

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE/LOCATION INSPECTED:

Essential Isotopes
1513 Research Park Drive
Columbia, MO 65211

REPORT NUMBER(S) 2016-001

2. NRC/REGIONAL OFFICE

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

3. DOCKET NUMBER(S)

030-38129/0 30-38132

4. LICENSE NUMBER(S)

24-32762-01MD/24-32762-02

5. DATE(S) OF INSPECTION

April 14, 2016

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:

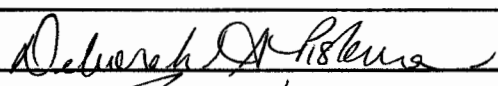

- ☒ 1. Based on the inspection findings, no violations were identified.
- ☐ 2. Previous violation(s) closed.
- ☐ 3. The violation(s), specifically described to you by the inspector as non-cited violations, are not being cited because they were self-identified, non-repetitive, and corrective action was 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	Deborah A. Piskura, Senior Health Physicist		4/14/16
BRANCH CHIEF	Aaron T. McCraw, Chief, MIB		4/21/16

Docket File Information

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6. INSPECTION PROCEDURES USED

87125/87127

7. INSPECTION FOCUS AREAS

03.01 - 03.07

SUPPLEMENTAL INSPECTION INFORMATION

1. PROGRAM CODE(S)

02500/03210

2. PRIORITY

2

3. LICENSEE CONTACT

Ronald Dobey, CHP, RSO

4. TELEPHONE NUMBER

(573) 882-5218

☒ Main Office Inspection

Next Inspection Date: 04/14/2018

☐ Field Office Inspection

☐ Temporary Job Site Inspection

PROGRAM SCOPE

This was a routine inspection of the cyclotron production license. The licensee used its GE cyclotron daily to produce F-18 for PET imaging agents; the majority of production involved F-18 FDG. One individual serving as the cyclotron engineer operated the cyclotron. Production activities typically ran between 12:00 am to 6:30 am, Monday thru Friday. As material was produced, it was transferred via shielded lines to a hot cell. Once the radiopharmaceuticals were developed and removed from the hot cell, the material was packaged for transfer to the company's radiopharmacy license (-01 MD) for distribution. Three individuals served as ANPs. Two individuals performed technician and courier duties. The licensee's RSO conducted annual audits of the radiation safety program. Individuals operating the cyclotron as well as the individuals handling the materials wore whole body and extremity (right and left rings) dosimetry. The maximum whole body and extremity exposures were reported (in millirem) as follows:

YTD 2/2016	2015
61	707
876	8,646

This inspection consisted of interviews with select licensee personnel; a review of select records; and independent surveys. The inspector toured the facility and observed operations. The inspector observed cyclotron operations and safety checks, surveys, and F-18 chemistry, purification, and QA/QC. For the pharmaceutical operations, the inspector observed early and mid-morning runs. These observations included dose calibrator QC/QA tests, drawing doses, packaging doses for shipment, and conducting surveys for compliance with NRC and DOT requirements. The inspector observed the licensee personnel performing the following radiation safety practices:

- All pharmacy personnel wore their assigned dosimetry
- Staff performed personal surveys prior to leaving the restricted area
- Staff wore gloves/protective clothing & used tongs/remote handling tools & remote manipulators while handling RAM
- No evidence of eating or drinking in the restricted areas

No violations of NRC requirements were identified during this inspection.