

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE/LOCATION INSPECTED

Roane General Hospital
200 Hospital Drive
Spencer, WV 25276-1060

2. NRC/REGIONAL OFFICE

Region 1
475 Allendale Rd
Suite 102
King of Prussia, PA 19406

REPORT NUMBER(S) 2022001

3. DOCKET NUMBER(S)

030-12105

4. LICENSE NUMBER(S)

47-17046-01

5. DATE(S) OF INSPECTION

10/17/2022 - 11/15/2022

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 violation(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.

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

- ☒ 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 the 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)

A) 10 CFR 20.1801 states that the licensee shall secure from unauthorized removal or access licensed materials that are stored in controlled or unrestricted areas.

Contrary to the above, prior to October 17, 2022, the licensee did not secure from unauthorized removal or access licensed materials that are stored in controlled or unrestricted areas. Specifically, the licensee was storing licensed material in the designated hot lab, which was accessible by custodial staff who were not authorized for access to radioactive materials, and the materials were not otherwise secured or under surveillance.

This is a Severity Level IV violation (Enforcement Policy Section 6.7.d).

B) 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 than 20 percent.

Contrary to the above, without being otherwise directed by the authorized user, the licensee used dosages that did not fall within the prescribed dosage range or the dosage differed from the prescribed dosage by more than 20 percent. Specifically, throughout calendar years 2021 and 2022, multiple instances were identified of the licensee administering Tc-99m dosages greater than the approved dosage range of 25-30mCi of Tc-99m for stress tests. For example, between October 3 and October 6, 2022, stress doses of Tc-99m were administered with activities of 32.90 mCi, 32.7 mCi, 32 mCi, 31.8 mCi, and 31.7 mCi.

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

The NRC has concluded that information regarding: (1) the reason for the violation(s); (2) the corrective actions that have been taken and the results achieved; and (3) the date when full compliance was achieved is already adequately addressed on the docket and include:

For violation A, on October 17, 2022, the licensee temporarily removed access to the area for non-radiation workers until the licensee could relocate the licensed materials to a new, secure storage location as confirmed on October 31, 2022.

For violation B, on October 20, 2022, an authorized user for the licensee expanded the approved dosage range for stress tests and provided training to the nuclear medicine technologist(s) to seek approval for the administering of doses outside of the approved dosage range.

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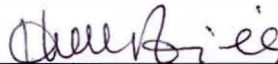
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Statement of Corrective Actions

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	Holly Fields, Radiology Manager		12-12-22
NRC INSPECTOR	Jonathan Pfingsten	Jonathan B. Pfingsten <small>Digitally signed by Jonathan B. Pfingsten Date: 2022.12.05 09:14:17 -05'00'</small>	
BRANCH CHIEF	Anne DeFrancisco	Anne E. DeFrancisco <small>Digitally signed by Anne E. DeFrancisco Date: 2022.12.09 08:20:38 -05'00'</small>	