

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE/LOCATION INSPECTED: Essential Isotopes 1513 Research Park Drive Columbia, MO 65211 REPORT NUMBER(S) 2018001		2. NRC/REGIONAL OFFICE Region III U. S. Nuclear Regulatory Commission 2443 Warrenville Rd, Suite 210 Lisle, IL 60532	
3. DOCKET NUMBER(S) 030-38132; 030-38129	4. LICENSE NUMBER(S) 24-32762-02; 24-32762-01MD	5. DATE(S) OF INSPECTION April 11, 2018	

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	Zahid Sulaiman, Health Physicist	<i>Zahid Sulaiman</i>	5-8-2018
BRANCH CHIEF	Aaron T. McCraw, Chief, MIB	<i>ATM</i>	5/10/18

Docket File Information
SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE/LOCATION INSPECTED: Essential Isotopes 1513 Research Park Drive Columbia, MO 65211 REPORT NUMBER(S) 2018001	2. NRC/REGIONAL OFFICE Region III U. S. Nuclear Regulatory Commission 2443 Warrenville Rd, Suite 210 Lisle, IL 60532
---	--

3. DOCKET NUMBER(S) 030-38132; 030-38129	4. LICENSE NUMBER(S) 24-32762-02; 24-32762-01MD	5. DATE(S) OF INSPECTION April 11, 2018
---	--	--

6. INSPECTION PROCEDURES USED 87125; 87126	7. INSPECTION FOCUS AREAS 03.01 - 03.07
---	--

SUPPLEMENTAL INSPECTION INFORMATION

1. PROGRAM CODE(S) 02500; 03210	2. PRIORITY 2	3. LICENSEE CONTACT Ronald Dubey, CHP, RSO	4. TELEPHONE NUMBER (573) 882-5218
--	----------------------	---	---

Main Office Inspection Next Inspection Date: 04/11/2020

Field Office Inspection _____

Temporary Job Site Inspection _____

PROGRAM SCOPE

This was a routine inspection of a cyclotron production license with authorization to produce, prepare, and distribute radioactive drugs to authorized clients. The licensee used a GE cyclotron to produce flourine-18 (F-18), nitrogen-13 (N-13), and ammonia thallium; the majority of production involved F-18 FDG. The licensee had eight regular customers located in central Missouri and distributed approximately 22 doses each weekday. The licensee's two to three production runs occurred between 12:00 am and 8:00 am, Monday thru Friday. The radiochemical produced by the cyclotron was transferred via shielded lines to a hot cell to be process and developed for distribution. The licensee was staffed with three authorized nuclear pharmacist (ANP), one cyclotron engineer, two technicians, and two drivers. The technicians also performed courier duties.

Performance Observations

The inspection consisted of interviews with select licensee personnel; a review of select records; a tour of the facility; and independent measurements. The inspector observed a variety of activities on the licensee's second run, clients order processing, kit labeling and preparation, dose drawing, client package preparation, DOT package labeling, package surveys, and vehicle loading for compliance with NRC and DOT requirements, as well as client package return and waste handling. The ANP 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. The technician demonstrated the cyclotron maintenance and production run process, F-18 chemistry, radionuclide purity check, and QA/QC. Interviews with licensee staff and through demonstrations indicated the licensee's staff to be knowledgeable of radiation protection principles and regulatory requirements. 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 reviewed the dose calibrator constancy, linearity, accuracy, and a dose calibrator geometry test performed on Oct 10, 2017; weekly wipes and daily survey records; waste disposals; DOT hazmat training; annual audits; annual radionuclide purity check; sealed source inventory and leak test reports; and annual COMPLY air emission calculation.

Continued on next page.

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE/LOCATION INSPECTED: Essential Isotopes 1513 Research Park Drive Columbia, MO 65211 REPORT NUMBER(S) 2018001		2. NRC/REGIONAL OFFICE Region III U. S. Nuclear Regulatory Commission 2443 Warrenville Rd, Suite 210 Lisle, IL 60532	
3. DOCKET NUMBER(S) 030-38132; 030-38129	4. LICENSE NUMBER(S) 24-32762-02; 24-32762-01MD	5. DATE(S) OF INSPECTION April 11, 2018	

(Continued)

The inspector performed independent and confirmatory radiation measurements which indicated results consistent with the licensee's survey results and within regulatory limits. At the time of inspection, the inspector observed a radiation reading of approximately 40 mrem/hour at 30 centimeter, at the back of the hot cell exhaust line. While not a violation of regulatory requirements, the licensee stated it would implement additional controls to keep doses as low as reasonable achievable.

The inspector reviewed the dosimetry records for 2016, and till February 28, 2018 indicating the maximum annual dose to be 4.14 rem - DDE; and 12.28 rem - SDE. The inspector observed that the DDE reading of 4.14 rem was from one of the driver's October 2017 dosimetry badge result. The licensee investigated the driver's unusual monthly dosimetry reading and compared with rest of the year dosimetry reading which was minimal. The licensee concluded that it could be due to a bad badge reading. The inspector also reviewed the driver's dosimetry records since October 2017 till February 28, 2018 and the dosimetry results were minimal.

No violations of NRC requirements were identified during this inspection.