

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE/LOCATION INSPECTED:
Saint Joseph Mercy Health Systems
5301 E. Huron River Drive
Ann Arbor, Michigan
REPORT NUMBER(S): ~~2011-004~~ 11-01

2. NRC/REGIONAL OFFICE
U.S. Nuclear Regulatory Commission, Region III
2443 Warrenville Road, Suite 210
Lisle, Illinois 60532

3. DOCKET NUMBER(S)
030-01997

4. LICENSEE NUMBER(S)
21-00943-03

5. DATE(S) OF INSPECTION
April 11-12, 2011

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, NUREG-1600, 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. This form is a NOTICE OF VIOLATION, which may be subject to posting in accordance with 10 CFR 19.11

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	Geoffrey M. Warren/Andrew M. Bramnik	<i>[Signature]</i>	4/12/11
Branch Chief	Tamara E. Bloomer	<i>[Signature]</i>	4/26/11

Docket File Information
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1. LICENSEE Saint Joseph Mercy Health Systems Ann Arbor, MI REPORT NUMBER(S) 11-01	2. NRC/REGIONAL OFFICE U.S. Nuclear Regulatory Commission, Region III 2443 Warrenville Road, Suite 210 Lisle, Illinois 60532
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3. DOCKET NUMBER(S) 030-01997	4. LICENSEE NUMBER(S) 21-00943-03	3. DOCKET NUMBER(S) 030-01997
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6. INSPECTION PROCEDURES 87131, 87132	7. INSPECTION FOCUS AREAS 03.01 – 03.08; 03.01 – 03.08
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SUPPLEMENTAL INSPECTION INFORMATION

1. PROGRAM 02230	2. PRIORITY 2	1. PROGRAM 02230	2. PRIORITY 2
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- Main Office Inspection Next Inspection Date: April 2013
- Field Office Inspection St. Joseph Mercy Hospital-Saline, 400 W. Russell St., Saline, MI
- Temporary Job Site Inspection _____

PROGRAM SCOPE

The licensee was a 535-bed hospital located in Ann Arbor, Michigan, with authorization to use byproduct materials in Sections 35.100, 35.200, 35.300, and 35.400, as well as a high dose rate (HDR) remote afterloader and a blood irradiator. Licensed activities were conducted only at the facilities identified on the license.

The licensee's nuclear medicine program employed 12 full-time technologists plus several students on 9-month rotational assignments. The main hospital's department averaged approximately 5,000 total procedures per year, including 8-10 cardiac studies per day and 50 therapeutic administrations per quarter. The licensee was also cross-training four technologists in PET for mobile services. The licensee had performed one inpatient I-131 therapy since the previous inspection, with no complications. In addition, the licensee performed diagnostic nuclear medicine scans at an outpatient clinic in Saline, MI, and at a 200 bed hospital in Howell, MI. At the Saline facility, the licensee performed approximately 45 procedures per month, performing mostly bone, cardiac, and gastric emptying studies.

The radiation therapy department was staffed with six physician authorized users and three medical physicists and dosimetrists. The radiation therapy staff performed approximately 35 to 55 HDR fractions quarterly, five permanent prostate implants annually using I-125 seeds, and four Y-90 radiopharmaceutical therapies annually.

Performance Observations

The inspectors observed one diagnostic administration of licensed material in nuclear medicine, including dose preparation and disposal, as well as an HDR treatment and daily checks on the HDR unit. Licensee personnel demonstrated dose calibrator constancy, package receipt, area surveys, survey meter QC, and blood irradiator operation, and described prostate implant, Y-90 therapy, and emergency procedures. The inspectors reviewed written directives for radiopharmaceutical therapies, HDR treatments, and prostate implant procedures, and identified no concerns. Interviews with licensee personnel indicated adequate knowledge of radiation safety concepts and procedures. The inspector performed independent and confirmatory radiation measurements which indicated results consistent with licensee survey records and postings.

The licensee was previously cited for a failure to perform monthly checks of the HDR unit at the required frequency. The licensee has performed these checks each month for the last two years; based on this information, this violation is considered closed.