



## Materials Inspection Report

<b>1. Licensee/Location Inspected:</b> RLS (USA) Inc.  1623 Lotsie Blvd. Overland, MO 63132  Report Number(s) 2023001	<b>2. NRC/Regional Office</b>  Region III U. S. Nuclear Regulatory Commission 2443 Warrenville Road, Suite 210 Lisle, IL 60532-4352
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<b>3. Docket Number(s)</b> 030-36453	<b>4. License Number(s)</b> 24-32462-01MD	<b>5. Date(s) of Inspection</b> October 26, 2023
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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: 2023.11.15 14:28:28 -06'00'</small>
BRANCH CHIEF	Rhex Edwards, Chief, MIB	 <small>Digitally signed by Rhex A. Edwards Date: 2023.11.18 08:35:13 -06'00'</small>



### Materials Inspection Record

1. Licensee Name: RLS (USA) Inc.		2. Docket Number(s): 030-36453		3. License Number(s) 24-32462-01MD	
4. Report Number(s): 2023001			5. Date(s) of Inspection: October 26, 2023		
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): Kevin Grant, R.Ph., RSO		11. Licensee E-mail Address: kevin.grant@rls.bio		12. Licensee Telephone Number(s): Work: 314-427-6888	

13. Inspection Type: <input type="checkbox"/> Initial <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"/> Hybrid <input checked="" type="checkbox"/> Main Office <input type="checkbox"/> Field Office <input type="checkbox"/> Temporary Job Site <input type="checkbox"/> Remote	15. Next Inspection Date (MM/DD/YYYY): <div style="text-align: center; font-size: 1.2em;">10/26/2025</div> <input checked="" type="checkbox"/> Normal <input type="checkbox"/> Extended <input type="checkbox"/> Reduced <input type="checkbox"/> No change
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16. Location(s) Inspected List:  
1623 Lotsie Boulevard, Overland, MO 63132

17. Scope and Observations:

This was an unannounced routine inspection of a radiopharmacy authorized under NRC license to prepare and distribute diagnostic and therapeutic radiopharmaceuticals to approximately 15 clients in the St. Louis area. The licensee was staffed with two authorized nuclear pharmacists, two pharmacy technicians, and three drivers. The radiopharmacy's first run began around 3:00 am with deliveries out by 5:00 am; the second run began around 8:00 am and out by 10:00am; and additional runs were made as needed. The licensee receives one Mo-99/Tc-99m generator each week for preparation and distribution of unit doses and some bulk Tc-99m. The licensee received and redistributed Xe-133 gas vials. The licensee compounded iodine-131 capsules inside a ventilated hood. The licensee occasionally prepared and distributed unit doses of Tl-201, In-111, and Ga-67. The licensee also prepared and distributed approximately 2 ready to use unit dosage of yttrium-90 Sir-Spheres microspheres weekly. Licensee stopped the production operation using the NorthStar RadioGenix Mo-99/Tc-99 generator system around April 2023. The licensee decommissioned and shipped the NorthStar RadioGenix system back to the manufacturer on October 25, 2023.

**PERFORMANCE OBSERVATIONS**

The inspection consisted of interviews with select licensee personnel; a review of select records; a tour of the facility; and independent measurements. The inspector observed special process required in preparation, verification, and shipment of In-111 unit dose. The inspector observed a variety of activities on the licensee's second run, including generator elution, molybdenum breakthrough evaluation, kit preparation, dose drawing, client package preparation, DOT package labeling and vehicle loading, as well as client package return and waste handling. The inspector had the staff demonstrate area surveys, I-131 capsule preparation, ventilation hood air monitoring and filter change out procedures, spill response, and decay-in-storage waste handling. Interviews with licensee staff and demonstrations indicated that licensee staff were knowledgeable of radiation protection principles and regulatory requirements. The inspector observed that staff wore the assigned dosimetry ring and body badge, wore gloves and protective clothing while handling radioactive materials, and monitored their hands and feet for contamination before exiting the restricted area. The inspector reviewed the dose calibrator constancy, linearity, and accuracy; air monitoring, area survey, waste disposals, DOT hazmat training, annual program audits, bioassay results, sealed source inventory,

**Materials Inspection Record (Continued)**

leak test, and air comply code (3/9/2023) reports. The inspector performed independent and confirmatory radiation measurements which indicated results consistent with the licensee's survey results and within regulatory limits. The inspector reviewed the dosimetry records through September 30, 2023, indicating the maximum annual dose to be 0.085 rem - DDE; and 7.170 rem - SDE.

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

Signature and Date - Branch Chief



Digitally signed by Rhex A. Edwards  
Date: 2023.11.18 08:34:20 -06'00'