NRC FORM 592M
(10-2020)

U.S. NUCLEAR REGULATORY COMMISSION

Materials Inspection Record

1. Licensee Name:	2. Docket Number(s):	3. License Number(s)
RLS (USA) Inc.	030-29642	21-24828-01MD

4. Report Number(s):	5. Date(s) of Inspection:
2022-001	February 24, 2022

6. Inspector(s):	7. Program Code(s):	8. Priority:	9. Inspection Guidance Used:
Ryan Craffey	02500	2	IP 87122

10. Licensee Contact Name(s):	11. Licensee E-mail Address:	12. Licensee Telephone Number(s):
Jill Twehues, RPh - Manager	Jill.Twehues@rls.bio	734-425-0425

13. Inspection Type:	14. Locations Inspected:	15. Next Inspection Date (MM/DD/YYYY):
☐ Initial	☑ Main Office ☐ Field Office	02/24/2024
☑ Routine ☐ Announced	☐ Temporary Job Site ☐ Remote	☑ Normal ☐ Extended
☐ Non-Routine ☑ Unannounced		☐ Reduced ☐ No change

16. Scope and Observations:

This commercial radiopharmacy in Livonia, Michigan, prepared and distributed 300-400 diagnostic and therapeutic doses of radiopharmaceuticals per day to clients in the Detroit metro area and in northwest Ohio. The licensee had four authorized nuclear pharmacists (including the facility manager and the RSO), four pharmacy technicians, and six drivers plus two contracted couriers. The pharmacy's first run began around 1:00 am with doses out by 5:30 am, and the second run began around 6:30 am with doses out by 9:00 am. Additional doses were prepared on an as-needed basis after that. The licensee received Mo-99/Tc-99m generators every Monday, Tuesday, and Thursday for unit and bulk doses of Tc-99m. The licensee also occasionally prepared and/or distributed I-131 liquids and capsules, Cu-64 dotatate, and Ga-67, In-111, and Tl-201 radiopharmaceuticals.

The inspector toured the facility in Livonia and observed a variety of activities on the pharmacy's second run, including generator elution and breakthrough testing, dose drawing, I-131 capsule preparation, outgoing package preparation, return waste handling, area surveys, and vehicle loading for dose transport. The inspector conducted independent surveys of restricted and unrestricted areas, and found no evidence of residual contamination nor exposures to members of the public in excess of regulatory limits. The inspector interviewed the licensee's pharmacists, technologists, drivers and management. 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 facility audits, dose calibrator and multi-channel analyzer quality control records, sealed source inventories and leak tests, air monitoring results, as well as in-vivo bioassay measurements and personnel dosimetry reports, which indicated maximum doses of 50 mrem whole-body / 3,178 mrem extremity in 2020, and 232 mrem whole-body / 11,000 mrem extremity in 2021.

The inspector also reviewed EN 55269, NMED 210220, and the licensee's 30-day written report for an event reported on May 21, 2021, where a package of radioactive material being sent to the licensee was delivered by the common carrier to the wrong address. The licensee subsequently retrieved the package when notified by the recipient. The inspector identified no violations associated with this event. The NMED item is considered closed.

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