



**UNITED STATES
NUCLEAR REGULATORY COMMISSION**

Region III
2443 Warrenville Road, Suite 210
Lisle IL 60532-4352

June 25, 2012

EA-12-077

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

**SUBJECT: NOTICE OF VIOLATION – AMERICAN RADIOLABELED CHEMICALS
NRC ROUTINE INSPECTION REPORT NO. 03020567/2012-001(DNMS)**

Dear Dr. Gupta:

This refers to the inspection conducted on April 2 through 4, 2012, at your facility located in St. Louis, Missouri with continued in-office review through April 23, 2012. The purpose of the inspection was to determine whether activities authorized under your license were conducted safely and in accordance with NRC requirements. During the inspection, an apparent violation of NRC requirements was identified. The significance of the issue and the need for lasting and effective corrective actions were discussed with you at the final inspection exit meeting on April 23, 2012. Details regarding the apparent violation were provided in the subject NRC Inspection Report No. 03020567/2012-001(DNMS) dated May 22, 2012.

In the letter transmitting the inspection report, we provided you with the opportunity to address the apparent violation identified in the report in one of three ways: (1) by providing a written response; (2) by requesting a pre-decisional enforcement conference; or (3) by verbally responding to the NRC that no additional information would be provided. In a letter dated June 5, 2012, you provided a response to the apparent violation. In your response, you did not contest the violation; however, based on the isolated nature of the incident and the timely and extensive corrective action, you requested no escalated enforcement action be taken.

Based on the information developed during the inspection, as documented in the inspection report and in your response dated June 5, 2012, the NRC has determined that a violation of NRC requirements occurred. The violation is cited in the enclosed Notice of Violation (Notice), and the circumstances surrounding it are described in detail in our inspection report dated May 22, 2012. Specifically, the inspector identified that a door was not secured, which had the potential for an unauthorized person to enter the American Radiolabeled Chemical facilities and to remove radioactive materials. Upon identification of the unsecured door, the inspector immediately closed it and your staff later confirmed that no material had been removed from the area while the door was not secured.

The failure to secure license material is of concern to the NRC because of the potential for radioactive material to have been stolen and the resultant exposures to members of the public. The root causes of the violation were personnel error in failing to ensure that the door was secure along with a mechanical problem that contributed to the door not aligning such that it did

not completely close when personnel entered and exited. Our assessment of the significance of the violation took into consideration the quantity of material involved, the duration and specific circumstances associated with occurrence and determined the violation be categorized, in accordance with the NRC Enforcement Policy, as a Severity Level III violation.

In accordance with the NRC Enforcement Policy, a base civil penalty in the amount of \$3500 is considered for a Severity Level III violation. Because your facility has not been the subject of escalated enforcement actions within the last two inspections, the NRC considered whether credit was warranted for *Corrective Action* in accordance with the civil penalty assessment process in Section 2.3.4 of the Enforcement Policy. Credit was warranted for the corrective actions taken. Your corrective actions included, but were not limited to aligning the door with the door jamb and installing an automatic door-closing mechanism and an entry point monitor. You also installed automatic door-closing mechanisms on two other doors, reviewed other doors to verify that no others were misaligned and scheduled staff members to conduct daily checks to verify that all applicable doors were secured as required.

Therefore, to encourage prompt correction of violations, and in recognition of the absence of previous escalated enforcement action, I have been authorized, after consultation with the Director, Office of Enforcement, not to propose a civil penalty in this case. However, significant violations in the future could result in a civil penalty. In addition, issuance of this Severity Level III violation constitutes escalated enforcement action that may subject you to increased inspection effort.

The NRC has concluded that information regarding the reason for the violation, the corrective actions taken and planned to correct the violation and the date when full compliance was achieved is already adequately addressed on the docket in Inspection Report No. 03020567/2012-001 (DNMS) and in your letter dated June 5, 2012. Therefore, you are not required to respond to this letter unless the description therein 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 any, 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, any response should not

S. Gupta

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include any personal privacy, proprietary, or safeguards information so that it can be made available to the Public without redaction. The NRC also includes significant enforcement actions on its Web site at <http://www.nrc.gov/reading-rm/doc-collections/enforcement/actions>.

Sincerely,

/RA by C. Pederson/

Charles A. Casto
Regional Administrator

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

Enclosure:
Notice of Violation

cc w/encl: State of Missouri

NOTICE OF VIOLATION

American Radiolabeled Chemicals
St. Louis, Missouri

Docket No. 030-20567
License No. 24-21362-01
EA-12-077

During an NRC inspection conducted on April 2 through 4, 2012, with continued in-office inspection through April 22, 2012, a 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 Section 20.1801 requires that licensees secure from unauthorized removal or access licensed materials that are stored in controlled or unrestricted areas.

Contrary to the above, on April 2, 2012, the licensee did not secure from unauthorized removal or limit access to licensed material stored in a controlled area. Specifically, an NRC inspector had unchallenged access to an exterior door to a liquid radioactive waste storage area on the licensee's property. The door was left ajar and no members of the licensee's staff were present.

This is a Severity Level III violation (Section 6.7)

The NRC has concluded that information regarding the reason for the violation, the corrective actions taken and planned to correct the violation, and the date when full compliance was achieved, is already adequately addressed on the docket in Inspection Report No. 03020567/2012-001(DNMS) and in your letter dated June 5, 2012. 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, EA-12-077," 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 of Violation.

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, United States Nuclear Regulatory Commission, Washington, DC 20555-0001.

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, or proprietary, 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 of Violation within two working days of receipt.

Dated this 25th day of June 2012

ENCLOSURE

include any personal privacy, proprietary, or safeguards information so that it can be made available to the Public without redaction. The NRC also includes significant enforcement actions on its Web site at <http://www.nrc.gov/reading-rm/doc-collections/enforcement/actions>.

Sincerely,

/RA by C. Pederson/

Charles A. Casto
Regional Administrator

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

Enclosure:
Notice of Violation

cc w/encl: State of Missouri

DISTRIBUTION:
See next page

See previous concurrences

FILE NAME: G:\ORAI\IICS\ENFORCEMENT\Cases\Enforcement Cases 2012\EA-12-077 ARC Door\EA-12-077
ARC draft Final Action.docx
Publicly Available, Non-Sensitive

OFFICE	RIII	RIII	RIII	D:OE	RIII	RIII
NAME	Bakhsh for Lougheed	Gattone for Peterson	Boland	Faria for Zimmerman ¹	Orth	Casto CP for
DATE	6/12/12	6/13/12	6/14/12	6/22/12	6/22/12	6/22/12

OFFICIAL RECORD COPY

¹ OE concurrence received via e-mail from C. Faria on June 22, 2012.

Letter to Surendra K. Gupta from Charles A. Casto dated June 25, 2012

SUBJECT: NOTICE OF VIOLATION – AMERICAN RADIOLABELED CHEMICAL
NRC ROUTINE INSPECTION REPORT NO. 03020567/2012-001(DNMS)

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