

**SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION**

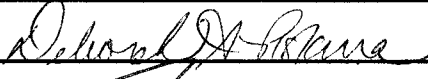
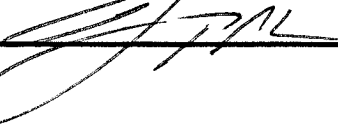
1. LICENSEE/LOCATION INSPECTED:  Indiana University - IUPUI Medical Center Campus 1120 W. Michigan Street Radiation Safety Room 159 Indianapolis, IN 46202-5111  REPORT NUMBER(S) 2019001		2. NRC/REGIONAL OFFICE  Region III U. S. Nuclear Regulatory Commission 2443 Warrenville Road, Suite 210 Lisle, IL 60532-4352
3. DOCKET NUMBER(S)  030-01609	4. LICENSE NUMBER(S)  13-02752-03	5. DATE(S) OF INSPECTION  June 3-7, 2019

**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, to exercise discretion, were satisfied.  
  
\_\_\_\_\_ Non-cited violation(s) were discussed involving the following requirement(s):  
  
\*\*\*\*Corrected Copy\*\*\*\*
- 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	Deborah A. Piskura, Senior Health Physicist		6/21/19
BRANCH CHIEF	Aaron T. McCraw, Chief, MIB		6/21/19

**Docket File Information**  
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6. INSPECTION PROCEDURES USED  87134	7. INSPECTION FOCUS AREAS  03.01 - 03.07
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**SUPPLEMENTAL INSPECTION INFORMATION**

1. PROGRAM CODE(S)  02110	2. PRIORITY  2	3. LICENSEE CONTACT  T. Michael Martin, Ph.D., CHP	4. TELEPHONE NUMBER  (317) 274-0331
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Main Office Inspection      Next Inspection Date: 6/3/2021  
 Field Office Inspection    IU Methodist Hosp., Riley Children's Hosp., &  
 Temporary Job Site Inspection Eskenazi Hosp.

**PROGRAM SCOPE**

This was a routine inspection of a large Type A broad scope medical educational institution, authorized to use a variety of isotopes in medical, research, and teaching applications. The radiation safety committee (RSC), which met at least quarterly, approved approximately 100+ authorized users. The radiation safety office was staffed with a dedicated, full-time RSO, four HPs, one student intern, and two admins. The RSO audited the R&D and clinical labs at least monthly. The licensee operated three hospitals (University, Eskenazi, and Riley Children's Hospital) at the IUPUI main campus. The licensee also conducted medical use at IU Methodist Hospital, IU Saxony Hospital and a satellite cardiac clinic. The licensee operated a large nuclear medicine program conducting approximately 1000+ procedures monthly in multiple nuclear medicine areas; the licensee administered a full spectrum of diagnostic studies. Doses were primarily Tc-99m and F-18 unit doses from a radiopharmacy. Nuclear medicine use included I-131, Ra-223, Lu-177, human research protocols, and Y-90 microsphere treatments.

The radiation oncology departments administered numerous patient treatments using its two HDR units; the units were used at the University and IU Methodist Hospitals. The majority of these treatments were for breast, bronchial/lung, and gynecological cancers. All HDR patient treatments were administered by the attending radiation oncologist, the medical physicist, and a nurse. Service, maintenance, and source exchanges were performed by the respective device manufacturer. The licensee also administered permanent prostate seed implants (25-50 cases/year).

R&D activities were conducted under the supervision of approximately 50 principal investigators (PI), in about 50 laboratories, that were approved by the RSC. The R&D uses included in vivo and in vitro experiments with CHIPS. Research involving human subjects was conducted by 5-10 PIs. These studies were reviewed and approved by the licensee's Institutional Review Board and the Radioactive Drug Research Committee in accordance with 10 CFR 35.6. Con't. on Part 2

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(Continued)

This inspection consisted of interviews with select licensee personnel and a review of select records including program audits, RSC meeting minutes, user permits. The inspector toured selected research laboratories, the University, Riley, and Eskenazi nuclear medicine departments and the University and IU Methodist radiation oncology departments. The inspector observed the licensee staff assay, prepare and administer several diagnostic imaging procedures. The inspector observed the licensee staff assay, prepare and administer a Y-90 TheraSphere treatment at the Eskenazi Hospital and a Lu-177 Lutathera treatment at University Hospital. The inspector observed staff perform package receipt surveys, daily area surveys, patient surveys at the completion of the respective therapeutic procedures, and decontamination of a patient treatment area following a Lu-177 infusion. The inspector observed the licensee administer two HDR patient treatments at University Hospital. The inspector reviewed the written directives and the respective treatment plans and interviewed the authorized medical physicist, the nurse, and the physician authorized user who attended the patient. The inspection included observations of dose calibrator QA checks, HDR safety/QA checks, security of byproduct material, use of personnel monitoring, and patient surveys. The inspector observed the radiation safety staff collect, package and transport laboratory radioactive waste to the university's central waste processing building. The licensee is authorized to incinerate its radioactive waste in accordance with the provisions in License Conditions 22 and 23. Based on the licensee's calculations, for 2018, the total effective dose to the public from its incineration activities was 0.016 millirem.

No violations of NRC requirements were identified during this inspection. A clear Form-591 Part 1 was issued in the field at the conclusion of the on-site inspection. Further review identified an error on the Form-591 Part 1 where an incorrect docket number was referenced on the form. A corrected Form-591 Part 1 was issued from the office.