

**SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION**

<b>1. LICENSEE/LOCATION INSPECTED:</b> Lakeland Medical Center, St. Joseph 1234 Napier Avenue St. Joseph, Michigan 49085  <b>REPORT NUMBER(S)</b> 2008-001	<b>2. NRC/REGIONAL OFFICE</b>  <b>Region III</b> <b>U.S. Nuclear Regulatory Commission</b> <b>2443 Warrenville Road, Suite 210</b> <b>Lisle, Illinois 60532-4351</b>
---	---

<b>3. DOCKET NUMBER(S)</b> 030-02049	<b>4. LICENSEE NUMBER(S)</b> 24-04177-01	<b>5. DATE(S) OF INSPECTION</b> October 27-28, 2008
---	---	--

**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) was/were discussed involving the following requirement(s) and Corrective Action(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)

License Condition No. 19A of NRC License No. 21-04177-01 requires, in part, that the licensee conduct its program in accordance with the statements contained in the application dated December 28, 2004. Section 8.24, Item 10, of that application states that the licensee has developed and will implement and maintain procedures for safe use of unsealed byproduct material. The licensee's procedure requires no eating or drinking in patient treatment areas. Contrary to the above, on October 27, 2008, at the licensee's facility in Niles, Michigan, the inspector observed a nuclear medicine technologist eating and drinking in a camera room, which is a patient treatment area. As corrective action, the licensee will retrain all nuclear medicine staff on the requirement for no eating or drinking in patient treatment areas.

**Licensee's Statement of Corrective Actions for Item 4, above.**

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	Laurie FLEMING Vice President Outpatient	<i>Laurie Fleming</i>	10/28/08
NRC INSPECTOR	Geoffrey M. Warren	<i>Geoffrey Warren</i>	10/28/08

SAFETY INSPECTION REPORT  
AND COMPLIANCE INSPECTION

1. LICENSEE Lakeland Medical Center, St. Joseph REPORT NUMBER(S) 2008-001		2. NRC/REGIONAL OFFICE <b>NRC Region III</b> 2443 Warrenville Road, Suite 210 Lisle, Illinois 60532-4351	
3. DOCKET NUMBER(S) 030-02049	4. LICENSE NUMBER(S) 24-04177-01	5. DATE(S) OF INSPECTION Oct. 27-28, 2008	
6. INSPECTION PROCEDURES USED 87131, 87132		7. INSPECTION FOCUS AREAS 03.01 – 03.08, 03.01 – 03.08	

## SUPPLEMENTAL INSPECTION INFORMATION

1. PROGRAM CODE(S) 02230	2. PRIORITY 2	3. LICENSEE CONTACT David E. Sieffert, M.S, RSO	4. TELEPHONE NUMBER 616-393-6900
<input checked="" type="checkbox"/> Main Office Inspection		Next Inspection Date: <u>Oct. 2010</u>	
<input checked="" type="checkbox"/> Field Office		<u>Lakeland Medical Center – Niles, 31 N. St. Joseph Ave., Niles, MI</u>	
<input type="checkbox"/> Temporary Job Site Inspection			

## PROGRAM SCOPE

The licensee operated hospitals in St. Joseph and Niles, MI. While authorized to perform diagnostic activities at a second location in St. Joseph, the licensee had not yet started such activities.

The hospital in St. Joseph was a 300-bed hospital which served patients primarily from local and surrounding counties. At this location, the licensee performed activities under 10 CFR 35.100 through 35.400. While authorized to possess iridium-192 for a high dose rate (HDR) remote afterloader, the licensee had not yet acquired a source for the HDR device and intended to amend the license to authorize a different device. In nuclear medicine, four full-time technologists performed around 250 diagnostic procedures monthly, mostly bone, thyroid, and hepatobiliary studies, using doses received as unit doses from a licensed radiopharmacy or prepared from bulk technetium-99m. In addition, the licensee performed around 25 therapeutic procedures annually using iodine-131 capsules, including thyroid ablations, hyperthyroid treatments, and whole body scans. Thyroid ablations were performed only as inpatient procedures. The licensee's radiation oncology staff included one authorized user oncologist, two physicists, and two dosimetrists. In 2008 so far, oncology staff had performed 14 prostate implants using iodine-125 seeds and ten temporary implants using cesium-137 and iridium-192 seeds.

The hospital in Niles was an 80-bed hospital which served patients primarily from the local county. At this location, the licensee performed activities under 10 CFR 35.100 through 35.300. While authorized to perform activities under 35.400, they had not done so. One full-time nuclear medicine technologist who rotated from the hospital in St. Joseph performed around 80 procedures monthly, mostly hepatobiliary, bone, and cardiac studies, using doses received as unit doses from a licensed radiopharmacy. In addition, the licensee performed around five hyperthyroid treatments annually using iodine-131 capsules.

## Performance Observations

The inspector observed four diagnostic administrations of licensed material including dose preparation and disposal, a package receipt survey including package surveys and wipes, and a daily contamination survey, and noted no concerns. Licensee staff demonstrated wipe counter, thyroid probe, and survey meter QC, dose calibrator constancy checks, wipe surveys, and long-term waste storage, and described a variety of diagnostic procedures, radiopharmaceutical therapies, iodine-131 patient room monitoring and clearance, temporary and permanent seed implant procedures, and HDR procedures to be used when the device is acquired, and the inspector noted no issues with the activities. The inspector reviewed written directives for radiopharmaceutical and oncology procedures and found no issues. Interviews with licensee staff indicated adequate knowledge of radiation safety procedures. Radiation surveys indicated radiation levels appropriate for restricted and unrestricted areas