



UNITED STATES
NUCLEAR REGULATORY COMMISSION

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

November 22, 2017

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

SUBJECT: NRC ROUTINE INSPECTION REPORT NO. 03020567/2017001(DNMS) AND
NOTICE OF VIOLATION – AMERICAN RADIOLABELED CHEMICALS

Dear Dr. Gupta:

On October 10 through 12, 2017, inspectors from the U.S. Nuclear Regulatory Commission (NRC) conducted a routine inspection at your St. Louis, Missouri facility, with continued in-office review through October 26, 2017. 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 corrective actions to prevent recurrence of a violation of NRC regulatory requirements that were not available during the onsite inspection. Messrs. Robert Gattone and Edward Harvey of my staff conducted a final exit meeting by telephone with Mr. Jeffrey Vollmer of your staff on October 26, 2017, 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 four 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 website at <http://www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html>. The violations concerned the licensee's failure to: (1) have the individual named on the license perform the duties and responsibilities of the Radiation Safety Officer (RSO) for the period of November 2, 2016, to April 12, 2017, as required by Condition 12 of Amendment No. 55 of NRC License No. 24-21362-01 (NRC license); (2) conduct adequate personal radiation surveys, as required by Title 10 of the *Code of Federal Regulations* (CFR) Section 20.1501 and Condition 22 of Amendment No. 55 of your NRC license; (3) determine the future usefulness of surface contaminated objects (SCOs) prior to moving them to temporary storage, as required by Condition 22 of Amendment No. 55; and (4) decontaminate or dispose of SCOs labeled for temporary storage that have been in the licensee's inventory greater than 15 months, as required by Condition 21 of Amendment No. 56. The violations are cited in the enclosed Notice of Violation (Notice). The NRC is citing the violations in the enclosed Notice because the inspectors identified the violations.

The inspectors determined that the root cause of the violations were: (1) licensee oversight regarding the RSO violation; (2) incorrect technique and staff unawareness of the requirements regarding personal surveys, especially the measurements of hands and feet; (3) management oversight of the SCO inventory; and (4) lack of dedicated resources to ensure timely decontamination and removal of SCOs.

As corrective actions to restore compliance and to prevent recurrence: (1) the licensee appointed a new RSO and requested an amendment to its NRC license; (2) the licensee committed to revise its Radiation Protection Program to inform the NRC whenever an individual notifies the licensee that he/she announces the date when he/she will stop being the RSO, start the process of hiring a new RSO, and notify the NRC if there are any problems with the process of naming the new RSO on the license; (3) the licensee had managers and health physics staff members observe authorized users conduct personal surveys/full body frisks with a survey meter to confirm that the surveys are as required and continued that practice as of October 26, 2017; (4) required individuals to survey their hands and feet every time they exit the laboratory, and generated a root cause evaluation plan to prevent and reduce contamination outside of restricted areas that was approved by the licensee's president during the onsite inspection; (5) the RSO and Senior Chemist determined the future usefulness of all SCOs in temporary storage and updated the inventory accordingly; (6) the RSO reviewed its Standard Operating Procedure with the Senior Chemist and pertinent maintenance staff to ensure that a determination of future usefulness is made for all newly generated SCOs prior to moving them to temporary storage; and (7) the licensee dedicated more resources and effort to dispose of SCOs that have been in temporary storage greater than 15 months, resulting in a large reduction of SCO inventory since the last inspection.

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 or 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.

S. Gupta

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

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: Jeffrey Vollmer, RSO
State of Missouri

Letter to Surendra K. Gupta, Ph.D. from Aaron T. McCraw dated November 22, 2017

SUBJECT: NRC ROUTINE INSPECTION REPORT NO. 03020567/2017001(DNMS) AND
NOTICE OF VIOLATION – AMERICAN RADIOLABELED CHEMICALS

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| OFFICE | RIII-DNMS | | RIII-DNMS | | RIII-DNMS | | | |
| NAME | RGattone:ps | | EHarvey | | AMcCraw | | | |
| DATE | 11/21/17 | | 11/21/17 | | 11/22/17 | | | |

OFFICIAL RECORD COPY

NOTICE OF VIOLATION

American Radiolabeled Chemicals
St. Louis, Missouri

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

During a U.S. Nuclear Regulatory Commission (NRC) inspection conducted on October 10 through 12, 2017, at your St. Louis, Missouri facility, with continued in-office review through October 26, 2017, four violations of NRC requirements were identified. In accordance with the NRC Enforcement Policy, the violations are listed below:

- A. Condition 12. of Amendment No. 55 of NRC License No. 24-21362-01 (license) dated January 20, 2015, states the name of the individual who is the licensee's radiation safety officer (RSO).

Contrary to the above, from November 2, 2016, to April 12, 2017, the individual named as the licensee's RSO in Condition 12 of Amendment No. 55 of the license did not perform the duties and responsibilities of RSO. Specifically, on November 2, 2016, the individual who was listed on the license as the RSO left the licensee's employ and stopped performing the duties and responsibilities of RSO.

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

- B. Title 10 of the *Code of Federal Regulations* (CFR) Section 20.1501(a) states, in part, that each licensee shall make or cause to be made, surveys of areas, including the subsurface, that: (1) may be necessary for the licensee to comply with the regulations in this part; and (2) are reasonable under the circumstances to evaluate: (i) the magnitude and extent of radiation levels; and (ii) concentrations or quantities of residual radioactivity; and (iii) the potential radiological hazards of the radiation levels and residual radioactivity detected.

Condition 22. of Amendment No. 55 of the license states, in part, "...the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in documents, including any enclosures listed below." One of those documents is the licensee's letter dated June 29, 2012, that includes the licensee's Radiation Protection Program (RPP). Section 5.2.3.1 of the RPP states, in part, "Individuals shall survey their hands every time they exit the laboratory. At the end of the workday, a full body frisk with the survey meter is required."

Contrary to the above, on November 15, 2016, and January 9, 2017, licensee staff members failed to conduct adequate surveys of their hands when they exited the laboratory and failed to conduct adequate full body frisks, which allowed radioactive contamination to be spread from restricted areas to unrestricted areas.

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

- C. Condition 22 of Amendment No. 55 of the license states, in part, "...the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in documents, including any enclosures listed below." One of those documents is the licensee's letter dated September 30, 2014, that includes a commitment to follow the licensee's Standard Operation Procedure-29 (SOP-29) titled "Storage of Surface Contaminated Objects."

Paragraph 1.1 of SOP-29 states, when no longer being used, surface contaminated objects (SCOs) are transferred to building 200 for temporary storage or storage for future use, and a decision is made by the Senior Chemist and the RSO prior to movement of the item.

Contrary to the above, between October 1, 2014, and February 18, 2015, the licensee moved approximately 100 SCOs into temporary storage without first identifying the future usefulness of the items.

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

- D. Condition 21 of Amendment No. 56 of the license states, in part, "...the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in documents, including any enclosures listed below." One of those documents is the licensee's letter dated September 30, 2014, that includes a commitment to follow the licensee's Standard Operation Procedure-29 (SOP-29) titled "Storage of Surface Contaminated Objects."

Paragraph 1.1 of SOP-29 states that SCOs marked as temporary storage shall spend no longer than 12 months in the inventory. After 12 months, temporary storage items will have a 3 month grace period where it must either be disposed of as radioactive waste or decontaminated. The entry date in the inventory for all previously entered temporary storage items will be taken as October 1, 2014; therefore, the 12 and 3 month time frames shall take effect as of that date.

Contrary to the above, as of October 12, 2017, the licensee's inventory of SCOs contained approximately 20 items marked as temporary storage that had been added between October 1, 2014, and February 18, 2015, a period exceeding 12 months plus a 3-month grace period.

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

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 03020567/2017001(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 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.

If you respond, 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, any response should not include any personal privacy, proprietary, or safeguards information so that it can be made publicly available 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 22nd day of November 2017.