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RADIATION
SAFETY OFFICE

April 13, 2006

U.S. Nuclear Regulatory Commission, Region III
Material Licensing Section
2443 Warrenville Road
Suite 210
Lisle, IL 60532-4352

Re: Report of Medical Events (2) – NRC License No. 13-02752-03

Dear Sir/Madam:

Attached please find written reports for two (2) medical events that were identified on March 29, 2006 and April 3, 2006. These reports are being submitted in compliance with the requirements of 10 CFR 35.3045(d). Should you have any questions regarding these reports or the circumstances surrounding the medical events, please do not hesitate to contact this office.

Sincerely,

A handwritten signature in cursive script that reads "Mack L. Richard".

Mack L. Richard, M.S., C.H.P.
Radiation Safety Officer

Attachments: 2

Cc: J. Froehlich
O. Pescovitz
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*IU School of Medicine
IU Medical Center &
Associated Facilities*

RECEIVED APR 17 2006

REPORT OF MEDICAL EVENT DISCOVERED MARCH 29, 2006
PER 10 CFR 35.3045(d)

On March 29, 2006 a "medical event" involving a manual brachytherapy patient was discovered. The NRC Operations Center was notified by the Radiation Safety Officer, Mr. Mack L. Richard on March 30, 2006 in accordance with the requirements of 10 CFR 35.3045(c).

Licensee Name: IUPUI/Indiana University Medical Center – NRC License No. 13-02752-03

Name of Prescribing Physician: Higinia Cardenes, M.D.

Brief Description of the Event: While returning ^{137}Cs sources from two separate patients to the storage safe on March 29, 2006, a radiation oncology physicist noted that the source carriers inserted into the ovoid applicators (ovoid applicators are also referred to as colpostats) were not the same length. Since the applicators were the same length, the physicist suspected that when the shorter source carriers were inserted into the longer applicators, the position of the sources within the applicators was not in accordance with the treatment plan (i.e., the sources were located in the lower stem rather than the distal end of the applicator). The physicist reviewed the x-ray films of the applicators and source carriers in place for the two patients. A side-by-side review of the anterior-posterior (AP) x-ray films from both patients confirmed the physicist's suspicion that the sources contained in the shorter source carriers were positioned incorrectly. The radiation dose to the treatment site was recalculated and determined to be 65% lower than what was prescribed by the radiation oncology physician. Since the dose varied from the prescribed dose by more than 20%, it was concluded that a medical event had occurred. The referring physician, Dr. Jeanne Schilder was notified of the medical event by Dr. Cardenes on March 30, 2006. The Nuclear Regulatory Commission (NRC) Operations Center was also notified of the medical event on March 30, 2006.

Why the Event Occurred: The medical event occurred due to the use of source carriers that were shorter than the applicators. While the source carriers and applicators are generally utilized in "sets", the shorter applicators had apparently been discarded but the shorter source carriers were not discarded and subsequently utilized with the longer applicators. Even though performance and review of AP and lateral (LAT) x-rays of the source carrier/applicator after insertion into the patient is a standard procedure, those x-rays are performed to verify correct positioning of the applicator within the patient and for dose calculation and treatment planning, not to determine if the source carriers are of the correct length.

The Effect on the Patient Subject to the Medical Event: The patient was examined by Dr. Cardenes on the day the medical event was discovered (March 29, 2006) as part of her standard follow up. Dr. Cardenes noted no symptoms or findings during the examination that were inconsistent with what would have been expected had the dose been delivered as prescribed. Thus, no significant impact on the patient was observed or expected.

Actions Taken to Prevent Recurrence: A number of actions have been implemented to prevent a recurrence of this medical event. Those actions include:

1. The short source carriers have been taken out of service and are now in the possession of the Radiation Safety Office.
2. A new set of source carriers and applicators has been ordered and received from Best Industries.

3. The brachytherapy check sheet (used to assure treatment is delivered as planned) has been modified to include a specific check of source carrier placement within the applicator.
4. Source carrier and applicator sets have been uniquely identified to prevent mismatch in the future.
5. The written procedures required by 10 CFR 35.41 will be modified to specifically require that the compatibility of the source carriers and applicators be verified from the radiographs of those devices after they are inserted into the patient. This change will be reviewed and approved by the Radionuclide Radiation Safety Committee (RRSC) at the next quarterly meeting (scheduled for June, 2006).

Notification of the Patient Involved in the Medical Event: After conferring, the radiation oncology physician and the referring physician (Drs. Cardenes and Schilder) determined that notifying the patient was not in the patient's best interest due to the patient's mental state and psychological distress from previous medical procedures.

REPORT OF MEDICAL EVENT DISCOVERED APRIL 3, 2006
PER 10 CFR 35.3045(d)

On April 3, 2006 a “medical event” involving a manual brachytherapy patient was discovered. The NRC Operations Center was notified by the Assistant Radiation Safety Officer, Mr. Jeffrey S. Mason on the date of discovery in accordance with the requirements of 10 CFR 35.3045(c).

Licensee Name: IUPUI/Indiana University Medical Center – NRC License No. 13-02752-03

Name of Prescribing Physician: Higinia Cardenes, M.D.

Brief Description of the Event: This medical event was discovered on April 3, 2006 as a result of an investigation by the radiation oncology physics staff of a previously identified medical event that was discovered on March 29, 2006 and reported to the NRC on March 30, 2006 (a copy of the written report for that event is appended to this report as Attachment 1). Since the previously reported medical event resulted from the use of source carriers and applicators of different lengths, the physics staff initiated a review of patient charts and x-ray films from patients that had received similar treatments in the past. New source carrier/applicator sets had been received in late 2003 and were used as “sets” (i.e., the source carriers and/or applicators were not used interchangeably with existing sets). Simultaneous treatments with the applicator sets were performed in late June of 2004 and a review of the x-rays from those treatments indicated source carriers and applicators of the correct lengths were used. The charts and x-rays of all patients receiving similar treatments were reviewed from June, 2004 to the present and the earliest error noted (although that error did not meet the definition of a medical event) was for a patient treated in October of 2004. Thus, it was concluded that the interchanging of the source carriers and applicators began sometime between June, 2004 and October, 2004.

The aforementioned investigation by the physics staff indicated that the use of non-compatible source carrier/applicator sets were utilized on 6 patients in addition to the one that was reported as a medical event in Attachment 1. A recalculation of the dose actually received by those patients indicated that 1 of the 6 patients received a dose that varied more than 20% from the prescribed dose, which is the basis for this report. Prior to the recalculation of the doses delivered to these patients, it was not known if these errors met the definition of a medical event; however, Dr. Cardenes acknowledged that an error in treatment had occurred and notified the referring physician, Dr. Katherine Look of the errors on March 30, 2006. Once this error was identified as a medical event on April 3, 2006, the Nuclear Regulatory Commission (NRC) Operations Center was also notified by the Assistant Radiation Safety Officer, Mr. Jeffrey S. Mason on the date it was identified (April 3, 2006).

Why the Event Occurred: The medical event occurred due to the use of source carriers that were shorter than the applicators. While the source carriers and applicators are generally utilized in “sets”, the shorter applicators had apparently been discarded but the shorter source carriers were not discarded and subsequently utilized with the longer applicators. Even though performance and review of AP and LAT x-rays of the source carrier/applicator after insertion into the patient is a standard procedure, those x-rays are performed to verify correct positioning of the applicator within the patient and for dose calculation and treatment planning, not to determine if the source carriers are of the correct length.

The Effect on the Patient Subject to the Medical Event: Dr. Cardenes conferred with the referring physician regarding the routine follow up that had been conducted on this patient. The referring physician indicated that there has been no recurrence of her initial disease and that no observable

negative effects related to the misplacement of the vaginal sources had been noted during those follow up examinations.

Actions Taken to Prevent Recurrence: A number of actions have been implemented to prevent a recurrence of this medical event. Those actions include:

1. The short source carriers have been taken out of service and are now in the possession of the Radiation Safety Office.
2. A new set of source carriers and applicators has been ordered and received from Best Industries.
3. The brachytherapy check sheet (used to assure treatment is delivered as planned) has been modified to include a specific check of source carrier placement within the applicator.
4. Source carrier and applicator sets have been uniquely identified.
5. The written procedures required by 10 CFR 35.41 will be modified to specifically require that the compatibility of the source carriers and applicators be verified from the radiographs of those devices after they are inserted into the patient. This change will be reviewed and approved by the Radionuclide Radiation Safety Committee (RRSC) at the next quarterly meeting (scheduled for June, 2006).

Notification of the Patient Involved in the Medical Event: Taking a proactive approach, Dr. Cardenes attempted to notify the patient of the error via telephone on March 30, 2006 (before it was actually identified as a medical event); however, there was no answer. Dr. Cardenes left a message on the patient's answering machine to call her back to discuss an important medical matter. Subsequently, the patient was notified by Dr. Cardenes via certified letter on March 31, 2006 that she needed to contact Dr. Cardenes immediately to discuss an important clinical matter. No details were given in the letter regarding the event. The patient was seen by the referring physician (Dr. Look) on April 4, 2006 and the referring physician discussed the event with the patient at that time. Finally, the patient contacted Dr. Cardenes via telephone on April 5, 2006 and they discussed the event at that time as well.

ATTACHMENT 1

REPORT OF MEDICAL EVENT DISCOVERED MARCH 29, 2006 PER 10 CFR 35.3045(d)

On March 29, 2006 a "medical event" involving a manual brachytherapy patient was discovered. The NRC Operations Center was notified by the Radiation Safety Officer, Mr. Mack L. Richard on March 30, 2006 in accordance with the requirements of 10 CFR 35.3045(c).

Licensee Name: IUPUI/Indiana University Medical Center – NRC License No. 13-02752-03

Name of Prescribing Physician: Higinia Cardenes, M.D.

Brief Description of the Event: While returning ^{137}Cs sources from two separate patients to the storage safe on March 29, 2006, a radiation oncology physicist noted that the source carriers inserted into the ovoid applicators (ovoid applicators are also referred to as colpostats) were not the same length. Since the applicators were the same length, the physicist suspected that when the shorter source carriers were inserted into the longer applicators, the position of the sources within the applicators was not in accordance with the treatment plan (i.e., the sources were located in the lower stem rather than the distal end of the applicator). The physicist reviewed the x-ray films of the applicators and source carriers in place for the two patients. A side-by-side review of the anterior-posterior (AP) x-ray films from both patients confirmed the physicist's suspicion that the sources contained in the shorter source carriers were positioned incorrectly. The radiation dose to the treatment site was recalculated and determined to be 65% lower than what was prescribed by the radiation oncology physician. Since the dose varied from the prescribed dose by more than 20%, it was concluded that a medical event had occurred. The referring physician, Dr. Jeanne Schilder was notified of the medical event by Dr. Cardenes on March 30, 2006. The Nuclear Regulatory Commission (NRC) Operations Center was also notified of the medical event on March 30, 2006.

Why the Event Occurred: The medical event occurred due to the use of source carriers that were shorter than the applicators. While the source carriers and applicators are generally utilized in "sets", the shorter applicators had apparently been discarded but the shorter source carriers were not discarded and subsequently utilized with the longer applicators. Even though performance and review of AP and lateral (LAT) x-rays of the source carrier/applicator after insertion into the patient is a standard procedure, those x-rays are performed to verify correct positioning of the applicator within the patient and for dose calculation and treatment planning, not to determine if the source carriers are of the correct length.

The Effect on the Patient Subject to the Medical Event: The patient was examined by Dr. Cardenes on the day the medical event was discovered (March 29, 2006) as part of her standard follow up. Dr. Cardenes noted no symptoms or findings during the examination that were inconsistent with what would have been expected had the dose been delivered as prescribed. Thus, no significant impact on the patient was observed or expected.

Actions Taken to Prevent Recurrence: A number of actions have been implemented to prevent a recurrence of this medical event. Those actions include:

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2. A new set of source carriers and applicators has been ordered and received from Best Industries.
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4. Source carrier and applicator sets have been uniquely identified to prevent mismatch in the future.
5. The written procedures required by 10 CFR 35.41 will be modified to specifically require that the compatibility of the source carriers and applicators be verified from the radiographs of those devices after they are inserted into the patient. This change will be reviewed and approved by the Radionuclide Radiation Safety Committee (RRSC) at the next quarterly meeting (scheduled for June, 2006).

Notification of the Patient Involved in the Medical Event: After conferring, the radiation oncology physician and the referring physician (Drs. Cardenes and Schilder) determined that notifying the patient was not in the patient's best interest due to the patient's mental state and psychological distress from previous medical procedures.

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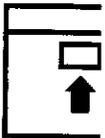
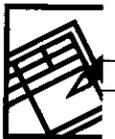
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