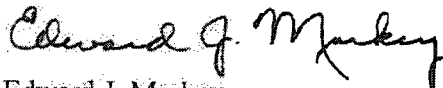
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11. In patients with doses in excess of the default limits, has the NRC ever attempted to determine whether these I-131 licensee facilities always perform individualized analysis of each patient's living circumstances prior to releasing them? If not, why not? If so, has NRC ever encountered situations when individual analyses and/or dose calculations were not performed when they were required? Please provide reports and documentation relating to these cases.
12. What are the disclosure rules for patients who go to a hotel following treatment? Are licensees required to give patients explicit instructions to provide to hotel management?
13. The health departments of Minnesota, Washington State, and New York City have all issued advisories warning licensees not to send radioactive patients to hotels. Is it the NRC's view that these advisories were uncalled-for? If not, why has the NRC issued no such guidance?
14. In 2002, the NRC Commissioners voted against receiving reports of instances in which released I-131 patients caused radiation exposure to family members or members of the public.³ How can NRC be confident that its rule is not causing harm when it has declared its unwillingness to be notified of events in which harm occurs? Do you believe that this proposal should be reconsidered? Why or why not?
15. Please also provide reports for instances in which documents relating to patient release were found to be missing, inadequate, or unclear during the course of a sampling inspection. If your sampling inspections found that a licensee knew of a patient who went to a hotel after treatment, whether or not by explicit instruction, please provide all documentation relating to those cases.

Thank you very much for your prompt attention to this important matter. Please provide your response no later than Wednesday February 3, 2010. If you have any questions or concerns, please have your staff contact Dr. Avenel Joseph or Dr. Michal Freedhoff of my staff at 202-225-2836.

Sincerely,



Edward J. Markey

Chairman

Subcommittee on Energy and Environment

³ Nuclear Regulatory Commission, *Commission Voting Record*, August 27, 2002, (online at <http://www.nrc.gov/reading-rm/doc-collections/commission/cvr/2002/2002-0111vtr.pdf>).

The Honorable Greg Jaczko

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cc: The Honorable Henry A. Waxman
Chairman

The Honorable Joe Barton
Ranking Member

The Honorable Fred Upton
Ranking Member
Subcommittee on Energy and Environment