

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE/LOCATION INSPECTED: American Radiolabeled Chemicals, Inc. 101 Arc Dr. St. Louis, MO 63146 REPORT NUMBER(S) 2021001		2. NRC/REGIONAL OFFICE Region III U. S. Nuclear Regulatory Commission 2443 Warrenville Road, Suite 210 Lisle, IL 60532-4352	
3. DOCKET NUMBER(S) 030-20567	4. LICENSE NUMBER(S) 24-21362-01	5. DATE(S) OF INSPECTION August 26, 2021 with in-office review through 9/2/2021	

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 violation(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.

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

License Condition 21. of Amendment No. 56 issued on April 12, 2017 of the license states, in part, "...the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in documents, including any enclosures listed below." One of those documents is the licensee's letter dated June 29 2012, that includes the licensee's Radiation Protection Program (RPP). Section 5.2.3.1 of the RPP states, in part, "Individuals shall survey their hands every time they exit the laboratory. At the end of the workday a full body frisk with the survey meter is required."

Continued in Part 2.

- ☐ 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	Jeffrey S. Vollmer, RSO	Jeffrey S. Vollmer, RSO	10/17/21
NRC INSPECTOR	Zahid Sulaiman, Health Physicist	Zahid M. Sulaiman Digitally signed by Zahid M. Sulaiman Date: 2021.09.17 18:09:02 -05'00'	
BRANCH CHIEF	Michael Kunowski, Chief, MIB	Michael A. Kunowski Digitally signed by Michael A. Kunowski Date: 2021.09.28 10:41:48 -05'00'	

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American Radiolabeled Chemicals, Inc.

101 Arc Dr.

St. Louis, MO 63146

REPORT NUMBER(S) 2021001

2. NRC/REGIONAL OFFICE

Region III

U. S. Nuclear Regulatory Commission

2443 Warrenville Road, Suite 210

Lisle, IL 60532-4352

3. DOCKET NUMBER(S)

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5. DATE(S) OF INSPECTION

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review through 9/2/2021

(Continued)

License Condition 18. of Amendment No. 58 issued on December 12, 2018 of the license states, in part, "...the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in documents, including any enclosures listed below." One of those documents is the licensee's application dated June 13, 2018, that includes the licensee's Standard Operating Procedure -33. Section 5.0 of the procedure states, in part, "If the monitor reading is greater than twice background, wash hand thoroughly and re-monitor. If still greater than twice the background, call the RSO for assistance."

Contrary to the above, on January 10, 2018 and March 8, 2018 licensee staffs failed to conduct adequate surveys of their hands and body when they exited the restricted area. In addition, on February 22, 2019, March 8, 2019, and April 8, 2019 licensee staffs failed to conduct adequate surveys of their hands and failed to call the RSO for assistance.



Materials Inspection Record

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4. Report Number(s): 2021001			5. Date(s) of Inspection: August 26, 2021 with in-office review through 9/2/2021		
6. Inspector(s): Zahid Sulaiman, Health Physicist		7. Program Code(s): 03214		8. Priority: 5	9. Inspection Guidance Used: 87125
10. Licensee Contact Name(s): Jeffrey S. Vollmer, CHP, RSO		11. Licensee E-mail Address: jeff@arc-inc.com		12. Licensee Telephone Number(s): (314) 991-4545	
13. Inspection Type:		14. Locations Inspected:		15. Next Inspection Date (MM/DD/YYYY):	
<input type="checkbox"/> Initial <input checked="" type="checkbox"/> Routine <input checked="" type="checkbox"/> Announced <input type="checkbox"/> Non-Routine <input type="checkbox"/> Unannounced		<input checked="" type="checkbox"/> Main Office <input type="checkbox"/> Field Office <input type="checkbox"/> Temporary Job Site <input checked="" type="checkbox"/> Remote		08/26/2024 <input type="checkbox"/> Normal <input type="checkbox"/> Extended <input checked="" type="checkbox"/> Reduced <input type="checkbox"/> No change	

16. Scope and Observations:

This was an announced remote routine inspection of a manufacturer and distributor of radiolabeled chemicals licensee authorized for possession, use, and processing incident to manufacture and synthesis of radiolabeled chemicals for distribution to authorized persons. The licensee was staffed with eight chemists, two health physicists, and two maintenance and cleaning persons. The next routine inspection interval was reduced and will be tentatively set at 36 months from the date of this inspection. The licensee continues to have radioactive contamination events in unrestricted areas and has a history of non-compliance. The licensee needs to demonstrate sustained improved performance before it goes back to the routine five-year inspection frequency.

PERFORMANCE OBSERVATIONS

This inspection was conducted virtually through the Microsoft Team meeting, consisted of interview with select licensee personnel, a virtual tour of changing area, package in-processing and outgoing area, a review of select records, and an observation of security of the materials. Through Microsoft Team meeting, the inspector had the staff demonstrate and explained ordering and receipt of licensed materials, the inventory tracking system, package receipt procedures, proper handling of radioactive waste and disposal procedures, contamination surveys, and spill response. The inspector observed an authorized user inside the restricted area donned the proper PPE (shoes cover, lab coat, gloves, and safety glass). Through these demonstrations and other discussion, the inspector found that the licensee personnel was knowledgeable of radiation protection principles, licensee procedures, and regulatory requirements.

The inspector reviewed the following records: radiation safety committee minutes, annual program audits, monthly health physics summary report, inventory tracking system, SCO inventory, annual liquid waste report, package receipts, waste disposal records, instrument calibration, materials inventory, area surveys, wipe tests, contamination investigation report, apparent cause evaluation, annual air COMPLY report, bio-assay records, package receipts, waste disposal records, annual radiation safety and DOT Hazmat training, area surveys, and contamination wipe tests.

The licensee identified several contamination incidents, root cause and the corrective actions. The inspector cited this contamination incidents as a NCV, violation of License Condition 21. of Amendment No. 56 issued on April 12, 2017 of the license for the licensee's staff failure to conduct adequate surveys of their hands and body when they exited the restricted area and violation of License Condition 18. of Amendment No. 58 issued on December 12, 2018 of the license for the licensee's staff failure to conduct adequate surveys of their hands and failure to call the RSO for assistance. The root cause of the violation was poor radiation protection practices causing contamination in the

Materials Inspection Record (Continued)

unrestricted areas, on the shoes, jacket, pant, shirt, and in the car. As corrective action and to prevent recurrence, the licensee coached the worker on need to perform proper surveys and good work practices.