

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE/LOCATION INSPECTED:

Essential Isotopes  
1513 Research Park Drive  
Columbia, MO 65211

REPORT NUMBER(S) 2019-001

2. NRC/REGIONAL OFFICE

Region III  
U. S. Nuclear Regulatory Commission  
2443 Warrenville Road, Suite 210  
Lisle, IL 60532-4352

3. DOCKET NUMBER(S)

030-38132 ; 030-38129

4. LICENSE NUMBER(S)

24-32762-02 ; 24-32762-01(M)

5. DATE(S) OF INSPECTION

10/23/19

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:


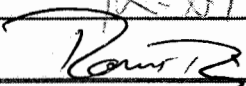
- ☒ 1. Based on the inspection findings, no violations were identified.
- ☐ 2. Previous violation(s) closed.
- ☐ 3. The violation(s), specifically described to you by the inspector as non-cited violations, are not being cited because they were self-identified, non-repetitive, and corrective action was 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 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	Kevin G. Null		10/23/19
BRANCH CHIEF	Robert Ruiz		11/18/19

**Docket File Information****SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION**

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24-32762-01MD; 24-32760-02

## 5. DATE(S) OF INSPECTION

October 23, 2019

## 6. INSPECTION PROCEDURES USED

87125 and 87126

## 7. INSPECTION FOCUS AREAS

All

**SUPPLEMENTAL INSPECTION INFORMATION**

## 1. PROGRAM CODE(S)

2500 and 3210

## 2. PRIORITY

2

## 3. LICENSEE CONTACT

Ronald Doby, CHP, RSO

## 4. TELEPHONE NUMBER

(573) 882-5218

☒ Main Office Inspection

Next Inspection Date: 10/23/2021

☐ Field Office Inspection☐ Temporary Job Site Inspection**PROGRAM SCOPE**

This was a routine, unannounced inspection of a licensee that possessed a cyclotron-production and a radiopharmacy distribution license. The licensee employed 3 nuclear pharmacists, 3 pharmacy technicians/delivery drivers, 1 cyclotron engineer, 1 delivery driver, and 1 radiation safety officer (RSO). The licensee had 10 clients within a 100 mile radius. Ninety-eight percent of the licensee's sales were unit doses of fluorine-18 (F-18) labeled FDG, and unit doses of F-18 labeled sodium fluoride, and nitrogen-13 labeled ammonia.

**Performance Observations**

The inspector toured the cyclotron-production and nuclear pharmacy manufacturing areas, and interviewed two nuclear pharmacists, the RSO, 2 pharmacy technicians, and the cyclotron engineer. Staff members described the flow-through of licensed material from radionuclide production in the cyclotron to pharmaceutical preparation, and delivery of unit doses to customers.

The inspector arrived at the facility prior to the licensee's second radiopharmaceutical run for day and observed a nuclear pharmacist prepare and measure a unit dose of F-18 labeled FDG. The inspector noted that the pharmacist utilized appropriate protective equipment and clothing, whole body and extremity dosimetry, and a calibrated survey meter and dose calibrator. The inspector noted that the licensee possessed, and staff members used, calibrated portable surveys meters for package and area surveys. The technicians demonstrated and/or described daily and weekly surveys of the cyclotron and radiopharmaceutical preparation areas.

The inspector was escorted by the RSO and a pharmacist to the roof of the licensee's facility and observed the exhaust system where F-18 effluent was released from licensed operations. The RSO and pharmacist described HEPA and charcoal filters that were in place to trap and reduce F-18 effluent to unrestricted areas. The RSO also explained the process and criteria for filter replacement.

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- ☐ Temporary Job Site Inspection \_\_\_\_\_

**PROGRAM SCOPE**

(continued)

The inspector interviewed the cyclotron engineer who described procedures that were followed for safety handling cyclotron targets and performing target rebuilds. The engineer described the use of protective equipment that included a laboratory coat, gloves, remote handling tools, whole body and extremity dosimetry, and a calibrated survey meter. The engineer also showed the inspector where target rebuilds were performed, and how and where old targets were stored to provide shielding and security.

The pharmacy technicians demonstrated package preparation for shipment of unit doses to client facilities which included surveys for radiation levels and removable contamination. The technicians also demonstrated how packages were secured in vehicles for shipment, and how they were marked and labeled for compliance with DOT regulations. The inspector also reviewed examples of shipping papers that accompanied each shipment.

The inspector reviewed personal dosimetry results for 2018 and 2019 to date, and records of daily and weekly area surveys, vehicle and package surveys, dose calibrator QA/QC for 3 dose calibrators, radioactive waste disposal, and records of effluent release and annual COMPLY code results.

No violations of NRC requirements were identified.