NRC FORM 591M PART 1
(07-2012)
10 CFR 2.201

U.S. NUCLEAR REGULATORY COMMISSION

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE/LOCATION INSPECTED:	2. NRC/REGIONAL OFFICE
RLS (USA) Inc. 1623 Lotsie Boulevard Overland, MO 63132 REPORT NUMBER(S) 2021001	Region III U. S. Nuclear Regulatory Commission 2443 Warrenville Road, Suite 210 Lisle, IL 60532-4352

3. DOCKET NUMBER(S)	4. LICENSE NUMBER(S)	5. DATE(S) OF INSPECTION
030-36453	24-32462-01MD	February 3, 2021

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. The violations(s), specifically described to you by the inspector as non-cited violations, are not being cited because they were self-identified, non-repetitive, and corrective action was or is being taken, and the remaining criteria in the NRC Enforcement Policy, to exercise discretion, were satisfied.

_____ Non-cited violation(s) were discussed involving the following requirement(s):

☐ 4. During this inspection, certain of your activities, as described below and/or attached, were in violation of NRC requirements and 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	DATE
LICENSEE'S REPRESENTATIVE			
NRC INSPECTOR	Zahid Sulaiman, Health Physicist	Zahid M. Sulaiman Digitally signed by Zahid M. Sulaiman Date: 2021.02.17 16:53:07 -06'00'	
BRANCH CHIEF	Michael Kunowski, Chief, MIB	Michael A. Kunowski Digitally signed by Michael A. Kunowski Date: 2021.02.18 05:43:04 -06'00'	

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.	030-36453	24-32462-01MD

4. Report Number(s):	5. Date(s) of Inspection:
2021001	February 3, 2021

6. Inspector(s):	7. Program Code(s):	8. Priority:	9. Inspection Guidance Used:
Zahid Sulaiman, Health Physicist	02500	2	87127

10. Licensee Contact Name(s):	11. Licensee E-mail Address:	12. Licensee Telephone Number(s):
Kevin Grant	kevin.grant@rls.bio	(314) 427-6888

13. Inspection Type:	14. Locations Inspected:	15. Next Inspection Date (MM/DD/YYYY):
☐ Initial ☑ Routine ☑ Announced ☐ Non-Routine ☐ Unannounced	☑ Main Office ☐ Field Office ☐ Temporary Job Site ☑ Remote	02/03/2023 ☑ Normal ☐ Extended ☐ Reduced ☐ No change

16. Scope and Observations:

This was an announced remote routine inspection of a radiopharmacy authorized under NRC license to prepare and distribute diagnostic and therapeutic radiopharmaceuticals to approximately 20 clients in the St. Louis area. RLS (USA) Inc. purchased Medi-Physics d/b/a GE Healthcare on August 31, 2020, and the official transfer of control was done on September 1, 2020. The licensee was staffed with three authorized nuclear pharmacists (ANPs), two pharmacy technicians, and four drivers. The radiopharmacy's first run began around 2:00 am with deliveries out by 5:00 am; the second run began around 8:00 am and out by 10:00 am; and additional runs were made as needed throughout the day. The licensee received two Mo-99/Tc-99m generators each week for preparation and distribution of unit doses and some bulk Tc-99m. The licensee compounded liquid iodine-123 (I-123) into capsules, under the newly installed hood, for use in whole body diagnostic. The licensee has not dispensed any I-123 capsules yet. The licensee compounded iodine-131 capsules inside a ventilated hood. The licensee installed NorthStar RadioGenix Mo-99/Tc-99 generator system Model 1.1 on October 29, 2018, and upgraded the RadioGenix system to Model 1.2 on October 19, 2020. The licensee receives concentrated Mo-99 for RadioGenix generator system every three weeks from NorthStar for preparation and distribution of radioactive drugs and radiochemicals. The licensee received and redistributed Xe-133 gas vials. The licensee occasionally prepared and distributed unit doses of Tl-201, In-111, and Ga-67.

Performance Observations

This inspection was conducted virtually through the Microsoft Team meeting and iPhone facetime, and consisted of interviews with select licensee personnel, review of select records, and an observation of security of the materials. Through facetime, the inspector had the ANP demonstrate the Northstar RadioGenix generator system operations, computer system login process, generator elution and production of Tc-99, and waste management process. The ANP described variety of activities: 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 conduct the physical inventory of the sealed sources and all sources were accounted for. The inspector had the staff demonstrate area surveys, I-131 capsule preparation, ventilation hood air monitoring and filter change out procedures, and decay-in-storage waste handling. 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 also observed the transportation vehicle package block and bracing and emergency response procedures. Through interviews and demonstrations indicated that licensee staff were knowledgeable of radiation protection principles and regulatory requirements.

Materials Inspection Record (Continued)

The inspector reviewed the selected documents: dose calibrator constancy, linearity, and accuracy, air monitoring, area survey, decay-in-storage waste disposals, DOT hazmat training, internal and external program audits, bioassay results, sealed source inventory, and leak test reports. The inspector also reviewed the required manufacturer training to operate the RadioGenix generator system and verified that the ANP has successfully completed the training. The inspector also reviewed the dosimetry records for 2019 and till November 30, 2020, indicating the maximum annual dose to be 0.25 rem - DDE; and 7.58 rem - SDE.

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