August 16, 2012

Mr. Charles Sherwin
Vice President
Alpena Regional Medical Center
1501 Chisholm Street
Alpena, Michigan 49707

SUBJECT: NRC ROUTINE INSPECTION REPORT NO. 03013274/12001(DNMS) AND NOTICE OF VIOLATION – ALPENA REGIONAL MEDICAL CENTER

Dear Mr. Sherwin:

On June 28 and 29, 2012, a U.S. Nuclear Regulatory Commission (NRC) inspector conducted a routine inspection at your Alpena, Michigan, facility with continued NRC in-office review through August 2, 2012. The NRC in-office review included an evaluation of administrations that required the preparation of a written directive since the previous NRC inspection. A telephone exit meeting between you, your Radiation Safety Officer (RSO) Mr. Martin Andrzejewski, and Andrew Bramnik of my staff was conducted on August 2, 2012, to discuss the inspection findings.

During this inspection, the NRC staff examined activities conducted under your license related to public health and safety. Additionally, the staff examined your compliance with the Commission's rules and regulations as well as the conditions of your license. Within these areas, the inspection consisted of selected examination of procedures and representative records, observations of activities, and interviews with personnel.

Based on the results of this inspection, the NRC has determined that three Severity Level IV violations of NRC requirements occurred. The violations were evaluated in accordance with the NRC Enforcement Policy. The current Enforcement Policy is included on the NRC's Web site at http://www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html. The violations involved the failure to: (1) have an authorized user sign and date a written directive before the administration of I-131 sodium iodide greater than 1.11 megabecquerels (30 microcuries); (2) complete a written revision to an existing written directive before the administration of a dosage of unsealed byproduct material; and (3) notify the Commission no later than 30 days after an authorized user permanently discontinues performance of duties under the license. The violations are cited in the enclosed Notice of Violation (Notice). The violations are being cited in the Notice because they were identified by the NRC inspector.

The root cause of the first violation was inadequate management oversight of the nuclear medicine program. Specifically, your staff allowed a physician who was not listed on your NRC license to sign and date a written directive on April 18, 2012. One contributing cause of the violation was an incorrect opinion that your RSO received from your consulting physicist, which was interpreted to mean that the physician could proceed with the administration. Another contributing cause was that your Nuclear Medicine Policies "NM I-131 Thyroid Therapy" and

"NM I-131 Whole Body Scan With Quantitative Neck Analysis" did not specify that radiologists who sign written directives must be listed as authorized users on your NRC license.

As corrective actions, your RSO committed to retrain nuclear medicine staff that written directives are required to be signed and dated by an authorized user prior to the administration of I-131 sodium iodide greater than 30 microcuries. This training will be completed before August 17, 2012. The physician was informed that he could not sign written directives until a license amendment was approved by the NRC to add him as an authorized user, and your RSO submitted a license amendment request to the NRC on June 28, 2012, to add the physician to your license as an authorized user. Your RSO also committed to conduct regular reviews of written directives to ensure that they are being completed in accordance with regulatory requirements. Your RSO stated his intent to have at least one authorized user available at all times to avoid this situation in the future. As long-term corrective actions, your RSO committed to revise and update the two policies to accurately reflect regulatory requirements and hospital operations. These revisions will be completed by August 31, 2012.

The root cause of the second violation was inadequate management oversight of the nuclear medicine program. Specifically, your staff did not ensure that a written revision to an existing written directive was made, signed, and dated by an authorized user before the administration of unsealed byproduct material on March 1, 2010, where there was no jeopardy to the patient to pause to revise the directive. A contributing cause was that your Nuclear Medicine Policies "NM I-131 Thyroid Therapy" and "NM I-131 Whole Body Scan With Quantitative Neck Analysis" did not provide instructions for staff members regarding how to revise an existing written directive. Additionally, both Nuclear Medicine Policies were each last reviewed over nine years ago on January 10, 2003. As corrective actions, your RSO committed to retrain nuclear medicine staff regarding written directive requirements. This training will be completed before August 17, 2012. As long-term corrective actions, your RSO committed to revise and update the two policies to accurately reflect regulatory requirements and hospital operations. These revisions will be completed by August 31, 2012.

The root cause of the third violation was an oversight of the requirement to notify the NRC. Specifically, your staff thought that the authorized user had already been removed from the NRC license. As corrective actions, your RSO submitted a license amendment request to the NRC on June 28, 2012, to remove the authorized user from your license.

The NRC has concluded that information regarding the reason for the violations, the corrective actions taken and planned to be taken to correct the violations and prevent recurrence, and the date when full compliance will be achieved, is already adequately addressed on the docket in this letter. Therefore, you are not required to respond to this letter unless the description herein 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 Title 10 of the Code of Federal Regulations 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 http://www.nrc.gov/reading-rm/adams.html. 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.

We will gladly discuss any questions you have concerning this inspection.

Sincerely,

/RA/

Tamara E. Bloomer, Chief
Materials Inspection Branch
Division of Nuclear Materials Safety

Docket No. 030-13274
License No. 21-17754-01

Enclosure:
Notice of Violation

cc w/encl: Martin J. Andrzejewski,
Radiation Safety Officer
State of Michigan

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We will gladly discuss any questions you have concerning this inspection.

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Notice of Violation

cc w/encl: Martin J. Andrzejewski,
Radiation Safety Officer
State of Michigan

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NOTICE OF VIOLATION

Alpena Regional Medical Center Michigan
Alpena, Michigan

Docket No. 030-13274
License No. 21-17754-01

During a U.S. Nuclear Regulatory Commission (NRC) inspection conducted on June 28 and 29, 2012, with continued NRC in-office review through August 2, 2012, three violations of NRC requirements were identified. In accordance with the NRC Enforcement Policy, the violations are listed below:

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

Condition 12.A of NRC License No. 21-17754-01 states, in part, that 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 NRC license states, in part, that two individuals are authorized users for medical use under 10 CFR 35.300.

Contrary to the above, on April 18, 2012, the licensee administered greater than 30 microcuries of I-131 sodium iodide and the written directive for that administration was not dated and signed by an authorized user. Specifically, the licensee administered 1.97 millicuries of I-131 for a diagnostic procedure and the physician who signed the written directive was not listed on NRC License No. 21-17754-01 as an authorized user.

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

B. Title 10 CFR 35.40(c) states, in part, that a written revision to an existing written directive may be made if the revision is dated and signed by an authorized user before the administration of the dosage of unsealed byproduct material.

Contrary to the above, on March 1, 2010, the licensee failed to complete a written revision to an existing written directive before the administration of a dosage of unsealed byproduct material. Specifically, a written directive called for a prescribed dose of 2.00 millicuries of I-131 for a diagnostic procedure; however, as of the date of the inspection, the licensee administered 2.75 millicuries of I-131 in accordance with an authorized user's oral revision, and the licensee did not revise the written directive prior to the administration where there was no jeopardy to the patient to pause to revise the directive.

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

C. Title 10 CFR 35.14(b)(1) states, in part, that a licensee shall notify the Commission not later than 30 days after an authorized user permanently discontinues performance of duties under the license or has a name change.

Contrary to the above, as of June 29, 2012, the licensee failed to notify the Commission that an authorized user had permanently discontinued performance of duties under NRC

License No. 21-17754-01. Specifically, an authorized user that was listed in Condition 12.B. of the license for activities under 10 CFR 35.100, 35.200, and 35.300 permanently left the licensee's employ before September 2011, and the licensee did not notify the Commission to request his removal from the NRC license.

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

The NRC has concluded that information regarding the reason for the violations, the corrective actions taken and planned to be taken to correct the violation and prevent recurrence, and the date when full compliance will be achieved, is already adequately addressed on the docket in the cover letter transmitting this Notice of Violation. 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," 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, within 30 days of the date of the letter transmitting this Notice.

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, proprietary, or safeguards 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 within two working days.

Dated this 16th day of August 2012.