May 4, 2006

EA-06-095
NMED No. 060216
NMED No. 060219

John W. Talbott, Chief Operating Officer
IUPU/Indiana University Medical Center
541 Clinical Drive
Indianapolis, IN 46202

SUBJECT: NRC SPECIAL INSPECTION REPORT 030-01609/06-001(DNMS), IUPU/INDIANA UNIVERSITY MEDICAL CENTER

Dear Mr. Talbott:

This refers to the special inspection conducted on April 3-4, 2006, at IUPU/Indiana University Medical Center in Indianapolis, Indiana, with continued in-office review through April 24, 2006. The purpose of the in-office review was to review the written directives and treatment plans that you provided to us on April 20, 2006. The inspection was conducted in response to a telephonic notification of two brachytherapy medical events that occurred on January 17, 2005 and March 15, 2006. The inspection findings were discussed with you and other members of your staff during a exit briefing on April 4, 2006.

The purpose of the inspection was to review the medical events that occurred on January 17, 2005 and March 15, 2006, due to the incorrect positioning of the sources in the brachytherapy applicators that caused the dose delivered to each treatment site to be more than 20 percent less than the prescribed dose. In addition to the two medical events, the NRC also reviewed an additional five under-dose treatments of similar incorrect source positioning that caused the dose to be delivered to be less than 20 percent from the prescribed doses. These five under-dose cases did not constitute medical events. The enclosed report presents the results of this inspection.

Based on the results of this inspection, one apparent violation was identified and is being considered for escalated enforcement action in accordance with the NRC Enforcement Policy. The current Enforcement Policy is included on the NRC's Web site at www.nrc.gov; select **What We Do**, **Enforcement**, then **Enforcement Policy**. The violation involved the failure to develop, implement, and maintain written procedures to provide high confidence that each administration is in accordance with the written directive. The circumstances surrounding the apparent violation, the significance of the issue, and the need for lasting and effective corrective action were discussed during the exit meeting on April 4, 2006. As a result, it may not be necessary to conduct a predecisional enforcement conference in order to enable the NRC to make an enforcement decision.

Since your facility has not been the subject of escalated enforcement actions within the last two inspections, and based on our understanding of your corrective actions, a civil penalty may not be warranted in accordance with Section VI.C.2 of the Enforcement Policy. The final decision will be based on your confirming on the license docket that the corrective actions previously described to the staff have been or are being taken.

Before the NRC makes its enforcement decision, we are providing you an opportunity to either: (1) respond to the apparent violation addressed in this inspection report within 30 days of the date of this letter or (2) request a predecisional enforcement conference. If a conference is held, it will be open for public observation. The NRC will also issue a press release to announce the conference. Please contact John Madera at 630-829-9834 within 7 days of the date of this letter to notify the NRC of your intended response.

If you choose to provide a written response, it should be clearly marked as a "Response to An Apparent Violation in Inspection Report No. 030-01609/06-001(DNMS); EA-06-095" and should include: (1) the reason for the apparent violation, or, if contested, the basis for disputing the apparent violation, (2) the corrective steps that have been taken and the results achieved, (3) the corrective steps that will be taken to avoid further violations, and (4) the date when full compliance will be achieved. Your response should be addressed to the U. S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, DC 20555-0001, with a copy to the Regional Administrator, Region III, 2443 Warrenville Road, Lisle, IL 60532-4352. In presenting your corrective actions, you should be aware that the promptness and comprehensiveness of your actions will be considered in assessing any civil penalty for the apparent violation. The guidance in the enclosed excerpt from NRC Information Notice 96-28, "SUGGESTED GUIDANCE RELATING TO DEVELOPMENT AND IMPLEMENTATION OF CORRECTIVE ACTION," may be helpful. Your response may reference or include previous docketed correspondence, if the correspondence adequately addresses the required response. If an adequate response is not received within the time specified or an extension of time has not been granted by the NRC, the NRC will proceed with its enforcement decision or schedule a predecisional enforcement conference.

Please be advised that the number and characterization of apparent violations described in the enclosed inspection report may change as a result of further NRC review. You will be advised by separate correspondence of the results of our deliberations on this matter.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter and its enclosure will be available electronically in the NRC Public Document Room or from the Publicly Available Records (PARS) component of NRC's document system (ADAMS). The NRC's document system is accessible from the NRC Web site at http://www.nrc.gov/reading-rm/adams.html. To the extent possible, your response should not include any personal privacy, proprietary, or safeguards information so that it can be made available to the Public without redaction.

Sincerely,

/RA/

Steven A. Reynolds, Director
Division of Nuclear Materials Safety

Docket No. 030-01609
License No. 13-02752-03

Enclosures:
1. Inspection Report No. 030-01609/06-001(DNMS)
2. Excerpt from NRC Information Notice 96-28

J. Talbott

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NUCLEAR REGULATORY COMMISSION

REGION III

Docket No.:	030-01609
License No.:	13-02752-03
Report No.:	030-01609/06-001 (DNMS)
Licensee:	IUPU/Indiana University Medical Center
Locations:	550 University Blvd. (main hospital) Indianapolis, Indiana
Dates of Inspection:	April 3 through 4, 2006
Inspectors:	Darrel Wiedeman, Senior Health Physicist Tony Go, Health Physicist
Approved By:	John R. Madera, Chief Materials Inspection Branch

EXECUTIVE SUMMARY

IUPU/Indiana University Medical Center
Indianapolis, Indiana
Inspection Report No. 030-01609/06-001 (DNMS)

This was a special inspection in response to a telephonic notification of two medical events that occurred on January 17, 2005 and March 15, 2006. Each medical event resulted in an under-dose from an incorrectly positioned radioactive source in a brachytherapy applicator that was caused by the use of the wrong source bucket carrier (SBC). The inspection focused on the events, the direct root and contributing causes, notifications, reports, records, and the licensee's procedures and implementation of those procedures.

Based on the results of this inspection, one apparent violation was identified. The apparent violation includes the failure to develop written procedures to provide high confidence that each administration is in accordance with the written directive. Specifically, the licensee did not have a procedure to determine or verify the correct position of each radioactive source in the Fletcher-Suit-Delclos ovoid brachytherapy applicator prior to their placement for patient treatments. The licensee's use of the wrong length SBC containing the cesium-137 sealed sources caused the sources to be displaced from the correct position in the ovoid applicators during brachytherapy treatments, resulting in two medical events and five treatments that were considered under-doses but did not meet the definition of a medical event.

The inspectors and the licensee's staff evaluated the other five under-dose brachytherapy treatments and determined these under-dose brachytherapy treatments did not differ by more than 20 percent from the prescribed dose. The licensee's assessment of these additional under-doses was based on point-by-point calculations using a treatment planning computer with the cesium-137 sources displaced from the correct position in the ovoid applicators. The inspectors reviewed additional brachytherapy treatment records for patients treated between 2001 through 2006, and did not identify any additional medical events.

The root cause of the medical event was the licensee's failure to use the appropriate SBC with the ovoid applicator. Several contributing causes were: (1) failure to verify the correct position of the SBCs containing the radioactive sources within the ovoid applicator, (2) failure to establish procedures for verification that the sources are in the correct position within the ovoid, (3) failure to assign responsibility for custody and maintenance of the applicators containing old and new parts among the qualified staff, and (4) failure to establish and implement a program for removal of unmatched parts (long and short SBCs) from the usable inventory.

The licensee implemented immediate corrective actions that included: (1) removal from service of the short SBCs and a pair of the ovoid applicators. In addition, the licensee ordered a new pair of Fletcher-Suit Delclos ovoid applicators; (2) the licensee's staff modified its procedure "Brachytherapy Implant Checklist," to include a dual verification of the source position prior to each brachytherapy implant; (3) a sticker will be added to the front view simulator films to remind the staff to check for any displaced source carriers, (4) each set of Fletcher-Suit Delclos ovoid applicators kits will be marked (possible color coded) for unique identifications so that each applicator is matched with it's correct SBC, and (5) a staff physicist was assigned the task of being responsible for

ensuring all applicator parts are compatible and any unmatched parts are removed from the inventory.

Report Details

1 Program Scope and Inspection History

Nuclear Regulatory Commission (NRC) License No. 13-02752-03 authorizes Indiana University Medical Center (licensee) to use a variety of byproduct materials for diagnostic and therapeutic medical purposes. The therapeutic procedures include cesium-137 sealed sources in intracavity applicators for low-dose-rate gynecologic brachytherapy treatments. The licensee possessed two sets of Fletcher-Suit-Delclos Afterloading Applicators. Typically, the licensee administers ten to twenty gynecologic brachytherapy treatments per year utilizing these applicators.

All gynecologic brachytherapy implants were performed at the main hospital located at IUPU/Indiana University Medical Center, Indianapolis, Indiana. Radiation therapy staff involved with brachytherapy procedures included five radiation oncologists (physicians) and six medical physicists/dosimetrists. Past routine inspections conducted in April 30, 2002, identified one Severity Level IV violation. The last inspection conducted was on September 13, 2004. No violations of NRC regulatory requirements were identified during that inspection.

2 Summary of Events

2.1 Inspection Scope

The inspectors reviewed the timeline and set of facts surrounding each of the seven brachytherapy patients' treated between October 26, 2004 through March 15, 2006. The inspectors interviewed the authorized users, medical physicists, and selected oncology staff.

2.2 Observations and Findings

According to the licensee, in early 2001 the licensee possessed two sets of Fletcher-Suit-Delclos Afterloading Applicators for manual brachytherapy treatments, one was a set of short handle applicators with it's associated source bucket carrier (SBC) and one set of long handle applicators with it's SBC. Due to the fact that the parts from each applicator were not compatible a decision was made to remove the short handle applicator from service and replace it with a long handle applicator. The short handle applicator was disposed of, however, the SBCs were kept in storage in the source storage room until June 2004, when they were placed back into the usable inventory. The incompatible SBCs were used during the brachytherapy treatments and remained in the usable inventory until it was discovered that the SBCs did not match the applicator. In early 2003, the licensee's oncology staff replaced the short handled applicator with a new long handle applicator with all the related parts. According to the licensee's staff, the oncologists preferred the longer handle applicators for manual afterloading treatments. In addition, having an extra set of the long handle applicators, the licensee could perform additional treatments simultaneously.

According to the licensee's staff, the short handle applicator containing the related short set of SBCs were removed from service by the staff physicists. In June 2004, during a routine inventory, a physicist discovered the extra set of SBCs in the physics lab. At that time he was not aware that these SBCs were the short set from the short handle

applicator that was disposed of in early 2001. The physicist inadvertently placed the extra SBC set back into the inventory of brachytherapy equipment. On March 29, 2006, during a post-treatment clean up of equipment and applicators after two brachytherapy treatments, the licensee's physicist discovered that the set of SBCs used for one of the treatments was shorter than the brachytherapy applicator. The physics staff concluded that the use of the short SBCs with a long handle applicator could cause a displacement of the sources from the correct position because the short SBC were two centimeters shorter than the original part, resulting in radiation doses to the planned treatment site that was less than the prescribed doses. Specifically, the SBCs were too short for the radioactive sources to drop completely into the ovoids, therefore, the carriers did not position the source correctly in the ovoids.

The licensee determined that in two cases (case Nos. 1 and 2) the incorrect positioning of the sources caused the dose delivered to the treatment site to differ from the prescribed dose by more than 20 percent, constituting two medical events. For case No. 1, the authorized user physician prescribed a dose of 1600 centigray (cGy), and because of the source displacement, the treatment site received a dose of 612 cGy, 62 percent less than the prescribed dose. For case No. 2 the authorized user prescribed 2500 cGy, however, the treatment site received 1203 cGy, 52 percent less than prescribed. The physicists completed independent dose assessments for the remaining five patients that received an under-dose (case Nos. 3 through 7) and concluded that the greatest deviation from the prescribed dose was approximately -19 percent (case No. 5), and the smallest deviation from the prescribed dose was approximately -10 percent (case No. 3). The NRC's dose assessments for all cases (Nos. 1 through 7) agreed with the licensee's assessment for these patients. The NRC Health Physics expert in NRC headquarters reviewed the written directives and treatment plans for the under-dose cases and agreed with the licensee's dose assessments.

2.3 Conclusions

The licensee's assessment of the under-doses received by the seven patients was adequate and reasonable. The NRC reviewed the written directives and treatment plans for each of the seven under-dose cases and agreed with the licensee's dose assessments.

3 Root and Contributing Causes

3.1 Inspection Scope

The inspectors interviewed the authorized user and medical physics staff and discussed the clinical use of the brachytherapy equipment and procedures. The inspectors evaluated the events to determine its direct, root and contributing causes.

3.2 Observations and Findings

The medical events (case Nos. 1 and 2) were directly caused by use of an incompatible SBC that was designed for a short handle Fletcher-Suit Delclos ovoid applicator. The use of the short SBC resulted in the incorrectly positioned radioactive source within the ovoid portion of the applicator. A contributing cause of the event was the licensee's failure to properly identify the length discrepancy of the SBC or verify the correct source position prior to each patient treatment.

On the day of the events the oncologist inserted the empty SBCs into the applicator following surgical placement of the applicator. During treatment planning x-rays (front and side) views were taken to locate each ovoid and its position relative to the treatment site and critical structures including the rectum and bladder. Although the metal ovoid applicators could easily be visualized on both the front and side view x-rays, the SBCs when fully inserted into the applicator was either invisible or difficult to image on the x-ray. Consequently, the treatment planning was based upon assumptions from previous experience and knowledge that the cesium-137 sources were in their expected locations within the applicator. The coordinates of each afterloaded cesium-137 ovoid source and other source information was subsequently entered into the treatment planning computer for use in calculating various treatment parameters including the isodose distribution, dose rate, total dose, and time required for treatment.

The licensee did not attempt to verify the position of the source carrier by checking for any displacement because the oncology staff assumed that its relative position would not change within the ovoid. The oncology staff indicated that they had no reason to suspect any source change and were accustomed to focusing their attention on the readily visible ovoids during their reviews of the x-ray films and did not notice the misplaced SBC. According to the medical physics staff, the difference in SBC lengths was not immediately noticeable unless all four SBCs are compared side by side as occurred when the medical physicist accidently discovered the length discrepancy following two patient treatments on March 29, 2006.

After the first medical event was discovered (case No.1) on March 30, 2006, the licensee independently reviewed all documentation and x-rays associated with brachytherapy treatments involving the device from 2003 through 2006. The licensee identified an additional medical event (case no. 2) that occurred on January 17, 2005, and five treatments of similar incorrect source positioning due to the use of short SBCs for the brachytherapy applicator device. The licensee's staff also evaluated the other five under-dose brachytherapy cases and determined the doses to the treatment sites were less than the prescribed dose but did not differ by more than 20 percent from the prescribed doses.

10 CFR 35.41(a) states in part, for any administration requiring a written directive, licensees are required to develop, implement, and maintain written procedures to provide high confidence that each administration is in accordance with the written directive. Procedures must meet the requirements described in 10 CFR 35.41(b).

The inspectors determined that the licensee did not have written procedures that required the staff to verify the correct position of the SBC or actual location of the sources that would provide high confidence that each administration is in accordance with the written directive. The licensee's failure to have written procedures to verify the correct position of the radioactive sources within the ovoids is an apparent violation of 10 CFR 35.41(a).

3.3 Conclusions

The medical events (case Nos. 1 and 2) were directly caused by use of an incompatible SBC that was designed for a short handle Fletcher-Suit-Delclos ovoid applicator. The use of the short SBC resulted in the incorrectly positioned radioactive source within the

ovoid portion of the applicator. A contributing cause of the event was the licensee's failure to properly identify the length discrepancy of the SBC or verify the correct source position prior to each patient treatment. The licensee did not have written procedures that required the staff to verify the correct position of the SBC or actual location of the sources that would provide high confidence that each administration is in accordance with the written directive. One apparent violation of NRC requirements was identified.

4 Event Evaluation

4.1 Inspection Scope

The inspectors evaluated the licensee's dose evaluation of the seven cases identified as under-doses. The inspectors interviewed the authorized user, selected medical physicists, and radiation safety staff. The inspectors reviewed selected patient records, including written directives and treatment plans.

4.2 Observations and Findings

Using the licensee's treatment planning computer, the licensee recalculated the doses to the treatment site, bladder, rectum and adjacent organs and tissues on all seven patients that were identified as being treated with the incompatible SBC. The inspectors and the licensee's staff evaluated the other five under-dose brachytherapy treatments and determined these under-dose brachytherapy treatments did not differ by more than 20 percent. The licensee's assessment of these additional under-doses was based on point-by-point calculations using a treatment planning computer with the cesium-137 sources displaced from the correct position in the ovoid applicators. The inspectors reviewed additional brachytherapy treatment records for patients treated between 2001 through 2006, and did not identify any additional medical events.

The following provides the date of treatment, prescribed dose in centigray (cGy), delivered dose and percent of estimated under-dose for each case identified::

Case No.	Date Treated	Prescribed Dose	Dose Received	% Diff
1.	03/15/2006	1,600 cGy	612 cGy	-62%
2.	01/17/2005	2,500 cGy	1,203 cGy	-52%
3.	10/26/2004	2,200 cGy	1,970 cGy	-10%
4.	11/15/2004	3,000 cGy	2,618 cGy	-13%
5.	12/13/2004	3,500 cGy	2,937 cGy	-16%
6.	02/02/2005	3,500 cGy	3,118 cGy	-10.9%
7.	03/27/2006	1,400 cGy	1,130 cGy	-19.3%

Note: Cases 1 & 2 were treated with Fletcher-Suit-Delclos ovoids only,
Cases 3 through 7 were treated with Fletcher-Suit-Delclos tandem and ovoids

4.3 Conclusions

Two medical events and five treatments that were considered under-doses were identified. The five cases resulting in under-doses (case nos. 3 through 7) did not meet the definition of a medical event. No additional medical events were identified.

5 Notifications and Reports

5.1 Inspection Scope

The inspectors interviewed selected radiation safety staff, an authorized user, and selected medical physicists to verify that the licensee made the required notifications. In addition, the inspectors reviewed the written 15-day report submitted to the NRC.

5.2 Observations and Findings

The licensee identified the first medical event (case No.1) on March 30, 2006, and the second medical event (case No. 2) was discovered on April 3, 2006. Both events were immediately reported to the NRC Operation Center (Event Nos. 42453 and 42469). The referring physicians were also notified at the same time as the NRC was notified. All patients were notified of the under dose except case no. 1. The authorized user physician stated that it was in her medical opinion that it would be harmful to notify the patient and the patient's referring physician agreed. In accordance with 10 CFR 35.3045(d) the licensee submitted it's 15-day report on April 13, 2006.

5.3 Conclusion

All reporting requirements in 10 CFR 35.3045 were met. The written report included a description of the events, why the events occurred, the effects on the patients, and immediate and long-term corrective actions. The written report included all of the required information

6 Licensee Corrective Actions

6.1 Inspection Scope

The inspectors reviewed the licensee's proposed corrective actions for the two medical events involving the under-dose to the treatment site. The review included interviews of selected licensee personnel.

6.2 Observations and Findings

The licensee's corrective actions appeared to be comprehensive. These corrective actions included: (1) removal from service of the short SBCs and a pair of the ovoid applicators. In addition, the licensee also ordered a new pair of Fletcher-Suit-Delclos ovoid applicators; (2) the licensee's staff modified its procedure "Brachytherapy Implant Checklist," to include a dual verification of the source position prior to each brachytherapy implant; (3) a sticker will be added to the front view simulator films to remind the staff to verify for any displaced source carriers, and (4) each set of Fletcher-Suit-Delclos ovoid

applicators kits will be marked (possible color coded) for unique identifications so that each applicator is matched with it's correct SBC.

6.3 Conclusions

The licensee's corrective actions appeared to be comprehensive and should prevent any further errors associated with SBCs that are not compatible with the applicator being used.

7 Exit Meeting

At the completion of the onsite inspection, the inspectors conducted a exit meeting with licensee management and staff. The inspectors discussed the apparent violation, the root and contributing causes of the medical events, and the licensee's proposed corrective actions. The licensee did not identify any information reviewed during the inspection and proposed for inclusion in this report as proprietary in nature.

Partial List of Persons Contacted

* John Talbott, Corporate Operations Officer (COO)
* Colleen Desrosiers, Ph.D, Physicist, Radiation Oncology
* Higinia Cardenes, M.D., Authorized User Physician, Radiation Oncologist
* Phillip Dittmer, Ph.D, Physicist, Radiation Oncology
* Jeff Mason, Assistant Radiation Safety Officer
* Ewa Papiez, Physicist, Radiation Oncology
* Other medical center staff

* Individuals who participated during the onsite exit meeting held on April 4, 2006.