



Materials Inspection Report

1. Licensee/Location Inspected: Jubilant DraxImage, Inc. d/b/a Jubilant Radiopharma 3101 Terrace St. Kansas City, Missouri 64111 Report Number(s) 2024001	2. NRC/Regional Office Region III U. S. Nuclear Regulatory Commission 2443 Warrenville Road, Suite 210 Lisle, IL 60532-4352
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3. Docket Number(s) 030-38280	4. License Number(s) 09-32781-04MD	5. Date(s) of Inspection July 25, 2024
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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. During this inspection, certain of your activities, as described below and/or attached, were in violation of NRC requirements, and were assessed at Severity Level IV, in accordance with the NRC Enforcement Policy.
 - A. 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, corrective action was or is being taken, and the remaining criteria in the NRC Enforcement Policy were satisfied.
 (Non-cited violation(s) was/were discussed involving the following requirement(s))

 - B. The following violation(s) is/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 AND DATE
LICENSEE'S REPRESENTATIVE		
NRC INSPECTOR	Zahid Sulaiman, Health Physicist	Zahid M. Sulaiman <small>Digitally signed by Zahid M. Sulaiman Date: 2024.08.20 21:00:02 -05'00'</small>
BRANCH CHIEF	Rhex Edwards, Chief, MIB	<i>Rhex Edwards</i> <small>Digitally signed by RYAN CRAFFEY Date: 2024.08.21 08:02:48 -05'00'</small>



Materials Inspection Record

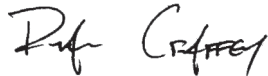
1. Licensee Name: Jubilant DraxImage, Inc.		2. Docket Number(s): 030-38280		3. License Number(s) 09-32781-04MD	
4. Report Number(s): 2024001			5. Date(s) of Inspection: July 25, 2024		
6. Inspector(s): Zahid Sulaiman, Health Physicist		7. Program Code(s): 02500	8. Priority: 2	9. Inspection Guidance Used: 87127	
10. Licensee Contact Name(s): David Persinger, R,Ph., RSO		11. Licensee E-mail Address: David.Persinger@jubl.com		12. Licensee Telephone Number(s): 816-931-0515	
13. Inspection Type: <input checked="" type="checkbox"/> Routine <input type="checkbox"/> Announced <input type="checkbox"/> Non-Routine <input checked="" type="checkbox"/> Unannounced		14. Locations Inspected: <input type="checkbox"/> Main Office <input checked="" type="checkbox"/> Field Office <input type="checkbox"/> Temporary Job Site <input type="checkbox"/> Remote		15. Next Inspection Date (MM/DD/YYYY): 07/25/2026 <input checked="" type="checkbox"/> Normal <input type="checkbox"/> Extended <input type="checkbox"/> Reduced <input type="checkbox"/> No change	
16. Location(s) Inspected List: Field Office: 3101 Terrace St., Kansas City, Missouri 64111					
17. Scope and Observations: This was an unannounced routine inspection of a radiopharmacy located in Kansas City, Missouri. The licensee was authorized to produce, prepare, and distribute radioactive drugs to authorized clients. The licensee dispensed approximately 180-220 unit doses daily to 25 customers in the Kansas City area. The licensee was staffed with three authorized nuclear pharmacists (ANPs), two pharmacy technicians, a chemist, and six drivers. The licensee was open from 12:30 AM to 4:00 PM on weekdays and from 3:30 AM to 8:00 AM on weekends. The licensee also compounded I-131 in capsules using a DraxSmart fill device and prepared and redistributed yttrium-90 SIR-Sphere microspheres.					
PERFORMANCE OBSERVATIONS					
This inspection consisted of interviews with select licensee personnel, a review of select records, a tour of the facility, and independent measurements. The inspector observed the preparation Tc-99m white blood cell tagging. The inspector also had the ANP demonstrate a variety of activities, including: the production run, client order processing, kit labeling and preparation, dose drawing, client package preparation, DOT package labeling, package surveys, and client package return and waste handling. The ANP discussed and demonstrated the radiochemical elution process, test for breakthrough, drawing of unit doses, and package preparation for distribution. The ANP also demonstrated radionuclide purity checks and other QA/QC processes. The inspector observed staff wearing assigned dosimetry ring and body badge, gloves and protective clothing while handling radiochemicals, as well as monitoring their hands and feet for contamination before exiting the restricted area. Interviews with licensee staff and through demonstrations indicated the licensee's staff to be knowledgeable of radiation protection principles and regulatory requirements.					
The inspector reviewed following records: dose calibrator constancy, linearity, and accuracy tests; well counter efficiency tests, survey meter calibration records, weekly wipes and daily survey records; waste disposals and waste shipment manifests; DOT hazmat training records; Quarterly and annual audits; bioassay results; sealed source					

Materials Inspection Record (Continued)

inventory and leak test reports; weekly air monitoring results, charcoal filter tests, and an annual air emission (COMPLY) report dated January 2, 2024. The inspector reviewed dosimetry records for 2023 through June 23, 2024 indicating the maximum annual dose to be 0.298 rem - DDE and 11.63 rem - SDE. The inspector performed independent and confirmatory radiation measurements which were consistent with the licensee's survey results and within regulatory limits.

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

Signature and Date - Branch Chief



Digitally signed by RYAN CRAFFEY
Date: 2024.08.21 08:01:54 -05'00'