



Materials Inspection Report

1. Licensee/Location Inspected: RLS (USA) Inc. 12300 Hubbard Rd. Livonia, MI 48150 Report Number(s) 2024-001	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) 030-29642	4. License Number(s) 21-24828-01MD	5. Date(s) of Inspection August 6, 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	Ryan Craffey / Carol Dye	Digitally signed by RYAN CRAFFEY Date: 2024.08.21 18:10:53 -05'00' Carol J. Dye Digitally signed by Carol J. Dye Date: 2024.08.22 08:12:46 -05'00'
BRANCH CHIEF	Rhex Edwards	Digitally signed by RHEX EDWARDS Date: 2024.08.23 14:12:27 -05'00'



Materials Inspection Record

1. Licensee Name: RLS (USA) Inc.		2. Docket Number(s): 030-29642		3. License Number(s) 21-24828-01MD	
4. Report Number(s): 2024-001			5. Date(s) of Inspection: August 6, 2024		
6. Inspector(s): Ryan Craffey, Carol Dye		7. Program Code(s): 02500	8. Priority: 2	9. Inspection Guidance Used: IP 87127	
10. Licensee Contact Name(s): Brad Ambs, RPh - RSO Jill Twehues, RPh - Manager		11. Licensee E-mail Address: Bradley.Ambs@rls.bio Jill.Twehues@rls.bio		12. Licensee Telephone Number(s): 734-425-0425	

13. Inspection Type:		14. Locations Inspected:		15. Next Inspection Date (MM/DD/YYYY):	
<input type="checkbox"/> Initial <input checked="" type="checkbox"/> Routine <input type="checkbox"/> Announced <input type="checkbox"/> Non-Routine <input checked="" type="checkbox"/> Unannounced		<input type="checkbox"/> Hybrid <input checked="" type="checkbox"/> Main Office <input type="checkbox"/> Field Office <input type="checkbox"/> Temporary Job Site <input type="checkbox"/> Remote		08/06/2026 <input checked="" type="checkbox"/> Normal <input type="checkbox"/> Extended <input type="checkbox"/> Reduced <input type="checkbox"/> No change	

16. Location(s) Inspected List:

12300 Hubbard Rd.
Livonia, MI 48150

17. Scope and Observations:

RLS (USA) operated a commercial radiopharmacy in Livonia, Michigan. The pharmacy prepared and distributed up to 150 diagnostic and therapeutic doses of radiopharmaceuticals daily to clients in the Detroit metro area and in northwest Ohio. The pharmacy had two full-time and five part-time authorized nuclear pharmacists, four pharmacy technicians, and three drivers. The pharmacy's first and sometimes only run began around 3:30 am with doses out by 5:30 am. If the licensee had a second run (generally the case on Thursdays, sometimes on Tuesdays and Wednesdays, and no longer on Mondays and Fridays), it began around 6:30 am with doses out by 9:00 am. Additional doses were prepared on an as-needed basis afterwards. The pharmacy received a Mo-99/Tc-99m generator weekly on Sunday night or Monday morning, and began using Ge-68/Ga-68 generators in February 2024 for preparation of Ga-68 Illucox. The pharmacy also occasionally prepared and/or distributed I-131 liquids and capsules, redistributed I-123 capsules, and tagged blood products with In-111.

The inspection consisted of a tour of the pharmacy, observation of select activities from the first and second runs, review of records, independent measurements, and interviews with licensee personnel. The inspectors observed generator elution and breakthrough testing, dose drawing, outgoing package preparation and contamination checks, return waste handling, area surveys, and vehicle loading for dose transport. The inspectors conducted independent surveys using agency-issued survey meters (Thermo Scientific RadEye G, s/n 30646, last calibrated April 8, 2024 and Ludlum 26-1, s/n PF014246, last calibrated May 9, 2024) and found neither contamination nor exposures to members of the public distinguishable from background. The inspectors 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 inspectors also reviewed a selection of records including facility audits; documentation of radiation safety training for drivers, pharmacy technicians, and pharmacists; area surveys; dose calibrator quality assurance documentation; sealed source inventories; in-vivo bioassay measurement results; and personnel dosimetry reports.

Materials Inspection Record (Continued)

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

Signature and Date - Branch Chief

A handwritten signature in black ink, appearing to be 'RHEX EDWARDS', with a long horizontal line extending to the right.

 Digitally signed by RHEX EDWARDS
Date: 2024.08.23 14:11:51 -05'00'