NRC FORM 591M PART 1
(1-2012)
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, Missouri 65211 REPORT NUMBER(S) 2012-001	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
030-38129, 030-38132	24-32762-01MD, 24-32762-02	May 24, 2012

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	Geoffrey M. Warren	GM Warren	5/24/12
BRANCH CHIEF	Tamara E. Bloomer	Ken Lambert for	6/8/12

NRC FORM 591M PART 3
(1-2012)
10 CFR 2.201

U.S. NUCLEAR REGULATORY COMMISSION

Docket File Information

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6. INSPECTION PROCEDURES USED	7. INSPECTION FOCUS AREAS
87127, 87125	03.01 – 03.07, 03.01 – 03.07

SUPPLEMENTAL INSPECTION INFORMATION

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

☑ Main Office Inspection Next Inspection Date: May 2014

☐ Field Office Inspection

☐ Temporary Job Site Inspection

PROGRAM SCOPE

This was the initial inspection of activities performed under these two licenses.

This licensee operated a cyclotron for production of fluorine-18 (F-18) FDG and sodium fluoride and a radiopharmacy for distribution of these materials to clients. This radiopharmacy employed three pharmacists, one technologist, and one cyclotron engineer. These same individuals rotated duties to deliver the materials to client sites. The licensee had five regular customers located in central Missouri, and distributed approximately 15 to 20 doses each weekday. The pharmacy was open weekdays from 2:00 to 10:00 am. One cyclotron run was scheduled daily, ending at around 5:00 am. Shipments left the facility at around 7:00 am, and as needed after that time. The maximum dose received by licensee personnel in 2011 was 753 mrem whole body and 3.8 rem extremity. For January through March 2012, the maximum doses received were 194 mrem whole body and 1.8 rem extremity; this extremity dose was under investigation by the licensee.

Performance Observations

The inspector observed F-18 receipt from the cyclotron, QC analysis and retesting, dose preparation, dose wiping and packaging, package wipes and surveys, preparation and placement of shipping papers, blocking and bracing of packages, and daily surveys. Licensee personnel demonstrated chemistry setup and dose calibrator constancy, and described cleaning of the hot cell, well counter QC, and other procedures. The inspector noted no concerns with these activities. The inspector observed that the licensee used remote systems and a hot cell for dose preparation and proper shielding for doses removed from the hot cell. Interviews with licensee personnel indicated adequate knowledge of radiation safety concepts and procedures. The inspector performed independent and confirmatory radiation measurements which indicated results consistent with licensee survey records and postings.

The next inspector should notify the licensee the day before the inspection in order to arrange for early-morning access to the facility. The lead pharmacist is Marc Weichelt, R.Ph. at (573) 882-0245.

KQ