

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE/LOCATION INSPECTED: Jubilant Draximage Radiopharmacies, Inc. d/b/a Triad Isotopes 790 Township Line Rd. STE. 175 Yardley, PA 19067 REPORT NUMBER(S) 2019001		2. NRC/REGIONAL OFFICE Region III U. S. Nuclear Regulatory Commission 2443 Warrenville Road, Suite 210 Lisle, IL 60532-4352	
3. DOCKET NUMBER(S) 030-38278	4. LICENSE NUMBER(S) 09-32781-02MD	5. DATE(S) OF INSPECTION 7/31/2019	

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:

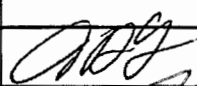
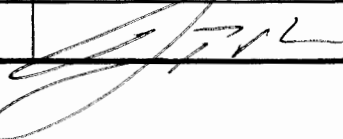
- 1. Based on the inspection findings, no violations were identified.
- 2. Previous violation(s) closed.
- 3. The violation(s), specifically described to you by the inspector as non-cited violations, are not being cited because they were self-identified, non-repetitive, and corrective action was or is 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)

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	Luis Nieves Folch		7/31/19
BRANCH CHIEF	Aaron McCraw		8/13/19

Docket File Information
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6. INSPECTION PROCEDURES USED 87127	7. INSPECTION FOCUS AREAS All
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SUPPLEMENTAL INSPECTION INFORMATION

1. PROGRAM CODE(S) 02500	2. PRIORITY 2	3. LICENSEE CONTACT Kaylene Evans - RSO	4. TELEPHONE NUMBER (586) 268-5300
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Main Office Inspection Next Inspection Date: July 31, 2021
 Field Office Inspection 14 Mile Rd. Warren, Michigan
 Temporary Job Site Inspection _____

PROGRAM SCOPE

This was an unannounced, routine inspection of a radiopharmacy in Warren, Michigan, which served approximately 25-30 clients in southeast Michigan and northern Ohio. The pharmacy operated seven days per week from 12:00 am to 3:30pm. The pharmacy distributed 850-900 doses each weekday. Deliveries for the three runs were around 3:00am 4:30am and the last run at 3:30pm. In addition to unit and bulk doses of technetium-99m, the pharmacy also compounded between two and six iodine-131 capsules per week and 15 doses of NETSPOT (Ge-68/Ga-68 generator). The licensee staffed the radiopharmacy with three pharmacist, two techs, and seven drivers.

PERFORMANCE OBSERVATIONS

The inspector toured the facility to evaluate the licensee's measures for materials security, hazard communication, and exposure control. The inspector conducted independent surveys of unrestricted areas, and found no residual contamination or exposures to members of the public in excess of regulatory limits. 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, and vehicle loading. The licensee's staff demonstrated the implementation of procedures for area surveys, package surveys, and decay-in-storage waste handling. Through these demonstrations and other discussions, the inspector found the licensee's staff to be knowledgeable of radiation protection principles and regulatory requirements. The inspector reviewed a selection of licensee records for molybdenum and germanium breakthrough checks, dose calibrator quality control, iodine-131 release evaluations, bioassays, daily restricted area and weekly unrestricted area surveys, decay-in-storage waste disposals, hazmat training, quarterly program audits, and personnel dosimetry.

No violations of NRC requirements were identified during this inspection.