

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE/LOCATION INSPECTED: American Radiolabeled Chemicals, Inc. 101 ARC Drive St. Louis, MO 63146 REPORT NUMBER(S) 2018001		2. NRC/REGIONAL OFFICE Region III U. S. Nuclear Regulatory Commission 2443 Warrenville Rd, Suite 210 Lisle, IL 60532	
3. DOCKET NUMBER(S) 030-38510	4. LICENSE NUMBER(S) 24-21362-02E	5. DATE(S) OF INSPECTION October 10, 2018	

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. *IR-2014-001*
- 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.

_____ 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	<i>Zahid Sulaiman</i>	10/10/18
BRANCH CHIEF	Aaron T. McCraw, Chief, MIB	<i>ATM</i> — for ATM	10/26/18

Docket File Information
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6. INSPECTION PROCEDURES USED 87125	7. INSPECTION FOCUS AREAS 03.01 - 03.07
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SUPPLEMENTAL INSPECTION INFORMATION

1. PROGRAM CODE(S) 03253	2. PRIORITY 5	3. LICENSEE CONTACT Jeffrey Vollmer, RSO	4. TELEPHONE NUMBER (314) 991-4545
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Main Office Inspection Next Inspection Date: 10/10/2023

Field Office Inspection _____

Temporary Job Site Inspection _____

PROGRAM SCOPE

This was a routine, unannounced inspection of an exempt distribution license held by a manufacturer and distributor of radio labeled products for life sciences and biomedical research. The license authorizes the distribution of Carbon-14 and Hydrogen-3 in individual quantities not to exceed 50 microcuries to persons exempt from NRC licensing requirements for byproduct material.

Performance Observations:

The inspection consisted of interviews with select licensee personnel; a review of select records; and tour of the facility. The inspector reviewed the licensee's shipping and distribution process. The inspector had the shipping clerk demonstrate: (1) the package receipt survey and wipe test, (2) preparation, labeling, and packaging of exempt quantities materials distributed under this license, (3) outgoing shipping packages contamination wipe test and survey, and (4) contamination survey of the shipping areas. The staff demonstrated how each product vial was labeled and the shipping package marked with appropriate shipping information. Both the RSO for the manufacturer and distributor license (24-21362-01) and the shipping clerk demonstrated an adequate level of understanding of licensee procedures and regulatory requirements. The inspector reviewed the annual exempt distribution summary report submitted to the NRC and the DOT hazmat training document.

The inspector also reviewed the licensee's corrective action of a SL IV violation (inspection report: 2014-01) for failure to file a summary report with the NRC for each calendar year. The inspector verified that the licensee had submitted the annual summary report no later than January 31 of the following year indicating the total quantities of materials transferred under the exempt distribution license for each calendar year from 2013 through 2017. The inspector verified the licensee's corrective action and closed the previous violation.

No violation of NRC requirements were identified during this inspection