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
Essential Isotopes 1513 Research Park Drive Columbia, MO 65211 REPORT NUMBER(S) 2022001	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
030-38132 & 030-38129	24-32762-02 & 24-32762-01MD	August 30, 2022 with in-office review through Sept 13, 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.

_____ 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)

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 17:54:39 -05'00'	
BRANCH CHIEF	Michael Kunowski, Chief, MIB	Michael A. Kunowski Digitally signed by Michael A. Kunowski Date: 2022.09.16 07:42:52 -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)
Essential Isotopes	030-38132 & 030-38129	24-32762-02 & 24-32762-01MD

4. Report Number(s):	5. Date(s) of Inspection:
2022001	August 30, 2022 with in-office review through Sept 13, 2022

6. Inspector(s):	7. Program Code(s):	8. Priority:	9. Inspection Guidance Used:
Zahid Sulaiman, Health Physicist	03210; 02500	2	87125 & 87127

10. Licensee Contact Name(s):	11. Licensee E-mail Address:	12. Licensee Telephone Number(s):
Andrew Borrok, ANP, RSO	Aborrok@radiopharmacy.com	Work: (573) 882-0245 Cell: (660) 341-4235

13. Inspection Type:	14. Locations Inspected:	15. Next Inspection Date (MM/DD/YYYY):
☐ Initial		
☑ Routine ☐ Announced	☑ Main Office ☐ Field Office	08/30/2024 ☑ Normal ☐ Extended
☐ Non-Routine ☑ Unannounced	☐ Temporary Job Site ☐ Remote	☐ Reduced ☐ No change

16. Scope and Observations:

This was an unannounced routine inspection of a licensee that possessed a cyclotron-production and a radiopharmacy manufacturing and distribution license. The licensee was authorized to produce, prepare, and distribute radioactive drugs to authorized clients. The licensee used its cyclotron to produce flourine-18 (FDG), and nitrogen-13 (N-13) labeled ammonia; the majority of production involved F-18 FDG. The licensee was staffed with three authorized nuclear pharmacists (ANPs), two production technicians, two radiochemists, a cyclotron engineer, and six drivers. The licensee had 25 clients, dispensed approximately 59-60 unit doses daily, and distributed to customers within a 100-mile radius. The licensee's two production runs occurred between 3:00 am and 7:00 am, Monday - Friday. The radiochemical produced by the cyclotron was transfered via shielded lines to a hot cell to be processed and developed for distribution. The PharmaLogic Holdings Corp. acquired 55% of the licensee's ownership and plan to own 100% within a few months.

PERFORMANCE OBSERVATIONS

This inspection consisted of interviews with select licensee personnel; a review of select records; a tour of the facility; and independent measurements. At the time of inspection, the inspector observed the N-13 production run activities, transfer of materials to hot cell, chemical processing, QA/QC process, kit labeling and preparation, the use of robotic arms to draw a unit dose, clients order processing, client package preparation, DOT package labeling, package surveys, a driver blocked and braced the package in the car for delivery and kept the bill of lading within arms reach; no issues noted. The inspector had the ANP discussed and demonstrated how the radiochemicals are developed and processed in the hot cell, the use of robotic arms to draw doses, and how the packages are prepared for distribution, and as well as client package return and waste handling. The ANP also demonstrated the F-18 chemistry process, radionuclide purity check, and QA/QC process. The inspector observed that staff wore the assigned dosimetry ring and body badge, wore gloves and protective clothing while handling radiochemical, and monitored their hands and feet for contamination before exiting the restricted area.

The inspector had the cyclotron engineer demonstrate the daily cyclotron pre-initialization process, implementation procedures for cyclotron operations, byproduct materials productions, maintenance, area surveys, and waste handling. Interviews with licensee staff and through demonstrations indicated the licensee's staff to be knowledgeable of radiation protection principles and regulatory requirements.

The inspector reviewed the annual program audit reports (2020 & 2021), dose calibrator constancy, linearity, accuracy; well counter efficiency test, survey meter calibration, weekly wipes and daily survey records; waste

Materials Inspection Record (Continued)

disposals records and waste shipment manifest; DOT hazmat training; radionuclide purity check; sealed source inventory and leak test reports; and the 2021 annual air emission COMPLY report. The inspector also reviewed the dosimetry records for 2021 through May 31, 2022, which indicated the maximum annual dose to be 2.02 rem - DDE and 12.86 rem - SDE. The inspector performed independent and confirmatory radiation measurements which indicated results consistent with the licensee's survey results and within regulatory limits.

No violations of NRC requirements were identified as a result of this inspection.