

EDO Principal Correspondence Control

FROM: DUE: 11/02/10

EDO CONTROL: G20100662
DOC DT: 10/26/10
FINAL REPLY:

Representative Edward J. Markey

TO:

Chairman Jaczko

FOR SIGNATURE OF :

** PRI **

CRC NO: 10-0477

Chairman Jaczko

DESC:

ROUTING:

Medical Event Reporting and Notification by the
Nuclear Regulatory Commission and the Agreement
States (EDATS: SECY-2010-0520)

Borchardt
Weber
Virgilio
Ash
Mamish
OGC/GC
Miller, FSME
Burns, OGC
Schmidt, OCA

DATE: 10/28/10

ASSIGNED TO:

CONTACT:

EDO

Rihm

SPECIAL INSTRUCTIONS OR REMARKS:

Note: OEDO is coordinating due date extension with
OCA. Please prepare response in accordance with
OEDO Notice 2009-0441-02 (ML093290179). FSME and
OGC to provide input to Roger Rihm, OEDO, if
required. Roger Rihm will coordinate response with
OGC and OCA.

EDATS

Electronic Document and Action Tracking System

EDATS Number: SECY-2010-0520

Source: SECY

General Information

Assigned To: OEDO

OEDO Due Date: 11/2/2010 11:00 PM

Other Assignees:

SECY Due Date: 11/4/2010 11:00 PM

Subject: Medical Event Reporting and Notification by the Nuclear Regulatory Commission and the Agreement States

Description:

CC Routing: FSME; OGC; OCA

ADAMS Accession Numbers - Incoming: NONE

Response/Package: NONE

Other Information

Cross Reference Number: G20100662, LTR-10-0477

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: Chairman Jaczko

Urgency: NO

Approval Level: No Approval Required

OEDO Concurrence: YES

OCM Concurrence: NO

OCA Concurrence: NO

Special Instructions: Note: OEDO is coordinating due date extension with OCA. Please prepare response in accordance with OEDO Notice 2009-0441-02 (ML093290179). FSME and OGC to provide input to Roger Rihm, OEDO, if required. Roger Rihm will coordinate response with OGC and OCA.

Document Information

Originator Name: Representative Edward J. Markey

Date of Incoming: 10/26/2010

Originating Organization: Congress

Document Received by SECY Date: 10/28/2010

Addressee: Chairman Jaczko

Date Response Requested by Originator: NONE

Incoming Task Received: Letter

OFFICE OF THE SECRETARY
CORRESPONDENCE CONTROL TICKET

Date Printed: Oct 28, 2010 13:16

PAPER NUMBER: LTR-10-0477 **LOGGING DATE:** 10/27/2010
ACTION OFFICE: EDO

AUTHOR: REP Edward Markey
AFFILIATION: CONG
ADDRESSEE: Gregory Jaczko
SUBJECT: Subcommittee on Energy and Environ examination in the way in which medical errors are processed and managed by the NRC

ACTION: Signature of Chairman
DISTRIBUTION: RF, OGC, OCA to Ack

LETTER DATE: 10/26/2010
ACKNOWLEDGED No
SPECIAL HANDLING: EDO should coordinate due date extension with OCA
NOTES: Chairman Correspondence
FILE LOCATION: ADAMS

DATE DUE: 11/~~18~~⁴/2010 **DATE SIGNED:**

EDO --G20100662

HENRY A. WAXMAN, CALIFORNIA
CHAIRMAN

JOE BARTON, TEXAS
RANKING MEMBER

ONE HUNDRED ELEVENTH CONGRESS
Congress of the United States
House of Representatives
COMMITTEE ON ENERGY AND COMMERCE
2125 RAYBURN HOUSE OFFICE BUILDING
WASHINGTON, DC 20515-6115

Majority (202) 225-2927
Minority (202) 225-3641

October 26, 2010

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

Dear Chairman Jaczko:

Pursuant to its ongoing legislative and oversight responsibilities, the Subcommittee on Energy and Environment is examining the way in which medical events and medical errors are processed and managed by the Nuclear Regulatory Commission (NRC) and the Agreement States. In particular the Subcommittee is looking into the manner in which medical event patient notification occurs as per regulations set forth in 10CFR 35.3045.

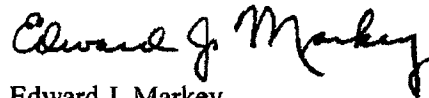
In order to assist the Subcommittee in its investigation of medical event reporting and notification, we request that you provide the Subcommittee with the following information.

- For each of the previous 5 years 2005-2010, please provide the number of "medical events" which were reported to the NRC.
- For each of the previous 5 years 2005-2010, please provide the number of times in which the NRC was made aware that the therapeutic and diagnostic medical use of radioactive materials was investigated, questioned, or identified as being at odds with the original medical treatment plan, but was ultimately not designated as a "medical event".
- All documents and records relating to the above instances, including but not limited to all medical event reports, patient notification records and any other communications between NRC, Agreement States, licensees and patients.

In your response, please also ensure that you include all documents and communication relating to any actual or potential medical events occurring at Akron General Medical Center in Akron, Ohio from 2005-2010, including all documentation on when and how patients involved in the medical event were notified.

Please note that, for the purpose of responding to the above request, the terms "documents", "communication" and "relating" should be interpreted in accordance with the attachment to this letter. We ask that you supply all requested information no later than the close of business on November 12, 2010. If you have any questions relating to this request, please contact Dr. Avenel Joseph of my staff or Dr. Michal Freedhoff of the Energy and Environment Subcommittee Staff at 202-225-2836.

Sincerely,

A handwritten signature in black ink that reads "Edward J. Markey". The signature is written in a cursive style with a large, prominent "E" and "M".

Edward J. Markey
Chairman
Subcommittee on Energy and Environment

Responding to this request

In responding to this document request, please apply the instructions and definitions set forth below.

Instructions

1. In complying with the request, you should produce all responsive documents in your possession, custody, or control.
2. Documents responsive to the request should not be destroyed, modified, removed, transferred, or otherwise made inaccessible to the Subcommittee.
3. In the event that any entity, organization, or individual denoted in the request has been, or is currently, known by any other name than that herein denoted, the request should be read also to include them under that alternative identification.
4. Each document produced should be produced in a form that renders the document capable of being copied.
5. When you produce documents, you should identify the paragraph or clause in the Subcommittee's request to which the documents respond.
6. Documents produced in response to this request should be produced together with copies of file labels, dividers, or identifying markers with which they were associated when this request was issued. To the extent that documents were not stored with file labels, dividers, or identifying markers, they should be organized into separate folders by subject matter prior to production.
7. Each folder and box should be numbered, and a description of the contents of each folder and box, including the paragraph or clause of the request to which the documents are responsive, should be provided in an accompanying index.
8. It is not a proper basis to refuse to produce a document that any other person or entity also possesses a nonidentical or identical copy of the same document.
9. If any of the requested information is available in machine-readable or electronic form (such as on a computer server, hard drive, CD, DVD, memory stick, or computer backup tape), you should consult with Subcommittee staff to determine the appropriate format in which to produce the information. Documents produced in electronic format should be organized, identified, and indexed electronically in a manner comparable to the organizational structure called for in (6) and (7) above. Documents produced in an electronic format should also be produced in a searchable format.
10. In the event that a responsive document is withheld on any basis, you should provide the following information concerning the document: (a) the reason the document is not being produced; (b) the type of document; (c) the general subject matter; (d) the date, author, and addressee; and (e) the relationship of the author and addressee to each other.
11. If any document responsive to this request was, but no longer is, in your possession, custody, or control, you should identify the document (stating its date, author, subject and

recipients) and explain the circumstances by which the document ceased to be in your possession, custody, or control.

12. If a date or other descriptive detail set forth in this request referring to a document is inaccurate, but the actual date or other descriptive detail is known to you or is otherwise apparent from the context of the request, you should produce all documents which would be responsive as if the date or other descriptive detail were correct.
13. This request is continuing in nature and applies to any newly discovered document. Any document not produced because it has not been located or discovered by the return date should be produced immediately upon location or discovery subsequent thereto.
14. All documents should be bates-stamped sequentially and produced sequentially.
15. Upon completion of the document production, you should submit a written certification, signed by you or your counsel, stating that: (1) a diligent search has been completed of all documents in your possession, custody, or control which reasonably could contain responsive documents; and (2) all documents located during the search that are responsive have been produced to the Subcommittee or identified in a privilege log provided to the Subcommittee.

Definitions

1. The term "document" means any written, recorded, or graphic matter of any nature whatsoever, regardless of how recorded, and whether original or copy, including, but not limited to, the following: memoranda, reports, expense reports, books, manuals, instructions, financial reports, working papers, records notes, letters, notices, confirmations, telegrams, receipts, appraisals, pamphlets, magazines, newspapers, prospectuses, interoffice and intra-office communications, electronic mail (email), contracts, cables, notations of any type of conversation, telephone calls, meetings or other communications, bulletins, printed matter, computer printouts, teletypes, invoices, transcripts, diaries, analyses, returns, summaries, minutes, bills, accounts, estimates, projections, comparisons, messages, correspondence, press releases, circulars, financial statements, reviews, opinions, offers, studies and investigations, questionnaires and surveys, and work sheets (and all drafts, preliminary versions, alterations, modifications, revisions, changes, and amendments of any of the foregoing, as well as any attachments or appendices thereto). The term also means any graphic or oral records or representations of any kind (including without limitation, photographs, charts, graphs, voice mails, microfiche, microfilm, videotape, recordings and motion pictures), electronic and mechanical records or representations of any kind (including, without limitation, tapes, cassettes, disks, computer server files, computer hard drive files, CDs, DVDs, memory sticks, and recordings), and other written, printed, typed, or other graphic or recorded matter of any kind or nature, however produced or reproduced, and whether preserved in writing, film, tape, disk, videotape or otherwise. A document bearing any notation not a part of the original text is to be considered a separate document. A draft or non-identical copy is a separate document within the meaning of this term.
2. The term "documents in your possession, custody, or control" means (a) documents that are in your possession, custody, or control, whether held by you or your past or present agents, employees, or representatives acting on your behalf; (b) documents that you have a legal right to obtain, that you have a right to copy, or to which you have access; and (c) documents that you have placed in the temporary possession, custody, or control of any third party.
3. The term "communication" means each manner or means of disclosure or exchange of information, regardless of means utilized, whether oral, electronic, by document or otherwise, and whether face-to-face, in a meeting, by telephone, mail, telexes, discussions, releases, personal delivery, or otherwise.
4. The terms "and" and "or" shall be construed broadly and either conjunctively or disjunctively to bring within the scope of the request any information which might otherwise be construed to be outside its scope. The singular includes plural number, and vice versa. The masculine includes the feminine and neuter genders.
5. The terms "person" or "persons" means natural persons, firms, partnerships, associations, corporations, subsidiaries, divisions, departments, joint ventures, proprietorships, syndicates, or other legal, business or government entities, and all subsidiaries, affiliates, divisions, departments, branches, and other units thereof.
6. The terms "referring" or "relating," with respect to any given subject, means anything that constitutes, contains, embodies, reflects, identifies, states, refers to, deals with, or is in any manner whatsoever pertinent to that subject.