

NRC FORM 591M PART 1 (10-2003) 10 CFR 2.201 U.S. NUCLEAR REGULATORY COMMISSION  
**SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION**

1. LICENSEE/LOCATION INSPECTED: <b>St. Francis Hospital 3401 Ludington Street Escanaba, MI 49829</b>		2. NRC/REGIONAL OFFICE <b>U.S. Nuclear Regulatory Commission Region III 2443 Warrenville Road Suite 210 Lisle, Illinois 60532-4351</b>	
3. DOCKET NUMBER(S) <b>030-11102</b>		4. LICENSEE NUMBER(S) <b>21-16481-01</b>	
REPORT NUMBER(S) <b>2010-01</b>		5. DATE(S) OF INSPECTION <b>September 14, 2010</b>	

**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 violation(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, NUREG-1600, to exercise discretion, were satisfied.

Non-Cited Violation(s) was/were discussed involving the following requirement(s) and Corrective Action(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. This form is a NOTICE OF VIOLATION, which may be subject to posting in accordance with 10 CFR 19.11.  
 (Violations and Corrective Actions)  
 10 CFR 35.40(a) requires, in part, that a written directive must be signed by an authorized user before the administration of I-131 sodium iodide greater than 30 microcuries.  
 Contrary to the above, on November 7, 2008, the licensee prepared a written directive to administer 11.0 Curies of I-131 sodium iodide to a patient; however, the written directive was not signed by the authorized user prior to the administration.  
 The licensee's failure to have the written directive signed by an authorized user was an isolated occurrence. A review of subsequent administrations requiring a written directive determined that each written directive was signed by an authorized user before each administration as required. The licensee's corrective actions will be to ensure that each written directive is properly completed including the signature of an authorized user prior to the administration.

**Licensee's Statement of Corrective Actions for Item 4, above.**

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	Gregory M. Stupak		10-5-10
NRC INSPECTOR	Robert P. Hays		10/5/2010

*Handwritten initials*

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AND COMPLIANCE INSPECTION**

1. LICENSEE <b>St. Francis Hospital</b> REPORT NUMBER(S) <b>2010-01</b>		2. NRC/REGIONAL OFFICE <b>Region III</b> <b>2443 Warrenville Road, Suite 210</b> <b>Lisle, IL 60532</b>	
3. DOCKET NUMBER(S) <b>03011102</b>	4. LICENSE NUMBER(S) <b>21-16481-01</b>	5. DATE(S) OF INSPECTION <b>September 14, 2010</b>	
6. INSPECTION PROCEDURES USED <b>87131</b>	7. INSPECTION FOCUS AREAS <b>03.01-03.07</b>		

**SUPPLEMENTAL INSPECTION INFORMATION**

1. PROGRAM CODE(S) <b>02120</b>	2. PRIORITY <b>3</b>	3. LICENSEE CONTACT <b>Greg Stupak, Manager</b>	4. TELEPHONE NUMBER <b>906-786-5707</b>
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Main Office Inspection      Next Inspection Date: **September 2013**

Field Office \_\_\_\_\_

Temporary Job Site Inspection      **Joe Russo, Kay Carleson, and Tina Casey, NMTs**

**PROGRAM SCOPE**

The licensee was a medical institution located in Escanaba, Michigan, with authorization by the license for diagnostic and therapeutic nuclear medicine procedures, excluding iodine-131 for carcinoma therapy. The nuclear medicine department was staffed with 3 nuclear medicine technologists (NMTs) who perform an average of 15-20 diagnostic studies each day using unit doses prepared from a generator received each week. The licensee averaged 3-4 iodine-131 administrations/cases each year. No change in RSO or NMTs since the previous inspection. The inspector performed independent and confirmatory radiation measurements which indicated results consistent with licensee survey records and postings.

**Performance Observations**

During the inspection, the licensee's available staff demonstrated/discussed: (1) survey instruments and required surveys; (2) package receipt and check-in procedures; (3) wipe tests and efficiency; (4) safe use procedures including radiopharmaceutical prep and labeling; (5) generator elutions and moly tests; (6) dose calibrator tests and procedures; (7) dosimetry and records (<10% of part 20 limits); (8) security and storage of licensed material; (9) radiation safety program audit results; (10) radiation safety committee meeting minutes; and (11) written directives and iodine-131 procedures. One SL IV violation was identified for a failure to have a written directive signed by an authorized user prior to an 11.8 millicurie administration of iodine-131 on November 7, 2008. A review of written directives determined that the unsigned written directive was an isolated event. The NMT described the procedure that is used for an iodine-131 administration which included the authorized user observing the assay of the dosage and administration. No medical event was associated with the administration.

**NMED Number 090603.** Follow up on a contaminated package event pertaining to a TI-210 package with contamination limits exceeding 25,000 dpm/sq.cm. The TI-201 vendor's evaluation of the contamination event could not determine the source of contamination and was considered a "fluke" event. The licensee concluded that it was likely that the package became contaminated when it was handled in the hot lab after it was delivered. Also, the licensee's conversion factor used to convert CPM to DPM contributed to overestimating the activity on the smears.

**NMED Number 090603 is now considered closed.**