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3 December 2010

U.S. Nuclear Regulatory Commission
ATTN: Document Control Desk
Washington, DC 20555-0001

Reference: Docket No 030-20567
License No: 24-21362-01

Subject: Reply to Notice of Violation

Gentlemen,

Enclosed you will find a copy of American Radiolabeled Chemicals reply to the Notice of Violation dated 3 November 2010.

Thank you for your attention in this matter.

Sincerely,

A handwritten signature in black ink, appearing to read 'Surendra K. Gupta'.

Surendra K. Gupta, PhD
President
American Radiolabeled Chemicals

JEON
FSMB

American Radiolabeled Chemicals, Inc (ARC)
Reply to USNRC
Notice of Violation (NOV)

Docket No. 030-20567

License No. 24-21362-01

During a Nuclear Regulatory Commission (NRC) inspection conducted on August 2 through 6 and 9 and 10 2010, violations of the NRC requirements was identified

ARC does not contest the violations, and admits that the listed examples did occur.

ARC will discuss the violation stating the reason for the occurrence; corrective actions taken; the results of these actions; action to prevent recurrence; and the date for full compliance. For clarity and to prevent confusion, the text from the NOV will be quoted, followed by ARC's reply.

- A. *Condition 22 of NRC License No. 24-21362-01 requires, in part, that the licensee conduct its program in accordance with the statements, representations, and procedures contained in its letter to the NRC dated March 24, 2005. The letter contains Standard Operating Procedure (SOP)-16; "Radioactive Contamination Control Program" dated January 7, 2005. Item 1.0 of SOP-16 states, in part, that representative removable contamination surveys are required in Controlled Areas and Restricted Areas. Item 2.0 of SOP-16 states, in part, that wipe surveys are taken in Controlled Areas to assure that radioactivity has been contained within restricted areas, and wipe surveys are performed to determine the "worst case" conditions in restricted areas. In addition, Item 2.1 of SOP-16 states that the frequency of Controlled Area surveys is the same as that for Contamination Areas, which is the end of the week prior to cleaning (last workday of the week, usually Friday), and at the start of the week, after cleaning (usually Monday morning).*

Contrary to the above, from approximately November 2009 until August 2, 2010, the licensee failed to conduct removable contamination surveys in controlled areas and contamination areas at the end of the week prior to cleaning and at the start of the week after cleaning. Specifically, the licensee had not conducted removable contamination surveys of the exterior surfaces of the air exhaust stacks on Buildings 100/200 and 300 or the sand below the stacks, which were controlled areas, from approximately November 2009 until August 2, 2010. In addition, the licensee had not conducted removable contamination surveys of

"work areas" inside Restricted Contamination Areas (e.g., the interior of fume hoods and the inside of spill trays) as of August 6, 2010.

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

ARC agrees with the original finding.

Cause

The cause for this violation was confusion on our part.

Example 1 The Stack areas are enclosed by a No Access barrier and were scheduled to be surveyed on an as needed basis, for example when the barrier was removed for maintenance.

Example 2 The inside of fume hoods and spill trays had historically been considered to be highly contaminated and the survey schedule was set up to monitor contamination escaping from these areas.

Corrective Actions

The stacks and the sand below them have been added to the appropriate survey schedule. These surveys are taken at the end of the work week and at the beginning of the new work week.

The inside of hoods and the inside of spill trays have been added, on a rotating basis, to the appropriate survey schedule. These surveys are taken at the end of the work week and at the beginning of the new work week.

Actions to prevent recurrence

The required survey locations have been added to the written survey schedules. These surveys are taken at the end of the work week and at the beginning of the new work week.

Full compliance

We are currently in full compliance.

B. Condition 22 of NRC License No. 24-21362-01 requires, in part, that the licensee conduct its program in accordance with the statements, representations, and procedures contained in its letter to the NRC dated March 24, 2005. The letter contains SOP-09; "Hood Face Velocity Maintenance Program" dated December 17, 2004. Item 3.0 of SOP-09 states, in part, that hoods cannot be used with a face velocity that is less than 100 feet per minute (FPM).

Contrary to the above, on August 5 and 9, 2010, the licensee used fume hoods

with face velocities that were less than 100 FPM. Specifically, on August 5, 2010, a High-performance Liquid Chromatography (HPLC) fume hood was used with a face velocity of less than 50 FPM. In addition, on August 9, 2010, a fume hood was used with a face velocity of less than 0 FPM such that the fume hood was at positive pressure.

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

ARC agrees with the original finding.

HPLC is the acronym for High Pressure Liquid Chromatography.

Cause

The cause in both cases was venting portable area coolers to the fume hood instead of to the void space above the suspended ceiling. This disturbed the normal flow path of exhaust air.

Corrective action

The exhaust of all portable cooling units has been removed from fume hoods and has been vented to the void space.

For the record measurements of hood flows are now made Monday mornings before work starts. These measurements are made in the breathing zone of the using chemist, and not in locations where it would be unlikely for anyone to be breathing.

Actions to prevent recurrence

Hoods which fail to meet the use criteria are taken out of service until corrected. Starting with the New Year, a log will be kept of which hood, why and how long out of service.

Full compliance

Full compliance will be achieved January 2011.

- C. *Title 10 of the Code of Federal Regulations (10 CFR) 20.1501 requires that each licensee make or cause to be made surveys that may be necessary for the licensee to comply with the regulations in Part 20 and that are reasonable under the circumstances to evaluate the extent of radiation levels, concentrations or quantities of radioactive materials, and the potential radiological hazards that could be present.*

Title 10 CFR 20.1302 requires, in part, that the licensee shall; (1) make appropriate surveys of radioactive materials in effluents released to unrestricted and controlled areas to demonstrate compliance with the public

dose limits; and (2) demonstrate by measurement or calculation that the total effective dose equivalent to the individual likely to receive the highest dose from the licensed operation does not exceed the public dose limit.

Contrary to the above, from approximately January 2005 through August 6, 2010, the licensee failed to conduct an appropriate survey of radioactive materials in air effluents released to unrestricted and controlled areas to demonstrate compliance with dose limits to members of the public. Specifically, the licensee's method of averaging the concentration of radioactive materials in each of four controlled area zones within Building 400 for each air sampling period was inadequate because the air was not mixed before entering the breathing areas in each of the four zones.

This is a Severity Level IV violation (Supplement 6.7).

ARC agrees with the original finding.

Cause

Confusion on our part. ARC was under the impression that our methodology was correct as two previous focused inspections specifically covering only this air sampling and calculational method had not found any fault.

Corrective action

Short term, the only individual to spend a full work week in the high zone will be trained as a radiation worker.

Long term, as part of ARC's reworking of the entire airborne effluent program required as part of the license renewal, ARC will implement the recommendations given in the report from CNWRA.

Actions to prevent recurrence

As part of ARC's reworking of the entire airborne effluent program required as part of the license renewal, ARC will implement the recommendations given in the report from CNWRA.

Full compliance

As stated in the letter transmitting the License renewal, full compliance will be achieved by October 2011.

Safety Culture and SCWE

Actions taken and / or scheduled

1. SOP-35, "Maintaining a Safety Conscious Work Environment" has been implemented and is tied to the renewed license.
2. An ARC policy on consequence for failure to comply with company policies and procedures has been approved, and will take effect on 1 January 2011.
3. ARC has signed up for the State of Missouri Health and Safety Consultation Service and agreed to correct any deficiencies found.
4. All employees are invited and encouraged to attend Radiation Safety Committee meetings.
5. General employee safety meetings are scheduled quarterly.
6. Monthly training is given on various safety topics.
7. Starting in January, the company President will accompany the RSO and /or the Assistant RSO on frequent observation tours of the facility.
8. The Weekly Summary Report has been expanded in scope and is given to the President and the RSC each week.