



**UNITED STATES  
NUCLEAR REGULATORY COMMISSION**

REGION III  
2443 WARRENVILLE ROAD, SUITE 210  
LISLE, ILLINOIS 60532-4352

July 13, 2007

Donald J. Peck, Ph.D.  
Radiation Safety Officer  
Henry Ford Bi County Hospital  
13355 East Ten Mile Road  
Warren, MI 48089

**SUBJECT: NRC INSPECTION REPORT NO. 30-02042/07-01  
(REVISED FORM 591M PART 1)**

Dear Dr. Peck:

This refers to the inspection conducted on May 24, 2007, at Henry Ford Bi County Hospital of activities conducted under your license. Please disregard the NRC Form 591M dated May 24, 2007, which referenced an inaccurate requirement that was cited in Item 4, Notice of Violation. As a result of further NRC review, the enclosed revised NRC Form 591M cites the appropriate violation in Item 4. We apologize for any inconvenience to you and your staff.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter and its enclosure will be made available electronically for public inspection in the NRC Public Document Room or from the NRC's document system (ADAMS), accessible from the NRC Web site at <http://www.nrc.gov/readingrm/adams.html>.

We will gladly discuss any questions you have concerning this inspection.

Sincerely,

A handwritten signature in cursive script that reads "Kenneth J. Lambert for".

John R. Madera, Chief  
Materials Inspection Branch

Docket No. 030-02042  
License No. 21-04082-01

Enclosure:  
NRC Form 591M

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>Henry Ford BI County</b> <b>13355 East Ten Mile Road</b> <b>Warren, MI</b>	2. NRC/REGIONAL OFFICE <b>U.S. Nuclear Regulatory Commission</b> <b>Region III</b> <b>2443 Warrenville Road</b> <b>Suite 210</b> <b>Lisle, Illinois 60532-4351</b>
REPORT 2007-001	

3. DOCKET NUMBER(S) 030-02042	4. LICENSEE NUMBER(S) 21-04082-01	5. DATE(S) OF INSPECTION May 24, 2007
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**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)

On May 14, 2007, the licensee administered a 31.5 millicurie NaI-131 treatment for hyperthyroidism without a signed written directive as required by 10 CFR 35.40 (a). As corrective action, the licensee will conduct an in-service to remind physicians and nuclear medicine staff on written directive requirements.

**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	Donald Peck, PhD		7/11/2007
NRC INSPECTOR	Deborah A. Pliskura		7/11/2007

NRC FORM 591M PART 1 (10-2003)

**NRC FORM 591M PART 3**

(10-2003)

10 CFR 2.201

**Docket File Information****SAFETY INSPECTION REPORT  
AND COMPLIANCE INSPECTION**

1. LICENSEE <b>Henry Ford: Bi County</b> REPORT <b>2007-001</b>	2. NRC/REGIONAL OFFICE <b>Region III</b> <b>2443 Warrenville Road, Suite 210</b> <b>Lisle, IL 60532</b>
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3. DOCKET NUMBER(S) 030-02042	4. LICENSE NUMBER(S) 21-04082-01	5. DATE(S) OF INSPECTION May 24, 2007
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6. INSPECTION PROCEDURES USED 87130, 87131 and 87132	7. INSPECTION FOCUS AREAS 03.01, 03.02, 03.03, 03.04, 03.05, 03.06, 03.07, and 03.08
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**SUPPLEMENTAL INSPECTION INFORMATION**

1. PROGRAM CODE(S) 02120	2. PRIORITY G 3	3. LICENSEE CONTACT Donald J. Peck, Ph.D., RSO	4. TELEPHONE NUMBER 810-759-7320
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<input checked="" type="checkbox"/> Main Office Inspection	Next Inspection Date: <u>May 2010</u>
<input type="checkbox"/> Field	
<input type="checkbox"/> Temporary Job Site	

**PROGRAM SCOPE**

This licensee was a community hospital with authorization to use materials in Sections 35.100, 35.200, 35.300, and I-125 permitted by 35.400. The nuclear medicine department was staffed with 3 full-time technologists who performed approximately 175-200 diagnostic nuclear medicine procedures per month. The department received unit doses and bulk Tc-99m from a licensed nuclear pharmacy and performed a full spectrum of diagnostic studies. The licensee operated an active radiopharmaceutical therapy program. Typically, in a year, the hospital administered, 100-150 dosages for hyperthyroidism, 30-40 dosages for thyroid carcinoma, and 40-50 whole body follow up scans. Radioiodine was obtained in capsule form from a licensed radiopharmacy. The hospital retained the services of a consultant physicist to audit the nuclear medicine radiation safety program on a quarterly basis.

The radiation therapy activities were performed by a contract medical physicist. Brachytherapy activities were limited to I-125 permanent implants (10-15 cases annually).

This inspection consisted of interviews with licensee personnel, a review of selected records, tour of the nuclear medicine department, and independent measurements. The inspection included observations of security of byproduct material, use of personnel monitoring, dose calibrator QA checks, and area surveys. The inspector observed licensee nuclear medicine personnel prepare, assay and administer several dosages for various imaging procedures.

One violation of NRC requirements was identified for the administration of a 31.5 mCi NaI-131 treatment for hyperthyroidism on May 14, 2007, without a properly signed written directive as required by 10 CFR 35.40(a). Although a written directive was prepared for the administration, the authorized user forgot to sign the document. The licensee committed to conduct an inservice to remind the physicians and nuclear medicine staff on written directive requirements.



UNITED STATES  
NUCLEAR REGULATORY COMMISSION  
REGION III  
2443 Warrenville Road, Suite 210  
Lisle, Illinois 60532-4352

TELEFAX TRANSMITTAL

DATE: 7/11/2007

NUMBER OF PAGES: 2  
(including this page)

SEND TO: Dr. Donald Peck, RSO

LOCATION: Henry Ford

FAX NUMBER: 313 - 916 - 7925  **VERIFY BY CALLING SENDER**

FROM: (SENDER) D. A. Piskura

TELEPHONE NUMBER: 630 - 829 - 9867 FAX NUMBER: 630 - 515 - 1259

If you do not receive the complete fax transmittal, please contact the sender as soon as possible at the telephone number provided above.

MESSAGE

Dear Dr. Peck,  
As we discussed today, please find the revised 591 with the correct citation of 35.40(a) rather than 35.41(a). You need to sign the revised form 591 and send a copy via fax to our office. So sorry about this error and thank you for your patience.  
Best regards,  
Debbie Holme

NOTICE

This message is intended only for the use of the individual or entity to which it is addressed and may contain information that is privileged, confidential, or exempt from disclosure under applicable law. If the reader of this message is not the intended recipient or the employee responsible for delivering the message to the intended recipient, you are hereby notified that any dissemination, distribution or copying of this communication is strictly prohibited. If you have received this communication in error, please notify the sender immediately by telephone and return the original to the above address, by U.S. Mail. Thank you.

### SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE/LOCATION INSPECTED: <i>Henry Ford: Bi County Warren, MI</i>		2. NRC/REGIONAL OFFICE <b>U.S. Nuclear Regulatory Commission Region III 2443 Warrenville Road Suite 210 Lisle, Illinois 60532-4351</b>	
REPORT NUMBER(S) <i>2007001</i>			
3. DOCKET NUMBER(S) <i>030-02042</i>	4. LICENSEE NUMBER(S) <i>21-04082-01</i>	5. DATE(S) OF INSPECTION <i>May 24, 2007</i>	

**LICENSEE:**

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(Violations and Corrective Actions)

*On May 14, 2007, the licensee administered a 31.5 mCi NaI-131 treatment for hyperthyroidism without a signed written directive as required by 10 CFR 35.41(a). Licensee will conduct an in-service to remind physicians and nuclear medicine staff on written directive requirements.*

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

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LICENSEE'S REPRESENTATIVE	<i>Donald Peck, PhD</i>		<i>5/24/07</i>
NRC INSPECTOR	<b>Deborah A. Piskura</b>		<i>5/24/07</i>