INSPECTION RECORD

Region: III **Inspection Report No.** 2016001 **License No.** 24-01565-01
Docket No. 030-02304

Licensee: Boone Hospital Center
1600 East Broadway
Columbia, Missouri 65201

Locations Inspected: Same as above

Licensee Contact: Liesje Myers, Radiation Safety Officer **Telephone No**. 573-815-3729

Program Code: 02120 **Priority**: 3

Type of Inspection: ( ) Initial ( ) Routine (X) Announced
(X) Special ( ) Unannounced

Last Inspection Date: August 6-7, 2015 **Date of This Inspection**: October 18, 2016, with continued in-office review through February 17, 2017

Next Inspection Date: August 6, 2018 (X) Normal ( ) Reduced

Justification for reducing the routine inspection interval: N/A

Summary of Findings and Actions:

( ) No violations cited, clear U.S. Nuclear Regulatory Commission (NRC) Form 591 or regional letter issued
(X) Noncited violations (NCVs)
( ) Violation(s), Form 591 issued
( ) Violation(s), regional letter issued
( ) Follow-up on previous violations

Inspector: Dennis P. O'Dowd, Health Physicist

/RA/ Date 3/9/2017
Signature

Approved Aaron T. McCraw, Chief, MIB

/RA/ Date 3/9/2017
Signature

PART I – LICENSE, INSPECTION, INCIDENT/EVENT AND ENFORCEMENT HISTORY

1. AMENDMENTS AND PROGRAM CHANGES SINCE LAST INSPECTION:

AMENDMENT #	DATE	SUBJECT
87	01/20/2016	New authorized users; additional authorization for an authorized user
88	11/08/2016	New authorized user
89	02/16/2017	New authorized user

2. INSPECTION AND ENFORCEMENT HISTORY:

The last routine inspection of this licensee was conducted on August 6-7, 2015. The previous inspection was on February 14, 2012, with continued review through March 21, 2012. No violations of NRC requirements were identified during either inspection.

3. INCIDENT/EVENT HISTORY:

No open items or events since the last routine inspection.

PART II – INSPECTION DOCUMENTATION

1. ORGANIZATION AND SCOPE OF PROGRAM:

Boone Hospital Center was authorized under NRC Materials License No. 24-01565-01 to use licensed material permitted by Title 10 *Code of Federal Regulations* (CFR) Sections 35.100, 35.200 (including PET), 35.300, 35.400, and 31.11, as well as depleted uranium for shielding. This licensee was a 400-bed full service hospital located in Columbia, Missouri, which also had a second site, the Boone Hospital Cardiac Diagnostic Center (35.100 and 35.200 only). The Radiation Safety Officer (RSO) reported to the Director of Imaging Services. The Director of Imaging Services reported to the Vice President and Chief Operating Officer. The Vice President and Chief Operating Officer reported to the President. The RSO oversaw all program areas.

The main hospital nuclear medicine department provided an array of diagnostic imaging studies and therapeutic uses. The Nuclear Medicine department opened at 6:00 am Mondays through Fridays. Up to approximately 25 imaging scans per day were performed by up to five nuclear medicine technologists (NMTs). The licensee used iodine-131 (I-131) to treat patients for hyperthyroidism and thyroid cancer about 100 times per year. Samarium-153 (unit dosages only) was also used to treat patients.

2. SCOPE OF INSPECTION:

Inspection Procedure(s) Used: 87131

Focus Areas Evaluated: 03.01, 03.06, and 03.07, as relevant to the medical use of licensed material by a physician not listed on the license.

The inspector interviewed the RSO, authorized users, nuclear medicine staff, members of management, members of the licensee's radiation safety committee, and the non-authorized physician, concerning the non-authorized physician's use of licensed material requiring a written directive, in this case, 35.300 material, in particular, the circumstances in which this occurred, the licensee's response upon identification of the issue, and actions taken to correct and prevent recurrence. The inspector reviewed in detail licensee records relevant to the use of licensed material requiring a written directive, including documentation going back to the previous routine inspection, with emphasis on determining extent of condition and the circumstances of this case.

3. INDEPENDENT AND CONFIRMATORY MEASUREMENTS:

As a matter of routine, the inspector conducted independent surveys in general areas where materials are used and stored, using a Radiac Model meter, and found no readings which would indicate exposures to members of the public in excess of regulatory limits.

4. VIOLATIONS, NCVs, AND OTHER SAFETY ISSUES:

The inspector conducted the onsite portion of the special inspection on October 18, 2016. The inspector confirmed as per the licensee's emailed report to Patricia Pelke, Chief, Materials Licensing Branch, Division of Nuclear Materials Safety, dated October 3, 2016, that a radiologist not listed on NRC License No. 24-01565-01 performed six administrations of I-131 sodium iodide (NaI-131), all in quantities less than 33 millicuries (mCi), and had signed the written directives for each of the six procedures. The doses were administered in July and August of 2016. The specific dates and the dosage administered were as follows:

July 8, 2016	15.8 mCi oral NaI-131 for treatment of hyperthyroidism
July 8, 2016	15.1 mCi oral NaI-131 for treatment of hyperthyroidism
July 13, 2016	4.2 mCi oral NaI-131 for whole body imaging
August 5, 2016	15.3 mCi oral NaI-131 for treatment of hyperthyroidism
August 12, 2016	15.3 mCi oral NaI-131 for treatment of hyperthyroidism
August 25, 2016	14.7 mCi oral NaI-131 for treatment of hyperthyroidism

The RSO identified the violation during a periodic audit, specifically, the third quarter of 2016 Quality Management Program Review of Therapeutic Radionuclide Administrations conducted under the license. In the audit record dated September 7, 2016, the RSO indicated that the issue was identified, and was immediately investigated by the RSO, which included interviews of nuclear medicine technology staff, and authorized users in nuclear medicine. Authorized users, nuclear medicine staff, and the physician who

performed the therapeutic administrations, were all notified that the physician was no longer to administer doses until authorized to do so on the license. An amendment requesting that the physician be added to the license for 35.100, 35.200, and limited 35.300 materials and uses was prepared by the RSO and submitted by the licensee in an amendment application dated September 13, 2016. The licensee notified the NRC on October 3, 2016, of the violation. Based on a telephonic conversation with a Materials License Reviewer assigned to review the amendment application, in a letter dated October 6, 2016, the licensee requested that the amendment request to add the physician be withdrawn, in order to obtain additional information regarding the physician's qualifications and ultimately provide a more detailed application. The licensee submitted a revised request to add the physician to the license as an authorized user for 35.100, 35.200, 35.300 (limited to the oral administration of NaI-131 in quantities less than or equal to 33 mCi), and 31.11 materials, in a letter dated November 3, 2016. The request to add this physician as an authorized user was approved, as issued in Amendment No. 89 of the license on February 16, 2017. In a letter dated December 13, 2016, the licensee provided details of the RSO's investigation into the root and contributing causes to the violation that took place, as well as describing the prompt corrective and preventative actions taken by the licensee. These corrective actions included (1) providing education and training to authorized users and nuclear medicine staff on the requirements to be named as an authorized user, (2) posting of signage with the listing of authorized users and each of their authorizations, and (3) having discussions with senior management regarding the situation to ensure full awareness to the significance of the issue.

On each of the dates in July and August 2016, as listed above, the licensee failed to have an individual listed on the license as an authorized user for medical uses under 10 CFR 35.300 date and sign a written directive before the administration of NaI-131, in each of the activities specified, to patients. Specifically, the written directive was signed by an individual who was not listed as an authorized user on NRC License No. 24-01565-01. However, as of February 13, 2017, the NRC's Region III, Division of Nuclear Materials Safety, Materials Licensing Branch, made a final determination that, based on previous training and experience, the individual was clearly qualified to use 35.300 (limited to the oral administration of NaI-131 in quantities less than or equal to 33 mCi) at the time the individual signed and dated the six written directives. On February 13, 2017, Amendment No. 89 to NRC License No. 24-01565-01 was issued adding this individual to the license as an authorized user for 10 CFR 35.100, 35.200, 35.300 (limited to the oral administration of NaI-131 in quantities less than or equal to 33 mCi) and 31.11 licensed materials.

The failure by the licensee to have an individual sign and date each of the written directives before the administration of NaI-131 to patients is a violation of 10 CFR 35.40(a), which requires, in part, that a written directive be signed and dated by an authorized user before the administration of NaI-131 greater than 30 microcuries, and License Condition No. 12.B., of NRC License No. 24-01565-01, which lists the individuals who are authorized users on the license and the specific type of medical use for which they are authorized. The root cause of the violation was inadequate training of licensee staff. As a result of this lack of training, an authorized user in nuclear medicine did not have a complete understanding of the process to be an authorized user, a nuclear medicine technologist did not question information provided by the authorized user, nor did the technologist contact the RSO for confirmation of the physician's authorized user status, and furthermore, after the first occurrence, the nuclear medicine

technologist staff relied on the initial information provided and continued to call on the physician to administer NaI-131. As corrective action, the licensee took immediate steps by directing that no further administrations were to be performed by the individual, all staff received training and education regarding the issue, senior management and the Radiation Safety Committee were fully informed of the issue, an amendment request was submitted to add the individual to the license as an authorized user for 35.300 materials, and the NRC was contacted.

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.

5. PERSONNEL CONTACTED:

Liesje Myers, CNMT, ARRT(N) – Radiation Safety Officer
Danielle Atterbury - Manager of Radiology
Rhonda Parton - Executive Director of Boone Medical Center
Terry Elwing, M.D. - Authorized User
Logan Frank, M.D.
Mike Devine, CNMT – Nuclear Medicine Technologist
Denise Vaughn, CNMT - Nuclear Medicine Technologist

Attended telephonic exit meeting on February 17, 2017.

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