

Docket File Information

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

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| 1. LICENSEE/LOCATION INSPECTED: Global Isotopes, LLC d/b/a Zevacor Molecular 1968 Innerbelt Business Center Drive Overland, MO 63114 REPORT NUMBER(S) 2016001 | 2. NRC/REGIONAL OFFICE Region III U. S. Nuclear Regulatory Commission 2443 Warrenville Rd, Suite 210 Lisle, IL 60532 |
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| 3. DOCKET NUMBER(S) 030-38460 | 4. LICENSE NUMBER(S) 24-32827-01MD | 5. DATE(S) OF INSPECTION June 23, 2016 |
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| 6. INSPECTION PROCEDURES USED 87127 | 7. INSPECTION FOCUS AREAS 03.01 - 03.07 |
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SUPPLEMENTAL INSPECTION INFORMATION

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

ATM
2/13/16