

July 22, 2008

EA-08-126
EA-08-127

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

SUBJECT: NOTICE OF VIOLATION AND PROPOSED IMPOSITION OF CIVIL PENALTY -
\$6500 – NRC INSPECTION REPORT 030-20567/2008-001(DNMS)
AMERICAN RADIOLABELED CHEMICALS, INC.

Dear Dr. Gupta:

This refers to the inspections conducted January 22 through 25, and March 11 through 14, 2008, at American Radiolabeled Chemicals, Inc. (ARC), St. Louis, Missouri, with continued in-office review through March 26, 2008. The purpose of the inspections was to determine if licensed activities were conducted safely and in accordance with NRC requirements. Following the completion of the onsite inspections and the in-office review, the NRC inspectors discussed the preliminary findings with you and members of your staff. In addition, on February 21, 2008, the NRC issued a Confirmatory Action Letter (CAL 3-08-002) to American Radiolabeled Chemicals, Inc. to document your commitment to address specific observations and findings developed during the January 2008 inspection. On April 23, 2008, we issued to you an inspection report which described in detail the inspection results, including five apparent violations of NRC regulatory requirements.

On May 20, 2008, a pre-decisional enforcement conference (PEC) was conducted in the Region III office with members of your staff to discuss the apparent violations, their significance and root causes, and your corrective actions.

Based on the information developed during the inspections and that you provided during the PEC, the NRC has determined that a violation of NRC requirements occurred. The violation is cited in the enclosed Notice of Violation (Notice) and the circumstances surrounding it are described in detail in the subject inspection report.

The violation involved multiple examples of your failure to adhere to license conditions and regulations. Specifically, between January 22 and March 14, 2008, the licensee failed to: (1) secure from unauthorized removal or limit access to licensed material in an aggregate quantity greater than 1000 times Appendix C to 10 CFR Part 20 limits; (2) comply with license conditions related to management oversight of the Radiation Protection Program, including a

failure to conduct monthly meetings of the Radiation Safety Committee and a failure to implement timely and adequate corrective actions for issues identified during annual program reviews; (3) comply with license conditions related to radiological surveys; and (4) perform and document required investigations of contamination found in controlled and unrestricted areas. The root cause of the violation appeared to be inadequate management oversight of and inattention to the Radiation Protection Program.

The NRC considered your failure to adhere to license conditions and regulations, including your failure to ensure that radioactive materials were properly controlled and secured when not in use or under continuous surveillance, a significant regulatory concern because it could have permitted unauthorized access to and unnecessary exposure from radioactive materials. Therefore, this violation has been categorized in accordance with the NRC Enforcement Policy as a Severity Level III problem.

In accordance with the Enforcement Policy, a base civil penalty in the amount of \$6500 is considered for a Severity Level III problem. Because your facility has not been the subject of escalated enforcement actions within the last two years or the last two inspections, the NRC considered whether credit was warranted for *Corrective Action* in accordance with the civil penalty assessment process in Section VI.C.2 of the Enforcement Policy. As a part of your presentation at the PEC, you provided a summary of the corrective actions taken or planned to address the violations. These corrective actions included: (1) securing the area designated for the storage of radioactive materials; (2) re-initiating required periodic meetings of the Radiation Safety Committee; (3) developing and implementing corrective actions for findings developed as a part of your past Radiation Protection Program annual audits; (4) re-initiating the conduct of routine radiation surveys and investigations of contamination events consistent with the procedural requirements; and (5) reinforcing with staff the requirement to conduct proper contamination surveys prior to leaving radiation and contamination controlled areas.

While each of the completed or proposed corrective actions addressed, in part, the immediate safety or regulatory issues raised by the violations, we determined that your actions did not address the root cause for the violation, that is, management's lack of adequate oversight of the Radiation Protection Program and the resultant long-standing violation. Specifically, your corrective actions did not address the root cause for your failure to ensure that radioactive materials were properly secured during the January 2008 inspection and again during the March 2008 inspection. In addition, your corrective actions did not address the apparent conflicting production and safety priorities of the Radiation Safety Officer during building renovations. You and your Radiation Safety Officer both identified this issue at the PEC. Therefore, we determined that credit was not warranted for prompt and comprehensive corrective actions.

To emphasize the importance of compliance with regulatory requirements, prompt and comprehensive corrective actions, and the need for an adequate oversight of the Radiation Protection Program, I have been authorized, after consultation with the Director, Office of Enforcement, to issue the enclosed Notice of Violation and Proposed Imposition of Civil Penalty (Notice) in the base amount of \$6500 for the Severity Level III problem. Furthermore, issuance of this Notice constitutes escalated enforcement action that may subject you to increased inspection effort.

In addition to the above detailed issues, the NRC inspection report referenced in the subject line to this letter also described an apparent violation associated with your failure to ensure that licensed material was discharged into the sanitary sewer in accordance with 10 CFR 20.2003 (APV 03020567/08-01-04). Following the PEC, you provided additional information to the NRC regarding this issue. Once we have completed our review of this additional information, we will communicate our final assessment of this item to you in a separate correspondence (EA-08-127).

You are required to respond to this letter and should follow the instructions specified in the enclosed Notice when preparing your response. In your response, we request that you specifically address your assessment of the root causes for the violation and those actions that you plan to take to address the root causes and to prevent recurrence of the violation. We also request that your response identify those actions that you determine are necessary to verify, now and in the future, to yourself and the NRC that the actions required by your license are and will be completed in a comprehensive and timely manner, without regard to conflicting or production pressures. The NRC will use your response, in part, to determine whether further enforcement action is necessary to ensure compliance with regulatory requirements.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter, its enclosures, and your response will be made available electronically for public inspection in the NRC Public Document Room or from the NRC's document 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. If personal privacy or proprietary information is necessary to provide an acceptable response, 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 information, you must specifically identify the portions of your response that you seek to have withheld and provide in detail the bases for your claim of withholding (e.g., explain why the disclosure of

S. Gupta

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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). The NRC also includes significant enforcement actions on its Web site at <http://www.nrc.gov/about-nrc/regulatory/enforcement/current.html>.

Sincerely,

/RA/

James L. Caldwell
Regional Administrator

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

Enclosures:

1. Notice of Violation and Proposed Imposition of Civil Penalty
2. NUREG/BR-0254 Payment Methods (Licensee only)

cc w/encl 1: Regis Greenwood, Radiation Safety Officer
State of Missouri

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See next page

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NAME	Caldwell		Burgess ²		Marco NLO ³					
DATE	07/12/08		6/26/08		7/16/08					

OFFICIAL RECORD COPY

1, 2, 3 OE/FSME/OGC concurrences received July 17, 2008, via E-mail from S. Magruder.

Letter to Surendra K. Gupta, Ph.D from James L. Caldwell dated July 22, 2008

SUBJECT: NOTICE OF VIOLATION AND PROPOSED IMPOSITION OF CIVIL PENALTY -
\$6500 – NRC INSPECTION REPORT 030-20567/2008-001(DNMS)
AMERICAN RADIOLABELED CHEMICALS, INC.

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NOTICE OF VIOLATION
AND
PROPOSED IMPOSITION OF CIVIL PENALTY

American Radiolabeled Chemicals, Inc.
St. Louis, Missouri

Docket No. 030-20567
License No. 24-21362-01
EA-08-126

During an NRC inspection conducted from January 22, 2008, through March 26, 2008, a violation of NRC requirements was identified. In accordance with the NRC Enforcement Policy, the NRC proposes to impose a civil penalty pursuant to Section 234 of the Atomic Energy Act of 1954, as amended (Act), 42 U.S.C. 2282, and 10 CFR 2.205. The particular violation and associated civil penalty are set forth below:

- A. 10 CFR 20.1801 requires that the licensee secure from unauthorized removal or access licensed materials that are stored in controlled or unrestricted areas. As defined in 10 CFR 20.1003, controlled area means an area, outside of a restricted area but inside the site boundary, access to which can be limited by the licensee for any reason; and unrestricted area means an area, access to which is neither limited nor controlled by the licensee.

Contrary to the above, on January 23 and March 11, 2008, the licensee did not secure licensed material in storage in a controlled area from unauthorized removal or access. Specifically, licensed radioactive materials were stored in a controlled area, while the exterior door remained unlocked and unsecured.

- B. Condition 22 of License No. 24-21362-01 requires, in part, that the licensee conduct its program in accordance with the statements, representations, and procedures contained in the referenced documents, including any enclosures. License Condition 22.B. references the licensee's Radiation Protection Program in a letter dated February 8, 2005.

Section 3.2.1 of the Radiation Protection Program states that "the Radiation Safety Committee administers the Radiation Protection Program to assure control of the procurement, use and disposition of radioactive materials and assures that the Radiation Protection Program meets all requirements of the American Radiolabeled Chemicals, Inc. Radioactive Materials License."

Section 3.2.5 of the Radiation Protection Program specifies that the Radiation Safety Committee is held at least monthly and under any of the following circumstances: (a) to fulfill the listed duties of the Committee, or (b) whenever any Committee member requests the Chairman or Vice Chairman to call a meeting at any time for any valid reason.

Section 3.3.3.5 of the Radiation Protection Program states that the Radiation Safety Officer "annually reviews and updates, as necessary, the Radiation Protection Program to assure compliance with established standards and procedures."

Contrary to the above, the licensee failed to conduct its program in accordance with the statements, representations, and procedures contained in referenced documents, including any enclosures, of License Condition 22.B, as evidenced by the following examples:

1. The licensee failed to conduct Radiation Safety Committee meetings during the months of February, June, July, and September through December, 2006, and January through October, 2007.
 2. The Radiation Safety Committee and Radiation Safety Officer failed to update the Radiation Protection Program to prevent the recurrence of repetitive program violations and weaknesses identified in annual program reviews on December 2004, June 2, 2005, April 13, 2006, and November 2007.
- C. Condition 22 of License No. 24-21362-01 requires, in part, that the licensee conduct its program in accordance with the statements, representations, and procedures contained in the referenced documents, including any enclosures. License Condition 22.B. references the licensee's Radiation Protection Program in a letter dated February 8, 2005, and references the licensee's Standard Operating Procedures in letter dated March 24, 2005.

Section 4.1.3 of the Radiation Protection Program states, in part, that "surveys shall be made as ... (2) are reasonable to evaluate radiation levels, concentrations or quantities of RAM [radioactive material], and radiological hazards."

Section 5.2.3 of the Radiation Protection Program states "any contamination detectable above background indicates excessive loose contamination and should be reported to the RSO [Radiation Safety Officer]. Individuals shall survey their hands upon leaving the laboratory. Individuals should survey items being taken from the laboratory to prevent the transfer of contamination to non-contaminated areas."

Section 2.0 of Standard Operating Procedure 16 "Radioactive Contamination Control Program," states, in part, that controlled areas are required to be surveyed twice weekly for radiological contamination: at the end of the week and at the beginning of the week. Section 2.0 also states, in part, that controlled areas are required to be surveyed daily as conditions and manpower permit.

Section 2.0 of Standard Operating Procedure 30 "Release of Equipment to Vendors" states, in part, that Health Physics personnel are required to "scan the equipment with a GM survey meter and outline any areas where contamination is detected. Wipe test the outlined areas and take a few random wipes at other locations where contamination is likely. Stamp the survey sheet from the LSA....Enter the next consecutive number in the Item blank and pen in the Description. Decon and rewipe until the areas are below the release level, which is 1000 dpm/100 cm² for the sum of tritium and carbon-14. Briefly describe where the wipe was taken."

Contrary to the above, the licensee failed to conduct its program in accordance with the statements, representations, and procedures contained in referenced documents, including any enclosures, of License Condition 22.B, as evidenced by the following examples:

1. Since 2006, the licensee failed to survey controlled areas as required by Standard Operating Procedure 16. Specifically, the licensee failed to perform radiation surveys in Building 200, a controlled area, at the start of every week or daily in accordance with Section 2.0 of Standard Operating Procedure 16.
 2. The licensee failed to make surveys as reasonable to evaluate radiation levels, concentrations or quantities of radioactive material, and radiological hazards. Specifically, NRC inspectors identified radiological contamination in unrestricted areas in excess of the licensee's release level on January 23, 24, and 25, 2008, but no surveys were performed by the licensee.
 3. The licensee failed, on January 23 and 24, and March 12, 2008, to ensure that employees surveyed their hands upon leaving laboratories.
 4. The licensee failed, on March 13, 2008, to perform radiation surveys and complete required documentation prior to releasing empty nitrogen gas tanks to a vendor.
- D. Condition 22 of License No. 24-21362-01 requires, in part, that the licensee conduct its program in accordance with the statements, representations, and procedures contained in the referenced documents, including any enclosures. License Condition 22.B. references the licensee's Standard Operating Procedures in letter dated March 24, 2005.

Section 5.0 of Standard Operating Procedure 16 "Radioactive Contamination Control Program" states, with regard to Health Physics personnel, "if initial contamination levels are identified exceeding 10 times the action levels, attempt to determine the source and cause. The results of this investigation shall be documented and filed in the Off-Normal Occurrence File."

Contrary to the above, the licensee failed to perform and document investigations of contamination found in controlled and unrestricted areas at levels greater than 10 times the licensee's radiological action levels on multiple instances, including June 19, 2006, February 20, 2006, January 30, 2007, November 19, 2007, July 16, 2007, May 21, 2007, and August 14, 2007.

This is a Severity Level III problem (Supplement IV).

Civil Penalty - \$6500 (EA-08-126)

Notice of Violation and Proposed
Imposition of Civil Penalty

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Pursuant to the provisions of 10 CFR 2.201, American Radiolabeled Chemicals, Inc. (Licensee) is hereby required to submit a written statement or explanation to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, DC 20555, with a copy to the Regional Administrator, Region III, transmitting this Notice of Violation (Notice) and Proposed Imposition of a Civil Penalty (Notice) within **30 days** of the date of the letter. This reply should be clearly marked as a "Reply to a Notice of Violation" and should include: (1) admission or denial of the alleged violation, (2) the reason for the violation, or, if contested, the basis for disputing the violation or severity level, (3) the corrective steps that have been taken and the results achieved, (4) the corrective steps that will be taken to avoid further violations, and (5) 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.

Within the same time as provided for the response required above under 10 CFR 2.201, the Licensee may pay the civil penalty proposed above in accordance with NUREG/BR-0254 and by submitting to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, Washington, DC 20555, a statement indicating when and by what method payment was made, or may protest imposition of the civil penalty in whole or in part, by a written answer addressed to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission. Should the Licensee fail to answer within the time specified, an order imposing the civil penalty will be issued. Should the Licensee elect to file an answer in accordance with 10 CFR 2.205 protesting the civil penalty, in whole or in part, such answer should be clearly marked as an "Answer to a Notice of Violation" and may: (1) deny the violations listed in this Notice, in whole or in part, (2) demonstrate extenuating circumstances, (3) show error in this Notice, or (4) show other reasons why the penalty should not be imposed. In addition to protesting the civil penalty, in whole or in part, such answer may request remission or mitigation of the penalty.

In requesting mitigation of the proposed penalty, the factors addressed in Section VI.C.2 of the Enforcement Policy should be addressed. Any written answer in accordance with 10 CFR 2.205 should be set forth separately from the statement or explanation in reply pursuant to 10 CFR 2.201, but may incorporate parts of the 10 CFR 2.201 reply by specific reference (e.g., citing page and paragraph numbers) to avoid repetition. The attention of the Licensee is directed to the other provisions of 10 CFR 2.205, regarding the procedure for imposing a civil penalty

Upon failure to pay any civil penalty due which subsequently has been determined in accordance with the applicable provisions of 10 CFR 2.205, this matter may be referred to the Attorney General, and the penalty, unless compromised, remitted, or mitigated, may be collected by civil action pursuant to Section 234(c) of the Act, 42 U.S.C. 2282c.

Notice of Violation and Proposed
Imposition of Civil Penalty

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The responses noted above, i.e., Reply to Notice of Violation, Statement as to payment of civil penalty, and Answer to a Notice of Violation, should be addressed to: Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, One White Flint North, 11555 Rockville Pike, Rockville, MD 20852-2738, with a copy to the Regional Administrator and Enforcement Officer, U.S. Nuclear Regulatory Commission, Region III.

Because your response will be made available electronically for public inspection in the NRC Public Document Room or from the NRC's document 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 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). If safeguards information is necessary to provide an acceptable response, please provide the level of protection described in 10 CFR 73.21.

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

Dated this 22nd day of July 2008