

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE/LOCATION INSPECTED:

Jubilant DraxImage Radiopharmacies, Inc.  
2795 Universal Drive  
Saginaw, MI 48603

REPORT NUMBER(S) 2019-001

2. NRC/REGIONAL OFFICE

Region III  
U. S. Nuclear Regulatory Commission  
2443 Warrenville Road, Suite 210  
Lisle, IL 60532-4352

3. DOCKET NUMBER(S)

030-38279

4. LICENSE NUMBER(S)

09-32781-03MD

5. DATE(S) OF INSPECTION

2/12/19

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:

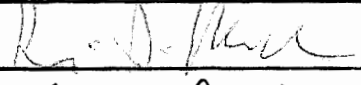
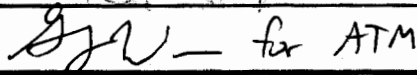
- ☒ 1. Based on the inspection findings, no violations were identified.
- ☐ 2. Previous violation(s) closed.
- ☐ 3. The violation(s), specifically described to you by the inspector as non-cited violations, are not being cited because they were self-identified, non-repetitive, and corrective action was 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	Kevin G. Null		2/12/19
BRANCH CHIEF	Aaron T. McCraw	 for ATM	2/26/19

## Docket File Information

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February 12, 2019

## 6. INSPECTION PROCEDURES USED

87127

## 7. INSPECTION FOCUS AREAS

All

## SUPPLEMENTAL INSPECTION INFORMATION

## 1. PROGRAM CODE(S)

02500

## 2. PRIORITY

2

## 3. LICENSEE CONTACT

Robert Bjurstrom

## 4. TELEPHONE NUMBER

(989) 799-7669

☒ Main Office Inspection

Next Inspection Date: 02/12/2021

☐ Field Office Inspection☐ Temporary Job Site Inspection

## PROGRAM SCOPE

This was a routine, unannounced inspection of a nuclear pharmacy located in Saginaw, Michigan. At the time of the inspection, the company employed two nuclear pharmacists, two nuclear pharmacy technicians, and six drivers. The licensee primarily prepared and distributed unit doses of technetium-99m (Tc-99m). They also redistributed unit doses of thallium-201, gallium-67, bulk vials of Tc-99m, and iodine-131 capsules for therapy which were compounded by, and received from the company's Detroit nuclear pharmacy. The licensee received one molybdenum-99/technetium-99m generator each week, and performed molybdenum-99 breakthrough after each elution.

## Performance Observations

The inspector arrived to observed the licensee's second run which began at 6:00 a.m. The first run was from 1:00 - 3:00 a.m. One pharmacist and both technicians were present. The inspector noted that the pharmacist wore appropriate protective clothing and dosimetry while preparing and measuring unit doses of Tc-99m. The pharmacist also used a calibrated survey meter to periodically check for radiation levels and contamination. The pharmacy technician gave the inspector a tour of the pharmacy that included dose and vial preparation areas, packaging, and waste storage and decay areas.

The technician demonstrated package prep and survey meter measurements for radiation levels, as well as smears for contamination and analysis. The technician also explained and demonstrated how waste was stored for decay and surveyed prior to disposal. The pharmacist demonstrated security of material within the pharmacy and the facility. The inspector reviewed records pertaining to area and package surveys, sealed source leak test and physical inventory, dose calibrator calibration, survey meter calibration, dosimetry, and training.

No violations of NRC requirements were identified.