

(07-2012)
10 CFR 2.201

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE/LOCATION INSPECTED:

Mercy Health Saint Mary's
200 Jefferson SE
Grand Rapids, MI 49503

REPORT NUMBER(S) 2015-001

2. NRC/REGIONAL OFFICE

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

3. DOCKET NUMBER(S)

030-08291

4. LICENSE NUMBER(S)

21-01078-01

5. DATE(S) OF INSPECTION

April 21-22, 2015

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 35.610(b), from October 1, 2014 until April 22, 2015, the licensee failed to have a copy of the emergency procedures required by 10 CFR 35.610(a)(4) physically located at the HDR unit console.

As corrective action, the licensee located a copy of its HDR emergency procedures and placed it at the HDR unit console.

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 | Dale Schippers | <i>Dale Schippers</i> | 5/6/15 |
| NRC INSPECTOR | Ryan Craffey | <i>Rh Craffey</i> | 4/27/15 |
| BRANCH CHIEF | Aaron McCraw | <i>[Signature]</i> | 5/6/15 |

Docket File Information

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

| | | | |
|---|---|---|--|
| 1. LICENSEE/LOCATION INSPECTED: Mercy Health Saint Mary's 200 Jefferson SE Grand Rapids, MI 49503 REPORT NUMBER(S) 2015-001 | | 2. NRC/REGIONAL OFFICE Region III U. S. Nuclear Regulatory Commission 2443 Warrenville Road, Suite 210 Lisle, IL 60532-4352 | |
| 3. DOCKET NUMBER(S) 030-08291 | 4. LICENSE NUMBER(S) 21-01078-01 | 5. DATE(S) OF INSPECTION April 21-22, 2015 | |
| 6. INSPECTION PROCEDURES USED 87131, 87132 | 7. INSPECTION FOCUS AREAS All | | |

SUPPLEMENTAL INSPECTION INFORMATION

| | | | |
|---------------------------------|----------------------|---|---|
| 1. PROGRAM CODE(S) 02240 | 2. PRIORITY 2 | 3. LICENSEE CONTACT Dale J. Shippers, MS - RSO | 4. TELEPHONE NUMBER (616) 752-6744 |
|---------------------------------|----------------------|---|---|

☒ Main Office Inspection Next Inspection Date: 04/21/2017

☒ Field Office Inspection 250 Cherry Street SE, Grand Rapids, Michigan

☐ Temporary Job Site Inspection

PROGRAM SCOPE

This was a routine inspection of a 344-bed hospital authorized to use byproduct material for medical purposes at three locations on its campus in Grand Rapids, Michigan, and at one off-site location in Grand Rapids. At the time of the inspection, the licensee performed a full spectrum of diagnostic procedures, including PET scans using F-18, at the main hospital on 200 Jefferson SE. This department also performed 2-3 administrations of therapeutic I-131 weekly, as well as 8-12 administrations of Y-90 TheraSpheres and 3-4 administrations of Ra-223 Xofigo annually. The licensee also performed injections of diagnostic radiopharmaceuticals at the 310 E Lafayette location, using doses prepared at the main hospital. The licensee performed 10 cardiac stress tests weekly at the off-site location on 1000 E Paris SE. The licensee's radiation oncology department at 250 Cherry Street SE performed 32 fractionated HDR treatments, three prostate seed implants, and one temporary implant brachytherapy treatment in 2014, and a similar number in 2013.

PERFORMANCE OBSERVATIONS

The inspector toured the main nuclear medicine facility and radiation oncology department, conducted independent and confirmatory surveys of restricted and unrestricted areas, and found no residual contamination or exposures to members of the public in excess of regulatory limits. The inspector observed the preparation and administration of one PET scan using F-18, as well as one fraction of an HDR breast cancer treatment using a SAVI applicator. The licensee's nuclear medicine and radiation oncology staff demonstrated the implementation of various licensee procedures, and in doing so demonstrated adequate knowledge of radiation safety principles and regulatory requirements. The inspector reviewed a selection of written directives and other records for HDR treatments, permanent and temporary implant brachytherapy, Y-90 administrations, and other therapies. The inspector also reviewed a variety of other records, including radiation safety committee minutes, program reviews, dosimetry, and routine nuclear medicine records.

The inspector identified a violation of 10 CFR 35.610(b) for the licensee's failure to have a copy of the emergency procedures required by 10 CFR 35.610(a)(4) physically located at the HDR unit console. The inspector determined that the root cause of the violation was an oversight by the licensee, who, in October 2014, inadvertently removed the posted emergency procedures during a facility renovation. As corrective action, the licensee located and re-posted the procedures at the console.