

May 22, 2012

EA-12-077

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

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

Dear Dr. Gupta:

On April 2 through 4, 2012, the U.S. Nuclear Regulatory Commission (NRC) conducted a routine inspection of your facility located in St. Louis, Missouri with continued in-office review. The purpose of the inspection was to determine whether activities authorized under your license were conducted safely and in accordance with NRC requirements. The in-office review was to assess information not available at the time of the inspection. The enclosed non-public report presents the results of this inspection.

During this inspection, the NRC staff examined activities conducted under your license as they relate to public health and safety, compliance with the Commission's rules and regulations, and compliance with 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, an apparent violation was identified and is being considered for escalated enforcement action 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 apparent violation involved failure to secure from unauthorized removal or access licensed materials that were stored in a controlled area. Details about this violation are available in the non-public inspection report enclosed with this letter. Corrective actions for this apparent violation were observed by the inspector during the onsite inspection. The circumstances surrounding the apparent violation, the significance of the issue, and the need for lasting and effective corrective actions were discussed with Regis Greenwood of your staff during the inspection exit meeting on April 23, 2012. As a result, it may not be necessary to conduct a Pre-decisional Enforcement Conference (PEC) in order to enable the NRC to make an enforcement decision.

Enclosures 1 and 2 Contain Sensitive Unclassified Non-Safeguards Information. When separated from Enclosure 1 and 2, this transmittal letter is decontrolled.
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S. Gupta

-2-

In addition, since your facility has not been the subject of escalated enforcement actions within the last two years or two inspections, and based upon NRC's understanding of your corrective actions, a civil penalty may not be warranted in accordance with Section 2.3.4 of the Enforcement Policy.

Before the NRC makes its enforcement decision, we are providing you an opportunity to: (1) respond in writing to the apparent violation addressed in the enclosed non-public inspection report within 30 days of the date of this letter; (2) request a PEC; or (3) respond to the NRC that the information contained in this letter and the enclosed inspection report is correct, and that no additional information will be provided. If a PEC is held, it will not be open for public observation due to the potential to discuss Security-Related Information. However, the NRC will issue a press release to announce the time and date of the conference. A PEC should be held within 30 days of the date of this letter.

If you choose to provide a written response, it should be clearly marked as "Response to the Apparent Violation in Inspection Report No. 03020567/2012-001(DNMS); EA-12-077." Because the apparent violation involves Security-Related Information, your response, if you choose to provide one, will not 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>. Mark your entire response Security-Related Information in accordance with Title 10 of the Code of Federal Regulations (CFR) Section 2.390(d)(1) and follow the instructions for withholding in 10 CFR 2.390(b)(1). However, to the extent possible, your response should not include any personal privacy, proprietary, or safeguards information.

In addition, you may request a PEC. If you choose to request a PEC, the conference will afford you the opportunity to provide your perspective on the apparent violation and any other information that you believe the NRC should take into consideration before making an enforcement decision. The topics discussed during the conference may include the following: information to determine whether a violation occurred, information to determine the significance of a violation, information related to the identification of a violation, and information related to any corrective actions taken or planned to be taken. If a conference is held, it will not be open for public observation.

Please contact Hironori Peterson at 630-829-9707 within ten days of the date of this letter to notify the NRC of your choice.

The NRC has also determined that two Severity Level IV violations of NRC requirements occurred. The violations were evaluated in accordance with the NRC Enforcement Policy. The violations are cited in the enclosed non-public Notice of Violation (Notice). The NRC is citing the violations in the Notice because they were identified by the inspectors.

The NRC has concluded that information regarding the reasons for the violations, the corrective actions taken and planned to correct the violations and prevent recurrence, and the date when full compliance will be achieved are adequately addressed on the docket in the non-public inspection report enclosed with this letter. Therefore, you are not required to respond to the violations described in the Notice unless the descriptions in the inspection report enclosed with this letter do not accurately reflect your corrective actions or your position. In that case, or if you

S. Gupta

-3-

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 will be made available electronically for public inspection in the NRC's Public Document Room or from ADAMS. However, the enclosed Notice and inspection report contain Security-Related Information; their disclosure to unauthorized individuals could present a security vulnerability. Therefore, the Notice and the inspection report will not be made available electronically for public inspection in the NRC Public Document Room or ADAMS. Security-Related Information is also discussed in Regulatory Information Summary RIS-2005-031, "Control of Security-Related Sensitive Unclassified Non-Safeguards Information" (ML053480073), which is available on the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>.

If you have any questions concerning this matter, please contact Robert Gattone of my staff at 630-829-9823.

Sincerely,

/RA/

Anne T. Boland, Director
Division of Nuclear Materials Safety

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

Enclosures:

1. Notice of Violation (Non-Publicly Available)
2. NRC Inspection Report No. 03020567/2012-001(DNMS)
(Non-Publicly Available)

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

S. Gupta

-3-

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

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Letter to Surendra K. Gupta from Tamara E. Bloomer, dated May 22, 2012.

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AMERICAN RADIOLABELED CHEMICALS

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