



Materials Inspection Report

1. Licensee/Location Inspected: RLS (USA) Inc. 4380 Brockton SE Suite 3 Kentwood, MI 49512 Report Number(s) 2022001	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) 030-34090	4. License Number(s) 21-26707-01MD	5. Date(s) of Inspection March 25, 2022
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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	Jason Draper, Health Physicist	Jason D. Draper <small>Digitally signed by Jason D. Draper Date: 2022.04.11 15:05:00 -05'00'</small>
BRANCH CHIEF		Michael A. Kunowski <small>Digitally signed by Michael A. Kunowski Date: 2022.04.13 14:47:14 -05'00'</small>



Materials Inspection Record

1. Licensee Name: RLS (USA) Inc.		2. Docket Number(s): 030-34090		3. License Number(s) 21-26707-01MD	
4. Report Number(s): 2022001			5. Date(s) of Inspection: March 25, 2022		
6. Inspector(s): Jason Draper		7. Program Code(s): 02500	8. Priority: 2	9. Inspection Guidance Used: IP 87127	
10. Licensee Contact Name(s): Timothy B. Burke, R.Ph		11. Licensee E-mail Address: Timothy.Burke@rls.bio		12. Licensee Telephone Number(s): (616) 554-5717	
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 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): 03/25/2024 <input checked="" type="checkbox"/> Normal <input type="checkbox"/> Extended <input type="checkbox"/> Reduced <input type="checkbox"/> No change	

16. Scope and Observations:

This was an unannounced routine inspection of a radiopharmacy in Kentwood, Michigan, which served approximately 20 clients in southwest Michigan. The pharmacy employed three Authorized Nuclear Pharmacists, four nuclear pharmacy technicians, and 8-10 couriers. The pharmacy operated Monday through Friday from approximately 12:30am to 4:00pm with limited hours on weekends. The pharmacy distributed approximately 220 dosages each weekday on two runs (occasional third runs) with first run deliveries out by 4:00am and second run deliveries out by 8:30am. In addition to unit and bulk dosages of technetium-99m, the pharmacy also performed indium-111 white blood cell tagging and prepared iodine-131 capsules. In addition to traditional technetium-99m generators, the licensee also uses a NorthStar RadioGenix system. The RSO performed annual audits of the program.

The inspector toured the facility in Kentwood to evaluate the licensee's measures for materials security, hazard communication, and exposure control. The inspector conducted independent surveys of unrestricted areas, and found no residual contamination that could result in exposures to members of the public in excess of regulatory limits. The inspector observed a variety of activities including RadioGenix elution, kit preparation, dose drawing, client package preparation, and waste handling. The licensee's staff demonstrated the implementation of procedures for instrument checks and calibrations, area surveys, decay-in-storage waste handling, generator elution, and molybdenum breakthrough evaluation.

The inspector reviewed a selection of licensee records for molybdenum breakthrough checks, dose calibrator quality control, effluent release evaluations, area radiation and contamination surveys, waste disposal, training, bioassays, and radiation safety program reviews. The inspector also reviewed dosimetry records and found occupational dose to be below regulatory limits.

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