



American Radiolabeled
Chemicals, Inc.

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Saturday, 16 August, 2008

Regional Administrator
U.S. Nuclear Regulatory Commission, Region III
2443 Warrenville Road, Suite 210
Lisle, IL 60532-4352

Reference: License No. 24-21362-01

Dear Sir,

Enclosed you will find a copy of American Radiolabeled Chemicals, Inc Reply to a Notice of Violation.

The original of this document has been sent to:

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

If additional information is required, please contact our Radiation Safety Officer, Regis A. Greenwood, CHP, directly.

Thank you for your attention.

Sincerely,

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

Surendra K Gupta, PhD.
President, American Radiolabeled Chemicals, Inc
Chair, Radiation Safety Committee

CC: Radiation Safety Committee File

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American Radiolabeled Chemicals, Inc (ARC)
Reply to USNRC
Notice of Violation (NOV) and Proposed Civil Penalty

Docket No. 030-20567

License No. 24-21362-01

EA-08-126

During an NRC inspection conducted from January 22, 2008 through March 26, 2008, a violation of NRC requirements was identified. The particular violation involved multiple examples of ARC's failure to adhere to License conditions and regulations. Details of these examples are given below.

ARC does not contest the violation or the imposition of a Civil Penalty and admits that each listed example did occur. The penalty has been submitted in accordance with NUREG/BR-0254.

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. The text from the NOV will be quoted, followed by ARC's reply for each example.

A. *10 CFR 20.1801 requires that the licensee secure from unauthorized removal or access licensed materials that are stored in controlled or unrestricted areas. As defined in 10 CFR 20.1003, controlled area means an area, outside of a restricted area but inside the site boundary, access to which can be limited by the licensee for any reason; and unrestricted area means an area, access to which is neither limited nor controlled by the licensee.*

Contrary to the above, on January 23 and March 11, 2008, the licensee did not secure licensed material in storage in a controlled area from unauthorized removal or access. Specifically, licensed radioactive materials were stored in a controlled area, while the exterior door remained unlocked and unsecured.

ARC Response

ARC agrees with the original finding.

Cause

The cause was inattention to detail on the part of the individuals responsible for re-locking of the areas

Corrective Actions

1. The door to the shipping area now has a combination lock which is auto locking on closure.
2. The door to the Building 200 evaporation and compacting area has a similar lock.
3. The garage door to the Building 200 storage area has external padlocks with the keys controlled by the RSO.
4. The door to the Building 300 garage has been repaired; it now requires a key to open from the outside. This key is controlled by the RSO. As this door is an emergency exit from the 300 laboratory, a pad lock is not suitable.

Actions to prevent recurrence

1. All personnel have been counseled on the need for unattended areas to be locked.
2. The boundary of the area has been moved outward to the building entrance. The entrance to the lab buildings no longer is electronically unlocked during working hours. These doors have automatic combination locks which lock on closure.

Full compliance

ARC believes that full compliance has been achieved

B. Condition 22 of License No. 24-21362-01 requires, in part, that the licensee conduct its program in accordance with the statements, representations, and procedures contained in the referenced documents, including any enclosures. License Condition 22.B. references the licensee's Radiation Protection Program in a letter dated February 8, 2005.

Section 3.2.1 of the Radiation Protection Program states that "the Radiation Safety Committee administers the Radiation Protection Program to assure control of the procurement, use and disposition of radioactive materials and assures that the Radiation Protection Program meets all requirements of the American Radiolabeled Chemicals, Inc. Radioactive Materials License."

Section 3.2.5 of the Radiation Protection Program specifies that the Radiation Safety Committee is held at least monthly and under any of the following circumstances: (a) to fulfill the listed duties of the Committee, or (b) whenever any Committee member requests the Chairman or Vice Chairman to call a meeting at any time for any valid reason.

Section 3.3.3.5 of the Radiation Protection Program states that the Radiation Safety Officer "annually reviews and updates, as necessary, the Radiation Protection Program to assure compliance with established standards and procedures."

Contrary to the above, the licensee failed to conduct its program in accordance with the statements, representations, and procedures contained in referenced documents, including any enclosures, of License Condition 22.B, as evidenced by the following examples:

- 1. The licensee failed to conduct Radiation Safety Committee meetings during the months of February, June, July, and September through December, 2006, and January through October, 2007.*
- 2. The Radiation Safety Committee and Radiation Safety Officer failed to update the Radiation Protection Program to prevent the recurrence of repetitive program violations and weaknesses identified in annual program reviews on December 2004, June 2, 2005, April 13, 2006, and November 2007.*

ARC Response

ARC agrees with the original finding.

Cause (example 1)

ARC agrees that no formal meetings of the RSC, with documented minutes, were held during this period. However daily meetings between the RSO and the Chairman of the RSC are held as a matter of routine. The RSO also meets with member of the RSC several times per week. During this period, extensive remodeling of the exterior of the buildings was taking place. In addition, additional lab space was created by moving interior walls, etc. The RSO as Director of Safety was responsible for these activities.

Corrective Action (example 1)

Since the start of the inspection in January of 2008, ARC has held Radiation Safety Committee (RSC) meetings weekly (with the exception of Holiday weeks). These

meetings are fully documented and the minutes are available for inspection. It is our intention to revert to monthly meetings prior to the end of the calendar year, as the back log of actions necessitated by other findings of the inspection process will be completed by that time

Action to prevent recurrence (example 1)

Meetings of the RSC will be scheduled for a fixed date in each month, with full minutes to be taken by one of the ARC secretaries. We intend to send a copy of the minutes to the NRC inspector assigned to ARC. It is our intent to place an outside Health Physicist on the ARC RSC at this time to increase the diversity of outlook. Dr. Susan Langhorst, CHP, of the National Council on Radiation Protection and Measurement (NCRP) has agreed to serve in this capacity. Dr Langhorst is also RSO for Washington University.

Additionally, ARC has scheduled meetings with NRC licensing specialists to discuss license amendments to remove any ambiguities from the license.

Full Compliance (example 1)

Arc will be in full compliance at the time (prior to the end to the calendar year) when minute copies are forwarded to the Region III inspector.

Cause (example 2)

ARC agrees that corrective actions taken in response to annual audits have been demonstrated to have been inadequate. Those corrective actions taken in response to audit findings have been informal in nature and not properly documented. Actions such as increase in areas surveyed or increased frequency of survey have been instituted without documentation of the reason.

Corrective Action (example 2)

ARC is engaged in a review of all annual audits made during the previous four years. The Radiation Safety Program (RSP) will be revised to include all legitimate findings from these audits.

Action to prevent recurrence (example 2)

Arc intends to have a comprehensive audit performed by a third party auditor. Dr. Howard Dickson, CHP has agreed to serve in this capacity. The results of this audit will be forwarded to the NRC inspector assigned to ARC. The forwarding document will include a time table for the completion of recommended actions.

Additionally, ARC has scheduled meetings with NRC licensing specialists to discuss license amendments to remove any ambiguities from the license.

Full Compliance (example 2)

Arc will be in full compliance at the time (prior to the end to the calendar year) when audit copies are forwarded to the Region III inspector.

C. *Condition 22 of License No. 24-21362-01 requires, in part, that the licensee conduct its program in accordance with the statements, representations, and procedures contained in the referenced documents, including any enclosures. License Condition 22.B. references the licensee's Radiation Protection Program in a letter dated February 8, 2005, and references the licensee's Standard Operating Procedures in letter dated March 24, 2005.*

Section 4.1.3 of the Radiation Protection Program states, in part, that "surveys shall be made as ... (2) are reasonable to evaluate radiation levels, concentrations or quantities of RAM [radioactive material], and radiological hazards."

Section 5.2.3 of the Radiation Protection Program states "any contamination detectable above background indicates excessive loose contamination and should be reported to the RSO [Radiation Safety Officer]. Individuals shall survey their hands upon leaving the laboratory. Individuals should survey items being taken from the laboratory to prevent the transfer of contamination to non-contaminated areas."

Section 2.0 of Standard Operating Procedure 16 "Radioactive Contamination Control Program," states, in part, that controlled areas are required to be surveyed twice weekly for radiological contamination: at the end of the week and at the beginning of the week. Section 2.0 also states, in part, that controlled areas are required to be surveyed daily as conditions and manpower permit.

Section 2.0 of Standard Operating Procedure 30 "Release of Equipment to Vendors" states, in part, that Health Physics personnel are required to "scan the equipment with a GM survey meter and outline any areas where contamination is detected. Wipe test the outlined areas and take a few random wipes at other locations where contamination is likely. Stamp the survey sheet from the LSA Enter the next consecutive number in the Item blank and pen in the Description. Decon and rewipe until the areas are below the release level, which is 1000 dpm/1 00 cm² for the sum of tritium and carbon-14. Briefly describe where the wipe was taken."

Contrary to the above, the licensee failed to conduct its program in accordance with the statements, representations, and procedures contained in referenced documents, including any enclosures, of License Condition 22.B, as evidenced by the following examples:

Since 2006, the licensee failed to survey controlled areas as required by Standard Operating Procedure 16. Specifically, the licensee failed to perform radiation surveys in Building 200, a controlled area, at the start of every week or daily in accordance with Section 2.0 of Standard Operating Procedure 16.

The licensee failed to make surveys as reasonable to evaluate radiation levels, concentrations or quantities of radioactive material, and radiological hazards. Specifically, NRC inspectors identified radiological contamination in unrestricted areas in excess of the licensee's release level on January 23, 24, and 25, 2008, but no surveys were performed by the licensee.

The licensee failed, on January 23 and 24, and March 12, 2008, to ensure that employees surveyed their hands upon leaving laboratories.

The licensee failed, on March 13, 2008, to perform radiation surveys and complete required documentation prior to releasing empty nitrogen gas tanks to a vendor.

ARC Response

ARC agrees with the original finding.

Cause

ARC agrees that the surveys conducted and documented were not adequate. Had they been adequate, the inspectors would not have found levels of contamination we did not know about. Although survey meter surveys were taken prior to the inspection, they were limited to door knobs, telephones, computers, etc and were not documented.

ARC disagrees, in part, with the Building 200 example. Building 200, which is a Restricted Area / Contaminated Area used for Radioactive Waste processing, is not routinely cleaned on a weekly basis. It was the intent of SOP 16 that the Monday (beginning of week) surveys were for the purpose of determining the efficacy of the week end cleaning process. For this reason the building was deleted from the beginning of week survey.

No pick up of empty tanks was supposed to take place on that day due to the uncertainty as to whether a survey had been made. These instructions were not passed to all personnel. When the truck arrived, a maintenance man, not knowing that the pick up had been cancelled, opened the door and assisted the driver. When the RSO arrived, he assumed a survey had been made and that the pick-up had been re-authorized.

Corrective Action

SOP 16 and 30 have been rewritten to remove any ambiguities. A new SOP detailing the wear of Protective Clothing and the requirements for personal survey has been instituted. All updated SOPs have been submitted as a License amendment.

Each week 300+ areas are surveyed. All are surveyed for removable contamination. Two thirds of these areas are in buffer zones or unrestricted areas; these areas are also surveyed with G-M survey meters. All surveys are documented.

Areas in Building 200 have been restored to the Monday survey schedule. In consultation with the vendor, the following procedure has been instituted. Empty tanks will be cleaned, surveyed and placed outside the garage area. The driver will not pick-up any empties until he has received a written certification that the tanks are clean. The driver will not enter the building.

The RSO, Assistant RSO, and members of the RSC are conducting spot checks at the change areas and randomly throughout the site of employees hands and clothing.

Action to prevent recurrence

The results of these surveys are summarized in the Weekly Summary Report to the RSC.

Full Compliance

ARC believes that the actions taken above have resulted in full compliance.

D. Condition 22 of License No. 24-21362-01 requires, in part, that the licensee conduct its program in accordance with the statements, representations, and procedures contained in the referenced documents, including any enclosures. License Condition 22.8. references the licensee's Standard Operating Procedures in letter dated March 24, 2005.

Section 5.0 of Standard Operating Procedure 16 "Radioactive Contamination Control Program" states, with regard to Health Physics personnel, "if initial contamination levels are identified exceeding 10 times the action levels, attempt to determine the source and cause. The results of this investigation shall be documented and filed in the Off-Normal Occurrence File."

Contrary to the above, the licensee failed to perform and document investigations of contamination found in controlled and unrestricted areas at levels greater than 10 times the licensee's radiological action levels on multiple instances, including June 19, 2006, February 20, 2006, January 30, 2007, November 19, 2007, July 16, 2007, May 21, 2007, and August 14, 2007.

ARC Response

ARC agrees with the original finding.

Cause

This was an error on the part of the RSO. When the program and the implementing procedures were written, the intent was to require investigation of the end of week surveys only. This intent was not clearly stated. As written, any occurrence greater than ten times action level requires investigation.

Corrective Action

SOP 16 and 30 have been rewritten to remove any ambiguities. The RSC has decided to lower the action level at which investigations are conducted. The new level has not been determined at this time.

Action to prevent recurrence

ARC contends that lower investigation levels and the use of a Weekly Summary Report from the RSO to the Members of the RSC will force all involved to be aware of the current status and developing trends. This awareness will preclude items from “falling through the cracks”, and prevent recurring violations.

Full Compliance

Full compliance will be accomplished by the end of the current calendar quarter.



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