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
BluePearl Michigan, LLC 29080 Inkster Road Southfield, MI 48034 REPORT NUMBER(S) 2022-001	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
030-37095	21-32607-01	03/29/22; exit 07/18/22

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.

_____ 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 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)

Contrary to 10 CFR 20.2103(a), as of March 29, 2022, BluePearl Michigan, LLC failed to maintain records showing the results of surveys required by §§ 20.1501(a) to demonstrate compliance with §§ 20.1301(a) prior to releasing patients administered licensed material. As corrective action for this Severity Level IV violation, licensee revised its forms to include a line for documenting surveys of patients prior to their release.

Contrary to 10 CFR 71.5(a), as of March 29, 2022, BluePearl Michigan, LLC failed to comply with 49 CFR 172.704(c)(2) which requires that hazmat employees receive hazmat training once every three years. As corrective action for this Severity Level IV violation, on July 18, 2022, the licensee's hazmat employee completed hazmat training, and set an electronic reminder to complete it again every three years.

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	MARC ELIE		08/4/22
NRC INSPECTOR	Ryan Craffey	Ryan Craffey Digitally signed by Ryan J. Craffey Date: 2022.07.18 13:41:00 -04'00'	
BRANCH CHIEF	Michael Kunowski	Michael A. Kunowski Digitally signed by Michael A. Kunowski Date: 2022.08.01 14:46:41 -05'00'	

NRC FORM 592M
(10-2020)

U.S. NUCLEAR REGULATORY COMMISSION

Materials Inspection Record

1. Licensee Name:	2. Docket Number(s):	3. License Number(s)
BluePearl Michigan, LLC	030-37095	21-32607-01

4. Report Number(s):	5. Date(s) of Inspection:
2022-001	March 29, 2022; exit July 18, 2022

6. Inspector(s):	7. Program Code(s):	8. Priority:	9. Inspection Guidance Used:
Ryan Craffey	02400	5	IP 87126

10. Licensee Contact Name(s):	11. Licensee E-mail Address:	12. Licensee Telephone Number(s):
Marc Elie, DVM - RSO	marc.elie@bluepearlvet.com	248-354-6640

13. Inspection Type:	14. Locations Inspected:	15. Next Inspection Date (MM/DD/YYYY):
☐ Initial		
☑ Routine ☐ Announced	☑ Main Office ☐ Field Office	03/30/2027 ☑ Normal ☐ Extended
☐ Non-Routine ☑ Unannounced	☐ Temporary Job Site ☐ Remote	☐ Reduced ☐ No change

16. Scope and Observations:

BluePearl Michigan was a specialty and emergency veterinary hospital authorized to use I-131 for treatment of hyperthyroidism in cats at its facility in Southfield, Michigan. At the time of the inspection, the licensee administered around a dozen capsules of I-131 to patients annually. Capsules containing between 2 and 4.5 mCi of I-131 were received from a local radiopharmacy and administered on Tuesdays. Patients were held at the facility at least 96 hours in lead-lined enclosures prior to being surveyed for release. All waste was held in the licensee's restricted area for decay in storage. The RSO (an internal medicine specialist) and one vet tech performed the administrations.

The inspector toured the facility in Southfield. All areas were adequately posted, and adequate ALARA measures were available. No licensed material nor residual contamination was present, as confirmed by surveys. No patients were scheduled for treatment in the near future. The inspector interviewed the RSO, observed demonstrations of receiving packages containing licensed material, and discussed procedures for administration of licensed material, holding patients, and handling waste. The inspector also reviewed a selection of records, including package receipt documentation, administration records, post-treatment instructions to owners, and waste handling records.

During a review of records, the inspector two SLIV violations. The first was of 10 CFR 20.2103(a) for failing to maintain records of patient release surveys required by 10 CFR 20.1501(a)(1) to demonstrate compliance with dose limits to members of the public in 10 CFR 20.1301(a)(2). The licensee did not document surveys of patients administered I-131 prior to release; therefore, the inspector was unable to verify that patients were released only after levels of radioactivity were confirmed to be less than 0.25 mR/hr at 1 foot, the criteria to which the licensee committed via License Condition 17.B. The second violation was of 10 CFR 71.5(a) for failing to provide hazmat training every three years, as required by 49 CFR 172.704(c)(2). The licensee's RSO and sole hazmat employee (he received all packages containing I-131) did not recall having previously taken this training.

The root cause of both violations was a lack of understanding of regulatory requirements. As corrective action for the first violation, the licensee revised form SOP-005, Material Receipt and Accountability, to include a line for documenting surveys of patients prior to their release. As corrective action for the second violation, on July 18, 2022, the licensee's RSO completed hazmat training and set an electronic reminder to complete it again once every three years.