

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

<p>1. LICENSEE/LOCATION INSPECTED:</p> <p>Essential Isotopes 1513 Research Park Drive Columbia, Missouri</p> <p>REPORT NUMBER(S) 2014-001</p>	<p>2. NRC/REGIONAL OFFICE</p> <p>Region III U. S. Nuclear Regulatory Commission 2443 Warrenville Road, Suite 210 Lisle, IL 60532-4352</p>	
<p>3. DOCKET NUMBER(S)</p> <p>030-38132</p>	<p>4. LICENSE NUMBER(S)</p> <p>24-32762-02</p>	<p>5. DATE(S) OF INSPECTION</p> <p>July 22, 2014, in-office review through December 15, 2014</p>

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)

10 CFR 30.34(c) requires, in part, that each licensee confine his possession and use of byproduct materials to the locations and purposes authorized by the license. Condition 20 of Amendment No. 01 of License No. 24-32762-02 requires, in part, that the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in referenced documents, including the licensee's application dated August 10, 2009, with attachments. The application dated August 10, 2009, with attachments requires, in part, that the licensee perform a COMPLY calculation annually to determine compliance with the constraint on air emissions required by 10 CFR 20.1101(d). Specifically, between approximately May 24, 2012, and December 8, 2014, the licensee did not perform annual COMPLY calculations to determine compliance with the constraint on air emissions required by 10 CFR 20.1101(d).

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	Ronald J. Doby, Jr.	<i>Ronald J. Doby, Jr.</i>	12-22-14
NRC INSPECTOR	Robert G. Gattone, Jr.	<i>Robert G. Gattone, Jr.</i>	12/18/14
BRANCH CHIEF	Aaron T. McCraw	<i>Aaron T. McCraw</i>	12/18/14

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(Continued)

Corrective Actions:

The licensee achieved compliance with the requirement on 12/8/14. The delay was caused, in part, by several inspector requests for information needed to obtain reasonable assurance that the licensee's air effluent monitoring system was adequately calibrated. In addition, the licensee determined the ratio of radioactivity production relative to reliable radioactive air effluent results to retrospectively calculate the radioactive effluent results for 2012, 2013, and 2014 to date based on the applicable production records for those periods. As corrective action to prevent a similar violation, the licensee initiated a plan to conduct the annual COMPLY calculations for the licensed material effluents when the licensee conducts the annual COMPLY calculations for different radioactive effluents released from a research reactor, which had been done for years.

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

1. LICENSEE/LOCATION INSPECTED:

Essential Isotopes
1513 Research Park Drive
Columbia, Missouri

REPORT NUMBER(S) 2014-001

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

4. LICENSE NUMBER(S)

24-32762-02

5. DATE(S) OF INSPECTION

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through December 15, 2014

6. INSPECTION PROCEDURES USED

87125

7. INSPECTION FOCUS AREAS

02.01 through 02.07

SUPPLEMENTAL INSPECTION INFORMATION

1. PROGRAM CODE(S)

03210

2. PRIORITY

2

3. LICENSEE CONTACT

Ron Dobey, RSO

4. TELEPHONE NUMBER

(573) 882-5218

 Main Office Inspection

Next Inspection Date: 07/22/2016

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

The licensee primarily produced, possessed, and handled radiochemicals for transfer to authorized persons. Sodium flouride-18 and copper-64 chloride solutions were produced for transfer to authorized persons for labeling. Two to three flourine-18 production runs occurred per day. Copper-64 runs occurred twice per month. Licensed activities were conducted by, or under the supervision of, four authorized users from midnight to 8:00 am on weekdays. No cyclotron use or cyclotron maintenance occurred during the onsite inspection.

Performance Observations

The inspector: (1) reviewed selected records showing that the licensee transferred licensed material to authorized persons; (2) reviewed selected shipping papers that had been used; (3) observed that the facility was posted as required; (4) observed that the cyclotron facility was secured and had operable safety features (e.g., cyclotron status indicators, interlocks, etc.); (5) observed an authorized user demonstrate how licensed material was produced; (6) observed that licensed material was secured; (7) observed a personal protection equipment don & doff area that was equipped with hand and foot radiation monitors that were used to conduct personal radiation surveys prior to leaving a restricted area; (8) observed that the facility was as authorized; (9) used a calibrated NRC survey instrument to measure 10 milliroentgens per hour just beyond the shielded cyclotron facility maze with the cyclotron beam off; (10) observed the air effluent filter beds and stacks on the roof of the facility; (11) observed that selected fire extinguishers were charged and checked at the frequency on the affixed tags; (12) observed selected air sampling system hardware; (13) observed that a licensee survey instrument was calibrated as required; (14) reviewed dosimetry badge records showing that the highest whole body and extremity doses received by radiation workers since May 2012 were 1077 millirems and 10686 millirems, respectively; (15) reviewed recent area ambient dose rate survey records; (16) reviewed recent area removable contamination survey records; (17) observed an authorized user conduct an inventory of selected sealed sources and there was no discrepancy with the inventory record; (18) observed sealed source leak test records; (19) observed a Reactor Services Engineer demonstrate how she had measured the face velocity of a fume hood; (20) observed an authorized user handle licensed material in a hot cell while wearing two ring dosimeters and a whole body dosimeter; (21) observed an authorized user conduct radioactive package surveys prior to transfer; (22) observed that a radioactive package was marked and labeled as required; (23) reviewed audit records for 2012 and 2013; (24) reviewed information regarding how the air effluent monitoring system was calibrated; and (25) reviewed the licensee's COMPLY calculations for 2012, 2013, and 2014 to date which showed the licensee complied with 10 CFR 20.1101(d).