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

March 9, 2017

Ms. Rhonda Parton
Executive Director
Boone Hospital Center
1600 East Broadway
Columbia, MO 65201

SUBJECT: NRC SPECIAL INSPECTION REPORT NO. 03002304/2016001(DNMS) BOONE HOSPITAL CENTER

Dear Ms. Parton:

On October 18, 2016, an inspector from the U.S. Nuclear Regulatory Commission (NRC) conducted a special inspection at your facility in Columbia, Missouri, with continued in-office review through February 17, 2017. The purpose of the inspection was to review the circumstances, root and contributing causes, and proposed corrective actions associated with the medical administration of iodine-131 (I-131) and the signing of written directives, by a physician not listed on your license as an Authorized User, as you reported in an email to the NRC dated October 3, 2016. The purpose of the in-office review was to evaluate information not available at the time of the inspection concerning whether the physician was qualified by training and experience to use unsealed licensed material requiring a written directive. Mr. Dennis O'Dowd of my staff conducted a final exit meeting by telephone with Ms. Liesje Myers and Ms. Danielle Atterbury of your staff on February 17, 2017, to discuss the inspection findings.

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 review of records, and interviews with personnel.

Based on the results of this inspection, the NRC has determined that one Severity Level IV violations 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 concerned the licensee's failure to ensure that an authorized user signed and dated written directives prior to the administrations of I-131 sodium iodide greater than 1.11 megabecquerels (MBq) (30 microcuries), as required by Title 10 of the *Code of Federal Regulations* (CFR) Section 35.40(a) and License Condition 12.B of NRC License No. 24-01565-01. Specifically, an individual who was not listed as an authorized user on your NRC license signed and dated written directives for medical uses of I-131 on six occasions between July 8, 2016, and August 25, 2016. This non-repetitive, licensee-identified, and corrected violation is being treated as a Noncited Violation, consistent with Section 2.3.2.b of the Enforcement Policy.

The inspector determined that the root cause of the violation was inadequate training of licensee staff, which led to a misunderstanding by an authorized user in nuclear medicine, and by the physician who signed the written directive and administered the dose, that a physician who has undergone training and experience as stated in 10 CFR 35.392(b) can prescribe, sign, and date a written directive prior to being added to the license. In addition, inadequate training led to the licensee's nuclear medicine staff, who also lacked an understanding of the requirements regarding authorized users and who took their direction from the authorized user, not questioning the information provided by the authorized user as to whether the physician was authorized, and not confirming the authorized user status of the individual with the licensee's Radiation Safety Officer (RSO). As corrective actions to restore compliance and to address the potential for recurrence, you submitted an application for license amendment dated October 3, 2016, and a revised application dated November 3, 2016, requesting that the physician be added to the license as an authorized user for 35.100, 35.200, 35.300 (limited to the oral administration of sodium iodide I-131 in quantities less than or equal to 33 millicuries (mCi)), and 31.11 materials. In addition, nuclear medicine staff, including authorized users, were provided training, completed in September 2016, on the requirement that only individuals listed as authorized users on the license may date and sign written directives. On February 13, 2017, License No. 24-01565-01 was amended (Amendment No. 89) to add the physician as an authorized user for the requested materials. This licensing action was based on the individual's previous training and experience, which met the criteria set out in 10 CFR 35.392(b).

The NRC has concluded that information regarding the reason for the violation, the corrective actions taken and planned to correct the violation and prevent recurrence, and the date when full compliance will be achieved 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 corrective actions or your position. In that case, or if you choose to provide additional information, clearly mark your response as a "Reply to IR 03002304/2016001(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. 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.

In accordance with 10 CFR Section 2.390 of the NRC's "Rules of Practice," a copy of this letter, its enclosure, and your response if you choose to provide one, 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. To the extent possible, your response should not include any personal privacy, proprietary, or safeguards information so that it can be made publicly available without redaction.

Please feel free to contact Mr. O'Dowd if you have any questions regarding this inspection. Mr. O'Dowd can be reached at 630-829-9573.

Sincerely,

/RA/

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

Docket No. 030-02304
License No. 24-01565-01

cc: State of Missouri
Liesje Myers, CNMT, RSO

Letter to Ms. Rhonda Parton from Aaron McCraw, dated March 9, 2017

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