UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION III
2443 WARRENVILLE ROAD, SUITE 210
LISLE, ILLINOIS 60532-4352

June 26, 2012

Ms. Mary-Anne Ponti, RN, MS, MBA
Chief Operating Officer
McLaren – Northern Michigan
416 Connable Avenue
Petoskey, MI 49770

SUBJECT: NRC ROUTINE INSPECTION REPORT 03011715/12-001(DNMS) — NORTHERN MICHIGAN REGIONAL HOSPITAL, AND ACKNOWLEDGMENT OF LETTER DATED MAY 25, 2012

Dear Ms. Ponti:

On May 23, 2012, a U.S. Nuclear Regulatory Commission (NRC) inspector conducted a routine inspection at your Petoskey, Michigan facility. A telephone exit meeting between your Radiation Safety Officer Mr. Dan Dryden and Aaron McCraw of my staff was conducted on May 31, 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 two 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 website at http://www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html.

The first violation involved the licensee's administration of a dosage of iodine-131 that was outside of twenty percent of the prescribed dose without approval of an authorized user, which is prohibited by Title 10 of the Code of Federal Regulations (10 CFR) Section 35.63(d). The second violation involved the licensee's failure to develop written procedures to provide high confidence that each administration is in accordance with the written directive, as required by 10 CFR 35.41(a). The violations are cited on the enclosed NRC Form 591M, "Safety Inspection Report and Compliance Inspection," Parts 1 and 2.

This letter also acknowledges your letter dated May 25, 2012, in which you provided corrective actions for the first violation, which the NRC inspector identified to you during a preliminary debrief meeting on May 23, 2012. The corrective actions for the first violation also adequately addressed any actions needed to achieve compliance for the second violation; therefore, no additional information is required for the second violation.

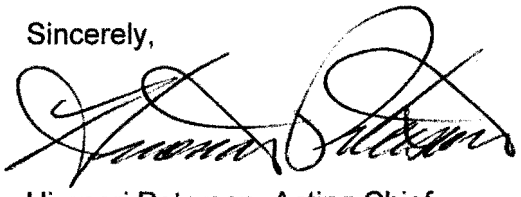
The NRC has concluded that information regarding the reason for the violations, the corrective actions taken and planned to be taken to correct the violation and prevent recurrence, and the

date when full compliance was achieved, is already adequately addressed on the docket in NRC Inspection Report No. 03011715/12-001(DNMS); therefore, you are not required to respond to this letter unless you contest the violations or their significance, or if the description herein does not accurately reflect your corrective actions or your position. If you choose to respond, you should provide a response within 30 days of the date of this letter, to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington DC 20555-0001, with copies to: (1) the Regional Administrator, Region III; and (2) the Director, Office of Enforcement, U. S. Nuclear Regulatory Commission, Washington, DC 20555-0001.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter, its enclosure, and 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. To the extent possible, your response should not include any personal privacy, proprietary, or safeguards information so that it can be made publicly available without redaction.

If you have any questions concerning this matter, please contact Aaron McCraw of my staff at 630-829-9650 or Aaron.McCraw@nrc.gov.

Sincerely,



Hironori Peterson, Acting Chief
Materials Inspection Branch
Division of Nuclear Materials and Safety

Docket No. 030-11715
License No. 21-16732-01

Enclosure w/encl:
IR 03011715/12-001(DNMS), NRC Form 591M
Parts 1 and 2

cc w/encl: Dan Dryden, MS, RSO, DABR
State of Michigan

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/RA/

Hironori Peterson, Acting Chief
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State of Michigan

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OFFICE	RIII DNMS		RIII DNMS		RIII DNMS		RIII	
NAME	ATMcCraw: jm ATM		HPeterson HP					
DATE	6/25/12		6/26/12					

OFFICIAL RECORD COPY

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.