

December 3, 2010

EA-10-097

EA-10-170

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

SUBJECT: NOTICE OF VIOLATION; RESULTS OF OFFICE OF INVESTIGATIONS (OI)
REPORTS NOS. 3-2010-004 AND 3-2010-006 – AMERICAN RADIOLABELED
CHEMICALS, INC.

Dear Dr. Gupta:

This refers to two U.S. Nuclear Regulatory Commission (NRC) inspections, the first conducted on October 27 and 28, 2009, with continued in-office review through December 4, 2009, and the second conducted from November 16 through 20, 2009, with continued in-office review through January 5, 2010. The inspections occurred at the American Radiolabeled Chemicals, Inc., (ARC) facility located in St. Louis, Missouri. The purpose of the first inspection was to review a tritium contamination event that was discovered by the Florida Bureau of Radiation Control at Lockheed Martin Corporation (Lockheed) in Orlando, Florida; the second inspection was a routine NRC inspection. During both inspections, the inspectors identified several violations as described in NRC Inspection Report Nos. 030-20567/09-03 (DNMS), dated December 28, 2009, and 030-20567/09-04(DNMS) dated February 4, 2010.

The NRC identified several instances where your Radiation Protection Program was not followed. On November 16 and 30, 2009, the NRC Office of Investigations (OI) initiated two investigations into these issues. On May 21, 2010, the NRC OI completed its investigation into the circumstances surrounding a failure to restrict contract personnel from performing work with radionuclides once they exceeded the limit specified in your Radiation Protection Program of greater than 100 millirem in a week of a committed effective dose equivalent. In a letter dated August 12, 2010, the NRC provided you a synopsis of the OI investigation results of this issue and identified an apparent willful violation of a license condition.

On September 29, 2010, a Predecisional Enforcement Conference was conducted at the NRC's Region III office in Lisle, Illinois, with you and your Radiation Safety Officer to discuss the apparent violation of failing to restrict individuals who had exceeded the weekly internal exposure limit from further performing work with radionuclides, the significance and root cause of the apparent violation and ARC's corrective actions. A list of conference attendees is included in Enclosure 1. During the conference, you and the Radiation Safety Officer acknowledged the apparent violation, discussed the facts of the issue, denied any willful intent, and discussed corrective actions that were taken and the overall impact on ARC's business.

On August 11, 2010, the NRC OI completed its second investigation. This investigation reviewed the circumstances surrounding at least four weekly surveys not being completed and at least ten instances where ARC internal investigations to determine the source and cause of contamination

levels exceeding internal action levels were not documented. The NRC did not identify any apparent willful violations as a result of this investigation.

Based on the information developed during the inspections and investigations and the information provided during the conference, the NRC has determined that the issues described above did not involve any willfulness. In addition, the NRC evaluated the underlying technical issues and identified violations of license requirements. Two of the three violations have been categorized in accordance with the NRC Enforcement Policy as Severity Level IV violations. These violations are cited in the enclosed Notice of Violation (Enclosure 2) because they were identified by the inspectors. The third violation concerning internal ARC investigations of contamination levels was determined to constitute a violation of minor significance and is not subject to formal enforcement action.

Although the NRC did not identify any willfulness, the NRC continues to be concerned with the ARC safety culture as it pertains to compliance with license requirements. Specifically, the NRC has observed continuing failures by the Radiation Safety Committee to provide a strong and consistent message—not only to your Radiation Safety Officer and his staff—but to all ARC employees about the need to comply with contamination control procedures and your Radiation Protection Program. You are ultimately responsible for providing adequate oversight of your Radiation Protection Program.

Additionally, the NRC had identified an Open Item pertaining to issues associated with surveys, as discussed in Section 3.2.a. of NRC Inspection Report No. 030-20567/09-04 (DNMS) dated February 4, 2010. The Open Item is considered closed.

You are required to respond to this letter and should follow the instructions specified in the enclosed Notice of Violation when preparing your response. The NRC review of your response to the Notice will also determine whether further enforcement action is necessary to ensure compliance with regulatory requirements.

In accordance with Title 10 of the Code of Federal Regulations (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 Agencywide Documents Access and Management System (ADAMS), accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>. Therefore, 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

S. Gupta

-3-

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).

Sincerely,

/RA/

Mark A. Satorius
Regional Administrator

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

Enclosures:

1. List of Attendees at Predecisional Enforcement Conference
2. Notice of Violation

cc w/enclosures: Regis Greenwood
Radiation Safety Officer
State of Missouri

S. Gupta

-3-

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).

Sincerely,

/RA/

Mark A. Satorius
Regional Administrator

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

Enclosures:

1. List of Attendees at Predecisional Enforcement Conference
2. Notice of Violation

cc w/enclosures: Regis Greenwood
Radiation Safety Officer
State of Missouri

DISTRIBUTION:

See next page

FILE NAME: G:\ORAI\IICS\ENFORCEMENT\Enforcement Cases 2010\EA-10-097 ARC\EA-10-097 ARC Final Letter SL IV NOV kjd (2).docx

Publicly Available Non-Publicly Available Sensitive Non-Sensitive

OFFICE	RIII	RIII	D:FSME	D:OE	D:OGC
NAME	Lougheed	Bloomer	White for Luehman ¹	Day for Zimmerman ²	Barkman for Scott ³
DATE	11/30/10	11/30/10	11/08/10	11/26/10	11/19/10
OFFICE	RIII	RIII	RIII	RIII	
NAME	Lipa for Reynolds	Heck	Orth	Satorius	
DATE	12/02/10	12/02/10	12/02/10	12/03/10	

OFFICIAL RECORD COPY

1 FSME concurrence received via e-mail from D. White on November 8, 2010.
2 OE concurrence received via e-mail from K. Day on November 26, 2010.
3 OGC "No Legal Objection" received via e-mail from M. Barkman on November 19, 2010.

Letter to Surendra K. Gupta, Ph.D. from Mark A. Satorius dated December 3, 2010

SUBJECT: NOTICE OF VIOLATION; RESULTS OF OFFICE OF INVESTIGATIONS (OI)
REPORTS NOS. 3-2010-004 AND 3-2010-006 – AMERICAN RADIOLABELED
CHEMICALS, INC.

DISTRIBUTION:

Docket File
Roy Zimmerman
Nick Hilton
Kerstun Day
Molly Barkman
Mark Satorius
Cynthia Pederson
Michele Burgess
Glenda Villamar
Duane White
Daniel Holody
Carolyn Evans
William Jones
Steven Reynolds
Patrick Loudon
Christine Lipa
Tamara Bloomer
Kevin Null
Robert Gattone
Andrew Bramnik
Steven Orth
Jared Heck
Patricia Lougheed
Paul Pelke
Magdalena Gryglak
Patricia Buckley
Tammy Tomczak
OEMAIL.Resource
OEWEB Resource

LIST OF ATTENDEES
AT SEPTEMBER 29, 2010
PREDECISIONAL ENFORCEMENT CONFERENCE

ARC

Surendra Gupta, Ph.D., President
Regis Greenwood, Radiation Safety Officer

NRC

Mark Satorius, Regional Administrator, Region III (RIII)
Christine Lipa, Acting Deputy Director, Division of Nuclear Materials Safety (DNMS), RIII
Tamara Bloomer, Branch Chief, Materials Inspection Branch, DNMS, RIII
Kevin Null, Inspector, Materials Licensing Branch, DNMS, RIII
Steven Orth, Enforcement Officer, Enforcement and Investigation Coordination Staff, RIII
Kerstun Day, Enforcement Specialist, Office of Enforcement (by phone)
Glenda Villamar, Health Physicist, Office of Federal and State Materials Environmental
Management Programs (by phone)
Molly Barkman, Attorney, Office of General Counsel (by phone)

NOTICE OF VIOLATION

American Radiolabeled Chemicals, Inc.
St. Louis, Missouri

Docket No. 030-20567
License No. 24-21362-01
EA-10-097; EA-10-170

The U.S. Nuclear Regulatory Commission (NRC) performed inspections at American Radiolabeled Chemicals, Inc., (ARC) on October 27 and 28, 2009, with continued in-office review through December 4, 2009, and from November 16 through 20, 2009, with continued in-office review through January 5, 2010. In addition, the NRC Office of Investigations (OI) conducted investigations that were completed on May 21, 2010, and on August 11, 2010. In accordance with the NRC Enforcement Policy, the violations that were identified are listed below:

1. Condition 22.B of NRC License No. 24-21362-01, Amendment 38, requires, in part that the licensee conduct its program in accordance with statements, representations, and procedures contained in a letter dated February 8, 2005 (including the Radiation Protection Program dated October 21, 2004).

Item 4.2.2.2 of the licensee's Radiation Protection Program entitled "Requirements for Limiting Internal Exposures of Individuals" requires, in part, that for individuals who receive greater than 100 millirem in a week of a committed effective dose equivalent (CEDE), the licensee shall restrict the individual from further work with radionuclides until the dose rate falls below 50 millirem in a week.

Contrary to the above, on January 15, 2009, an individual received a CEDE of at least 148 millirem (combined for hydrogen-3 and carbon-14) and the licensee failed to restrict the individual from further work with radionuclides until his dose rate fell below 50 millirem in a week.

This is a Severity Level IV violation (Section 6.7)

2. Condition 22.B of NRC License No. 24-21362-01, Amendments 38, 39, and 40¹, requires, in part, that the licensee conduct its program in accordance with the statements, representations, and procedures contained in licensee letters dated March 24, 2005.

One of the March 24, 2005, licensee letters includes Standard Operating Procedure (SOP)-16, "Radioactive Contamination Control Program." Item 1.0 of SOP-16 states, in part, that removable contamination surveys are required in Restricted, Controlled, and Unrestricted areas. Item 2.0 of SOP-16 states, in part, that the routine survey frequency for each type of survey is weekly. Item 2.1.1 of SOP-16 states that contamination area surveys are done at the "End of Week prior to cleaning – Last workday of the week, usually Friday." Item 2.1.2 of SOP-16 states that contamination area surveys are done at the "Start of Week, after cleaning – usually Monday morning."

¹ Amendment 38 was applicable from October 13, 2008, through March 13, 2009. Amendment 39 was applicable from March 13, 2009, through October 29, 2009. Amendment 40 was applicable from October 29, 2009, through July 6, 2010.

Contrary to the above, on November 28, 2008, May 15, 2009, and October 9, 2009, the licensee failed to conduct contamination restricted area surveys in Buildings 100 and 300 at the end of the week prior to cleaning. On October 26, 2009, the licensee failed to conduct contaminated restricted area surveys in Buildings 100 and 300 at the start of the week after cleaning.

This is a Severity Level IV Violation (Section 6.7)

Pursuant to the provisions of Title 10 of the Code of Federal Regulations (10 CFR) 2.201, ARC is hereby required to submit a written statement or explanation to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, with a copy to the Regional Administrator, U.S. Nuclear Regulatory Commission, Region III, 2443 Warrenville Road, Suite 210, Lisle, IL 60532, within 30 days of the date of this Notice of Violation (Notice). This reply should be clearly marked as a "Reply to a Notice of Violation: EA-10-097, EA-10-170" 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) any additional corrective steps that will be taken; and (4) the date when full compliance will be or was 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, the NRC may issue an Order or a Demand for Information requiring you to explain why your 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 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, it should not include any personal privacy or proprietary 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).

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

Dated this 3rd day of December 2010