



**Docket File Information**

**SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION**

<p>1. LICENSEE/LOCATION INSPECTED:</p> <p>Essential Isotopes 1513 Research Park Drive Columbia, Missouri 65211</p> <p>REPORT NUMBER(S) 2012-001; 2012-001</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>
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<p>3. DOCKET NUMBER(S)</p> <p>030-38129, 030-38132</p>	<p>4. LICENSE NUMBER(S)</p> <p>24-32762-01MD, 24-32762-02</p>	<p>5. DATE(S) OF INSPECTION</p> <p>May 24, 2012</p>
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<p>6. INSPECTION PROCEDURES USED</p> <p>87127, 87125</p>	<p>7. INSPECTION FOCUS AREAS</p> <p>03.01 – 03.07, 03.01 – 03.07</p>
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**SUPPLEMENTAL INSPECTION INFORMATION**

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