NRC FORM 591M PART 1
(07-2012)
10 CFR 2.201

U.S. NUCLEAR REGULATORY COMMISSION

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE/LOCATION INSPECTED:	2. NRC/REGIONAL OFFICE
Global Isotopes, LLC d/b/a Zevacor Molecular 1968 Innerbelt Business Center Drive Overland, MO 63114 REPORT NUMBER(S) 16-001	Region III U. S. Nuclear Regulatory Commission 2443 Warrenville Rd, Suite 210 Lisle, IL 60532

3. DOCKET NUMBER(S)	4. LICENSE NUMBER(S)	5. DATE(S) OF INSPECTION
030-38460 / 030 -37831	24-32827-01MD	June 23, 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 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	Zahid Sulaiman, Health Physicist	Zahid Sulaiman	6/23/16
BRANCH CHIEF	Aaron T. McCraw, Chief, MIB	/RA/ for ATMcCraw	7/13/16

NRC FORM 591M PART 3
(07-2012)
10 CFR 2.201

U.S. NUCLEAR REGULATORY COMMISSION

Docket File Information

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE/LOCATION INSPECTED:	2. NRC/REGIONAL OFFICE
Global Isotopes, LLC d/b/a Zevacor Molecular 1968 Innerbelt Business Center Drive Overland, MO 63114 REPORT NUMBER(S) 2016001	Region III U. S. Nuclear Regulatory Commission 2443 Warrenville Rd, Suite 210 Lisle, IL 60532

3. DOCKET NUMBER(S)	4. LICENSE NUMBER(S)	5. DATE(S) OF INSPECTION
030-38460	24-32827-01MD	June 23, 2016

6. INSPECTION PROCEDURES USED	7. INSPECTION FOCUS AREAS
87127	03.01 - 03.07

SUPPLEMENTAL INSPECTION INFORMATION

1. PROGRAM CODE(S)	2. PRIORITY	3. LICENSEE CONTACT	4. TELEPHONE NUMBER
02500	2	Rachel Ziegler, R.Ph, RSO	(314) 426-5290

☑ Main Office Inspection Next Inspection Date: 06/23/2018

☐ Field Office Inspection _____

☐ Temporary Job Site Inspection _____

PROGRAM SCOPE

This was a routine inspection of the Overland, Mo radiopharmacy facility authorized under NRC license to prepare and distribute diagnostic and therapeutic radiopharmaceuticals to clients in St. Louis area. The licensee is also authorized to use radioactive materials at its radiopharmacy facilities located in Noblesville, IN and Springfield, MO. The radiopharmacy was staffed with one authorized nuclear pharmacists, one pharmacy technicians, and four drivers. The licensee receives two Mo99/Tc99m generators each week for primarily preparation and distribution of unit doses of technetium-99. The radiopharmacy's first run began around 1:00 AM with deliveries out by 5:00 AM; the second run began around 6:30 AM and out by 9:00 AM; and additional runs were made as needed through the day. No Xe-133 gas vials or I-131 capsules are compounded or redistributed. The licensee occasionally redistributes Tl-201 and I-123.

Performance Observations:

The inspection consisted of interviews with select licensee personnel; review of select records; tour of the facility; and independent measurements. The inspector observed a variety of activities on the licensee's second run, including generator elution, molybdenum breakthrough evaluation, kit preparation, dose drawing, client package preparation, DOT package labeling and vehicle loading, as well as client package return and waste handling. The licensee's staff also demonstrated the implementation of procedures for area surveys, and decay-in-storage waste handling. 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 staff monitoring their hands and feet for contamination before exiting the restricted area. The inspector reviewed the molybdenum breakthrough check records, dose calibrator quality control, survey records, decay-in-storage waste disposals, hazmat training, quarterly program audits, sealed source inventory, and leak test reports. The inspector performed independent and confirmatory radiation measurements which indicated results consistent with the licensee's survey results and within regulatory limits.

The maximum TEDE and SDE exposures were reported (in millirem) as follows:

	2014	2015	YTD 2016
TEDE	157	103	88
SDE	7,464	7,440	4,220

No violations of NRC requirements were identified as a result of this inspection.

7/13/16