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
Jubilant DraxImage Radiopharmacies, Inc. d/b/a Triad Isotopes 712 Westport Road, Kansas City, MO REPORT NUMBER(S) 2019001	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
030-38280	09-32781-04MD	7/10/2019

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 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	Robert G. Gattone, Jr.	Robert G. Gattone, Jr.	7/30/19
BRANCH CHIEF	Aaron T. McCraw		7/30/19

NRC FORM 591M PART 3
(07-2012)
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	All

SUPPLEMENTAL INSPECTION INFORMATION

1. PROGRAM CODE(S)	2. PRIORITY	3. LICENSEE CONTACT	4. TELEPHONE NUMBER
02500	2	Dave Persinger, RSO	(816) 931-0515

☐ Main Office Inspection Next Inspection Date: 07/10/2021

☑ Field Office Inspection 712 Westport Rd., Kansas City, MO

☐ Temporary Job Site Inspection

PROGRAM SCOPE

This was an unannounced, routine inspection. The licensee had approximately 25 clients in the Kansas City area, the furtherest being about 55 miles away. There were three Authorized Nuclear Pharmacists (ANPs) who primarily tagged radiopharmaceuticals with Tc-99m, and prepared unit dosages for distribution to medical facilities. Licensee staff performed a minimum of two runs per day, beginning at 2:00 am and the second at 6:00 am. Emergency unit dosages were periodically prepared and transported to client facilities when needed. ANPs also compounded I-131 capsules for radiopharmaceutical therapy as needed.

Performance Observations

The inspector: (1) observed a radiopharmacist generate unit dosages, including quality control tests while wearing proper personal protection equipment; (2) observed the radiopharmacist using time, distance and shielding while handling licensed material; (3) observed the radiopharmacist wearing whole body and extremity dosimeters; (4) observed that several survey instruments were calibrated as required; (5) used a calibrated NRC-owned survey meter to conduct independent ambient exposure surveys at selected surfaces in restricted areas, and there were no concerns; (6) noted that the facility was as per the diagram in accordance with Condition 20 of the license; (7) observed an ANP demonstrate how he used a DraxImage Smart-fill computer controlled capsule filling machine with shielded enclosure, manipulator and transfer arms, integrated dose calibrator, and a multi-well carousel for preparation of I-131 capsules, and there were no concerns; (8) reviewed records of the licensee's radiation protection program audit for 2017 and 2018; (9) reviewed records of the COMPLY code results for air effluent release of licensed material for 2017 and 2018, and there were no concerns; (10) observed that the licensee used proper air filters to prevent licensed material from entering the atmosphere; (11) the licensee monitored the type and quantities of licensed material that entered the atmosphere by way of a stack as a means of determining the public dose results, and there were no concerns; (12) reviewed records of iodine-131 bioassays for selected staff and there were no concerns; (13) reviewed dosimeter badge dose records for 2017, 2018, and 2019 (through May 31, 2019), and there were no concerns; (14) reviewed selected area survey records, and there were no concerns; (15) reviewed selected records of dose calibrator calibrations and there were no concerns; (16) observed that syringe labels were as required; and (17) reviewed selected records of sealed source inventories and leak tests, and there were no concerns. No violations of NRC requirements were identified as a result of this inspection.