

**SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION**

1. LICENSEE/LOCATION INSPECTED: McLaren Regional Medical Center Department of Radiology 401 South Ballenger Highway Flint, MI 48532 REPORT NUMBER(S) 2012-001		2. NRC/REGIONAL OFFICE  Region III: 2443 Warrenville Rd., Ste. 210 Lisle, IL 60532-4352	
3. DOCKET NUMBER(S) 030-02048	4. LICENSE NUMBER(S) 21-04171-04	5. DATE(S) OF INSPECTION <i>Jan 26-27, 2012</i>	

**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. 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	Deborah A. Piskura / Claire Wellinghoff	<i>Deborah A. Piskura / Claire Wellinghoff</i>	<i>1/27/2012</i>
BRANCH CHIEF	Tamara E. Bloomer	<i>Tamara E. Bloomer</i>	<i>2/2/12</i>

**Docket File Information**

**SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION**

1. LICENSEE/LOCATION INSPECTED:  McLaren Regional Medical Center Department of Radiology 401 South Ballenger Highway Flint, MI 48532  REPORT NUMBER(S) 2012-001	2. NRC/REGIONAL OFFICE  Region III U. S. Nuclear Regulatory Commission 2443 Warrenville Road, Suite 210 Lisle, IL 60532-4352
--	---

3. DOCKET NUMBER(S)  030-02048	4. LICENSE NUMBER(S)  21-04171-04	5. DATE(S) OF INSPECTION  Jan 26-27, 2012
--------------------------------------	---	---

6. INSPECTION PROCEDURES USED  87130, 87131, 87132	7. INSPECTION FOCUS AREAS  03.01 - 07
--	---

**SUPPLEMENTAL INSPECTION INFORMATION**

1. PROGRAM CODE(S)  02240	2. PRIORITY  2	3. LICENSEE CONTACT  Christopher J. Conlin, M.D., RSO	4. TELEPHONE NUMBER  (810) 342-3830
---------------------------------	----------------------	---	---

- Main Office Inspection                      Next Inspection Date:                      Jan. 2014
- Field Office Inspection    501 S. Ballenger Hwy, Flint, MI
- Temporary Job Site Inspection

**PROGRAM SCOPE**

This licensee was a large medical institution (360+ bed hospital) authorized to use licensed materials in Sections 35.100, 35.200, 35.300, 35.400, I-125 in the Gliasite system, and Ir-192 within an HDR unit. The licensee retained a consulting physicist who audited the nuclear medicine radiation safety program on a quarterly basis (last 11/1/2011). The nuclear medicine department was staffed with 5 technologists who performed approximately 220-240 diagnostic nuclear medicine procedures monthly which included a full spectrum of diagnostic imaging studies. The licensee received unit doses and a Mo-99/Tc-99m generator for kit preparation. The licensee maintained an active therapy program and administered several I-131 dosages for CA, whole body follow up studies, and hyperthyroidism (capsules only). Occasionally, the department administered Sm-153 dosages for treatment of metastatic bone disease (1-2 cases annually).

The radiation therapy department was staffed with three authorized physician users and six medical physicists. The licensee administered 5+ Pd-103 permanent prostate implants each year. Although the licensee possessed Cs-137 "tube" source for LDR implants, these sources remained in secured storage since 2003. The licensee used its HDR unit to administer approximately 1,300 patient treatments per year; these treatments consisted of breast, surface, gyn and prostate cancers. All HDR patient treatments were administered by the attending radiation oncologist and an authorized medical physicist. Service, maintenance, and source exchanges were performed by the HDR device manufacturer. Occasionally, the department administered Bexxar and Zevalin treatment (1-2 cases annually). The department's use of the Gliasite system had been "inactive" since the previous inspection, however the licensee anticipated resuming these treatments.

This inspection consisted of interviews with select licensee personnel; a review of select records; tours of the nuclear medicine and radiation oncology departments; and independent measurements. The inspectors observed the administration of two diagnostic nuclear medicine procedures. inspector also observed the licensee staff administer two patient treatments utilizing its HDR unit. The inspection included observations of dose calibrator and HDR QA checks, security of byproduct material, a confirmation of the Cs-137 "tube" source inventory, use of personnel monitoring, package receipts and surveys, and patient surveys for compliance with Section 35.75 and 35.604.