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

March 9, 2016

EN 50982
NMED No. 150206 (Closed)

Ms. Erika W. Wehrmeister
Chief Operating Officer
St. Vincent Hospital & Health Care Center
2001 West 86th Street
Indianapolis, IN 46260

SUBJECT: CLOSURE OF OPEN ITEMS REFERENCED IN NRC INSPECTION REPORT NO. 03001579/2015001(DNMS) DATED JULY 7, 2015 – ST. VINCENT HOSPITAL & HEALTH CARE CENTER

Dear Ms. Wehrmeister:

On April 20 and 21, 2015 two inspectors from the U.S. Nuclear Regulatory Commission (NRC) conducted a reactive inspection at St. Vincent Hospital & Health Care Center in Indianapolis, Indiana, with continued in-office review through June 12, 2015. As a result of the inspection, the NRC issued NRC Inspection Report No. 03001579/2015001 (DNMS) on July 7, 2015, which referenced two Open Items that required further review. The Open Items concerned (1) the probable causes of the damaged check cables and any generic implications; and (2) your performance of daily obstruction tests on your high dose rate (HDR) remote afterloading brachytherapy unit and any generic implications. The inspectors reviewed the circumstances of a medical event that occurred as a result of damage to the check cable within the HDR unit. The damage to the check cable prevented your staff from operating the HDR unit and completing the patient's treatment fraction on April 13, 2015. Your staff terminated the treatment fraction once they recognized the error code for a friction error on the HDR computer console; this friction error indicated a possible obstruction within the treatment catheter. Your institution also experienced two issues with damaged check cables in November 2014 and May 2015. At the time of our inspection on April 20-21, 2015, it was unknown what factors could have attributed to these multiple occurrences of damage to the HDR check cables. Your institution sent these damaged HDR check cables to the device manufacturer for analysis in June 2015.

As discussed during a teleconference between Earl Dietrich and Travis Webb of your staff and Deborah Piskura of my staff on February 26, 2016, we have completed our review of the Open Items. The device manufacturer provided the results of its analysis of the most recent damaged check cable in its report dated August 21, 2015. According to the manufacturer, the manner that the hospital staff performed obstruction tests on the HDR unit using an older model catheter most likely caused the damage to the check cable. The older model catheter has a larger interior diameter that could allow the check cable to bend at a greater angle. In November 2015, the manufacturer issued a bulletin to its customers informing them that

obstruction tests on the HDR unit should not be performed by the user. On February 12, 2016, the device manufacturer informed our office that the two remaining damaged check cables (from November 2014 and May 2015 incidents) were presumed lost. Unfortunately, the device manufacturer was unable to evaluate these check cables.

Based on the results of our inspection and continued review of these issues, no violations of NRC requirements were identified concerning the manner in which your staff conducted obstruction tests. It is our understanding that your staff ceased performing an obstruction test on your HDR units and to date you have not experienced any additional damaged HDR check cable incidents; therefore, the Open Items are now considered closed.

The NRC has concluded that the information regarding the damaged check cable incidents and the obstruction tests is already adequately addressed on the docket in 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 you response as a "Reply to Closure of Open Items Referenced in NRC Inspection Report No. 03001579/2015001(DNMS) Dated July 7, 2015," 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 Title 10 of the *Code of Federal Regulations* (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 Public Document Room or from 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.

Please feel free to contact Deborah A. Piskura of my staff if you have any questions regarding this matter. Ms. Piskura can be reached at 630-829-9867.

Sincerely,

/RA/

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

Docket No. 030-01579
License No. 13-00133-02

cc: State of Indiana
Ed Wroblewski, M.A., Radiation Safety Officer

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NAME	DPiskura:ps		AMcCraw					
DATE	3/8/2016		3/9/2016					

OFFICIAL RECORD COPY

Letter to Erika Wehrmeister from Aaron McCraw dated March 9, 2016.

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