

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE/LOCATION INSPECTED

Beebe Medical Center
424 Savannah Road
Lewes, DE 19958

2. NRC/REGIONAL OFFICE

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

REPORT NUMBER(s) 2022001

3. DOCKET NUMBER(S)

030-13331

4. LICENSE NUMBER(S)

07-17792-01

5. DATE(S) OF INSPECTION

08/15/2022

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.

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

10 CFR 20.1501, in part, requires each licensee shall make or cause to be made, surveys of areas, including the subsurface, that are reasonable under the circumstances to evaluate concentrations or quantities of residual radioactivity. Contrary to the above, between June 22, 2022 and August 3, 2022 the licensee didn't make or cause to be made, surveys of areas, including the subsurface, that are reasonable under the circumstances to evaluate concentrations or quantities of residual radioactivity. Specifically, the licensee did not conduct surveys of the surgical areas where lymphoscintigraphy administrations of Tc99m were performed.

This is a SLIV in accordance with Section 6.3 of the NRC Enforcement Policy.

Corrective actions included staff education regarding surveys.

- 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)

10 CFR 35.27, in part, requires a licensee to instruct the supervised individual in the licensee's written radiation protection procedures, written directive procedures, regulations of this chapter, and license conditions with respect to the use of byproduct material. Contrary to the above, as of June 22, 2022 the licensee did not instruct the supervised individual in the licensee's written radiation protection procedures, written directive procedures, regulations of this chapter, and license conditions with respect to the use of byproduct material. Specifically, surgical staff performing lymphoscintigraphy procedures had not received training in the licensee's written radiation protection procedures, written directive procedures, regulations of this chapter, and license conditions with respect to the use of byproduct material.

This is a SLIV in accordance with Section 6.3 of the NRC Enforcement Policy.

Corrective actions include implementation of a training program for surgical staff operating under the supervision of an Authorized User. Training was completed by September 30, 2022.

10 CFR 35.63(d), in part, requires 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, between January 1, 2021 and March 24, 2022 without being otherwise directed by the authorized user, the licensee used a dosage that did not fall within the prescribed dosage range or the dosage differed from the prescribed dosage by more than 20 percent. Specifically, 5.5mCi, 5.6mCi, and 5.2mCi of Tc99m MAA was administered for lung perfusion studies on January 1, 2021, January 11, 2021, and March 24, 2022, respectively, outside of the dosage range of 1-5mCi. Similarly, on March 2, 2022, 4.2 mCi of Tc99m Mebrofenin was administered for a HIDA scan outside of the dosage range of 5-7mCi.

This is a SLIV in accordance with Section 6.3 of the NRC Enforcement Policy.

Corrective actions include establishment of a new dosage range and staff education on the new dosage range.

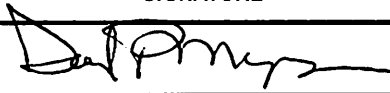
SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE/LOCATION INSPECTED Beebe Medical Center 424 Savannah Road Lewes, DE 19958 REPORT NUMBER(s) 2022001	2. NRC/REGIONAL OFFICE Region 1 475 Allendale Rd Suite 102 King of Prussia, PA 19406
--	---

3. DOCKET NUMBER(S) 030-13331	4. LICENSE NUMBER(S) 07-17792-01	5. DATE(S) OF INSPECTION 08/15/2022
---	--	---

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	Dan Mapes		10/13/22
NRC INSPECTOR	Patrick-John Hann	Patrick-John E. Hann <small>Digitally signed by Patrick-John E. Hann Date: 2022.10.12 13:32:41 -04'00'</small>	
BRANCH CHIEF	Anne DeFrancisco	Anne E. DeFrancisco <small>Digitally signed by Anne E. DeFrancisco Date: 2022.10.12 11:00:12 -04'00'</small>	