November 10, 2010

Mr. James J. Sexton, FACHE
President and CEO
Henry Ford Wyandotte Hospital
2333 Biddle Avenue
Wyandotte, MI 48192

SUBJECT: NRC INSPECTION (IR 030-02140/210-01(DNMS)) AND
NOTICE OF VIOLATION ─ HENRY FORD WYANDOTTE HOSPITAL

Dear Mr. Sexton:

On September 22, 2010, the U.S. Nuclear Regulatory Commission (NRC) conducted a routine inspection at the Henry Ford Wyandotte Hospital. Our inspection included an in-office review of the additional information you provided and your proposed corrective actions to the inspection findings. The purpose of the inspection was to determine whether activities authorized by the license were conducted safely and in accordance with NRC requirements. The inspection included a review of your notification of the use of certain byproduct material by an unauthorized physician, which your staff reported to us by telephone on September 3, 2010, and by letter dated September 17, 2010. At the conclusion of the inspection, the findings were discussed with you and members of your staff. A final exit meeting informing your staff of the inspection findings was conducted via telephone on October 26, 2010.

The inspection was an examination of activities conducted under your license as they relate to radiation safety and to compliance with the Commission's rules and regulations, and with the conditions of your license. Within these areas, the inspection consisted of selective examinations of procedures and representative records, and interviews with personnel.

Based on the results of this inspection, the NRC has determined that one Severity Level IV violation of NRC requirements occurred. The violation was 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 violation is cited in the enclosed Notice of Violation (Notice) and involves the use of licensed material by an unauthorized physician. The violation is being cited in the Notice because the NRC needs a better understanding of the specific long-term corrective actions that you are taking to ensure that licensed material is only used by specially authorized individuals.

There was no evidence that medical events occurred as a result of the unauthorized administrations of iodine-131 in quantities requiring a written directive. The root cause regarding the violation was due to the misunderstanding of the terms of its NRC license by your nuclear medicine staff. In addition, the nuclear medicine staff failed to confirm their understanding of the terms and conditions of your NRC license with your radiation safety office. Your radiation safety office implemented several corrective actions to prevent recurrence which included: (1) instructing the nuclear medicine staff on the terms of the license and how to

recognize the authorization terms for the authorized physician users; and (2) developing a list of physician users authorized for Section 35.300 materials and posting the list in the hot lab.

You are required to respond to this letter and should follow the instructions specified in the enclosed Notice when preparing your response. The guidance in NRC Information Notice 96-28, "Suggested Guidance Relating to Development and Implementation of Corrective Action," may be helpful. You can find the information notice on the NRC website at: http://www.nrc.gov/reading-rm/doc-collections/gen-comm/info-notices/ 1996/in96028.html. If you have additional information that you believe the NRC should consider, you may provide it in your response to the Notice. The NRC review of your response to the Notice will also determine whether further enforcement action is necessary to ensure compliance with regulatory requirements.

The NRC is concerned that your internal audits missed opportunities to identify the unauthorized administrations of iodine-131 because the audits focused other aspects of the administration. The physician administered 16 cases between April 24, 2008, and August 27, 2010, without detection during your audits. We request that your written response also address our concern with your audits and include actions you have taken or plan to take to improve the effectiveness of your audits.

The inspector identified prostate brachytherapy post-treatment plans where the administered dose to the treatment site appeared to exceed the prescribed dose by more than 20 percent. Due to questions regarding the methodology for assigning the dose to the treatment site, this issue has been identified as an unresolved issue. You will be notified in separate correspondence of the results of our review. In addition, please be advised that the number and characterization of this unresolved issue may change as a result of further NRC review.

In accordance with Title 10 of the Code of Federal Regulations (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 available to the Public without redaction.

Sincerely,

/RA/

Tamara E. Bloomer, Chief
Materials Inspection Branch

Docket No. 030-02140
License No. 21-12930-01

Enclosure:
Notice of Violation

cc: Donald J. Peck, Ph.D., Radiation Safety Officer
State of Michigan

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Sincerely,

/RA/

Tamara E. Bloomer, Chief
Materials Inspection Branch

Docket No. 030-02140
License No. 21-12930-01

Enclosure:
Notice of Violation

cc: Donald J. Peck, Ph.D., Radiation Safety Officer
State of Michigan

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NOTICE OF VIOLATION

Henry Ford Wyandotte Hospital
Wyandotte, Michigan

Docket No. 030-02140
License No. 21-12930-01

During a U.S. Nuclear Regulatory Commission (NRC) inspection conducted on September 22, 2010, a violation of NRC requirements was identified. In accordance with the Enforcement Policy, the violation is listed below:

> Condition 12.B. of License Number 21-12930-01, specifically names individuals as authorized users for specified materials in Title 10 of the Code of Federal Regulations (10 CFR), Part 35.
>
> 10 CFR 35.59, "Recentness of Training," states, in part, that the training and experience of an individual must have been obtained within seven years preceding the date of application or the individual must have had related continuing education and experience since the required training and experience was completed.
>
> Contrary to the above, on 16 occasions, between April 24, 2008, and August 27, 2010, a physician administered iodine-131, an unsealed byproduct material, as specified in Section 35.300 and the individual was not listed on the license as an authorized user of this material. Specifically, the physician was only authorized on the license for materials specified in Sections 35.100 and 35.200. In addition, the physician's training and experience with material specified in Section 35.300 was obtained between 1992 and 1996, a period greater than seven years from the dates the physician used this material, as required by Section 35.59, "Recentness of Training."
>
> This is a Severity Level IV Violation (Section 6.12).

Pursuant to the provisions of 10 CFR 2.201, Henry Ford Wyandotte Hospital is hereby required to submit a written statement or explanation to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, DC 20555-0001, with a copy to the Regional Administrator, Region III, within 30 days of the date of the letter transmitting this Notice of Violation (Notice). This reply should be clearly marked as a "Reply to a Notice of Violation and should include for each violation: (1) the reason for the violation, or, if contested, the basis for disputing the violation or severity level; (2) the corrective steps that have been taken and the results achieved; (3) the corrective steps that will be taken; and (4) the date when full compliance will be achieved. Your response may reference or include previous docketed correspondence, if the correspondence adequately addresses the required response. If an adequate reply is not received within the time specified in this Notice, an Order or a Demand for Information may be issued as to why the license should not be modified, suspended, or revoked, or why such other action as may be proper should not be taken. Where good cause is shown, consideration will be given to extending the response time.

If you contest this enforcement action, you should also provide a copy of your response, with the basis for your denial, to the Director, Office of Enforcement, U. S. Nuclear Regulatory Commission, Washington, DC 20555-0001.

Because 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, it should not include any personal privacy, proprietary, or safeguards information so that it can be made available to the public without redaction. If personal privacy or proprietary information is necessary to provide an acceptable response, then please provide a bracketed copy of your response that identifies the information that should be protected and a redacted copy of your response that deletes such information. If you request withholding of such material, you must specifically identify the portions of your response that you seek to have withheld and provide in detail the bases for your claim of withholding (e.g., explain why the disclosure of information will create an unwarranted invasion of personal privacy or provide the information required by 10 CFR 2.390(b) to support a request for withholding confidential commercial or financial information). If safeguards information is necessary to provide an acceptable response, please provide the level of protection described in 10 CFR 73.21. If Classified Information is necessary to provide an acceptable response, please provide the level of protection described in 10 CFR Part 95.

In accordance with 10 CFR 19.11, you may be required to post this Notice within two working days.

Dated this 10th day of November 2010.