EDO Principal Correspondence Control

FROM: DUE: 10/22/09 EDO CONTROL: G20090597
DOC DT: 10/13/09
FINAL REPLY:

Representative Edward J. Markey

TO:

Chairman Jaczko

FOR SIGNATURE OF : ** PRI ** CRC NO: 09-0512

Chairman Jaczko

DESC:

Commission's Regulation Involving the Treatment of Patients with Radioisotopes
(EDATS: SECY-2009-0457)

DATE: 10/14/09

ASSIGNED TO: CONTACT:

FSME Miller

SPECIAL INSTRUCTIONS OR REMARKS:

Coordinate response with NRR, OI, RI, OIP, and OGC, as appropriate.

POC: Roger Rihm, OEDO

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Template: SECY-017 E-RIDS: SECY-01

EDATS

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EDATS Number: SECY-2009-0457 **Source:** SECY

General Information

Assigned To: FSME
OEDO Due Date: 10/22/2009 5:00 PM
Other Assignees:
SECY Due Date: 10/26/2009 5:00 PM
Subject: Commission's Regulation Involving the Treatment of Patients with Radioisotopes
Description:

CC Routing: NONE
ADAMS Accession Numbers - Incoming: NONE
Response/Package: NONE

Other Information

Cross Reference Number: G20090597, LTR-09-0512
Staff Initiated: NO
Related Task:
Recurring Item: NO
File Routing: EDATS
Agency Lesson Learned: NO
OEDO Monthly Report Item: NO

Process Information

Action Type: Letter
Priority: High
Sensitivity: None
Signature Level: Chairman Jaczko
Urgency: NO
OEDO Concurrence: YES
OCM Concurrence: NO
OCA Concurrence: NO
Special Instructions: Cooridnate response with NRR, OI, RI, OIP, and OGC, as appropriate.

Document Information

Originator Name: Representative Edward J. Markey
Date of Incoming: 10/13/2009
Originating Organization: Congress
Document Received by SECY Date: 10/14/2009
Addressee: Chairman Jaczko
Date Response Requested by Originator: 10/30/2009
Incoming Task Received: Letter

OFFICE OF THE SECRETARY
CORRESPONDENCE CONTROL TICKET

Date Printed: Oct 14, 2009 11:35

PAPER NUMBER:	LTR-09-0512	**LOGGING DATE:**	10/14/2009
ACTION OFFICE:	EDO		
AUTHOR:	REP Edward Markey		
AFFILIATION:	CONG		
ADDRESSEE:	CHRM Gregory Jaczko		
SUBJECT:	Concerns Commission's regulation involving the treatment of patients with radioisotopes		
ACTION:	Signature of Chairman		
DISTRIBUTION:	RF, OCA to Ack		
LETTER DATE:	10/13/2009		
ACKNOWLEDGED	No		
SPECIAL HANDLING:	Commission Correspondence		
NOTES:			
FILE LOCATION:	ADAMS		
DATE DUE:	10/26/2009	**DATE SIGNED:**	

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October 13, 2009

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

Dear Chairman Jaczko:

I am writing regarding the Commission's regulation involving the treatment of patients with radioisotopes. While these materials certainly are tremendously important from a medical perspective, and the Subcommittee has been engaged in an ongoing legislative effort to ensure their continued availability, it is important that we ensure that they are used with careful oversight to protect the safety of patients, patients' family members, and the general public. I am concerned that current NRC regulations as well as its oversight of nuclear medicine practitioners may result in some unnecessary, unwitting and inappropriate exposures of individuals to dangerous levels of radiation.

As you are aware, in 1997 the NRC revised its regulations for how to treat patients who receive radiation treatment in a way that now permits immediate release of most cancer patients being treated with medical radioisotopes, including iodine-131 (I-131). In contrast with the NRC's policy, a European Commission document entitled "Radiation Protection Following Iodine-131 therapy (exposures due to out-patients or discharged in-patients[1])" states that "sending patients home immediately after the administration of the radionuclide cannot be justified in most situations because both excretion and external radiation (the patient is a source) will give rise to high doses to other individuals in contact with the patient for a few days." This risk is particularly high for infants and children who may come in contact with bodily fluids, such as saliva and sweat, as well as a treated patient's breath, all sources of I-131 radiation.

On September 2, 2005, Mr. Peter Crane, a former NRC career employee, filed a petition with the Commission to overturn this patient release rule.[2] His petition described a case in which a woman received 150 millicuries of I-131 as part of her cancer treatment, was sent home (using public transportation) to her husband and children, thereby exposing members of the general public as well as her family to radiation. I am informed that other patients are released from the hospital and are sent to stay in hotels instead of their homes. Clearly, individuals who share the public transportation, home,

[1] See http://ec.europa.eu/energy/nuclear/radioprotection/publication/doc/097_en.pdf
[2] See http://edocket.access.gpo.gov/2005/E5-7641.htm

and hotel rooms with the patients who received I-131 would also be receiving doses of radiation, often without their knowledge. Some of these individuals could be pregnant women or small children, who are particularly vulnerable when exposed to this radio-isotope. Mr. Crane's petition was denied by the Commission in 2008, and a court recently ruled that he did not have standing to continue to pursue it because he is not currently undergoing medical treatment with radio-isotopes.

The elimination of the requirement to hospitalize patients with the equivalent of 30 millicuries or more of radiation in their system means that many cancer patients are being treated as outpatients, with potentially dangerous levels of exposure for those with whom they come into contact as a result. Clearly, this outcome is one that might cause significant adverse health impacts.

I am also concerned about a recent article in the New York Times[3] that details a series of major medical errors at the Philadelphia Veterans Affairs Medical Center (VAMC) where a doctor retroactively altered treatment plans on procedures involving use of radioisotopes in order to cover up major medical errors, leading to adverse side effects as well as less potent and effective treatment. The incidents raised questions about the adequacy of the Commission's efforts to oversee and investigate these sorts of procedures.

The Commission has a responsibility to ensure that the administration of vital nuclear medicine treatments occurs in a manner that is consistent with the highest levels of safety for those treated and others who might be impacted. Unfortunately, in recent years it appears to not be living up to that responsibility. In order to better understand that facts and circumstances surrounding this matter, I ask your prompt assistance in answering the following questions:

Questions related to patient release criteria:

1) Do you plan to revisit the issues raised in Mr. Crane's petition? If so, please detail your plans. If not, please explain why you believe it makes sense for the U.S. regulations on this important public health matter to be so much less protective of public health than the European Union's.
2) It is my understanding that International Basic Safety Standards on radiation protection lists one of the criteria for an acceptable radiation protection regime to be the hospitalization of patients with more than 30 millicuries of I-131 in their bodies.[4] Why did the NRC choose to promulgate a rule that was not consistent with these international radiation safety standards?
3) At the time it promulgated the new rules, in 1997, NRC stated that releasing a patient with more than 30 millicuries of radiopharmaceutical content, would require an individualized analysis of the patient's living situation to determine the probable dose to others. Only if that dose did not exceed 500 millirem could the patient be released. But in recent issuances, NRC has been silent on the individualized analysis, suggesting this evaluation is not mandatory. Does NRC

[3] See http://www.nytimes.com/2009/06/21/health/21radiation.html?_r=2
[4] http://www-pub.iaea.org/MTCD/publications/PDF/Pub996_EN.pdf

enforce the requirement of an individualized analysis and calculation of radiation dose for administrations of I-131 and other radioisotopes in excess of 30 millicuries, and if so, how?

4) How is it possible to justify sending individuals who have been treated with I-131 to hotels, where cleaning staff and subsequent guests would have no way of knowing that the occupied room was contaminated? Isn't it possible that all the linens in the hotel would risk becoming contaminated if the linens used by the treated individual are laundered with the rest of the hotel's laundry? Isn't it possible that some of the resultant exposed individuals would be pregnant women, infants or young children?
5) A European Commission document entitled "Radiation Protection Following Iodine-131 therapy (exposures due to out-patients or discharged in-patients[5])" states that "sending patients home immediately after the administration of the radionuclide cannot be justified in most situations because both excretion and external radiation (the patient is a source) will give rise to high doses to other individuals in contact with the patient for a few days. After two or three days, however, the patients' residual activity will be sufficiently low to justify their discharge from the hospital."
    a. Does the Commission agree or disagree with this statement? If the Commission disagrees, why?
    b. If the Commission agrees with the statement made in this EC document, then why has it approved a rule which would allow for such exposures?
6) In its 1997 rulemaking, the Commission stated that "In the case of the released patient at home, therapeutic administrations usually occur no more than once in a year and probably no more than once in a lifetime; but in the case of a hospital, large therapeutic administrations are done repeatedly on many patients. Therefore, areas in hospitals have the potential for contamination from many patients, and people who frequent the hospital (e.g., clergy or a hospital orderly) have the potential to be exposed to contamination from many patients."
    a. Aren't hospitals better equipped to control the extent of radioactive contamination (i.e. by placing the patient, linens, etc under radioactive isolation and barring access to clergy and other non-essential personnel) and decontaminate areas and items than would most typical residential homes? Why or why not?
    b. Aren't hospitals better equipped to control the extent of radioactive contamination (i.e. by placing the patient, linens, etc. under radioactive isolation and barring access to clergy and other non-essential personnel) and decontaminate areas and items than would most typical hotels, especially since hotel management would not necessarily know that such contamination was occurring in the first place? Why or why not?
7) Are "safe" levels of radiation exposure different for pregnant women and young children? If so, on what basis is the exposure (witting or unwitting) to radioactive isotopes (particularly I-131) of these individuals justified?
8) In 2001, the Illinois Department of Nuclear Safety wrote to the NRC to warn of the problems posed by radioactive patients. Stating, "simply because NRC does

[5] See http://ec.europa.eu/energy/nuclear/radioprotection/publication/doc/097_en.pdf

not keep records on such events does not mean that such events are not occurring." [6] In response, the NRC Commissioners considered and voted down a proposal under which, if a licensee became aware that a released patient had caused a member of the public or family member to receive a dose ten times allowable limits, this would have to be reported to NRC. 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?

Questions related to incidents occurring at the Philadelphia VAMC:

The first reported error at the Philadelphia VAMC occurred in 2003, when the doctor implanted 40 radioactive seeds in a patient's healthy bladder rather than in his prostate gland as intended to treat his prostate cancer. Instead of reporting this as the error that it was, the doctor evidently altered his medical treatment plan to match the number of seeds that he correctly inserted into the prostate gland. The NRC evidently concluded that the retroactive alteration of the report was not a problem and determined that the incident was not an error in need of oversight by either the NRC or the VA. The doctor in question continued to practice until 2008, and evidently made errors in 92 out of 114 cases.

1) Does the Commission still concur with its earlier finding that if a doctor alters a treatment plan retroactively in order to cover up an error, the incident in question doesn't have to be reported or acted on? Why or why not? Please fully describe NRC's current policy in this area, as well as any proposed or planned revisions to this policy that might be undertaken in the future.
2) It is my understanding that the Advisory Committee on the Medical Uses of Isotopes (ACMUI) has advocated for a *relaxation* of medical reporting procedures, stating that "To the extent possible, NRC's ME reporting and follow-up procedures should be designed to not increase Licensee liability."[7] Does the Commission believe that the purpose of medical reporting is to protect patients from unsafe practices and incompetent physicians or to protect licensees and incompetent doctors from being sued? Please fully explain your response.
3) The ACMUI has historically had a "Patient's Rights Advocate" position. However, for the past decade, this position has been held by a variety of individuals who do not appear to be actual patients rights advocates (such as individuals who work for the medical isotopes industry). Do you think that the Patient's Rights Advocate should be someone free of actual or perceived conflicts of interest with the nuclear medicine industry or practitioners? Why or why not? What plans do you have to fill this position with someone who might be more able to objectively carry out its intended purpose?
4) Please provide an update on the case raised in the New York Times piece and the Commission's response. Did the NRC ever undertake an investigation to

[6] See Attachment A
[7] See Enclosure 2 to SECY-05-0234

determine if there was a pattern of mistakes at the VAMC? Has NRC taken any actions related to the events described in the article or to determine whether similar problems could have occurred elsewhere? Please describe what if any actions have been taken.

Thank you very much for your prompt attention to this important matter. Please provide your response no later than Friday, October 30, 2009. 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

Edward J. Markey