



*Docket File Information*

**SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION**

1. LICENSEE/LOCATION INSPECTED:  American Radiolabeled Chemicals 100 ARC Drive St. Louis, MO 63146  REPORT NUMBER(S) 2014-001		2. NRC/REGIONAL OFFICE  Region III U. S. Nuclear Regulatory Commission 2443 Warrenville Road, Suite 210 Lisle, IL 60532-4352	
3. DOCKET NUMBER(S)  030-38510	4. LICENSE NUMBER(S)  24-21362-02E	5. DATE(S) OF INSPECTION  March 31, 2014	
6. INSPECTION PROCEDURES USED  87125	7. INSPECTION FOCUS AREAS  All		

**SUPPLEMENTAL INSPECTION INFORMATION**

1. PROGRAM CODE(S)  03253	2. PRIORITY  5	3. LICENSEE CONTACT  Don Lite	4. TELEPHONE NUMBER  (314) 991-4545
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<input checked="" type="checkbox"/> Main Office Inspection	Next Inspection Date: March 31, 2019
<input type="checkbox"/> Field Office Inspection	
<input type="checkbox"/> Temporary Job Site Inspection	

**PROGRAM SCOPE**

This was a re-initial inspection of the exempt distribution license held by American Radiolabeled Chemicals, a manufacturer and distributor of radiolabeled products for life sciences and biomedical research. This license, issued in February 2012, 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. The licensee originally obtained this license in an effort to broaden the distribution of tritium-labeled shellfish toxins to encourage improved methods of research. At the time of this inspection, the licensee had only distributed one exempt quantity of tritium-labeled saxitoxin under this license. However, the licensee anticipated distributing additional quantities in the coming year, now that a protocol has finally been approved to use the improved methods. The licensee does routinely distribute these radiolabeled toxins to international customers, but requires those customer have a license that specifically authorizes the possession of such material.

**PERFORMANCE OBSERVATIONS**

The inspector reviewed the licensee's distribution process. The licensee's shipping clerk demonstrated procedures for preparation, labeling and packaging of exempt quantities distributed under this license. The clerk and the RSO for the company's possession license (24-21362-01) demonstrated measures for limiting the spread of contamination and for surveying outgoing packages and the shipping facilities. Both the RSO and the shipping clerk demonstrated an adequate level of understanding of licensee procedures and regulatory requirements.

The inspector reviewed records for the only distribution of material under this license, made in September 2013.

The inspector identified a violation of 10 CFR 32.20 for failure to file a summary report with the NRC for calendar years 2012 or 2013 indicating the total quantity of each radionuclide transferred under the license for each calendar year. The inspector determined that the root cause of the violation was an oversight by licensee staff. As corrective actions, the licensee committed to submit a report indicating the total quantities of material transferred under the exempt distribution license in calendar years 2012 and 2013 no later than April 11, 2014, and to file future reports no later than January 31 of the following year.

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5. DATE(S) OF INSPECTION

March 31, 2014

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.

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)

Contrary to 10 CFR 32.20, on February 1, 2013 and February 1, 2014, the license failed to file summary reports on or before January 31 of each year, indicating the total quantity of each radionuclide transferred under the specific license covering the preceding calendar year.

As corrective action to restore compliance, the licensee committed to file a report covering calendar years 2012 and 2013 no later than April 11, 2014, and to file future reports no later than January 31 of the following year.

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	Ryan Craffey		4/8/14
BRANCH CHIEF	Aaron McCraw		4/7/14