

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

<p>1. LICENSEE/LOCATION INSPECTED:</p> <p>Jubilant DraxImage Inc. d/b/a Jubilant Radiopharma 790 Township Line Rd. STE. 325, Yardley, PA 19067 Location Inspected, 2795 Universal Drive, Saginaw, Michigan 48603</p> <p>REPORT NUMBER(S) 202101</p>	<p>2. NRC/REGIONAL OFFICE</p> <p>Region III U. S. Nuclear Regulatory Commission 2443 Warrenville Road, Suite 210 Lisle, IL 60532-4352</p>
---	---

<p>3. DOCKET NUMBER(S)</p> <p>030-38279</p>	<p>4. LICENSE NUMBER(S)</p> <p>09-32781-03MD</p>	<p>5. DATE(S) OF INSPECTION</p> <p>November 17, 2021</p>
---	--	--

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		
BRANCH CHIEF	Michael Kunowski		



Materials Inspection Record

1. Licensee Name: Jubilant DraxImage Inc. d/b/a Jubilant		2. Docket Number(s): 030-38279		3. License Number(s) 09-32781-03MD	
4. Report Number(s): 2021001			5. Date(s) of Inspection: November 18, 2021		
6. Inspector(s): Luis Nieves		7. Program Code(s): 02500	8. Priority: 2	9. Inspection Guidance Used: 87127	
10. Licensee Contact Name(s): Robert Bjurstrom, PharmD, Radiation Safety Officer		11. Licensee E-mail Address: robert.bjurstrom@jubile.com		12. Licensee Telephone Number(s): 989-799-7669	
13. Inspection Type: <input type="checkbox"/> Initial		14. Locations Inspected:		15. Next Inspection Date (MM/DD/YYYY):	
<input checked="" type="checkbox"/> Routine <input checked="" type="checkbox"/> Announced		<input checked="" type="checkbox"/> Main Office <input type="checkbox"/> Field Office		November 18, 2023 <input checked="" type="checkbox"/> Normal <input type="checkbox"/> Extended	
<input type="checkbox"/> Non-Routine <input type="checkbox"/> Unannounced		<input type="checkbox"/> Temporary Job Site <input type="checkbox"/> Remote		<input type="checkbox"/> Reduced <input type="checkbox"/> No change	

16. Scope and Observations:

This was an announced, routine inspection of a radiopharmacy located in Saginaw, Michigan. This radiopharmacy employed one pharmacist, one pharmacy technician, and five drivers. The licensee distributed approximately 30 doses daily to nine regular customers. The pharmacy was open weekdays from 7:45 am through 2:30 pm, with limited hours on weekends, with deliveries made as needed throughout the day. The licensee received one technetium-99m generator each week for preparation and distribution of unit doses and bulk technetium to clients. In addition, the licensee distributed occasional thallium-201 and indium-111 unit doses prepared from bulk materials. The pharmacy did not compound iodine-131 therapy capsules; such capsules were prepared and distributed out of the Detroit pharmacy.

PERFORMANCE OPSEVATIONS

The inspector observed generator elution, molybdenum assay, kit preparation and QC, drawing doses and bulk technetium, packaging and surveying of doses, pig and package surveys and wipes, verification of package contents, preparation of labels and shipping papers, shipment assembly, blocking/bracing of packages, placement of shipping papers, waste disposal, and use of syringe shields and long-handled tools. Licensee personnel demonstrated and described daily area surveys and wipes, package receipt surveys, spill procedures, indium blood labeling, waste disposal, and other procedures. The inspector noted no concerns with these activities. Interviews with licensee personnel indicated adequate knowledge of radiation safety concepts and procedures. The inspector performed independent and confirmatory radiation measurements which indicated results consistent with licensee survey records and postings.

The inspector reviewed a selection of records, including internal audits, dose calibrator constancy, dose calibrator linearity, dose calibrator accuracy, survey meter calibration certificates, hazmat training records, well counter constancy, area surveys, and dosimetry reports.

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

From: [Nieves Folch, Luis](#)
To: robert.bjurstrom@jubile.com
Subject: Jubilant MI 591M corrected copy
Date: Wednesday, January 26, 2022 8:47:00 AM
Attachments: [Jubilant MI 591M rev 2.pdf](#)

Dear Mr. Bjurstrom

Attach is a corrected copy of the clear 591 report for the inspection conducted on November 17, 2021. Please discard the previous report and keep this one. At this point there is no further actions on your part.

In accordance with Title 10 of the Code of Federal Regulations 2.390 of the NRC's "Rules of Practice," a copy of this message will be available electronically for public inspection in the NRC's Public Document Room or from the NRC's Agencywide Documents Access and Management System (ADAMS), accessible from the NRC's website at <http://www.nrc.gov/reading-rm/adams.html>. Please feel free to contact me if you have any questions regarding this correspondence.

Thank you,

**Luis Nieves
Health Physicist
U.S. Nuclear Regulatory Commission
Division of Nuclear Materials Safety
Office: (630) 829-9571
Fax: (630) 515-1259**