

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

<p>1. LICENSEE/LOCATION INSPECTED: <i>Lakeland Medical Center, St. Joseph</i> <i>1234 Napier Avenue</i> <i>St. Joseph, MI</i></p> <p>REPORT NUMBER(S) <i>2013-01</i></p>	<p>2. NRC/REGIONAL OFFICE <i>U.S. NRC Region III</i> <i>2443 Warrenville Rd.</i> <i>Lisle, IL 60532</i> Select a location (Use keyboard arrows to select) . . .</p>
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<p>3. DOCKET NUMBER(S) <i>030-02049</i></p>	<p>4. LICENSE NUMBER(S) <i>21-04177-01</i></p>	<p>5. DATE(S) OF INSPECTION <i>1/28/13</i></p>
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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	<i>Robert G. Gattone, Jr.</i>	<i>Robert G. Gattone, Jr.</i>	<i>1/28/13</i>
BRANCH CHIEF	<i>TAMARA BLECHER</i>	<i>Tamara Blecher</i>	<i>2/6/13</i>

Docket File Information
SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE/LOCATION INSPECTED: Lakeland Medical Center, St. Joseph 1234 Napier Avenue St. Joseph, Michigan REPORT NUMBER(S) 2013-01	2. NRC/REGIONAL OFFICE Region III U. S. Nuclear Regulatory Commission 2443 Warrenville Road, Suite 210 Lisle, IL 60532-4352
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3. DOCKET NUMBER(S) 030-02049	4. LICENSE NUMBER(S) 21-04177-01	5. DATE(S) OF INSPECTION 1/28/13
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6. INSPECTION PROCEDURES USED 87131	7. INSPECTION FOCUS AREAS 03.01 and 03.06
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SUPPLEMENTAL INSPECTION INFORMATION

1. PROGRAM CODE(S) 02230	2. PRIORITY 2	3. LICENSEE CONTACT David Sieffert, RSO	4. TELEPHONE NUMBER (269) 982-4873
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Main Office Inspection Next Inspection Date: 9/13/2014

Field Office Inspection

Temporary Job Site Inspection

PROGRAM SCOPE

This enforcement follow-up inspection was limited to review of the effectiveness of the licensee's corrective actions taken to prevent a similar violation of 10 CFR 35.40(a) and License Condition 12.B. involving failure to have written directives for iodine-131 administrations signed by an authorized user. The violation was identified during the last inspection conducted on September 13, 2012, with continued in-office review through October 15, 2012. On December 6, 2012, the violation was cited as a Severity Level III violation. As corrective action, the licensee: (1) committed to ensure that written directives are signed only by authorized users who are trained and experienced, as required; (2) revised its written directive form to contain a nuclear medicine technologist's (NMT) signature attesting that the NMT verified that the authorized user who signs the written directive is listed as an applicable authorized user on the NRC license; (3) instructed the nuclear medicine staff on the new requirements for verifying that the authorized users who sign written directives are applicably authorized on the NRC license; (4) committed to do quarterly license reviews to identify additions and deletions of authorized users; and (5) committed to add 2 new authorized users for 10 CFR 300 to ensure adequate coverage. No 10 CFR 300 administrations occurred during the inspection.

INSPECTOR OBSERVATIONS

The inspector observed: (1) that since the last inspection, the licensee submitted license amendment requests to add 2 new authorized users for 10 CFR 300 to ensure adequate coverage; (2) an NMT demonstrate that she knew that administrations of greater than 30 microcuries of iodine-131 required a written directive; (3) an NMT demonstrate how she had referenced applicable information on the license to attest, in writing on the revised written directive form, that the authorized users who signed the written directives are listed as an applicable authorized user on the NRC license; (4) an NMT describe training she received regarding the contents of written directives and new actions taken to prevent a similar violation; (5) training records showing that the RSO and the NMTs were instructed on the new requirements for verifying that the authorized users who sign written directives are applicably authorized on the NRC license; (6) an NMT demonstrate the actions taken from receipt of an order of iodine-131 greater than 30 microcuries to administration of the material; (7) that written directives for all administrations of iodine-131 greater than 30 microcuries since the last inspection were signed by an authorized user; (8) an RSC record stating that the licensee will do quarterly license reviews to identify added and deleted authorized users.