

**SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION**

1. LICENSEE/LOCATION INSPECTED:

VHS Harper-Hutzel Hospital, Inc.  
3990 John R Street  
Detroit, MI 48201

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)

030-02045

4. LICENSE NUMBER(S)

21-04127-02

5. DATE(S) OF INSPECTION

NOVEMBER 16-17, 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:

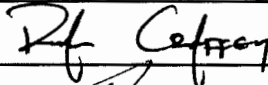

- ✓ 1. Based on the inspection findings, no violations were identified.
- 2. Previous violation(s) closed.
- 3. The violation(s), specifically described to you by the inspector as non-cited violations, are not being cited because they were self-identified, non-repetitive, and corrective action was or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

**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		11/17/15
BRANCH CHIEF	Aaron McCraw		11/25/15

**Docket File Information**

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6. INSPECTION PROCEDURES USED  87131, 87132	7. INSPECTION FOCUS AREAS  All
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**SUPPLEMENTAL INSPECTION INFORMATION**

1. PROGRAM CODE(S)  02240	2. PRIORITY  2	3. LICENSEE CONTACT  Richard N Joyrich, MD - RSO	4. TELEPHONE NUMBER  (313) 745-8417
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Main Office Inspection                      Next Inspection Date: 11/17/2017

Field Office Inspection    311 Mack Avenue, Detroit, Michigan

Temporary Job Site Inspection \_\_\_\_\_

**PROGRAM SCOPE**

This was an unannounced routine inspection of a regional hospital authorized to use byproduct material for medical purposes at three addresses on its campus in Detroit, Michigan. At the time of the inspection, the licensee performed a full spectrum of diagnostic procedures (around 15 per day) at a nuclear medicine department located in the main hospital on 3990 John R Street and cardiac stress tests (around five per day) at a separate department located at the newly-constructed Detroit Medical Center Heart Hospital on 311 Mack Avenue. The licensee also performed a variety of therapeutic administrations at the main hospital, including I-131 capsules, Ra-223 Xofigo injections, Y-90 TheraSphere treatments, and some clinical trials of radiopharmaceuticals prepared by a licensed radiopharmacy for use in accordance with Investigational New Drug protocols accepted by the FDA. The licensee retained the services of a medical physics consultant and maintained a Radiation Safety Committee which met quarterly.

PERFORMANCE OBSERVATIONS: The inspector toured the facilities at 3990 John R Street and 311 Mack Avenue in Detroit to evaluate the licensee's measures for materials security, hazard communication and exposure control. The inspector conducted independent surveys of these facilities and found no evidence of residual contamination or exposures to members of the public in excess of regulatory limits. The inspector observed the preparation and administration of various diagnostic procedures at both facilities, including lung ventilation studies, bone scans and cardiac stress tests, all using Tc-99m. The inspector also observed the receipt of packages containing licensed material. The staff demonstrated the implementation of additional licensee procedures, including Therasphere treatment planning and administration, waste handling, area surveys, and spill response. Through these observations, demonstrations, and other discussions, the inspector found the licensee's staff knowledgeable of radiation protection principles and licensee procedures.

The inspector also reviewed a selection of licensee records, including radiation safety committee minutes, quarterly consultant audits, personnel dosimetry, and written directives and associated documentation of various therapies, including clinical trials. The inspector found through this review that the licensee's procedures provided high confidence that therapeutic administrations had been performed in accordance with the written directives.

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