October 2, 2013

EA 13-197

Donald J. Peck, Ph.D.
Radiation Safety Officer
2333 Biddle Avenue
Wyandotte, Michigan 48192

SUBJECT: NRC ROUTINE INSPECTION REPORT NO. 03002140/2013001(DNMS) – HENRY FORD WYANDOTTE HOSPITAL

Dear Dr. Peck:

On August 28, 2013, a U.S. Nuclear Regulatory Commission (NRC) inspector conducted a routine inspection at your facility in Wyandotte, Michigan, with continued in-office review through September 11, 2013. The purpose of the inspection was to review activities performed under your NRC license to ensure that activities were being performed in accordance with NRC requirements. The in-office review included a review of the licensee's prostate implant procedure. A final exit meeting was held between Bill Lin of my staff and Alan Jackson and Brett Miller of your staff by telephone on September 11, 2013.

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. No violations were identified as a result of this inspection.

During the inspection, the NRC inspector also evaluated the Unresolved Issue from NRC Inspection Report 03002140/2010001, regarding the reporting criteria for Medical Events. In 2010, an NRC inspector randomly reviewed 15 pre- and post-treatment plans for permanent prostate implants. From the randomly selected 15 implants, the NRC inspector identified 10 patient brachytherapy post-treatment plans where the administered dose appeared to exceed the prescribed dose by more than 20 percent. The D90s for those ten cases ranged between 122.43 to 169 percent. All of the written directives were prescribed dose to the prostate of 145 Gy, isodose. According to the authorized user and medical physicist, the licensee's position, based on their understanding through information obtained through professional meetings and journal articles, was that there was no upper bounding dose limit for prostate implants, and therefore the 10 cases were not considered Medical Events. The current NRC inspector screened the Unresolved Issue by evaluating it in accordance with the NRC's Interim Enforcement Policy (IEP) Regarding Enforcement Discretion for Permanent Implant Brachytherapy Medical Event Reporting Under Title 10 *Code of Federal Regulations* (CFR) Part 35 that was issued in the NRC Regulatory Issue Summary (RIS) 2013-10 on July 30, 2013. As we stated in the IEP, enforcement discretion is provided for existing and future violations of the current Title 10 CFR 35.3045(a)(1)(i) Medical Event reporting requirement when

a treatment site total dose exceeds 120 percent of the prescribed dose. The enforcement discretion will apply if the licensee used absorbed dose to compare the dose delivered to the treatment site with the prescribed dose, the doses to normal tissues and structures do not exceed the regulatory dose threshold for reporting Medical Events; and the total dose for the treatment site was expressed in the written directive as absorbed dose. Based on discussion with your staff, a review of treatment documentation, and the NRC RIS, the failure to report 10 medical events to the NRC as required by 10 CFR 35.3045 warrants enforcement discretion. This Unresolved Issue is considered closed.

The NRC has concluded that information regarding the reason for the issue and the actions taken and planned to address the concern and prevent recurrence is already adequately addressed on the docket in NRC Inspection Report 03002140/2010001 and this letter. Therefore, you are not required to respond to this letter unless the description herein does not accurately reflect your understanding of the issue or your position. In that case, clearly mark your response as a "Reply to Inspection Report No. 03002140/2013001(DNMS)," and send it to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, DC 20555-000,1 with a copy to the Regional Administrator, Region III, within 30 days of the date of this letter.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter and your response, if you choose to provide one, will be made available electronically for public inspection in the NRC Public Document Room or from the NRC 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/

Aaron T. McCraw, Chief
Materials Inspection Branch
Division of Nuclear Materials Safety

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

cc: Alan Jackson, CHP-Site RSO
State of Michigan

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Sincerely,

/RA/

Aaron T. McCraw, Chief
Materials Inspection Branch
Division of Nuclear Materials Safety

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

cc: Alan Jackson, CHP – Site RSO
State of Michigan

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Letter to D. Peck, Ph.D., from Aaron T. McCraw, dated October 2, 2013

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