

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE/LOCATION INSPECTED:

Great Lakes Heart & Vascular Institute, P.C.
3950 Hollywood Avenue
Suite 110
St. Joseph, MI 49085

2. NRC/REGIONAL OFFICE

U.S. Nuclear Regulatory Commission
Region III
2443 Warrenville Road, Suite 210
Lisle, Illinois 60532-4351

REPORT NUMBER(S) **2011-01**

3. DOCKET NUMBER(S)
030-35393

4. LICENSEE NUMBER(S)
21-32256-01

5. DATE(S) OF INSPECTION
MAY 24, 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:


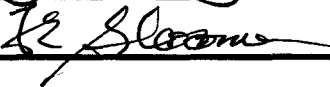
- 1. Based on the inspection findings, no violations were identified.
- 2. Previous violation(s) closed.
- 3. The violation(s), specifically described to you by the inspector as non-cited violations, are not being cited because they were self-identified, non-repetitive, and corrective action was or is 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	Robert P. Hays		5/24/11
Branch Chief	Tamara E. Bloomer		6/6/11

NRC FORM 591 M PART 3 (06-2010) 10 CFR 2.201	U.S. NUCLEAR REGULATORY COMMISSION <i>Docket File Information</i> SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION
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1. LICENSEE Great Lakes Heart & Vascual Institute 3950 Hollywood Road St. Joseph, MI 49085 REPORT NUMBER(S) 2011-01	2. NRC/REGIONAL OFFICE U.S. Nuclear Regulatory Commission Region III 2443 Warrenville Road, Suite 210 Lisle, Illinois 60532-4351	
3. DOCKET NUMBER(S) 03035393	4. LICENSE NUMBER(S) 21-32256-01	5. DATE(S) OF INSPECTION May 24, 2011
6. INSPECTION PROCEDURES 87130 (10/24/02)	7. INSPECTION FOCUS AREAS 03.01-03.07	

SUPPLEMENTAL INSPECTION INFORMATION			
1. PROGRAM 02201	2. PRIORITY 5	3. LICENSEE CONTACT D. Arora, MD, RSO	4. TELEPHONE NUMBER 269-985-1000

Main Office Inspection
Next Inspection Date: May 2016

Field Office Inspection _____

Temporary Job Site Inspection _____

PROGRAM SCOPE

The licensee is a medical clinic located in St. Joseph, Michigan, authorized by the license to use any byproduct material permitted by 10 CFR 35.100 and 35.200. Licensed activities were conducted only at the location indicated on the license. The nuclear medicine department was staffed with two FT, one PT (when needed) nuclear medicine technologists (NMTs). The licensee only performed cardiac studies and averaged 22-24 patient studies each weekday. Trained nurses are used to inject stress doses of sestimibi during patient stress testing. The department received unit doses as needed from a nearby nuclear pharmacy. All waste was either held for decay-in-storage (DIS) and unused doses returned to the nuclear pharmacy. No change in RSO or NMTs since the previous inspection. The inspector performed independent and confirmatory radiation measurements which indicated results consistent with licensee survey records and postings.

Performance Observations

The licensee's FT NMTs (Lisa Scheer, Stephanie McNeil) demonstrated/discussed: (1) survey meter use and calibrations; (2) package check-in procedures; (3) unit dose prep; (4) wipe test counting; (5) dosimetry (2009: 203mr DDE, 1360mr finger; 2010: 305mr DDE, 1310mr finger); (6) waste handling; (7) sealed source inventories; (8) security of licensed material; (9) dose calibrator tests; (10) radiation safety program audits by MPC; and (11) minor contamination events, which average one/year and are well-documented with corrective action training provided to nurses involved with the contamination events occurring during stress tests.