NRC FORM 591M PART 3
(10-2003)
10 CFR 2.201

U.S. NUCLEAR REGULATORY COMMISSION

Docket File Information

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE	2. NRC/REGIONAL OFFICE
IUPUI/Indiana University Medical Center REPORT **2006-002**	**Region III** **2443 Warrenville Road** **Lisle, IL 60532**

3. DOCKET NUMBER(S)	4. LICENSE NUMBER(S)	5. DATE(S) OF INSPECTION
030-01609	**13-02752-03**	**September 20, 2006**

6. INSPECTION PROCEDURES	7. INSPECTION FOCUS AREAS
87134	**Ltd. To review of corrective actions regarding escalated enforcement (IR No. 03001625/2006001(DNMS))**

SUPPLEMENTAL INSPECTION INFORMATION

1. PROGRAM CODE(S)	2. PRIORITY	3. LICENSEE CONTACT	4. TELEPHONE NUMBER
1100	**G2**	**Mack Richard, M.S., RSO**	**317-274-4797**

[X] Main Office Inspection — Next Inspection Date: **September 2006 (Routine)**

[ ] Field _____

[ ] Temporary Job Site _____

PROGRAM SCOPE

This follow-up inspection was conducted to review and verify the implementation of the licensee's submitted corrective actions following escalated enforcement as described in IR 03001609/06-001, dated May 4, 2006, (Ascension Number ML 061250047) and the subsequent issuance of a Notice of Violation dated July 10, 2006, in which one violation was issued and characterized as a Severity Level III problem (Ascension Number ML061920472). The violation involved failure to develop written procedures to provide high confidence that each administration is in accordance with the written directive and treatment plan. 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 source bucket carrier (SBC) containing 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.

The licensee described the corrective actions in a letter dated June 2, 2006, and included: 1) remove from service 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 modified its procedure "Brachytherapy Implant Checklist," to include specific verification of SBC placement within the source applicator prior to implant; (3) each set of Fletcher-Suit Delclos ovoid applicators kits will be color coded for unique identification so that each applicator is matched with the correct SBC, and (4) written procedures have been modified to specifically require that the compatibility of the SBC and the applicator be verified through radiographs after they have been inserted in the patient.

Performance Observations

Interviews conducted with available members of the Radiation Safety Office and the Department of Radiation Oncology revealed that cognizant parties were aware of the event and the corrective actions. A review of the licensee's written policy manual revealed all actions specified above have been incorporated in writing. The Brachytherapy Implant Checklist was reviewed and contained modifications as specified. Color coded applicator kits were observed available. A member of the physics staff initials the front simulator films verifying the correct placement of the source carriers. A staff physicist was assigned to verify the compatibility of all applicator parts and remove from inventory any unmatched parts.

Based on the above interviews and observations, the licensee had successfully implemented the stated corrective actions. Therefore, the aforementioned violation may be considered closed.

NRC FORM 591M PART 1
(10-2003)
10 CFR 2.201

U.S. NUCLEAR REGULATORY COMMISSION

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE/LOCATION INSPECTED:	2. NRC/REGIONAL OFFICE
IUPUI/Indiana University Medical Center **541 Clinical Dr.** **Indianapolis, IN 46202** REPORT **2006-002**	**U.S. Nuclear Regulatory Commission** **Region III** **2443 Warrenville Road** **Lisle, Illinois 60532-4351**

3. DOCKET NUMBER(S)	4. LICENSEE NUMBER(S)	5. DATE(S) OF INSPECTION
030-01609	**13-02752-03**	September 20, 2006

LICENSEE:

The inspection was an examination of the activities conducted under your license as they relate to radiation safety and to compliance with the Nuclear Regulatory Commission (NRC) rules and regulations and the conditions of your license. The inspection consisted of selective examinations of procedures and representative records, interviews with personnel, and observations by the inspector. The inspection findings are as follows:

☑ 1. Based on the inspection findings, no violations were identified.

☑ 2. Previous violation(s) closed.

☐ 3. The violation(s), specifically described to you by the inspector as non-cited violations, are not being cited because they were self-identified, non-repetitive, and corrective action was or is being taken, and the remaining criteria in the NRC Enforcement Policy, NUREG-1600, to exercise discretion, were satisfied.

_____ Non-Cited Violation(s) was/were discussed involving the following requirement(s) and Corrective Action(s):

☐ 4. During this inspection certain of your activities, as described below and/or attached, were in violation of NRC requirements and are being cited. This form is a NOTICE OF VIOLATION, which may be subject to posting in accordance with 10 CFR 19.11.

(Violations and Corrective Actions)

Licensee's Statement of Corrective Actions for Item 4, above.

I hereby state that, within 30 days, the actions described by me to the inspector will be taken to correct the violations identified. This statement of corrective actions is made in accordance with the requirements of 10 CFR 2.201 (corrective steps already taken, corrective steps which will be taken, date when full compliance will be achieved). I understand that no further written response to NRC will be required, unless specifically requested.

Title	Printed Name	Signature	Date
LICENSEE'S REPRESENTATIVE			
NRC INSPECTOR	**S. J. Mulay**	S. J. Mulay	9/20/06