UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION III
2443 WARRENVILLE ROAD, SUITE 210
LISLE, ILLINOIS 60532-4352

December 9, 2019

EN 54344

Mr. John McKenzie
Director of Radiology
Ozark Medical Center
1100 Kentucky Ave.
West Plains, MO 65775

SUBJECT: NRC SPECIAL INSPECTION REPORT NO. 03014280/2019001 (DNMS) AND NON-CITED VIOLATION – OZARKS MEDICAL CENTER

Dear Mr. McKenzie:

On October 23, 2019, an inspector from the U.S. Nuclear Regulatory Commission (NRC) conducted an in-office review by way of a telephone call with you and your radiation safety officer regarding information about the licensee's event notification to the NRC Operations Center on October 22, 2019, indicating a medical event involving an administration of 22 millicuries of technetium-99m Ceretec to the wrong patient on October 22, 2019.

As a result, Mr. Gattone noted that a violation of Title 10 of *the Code of Federal Regulations* (CFR) 35.63(d) occurred and it was identified by the licensee. On October 25, 2019, Mr. Gattone informed your radiation safety officer about the violation. Mr. Gattone obtained applicable information to conduct an independent assessment of the doses for the individual who was administered 22 millicuries of technetium-99m Ceretec. In addition, Mr. Gattone obtained the licensee's consultant's dose assessment document on how the consultant determined the doses for the individual. Based on these two assessments, the individual did not receive 5 Roentgen equivalent man (rem) effective dose equivalent, nor 50 rem for an organ or tissue and the NRC concluded that there was no medical event.

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 administration of a dosage to the wrong patient that differed from the prescribed dosage by more than 20 percent, contrary to 10 CFR 35.63(d). Since the licensee: (1) identified the violation; (2) found the root cause of the violation; (3) promptly implemented corrective actions to prevent a similar violation; (4) provided the study team with education, and a checklist to prevent similar violations; (5) immediately changed the Patient Identification Policy to provide applicable scenarios for education pertinent to the event as a means of assessing competence for patient identity verification (e.g., if the patient is confused, use the patient's I.D. arm band, chart, or order). As such, the violation is a Non-Cited Violation (NCV).

The inspector noted that the root cause of the 35.63(d) violation was that the patient was confused and could not declare his name and date of birth, and the NMT administered the dose without doing a dual patient identification check. As a result, the NMT administered 22 millicuries of technetium-99m Ceretec to the wrong patient. After administration, the staff

took the patient out of the area and turned towards a different unit. The NMT noticed this and asked where they were taking the patient. The NMT was told that the patient was going to the Cardiac Stress Unit (CSU). The NMT then questioned, “When did the patient get transferred to the CSU?” The NMT was told that the patient was always in the CSU. The NMT then realized she had the wrong patient. The NMT immediately notified the Director of Radiology who then escalated to the Patient Safety Risk Manager and the Administrator on call.

The NRC has concluded that information regarding the reason for the violation, the corrective actions taken to 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 accordance with 10 CFR 2.390 of the NRC’s “Rules of Practice,” a copy of this letter and any response you provide 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, any 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. Gattone of my staff if you have any questions regarding this inspection. Mr. Gattone can be reached at 630-829-9823.

Sincerely,

/RA Christine Lipa Acting for/

Rob Ruiz, Acting Chief
Materials Inspection Branch
Division of Nuclear Materials Safety

Docket No. 030-14280
License No. 24-18733-01

cc: State of Missouri
Lynn Carlton, M.D., Radiation
Safety Officer

Letter to John McKenzie from Robert Ruiz dated December 9, 2019.

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