UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION III
2443 WARRENVILLE RD. SUITE 210
LISLE, IL 60532-4352

May 6, 2016

EA-16-106
NMED No. 110107 (Closed)

Dr. Ashok B. Jain, Chief of Staff
Oakwood Hospital
33155 Annapolis Avenue
Wayne, MI 48184

SUBJECT: NRC ROUTINE INSPECTION REPORT NO. 03002099/2016001(DNMS)
AND CLOSURE OF OPEN ITEM FROM NRC INSPECTION REPORT
NO. 03002099/2010001(DNMS) – OAKWOOD HOSPITAL-ANNAPOLIS CENTER

Dear Dr. Jain:

On April 8, 2015, an inspector from the U.S. Nuclear Regulatory Commission (NRC) conducted a routine inspection at your facility in Wayne, Michigan. 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. Mr. Edward Harvey of my staff presented the results of this inspection during a final, onsite exit meeting with you and other licensee representatives on April 8, 2016.

During this inspection, the NRC staff examined activities conducted under your license related to public health and safety, and security. 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 of NRC regulatory requirements were identified as a result of this inspection.

During the inspection, the NRC inspector also evaluated an Open Item from NRC Inspection Report No. 03002099/2010001(DNMS), regarding the reporting criteria for Medical Events. In 2010, an NRC inspector identified six pre- and post-treatment plans for permanent prostate implants where the administered dose appeared to exceed the prescribed dose by more than 20 percent. The D90s, which is the dose to 90 percent of target volume, for those six cases ranged between 120.9 to 140.7 percent. The current NRC inspector screened the six administrations by evaluating them in accordance with the NRC's Interim Enforcement Policy (IEP) regarding "Enforcement Discretion for Permanent Implant Brachytherapy Medical Event Reporting (10 CFR 35.3045)" that was issued in the NRC Regulatory Issue Summary (RIS) 2013-10 on July 30, 2013. As stated in the IEP, enforcement discretion is provided for violations of the current 10 CFR 35.3045(a)(1)(i) Medical Event reporting requirement when: (1) they involved administered doses to the treatment sites that were greater than 20 percent higher than the prescribed doses on the written directives; (2) they involved permanent implant brachytherapy; (3) licensee staff used absorbed dose to compare the dose delivered to the treatment site with the prescribed dose; (4) doses to normal tissues and structures did not

exceed the regulatory dose thresholds for reporting Medical Events per the current 10 CFR 35.3045(a)(3); and (5) the total dose for the treatment site was expressed in the written directive as absorbed dose. Because all six administrations met the above criteria, in accordance with the IEP, and they did not result in harm to the patients as determined by the licensee, the NRC is exercising enforcement discretion not to cite six examples of a violation of 10 CFR 35.3045(c) for failure to notify by telephone the NRC Operations Center no later than the next calendar day after discovery of a Medical Event. The Open Item from NRC Inspection Report No. 03002099/2010001(DNMS) is closed.

You are not required to respond to this letter unless the description herein does not accurately reflect your understanding of the inspection findings or your position. In that case, clearly mark your response as a "Reply to NRC Inspection Report No. 03002099/2016001(DNMS)," and send it 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 this letter.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter will be made available electronically for public inspection in the NRC's Agencywide Documents Access and Management System (ADAMS), accessible from the NRC's website at http://www.nrc.gov/reading-rm/adams.html.

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

Sincerely,

/RA/

Aaron T. McCraw, Chief
Materials Inspection Branch

Docket No. 030-02099
License No. 21-11457-02

cc: State of Michigan

structures did not exceed the regulatory dose thresholds for reporting Medical Events per the current 10 CFR 35.3045(a)(3); and (5) the total dose for the treatment site was expressed in the written directive as absorbed dose. Because all six administrations met the above criteria, in accordance with the IEP, and they did not result in harm to the patients as determined by the licensee, the NRC is exercising enforcement discretion not to cite six examples of a violation of 10 CFR 35.3045(c) for failure to notify by telephone the NRC Operations Center no later than the next calendar day after discovery of a Medical Event. The Open Item from NRC Inspection Report No. 03002099/2010001(DNMS) is closed.

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/RA/

Aaron T. McCraw, Chief
Materials Inspection Branch

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cc: State of Michigan

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