NRC FORM 591M
(04-2022)

U.S. NUCLEAR REGULATORY COMMISSION

Materials Inspection Report

1. Licensee/Location Inspected:	2. NRC/Regional Office
Freeman - Oak Hill Health System 1102 W 32nd St. Joplin, Missouri 64804 Report Number(s) 2023001	Region III U. S. Nuclear Regulatory Commission 2443 Warrenville Road, Suite 210 Lisle, IL 60532-4352

3. Docket Number(s)	4. License Number(s)	5. Date(s) of Inspection
030-12360	24-17205-01	January 11-26, 2023

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. During this inspection, certain of your activities, as described below and/or attached, were in violation of NRC requirements, and were assessed at Severity Level IV, in accordance with the NRC Enforcement Policy.

A. 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, corrective action was or is being taken, and the remaining criteria in the NRC Enforcement Policy were satisfied.
(Non-cited violation(s) was/were discussed involving the following requirement(s)

B. The following violation(s) is/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)

License Condition No. 13.A. requires, in part, that the licensee conduct its program in accordance with the statements, representations, and procedures contained in the application dated March 18, 2013.

Item 10 of the application dated March 18, 2013, states that the licensee has developed and will implement and maintain procedures for safe use of unsealed byproduct material that meet the requirements of 10 CFR 20.1101 and 10 CFR 20.1301. (continued on Page 2)

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 AND DATE
LICENSEE'S REPRESENTATIVE	PETER SITH, PhD	2023 · Feb · 13
NRC INSPECTOR	Geoffrey Warren, Sr. HP	Geoffrey M. Warren Digitally signed by Geoffrey M. Warren Date: 2023.02.08 14:00:53 -06'00'
BRANCH CHIEF	Rhex Edwards	Digitally signed by Rhex A. Edwards Date: 2023.02.11 13:13:21 -06'00'

Add Continuation Page

Materials Inspection Report (Continued)

(continued from Page 1)

Item 13 of the licensee's "General Rules for the Safe Use of Radiopharmaceuticals" requires, in part, that each patient dosage be assayed in the dose calibrator before administration to assure it is within 10% of the prescribed activity.

Contrary to the above, on January 26, 2023, a technologist administered a diagnostic radiopharmaceutical, a nominal 30-mCi technetium-99m cardiac stress dose, without first assaying it in a dose calibrator. The root cause of the violation was that the technologist was unaware of the requirement, believing that it was sufficient to check that the dosage calibration time was within an hour of the time of administration. As corrective action, licensee management discussed with each technologist that assaying each dosage prior to administration is required. In addition, this will be a topic of discussion at a meeting on February 16, 2023.

NRC FORM 592M
(10-04-2022)

U.S. NUCLEAR REGULATORY COMMISSION

Materials Inspection Record

1. Licensee Name:	2. Docket Number(s):	3. License Number(s)
Freeman - Oak Hill Health System	030-12360	24-17205-01

4. Report Number(s):	5. Date(s) of Inspection:
2023001	January 11-26, 2023

6. Inspector(s):	7. Program Code(s):	8. Priority:	9. Inspection Guidance Used:
Geoffrey Warren, Sr. HP	02230	2	IP 87130, 87132

10. Licensee Contact Name(s):	11. Licensee E-mail Address:	12. Licensee Telephone Number(s):
Peter Situ, Ph.D, RSO	Peter.Situ@physics1.com	573-424-1845

13. Inspection Type:	14. Locations Inspected:	15. Next Inspection Date (MM/DD/YYYY):
☐ Initial	☑ Hybrid	
☑ Routine ☑ Announced	☑ Main Office ☑ Field Office	01/11/2025 ☑ Normal ☐ Extended
☐ Non-Routine ☐ Unannounced	☐ Temporary Job Site ☐ Remote	☐ Reduced ☐ No change

16. Location(s) Inspected List:
Freeman Hospital West, 1102 W. 32nd St., Joplin, Missouri
Freeman Hospital East, 932 E. 34th St., Joplin, Missouri

17. Scope and Observations:

This was an announced routine inspection. The licensee operated two medical facilities in Joplin, Missouri; Freeman Hospital West (West) was a 380-bed hospital and Freeman Hospital East (East) was an outpatient facility. The licensee had authorization to perform diagnostic and therapeutic nuclear medicine (NM) procedures as well as brachytherapy and high dose rate (HDR) remote afterloader procedures. While the licensee possessed cesium-137 seeds in storage, no brachytherapy procedures had been performed for several years.

The licensee operated four NM areas, two at West and two at East. Five technologists rotated through the four areas. Typically, at West, the licensee staffed one technologist at NM and two in cardiology; at East, one in NM and one in PET. Licensee staff performed approximately 800 procedures monthly combined in the four areas, the majority in cardiology. All doses were unit doses received from a licensed radiopharmacy except at NM West, where the licensee occasionally used bulk technetium-99m to prepare doses. The NM areas performed a variety of diagnostic procedures. Radiopharmaceutical therapy procedures were performed at both, around two monthly, but iodine-131 procedures over 33 mCi and radium-223 dichloride procedures were performed only at NM East; NM West was limited to iodine-131 below 33 mCi. Procedures in the cardiology area included only cardiac stress testing, and procedures in the PET area included fluorine-18 and copper-64 cancer imaging. All waste was either held for decay-in-storage or returned to the radiopharmacy. A physics consultant performed quarterly reviews of activities at all four NM areas.

The radiation oncology department was staffed with one physician authorized user, two medical physicists, and one dosimetrist. The radiation therapy staff performed approximately ten HDR fractions monthly on average, including gynecological (tandem and ring or cylinder), skin, and breast treatments, and was working toward adding prostate cancer and interstitial HDR procedures.

Performance Observations: The inspector observed three diagnostic administrations of licensed materials, including preparation of doses and disposal of waste; and one HDR procedure, including imaging and planning. Licensee staff

Materials Inspection Record (Continued)

demonstrated or described daily checks for nuclear medicine and HDR; package receipt and return surveys, a variety of diagnostic procedures, iodine-131 and radium-223 therapeutic procedures, and daily and weekly contamination surveys. The inspector noted no concerns with these activities except as noted below. The inspector verified the inventory of cesium-137 seeds in storage. The inspector reviewed written directives for radiopharmaceutical therapies and HDR treatments and identified no concerns. Interviews with licensee personnel indicated adequate knowledge of radiation safety concepts and procedures. Review of radiation dosimetry records indicated no exposures of concern. Review of Radiation Safety Committee minutes indicated good attendance and discussion of appropriate topics. The inspector performed independent and confirmatory radiation measurements that were consistent with licensee survey records and postings.

Note that this inspection was started remotely Jan. 11, 2022, and was completed on site Jan. 26.

The inspector observed a violation of License Condition 13.A. to the license concerning the failure for a technologist to verify a diagnostic dosage in the dose calibrator prior to administration, as described on the Form 591M. There is no indication that the dosage was outside the prescribed range for the procedure. The root cause of the violation was that the technologist was unaware of the requirement, believing that it was sufficient to check that the dosage calibration time was within an hour of the time of administration. As corrective action, licensee management discussed with each technologist that assaying each dosage prior to administration is required. In addition, this will be a topic of discussion at a meeting on February 16, 2023.

Signature and Date - Branch Chief

Digitally signed by Rhex A. Edwards
Date: 2023.02.11 13:12:50 -06'00'

From: Peter Situ
To: Geoffrey Warren
Subject: [External_Sender] Freeman-Oakhill Health System, response to report 2023001
Date: Monday, February 13, 2023 3:45:34 PM
Attachments: Doc Feb 13, 2023, 3_13.pdf

Geoff-

Attached is the signed and dated copy of the Materials Inspection Report for January 26, 2023.

As I mentioned on the phone, all of the NMTs have received what the Freeman Health System employee manual calls a "Verbal Coaching" (which is in our internal documentation in Section IX, C.1.) in the correct way to follow the published procedures- including the mentioned Items 10 & 13 which are subsets of the license condition No 13.A..

Our Nuclear Medicine department meeting is this Thursday, and the highlights of this report will be entered into the minutes-- including all Q&As, and acknowledgements of receiving corrective actions. I will add those minutes to the next Radiation Safety Committee meeting minutes to assure transparency and completeness of the record.

Thank you for the opportunity to improve,

-Peter