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-IUPUI Medical Center Campus 1120 W. Michigan Street Radiation Safety Room159 Indianapolis, IN 46202-5111 REPORT NUMBER(S) 2018001	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
030-01609	13-02752-03	May 21-25, 2018

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	Deborah A. Piskura, Senior Health Physicist	Deborah A. Piskura	5/25/18
BRANCH CHIEF	Aaron T. McCraw, Chief, MIB		6/8/18

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
87134	03.01 - 03.07

SUPPLEMENTAL INSPECTION INFORMATION

1. PROGRAM CODE(S)	2. PRIORITY	3. LICENSEE CONTACT	4. TELEPHONE NUMBER
02110	2	T. Michael Martin, Ph.D., CHP	(317) 274-0331

☑ Main Office Inspection Next Inspection Date: May 25, 2020

☑ Field Office Inspection 13000 and 13100 East 136th St., Fishers, IN

☐ Temporary Job Site Inspection

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 at least quarterly, approved approximately 200+ authorized users. The radiation safety office was staffed with a dedicated, full-time RSO, three HPs, one student intern, two HP technicians, and two admin staff. 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 satellite cardiac clinics. The licensee maintained a large nuclear medicine program conducting approximately 1000+ procedures monthly in multiple nuclear medicine areas. The most common procedures were cardiac, bone, and lung studies. Doses were primarily Tc-99m and F-18 unit doses from a radiopharmacy. Nuclear medicine use included I-131, Ra-223 and Y-90 microsphere patient treatments.

The radiation oncology program included numerous patient treatments using 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 cases/year).

R&D activities were conducted under the supervision of approximately 50-75 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

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)

This inspection consisted of interviews with select licensee personnel; a review of select records; tours of the nuclear medicine and radiation oncology departments. The inspector toured two of the nuclear medicine areas on the IUPUI campus as well as the IU Saxony hospital. The inspector observed several dose assay, preparation and patient administrations. The inspector observed staff perform package receipt surveys, daily and weekly area surveys. The inspector observed the licensee utilizing its HDR unit at University Hospital for a patient treatment. The inspector reviewed the written directive and the treatment plan and interviewed the authorized medical physicist and the physician authorized user who attended the patient. The inspection included observations of source inventories, dose calibrator QA checks, HDR safety/QA checks, security of byproduct material, use of personnel monitoring, and patient surveys. The inspection included observations of the radiation safety staff conducting its routine audits and surveys of selected research laboratories.

The inspection included a review of the licensee's corrective actions for a violation of 10 CFR 20.1801 identified during the previous inspection of the -03 license. During the previous inspection, the inspectors identified an unsecured vial of P-32 in an unlocked research laboratory. The licensee's corrective actions included: (1) immediately securing the vial of P-32; (2) instructing the laboratory staff on security procedures; (3) increasing the audit frequency for this PI to ensure that all materials were secured; and (4) reviewing security of licensed materials during its audits. The inspector verified that the corrective actions were taken and that there was no recurrence of the violation; the previous violation involving 10 CFR 20.1801 is considered closed.