



**UNITED STATES
NUCLEAR REGULATORY COMMISSION**

Region III
2443 Warrenville Road, Suite 210
Lisle IL 60532-4352

December 6, 2012

EA-12-202

Mr. David E. Sieffert
Radiation Safety Officer
Lakeland Medical Center, Saint Joseph
1234 Napier Boulevard
Saint Joseph, Michigan 49085

**SUBJECT: NOTICE OF VIOLATION – LAKELAND MEDICAL CENTER, SAINT JOSEPH;
NRC INSPECTION REPORT NO. 03002049/2012001(DNMS)**

Dear Mr. Sieffert:

This refers to a Nuclear Regulatory Commission (NRC) inspection conducted on September 13, 2012, with continued in-office review through October 15, 2012. During the inspection, an apparent violation of NRC requirements was identified. The significance of the issue and the need for lasting and effective corrective actions were discussed with representatives of Lakeland Medical Center during an exit meeting on October 17, 2012. Details regarding the apparent violation were provided in NRC Inspection Report No. 03002049/2012001(DNMS) dated October 28, 2012.

In the letter transmitting the inspection report, we provided you with the opportunity to address the apparent violation by (1) providing a written response or (2) requesting a Predecisional Enforcement Conference. You provided a written response by letter dated November 7, 2012.

Based on the information developed during the inspection and provided in your written response dated November 7, 2012, we determined that a violation of NRC requirements occurred. The violation is cited in the enclosed Notice of Violation (Notice) and the circumstances surrounding it are described in detail in our inspection report dated October 28, 2012. Specifically, contrary to Title 10 of the Code of Federal Regulations (10 CFR) 35.40(a) and License Condition 12.B, Lakeland Medical Center failed to have an authorized user sign and date three written directives dated February 28, 2012, February 29, 2012, and March 20, 2012. In these cases, an individual who was an authorized user on your license, but who was not authorized for these treatments, signed the written directives.

An unqualified individual conducting licensed activities is a significant regulatory concern. The root cause of the violation was that your staff misunderstood the requirement for an authorized user for 10 CFR 35.300 medical uses to sign written directives for the administration of iodine-131 sodium iodide in quantities greater than 30 microcuries. Your staff believed that, because the physician was an authorized user for diagnostic administrations under 10 CFR 35.100 and 10 CFR 35.200, the physician was authorized to sign written directives for diagnostic administrations of iodine-131 sodium iodide in quantities greater than 30 microcuries. Therefore, this violation has been categorized in accordance with the NRC Enforcement Policy at Severity Level III.

In accordance with the NRC Enforcement Policy, a base civil penalty in the amount of \$3500 is normally considered for a Severity Level III violation. Because your facility has not been the subject of escalated enforcement actions within the last two years, the NRC considered whether credit was warranted for Corrective Action in accordance with the civil penalty assessment process described in Section 2.3.4 of the Enforcement Policy. Credit was warranted for your corrective actions which included: (1) no further signing of written directives by those that do not possess the required training and experience; (2) revising the written directive form to contain a signature indicating that the authorized user has been verified on your license for 10 CFR 35.300 medical use and attested by the nuclear medicine technologist; (3) instructing the nuclear medicine staff on the new requirements for verifying license authorizations; (4) reviewing the license at the quarterly radiation safety meeting for additions and deletions of authorized users; and (5) initiating action to add two new authorized users for 10 CFR 35.300 medical use to ensure adequate coverage of physicians authorized to sign written directives.

Therefore, to encourage prompt and comprehensive correction of violations, and in recognition of the absence of previous escalated enforcement action, I have been authorized, after consultation with the Director, Office of Enforcement, not to propose a civil penalty in this case. However, significant violations in the future could result in a civil penalty. In addition, issuance of this Severity Level III violation constitutes escalated enforcement action that may subject you to increased inspection effort.

The NRC has concluded that information regarding the reason for the violation, the corrective actions taken and planned to correct the violation, and the date when full compliance was achieved, was adequately addressed on the docket in NRC Inspection Report No. 03002049/2012001(DNMS) dated October 28, 2012, and in your letter dated November 7, 2012. Therefore, you are not required to respond to this letter unless the description therein does not accurately reflect your corrective actions or your position. In that case, or if you choose to provide additional information, you should follow the instructions specified in the enclosed Notice.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter, its enclosure, and your response, if you choose to provide one, will be made available electronically for public inspection in the NRC Public Document Room or from the NRC's Agencywide Documents Access and Management System (ADAMS), accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>. Therefore, to the extent possible, your response should not include any personal privacy, proprietary, or safeguards information so that it can be made available to the Public without redaction. If personal privacy or proprietary information is necessary to provide an acceptable response, please provide a bracketed copy of your response that identifies the information that should be protected and a redacted copy of your response that deletes such information. If you request withholding of such information, you must specifically identify the portions of your response that you seek to have withheld and provide in detail the bases for your claim of withholding (e.g., explain why the disclosure of

D. Sieffert

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information will create an unwarranted invasion of personal privacy or provide the information required by 10 CFR 2.390(b) to support a request for withholding confidential commercial or financial information). The NRC also includes significant enforcement actions on its Web site at <http://www.nrc.gov/reading-rm/doc-collections/enforcement/actions/>.

Sincerely,

/RA by C. Pederson for/

Charles A. Casto
Regional Administrator

Docket No. 030-02049
License No. 21-04177-01

Enclosure:
Notice of Violation

cc w/encl: State of Michigan

NOTICE OF VIOLATION

Lakeland Medical Center
Saint Joseph, Michigan

Docket No. 030-02049
License No. 21-04177-01
EA-12-202

During a U.S. Nuclear Regulatory Commission (NRC) inspection conducted on September 13, 2012, with continued in-office review through October 15, 2012, a violation of NRC requirements was identified. In accordance with the NRC Enforcement Policy, the violation is listed below:

Title 10 of the Code of Federal Regulations (CFR) 35.40(a) states that a written directive must be signed and dated by an authorized user before the administration of I-131 sodium iodide greater than 1.11 megabecquerels (MBq) (30 microcuries).

Condition 12.A of NRC License No. 21-04177-01 states, in part, that licensed material is only authorized for use by, or under the supervision of, individuals permitted to work as an authorized user in accordance with 10 CFR 35.13 and 35.14. Condition 12.B. of the license states, in part, that four individuals are authorized users for medical use under 10 CFR 35.300.

Contrary to the above, on February 28, 2012, February 29, 2012, and March 20, 2012, the licensee administered greater than 30 microcuries of I-131 sodium iodide, and the written directives for those administrations were not dated and signed by an authorized user. Specifically, the licensee administered 2-millicurie diagnostic dosages on all three occasions, and the individual that signed the written directives was not listed as an authorized user for medical uses under 10 CFR 35.300 on NRC License No. 21-04177-01.

This is a Severity Level III Violation (Section 6.3).

The NRC has concluded that information regarding the reason for the violation, the corrective actions taken and planned to be taken to correct the violation, and the date when full compliance was achieved, is already adequately addressed on the docket in NRC Inspection Report No. 03002049/2012001(DNMS) dated October 28, 2012, and in your letter dated November 7, 2012. However, you are required to submit a written statement or explanation pursuant to 10 CFR 2.201 if the description therein does not accurately reflect your corrective actions or your position. In that case, or if you choose to respond, clearly mark your response as a "Reply to a Notice of Violation, EA-12-202," and send it to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, DC 20555-0001 with a copy to the Regional Administrator, Region III, 2443 Warrenville Road, Suite 210, Lisle, IL 60532, within 30 days of the date of the letter transmitting this Notice of Violation (Notice).

If you contest this enforcement action, you should also provide a copy of your response, with the basis for your denial, to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001.

ENCLOSURE

If you choose to respond, your response will be made available electronically for public inspection in the NRC Public Document Room or from the NRC's Agencywide Documents Access and Management System (ADAMS), accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>. Therefore, to the extent possible, the response should not include any personal privacy, or proprietary, information so that it can be made available to the Public without redaction.

In accordance with 10 CFR 19.11, you may be required to post this Notice of Violation within two working days of receipt.

Dated this 6th day of December 2012

information will create an unwarranted invasion of personal privacy or provide the information required by 10 CFR 2.390(b) to support a request for withholding confidential commercial or financial information). The NRC also includes significant enforcement actions on its Web site at <http://www.nrc.gov/reading-rm/doc-collections/enforcement/actions/>.

Sincerely,

/RA by C. Pederson for/

Charles A. Casto
Regional Administrator

Docket No. 030-02049
License No. 21-04177-01

Enclosure:
Notice of Violation
cc w/encl: State of Michigan

DISTRIBUTION
See next page

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DATE	11/16/12	11/16/12	11/16/12	12/05/12	12/05/12	12/06/12

OFFICIAL RECORD COPY

1 OE concurrence received via e-mail from T. Marenchin on December 5, 2012

Letter to David E. Sieffert from Charles A. Casto dated December 6, 2012

SUBJECT: NOTICE OF VIOLATION – LAKELAND MEDICAL CENTER, SAINT JOSEPH;
NRC INSPECTION REPORT NO. 03002049/2012001(DNMS)

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