May 25, 2012

EA-12-036

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

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

Dear Mr. Swank:

In your letter dated January 19, 2012, you disputed a Notice of Violation issued to you on December 23, 2011, which was associated with U.S. Nuclear Regulatory Commission (NRC) Inspection Report Nos. 03001609/11-001(DNMS) and 03009792/11-001(DNMS). Specifically, you disputed Violation A, a Severity Level IV violation involving Title 10 of the Code of Federal Regulations (CFR) 35.60(b).

Violation A, as cited, involved the manner in which your staff conducted daily constancy checks of a dose calibrator. Specifically, your staff did not measure the long-lived radioisotope (radium-226) on the radium-226 setting. Rather, your staff only measured the long-lived radioisotope on the typically used technetium-99m setting. The NRC had determined that the practice resulted in a failure to properly calibrate the dose calibrator.

In accordance with NRC policy and procedures, Region III has completed an independent assessment and review of the contested matter. Based on the independent review, the NRC has determined that Violation A should be withdrawn.

The attachment to your January 19, 2012, letter set forth several challenges to Violation A. First, you noted that the American National Standards Institute (ANSI) standard N42.13-2004, which is the "nationally recognized standard" referred to in 10 CFR 35.60(b), does not include constancy checks as a "calibration" task. Secondly, you disputed the implication that constancy checks were not being performed, because your staff in fact performed the checks. Although your staff performed the checks with the dose calibrator set on the most commonly used setting (technetium-99m) as opposed to the setting for the long-lived source (radium-226), you believed that method to be reliable because it not only assured that the measured current of the dose calibrator had remained constant, it also showed that the most commonly used electronic setting is properly converting the ionization current to the activity of the most commonly used radionuclide.

The independent reviewer considered all information available to the NRC pertaining to this matter, including ANSI N42.13-2004, the applicable manufacturer's instructions, and information

obtained during interviews of a representative of the dose calibrator manufacturer and a representative of ANSI.

Based on a discussion with an ANSI representative, when the word “check” is used in ANSI N42.13-2004 it means it is a check to determine if the dose calibrator needs to be calibrated rather than a “calibration” as defined in Section 3.1 of the ANSI Standard. In addition, measuring a radium-226 reference source with the instrument potentiometer set to read technetium-99m during reference source checks to assess that the displayed activities are constant over time, accomplishes the purpose of reference source checks per ANSI N42.13-2004. Although measuring a radium-226 reference source with the potentiometer set to read technetium-99m during constancy checks did not conform to the manufacturer’s instructions, NRC rules permit calibration to occur either in accordance with the manufacturer’s instructions *or* the ANSI standard.

Lastly, you noted that Violation A incorrectly stated that the violation occurred at Methodist Hospital. The independent review determined that the events occurred at University Hospital rather than Methodist Hospital.

In summary, the independent review found that your staff conducted the reference source checks/constancy checks in accordance with the nationally recognized standard, therefore, Violation A is withdrawn. Enclosed is the revised Notice citing only violations concerning the failure to maintain records to show the bases for the release of two patients, and develop prostate implant procedures that included verifying that the administration is in accordance with the treatment plan and the written directive. The Notice enclosed with NRC Inspection Report Nos. 03001609/11-001(DNMS) and 03009792/11-001(DNMS), dated December 23, 2011, is superseded by the revised Notice enclosed to this letter.

Based on your response and actions that you have taken, we do not require any further information concerning the violations.

In accordance with 10 CFR 2.390 of the NRC’s “Rules of Practice,” a copy of this letter 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.

If you have any questions regarding this matter please contact Anne Boland of my staff at 630-829-9800.

Sincerely,

/RA/

Cynthia D. Pederson
Deputy Regional Administrator

Docket Nos. 03001609 and 3009792
License Nos. 13-02752-03
and 13-02752-08

Enclosure:
Notice of Violation (revised)

cc w/encl: Mack L. Richard, CHP, RSO
State of Indiana

If you have any questions regarding this matter please contact Anne Boland of my staff at 630-829-9800.

Sincerely,

/RA/

Cynthia D. Pederson
Deputy Regional Administrator

Docket Nos. 03001609 and 3009792
License Nos. 13-02752-03
and 13-02752-08

Enclosure:
Notice of Violation (revised)

cc w/encl: Mack L. Richard, CHP, RSO
State of Indiana

DISTRIBUTION w/encl:

OCADistribution	Daniel Holody	James Lynch
Bill Borchardt	Carolyn Evans	Viktoria Mitlyng
Michael Weber	Heather Gepford	Prema Chandrathil
Roy Zimmerman	Holly Harrington	Patricia Lougheed
Aida Rivera Varona	Hubert Bell	Paul Pelke
Kerstun Day	Cheryl McCrary	Magdalena Gryglak
Marvin Itzkowitz	Mona Williams	Patricia Buckley
Catherine Scott	Anne Boland	Tammy Tomczak
Mark Satorius	Jack Giessner	MIB Inspectors
Brian McDermott	Jared Heck	OEMAIL
Michele Burgess	Allan Barker	
Duane White	Harral Logaras	
Penny Lanzisera		

***see previous concurrence**
ADAMS Accession Number: ML 12151A160
DOCUMENT NAME: G:\DNMSIII\Work in progress\iupui disputed vio withdraw letter (7).docx
■ Publicly Available ☐ Non-Publicly Available ☐ Sensitive ■ Non-Sensitive
To receive a copy of this document, indicate in the concurrence box "C" = Copy without attach/encl "E" = Copy with attach/encl "N" = No copy

OFFICE	RI		RIII DNMS		RIII DNMS		RIII	
NAME	PLanzisera:jc*by email		RGGattone: jc*RGG		TEBloomer*TEB		JKHeck*JKH	
DATE	04/13/12		04/19/12		04/26/12		04/26/12	
OFFICE	RIII EICS		OE		RIII DNMS		RIII	
NAME	SKOrth SKO		RPZimmerman*[1]		ATBoland*ATB		CDPederson CDP	
DATE	05/24/2012		05/21/12		04/30/12		05/25/2012	

OFFICIAL RECORD COPY

1 OE concurrence received via e-mail from Day Kerstun on May 21, 2012.

REVISED NOTICE OF VIOLATION

Revised Notice of Violation, Inspection Report Nos. 03001609/11-001(DNMS) and 03009792/11-001(DNMS), dated December 23, 2011

Replace the violations from that Notice of Violation (Notice) with the violations below:

A. 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).

B. 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).