NRC FORM 591M PART 1
(07-2012)
10 CFR 2.201

U.S. NUCLEAR REGULATORY COMMISSION

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE/LOCATION INSPECTED:	2. NRC/REGIONAL OFFICE
Alpena Regional Medical Center 1501 West Chisholm Street Alpena, MI 49707 REPORT NUMBER(S) 2015-001	Region III U. S. Nuclear Regulatory Commission 2443 Warrenville Road, Suite 210 Lisle, IL 60532-4352

3. DOCKET NUMBER(S)	4. LICENSE NUMBER(S)	5. DATE(S) OF INSPECTION
030-13274	21-17754-01	OCTOBER 22ND 2015

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 violations(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	Ryan Craffey / Luis Nieves	Ryan Craffey Luis Nieves	10/22/15
BRANCH CHIEF	Aaron McCraw		11/5/15

NRC FORM 591M PART 3
(07-2012)
10 CFR 2.201

U.S. NUCLEAR REGULATORY COMMISSION

Docket File Information

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3. DOCKET NUMBER(S)	4. LICENSE NUMBER(S)	5. DATE(S) OF INSPECTION
030-13274	21-17754-01	October 22, 2015

6. INSPECTION PROCEDURES USED	7. INSPECTION FOCUS AREAS
87130, 87131	03.01-03.07

SUPPLEMENTAL INSPECTION INFORMATION

1. PROGRAM CODE(S)	2. PRIORITY	3. LICENSEE CONTACT	4. TELEPHONE NUMBER
02120	3	Martin J Andrzej - RSO	(989) 356-7202

☑ Main Office Inspection Next Inspection Date: October 22, 2018

☐ Field Office Inspection _____

☐ Temporary Job Site Inspection _____

PROGRAM SCOPE

This was an unannounced routine inspection of a community hospital authorized to perform diagnostic and therapeutic administrations of radiopharmaceuticals at its facility in Alpena, Michigan. The licensee performed approximately eight diagnostic administrations per day, three therapeutic administrations of I-131 per month and three courses of Ra-223 Xofigo in the last year. The department received unit doses as needed from a licensed nuclear pharmacy. Nuclear medicine procedures were performed from Monday to Friday. The nuclear medicine department was staffed with four nuclear medicine technologists. The licensee also hosted a mobile nuclear medicine trailer, which conducted PET scans every Monday.

PERFORMANCE OBSERVATIONS:

The inspectors toured the nuclear medicine department and hot lab to evaluate the licensee's measures for materials security, hazard communication and exposure control. The inspectors conducted independent surveys of these areas, and found no exposures to members of the public distinguishable from background. The inspectors observed the preparation and administration of an I-125 capsule, cardiac stress test, and a bone scan. The inspectors also observed the licensee's consultant perform dose calibrator quality control, and the licensee's staff demonstrate the implementation of procedures for package receipt and area surveys. The inspectors reviewed a selection of written directives and treatment plans for I-131 and Ra-223 Xofigo administrations, in addition to routine nuclear medicine records, consultant audits, training and dosimetry.

The license was previously cited for violations relating to a written directive for a therapeutic administration of unsealed byproduct material that was not dated and signed by an authorized user, a written revision to an existing written directive that was not signed by the authorized user before administrations of the dosage of unsealed byproduct material, and the failure to notify the Commission that an authorized user had permanently discontinued performance of duties under NRC. The inspector reviewed the licensee's corrective actions, which appeared to be adequate, and found the violations to be non-recurring. Therefore, the NRC considers both of these violations to be closed. No other violations of NRC requirements were identified as a result of this inspection.