NRC FORM 591M PART 1
(05-2012)
10 CFR 2.201

U.S. NUCLEAR REGULATORY COMMISSION

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE/LOCATION INSPECTED:	2. NRC/REGIONAL OFFICE
Northern Michigan Regional Hospital 416 Connable Avenue Petoskey, MI 49770 REPORT NUMBER(S) 2012-01	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
030-11715	21-16732-01	May 23, 2012

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)

1) 10 CFR 35.63(d) requires that, unless otherwise directed by an authorized user, a licensee may not use a dosage if the dosage does not fall within the prescribed dosage range or if the dosage differs from the prescribed dosage by more than 20 percent.

Contrary to the above, on September 22, 2010, the licensee used a dosage that differed from the prescribed dosage by more than 20 percent without approval from an authorized user. Specifically, the licensee administered a 2.56 millicurie dosage of sodium iodide-131 when a dosage of 2 millicuries was prescribed, a difference of more than 20 percent.

This is a Severity Level IV violation (Section 6.3.d). (Continued on Part 2)

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	Aaron T. McCraw		6/18/12
BRANCH CHIEF	Hironori Peterson		6/18/12

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(Continued)

The root cause of this violation was human error. The nuclear medicine technologist did not recognize that the dosage was not within 20 percent of the prescribed dosage and proceeded to administer the dosage. A contributing cause to this violation was a lack of adequate procedures to address such instances.

Corrective action for this violation, as docketed on the record (ML12150A312), is to have a second nuclear medicine technologist verify that the dosage is within 20 percent of the prescribed dosage and to record that verification on the written directive.

2) 10 CFR 35.41(a) states that, for any administration requiring a written directive, licensees are required to develop, implement, and maintain written procedures to provide high confidence that: (1) The patient's or human research subject's identity is verified before each administration; and (2) Each administration is in accordance with the written directive. Procedures must meet the requirements described in 10 CFR 35.41(b).

Contrary to the above, the licensee did not develop written procedures to provide high confidence that each administration is in accordance with the written directive. Specifically, the licensee did not address, in its procedure for administrations of iodine-131 that require written directives, situations where dosages do not fall within the prescribed dosage range or differ from the prescribed dosage by more than 20 percent.

This is a Severity Level IV violation (Section 6.3.d.1).

The root cause of this violation was that the licensee was unaware that the procedures for administrations requiring written directives required such detail.

Corrective action for this violation, as docketed on the record (ML12150A312), was to revise the procedure for administrations of iodine-131 requiring a written directive to reflect the licensee's new practice of having a second nuclear medicine technologist verify the dosage and to provide instructions to nuclear medicine technologists not to administer dosages that fall outside of the 20 percent range of the prescribed dose.

NRC FORM 591M PART 3
(05-2012)
10 CFR 2.201

U.S. NUCLEAR REGULATORY COMMISSION

Docket File Information

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE/LOCATION INSPECTED:	2. NRC/REGIONAL OFFICE
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6. INSPECTION PROCEDURES USED	7. INSPECTION FOCUS AREAS
IP 87130, 87132	03.01 - 03.08, 03-01 - 03.10

SUPPLEMENTAL INSPECTION INFORMATION

1. PROGRAM CODE(S)	2. PRIORITY	3. LICENSEE CONTACT	4. TELEPHONE NUMBER
02120	3	Dan Dryden, RSO	(231) 487-4264

☑ Main Office Inspection Next Inspection Date: 5/1/2015

☐ Field Office Inspection

☐ Temporary Job Site Inspection

PROGRAM SCOPE

This was a routine inspection of a 200-bed hospital, authorized to use licensed materials permitted by 10 CFR 35.100, 35.200, 35.300, and 35.400. The nuclear medicine department was set up to perform the full spectrum of diagnostic and therapeutic procedures. The nuclear medicine department was staffed by three technologists that performed approximately 10-15 procedures per day. The licensee received unit doses from a nuclear pharmacy in Traverse City, Michigan. The licensee retained the services of a consulting physicist to perform quarterly audits of its nuclear medicine department. Brachytherapy activities under 10 CFR 35.400 were performed by an in-house medical physicist, who is the RSO for the license, and two dosimetrists. Activities were limited to iodine-125 and palladium-109 permanent prostate implants. The licensee performed over 100 implant procedures per year. The license was authorized for and possessed two cesium-137 sources for temporary gynecological implant procedures; however, the sources were in storage and had not been used in approximately 8 years.

PERFORMANCE OBSERVATIONS

The inspector reviewed the nuclear medicine and brachytherapy programs through a combination of personnel interviews, records reviews, and performance observations. In the brachytherapy program, the inspector reviewed patient treatment plans, verified source security and accountability, and interviewed available staff. Staff interviewed was knowledgeable of NRC's medical event criteria and reviewed each procedure against the criteria. No issues were identified in the inspector's review of the brachytherapy program.

In the nuclear medicine program, the inspector interviewed available staff, observed package receipt and surveys, reviewed records, and interviewed staff. During a review of records for written directives for iodine-131 therapy treatments, the inspector identified one treatment, in over 25 reviewed, that was not in accordance with the written directive. Specifically, the licensee administered a dose that was greater than 20 percent of what was described. This was a violation of 10 CFR 35.63(d) and was cited in Part 1 of this inspection record. The inspector identified the causes of the higher dosage being delivered as human error and inadequate procedures. The inspector also cited a violation of 10 CFR 35.41(a)(2) for a failure to develop procedures to provide high confidence that each administration is in accordance with the written directive. This "misadministration" did not meet the criteria for a medical event.