NRC FORM 591M PART 1
(07-2012)
10 CFR 2.201

U.S. NUCLEAR REGULATORY COMMISSION

# SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

| 1. LICENSEE/LOCATION INSPECTED: | 2. NRC/REGIONAL OFFICE |
|---|---|
| Indiana University Health Ball Memorial Hospital, Inc.<br>2401 West University Avenue<br>Muncie, IN 47303<br><br>REPORT NUMBER(S) 2017001 | Region III<br>U. S. Nuclear Regulatory Commission<br>2443 Warrenville Road, Suite 210<br>Lisle, IL 60532-4352 |

| 3. DOCKET NUMBER(S) | 4. LICENSE NUMBER(S) | 5. DATE(S) OF INSPECTION |
|---|---|---|
| 030-01586 | 13-00951-03 | May 10, 2017 |

**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 violations(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, to exercise discretion, were satisfied.

_____ Non-cited violation(s) were discussed involving the following requirement(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 in accordance with NRC Enforcement Policy. This form is a NOTICE OF VIOLATION, which may be subject to posting in accordance with 10 CFR 19.11.

(Violations and Corrective Actions)

Contrary to 10 CFR 35.67(g), between July 9, 2015 , and January 27, 2017, the licensee failed to conduct semi-annual physical inventories of all brachytherapy sources in its possession. Specifically, the licensee failed to inventory 14 palladium-103 brachytherapy sources during the period of July 9, 2015, to January 27, 2017 – a periodicity greater than semi-annually.

The failure to conduct the inventory was due to an oversight as the sources had been in storage since 2015. On January 27, 2017, the RSO performed a physical inventory and confirmed that all 14 sources were present and accounted for. The RSO reminded staff that the requirement to conduct a semi-annual physical inventory of sealed sources also applies to sources that are in storage.

## Statement of Corrective Actions

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 | Rhonda Harmon | Rhonda Harmon | 5/31/17 |
| NRC INSPECTOR | Kevin G. Null | Kevin G. Null | 5/31/17 |
| BRANCH CHIEF | Aaron McCraw | Aaron McCraw | 05/30/2017 |

NRC FORM 591M PART 3
(07-2012)
10 CFR 2.201

U.S. NUCLEAR REGULATORY COMMISSION

*Docket File Information*

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| 6. INSPECTION PROCEDURES USED | 7. INSPECTION FOCUS AREAS |
|---|---|
| 87131 | 03.01 - 03.07 |

## SUPPLEMENTAL INSPECTION INFORMATION

| 1. PROGRAM CODE(S) | 2. PRIORITY | 3. LICENSEE CONTACT | 4. TELEPHONE NUMBER |
|---|---|---|---|
| 2230 | 2 | Alvis Foster, Ph.D., RSO | (765) 287-8550 |

☑ Main Office Inspection  Next Inspection Date: May 2019

☐ Field Office Inspection _____

☐ Temporary Job Site Inspection _____

## PROGRAM SCOPE

This was a routine, unannounced inspection of a licensee that was authorized for material described in 10 CFR Parts 35.100, 35.200, 35.300, and 31.11, iodine-125 and palladium-103 seeds for permanent implant procedures, a high dose rate (HDR) afterloader device, and yttrium-90 microspheres. The licensee was staffed by a certified lead nuclear medicine technologist (NMT), 6 full-time/certified nuclear medicine technologists (NMT's), a radiation safety officer/ medical physicist, and 2 full-time medical physicists. The nuclear medicine department had 5 imaging rooms and 2 hot labs. The staff used only unit doses for diagnostic procedures and iodine -131 capsules for thyroid therapy received from a licensed, local radiopharmacy. The licensee performed an average of 18 diagnostic studies per day, primarily cardiac procedures. Since the last inspection, the licensee performed 24 HDR treatments, 9 prostate permanent implants using palladium-103 seeds, 9 yttrium-90 procedures, and 38 iodine-131 treatments requiring a written directive.

Performance Observations:
The inspector observed NMT's prepare and administer diagnostic dosages of technetium-99m, conduct package receipt surveys, and perform radiation level surveys and surveys for removable contamination. Staff members also described how the daily constancy check of dose calibrators was performed, and the frequency for conducting leak-testing and physical inventory of sealed sources. The inspector observed an NMT measure and administer a 12 millicurie iodine-131 capsule for a hyperthyroid procedure, and provide the patient and her spouse with safety instructions. The inspector noted that all NMT's wore proper protective clothing, personal dosimetry, and utilized syringe shields to minimize extremity exposure.

(Continued on Part 2)

NRC FORM 591M PART 2
(07-2012)
10 CFR 2.201

U.S. NUCLEAR REGULATORY COMMISSION

# SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

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(Continued)

The inspector followed up on a reported event dated June 5, 2015 (NMED number 150330 - closed), involving receipt of a package that exceeded removable contamination limits. The inspector observed an NMT demonstrate how incoming packages were smeared for contamination, and reviewed a selected number of package receipt records. No issues were identified.

The inspector toured the HDR treatment room with the RSO/medical physicist. The RSO demonstrated some periodic spot checks for the HDR unit and the proper use of a survey meter to verify retraction of the source, and described how patient surveys were conducted after a treatment to verify that the source had returned to its safe/shielded position. The RSO also demonstrated how and where the device was secured and stored when not in use.

The inspector reviewed personal dosimetry records for calendar years 2016 and 2017, selected written directives for iodine-131 treatments, prostate implants, and HDR procedures, package receipt surveys, results of daily and weekly surveys, records of survey instrument calibration, and records of the spot checks and full calibration that were performed on the HDR unit.

During the review of records, the inspector identified a violation of 10 CFR 35.67(g), as described on Part 1.