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. 2401 W University Ave. Muncie, IN 47303 REPORT NUMBER(S) 2021001	Region III U. S. Nuclear Regulatory Commission 2443 Warrenville Road, Suite 210 Lisle, IL 60532-4352

3. DOCKET NUMBER(S)	4. LICENSE NUMBER(S)	5. DATE(S) OF INSPECTION
030-01586	13-00951-03	October 28, 2021

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)

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			
NRC INSPECTOR	Zahid Sulaiman, Health Physicist	Zahid M. Sulaiman Digitally signed by Zahid M. Sulaiman Date: 2021.11.08 15:33:25 -06'00'	
BRANCH CHIEF	Michael Kunowski, Chief, MIB	Michael A. Kunowski Digitally signed by Michael A. Kunowski Date: 2021.11.12 07:22:13 -06'00'	

NRC FORM 592M
(10-2020)

U.S. NUCLEAR REGULATORY COMMISSION

Materials Inspection Record

1. Licensee Name:	2. Docket Number(s):	3. License Number(s)
Indiana University Health Ball Memorial	030-01586	13-00951-03

4. Report Number(s):	5. Date(s) of Inspection:
2021001	October 28, 2021

6. Inspector(s):	7. Program Code(s):	8. Priority:	9. Inspection Guidance Used:
Zahid Sulaiman, Health Physicist	02230	2	87130, 87131, & 87132

10. Licensee Contact Name(s):	11. Licensee E-mail Address:	12. Licensee Telephone Number(s):
Alvis Foster, RSO	Afoster8@iuhealth.org	(765) 747-4440

13. Inspection Type:	14. Locations Inspected:	15. Next Inspection Date (MM/DD/YYYY):
☐ Initial ☑ Routine ☑ Announced ☐ Non-Routine ☐ Unannounced	☑ Main Office ☐ Field Office ☐ Temporary Job Site ☐ Remote	10/28/2023 ☑ Normal ☐ Extended ☐ Reduced ☐ No change

16. Scope and Observations:

This was an announced routine inspection of a large hospital authorized by its NRC license to use unsealed byproduct material for diagnostic and therapeutic procedures under 10 CFR 35.100, 35.200, 35.300, 35.400, 35.600 and 35.1000 for yttrium-90 (Y-90) microspheres. The hospital had two hot labs, one for the main hospital nuclear medicine and one for the cardiac clinic. The nuclear medicine department was staffed with seven full-time nuclear medicine technologists (NMTs). The NMTs performed approximately 20 diagnostic nuclear medicine procedures daily, 25-30 iodine-131 (I-131 capsules form) hyperthyroid and thyroid ablations, 2 radium-223 (Xofigo), and 4-5 Y-90 (Theraspheres) procedures annually. The diagnostic administrations included a variety of imaging procedures using technetium-99m (Tc-99m) primarily for the cardiac stress tests, gastric emptying, bone scans, lung scans, HIDA scans, and parathyroid / thyroid uptake and whole body scan using I-131. The licensee retained the services of a consultant who performs quarterly audits of the radiation safety program.

The radiation oncology department was staffed with four oncologists, seven therapists, two dosimetrists, and three authorized medical physicists (AMPs) who performed approximately 20-25 high dose rate remote afterloader (HDR) procedures (mostly gynecological cancer treatments) and 2 prostate permanent seed implants using palladium-103 annually.

PERFORMANCE OBSERVATIONS

This inspection consisted of a tour of the main hospital nuclear medicine department and the cancer center; interviews with select licensee personnel; a review of select records; an observation of security of the materials; and independent measurements. The inspector observed an HDR procedures for GYN cancer treatment, and administrations of Tc-99m for cardiac stress test to two patients. The inspector had the NMT conduct a physical inventory of sealed sources, and all sources were accounted for. The inspector had the NMT demonstrate the dose calibrator constancy check, package receipt procedures, the end of the day daily and weekly area surveys, proper handling of radioactive waste and disposal procedures, with no issue noted. Through these demonstrations and other discussion, the inspector found that the licensee personnel was knowledgeable of radiation protection principles, licensee procedures, and regulatory requirements.

The inspector had the AMP demonstrate the HDR unit's: (1) security; (2) daily spot checks; (3) emergency equipment and procedures; (4) safety procedures and instructions; (5) door interlock system; and (6) radiation monitoring equipment checks. The inspector reviewed select HDR, I-131, Ra-223, palladium-103 permanent seed implants, and Y-90 written directives and treatment plans.

Materials Inspection Record (Continued)

The inspector reviewed the following records: annual radiation protection program audits, radiation safety committee minutes, quarterly program audits, package receipts, waste disposal records, DOT Hazmat training, linearity and accuracy of the dose calibrator, instrument calibration, sealed source leak tests and inventory, daily area surveys, and weekly wipe tests. The inspector reviewed dosimetry records for 2019 through September 30, 2021, indicating the maximum annual dose to be 215 mrem - DDE, and 2,376 mrem - SDE. The inspector performed independent and confirmatory radiation measurements which indicated results consistent with licensee survey records and postings.

No violations of NRC requirements were identified as a result of this inspection.