



Materials Inspection Record

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| 1. Licensee Name: Jubilant DraxImage Inc. | | 2. Docket Number(s): 030-38278 | | 3. License Number(s) 09-32781-02MD | |
| 4. Report Number(s): 2022-001 | | | 5. Date(s) of Inspection: April 1, 2022 | | |
| 6. Inspector(s): Ryan Craffey | | 7. Program Code(s): 02500 | 8. Priority: 2 | 9. Inspection Guidance Used: IP 87127 | |
| 10. Licensee Contact Name(s): Craig Kinne - Corporate RSO Bryan Brittain - RSO | | 11. Licensee E-mail Address: Craig.Kinne@jubl.com N/A | | 12. Licensee Telephone Number(s): 407-455-6755 989-799-7669 | |
| 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): 04/01/2024 <input checked="" type="checkbox"/> Normal <input type="checkbox"/> Extended <input type="checkbox"/> Reduced <input type="checkbox"/> No change | |

16. Scope and Observations:

This commercial radiopharmacy in Warren, Michigan, prepared and distributed 250-350 unit doses of Tc-99m radiopharmaceuticals per day to clients in and around southeast Michigan and northwest Ohio. The licensee had three authorized nuclear pharmacists and one in training, three pharmacy technicians, and ten drivers. The pharmacy's first run began around midnight with doses out by 4:00 am. The second run began around 5:30 am with doses out by 9:00 am, and a small third run began around 11:00 or earlier with doses out by 2:00 pm. The pharmacy received Mo-99/Tc-99m generators every Sunday and Monday for preparing unit and bulk doses of Tc-99m. The pharmacy also prepared and/or distributed I-123 and I-131 capsules, Sr-82/Rb-82 generators, Cu-64 dotatate, and Ga-67, In-111, and Th-201 radiopharmaceuticals. In addition, the pharmacy possessed a Ge-68/ Ga-68 generator for preparation of Ga-68 dotatate and Ga-68 PSMA for clinical trials.

The inspector toured the facility in Warren and observed a variety of activities on the pharmacy's second run, including generator breakthrough testing, kit preparation and dose drawing, radiopharmaceutical quality control, outgoing package preparation, and vehicle loading for product transport. The inspector also observed demonstrations of I-131 capsule preparation using a DraxImage Smart-Fill system and reviewed the licensee's measures for air sampling, public dose evaluation, and I-131 bioassay. The inspector performed independent surveys of restricted and unrestricted areas, and found no evidence of residual contamination or exposures to members of the public in excess of regulatory limits. The inspector interviewed the licensee's RSO, pharmacists, technologists, and drivers. All personnel implemented adequate ALARA practices, wore appropriate dosimetry, and used calibrated and operable survey instruments effectively.

The inspector reviewed a selection of records, including corporate audits, RSO internal audits and records reviews, area survey results, I-131 bioassay results (no detectable uptakes since the last routine inspection), third-party ventilation evaluations for iodine capsule preparation equipment, hazmat training records, dose calibrator and multi-channel analyzer quality control records, decay-in-storage waste handling documentation, sealed source inventories, public dose evaluations, and occupational dose reports, which indicated maximum doses from licensed activities of 191 mrem DDE / 12,848 mrem SDE to the extremities in 2020 and 156 milirem DDE / 10,522 mrem SDE to the extremities in 2021.

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