

February 20, 2013

Surrendra K. Gupta, Ph.D., President  
American Radiolabeled Chemicals  
101 ARC Drive  
St. Louis, Missouri 63146

SUBJECT: NRC SPECIAL INSPECTION REPORT NO. 03020567/12002(DNMS) AND  
NOTICE OF VIOLATION – AMERICAN RADIOLABELED CHEMICALS

Dear Dr. Gupta:

On November 28 and 29, 2012, a U.S. Nuclear Regulatory Commission (NRC) inspector conducted a special inspection at your facility located in St. Louis, Missouri, with continuing in-office review through February 5, 2013. The purpose of the inspection was to review your corrective actions to violations that had been previously cited in NRC Inspection Report No. 03020567/12001(DNMS)(ML12174A210). The in-office review included a review of records related to the export of byproduct materials. A final exit meeting was held between Mr. Andrew Bramnik of my staff and Regis Greenwood of your staff by telephone on February 5, 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 three Severity Level IV violations of NRC requirements occurred. The violations were evaluated in accordance with the NRC Enforcement Policy. The current Enforcement Policy is included on the NRC's Web site at <http://www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html>. The violations concerned the failure to: (1) equip all buildings with motion detectors and entry point monitors; (2) follow the required procedure for picking up, receiving, and opening incoming packages containing radioactive materials; and (3) adhere to the limitations for exporting byproduct material under a general license. The violations are cited in the enclosed Notice of Violation (Notice). The NRC is citing the violations in the Notice because the inspector identified the violations.

The first violation concerned the failure to equip all buildings with motion detectors and entry point monitors, which trigger an audible alarm and send a signal to the security company upon intrusion, as required by Item 8.2.1 of your Radiation Protection Program. This violation was also identified during the previous NRC inspection conducted in April 2012, when the NRC identified several doors that were not equipped with either motion detectors or entry point monitors. During this inspection, one exterior door was not equipped with a motion detector. The cause of the violation was the failure to ensure that all building doors had both motion detectors and entry point monitors installed by your security company in response to the previously-cited violation. As corrective action, the security company installed a motion detector

in the area and tested its functionality on November 29, 2012. As long term corrective actions, the security company conducts manual and electronic tests on all of your motion detectors and entry point monitors every quarter. The reports of those tests are reviewed and maintained by your Radiation Safety Officer (RSO).

The second violation concerned your staff's failure to follow the required Standard Operating Procedure (SOP) – 06: Program for Picking Up, Receiving, and Opening of Incoming Radioactive Materials. The first item under Section 2.0 "Procedure" for SOP-06 calls for staff to "Put on gloves to prevent hand contamination." On November 28, 2012, the inspector observed members of your staff receiving and opening incoming packages of radioactive materials without wearing gloves. The cause of the violation was a misunderstanding by the staff regarding the version of the procedure that was applicable. Specifically, your staff believed that a newer revision of the procedure was in effect that did not require the use of gloves until individual vials or containers of radioactive material were being handled. As immediate corrective actions, staff working in the shipping area donned gloves to prevent hand contamination. As long term corrective actions, you committed to hold an all-staff meeting to emphasize that SOPs currently in effect per the NRC license must be followed until an amendment is issued by the NRC. The all staff meeting was completed by December 31, 2012.

The third violation concerned the failure to adhere to the limitations for exporting byproduct material under the general license in Title 10 of the Code of Federal Regulations (CFR) Section 110.23. Exports under the general license in 10 CFR 110.23 for tritium in any dispersed form (e.g. labeled compounds) must not exceed 0.37 TBq (10 Curies) per item. On September 19, 2011, your staff exported five items containing tritium gas in a single shipment to India, and the contents of each item were 20 Curies of tritium. The cause of the violation was your staff's lack of awareness of the requirements and limitations in 10 CFR Part 110. As corrective actions, your RSO provided information and training on the requirements to individuals responsible for recording, filling, and packaging orders for export. Your RSO also posted instructions in the package shipment area of Building 300. These actions were completed by December 31, 2012.

The NRC has concluded that information regarding the reason for the violations, the corrective actions taken and planned to correct the violations 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 addition, the NRC inspector reviewed the immediate and long term corrective actions from the Severity Level III violation cited in the Notice of Violation dated June 25, 2012. The NRC determined that you implemented all of the corrective actions as described in your letter dated June 5, 2012, and therefore you are now in compliance. This violation is closed.

S. Gupta

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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 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, your response should not include any personal privacy, proprietary, or safeguards information so that it can be made available to the Public without redaction.

Please feel free to contact Mr. Andrew Bramnik of my staff, if you have questions regarding this inspection. You can reach Mr. Bramnik at 630-829-9543.

Sincerely,

*/RA/*

Tamara E. Bloomer, 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

S. Gupta

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Tamara E. Bloomer, 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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DATE	2/13/2013	2/12/2013	2/20/2013	

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## NOTICE OF VIOLATION

American Radiolabeled Chemicals  
St. Louis, Missouri

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

During a U.S. Nuclear Regulatory Commission (NRC) inspection conducted on November 28 and 29, 2012, with continuing in-office review through February 5, 2013, three violations of NRC requirements were identified. In accordance with the NRC Enforcement Policy, the violations are listed below:

- A. Condition 21 of NRC License No. 24-21362-01 states, in part, that the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the letter dated September 8, 2010, with the attached Radiation Protection Program.

Item 8.2.1 of the Radiation Protection Program attached to the letter dated September 8, 2010, states that all buildings are equipped with motion detectors and entry point monitors, which trigger an audible alarm and send a signal to the security company upon intrusion.

Contrary to the above, as of November 28, 2012, the licensee failed to equip all buildings with motion detectors. Specifically, a door was unequipped with a motion detector to trigger an audible alarm or send a signal to the security company upon intrusion.

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

- B. Condition 21 of NRC License No. 24-21362-01 states, in part, that the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the letter dated March 3, 2011.

Item 2.1 of the Standard Operating Procedure SOP-06 titled "Program for Picking Up, Receiving, and Opening of Incoming Radioactive Materials" enclosed with the letter dated March 3, 2011, requires employees to put on gloves to prevent hand contamination.

Contrary to the above, on November 28, 2012, the licensee failed to put on gloves to prevent hand contamination. Specifically, the licensee received and opened incoming packages containing radioactive materials without wearing gloves.

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

Enclosure

- C. Title 10 of the Code of Federal Regulations (CFR) 110.20(a) states that a person may use an NRC general license as authority to export or import nuclear equipment or material, if the nuclear equipment or material to be exported or imported is covered by the NRC general licenses described in 10 CFR 110.21 through 110.27. If an export or import is not covered by the NRC general licenses described in 10 CFR 110.21 through 110.27, a person must file an application with the Commission for a specific license in accordance with 10 CFR 110.31 through 110.32.

Title 10 CFR 110.23(a) states, in part, that a general license is issued to any person to export byproduct material to any country not listed in 10 CFR 110.28, and subject to the limitation that for tritium in any dispersed form (e.g. labeled compounds), exports under the general license must not exceed 0.37 TBq (10 Curies) per item.

Contrary to the above, on September 19, 2011, the licensee failed to limit its export of tritium to less than 0.37 TBq per item as required by 10 CFR 110.23. Specifically, the licensee exported five items containing tritium gas in a single shipment to India, the contents of each item were 20 Curies of tritium, and the licensee did not apply for a specific license.

This is a Severity Level IV Violation (Section 6.7).

The NRC has concluded that information regarding the reason for the violations, the corrective actions taken and planned to correct the violations 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 03020567/12002(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 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 20th day of February 2013.