

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE/LOCATION INSPECTED:
Spectrum Health Hospitals
100 Michigan N. E.
Grand Rapids, MI 49503
REPORT NUMBER(S) **2010-01**

2. NRC/REGIONAL OFFICE
U.S. Nuclear Regulatory Commission
Region III
2443 Warrenville Road
Suite 210
Lisle, Illinois 60532-4351

3. DOCKET NUMBER(S)
030-01989

4. LICENSEE NUMBER(S)
21-00243-06

5. DATE(S) OF INSPECTION
Nov. 30 - Dec. 1, 2010

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	S. J. Mulay	<i>S. J. Mulay</i>	12/1/10
Branch Chief	Tamara E. Bloomer	<i>T. E. Bloomer</i>	12/16/10

Docket File Information
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1. LICENSEE Spectrum Health Hospitals Grand Rapids, MI 49503 REPORT NUMBER(S) 2010-01		2. NRC/REGIONAL OFFICE Region III 2443 Warrenville Road, Suite 210 Lisle, Illinois 60532-4351	
3. DOCKET NUMBER(S) 030-01989		4. LICENSE NUMBER(S) 21-00243-06	5. DATE(S) OF INSPECTION November 30-December 1, 2010
6. INSPECTION PROCEDURES 87131, 87132		7. INSPECTION FOCUS AREAS 03.01-03.07	
SUPPLEMENTAL INSPECTION INFORMATION			
1. PROGRAM 2240	2. PRIORITY 2	3. LICENSEE CONTACT Bruce Hasselquist, Ph.D., RSO	4. TELEPHONE NUMBER 616-391-2498

◀ Main Office Inspection: 100 Michigan NE., Grand Rapids MI
Next Inspection Date: December 2012
◀ Field Office Inspection : 145 Michigan St., NE, Grand Rapids, MI
Helen DeVos Children's Hospital, 100 Michigan NE, Grand Rapids, MI (Tour Only)

PROGRAM SCOPE

This large medical institution maintains six authorized locations of use in the Grand Rapids and Holland, MI areas. The areas reviewed are indicated above.

100 Michigan N.E., Grand Rapids, MI: Approximately ten full-time technologists perform approximately 500 diagnostic nuclear medicine procedures monthly. The facility operates in three shifts between 6:30 am and 10:00pm. This department also performs about 15 iodine-131 treatments for hyperthyroid quarterly and four one iodine-131 ablation therapies annually both administered in capsule form. Cardiovascular studies are performed at the licensee's Heart Center (not reviewed). Licensed material is received as unit and bulk quantities from an area nuclear pharmacy. The licensee's conventional brachytherapy program consists of about 45 iodine-125 permanent prostate implants (with some Pd-103) and about eight cesium-137 implant treatments annually. Approximately 30 Yttrium-90 treatments with TheraSpheres are also performed annually. The licensee stores cesium-137 sources and strontium-90 sources on-site in authorized locations. Iodine-125 seeds are received in the nuclear medicine department for processing, delivered to the interventional suite and administered.

Helen DeVos Children's Hospital (HDVCH), 100 Michigan N.E., Grand Rapids, MI: This new children's hospital is planned to be operational on January 11, 2011. Overall security measures appeared adequately planned and implemented. Designated use areas appeared to be as indicated in submitted documentation.

145 Michigan N.E., Grand Rapids, MI: The licensee performs about 35 fractionated treatments per month utilizing a High Dose Rate Afterloader (HDR) device containing type and quantity of licensed material as authorized. Four authorized users and three medical physicists perform treatment administration, treatment planning, etc. PET/CT imaging utilizes fluorine-18 (FDG) to perform about 240 procedures per month. Four technologists are involved with daily studies.

PERFORMANCE OBSERVATIONS

Interviews conducted with available nuclear medicine staff revealed an adequate level of understanding of emergency and material handling procedures and techniques. Dose calibrator constancy checks, injection technique, daily surveys, waste handling and disposal, and package receipt procedures, were successfully demonstrated or observed at locations inspected. The licensee's RSO performs quarterly program audits which appear to adequately oversee licensed activities. The inspector visually verified the licensee's authorized sealed sources against the most recent inventory performed with no discrepancies noted.

Licensed material was observed adequately secured at the locations inspected and was not readily accessible to members of the general public. Survey meters were found to be calibrated and operational and compared well in side-by-side comparison with the NRC instrument. A daily QC check of the HDR unit was demonstrated and included all appropriate safety verifications. In addition, a patient treatment was observed with no issues identified. Written directives, patient instructions and staff responses to QMP questions for the various treatment modalities performed were adequately completed and addressed.

Independent measurements taken did not indicate readings in excess of 10 CFR Pt. 20 limits in restricted or unrestricted areas. In addition, personal dosimetry records reviewed for 2009 and YTD 2010 for nuclear medicine and brachytherapy staff did not reveal whole-body and extremity readings in excess of regulatory limits.