American Radiolabeled
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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 18 November 2010.

Thank you for your attention in this matter.

Sincerely,

Surendra K. Gupta, PhD
President
American Radiolabeled Chemicals

IE07

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

Docket No. 030-20567

License No. 24-21362-01

During a U.S. Nuclear Regulation Commission (NRC) inspection conducted from October 20,2009, through January 21,2010, the NRC identified an Unresolved Item pertaining to the extent of contamination identified by the NRC in outdoor areas and the modification of the building exhaust systems. During review of the Unresolved Item that was completed on October 19, 2010, violations of NRC requirements were identified. In accordance with the Enforcement Policy, the violations are listed below:

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

ARC will discuss each example stating the reason for the occurrence of the example; 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 for each example.

A. *Title 10 of the Code of Federal Regulations (10 CFR) 20.1501 (a) 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 20.1501 (b) requires that the licensee shall ensure that instruments and equipment used for quantitative radiation measurements (e.g. dose rate and effluent monitoring) are calibrated periodically for the radiation measured.*

Title 10 CFR 20.1003, survey means an evaluation of the radiological conditions and potential hazards incident to the production, use, transfer, release, disposal, or presence of radioactive material or other sources of radiation. Title 10 CFR 20.1301 requires the licensee to conduct operations so that the total effective dose equivalent to individual members of the public from the licensed operation does not exceed 0.1 rem (1 milli Sievert [mSv]) in a year.

Contrary to the above, as of October 19, 2010, the licensee failed to:

1. *Make surveys to assure compliance with 10 CFR 20.1301 that are reasonable under the circumstances to evaluate concentrations of radioactive material in air*

effluents. Specifically, during 11 of the 17 sampling periods in calendar year 2009, the licensee failed to make or cause to be made, surveys adequate to demonstrate compliance with public dose limits of 0.1 rem/yr to a member of the public provided in 10 CFR 20.1301.

2. *Ensure that instruments and equipment used for quantitative effluent monitoring radiation measurements are calibrated. Specifically, as of October 19, 2010, the licensee had failed to calibrate the system's instruments and equipment that are used in the air effluent monitoring system to determine the volume of air passed through the system to demonstrate compliance with the public dose limit of 0.1 rem per year to a member of the public provided in 10 CFR 20.1301.*

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

ARC Response

ARC agrees with the original finding.

Cause

1. The method in use, summing both wash bottles when the second ios higher than he first, has been used since the inception of the air sampling program more than twenty years ago. At that time a technical justification was submitted to the NRC. ARC's copy of this justification has been lost or misplaced. ARC felt that since the method had not been criticized in the twenty plus years that it was acceptable.

2. ARC has been using rotameter type flow meters on all air sample trains for some time. Our method has been to replace any suspect rotameter with a new meter as they are relatively inexpensive. As of this writing we have been unable to locate a vendor who can calibrate internally contaminated rotameters at this low flow rate.

   The original vendor can calibrate at this flow rate at a cost of $100 per device. New rotameters cost $47. The vendor is not licensed for calibration of contaminated meters.

   The vacuum pumps have not been calibrated as they are used as a vacuum source only and the pump flow rate is not used anywhere in the calculation of effluent concentration, total activity, dose or dose rate.

Corrective Actions

1. Apparently, the periods with second bottle being higher than the first are those where flow has been on the high side of desirable. The sample lines used for calculating dose to the public have been replaced by new stainless steel lines.

Critical orifices are being placed in the sample lines downstream of the sample trains. A lower flow rate will permit longer contact time for the gas stream in the sample rig.

2. ARC is continuing the search for either a calibration device suitable to these flow rates, or a vendor who can calibrate and has a license to handle contaminated rotameters.

Actions to prevent recurrence

1. ARC will continue to upgrade sample lines and to insert critical orifices into each sample train. Lowering the flow rate to provide longer contact time should alleviate the majority of the problem. In addition ARC is committed to following t he recommendations found in the report from CNWRA evaluating ARC's Air Effluent system.

2. ARC will either be successful in located a calibrator (or calibration service) or will replace all rotameters annually.

Full compliance

1. ARC will not be in full compliance until all of the recommendations of the CNWRA report are implemented. This is a license commitment which must take place prior to submitting the request for renewal.

2. ARC will not be in full compliance until all of the recommendations of the CNWRA report are implemented. This is a license commitment which must take place prior to submitting the request for renewal.

B. *Title 10 CFR 20.1302 (a) requires the licensee to make or cause to be made, as appropriate, surveys of radiation levels in unrestricted and controlled areas and radioactive material in effluents released to unrestricted and controlled areas to demonstrate compliance with the annual public dose limit in 10 CFR 20.1301.*

Title 10 CFR 20.1003, survey means an evaluation of the radiological conditions and potential hazards incident to the production, use, transfer, release, disposal, or presence of radioactive material or other sources of radiation.

Title 10 CFR 20.1301 requires the licensee to conduct operations so that the total effective dose equivalent to individual members of the public from the licensed operation does not exceed 0.1 rem (1 mSv) in a year.

Contrary to the above, as of November 4, 2009, the licensee did not make surveys to assure compliance with 10 CFR 20.1301, which limits radiation exposure to members of the public to 0.1 rem. Specifically, on October 22, 2009, the licensee had not conducted an evaluation or survey of the liquid effluent from the restricted

roof of Building 100 via downspouts. Following the licensee's identification of contamination on the roof and soil, the licensee failed to perform adequate surveys to identify the extent of contamination, levels of the on-going liquid effluent release, and the potential hazards associated with the radioactive material to ensure compliance with 10 CFR 20.1301.

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

ARC Response

ARC agrees with the original finding.

Cause

ARC thought that since we were sampling the stack effluent, this was sufficient to cover the fall out / wash out from the plume. See RIS 08-03 Return of RAM Effluent. However this sample was not used for calculating dose to the public.

Corrective Action

ARC has placed catch barrels on each down spout from the laboratory roofs. The water is then sampled. Water less than thew appropriate Title 10 limits is discharged to storm watyer drains. Any water equal or above Title 10 limits is discharged to the sanitary swewer and is charged against ARC's liquid effluent limit.

Action to prevent recurrence

As part of the actions to meet the requirements of the CNWRA report, ARC will revert to using COMPLY for calculating dose to the public. This has become necessary as Three new buildings have been built essentially surrounding the ARC facility. No longer is the ARC headquarters building a clear cut representative case for dose to the public.

Full Compliance

ARC will not be in full compliance until all of the recommendations of the CNWRA report are implemented. This is a license commitment which must take place prior to submitting the request for renewal.