NRC FORM 591M PART 1
(07-2012)
10 CFR 2.201

U.S. NUCLEAR REGULATORY COMMISSION

# SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

| 1. LICENSEE/LOCATION INSPECTED: | 2. NRC/REGIONAL OFFICE |
|---|---|
| Phelps County Regional Medical Center<br><br>1000 W. 10th St.,<br>Rolla, MO 65401<br><br>REPORT NUMBER(S) 2022001 | Region III<br>U. S. Nuclear Regulatory Commission<br>2443 Warrenville Road, Suite 210<br>Lisle, IL 60532-4352 |

| 3. DOCKET NUMBER(S) | 4. LICENSE NUMBER(S) | 5. DATE(S) OF INSPECTION |
|---|---|---|
| 030-14804 | 24-18295-01 | September 1, 2022 |

**LICENSEE:**

The inspection was an examination of the activities conducted under your license as they relate to radiation safety and to compliance with the Nuclear Regulatory Commission (NRC) rules and regulations and the conditions of your license. The inspection consisted of selective examinations of procedures and representative records, interviews with personnel, and observations by the inspector. The inspection findings are as follows:

☐ 1. Based on the inspection findings, no violations were identified.

☐ 2. Previous violation(s) closed.

☑ 3. The violations(s), specifically described to you by the inspector as non-cited violations, are not being cited because they were self-identified, non-repetitive, and corrective action was or is being taken, and the remaining criteria in the NRC Enforcement Policy, to exercise discretion, were satisfied.

1 Non-cited violation(s) were discussed involving the following requirement(s):

Condition 13A. of License No. 24-18295-01 (Amendment No. 57) of the license states in part "...the licensee shall conducts its program in accordance with the statements, representation, and procedures contained in the documents including any enclosures listed below." Item 4 of the licensee's injection procedures revised on December 2016, states in part "Prior to administration, the technologist will check the requisition...to ensure that the patient is receiving the correct radio pharmaceutical for the prescribed study."
Contrary to the above, on July 29, 2020, the licensee staff failed to check the requisition and administered 25 mCi of technetium-99m (Tc-99m) of MDP for bone scan instead of 30 mCi of Tc-99m of Sestamibi for cardiac scan.
Continued in Part 2.

☐ 4. During this inspection, certain of your activities, as described below and/or attached, were in violation of NRC requirements and are being cited in accordance with NRC Enforcement Policy. This form is a NOTICE OF VIOLATION, which may be subject to posting in accordance with 10 CFR 19.11.
(Violations and Corrective Actions)

## Statement of Corrective Actions

I hereby state that, within 30 days, the actions described by me to the Inspector will be taken to correct the violations identified. This statement of corrective actions is made in accordance with the requirements of 10 CFR 2.201 (corrective steps already taken, corrective steps which will be taken, date when full compliance will be achieved). I understand that no further written response to NRC will be required, unless specifically requested.

| TITLE | PRINTED NAME | SIGNATURE | DATE |
|---|---|---|---|
| LICENSEE'S REPRESENTATIVE | | | |
| NRC INSPECTOR | Zahid Sulaiman, Health Physicist | Zahid M. Sulaiman Digitally signed by Zahid M. Sulaiman Date: 2022.09.14 17:56:21 -05'00' | |
| BRANCH CHIEF | Michael Kunowski, Chief, MIB | Michael A. Kunowski Digitally signed by Michael A. Kunowski Date: 2022.09.16 08:50:08 -05'00' | |

NRC FORM 591M PART 2
(07-2012)
10 CFR 2.201

U.S. NUCLEAR REGULATORY COMMISSION

# SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

| 1. LICENSEE/LOCATION INSPECTED: | 2. NRC/REGIONAL OFFICE |
|---|---|
| Phelps County Regional Medical Center<br><br>1000 W. 10th St.,<br>Rolla, MO 65401<br><br>REPORT NUMBER(S) 2022001 | Region III<br>U. S. Nuclear Regulatory Commission<br>2443 Warrenville Road, Suite 210<br>Lisle, IL 60532-4352 |

| 3. DOCKET NUMBER(S) | 4. LICENSE NUMBER(S) | 5. DATE(S) OF INSPECTION |
|---|---|---|
| 030-14804 | 24-18295-01 | September 1, 2022 |

(Continued)

The licensee immediately identified the error and determined the root cause of the violation was human error, As corrective action, licensee standardized the process of sorting vials according to test to be performed prior to injecting any patients, and the staff will mark any non-cardiac testing isotope label with black marker. The licensee also provided the technologist with additional training on standardized process and checking patient's requisition prior to injecting patients.

NRC FORM 592M
(10-2020)

U.S. NUCLEAR REGULATORY COMMISSION

# Materials Inspection Record

| 1. Licensee Name: | 2. Docket Number(s): | 3. License Number(s) |
|---|---|---|
| Phelps County Regional Medical Center | 030-14804 | 24-18295-01 |

| 4. Report Number(s): | 5. Date(s) of Inspection: |
|---|---|
| 2022001 | September 1, 2022 |

| 6. Inspector(s): | 7. Program Code(s): | 8. Priority: | 9. Inspection Guidance Used: |
|---|---|---|---|
| Zahid Sulaiman, Health Physicist | 02230 | 2 | 87131 & 87132 |

| 10. Licensee Contact Name(s): | 11. Licensee E-mail Address: | 12. Licensee Telephone Number(s): |
|---|---|---|
| Christopher Spencer, M.D., RSO | spenc@phelpshealth.org | Work: (573) 458-7500<br>Cell: (314) 401-4431 |

| 13. Inspection Type: | 14. Locations Inspected: | 15. Next Inspection Date (MM/DD/YYYY): |
|---|---|---|
| ☐ Initial<br>☑ Routine ☐ Announced<br>☐ Non-Routine ☑ Unannounced | ☑ Main Office ☐ Field Office<br>☐ Temporary Job Site ☐ Remote | 09/01/2024<br>☑ Normal ☐ Extended<br>☐ Reduced ☐ No change |

16. Scope and Observations:

This was a routine, unannounced, inspection of a regional hospital located in Rolla, Missouri, with authorization to use byproduct materials under 10 CFR Sections 35.100, 35.200, 35.300, 35.400, and 35.600 (Iridium-192, high dose rate (HDR) remote afterloader). The nuclear medicine department at the main hospital was staffed with two full-time and a part-time nuclear medicine technologists (NMTs). The NMTs typically administered approximately 8 diagnostic doses daily using Technicium-99m (Tc-99m), primarily for cardiac, renal, HIDA, bone scan, gastric emptying, and thyroid uptake scan. Licensee performed all therapeutic administrations and brachytherapy treatments at the Delbert Day cancer institute located at 1060 W. 10th St.

The nuclear medicine department at the cancer institute was staffed with two full-time NMTs who performed approximately 4 PET/CT scans daily using fluorine-18 (FDG), 5 radium-223 Xofigos, and 9 iodine-131 (I-131) hyperthyroid and thyroid ablations annually. The cancer center was staffed with two oncologists, an authorized medical physicist (AMP), and four therapists who performed approximately 50 HDR gynecologic cancer treatments annually. The licensee has not performed manual brachytherapy procedures for over 5 years.

PERFORMANCE OBSERVATIONS

This inspection consisted of a tour of the nuclear medicine departments, cancer center, interviews with select licensee personnel, a review of select records, an observation of security of the materials, and independent measurements. The inspector observed an NMT prepare and administer a diagnostic dose using Tc-99m to a patient. The inspector had an NMT conduct a physical inventory of sealed sources, and all sources were accounted for. The inspector had the NMT demonstrate the dose calibrator constancy check, package receipt procedures, the end of the day daily and weekly area surveys, proper handling of radioactive waste and disposal procedures, with no issues noted. The inspector performed independent and confirmatory radiation measurements which indicated results consistent with licensee survey records and postings.

The inspector had the AMP demonstrate the HDR unit's: (1) security; (2) daily spot checks; (3) emergency equipment and procedures; (4) safety procedures and instructions; (5) door interlock system; (6) radiation monitoring equipment checks; and (7) full calibration measurement. The last HDR source was exchanged on August 24, 2022. The inspector reviewed select HDR, Ra-223, and I-131 written directives, pre- and post-treatment plans. Through these observations, demonstrations and other discussions, the inspector found that the licensee personnel were knowledgeable of radiation protection principles, licensee procedures, and regulatory requirements.

## Materials Inspection Record (Continued)

The inspector reviewed the following records: annual program reviews, radiation safety committee minutes, quarterly program audits, package receipts, waste disposal records, DOT hazmat training, constancy, linearity, and accuracy tests of the dose calibrator, sealed source leak tests and inventory, daily area surveys, and weekly wipe tests. The inspector reviewed the dosimetry records for 2021 through January 14, 2022, indicating the maximum annual dose to be 386 mrem - DDE, and 2,238 mrem - SDE. The inspector also reviewed a declared pregnancy fetal monitoring dose and the results were within the regulatory limits. The licensee had issues getting on-time dosimetry badge reports from the vendor, due to the vendor's delay in processing the dosimetry badges. The licensee was planning to switch to a new vendor to get timely dosimetry badges processed and reports issued.

During the inspection, the licensee informed the inspector of a misadministration that occurred on July 29, 2022, where the NMT administered 25 mCi of technetium-99m (Tc-99m) of MDP for bone scan instead of the intended 30 mCi of Tc-99m of Sestamibi for a cardiac scan. The NMT identified the error, immediately notified the RSO, authorized user, and the patient's exam was reschedule for 2 days later. The licensee determined that there was no adverse effect to the patient. The root cause determined was human error. As corrective action, the licensee standardized the process of sorting vials according to test to be performed and the staff will mark any non-cardiac testing isotope label with black marker prior to injecting any patients. The licensee provided the technologist with additional training on standardized process and checking patient's requisition prior to injecting patients. Since this violation was self-identified, non-repetitive, and non-willful, and corrective actions have already been taken to address the non-compliance and the potential for recurrence, the NRC characterized the violation as a Non-Cited Violation (NCV) in accordance with Section 2.3.2.b of the Enforcement Policy.