UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION III
2443 Warrenville Road, Suite 210
Lisle, IL 60532-4352

December 23, 2011

Mr. Eric D. Swank
Executive Director, Research Compliance, Bloomington
IUPUI/Indiana University Medical Center
Indiana University Office of Research Administration
509 E. Third Street
Bloomington, IN 47401

SUBJECT: NRC ROUTINE INSPECTION REPORT NOS. 03001609/11-001(DNMS) AND 03009792/11-001(DNMS) AND NOTICE OF VIOLATION - IUPUI/INDIANA UNIVERSITY MEDICAL CENTER

Dear Mr. Swank:

On October 3 through 7, 2011, U. S. Nuclear Regulatory Commission (NRC) inspectors conducted a routine inspection at the IUPUI/Indiana University Medical Center, Indianapolis, Indiana facility, with continued in-office review through December 12, 2011. The in-office review included receipt and review of information that was unavailable during the onsite inspection including, in part, information regarding the bases for the release of patients who had iodine-131 administrations. This inspection report presents the results of this inspection. The preliminary findings of the inspection were discussed with you at the conclusion of the onsite inspection. On December 12, 2011, Robert Gattone of my staff discussed the inspection findings with Mack Richard of your staff during the final, telephonic exit meeting.

During this inspection, the NRC staff examined activities conducted under your license as they relate to public health and safety to confirm compliance with the Commission's rules and regulations and with the conditions of your license. Within these areas, the inspection consisted of selected examination of procedures and representative records, observations of activities, and interviews with personnel. Additional information, provided in your correspondence dated October 17, 18, 24, and November 9, and 10, 2011, and during the telephone conversation on October 14, 2011, between Mr. Richard and Penny Lanzisera of the NRC's Region I office, was also examined as part of the inspection.

Based on the results of this inspection, the NRC has determined that three Severity Level IV violations of NRC requirements occurred. These violations were evaluated in accordance with the NRC Enforcement Policy. The current Enforcement Policy is included on the NRC's Web site at (http://www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html). The violations involved the failure to: (1) conduct daily constancy checks of the dose calibrator in use at Methodist Hospital; (2) maintain records to show the bases for the release of two patients; and (3) develop prostate implant procedures that included verifying that the administration is in accordance with the treatment plan and the written directive.

The violations are cited in the enclosed Notice of Violation (Notice). The violations are being cited because the NRC identified them.

Regarding the violation involving failure to conduct daily constancy checks of the dose calibrator, your staff did not measure the long-lived radioisotope (radium-226) on the radium-226 setting. Instead, your staff only measured the long-lived radioisotope on the typically used radioisotope settings (e.g., technetium-99m). A potential consequence of the failure to measure the long-lived radioisotope (radium-226) on the radium-226 setting is a missed opportunity to identify that the dose calibrator is not indicating the correct radioactivity of measured dosages prior to administration, which could result in a medical event.

A member of your staff provided a view that the dose calibrator check, referred to in the manufacturer's instructions and the American National Standards Institute (ANSI) standard, was not the same as a calibration. Therefore, failing to do the constancy check is not the same as failing to perform a calibration, as required by regulations. The NRC reviewed this perspective and notes that the Statements of Consideration for Title 10 of the Code of Federal Regulations (CFR) 35.60 found on page 43533 of Federal Register Notice Vol. 63, No. 156, dated August 13, 1998, include a discussion of daily constancy and describe it as part of the calibration. The Statements of Consideration also reference ANSI N42.13 as describing the essential elements of a calibration. The NRC maintains that failure to measure the long-lived standard on the long-lived setting on a daily basis is a violation of 10 CFR 35.60(b) because both ANSI N42.13 and the Biodex Atomlab 100 Dose Calibrator Operation Manual include a check of the long-lived standard daily as part of the calibration.

A potential consequence of the violation involving failure to maintain records to show the bases for the release of two patients is a missed opportunity to verify that patients who received iodine-131 were released as required by 10 CFR 35.75. On October 17, 2011, a member of your staff confirmed that the two patients that received iodine-131 and were released per 10 CFR 35.75 met the release criteria based on calculations performed following the on-site inspection. In addition, you implemented the use of a standard spreadsheet to be used at both University Hospital and Methodist Hospital that is required to be filled out and it includes verification that the resultant dose values are within the dose release criteria.

Regarding the violation involving failure to develop prostate implant procedures, your procedures required documentation of the final implant without verification that it is in accordance with the written directive. A potential consequence of the violation is a failure to identify and report a medical event.

The NRC has concluded that information regarding the reason for the violation involving failure to maintain records to show the bases for the release of two patients, and the corrective actions taken and planned to correct the violation and prevent recurrence are already adequately addressed on the docket in our records and in your correspondence dated October 17, 2011. Therefore, you are not required to respond to this letter with respect to the violation unless the description of your corrective actions in this report and your correspondence does not accurately reflect your corrective actions or your position. In that case, or if you choose to provide additional information, you should follow the instructions specified in the enclosed Notice.

You are required to respond to this letter regarding the violations involving the failure to conduct daily constancy checks of the dose calibrator in use at Methodist Hospital and the failure to develop prostate implant procedures that included verifying that the administration was in accordance with the treatment plan and the written directive. You should follow the instructions specified in the enclosed Notice when preparing your response. If you have additional information that you believe the NRC should consider, you may provide it in your response to the Notice. The NRC review of your response to the Notice will also determine whether further enforcement action is necessary to ensure compliance with regulatory requirements.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter, its enclosure, and your response, will be available electronically for public inspection in the NRC Public Document Room or from the NRC's Agencywide Documents Access and Management System (ADAMS), 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.

Please contact Robert Gattone at (630) 829-9823 if you have any questions regarding this matter.

Sincerely,

/RA/

Tamara E. Bloomer, Chief
Materials Inspection Branch
Division of Nuclear Materials Safety

Docket Nos. 030-01609 and 03009792
License Nos. 13-02752-03 and 13-02752-08

Enclosure:
Notice of Violation

cc w/encl: Mack L. Richard, C.H.P., RSO
State of Indiana

You are required to respond to this letter regarding the violations involving the failure to conduct daily constancy checks of the dose calibrator in use at Methodist Hospital and the failure to develop prostate implant procedures that included verifying that the administration was in accordance with the treatment plan and the written directive. You should follow the instructions specified in the enclosed Notice when preparing your response. If you have additional information that you believe the NRC should consider, you may provide it in your response to the Notice. The NRC review of your response to the Notice will also determine whether further enforcement action is necessary to ensure compliance with regulatory requirements.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter, its enclosure, and your response, will be available electronically for public inspection in the NRC Public Document Room or from the NRC's Agencywide Documents Access and Management System (ADAMS), 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.

Please contact Robert Gattone at (630) 829-9823 if you have any questions regarding this matter.

Sincerely,

/RA/
Tamara E. Bloomer, Chief
Materials Inspection Branch
Division of Nuclear Materials Safety

Docket Nos. 030-01609 and 03009792
License Nos. 13-02752-03 and 13-02752-08

Enclosure:
Notice of Violation

cc w/encl: Mack L. Richard, C.H.P., RSO
State of Indiana

bcc w/encl: Penny Lanzisera, RI
Farrah Gaskins, RI

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NOTICE OF VIOLATION

IUPUI/Indiana University Medical Center
Indianapolis, IN

Docket Nos. 03001609
03009792
License Nos. 13-02752-03
13-02752-08

During a U.S. Nuclear Regulatory Commission (NRC) inspection conducted on October 3 through 7, 2011, with continued in-office review until December 12, 2011, three violations of NRC requirements were identified. In accordance with the NRC Enforcement Policy, the violations are listed below:

A. 10 CFR 35.60(b) requires licensees to calibrate the instrumentation required in paragraph (a) of this section in accordance with nationally recognized standards or the manufacturer's instructions.

Contrary to the above, as of October 5, 2011, the licensee did not calibrate the instrumentation required in paragraph (a) of this section in accordance with nationally recognized standards or the manufacturer's instructions. Specifically, both American National Standards Institute (ANSI) N42.13 and the manufacturer's instructions require a check of the long-lived standard daily and that check was not being performed.

This is a Severity Level IV violation (Section 6.3).

B. 10 CFR 35.75(c) requires a licensee to maintain a record of the basis for authorizing the release of an individual in accordance with 10 CFR 35.2075(a).

Contrary to the above, on May 20 and June 9, 2011, the licensee did not maintain a record of the bases for authorizing the release of two iodine therapy patients treated at Methodist Hospital in accordance with 10 CFR 35.2075(a). Specifically, the licensee had calculated a maximum dosage of 178 millicuries using standard patient specific release criteria (e.g., occupancy factor, retained activity, etc.) to show that the 500 millirem dose threshold would not be exceeded; however, on May 20, and June 9, 2011, 216 millicuries and 210 millicuries were administered, respectively, with no dose calculation conducted and no record made of the bases for authorizing the release of the patients.

This is a Severity Level IV violation (Section 6.3).

C. 10 CFR 35.41(a) states that, for any administration requiring a written directive, licensees are required to develop, implement, and maintain written procedures to provide high confidence that: (1) the patient's or human research subject's identity is verified before each administration; and (2) each administration is in accordance with the written directive. Procedures must meet the requirements described in 10 CFR 35.41(b).

> Contrary to the above, as of October 6, 2011, the licensee did not develop written procedures to provide high confidence that each administration is in accordance with the written directive. Specifically, the licensee's procedures required documentation of the final implant without verification that it was in accordance with the written directive or treatment plan.

This is a Severity Level IV violation (Section 6.3).

The NRC has concluded that information regarding the reason for the violation in Item B, the corrective actions taken and planned to correct the violation and prevent recurrence, and the date when full compliance will be achieved is already adequately addressed on the docket. However, you are required to submit a written statement or explanation pursuant to 10 CFR 2.201 if the description therein does not accurately reflect your corrective actions or your position. In that case, or if you choose to respond, clearly mark your response as a "Reply to a Notice of Violation," and send it to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555 with a copy to the Regional Administrator, Region III, within 30 days of the date of the letter transmitting this Notice of Violation (Notice).

In addition, pursuant to 10 CFR 2.201, IUPUI/Indiana University Medical Center is hereby required to submit a written statement or explanation for the violations in Items A and C to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, DC 20555, with a copy to the Regional Administrator, Region III, within 30 days of the date of the letter transmitting this Notice of Violation (Notice). This reply should be clearly marked as a "Reply to a Notice of Violation" and should include for the violations: (1) the reason for the violation, or, if contested, the basis for disputing the 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 may reference or include previous docketed correspondence, if the correspondence adequately addresses the required response. If an adequate reply is not received within the time specified in this Notice, an Order or a Demand for Information may be issued as to why the license should not be modified, suspended, or revoked, or why such other action as may be proper should not be taken. Where good cause is shown, consideration will be given to extending the response time.

If you contest this enforcement action, you should also provide a copy of your response to the Director, Office of Enforcement, United States Nuclear Regulatory Commission, Washington, DC 20555-0001.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter, its enclosures, and your response, will be made available electronically for public inspection in the NRC Public Document Room or from the NRC's Agencywide Documents Access and Management System (ADAMS), accessible from the NRC Web site at http://www.nrc.gov/readingrm/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.

In accordance with 10 CFR 19.11, you may be required to post this Notice within two working days of receipt.

Dated this 23rd day of December 2011.