

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE/LOCATION INSPECTED:

Indiana University Health LaPorte Hospital
1007 Lincolnway
LaPorte, Indiana 46350

REPORT NUMBER(S) 2016-001

2. NRC/REGIONAL OFFICE

Region III
U. S. Nuclear Regulatory Commission
2443 Warrenton Road, Suite 210
Lisle, IL 60532-4352

3. DOCKET NUMBER(S)

030-08653

4. LICENSE NUMBER(S)

13-15151-01

5. DATE(S) OF INSPECTION

JANUARY 29TH 2016

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:

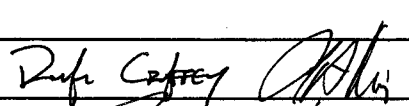
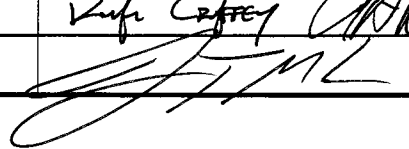
- ☒ 1. Based on the inspection findings, no violations were identified.
- ☐ 2. Previous violation(s) closed.
- ☐ 3. The violations(s), specifically described to you by the inspector as non-cited violations, are not being cited because they were self-identified, non-repetitive, and corrective action was 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	Ryan Craffey / Luis Nieves		1/29/16
BRANCH CHIEF	Aaron McCraw		2/5/16

Docket File Information

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE/LOCATION INSPECTED:

Indiana University Health LaPorte Hospital
1007 Lincolnway
LaPorte, IN 4350-0250

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)

030-08653

4. LICENSE NUMBER(S)

13-15151-01

5. DATE(S) OF INSPECTION

January 29, 2016

6. INSPECTION PROCEDURES USED

87130,87131,87132

7. INSPECTION FOCUS AREAS

03.01-03.07

SUPPLEMENTAL INSPECTION INFORMATION

1. PROGRAM CODE(S)

02240

2. PRIORITY

2

3. LICENSEE CONTACT

James C. Hatten - RSO

4. TELEPHONE NUMBER

(219) 326-1234

☒ Main Office Inspection

Next Inspection Date: January 29, 2018

☐ Field Office Inspection

☐ Temporary Job Site Inspection

PROGRAM SCOPE

This was an unannounced, routine inspection of a hospital authorized to perform diagnostic and therapeutic administrations of radiopharmaceuticals at its facility in LaPorte, Indiana. The licensee performed approximately a hundred procedures a month, including therapeutic administrations of I-131, Ra-223 Xofigo, and, Y-90 Sir-spheres in the last year. The majority of diagnostic studies were cardiac rest and stress tests. The department received unit doses as needed from a licensed nuclear pharmacy. Nuclear medicine procedures were performed from Monday to Friday. The nuclear medicine department was staffed with two full time nuclear medicine technologists.

PERFORMANCE OBSERVATIONS: The inspectors toured the nuclear medicine department and hot lab to evaluate the licensee's measures for materials security, hazard communication and exposure control. The inspectors conducted independent surveys of these areas, and found no exposures to members of the public distinguishable from background. The inspectors observed the preparation and administration of cardiac stress tests, a brain function test, package receipt, instrument quality control and waste handling by nuclear medicine staff. The inspectors reviewed a selection of written directives and treatment plans for I-131, Y-90, and Xofigo administrations, in addition to routine nuclear medicine records, consultant audits, training and dosimetry.

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