EDO Principal Correspondence Control

FROM: DUE: 03/12/10 EDO CONTROL: G20100089
DOC DT: 02/05/10
FINAL REPLY:

Joyce Lilya
San Diego, California

TO:

Commission

FOR SIGNATURE OF : ** GRN ** CRC NO: 10-0063

Miller, FSME

DESC: ROUTING:

Medical Radiation Overdose (EDATS: SECY-2010-0103)

Borchardt
Virgilio
Mallett
Ash
Mamish
Burns/Rothschild
Satorius, RIII
Burns, OGC
Franovich, OEDO

DATE: 02/19/10

ASSIGNED TO: CONTACT:

FSME Miller

SPECIAL INSTRUCTIONS OR REMARKS:

Template: SECY-017

E-RIDS: SECY-01

# EDATS

Electronic Document and Action Tracking System

**EDATS Number:** SECY-2010-0103 **Source:** SECY

## General Information

**Assigned To:** FSME
**OEDO Due Date:** 3/12/2010 11:00 PM
**Other Assignees:**
**SECY Due Date:** 3/12/2010 11:00 PM
**Subject:** Medical Radiation Overdose
**Description:**

**CC Routing:** RegionIII; OGC
**ADAMS Accession Numbers - Incoming:** NONE
**Response/Package:** NONE

## Other Information

**Cross Reference Number:** G20100089, LTR-10-0063
**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:** Medium
**Sensitivity:** None
**Signature Level:** FSME
**Urgency:** NO
**Approval Level:** No Approval Required
**OEDO Concurrence:** NO
**OCM Concurrence:** NO
**OCA Concurrence:** NO
**Special Instructions:**

## Document Information

**Originator Name:** Joyce Lilya
**Date of Incoming:** 2/5/2010
**Originating Organization:** Citizens
**Document Received by SECY Date:** 2/19/2010
**Addressee:** The Commission
**Date Response Requested by Originator:** NONE
**Incoming Task Received:** Letter

**OFFICE OF THE SECRETARY**
**CORRESPONDENCE CONTROL TICKET**

***Date Printed: Feb 18, 2010 15:35***

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|---|---|---|---|
| **PAPER NUMBER:** | LTR-10-0063 | **LOGGING DATE:** | 02/18/2010 |
| **ACTION OFFICE:** | EDO | | |
| **AUTHOR:** | Joyce Lilya | | |
| **AFFILIATION:** | CA | | |
| **ADDRESSEE:** | Gregory Jaczko | | |
| **SUBJECT:** | Concerns medical radiation overdose..... | | |
| **ACTION:** | Direct Reply | | |
| **DISTRIBUTION:** | RF, SECY to Ack | | |
| **LETTER DATE:** | 02/05/2010 | | |
| **ACKNOWLEDGED** | No | | |
| **SPECIAL HANDLING:** | | | |
| **NOTES:** | | | |
| **FILE LOCATION:** | ADAMS | | |
| **DATE DUE:** | 03/12/2010 | **DATE SIGNED:** | |

3636 Ingraham Street
San Diego, CA 92109
(858) 274-1408
jlilya@aol.com
February 5, 2010

Chairman Gregory B. Jaczko
Commissioner Dale E. Kline
Commissioner Kristine L. Svinicki
U.S. Nuclear Regulatory Commission
Washington, DC 20555

Dear Chairman Jaczko and Commissioners:

My mother, Myra Garman, was the victim of a medical mistake at Akron General Medical Center in 2006. You no doubt read about her case in the second of Walt Bogdanich's recent articles in the *New York Times* about mistakes in radiation medicine.

Let me begin by saying that my reason for pursuing this is not that I wish to profit financially from my mother's tragedy. This is not about money. It is about truthfulness, responsibility, and respect – respect for patients, and also respect for legal obligations.

For me, it is also about making sure that other patients do not have to suffer the same way my mother did, and that their loved ones do not have to go through what hers did. If it were your own family this had happened to, I am sure you would feel the same.

I am not a lawyer, but I have read the documents sent to me by the State of Ohio (including the relevant regulations) and the NRC, and some things are quite clear. The basic facts of the medical mistake are not disputed. My mother was supposed to get 3400 centrigray of radiation, divided into ten fractions of 340 centigray each. Through human error by a health physicist, she was instead given individual doses of 680 centigray, twice the intended amount. After five treatments had been given, a nurse noticed unusual effects on her skin, the calculations were checked, and the overdoses were discovered. The treatments were discontinued.

The hospital contacted the State of Ohio on September 28, 2006, the day after the error was discovered. The hospital's position was that this was not a reportable "medical event." The State nevertheless asked for a written report. A report was submitted, dated October 29, 2006, but it seems that the hospital did not submit it for almost four months, since the State did not receive it until February 26, 2007. The next day, the State notified the hospital that the event did meet the definition of a "medical event," and the state later cited the hospital for its failure to report it -- to the State.

According to the hospital's report, the "attending physician" notified my mother of the error. The attending physician was not identified.

I dispute that she was notified of the error. Presumably my mother was told that it was not necessary for her to receive any more radiation, but she was certainly not given the information that the hospital provided to the state: that tissue necrosis was found, that it was probably made worse by the excessive fractional doses, and that it was unclear whether this would require surgical intervention, possibly including a mastectomy.

The hospital's report to the State also said that my mother was at higher risk of side effects, including rib fractures, because of the overdoses. (My mother did in fact suffer rib fractures, and for her, that was the beginning of the end, until she could no longer endure her suffering, and took her own life.) If she had been told that she was at higher risk of rib fractures, I would certainly have known about it.

Ohio's regulations say that within 15 days of discovering a medical event, the licensee must furnish a written report to the patient, consisting either of the report submitted to the Ohio Department of Health or "a brief description of the event and its consequences for the patient provided that the patient is also made aware of the ODH report and that can be provided as well."

My mother received no written report from the hospital. That was a plain violation of the Ohio regulations. But though Ohio cited the hospital for failing to notify the State, it paid no attention to the failure to notify my mother. When I raised this with the State, I was told that this was a matter for the malpractice system to handle. I dispute that. The fact that someone may have the right to hire a lawyer and go to court to sue a wrongdoer does not mean that regulatory agencies that exist to protect the public can ignore their responsibilities.

I contacted the NRC in June 2009 and described what I saw as the inadequacy of the State's handling of this case. The NRC replied to me on October 7, 2009, with a letter that identified five concerns of mine, including "Whether or not the Concerned Individual's mother was appropriately notified that she was the subject of a treatment that resulted in a medical event." To this (and to three of the other four concerns), the NRC's answer consisted of four words: "The State has jurisdiction." To me, that answer says, about as plainly as can be, "We're not interested, go away." And at the same time, the cover letter from the NRC made the claim, "We believe that our actions in this matter have been responsive." In fact, they were just the opposite.

What I see in this case is an unbroken chain of indifference and neglect. First, we had a hospital that made a highly preventable error, with dreadful consequences for my mother, and that did not care whether my mother received the report to which she was entitled by law. Second, we had a State that made clear that its only interest was whether the hospital reported the event to the State, and did not care whether my mother was informed. Third, we had a federal agency that made clear that it did not care whether the State enforced its patient reporting requirements.

I am deeply disappointed in the NRC's actions in this case, and I hope you will revisit the matter. I do not intend to let this matter drop; I owe that to my parents' memory, and to all the other patients who

may be harmed, now and in the future, by the combination of medical mistakes and regulators who abdicate their responsibilities toward the people they are supposed to protect.

Sincerely,

Joyce Lilya

Joyce Lilya

Cc: Congressman Ed Markey
Walt Bogdanich, *New York Times*