

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE/LOCATION INSPECTED:

Indiana University-IUPUI / IU Medical Center
1120 W. Michigan Street
Radiation Safety Room 159
Indianapolis, IN 46202-5111

REPORT NUMBER(S) 2016-001

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 / 030-09792

4. LICENSE NUMBER(S)

13-02752-03 / 13-02752-08

5. DATE(S) OF INSPECTION

02/29/16 - 03/04/16

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):

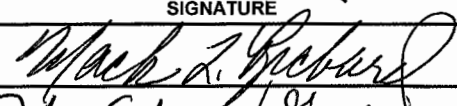
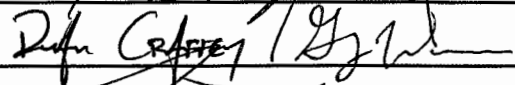

- 4. During this inspection, certain of your activities, as described below and/or attached, were in violation of NRC requirements and are being cited in accordance with NRC Enforcement Policy. This form is a NOTICE OF VIOLATION, which may be subject to posting in accordance with 10 CFR 19.11.
(Violations and Corrective Actions)

Contrary to 10 CFR 20.1801, on March 1, 2016, Indiana University-IUPUI / IU Medical Center failed to secure from unauthorized removal or access 342 microcuries of phosphorous-32 that were stored in a laboratory for which access was unrestricted during business hours, and the licensee did not maintain constant surveillance of this material.

As corrective action, the permit holder discussed the requirement with laboratory staff and transferred the material to a locked freezer.

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	Mack Richard		3/4/16
NRC INSPECTOR	Ryan Craffey / Geoff Warren		3/4/16
BRANCH CHIEF	Aaron McCraw		3/14/16

Docket File Information

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6. INSPECTION PROCEDURES USED 87126, 87131, 87132	7. INSPECTION FOCUS AREAS All
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SUPPLEMENTAL INSPECTION INFORMATION

1. PROGRAM CODE(S) 02110 / 02310	2. PRIORITY 2	3. LICENSEE CONTACT Mack Richard, MS, CHP - RSO	4. TELEPHONE NUMBER (317) 274-4797
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Main Office Inspection Next Inspection Date: 02/28/2018
 Field Office Inspection Methodist Hospital, Indianapolis, IN
 Temporary Job Site Inspection _____

PROGRAM SCOPE

This was an announced routine inspection of a public research university in Indianapolis, Indiana, authorized by its broad-scope license to use radioactive material for medical and research applications, and by an additional specific license to operate Gamma Stereotactic Radiosurgery (GSR) units. At the time of the inspection, the RSO, two assistant RSOs, one health physicist and two administrative staff oversaw the use of byproduct material for medical purposes at IU Medical Center (IUMC), Methodist Hospital, Eskanazi Hospital, and Riley Children's Hospital, and for research and development at various facilities on-campus. The licensee also synthesized PET radiopharmaceuticals for research at its Biotechnology Research and Training Center (BRTC), using radionuclides produced in a cyclotron operated by another licensee. The university maintained a Radiation Safety Committee (RSC) to review and approve authorized users and uses of materials, and to review the content and implementation of the radiation safety program.

PERFORMANCE OBSERVATIONS: The inspectors toured each hospital and numerous facilities on-campus, including ten research laboratories, six nuclear medicine departments, radiation oncology departments at IUMC and Methodist, all irradiator facilities, the cyclotron facility at BRTC, and the licensee's waste handling and incineration facility. The inspectors conducted independent and confirmatory surveys of these facilities, and observed the administration of two HDR fractions, one GSR treatment, one Y-90 TheraSpheres treatment, eight nuclear medicine procedures, the use of self-shielded irradiators, and the conduct of radiation awareness training for nursing staff. The licensee's staff demonstrated the implementation of routine procedures for the receipt and safe use and of radioactive material used in nuclear medicine, research and radiopharmaceutical synthesis applications, as well as procedures for receipt of radioactive material used in research and calibration of survey instruments.

The inspectors also reviewed a selection of written directives and treatment plans for HDR, GSR, TheraSphere, I-131, Ra-223 Xofigo, and Y-90 Zevalin treatments, spot checks and full calibration records for HDR and GSR units, RSC meeting minutes, quarterly ALARA and noncompliance reports, authorizations and audits of numerous research and medical permittees, inventory, leak test and transfer records for a variety of material, and incineration records.

(Continued on Part 2)

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(Continued)

The inspectors identified one SLIV violation of 10 CFR 20.1801 for the licensee's failure to secure from unauthorized removal or access 342 microcuries of phosphorous-32 that were stored in a laboratory for which access was unrestricted during business hours. During a tour of a research laboratory authorized for radioactive materials use, the inspectors found the lab and the fridge containing the material both unlocked, with no members of the laboratory present to maintain control and constant surveillance of the material until shortly after the inspectors' arrival.

The inspectors determined the root cause of the violation to be an oversight by laboratory staff. As corrective action, the permit holder discussed the requirement with the RSO and laboratory staff and transferred the material to a locked freezer.