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

August 18, 2016

EN 51981
NMED No. 160234 (Closed)

Christopher M. Wibbenmeyer, MBA, FACHE
Vice President of Operations
Perry County Memorial Hospital
434 Northwest Street
Perryville, MO 63775-1398

SUBJECT: NRC REACTIVE INSPECTION REPORT NO. 03018404/2016001(DNMS) AND NOTICE OF VIOLATION – PERRY COUNTY MEMORIAL HOSPITAL

Dear Mr. Wibbenmeyer:

On June 13, 2016, an inspector from the U.S. Nuclear Regulatory Commission (NRC) conducted a reactive inspection at Perry County Memorial Hospital, with continued in-office review through July 21, 2016. The purpose of this inspection was to review the circumstances, root cause, and proposed corrective actions regarding the medical event that your staff reported to the NRC on June 3, 2016. The in-office review included receipt and review of the written report that you provided to the NRC concerning the medical event. Mr. Dennis O'Dowd of my staff conducted a final exit meeting with you by telephone on July 21, 2016 to discuss the inspection findings. The enclosed report (Enclosure 2) presents the results of this inspection.

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 examination of procedures and representative records and interviews with personnel.

Based on the results of this inspection, the NRC has determined that a Severity Level IV violation 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 properly verify that a dose used for a diagnostic procedure was within the authorized range, as required by Title 10 of the *Code of Federal Regulations* (CFR) 35.63(d). The violation is cited in the enclosed Notice of Violation (Notice) (Enclosure 1). The NRC is citing the violation in the Notice because the inspector identified the violation.

The NRC has determined that the root cause of the violation was a lack of attention to detail on the part of a licensee staff member. Specifically, the staff member failed to verify that the administered dose was the appropriate radioactivity for a bone scintigraphy procedure. As corrective actions to address recurrence of the event and to prevent a similar violation, the applicable staff member was counseled and will undergo retraining in the licensee's procedures

for the safe use of unsealed licensed material. Upon completion of that training, the staff member will formally acknowledge responsibility and understanding of the licensee's procedures for the safe use of unsealed licensed materials. For a period of 90 days, the staff member will be re-evaluated every 30 days by a licensee manager regarding adherence to and performance of licensee procedures for the safe use of unsealed licensed materials. Also, during this 90 day period, a second individual will verify the following: correct patient, correct radioactive drug, correct prescribed dosage, and correct route of administration prior to administering any radiopharmaceutical to a patient. In addition, you will no longer keep bulk Tc-99m sodium pertechnetate or radiopharmaceutical cold kits on hand for imaging in the event of add-on patients.

The NRC has concluded that information regarding the root cause of the violation, the corrective actions planned to correct the violation and address its recurrence, and the date when full compliance will be achieved is already adequately addressed on the docket in the enclosed inspection report. Therefore, you are not required to respond to this letter unless the description therein does not accurately reflect your corrective actions or your position. In that case, or if you choose to provide additional information, you should follow the instructions specified in the enclosed Notice.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter and your response, if you choose to provide one, will be 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 Web site at http://www.nrc.gov/reading-rm/adams.html.

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

Sincerely,

/RA by Geoffrey Warren acting for/

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

Docket No. 030-18404
License No. 24-17037-02

Enclosures:
1. Notice of Violation
2. IR 03018404/2016001(DNMS)

cc w/encls: State of Missouri

for the safe use of unsealed licensed material. Upon completion of that training, the staff member will formally acknowledge responsibility and understanding of the licensee's procedures for the safe use of unsealed licensed materials. For a period of 90 days, the staff member will be re-evaluated every 30 days by a licensee manager regarding adherence to and performance of licensee procedures for the safe use of unsealed licensed materials. Also, during this 90 day period, a second individual will verify the following: correct patient, correct radioactive drug, correct prescribed dosage, and correct route of administration prior to administering any radiopharmaceutical to a patient. In addition, you will no longer keep bulk Tc-99m sodium pertechnetate or radiopharmaceutical cold kits on hand for imaging in the event of add-on patients.

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cc w/encls: State of Missouri

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OFFICE	RIII-DNMS		RIII-DNMS		RIII		RIII	
NAME	DO'Dowd:ps		AMcCraw G Warren for					
DATE	8/17/2016		8/18/2016					

OFFICIAL RECORD COPY

Letter to Christopher Wibbenmeyer from Aaron McCraw dated August 18, 2016.

SUBJECT: NRC REACTIVE INSPECTION REPORT NO. 03018404/2016001(DNMS) AND NOTICE OF VIOLATION – PERRY COUNTY MEMORIAL HOSPITAL

DISTRIBUTION w/encls:
Darrell Roberts
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MIB Inspectors

NOTICE OF VIOLATION

Perry County Memorial Hospital
Perryville, Missouri

License No. 24-17037-02
Docket No. 030-18404

During a U.S. Nuclear Regulatory Commission (NRC) inspection conducted on June 13, 2016, with continued in-office review through July 21, 2016, one violation of NRC requirements was identified. In accordance with the NRC Enforcement Policy, the violation is listed below:

> Title 10 of the *Code of Federal Regulations* (CFR) 35.63(d) requires that unless otherwise directed by the authorized user, a licensee may not use a dosage if the dosage does not fall within the prescribed dosage range or if the dosage differs from the prescribed dosage by more that 20 percent.
>
> Contrary to the above, on June 3, 2016, Perry County Memorial Hospital used a diagnostic dosage that did not fall within the prescribed dosage range. Specifically, the licensee administered approximately 128 millicuries (mCi) of technetium-99m to a patient for a bone scan procedure when the prescribed dosage range was 20 to 30 mCi.

This is a Severity Level IV violation (Section 6.3).

The NRC has concluded that information regarding the reason for the violation, the corrective actions planned to correct the violation and prevent recurrence, and the date when full compliance was or will be achieved is already adequately addressed on the docket in the inspection report enclosed with the letter transmitting this Notice of Violation. Therefore, you are not required to respond to this letter unless the description therein does not accurately reflect your corrective actions or your position. In that case, or if you choose to provide additional information, you are required to submit a written statement or explanation pursuant to 10 CFR 2.201. If you choose to respond, clearly mark your response as a "Reply to a Notice of Violation, IR 03018404/2016001(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 the letter transmitting this Notice.

If you choose to respond, your response 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.

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 19.11, you may be required to post this Notice within two working days of receipt.

Dated this 18th day of August, 2016.

U.S. Nuclear Regulatory Commission
Region III

Docket No.	030-18404
License No.	24-17037-02
Report No.	03018404/2016001(DNMS)
EN No./NMED No.	EN 51981/160234
Licensee:	Perry County Memorial Hospital
Facility:	434 Northwest Street Perryville, MO 63775-1398
Inspection Dates:	June 13, 2016, with continued in-office review through July 21, 2016
Exit Meeting Date:	July 21, 2016
Inspector:	Dennis P. O'Dowd, Health Physicist
Approved By:	Aaron T. McCraw, Chief Materials Inspection Branch Division of Nuclear Materials Safety

EXECUTIVE SUMMARY

Perry County Memorial Hospital
NRC Inspection Report 03018404/2016001(DNMS)

On June 13, 2016, an inspector from the U.S. Nuclear Regulatory Commission (NRC) conducted an announced, reactive inspection with continued NRC in-office review through July 21, 2016, to review the facts and circumstances associated with a medical event that Perry County Memorial Hospital (licensee) staff reported to the NRC on June 3, 2016. The in-office review included receipt and review of the licensee's written report.

The inspector determined that a medical event occurred as a result of administering a diagnostic dose of technetium-99m (Tc-99m) sodium pertechnetate that was above the prescribed dosage range for a bone scintigraphy procedure. A bulk unit dose of approximately 128 millicuries (mCi) of Tc-99m sodium pertechnetate was intravenously administered to a patient, and the patient was to receive a 25 mCi dosage of Tc-99m Medronate intravenously. According to a dose calculation performed by the licensee, the administration resulted in a whole body dose to the patient of 6 rem. As such, the administration was a medical event as defined in Title 10 of the *Code of Federal Regulations* (CFR) Section 35.2. The licensee determined that the medical event would not result in adverse effects to the patient.

The root cause of the medical event was a lack of attention to detail on the part of a licensee staff member. Specifically, the staff member failed to verify that the administered dosage was the appropriate radioactivity for a bone scintigraphy procedure. The inspector determined that the incident was isolated and it did not demonstrate a programmatic weakness. The inspector determined that the administration of a dosage outside the prescribed range is a violation of 10 CFR 35.63(d). As corrective actions to prevent recurrence of the event and to prevent a similar violation, the staff member was counseled and will undergo retraining in the licensee's procedures for the safe use of unsealed licensed material. Upon completion of this training, the staff member will formally acknowledge responsibility and understanding of the licensee's procedures for the safe use of unsealed licensed materials. For a period of 90 days, the staff member will be re-evaluated every 30 days by a licensee manager regarding adherence to and performance of the licensee's procedures for the safe use of unsealed licensed materials. Also, during the 90-day period, a second individual will verify the following: correct patient, correct radioactive drug, correct prescribed dosage, and correct route of administration, prior to administering any radiopharmaceutical to a patient. In addition, the licensee will no longer keep bulk Tc-99m sodium pertechnetate or radioisotope cold kits on hand for imaging in the event of add-on patients. Instead, the licensee will order unit dosages as needed.

REPORT DETAILS

1 Program Overview and Inspection History

Perry County Memorial Hospital is authorized under NRC Materials License No. 24-17037-02 to use licensed material for medical diagnosis pursuant to Title 10 of the *Code of Federal Regulations* (10 CFR) 35.100 and 35.200, including technetium-99m (Tc-99m) labeled radiopharmaceuticals for scintigraphy procedures.

The NRC last inspected the licensee on August 3, 2015. During that inspection, no violations of NRC regulatory requirements were identified.

The NRC previously inspected the licensee on August 13, 2010. During that inspection, no violations of NRC regulatory requirements were identified.

2 Sequence of Events and Licensee Investigation

2.1 Inspection Scope

The inspector interviewed selected licensee staff, including, in part, the Chief Nuclear Medicine Technologist (NMT), the manager of the radiology department, and the Vice President of Operations, regarding the sequence of events. In addition, the inspector reviewed the licensee's procedures and observed the organization of radiopharmaceuticals within the hot lab. The inspector reviewed the licensee's dose calculations that were completed by the licensee's consulting physicist.

2.2 Observations and Findings

a. Medical Events Details

On June 3, 2016, the licensee planned to administer a diagnostic unit dosage of Tc-99m Medronate to a patient for a bone scintigraphy study. According to the licensee's procedures, the acceptable dosage range for that type of study is 20 to 30 millicuries (mCi). The nuclear medicine department had only one patient that day. Since May 2016, the licensee received Tc-99m sodium pertechnetate (commonly referred to as "bulk tech") for use on an emergent basis in the event a patient was referred during the day. When the patient came in for the bone scan, a licensee staff member accidentally took the bulk Tc-99, and without assaying the dosage, administered it to the patient. Upon entering the information into the licensee's dose management system, the licensee staff member realized that the step of measuring the dosage was skipped, and that the bulk dosage was used instead of the intended Tc-99m Medronate dosage, resulting in the patient being injected with approximately 128 mCi of Tc-99m sodium pertechnetate instead of the prescribed 20 to 30 mCi of Tc-99m Medronate.

Title 10 CFR 35.63(d) requires that unless otherwise directed by the authorized user, a licensee may not use a dosage if the dosage does not fall within the prescribed dosage range or if the dosage differs from the prescribed dosage by more that 20 percent. The licensee's administration of a radiopharmaceutical dosage outside of the prescribed dosage range is a violation of 10 CFR 35.63(d).

b. Medical Events Assessment

Upon discovery of the incident, the licensee contacted its medical physicist to perform a dose calculation to determine the extent of the dose to the patient. The calculations showed a whole body dose of 6 rem. Licensee medical personnel determined that there were no expected adverse effects to the patient as a result of the administration. Based on the whole body dose, the administration met the definition of a medical event as defined in 10 CFR 35.2.

The inspector determined that the root cause of the medical event was a lack of attention to detail on the part of a licensee staff member. Specifically, the staff member failed to verify that the administered unit dosage was within the prescribed dosage range for a bone scintigraphy procedure. As corrective actions to prevent recurrence of the event and to prevent a similar violation, the staff member was counseled and will undergo retraining in the licensee's procedures for the safe use of unsealed licensed material. Upon completion of that training, the staff member will formally acknowledge responsibility and understanding of the licensee's procedures for the safe use of unsealed licensed materials. For a period of 90 days, the staff member will be re-evaluated every 30 days by a licensee manager regarding adherence to and performance of the licensee's procedures for the safe use of unsealed licensed materials. Also, during this 90-day period, a second individual will verify the following: correct patient, correct radioactive drug, correct prescribed dosage, and correct route of administration, prior to administering any radiopharmaceutical to any patient. In addition, the licensee will no longer keep bulk Tc-99m sodium pertechnetate or radiopharmaceutical cold kits on hand for imaging in the event of add-on patients, and will instead order unit dosages as needed.

2.3 Conclusions

The inspector determined that this was an isolated event in which the staff member failed to follow the licensee's procedure to ensure that the proper dosage was administered to a patient. The inspector determined that a violation of 10 CFR 35.63(d) occurred. The inspector determined that the licensee's corrective actions and assessment of the medical event were adequate.

3 Notifications and Reports

3.1 Inspection Scope

The inspector reviewed selected records and interviewed selected licensee staff to understand the licensee's response to the discovery of the medical event. The inspectors reviewed the initial notification to the NRC Operations Center and the licensee's written report to the Region III office.

3.2 Observations and Findings

The inspector determined that both the referring physician and the patient were notified of the incident within one day of the occurrence. The NRC Operations Center was notified of the event on June 3, 2016, which was within the one-day reporting requirement. The Region III office received the licensee's written report on June 16, 2016, which was within the 15-day written report requirement. After further review, the inspector determined that all of the information required by 10 CFR 30.3045(d) was included in the written report.

3.3 Conclusions

The inspector determined that the licensee provided the notifications and written report as required by 10 CFR 35.3045.

4 Exit Meeting Summary

On June 13, 2016, the NRC inspector presented preliminary inspection findings during the onsite reactive inspection. After further in-office review of pertinent documents, including the medical event written report; and additional telephonic discussions with the licensee to verify and clarify certain details, the inspector conducted a final exit meeting with the licensee by telephone on July 21, 2016.

PARTIAL LIST OF PERSONNEL CONTACTED

Avery L. Behrle, RT(R)(CT), CNMT, Chief Nuclear Medicine Technologist
#* Dan Moran, RT(R)(CT), RDMS, Radiology Manager
#* Christopher M. Wibbenmeyer, MBA, FACHE, Vice President of Operations
Teresa Denninger, RT(R), Nuclear Medicine Technologist

Attended preliminary exit meeting on June 13, 2016
* Participated in telephone exit meeting on July 21, 2016