

April 16, 2010

Surendra K. Gupta, Ph.D.
President
American Radiolabeled Chemicals
101 ARC Drive
St. Louis, MO 63146

SUBJECT: NRC ROUTINE INSPECTION REPORT NO. 030-20567/10-02(DNMS) AND
NOTICE OF VIOLATION – AMERICAN RADIOLABELED CHEMICALS

Dear Dr. Gupta:

On October 20 through 22 and November 4 through 5, 2009, the U. S. Nuclear Regulatory Commission (NRC) conducted a reactive inspection at your St. Louis, Missouri facility, with continued in-office review through April 8, 2010. The purpose of the inspection was to evaluate ARC's activities relating to characterization of soils in outdoor areas of the site and to determine if the activities were conducted safely and in accordance with NRC requirements. The results of the inspection were described in NRC Inspection Report No. 030-20567/09-02(DNMS) dated February 18, 2010. Additionally, the February 18 Inspection Report identified an Open Item involving the licensee's performance of an unauthorized activity pertaining to soil remediation work involving licensed materials. On April 8, 2010, an NRC inspector informed Mr. Regis Greenwood your Radiation Safety Officer of the results of the NRC's evaluation of the Open Item, described in the attached report.

Based on the results of the review of soil excavation activities, the NRC has determined that a Severity Level IV violation of NRC requirements occurred. The violation was evaluated in accordance with the NRC Enforcement Policy. The current Enforcement Policy is included on the NRC's Web site at <http://www.nrc.gov/about-nrc/regulatory/enforcement/enforcement-pol.html>. The violation involved failure to limit use of licensed material for manufacture and synthesis of radiolabeled chemicals for distribution as described in Item 9, "Authorized Use" of License No. 24-21362-01, Amendment 39, dated March 13, 2009.

The violation is cited in the enclosed Notice of Violation (Notice) and the circumstances surrounding it is described in detail in the subject inspection report. The violation is being cited in the Notice because the violation was identified by the NRC.

You are required to respond to this letter and should follow the instructions specified in the enclosed Notice when preparing your response. For your consideration and convenience, the guidance in NRC Information Notice 96-28, "Suggested Guidance Relating to Development and Implementation of Corrective Action," may be helpful. You can find the information notice on the NRC website at <http://www.nrc.gov/reading-rm/doc-collections/gen-comm/info-notices/1996/in96028.html>. The NRC will use your response, in part, to determine whether further enforcement action is necessary to ensure compliance with regulatory requirements.

Surendra K. Gupta, Ph.D.

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In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter, and its enclosures, will be made available electronically for public inspection in the NRC Public Document Room or from the NRC's Agencywide Documents Access and Management System (ADAMS), accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>. To the extent possible, your response should not include any personal privacy, Proprietary, or safeguards information so that it can be made available to the Public without redaction.

Sincerely,

/RA/

Tamara E. Bloomer, Chief
Materials Inspection Branch

Docket No. 030-20567
License No. 24-21362-01

Enclosures:

1. Notice of Violation
2. Inspection Report 030-20567/10-02(DNMS)

cc w/encls: Regis Greenwood, RSO
State of Missouri

Surendra K. Gupta, Ph.D.

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State of Missouri

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NOTICE OF VIOLATION

American Radiolabeled Chemicals
St. Louis, Missouri

Docket No. 030-20567
License No. 24-21362-01

During a U.S. Nuclear Regulatory Commission (NRC) inspection conducted on October 20 through 22 and November 4 through 5, 2009, a violation of NRC requirements was identified. In accordance with the NRC Enforcement Policy, the violation is listed below:

10 CFR 30.34(c) requires, in part, that each licensee confine his possession and use of byproduct materials to the locations and purposes authorized by the license. License Item 9 "Authorized Use" of License No. 24-21362-01, Amendment 39, dated March 13, 2009, limits the use of licensed materials for the manufacture and synthesis of radiolabeled chemicals for distribution.

Contrary to the above, between August 1 and August 20, 2009, the licensee failed to limit the use of licensed material to the manufacture and synthesis of radiolabeled chemicals for distribution. Specifically, the licensee performed excavation of 1,800 pounds of contaminated soil containing hydrogen-3 and carbon-14, which is a use and purpose not authorized by the American Radiolabeled Chemicals (ARC) license.

This is a Severity Level IV violation (Supplement VI).

Pursuant to the provisions of 10 CFR 2.201, ARC is hereby required to submit a written statement or explanation to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, DC 20555-0001, with a copy to the Regional Administrator, Region III, within 30 days of the date of the letter transmitting this Notice of Violation (Notice). This reply should be clearly marked as a "Reply to a Notice of Violation" and should include for each violation: (1) the reason for the violation, or, if contested, the basis for disputing the violation or severity level; (2) the corrective steps that have been taken and the results achieved; (3) the corrective steps that will be taken to avoid further violations; and (4) the date when full compliance will be achieved. Your response may reference or include previous docketed correspondence, if the correspondence adequately addresses the required response. If an adequate reply is not received within the time specified in this Notice, an order or a Demand for Information may be issued as to why the license should not be modified, suspended, or revoked, or why such other action as may be proper should not be taken. Where good cause is shown, consideration will be given to extending the response time. If you contest this enforcement action, you should also provide a copy of your response, with the basis for your denial, to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001.

Because your response will be made available electronically for public inspection in the NRC Public Document Room or from the NRC's Agency Documents Access and Management System (ADAMS), accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>, to the extent possible, it should not include any personal privacy, proprietary, or safeguards information so that it can be made available to the public without redaction. If personal privacy or proprietary information is necessary to provide an acceptable response, then please provide a bracketed copy of your response that identifies the information that should be protected and a redacted copy of your response that deletes such information. If you request withholding of such material, you must specifically identify the portions of your response

Notice of Violation

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that you seek to have withheld and provide in detail the bases for your claim of withholding (e.g., explain why the disclosure of information will create an unwarranted invasion of personal privacy or provide the information required by 10 CFR 2.390(b) to support a request for withholding confidential commercial or financial information).

In accordance with 10 CFR 19.11, you may be required to post this Notice within two working days.

Dated this 16th day of April 2010.

Enclosure 1

U.S. NUCLEAR REGULATORY COMMISSION

REGION III

Docket No.: 030-20567

License No.: 24-21362-01

Report No.: 030-20567/10-02(DNMS)

Licensee: American Radiolabeled Chemicals

Facilities: 100 and 104 ARC Drive
St. Louis, Missouri

Inspection Dates: October 20 through 22, 2009, and November 4
through 5, 2009 (on-site), with continuing in-
office review through April 8, 2010

Preliminary Exit Meeting: November 5, 2009

Final Exit Meeting: April 8, 2010 (by telephone)

Inspectors: Katie Streit, Health Physicist
Mike McCann, Senior Health Physicist

Approved By: Tamara E. Bloomer, Chief
Materials Inspection Branch
Division of Nuclear Materials Safety

EXECUTIVE SUMMARY
American Radiolabeled Chemicals
NRC Inspection Report 030-20567/10-02(DNMS)

On October 20 through 22 and November 4 through 5, 2009, the U. S. Nuclear Regulatory Commission (NRC) conducted a reactive inspection at the licensee's St. Louis, Missouri facility, with continued in-office review through April 8, 2010. The results of the inspection were described in NRC Inspection Report No. 030-20567/09-02(DNMS) dated February 18, 2010. The February 18 Report documented an Open Item regarding the licensee's compliance with "Authorized Use" limitations of its NRC license.

On April 8, 2010, the NRC completed its review of the Open Item and identified a violation involving the licensee's performance of an unauthorized activity pertaining to soil remediation work involving licensed materials.

During the April 8 telephone exit meeting call, the licensee committed not to perform any further soil or construction activities that could potentially release or mobilize radiological contamination to the environment or that could unnecessarily expose members of the public. The licensee also committed to submitting a license amendment for approval prior to performing any future construction or site beautification activities that could disturb contaminated site soil. On January 13, 2010, American Radiolabeled Chemicals (ARC) submitted a license amendment seeking approval to excavate soil in conjunction with the construction of a concrete pad next to one of the production buildings. Based on the licensee's commitment and submission of the license amendment, the previously identified Open Item is closed.

Report Details

1. Program Overview

Licensed Activities and Inspection History

The U.S. Nuclear Regulatory Commission (NRC) License No. 24-21362-01 authorizes American Radiolabeled Chemicals (licensee) to manufacture and synthesize radiolabeled chemicals for distribution to authorized persons. The majority of the licensee's radioactive material was hydrogen-3 and carbon-14. The licensee's radiolabeled chemical synthesis activities involved use of high specific activity hydrogen-3 and carbon-14 labelled organic chemicals.

The NRC completed a reactive inspection on January 21, 2010, to evaluate ARC's activities relating to characterization of soils in outdoor areas of the site and to determine if the activities were conducted safely and in accordance with NRC requirements. As a result, the NRC issued a Notice of Violation citing three violations involving: (1) failure to identify and evaluate the associated hazards of known contamination in outdoor areas of the ARC site; (2) failure to require the use of protective clothing in a contaminated area; and (3) failure to ensure the adequate survey of an individual's hands after performing decontamination work in one of the production buildings. An open Item was also identified regarding issues associated with authorized use of licensed materials.

2. Soil Excavation

2.1 Inspection Scope

The inspectors evaluated an unauthorized activity involving licensed materials during August 2009. The inspectors interviewed the RSO regarding the activity, toured the remediated areas, and reviewed an ARC August 24, 2009, Memorandum "Removal of Contaminated Soil."

2.2 Observations and Findings

Early in August 2009, the licensee's management replaced the grass sod in two on-site areas that became rutted due to truck traffic. These locations, were in an area between Building 200 and the garage entrance to Building 300 on the south side of the driveway and an area on the east side of Building 100. The licensee documented in an August 24, 2009, internal "Memorandum for Record" that an area near the Building 200 garage on the south side of the driveway contained a contaminated area that was believed to be a result of a spill that occurred in 2008. The licensee made a management decision to remove the contaminated area rather than covering it with an additional layer of sod.

The first excavation involved digging up an area approximately 1.5 meters in diameter by hand to a depth of 11.8 inches. The licensee placed the excavated soil on a plastic tarp. The licensee indicated that a direct measurement on the bottom of the excavated hole with a survey meter calibrated for carbon-14 did not identify any detectable contamination. After remediation of the spill area, the licensee used a "Bobcat" front-end-loader to remove the surrounding soil, totaling approximately ten square meters to the same depth. The licensee added the soil to the pile on the plastic tarp. The

contaminated soil was loaded into six boxes and placed in the licensee's on-site waste storage "SeaLand" container. The total weight of the soil was approximately 1800 pounds.

Other than the single measurement in the spill area, the licensee did not collect soil samples nor perform direct radiation measurements, prior to or after the soil excavation work. Rather, the licensee used a single soil analysis result [3390 picoCurie per gram (pCi/g) hydrogen-3 and 5450 pCi/g carbon-14] obtained by the NRC during an April 23, 2008, (NRC Inspection Report 030-20556/2008-001[DNMS]), to develop an estimate of residual contamination in the excavated soils. The licensee used the NRC single measurement value, to calculate total quantities and concentrations of licensed material for all the soil removed. The licensee estimated that approximately 2.8 millicuries (mCi) of hydrogen-3 with an average concentration 0.0016 mCi per pound, and 4.4 mCi of carbon-14, with an average of 0.0024 mCi per pound was contained in the soil.

During the April 23, 2008, NRC collected and analyzed soil samples and subsequently found that levels of hydrogen-3 and carbon-14 were above the NRC screening values for unrestricted use. Additionally, during an interim exit meeting on March 14, 2008, the NRC discussed the elevated hydrogen-3 and carbon-14 levels with the licensee. The licensee committed to perform a site characterization survey to ascertain the extent of contamination and any potential impacts.

The NRC inspectors noted that on August 28, 2008, a NRC Senior License Reviewer conducted a Licensing Site Visit with ARC management to discuss license issues and discuss the need for an amendment to address contamination discovered in unrestricted areas outside of their buildings during NRC inspection activities conducted in 2008. On May 25, 2009, the licensee submitted site characterization information for NRC review.

During the November 4 and 5, 2009, on-site inspection, the NRC inspectors evaluated the licensee's August 2009 soil remediation activities performed outside the production buildings. On October 29, 2009, the licensee's Item 9 "Authorized Use" was amended to add "Possession incident to radiological site characterization, collection and analysis of water and soil samples containing residual contamination." As stated in Section 1.2 of the NRC's February 18, 2010, Inspection Report No. 030-20567/09-02(DNMS) the licensee's authorized use of licensed material regarding soil excavation activities was an Open Item under continuing NRC review.

Title 10 Code of Federal Regulations (CFR) 30.34(c) requires, in part, that each licensee confine his possession and use of byproduct materials to the locations and purposes authorized by the license. License Item 9 "Authorized Use" of License No. 24-21362-01, Amendment 39, dated March 13, 2009, limits the use of licensed materials for the manufacture and synthesis of radiolabeled chemicals for distribution to persons authorized to receive the licensed material under the terms of a specific license issued by the Commission or an Agreement State. The licensee's performance of soil remediation activities in outdoor areas of the ARC site between August 1 and August 20, 2009, involving the excavation of 1,800 pounds of soil containing carbon-14 and hydrogen-3, a use and purpose not authorized by the ARC license, is a violation of 10 CFR 30.34(c).

2.3 Conclusions

The inspectors completed the review of the Open Item regarding soil excavation prior to site characterization, and identified a violation pertaining to the conduct of an unauthorized activity involving licensed materials. During an April 8 2010, telephonic exit meeting, the licensee committed to not perform any further soil or construction activities that could potentially release or mobilize radiological contamination to the environment or that could unnecessarily exposed members of the public. The licensee also committed to submitting a license amendment for approval prior to performing any future construction or site beautification activities that could disturb contaminated site soil. On January 13, 2010, ARC submitted a license amendment seeking approval to excavate soil in conjunction with the construction of a concrete pad next to one of the production buildings. Based on the licensee's commitment and submission of the license amendment, the previously identified Open Item is closed.

3. **Exit Meeting**

At the completion of the inspectors' review of the Open Item regarding the licensee's soil excavation activities, an inspector discussed the inspection findings in this report with the licensee's Radiation Safety Officer during a telephonic exit meeting on April 8, 2010. The licensee did not identify any information reviewed during the inspection as proprietary in nature.