



**UNITED STATES  
NUCLEAR REGULATORY COMMISSION**

REGION III  
2443 WARRENVILLE RD. SUITE 210  
LISLE, IL 60532-4352  
March 26, 2014

EA-13-259

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

**SUBJECT: NRC ROUTINE INSPECTION REPORT NO. 03020567/2013001(DNMS) AND  
NOTICE OF VIOLATION – AMERICAN RADIOLABELED CHEMICALS**

Dear Dr. Gupta:

On May 20 through 22, 2013, and February 3 and 4, 2014, the U.S. Nuclear Regulatory Commission (NRC) conducted inspections at your St. Louis facility, with continued in-office review through February 20, 2014. The purpose of the inspection was to review activities performed under your NRC license to ensure that activities were being performed in accordance with NRC requirements. The in-office review included a review of your procedure for storage of Surface Contaminated Objects (SCO), and actions taken to comply with that procedure. A final telephonic exit meeting was held between Ms. Claire Wellinghoff and Mr. Don Lite of your staff on February 27, 2014, to discuss the inspection findings.

As documented in Inspection Report No. 03020567/2012001(DNMS) dated May 22, 2012, the inspectors identified a violation of NRC License No. 24-21362-01 (license) involving storage of a surface contaminated blower (SCO) that was no longer in use on an outdoor concrete pad within a cyclone fence, rather than storing it in Building 200 as required. During the May 20-22, 2013, inspection, the inspectors observed that the contaminated blower had been moved to Building 200; however, the inspectors observed other SCOs that were not in use and stored in locations other than Building 200. As stated in NRC Inspection Report No. 03020567/2013001(DNMS) dated July 1, 2013, the inspectors identified this as an Open Item involving a potential violation for failure to store SCOs in building 200 that are not in use. Because of the surrounding circumstances, the NRC Office of Investigations (OI) initiated an investigation on July 8, 2013, and conducted an investigation at your facility which was completed on December 13, 2013.

The NRC has completed its review of the Open Item and the investigation, and determined that one Severity Level IV violation of NRC requirements occurred involving your failure to transfer SCOs, no longer in use, to Building 200 for storage as required by the license. The violation was evaluated in accordance with the NRC Enforcement Policy. The current Enforcement Policy is included on the NRC's website at <http://www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html>. The violation is cited in the enclosed Notice of Violation (Notice). The NRC is citing the violation in the Notice because the inspectors identified the violation. The NRC concluded, through its review of the investigation report, that there were not any willful aspects to this violation.

The NRC is concerned with the timeliness and comprehensiveness of your corrective actions taken in response to this concern. Storing equipment in approved locations reduces the risk of an unintended spread of contamination. While we recognize that situations, such as storage of unused or unwanted radioactive materials, may change as operations at a facility change, licensees are responsible for understanding their operations and changes to their activities and taking steps to ensure continued compliance, either through a license amendment or through proper disposal of material. Upon identification of a violation, the NRC also expects licensees to take timely and effective corrective actions in order to restore compliance and to ensure that they are in full compliance with all NRC requirements. In addition to correcting an identified example of non-compliance your corrective actions should be complete and comprehensive enough to sustain compliance with regulatory requirements. Although the inspection report includes your planned corrective action, the NRC is requesting a response to the violation in order for you to more fully explain how you will ensure compliance with your license conditions now and in the future.

You are required to respond to this letter and should follow the instructions specified in the enclosed Notice when preparing your response. The guidance in NRC Information Notice 96-28, "Suggested Guidance Relating to Development and Implementation of Corrective Action," may be useful in preparing your response. You can find the Information Notice on the NRC's 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.

In accordance with Title 10 of the *Code of Federal Regulations* (CFR) 2.390 of the NRC's "Rules of Practice," a copy of this letter, its enclosure, and your response, will be made available electronically for public inspection in the NRC's Public Document Room or from the NRC's Agencywide Documents Access and Management System (ADAMS), accessible from the NRC's website 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 publicly available without redaction.

S. Gupta

- 3 -

Please feel free to contact Mr. Robert Gattone of my staff if you have any questions regarding this inspection. Mr. Gattone can be reached at 630-829-9823.

Sincerely,

***/RA by John B. Giessner Acting for/***

Patrick L. Loudon, Director  
Division of Nuclear Materials Safety

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

Enclosure:  
Notice of Violation

cc w/encl: Don Lite, Radiation Safety Officer  
State of Missouri

S. Gupta

- 3 -

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Enclosure:  
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cc w/encl: Don Lite, Radiation Safety Officer  
State of Missouri

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OFFICE	RIII DNMS		RIII DNMS		RIII DNMS		RIII EICS	
NAME	CEWellinghoff:ps*CEW		RGGattone*ATM		ATMcCraw*ATM		SKOrth*1	
DATE	03/14/14		03/14/14		03/14/14		03/25/14	
OFFICE	OGC		OE		RIII DNMS			
NAME	MBarkmanMarsh*1		RPZimmerman*1		PLLouden*JBG for			
DATE	03/25/14		03/25/14		03/26/14			

\*1 – OGC no legal objection, FSME & OE concurrence indicated via e-mail from K. Day Norman on 3/25/14.

**OFFICIAL RECORD COPY**

## NOTICE OF VIOLATION

American Radiolabeled Chemicals  
St. Louis, MO

License No. 24-21362-01  
Docket No. 030-20567  
EA-13-259

During U.S. Nuclear Regulatory Commission (NRC) inspections conducted on May 20, 2013 through May 22, 2013, and February 3, 2014 through February 4, 2014, with continued in-office review through February 20, 2014, one violation of NRC requirements was identified. In accordance with the NRC Enforcement Policy, the violation is listed below:

Condition 22 of NRC 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 documents, including any enclosures, listed. Included in Condition 22.B of the list is a letter dated September 8, 2010, (including the attached Radiation Protection Program and Standard Operation Procedures). One of the Standard Operating Procedures (SOP) attached to the letter is SOP-29, "Storage of Surface Contaminated Objects (SCO)."

Item 1 of SOP-29 states, in part, that "SCOs are pieces of equipment or objects that have become contaminated on their surfaces by use in restricted areas. When no longer being used, these items are transferred to Building 200 for temporary storage."

Contrary to the above, as of February 4, 2014, the licensee failed to conduct its program in accordance with procedures contained in its license. Specifically, the inspectors observed SCOs, that were not being used, stored in Building 300. For example, on May 20, 2013, the inspectors noted an "auto sampler," which had measurable levels of contamination at its surface and was stored in the "Cold Room" of Building 300. Additionally, during a follow-up inspection conducted on February 3-4, 2014. The inspectors observed three "BetaRam" devices that were characterized as SCO, not in use, and stored in Building 300 "Cold Room."

This is a Severity Level IV violation (Section 6.3).

Pursuant to the provisions of CFR 2.201, American Radiolabeled Chemicals 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: (1) the reason for the violation, or, if contested, the basis for disputing the violation or its severity level, (2) the corrective steps that have been taken and the results achieved, (3) the corrective steps that will be taken, and (4) the date when full compliance will be achieved. Your response may reference or include previously 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.

Your response will be made available electronically for public inspection in the NRC's Public Document Room or from the NRC's Agencywide Documents Access and Management System (ADAMS), accessible from the NRC's website at <http://www.nrc.gov/reading-rm/adams.html>. Therefore, to the extent possible, the response should not include any personal privacy, proprietary, or safeguards information so that it can be made available to the Public without redaction.

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.

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

Dated this 26<sup>th</sup> day of March 2014.