

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE/LOCATION INSPECTED:

GREAT LAKES HEART & VASCULAR INSTITUTE
 3950 Holly Wood Rd
 St. Joseph, MI 49085

2. NRC/REGIONAL OFFICE

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

REPORT NUMBER(S) 15-01

3. DOCKET NUMBER(S)

030-35393

4. LICENSE NUMBER(S)

21-32256-01

5. DATE(S) OF INSPECTION

12/4/15

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:


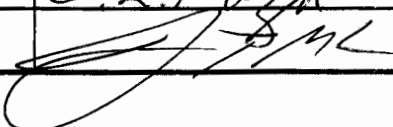
- 1. Based on the inspection findings, no violations were identified.
- 2. Previous violation(s) closed.
- 3. The violation(s), specifically described to you by the inspector as non-cited violations, are not being cited because they were self-identified, non-repetitive, and corrective action was or is 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)

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	E.L. Kulzer		12/4/15
BRANCH CHIEF	James T. McCann		12/15/15

Docket File Information

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE/LOCATION INSPECTED: Great Lakes Heart & Vascular Institute 3950 Hollywood Road St. Joseph, MI 49085 REPORT NUMBER(S) 2015001	2. NRC/REGIONAL OFFICE Region III U. S. Nuclear Regulatory Commission 2443 Warrenville Road, Suite 210 Lisle, IL 60532-4352
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3. DOCKET NUMBER(S) 030-35393	4. LICENSE NUMBER(S) 21-32256-01	5. DATE(S) OF INSPECTION 12/04/2015
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6. INSPECTION PROCEDURES USED IP 87130	7. INSPECTION FOCUS AREAS 03.01 through 03.07
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SUPPLEMENTAL INSPECTION INFORMATION

1. PROGRAM CODE(S) 02200	2. PRIORITY 3	3. LICENSEE CONTACT Dilip S. Arora, M.D.	4. TELEPHONE NUMBER (269) 985-1000
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Main Office Inspection Next Inspection Date: 12/04/2020

Field Office Inspection

Temporary Job Site Inspection

PROGRAM SCOPE

This was a routine unannounced inspection of a medical clinic located in St. Joseph, Michigan authorized to use any byproduct material for any study permitted by 10 CFR 35.100, and 35.200 at the location specified on the license. This nuclear medicine department was staffed with two nuclear medicine technologists (NMT). The licensee performs an average of 10-15 cardiac studies from Monday through Friday. The nuclear medicine department received unit doses from a local pharmacy as ordered. All waste was either held for decay-in-storage or returned to the nuclear pharmacy as limited quantity shipments.

The inspector interviewed and discussed the following with the licensee's NMT: (1) survey meter use and calibrations; (2) sealed source inventories and leak tests; (3) package check-in procedures; (4) wipe test counting; (5) waste handling; (6) routine security of licensed material; (7) dose calibrator tests; (8) quarterly radiation safety program audits; (9) HAZMAT refresher training; (10) contamination events (none); (11) written directives and 10 CFR 35.75 requirements; (12) security of licensed material; and (13) dosimetry; for 2015, 154 mrem DDE, and 950 mrem SDE; 2014, 243 mrem DDE, and 360 mrem SDE; 2013, 368 mrem DDE, and 1580 mrem SDE; and 2012, 285 mrem DDE and 660 mrem SDE.

No violations of NRC regulatory requirements were identified during this inspection.