



Date: August 10, 2005

P.O. Box 40970
Indianapolis, IN 46240-0970
(317) 338-CARE

www.stvincent.org

Mr. Sam Mulay
Radiation Specialist
Nuclear Materials License Branch
United States Nuclear Regulatory Commission
Region III
801 Warrenville Road
Lisle, IL 60532-4351

Socket No. 030-01579

Re: **Report and notification of Medical Event #41881**

Dear Mr. Mulay:

As required under 10 CFR 35.3045, this correspondence is provided as written notification within fifteen (15) days after discovery of a Medical Event as defined in 10 CFR 35.3045 (a) (1) (iii).

(i) Licensee name:

St. Vincent Hospital & Health Care Center
2001 West 86th Street
Indianapolis, IN 46240-0970

A member of



Core Values

We are called to:

Service of the Poor
Generosity of spirit for persons most in need.

Reverence
Respect and compassion for the dignity and diversity of life.

Integrity
Inspiring trust through personal leadership.

Wisdom
Integrating excellence and stewardship.

Creativity
Courageous innovation.

Dedication
Affirming the hope and joy of our ministry.

USNRC Materials License Number: 13-00133-02

(ii) Name of Prescribing Physician:

John "Jack" Horvath, M.D.

(iii) A brief description of the event:

An independent review of HDR treatment records occurred on July 28, 2005. During this review, a Medical Event was discovered which meets reporting requirements of 10 CFR 35.3045.

On July 21, 2003, an 87 year old male received what was to be the first of two High Dose Rate (HDR) treatments for esophageal cancer using a remote afterloading unit. The physician Authorized User prescribed a dose of 500 cGy at 0.5 cm from the surface of the NG (nasogastric) tube for an active length of 5.5 cm using a 5.551 Ci iridium-192 source*. The treatment plan called for 12 indexer step positions at 5.0 mm spacing. The Medical Physicist entered 12 indexer step positions with 2.5 mm spacing and treatment was delivered. Additionally, the treatment plans first dwell position was at position 3 but the actual treatment delivered was at dwell position 1 resulting in a shift of treatment position by 1 centimeter.

MEDICALEVENT.072805.doc

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(iii) A brief description of the event (continued):

On August 14, 2003, the second fraction was set up and delivered in accordance with the Authorized Users (AU's) written directive and occurred without incident.

(iii) A brief description of the event continued:

A simulated plan was calculated on July 29, 2005, to reproduce the initial treatment plan and actual treatment delivered. The simulations suggest the patient may have received as much as 74% over dosage to a portion of his esophagus and as much as 92% under dosage to a proximal portion of his esophagus.

The patient returned to the facility on July 14, 2005, for treatment and is currently under our care.

The prescribing physician Authorized User (AU) was not available at the time of discovery; however, the president of the radiation oncology group was notified on Monday, August 1, 2005. Subsequently the referring physician was notified. The referring physician did notify the patients' spouse.

The Radiation Safety Officer (RSO) was immediately notified on July 28, 2005, by the Medical Physicist completing monthly independent chart reviews. The Radiation Safety Officer notified the USNRC Operations Center by telephone at 15:55 ET on July 29, 2005, and spoke with Mr. Bill Huffman of the USNRC in Rockville, MD.

Mr. Sam Mulay, Senior Health Physicist, Nuclear Materials Inspection Branch completed an on-site visit to St. Vincent Hospital, Indianapolis, IN, on August 2, 2005. Mr. Mulay met with: Mr. Jeff Heffelfinger, Executive Director, Oncology, Edward Wroblewski, RSO, and Mr. Gary Huang, M.S., Medical Physicist. The purpose of the visit was to investigate the reported Medical Event of July 29, 2005.

(iv) Why the event occurred:

Upon investigation, it appears the error occurred at a time when the HDR treatment unit required manual adjustment of the default treatment settings. The Medical Physicist involved with this treatment did not manually change the default step length from a defaulted value of 2.5mm per step to 5.0mm per step value as stated in the HDR treatment plan. Additionally, it appears the second Medical Physicist did not recognize the treatment error upon verification.

(v) The effect, if any, on the individual who received the administration:

No adverse biological effects to the patient are expected to occur as a result of this patient treatment. This opinion is based upon the opinions of the Radiation Oncologists (Physician Authorized Users) on staff.

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(vi) Actions that have taken place or are planned to prevent recurrence:

In response to the events of July 29, 2005, concerning the High Dose Rate (HDR) afterloader:

- 1) Mr. Jeff Heffelfinger, Executive Director, Oncology, scheduled a meeting on August 1, 2005, with key personnel to discuss the discovery of the reported Medical Event of July 29, 2005, to assess the Medical Event and future direction;
- 2) The Physicians involved are no longer employed by St. Vincent Hospital;
- 3) A system software upgrade occurred since the date of this treatment (7/21/03). The system software upgrade electronically transfers the treatment plan data to the HDR computer; thereby preventing manual or user error;
- 4) Treatment parameters are checked and verified twice by both Medical Physicists and Authorized User(s) prior to HDR brachytherapy delivery;
- 5) Corrective action submitted to the United States Nuclear Regulatory Commission as a result of two Medical Event notifications on April 5, and October 18, 2004, has been followed without compromise or incident. The Medical Event described in this correspondence occurred prior to implementation of these corrective actions and was discovered as a result of implemented corrective actions. It is the opinion of this licensee, this type of event will not occur and is preventable with current policies and procedures already enacted;
- 6) In order to provide reasonable assuredness no other Medical Events have occurred, St. Vincent Hospital has proactively identified a number of patient records (109 HDR treatments which comprises 53 patients) that are to be reviewed by qualified Medical Physicists. Without prejudice, it was discovered the most common factor in the three reported Medical Events [April 5, October 18, 2004 and July 29, 2005] was the same Medical Physicist involved with the planning/treatment delivery of HDR brachytherapy. The 109 treatments to be reviewed have all occurred during the course of employment with the Medical Physicist as stated.

The parameters to be reviewed, compared and verified by qualified Medical Physicists include:

- | | |
|-----------------------------|-----------------------------------|
| - Patient's Name | - Patient Medical Number |
| - Treatment Site | - Prescription Point |
| - Fraction Dose | - Applicator Type |
| - Active Length | - Date & Time of Treatment |
| - Source Strength | - Catheter # |
| - Channel Reference Length | - Step Size |
| - Number of Dwell Positions | - Dwell Positions & Time Settings |
| - Total Treatment Time | |

It is anticipated the fifty-three patient records will be completed by **September 2, 2005**, (thirty days from announced USNRC special inspection by Mr. Sam Mulay). A report of findings will be compiled and sent to Region III, USNRC by **Sept 7, 2005**.

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(vii) Certification that the licensee notified the individual (or the individual's responsible relative or guardian):

Frank Peyton, M.D., as radiation oncology physician, has certified he has spoken with the referring physician regarding this Medical Event.

If you have any questions, please feel free to contact us at 317/338-3911 or 317/338-2381 respectively.

Sincerely,



Michael C. Wlemann, M.D.
Senior Vice President
Chief Medical Officer
St. Vincent Hospital



Edward E. Wroblewski, M.A., DABSNM
Radiation Safety Officer
St. Vincent Hospital

cc: Patricia Maryland, Doctor P.H., President, St. Vincent Hospital
Jean M. Meyer, R.N., MSN, Senior Vice President, Chief Nursing Officer
Jeff Heffelfinger, MSA, CHE, Executive Director, Oncology
Ben Wen Ni, Ph.D., Chief Radiation Therapy Physicist
Susann M. Stephenson, R.N., Risk Management
Frank Peyton, M.D. (Indiana Radiation Oncology)
John "Jack" Horvath, M.D. (Indiana Radiation Oncology)
NRC correspondence file

***Source Specific Information:**

Issue Date: May 7, 2003

Reference Air Kerma Rate: 45.24 mGy h⁻¹ +/- 5% @ 1m

Measured at: May 7, 2003, 13:51 CET

Product Code: REF 105.002

Serial Number: SN D36A4418

Production Code: LOT 37943/7

Apparent Activity: 411 GBq (11.1 Ci) at date of measurement

Source Type: MICROSELECTRON-HDR

Capsule Dimensions: 0.90 mm diameter, 4.5 mm length

Source Pellet Dimensions: 0.60 mm diameter, 2.5 mm length

Source Pellet Form: Solid iridium

Radionuclide: Ir-192

Encapsulation: Single

Capsule Material: Stainless Steel, AISI 316L

Special Form Certificate Number: D/0070/S-85 (REV.1)