INSPECTION RECORD

Region III **Inspection Report No.** 03013274 /12001(DNMS) **License No.** 21-17754-01
Docket No. 030-13274

Licensee (Name and Address):
Alpena Regional Medical Center
1501 Chisholm Street
Alpena, Michigan 49707

Licensee Contact: Martin Andrzejewski – RSO **Telephone No.** 989-356-7390

Priority: 3 **Program Code**: 02120

Date of Last Inspection: 6/11/2009 **Date of This Inspection**: 6/28-29/2012 with continued in-office review until 8/2/12 to assess administrations that required a written directive

Type of Inspection: () Initial ( ) Announced (X) Unannounced
(X) Routine ( ) Special

Next Inspection Date: 6/2015 (X) Normal ( ) Reduced

Summary of Findings and Actions:

( ) No violations cited, clear U.S. Nuclear Regulatory Commission (NRC) Form 591 or regional letter issued
( ) Non-cited violations (NCVs)
( ) Violation(s), Form 591 issued
(X) Violation(s), regional letter issued
( ) Followup on previous violations

Inspector Andrew M Bramnik Date 8/16/2012
Andrew M. Bramnik, Health Physicist

Approved Tamara E Bloomer Date 8/16/12
Tamara E. Bloomer, Chief
Materials Inspection Branch

PART I-LICENSE, INSPECTION, INCIDENT/EVENT, AND ENFORCEMENT HISTORY

1. AMENDMENTS AND PROGRAM CHANGES:

Amendment No.	Date	Subject
No license amendments since before the previous inspection in June 2009		

2. INSPECTION AND ENFORCEMENT HISTORY:

No violations were identified during the previous two routine inspections on June 11, 2009, and June 16, 2006.

3. INCIDENT/EVENT HISTORY:

None

PART II - INSPECTION DOCUMENTATION

1. ORGANIZATION AND SCOPE OF PROGRAM:

Management Structure:

Carmen Biala, Chief Executive Officer
Charles Sherwin, Vice President
Steve Smith, Radiology Manager
James R. Weeks, M.D., Medical Director of Radiology
Doug Christ, Director of Diagnostic Imaging
Martin Andrzejewski, Lead Nuclear Medicine Technologist (NMT) and Radiation Safety Officer (RSO)

The licensee operated a 200-bed hospital with four full-time NMTs that performed diagnostic and therapeutic nuclear medicine procedures. The licensee conducted approximately 30 diagnostic administrations per month, focusing primarily on cardiac, bone, and HIDA scans. In addition, the licensee conducted approximately 25 administrations of iodine-131 (I-131) per year that required the preparation of a written directive. All I-131 administrations were performed on an outpatient basis. The licensee obtained unit doses of licensed material from an area nuclear pharmacy for scheduled exams, and on average received one molybdenum/technetium generator per week for add-on studies. Two authorized users were listed on the NRC license for diagnostic radiology under Title 10 of the Code of Federal Regulations (CFR) 35.100 and 35.200. Two different authorized users were listed on the NRC license under 10 CFR 35.100, 35.200, and 35.300. One of the authorized users approved for administrations requiring a written directive under 10 CFR 35.300 permanently discontinued performance of duties under the license in September 2011. This item is discussed in Section 4, below. The licensee was planning to add a new physician as an authorized user under 10 CFR 35.100, 35.200, and 35.300; however, at the time of the onsite inspection, the licensee had not submitted any license amendment request to the NRC.

2. SCOPE OF INSPECTION:

Inspection Procedure(s) Used: 87131

Focus Areas Evaluated: Sections 03.01 through 03.07

No administrations of licensed materials were available for observation during the inspection. Interviews of available staff revealed an adequate level of understanding of emergency and material handling procedures and techniques. The licensee successfully described or demonstrated dose calibrator constancy checks, package receipt, daily surveys, and waste handling and disposal procedures. The inspector confirmed that these activities were successfully completed by reviewing selected records since the previous inspection. A contract physicist performed quarterly program audits that were adequate to oversee the program.

The inspector reviewed written directives and supporting documentation for administrations of I-131 that had been completed since the previous inspection. The licensee had conducted 7 administrations in 2012, 18 administrations in 2011, and 28 administrations in 2010. All of the administrations were completed in accordance

with the licensee's written procedures. The licensee's staff was familiar with the definition of a medical event and no medical events had occurred since the previous inspection. Several written directives were not clearly dated by an authorized user, as required by 10 CFR 35.40. One written directive was not signed by an authorized user, and a written revision was not made to a different written directive. These items are discussed in Section 4, below.

Licensed material was adequately secured and not readily accessible to members of the general public. Personal whole body and extremity dosimetry badges were observed being worn by the staff during the inspection, and records did not indicate doses in excess of 10 CFR Part 20 limits. Dosimetry records indicated that the highest annual whole body and extremity readings since the previous inspection were 397 millirem and 2,070 millirem, respectively.

3. INDEPENDENT AND CONFIRMATORY MEASUREMENTS:

Independent measurements taken at the licensee's facility did not indicate readings in excess of the limits in 10 CFR Part 20 in restricted or unrestricted areas. The licensee possessed a radiation survey meter that was calibrated, operational, and performed comparably to readings from an NRC survey meter.

4. VIOLATIONS, NCVs, AND OTHER SAFETY ISSUES:

A. Title 10 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 the NRC or license as an authorized user.

The root cause of this violation was inadequate management oversight of the nuclear medicine program. Specifically, the licensee allowed a physician who was not listed on the NRC license to sign and date a written directive on April 18, 2012. One contributing cause of the violation was an incorrect opinion that the licensee's RSO received from a consulting physicist, which was interpreted to mean that the physician could proceed with the administration. Another contributing cause was that the licensee's Nuclear Medicine Policies "NM I-131 Thyroid Therapy" and "NM I-131 Whole Body Scan With Quantitative Neck Analysis" did not specify that that radiologists who sign written directives must be listed as authorized users on the NRC license.

As a corrective action, the 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 the RSO submitted a license amendment request to the NRC on June 28, 2012, to add the physician to the license as an authorized user. The RSO also committed to conduct regular reviews of written directives to ensure that they are being completed in accordance with regulatory requirements. The RSO stated his intent to have at least one authorized user available at all times to avoid this situation in the future. As a long-term corrective action, the RSO committed to revise and update the two policies to reflect current regulatory requirements and hospital operations. These revisions will be completed by August 31, 2012.

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 this 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.

The root cause of this violation was inadequate management oversight of the nuclear medicine program. Specifically, the licensee 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 the licensee's 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. The inspector observed that both Nuclear Medicine Policies were last reviewed on January 10, 2003.

As a corrective action, the 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, the RSO also committed to revise and update the two policies to reflect current regulatory requirements and hospital operations. These revisions will be completed by August 31, 2012.

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.

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

5. PERSONNEL CONTACTED:

*& Martin Andrzejewski – Lead NMT and RSO
& Doug Christ – Director of Diagnostic Imaging
& Charles Sherwin – Vice President
* Steven Smith – Radiology Manager
James Weeks, M.D. – Authorized User
Other NMTs as available

* Individual present at June 29, 2012 preliminary exit meeting
& Individual present at August 2, 2012 final telephone exit meeting

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