

July 1, 2013

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 May 22, 2013, U.S. Nuclear Regulatory Commission (NRC) inspectors conducted a routine inspection at your St. Louis, Missouri, facility, with continued in-office review through June 4, 2013. The in-office review included receipt and review of information not available during the onsite inspection, including receipt and review of information about the diameter of an air effluent stack that was used to calculate the effective stack height that was used to determine public dose as a result of radioactive air effluent release. 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. A final exit meeting was held between Robert Gattone and Claire Wellinghoff of my staff and Regis Greenwood of your staff by telephone on June 6, 2013.

During this inspection, the NRC staff examined activities conducted under your license related to public health and safety. Additionally, the staff examined your compliance with the Commission's rules and regulations as well as the conditions of your license. Within these areas, the inspection consisted of selected examination of procedures and representative records, observations of activities, and interviews with personnel.

Based on the results of this inspection, the NRC has determined that one 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 website at <http://www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html>. The violation involved your staff's failure to provide recurrent hazmat training at the required frequency. The violation, which was identified by the inspectors, is cited in the enclosed Notice of Violation (Notice).

Your staff's incomplete understanding of the hazmat training requirements was the root cause of the violation. As immediate corrective action, a member of your staff provided the hazmat employee training to the two hazmat employees on May 23, 2013. In addition, your Radiation Safety Officer (RSO) committed to review Title 49 of the Code of Federal Regulations (CFR) Part 172 by May 25, 2013. As a long-term corrective action to prevent a similar violation, your RSO committed to institute a calendar "tickler" system by June 6, 2013, to remind the RSO to provide timely recurrent hazmat employee training. As such, you are now in compliance with NRC requirements.

S. Gupta

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In addition to the violation, the inspectors identified an Open Item involving a potential violation of Condition 21 of NRC license 24-21362-01, Amendment No. 49. The potential violation involves a failure to store Surface Contaminated Objects in the Building 200 roll-up door area. The NRC is continuing its review of the Open Item. Upon completion of the review, the results will be documented in a separate correspondence.

The NRC has concluded that information regarding the reason for the violation, the corrective actions taken and planned to correct the violation and prevent recurrence, and the date when full compliance will be achieved is already adequately addressed on the docket in this letter. Therefore, you are not required to respond to this letter unless the description herein does not accurately reflect your corrective actions or your position. In that case, or if you choose to provide additional information, you should follow the instructions specified in the enclosed Notice.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter, its enclosure, and your response, if you choose to provide one, 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.

Please feel free to contact Claire Wellinghoff of my staff if you have any questions regarding this inspection. Ms. Wellinghoff can be reached at (630) 829-9571.

Sincerely,

/RA/

Aaron T. McCraw, Chief
Materials Inspection Branch
Division of Nuclear Materials Safety

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

Enclosure:
Notice of Violation

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

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Please feel free to contact Claire Wellinghoff of my staff if you have any questions regarding this inspection. Ms. Wellinghoff can be reached at (630) 829-9571.

Sincerely,

/RA/

Aaron T. McCraw, Chief
Materials Inspection Branch
Division of Nuclear Materials Safety

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

Enclosure:
Notice of Violation

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

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NAME	CEWellinghoff:ps		RGGattone*RGG		PJLee*PJL		ATMcCraw*ATM	
DATE	6/21/2013		7/1/2013		6/25/2013		7/1/2013	

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NOTICE OF VIOLATION

American Radiolabeled Chemicals
St. Louis, MO

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

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

Title 10 of the Code of Federal Regulations (CFR) Part 71.5(a) requires that a licensee who transports licensed material outside of the site of usage, as specified in the NRC license, or where transport is on public highways, or who delivers licensed material to a carrier for transport, comply with the applicable requirements of the regulations appropriate to the mode of transport of the Department of Transportation (DOT) in 49 CFR Parts 107, 171-180, and 390-397.

49 CFR 172.702 requires that each hazmat employer shall ensure that each hazmat employee is trained and tested, and that no hazmat employee performs any function subject to the requirements of 49 CFR Parts 171-177 unless trained, in accordance with Subpart H of 49 CFR Part 172. The terms Hazmat Employer and Hazmat Employee are defined in 49 CFR 171.8.

49 CFR 172.704(a) specifies the elements of hazmat employee training as: (1) general awareness/familiarization training, (2) function-specific training, and (3) safety training. 49 CFR 172.704(c) requires, in part, that a hazmat employee receive initial training, and recurrent training at least once every three years.

Contrary to the above, the licensee, a hazmat employer, did not provide training that satisfied the requirements in Subpart H to 49 CFR Part 172 for two hazmat employees, in that the licensee did not provide recurrent hazmat training to the hazmat employees between November 4, 2009, and May 22, 2013, a period greater than 3 years.

This is a Severity Level IV violation (Section 6.8 d.).

The NRC has concluded that information regarding the reason for the violation, the corrective actions taken and planned to correct the violation and prevent recurrence, and the date when full compliance was achieved, is already adequately addressed on the docket in the letter transmitting this Notice of Violation (Notice). However, you are required to submit a written statement or explanation pursuant to 10 CFR 2.201 if the description therein does not accurately reflect your corrective actions or your position. In that case, or if you choose to respond, clearly mark your response as a "Reply to a Notice of Violation, IR 03020567/2013001(DNMS)," and send it 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.

Enclosure

If you choose to respond, your response will be made available electronically for public inspection in the NRC Public Document Room or from the NRC 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, the response should not include any personal privacy, proprietary, or safeguards information so that it can be made available to the Public without redaction.

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

Dated this 1st day of July 2013.