

INSPECTION RECORD

Region III Inspection Report No. 03020567/12002(DNMS)
License No. 24-21362-01 Docket No. 030-20567

Licensee (Name and Address):
American Radiolabeled Chemicals
101 ARC Drive
St. Louis, Missouri 63146

Licensee Contact: Regis Greenwood – RSO

Telephone No. (314) 991-4545

Priority: 5 Program Code: 03214

Date of Last Inspection: 4/2/2012 Date of This Inspection: 11/28-29/12 with continued in-
office review until 2/5/13 to
review export records

Type of Inspection: ☐ Initial ☒ Announced ☐ Unannounced
☐ Routine ☒ Special

Next Inspection Date: TBD ☒ Normal ☐ Reduced

Summary of Findings and Actions:

- ☐ No violations cited, clear U.S. Nuclear Regulatory Commission (NRC) Form 591 or regional letter issued
- ☐ Non-cited violations (NCVs)
- ☐ Violation(s), Form 591 issued
- ☒ Violation(s), regional letter issued
- ☐ Followup on previous violations

Inspector

Andrew M. Bramnik
Andrew M. Bramnik, Health Physicist

Date 2/15/2013

Approved

Tamara E. Bloomer
Tamara E. Bloomer, Chief, Materials Inspection Branch

Date 2/20/13

PART I-LICENSE, INSPECTION, INCIDENT/EVENT, AND ENFORCEMENT HISTORY

1. AMENDMENTS AND PROGRAM CHANGES:

<u>Amendment No.</u>	<u>Date</u>	<u>Subject</u>
49	August 2, 2012	Requests to repair damaged roof and procedures for safety and contamination control

2. INSPECTION AND ENFORCEMENT HISTORY:

The previous inspection in April 2012 identified one Severity Level III violation for the licensee's failure to secure from unauthorized removal or limit access to licensed material stored in a controlled area, and two Severity Level IV violations for the licensee's failure to equip all buildings with motion detectors and to transfer a Building 300 effluent air stack blower unit to Building 200 for temporary storage. The prior inspection in February 2011 identified one minor violation involving the licensee's failure to document the results of investigations of sources and causes of contamination levels that exceeded 10 times the action levels as required.

The prior inspection in August 2010 identified three Severity Level IV violations involving the licensee's failure to: (1) conduct removable contamination surveys in controlled areas and contamination areas at the end of the week prior to cleaning and at the start of the week after cleaning; (2) use fume hoods with face velocities that were less than 100 feet per minute; and (3) conduct an appropriate survey of radioactive materials in air effluents released to unrestricted and controlled areas to demonstrate compliance with dose limits to members of the public. In addition, the NRC identified additional examples of a weak safety culture and examples of a weak Safety Conscious Work Environment.

3. INCIDENT/EVENT HISTORY:

None in the last two years or two inspections

PART II - INSPECTION DOCUMENTATION

1. ORGANIZATION AND SCOPE OF PROGRAM:

American Radiolabeled Chemicals is authorized under NRC Materials License No. 24-21362-01 to possess and distribute licensed material in the manufacture and synthesis of radiolabeled chemicals for distribution to persons authorized to receive licensed material. The licensee primarily utilized carbon-14 and tritium for the production of radiolabeled chemicals for biomedical research.

A Health Physics Technician reported to the licensee's Radiation Safety Officer (RSO). A Health Physicist was hired in May 2011 and served as a "Deputy RSO" as part of the licensee's training of the individual to eventually assume the position of RSO. At the time of the inspection, the RSO worked part time Monday through Thursday. The RSO

reported to the licensee's President, who also served as the Chairman of the Radiation Safety Committee and an authorized user. Three additional authorized users reported to the President.

2. SCOPE OF INSPECTION:

Inspection Procedure(s) Used: 87125

Focus Areas Evaluated: Sections 03.01 through 03.07

The purpose of the inspection was to review the licensee's corrective actions to one Severity Level III violation and two Severity Level IV violations that had been previously cited in NRC Inspection Report No. 03020567/12001(DNMS). The inspector reviewed the corrective actions the licensee implemented in response to the previous inspection. The licensee had: purchased and installed automatic door closers; realigned a doorjamb to allow a door to fully close and latch; installed and tested motion detectors and entry point monitors with alarms; and instituted regular walkthroughs for laboratory and waste storage facilities to ensure that exterior doors are closed and locked. The inspector discovered an exterior door that was not equipped with a motion detector. This item is discussed in greater detail in Section 4, below.

The inspector was accompanied by the Deputy Regional Administrator during this inspection, and the licensee provided a brief tour of licensed operations including package shipment and receipt. The inspector observed the licensee implement their process for receiving and opening packages containing radioactive materials; however, the licensee's staff did not adhere to their approved procedure. This item is discussed in greater detail in Section 4, below.

As a part of the tour of licensed operations, the licensee provided information about their exports of byproduct material to foreign countries. The licensee's staff and management were not immediately aware of what regulatory authority allowed them to conduct such exports. The RSO sent the inspector an e-mail on December 19, 2012, with a spreadsheet documenting all international exports for calendar years 2011 and 2012. After reviewing the spreadsheet, the inspector identified several inconsistencies, such as annual activity levels per country that did not add up, and individual shipments that appeared to exceed the regulatory limits for exports in Title 10 of the Code of Federal Regulations (CFR) Part 110. On December 26, 2012, the Deputy RSO e-mailed the inspector a more detailed record of selected export shipments as well as the appropriate shipping papers for those orders. On September 19, 2011, the licensee made a shipment that exceeded the limitations under the general license for export of byproduct material. This item is discussed in greater detail in Section 4, below.

3. INDEPENDENT AND CONFIRMATORY MEASUREMENTS:

The inspector performed independent ambient count rate and dose rate measurements taken with a calibrated survey meter within and outside the licensee's St. Louis, Missouri facility. The inspector identified 750 counts per minute (cpm) on a two-wheeled pushcart in an unrestricted area outside Building 200. The licensee's deputy RSO took wipe surveys of the cart and identified a maximum of 4,291 disintegrations per minute (dpm)

of tritium and 517 dpm of carbon-14. After cleaning the cart using disposable alcohol wipes, wipe surveys identified a maximum of 1278 dpm of tritium and 105 dpm of carbon-14. Because the deputy RSO could not decontaminate the cart to acceptable levels for use in unrestricted areas, the cart was placed in Building 200. The inspector did not identify any ambient dose rate measurements in excess of the limits in 10 CFR Part 20 in unrestricted areas. The licensee possessed radiation survey meters that were calibrated, operational, and performed comparably to the NRC survey meter.

4. VIOLATIONS, NCVs, AND OTHER SAFETY ISSUES:

- A. Condition 21 of NRC License No. 24-21362-01 states, in part, that the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the letter dated September 8, 2010, with the attached Radiation Protection Program.

Item 8.2.1 of the Radiation Protection Program attached to the letter dated September 8, 2010 states that all buildings are equipped with motion detectors and entry point monitors, which trigger an audible alarm and send a signal to the security company upon intrusion.

Contrary to the above, as of November 28, 2012, the licensee failed to equip all buildings with motion detectors. Specifically, a door was unequipped with a motion detector to trigger an audible alarm or send a signal to the security company upon intrusion.

This violation was also identified during the previous NRC inspection conducted in April 2012, when the NRC identified several doors that were not equipped with either motion detectors or entry point monitors. During this inspection, the exterior door to the Building 100 / 200 Connector area was not equipped with a motion detector. The root cause of the violation was the licensee's failure to ensure that all building doors had both motion detectors and entry point monitors installed by their security company in response to the previously-cited violation. Specifically, the licensee believed that the contractor had installed both a motion detector and an entry point monitor on the Building 100 / 200 Connector area door in April 2012, when they had not. As corrective action, the security company installed a motion detector in the area and tested its functionality on November 29, 2012. As long term corrective actions, the security company conduct manual and electronic tests on all of your motion detectors and entry point monitors every quarter. The reports of those tests are reviewed and maintained by the RSO.

- B. Condition 21 of NRC License No. 24-21362-01 states, in part, that the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the letter dated March 3, 2011.

Item 2.1 of the Standard Operating Procedure SOP-06 titled "Program for Picking Up, Receiving, and Opening of Incoming Radioactive Materials" enclosed with the letter dated March 3, 2011 requires employees to put on gloves to prevent hand contamination.

Contrary to the above, on November 28, 2012, the licensee failed to put on gloves to prevent hand contamination. Specifically, the licensee received and opened incoming packages containing radioactive materials without wearing gloves.

The root cause of the violation was a misunderstanding by the staff regarding the version of the procedure that was applicable. Specifically, the licensee's staff believed that a newer revision of the procedure was in effect that did not require the use of gloves until individual vials or containers of radioactive material were being handled. As immediate corrective actions, staff working in the shipping area donned gloves to prevent hand contamination. As long term corrective actions, the licensee committed to hold an all-staff meeting to emphasize that SOPs currently in effect per the NRC license must be followed until an amendment is issued by the NRC. The all staff meeting was completed by December 31, 2012.

- C. Title 10 CFR 110.20(a) states that a person may use an NRC general license as authority to export or import nuclear equipment or material, if the nuclear equipment or material to be exported or imported is covered by the NRC general licenses described in 10 CFR 110.21 through 110.27. If an export or import is not covered by the NRC general licenses described in 10 CFR 110.21 through 110.27, a person must file an application with the Commission for a specific license in accordance with 10 CFR 110.31 through 110.32.

Title 10 CFR 110.23(a) states, in part, that a general license is issued to any person to export byproduct material to any country not listed in 10 CFR 110.28, and subject to the limitation that for tritium in any dispersed form (e.g. labeled compounds), exports under the general license must not exceed 0.37 TBq (10 Curies) per item.

Contrary to the above, on September 19, 2011, the licensee failed to limit its export of tritium to less than 0.37 TBq per item as required by 10 CFR 110.23. Specifically, the licensee exported five items containing tritium gas in a single shipment to India, the contents of each item were 20 Curies of tritium, and the licensee did not apply for a specific license.

The root cause of the violation was the licensee's lack of awareness of the requirements and limitations in 10 CFR 110. As corrective actions, the RSO provided information and training on the requirements to individuals responsible for recording, filling, and packaging orders for export. The RSO also posted instructions in the package shipment area of Building 300. These actions were completed by December 31, 2012.

- D. The NRC inspector reviewed the immediate and long term corrective actions from the Severity Level III violation of 10 CFR 20.1801 cited in the Notice of Violation dated June 25, 2012. Since the previous inspection, the licensee had implemented all of the corrective actions as described in their letter to the NRC dated June 5, 2012. Specifically, the licensee: purchased and installed automatic door closers; realigned a doorjamb to allow a door to fully close and latch; installed and tested motion detectors and entry point monitors with alarms; and instituted regular walkthroughs for laboratory and waste storage facilities to ensure that exterior doors are closed and locked. This violation is closed.

5. **PERSONNEL CONTACTED:**

- & Surrendra Gupta, President
- &* Regis Greenwood, Radiation Safety Officer
- & Donald Lite, Deputy Radiation Safety Officer
- Kamal Das, Vice President and Authorized User
- Janardhanam Selvasekaran, Vice President and Authorized User
- Nicholas Rice, Shipping Manager

- & Individual present at November 29, 2012 preliminary on-site exit meeting
- * Individual present at February 5, 2013 final telephone exit meeting

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