



UNITED STATES  
NUCLEAR REGULATORY COMMISSION

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

March 3, 2014

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

SUBJECT: NRC SPECIAL INSPECTION REPORT NO. 03020567/2014001(DNMS) AND  
NOTICE OF VIOLATION – AMERICAN RADIOLABELED CHEMICALS

Dear Dr. Gupta:

On February 3, 2014, through February 4, 2014, inspectors from the U.S. Nuclear Regulatory Commission (NRC) conducted a special inspection at your St. Louis facility. The purpose of the inspection was to follow up on an open item involving a potential violation identified during the May 20-22, 2013 routine inspection, and 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 the NRC, represented by Ms. Wellinghoff, Mr. Gattone, and me; and your company, represented by Mr. Lite, Mr. Greenwood, and you, on February 4, 2014, to discuss the inspection findings.

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 concerned the licensee's failure to only possess byproduct material as authorized in its specific license, as required by Title 10 of the *Code of Federal Regulations* (CFR) Part 30.3(a). Specifically, the licensee possessed a cesium-137 source that was not exempt from licensing without authorization for that isotope on its specific license or under a general license at the time it was acquired. 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 inspectors determined that the root cause of the violation was the licensee's lack of familiarity with 10 CFR 31.5 and the requirements for generally licensed devices. As a corrective action to restore compliance, the manufacturer of the device redistributed the device to American Radiolabeled Chemicals, Inc., under a general license on October 8, 2013. As corrective actions to prevent recurrence, the Radiation Safety Officer (RSO) committed to: (1) reviewing 10 CFR Parts 30 and 31; (2) verifying package contents prior to accepting it; and

S. Gupta

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(3) providing instruction to licensee staff about ordering radioactive material and verifying that material is authorized for possession.

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 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: Don Lite, RSO  
State of Missouri

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

Docket No. 030-20567  
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Enclosure:  
Notice of Violation

cc w/encl: Don Lite, RSO  
State of Missouri

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## NOTICE OF VIOLATION

American Radiolabeled Chemicals  
St. Louis, MO

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

During a U.S. Nuclear Regulatory Commission (NRC) inspection conducted on February 3, 2014 through February 4, 2014, 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 30.3 requires, in part, that that except for persons exempted, no person shall possess or use byproduct material except as authorized by a specific or general license issued pursuant to Title 10, Chapter 1, Code of Federal Regulations.

Items 6, 7, and 8 of NRC License No. 24-21362-01 limits the possession of licensed materials to those byproduct, source, and/or special nuclear materials listed.

Contrary to the above, from June 12, 2013 to October 8, 2013, the licensee failed to only possess byproduct material as authorized in Items 6, 7, and 8 of its specific license. Specifically, the licensee possessed a cesium-137 source in a liquid scintillation counter without authorization for such a source on its specific license or under a general license at the time it was acquired, and the source was not exempt from licensing.

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

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 (this letter, the subject inspection report, etc.). 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 03020567/2014001(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.

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'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, 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 3<sup>rd</sup> day of February 2014.