American Radiolabeled
Chemicals, Inc.

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30 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 December 2010.

Thank you for your attention in this matter.

Sincerely,

Surendra K. Gupta, PhD
President
American Radiolabeled Chemicals

IE07
FSME

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

Docket No. 030-20567

License No. 24-21362-01

EA-10-097; EA-10-170

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.

1. *Condition 22.8 of NRC License No. 24-21362-01, Amendment 38, requires, in part that the licensee conduct its program in accordance with statements, representations, and procedures contained in a letter dated February 8, 2005 (including the Radiation Protection Program dated October 21,2004).*

   Item 4.2.2.2 of the licensee's Radiation Protection Program entitled "Requirements for limiting Internal Exposures of Individuals" requires, in part, that for individuals who receive greater than 100 millirem In a week of a committed effective dose equivalent (CEDE), the licensee shall restrict the individual from further work with radionuclides until the dose rate falls below 50 millirem in a week.

   Contrary to the above, on January 15, 2009, an individual received a CEDE of at least 148 millirem (combined for hydrogen-3 and carbon-14) and the licensee failed to restrict the individual from further work with radionuclides until his dose rate fell below 50 millirem in a week.

   This is a Severity Level IV violation (Section 6.7)

ARC Response

ARC agrees with the original finding.

Cause

A. ARC believed that the RSC had the authority to change the SOPs and/or the RPP. This change was made so for the following reason.

B. Efforts to keep the dose as low as practical to as many individuals as possible

1. 1400 Ci of beta Carotene (1500 microliters) in the hood

2. The longer this solution was in use, the greater the potential for a catastrophic spill. (1 picoliter equaled approx 1 microcurie)

3. If these individuals were removed from lab, clean up and storage would have to be done by ARC personnel who were not as familiar with the process.

4. This was the second week of the New Year; these individuals had no other dose yet this year.

5. Further handing after leaving ARC would be of sealed units, therefore no further intake. This was a onetime dose for these individuals.

6. Any intake by ARC personnel would be at start of year, with other intakes likely throughout the rest of year.

Corrective Actions

ARC's License has been amended to remove all ambiguity.

Actions to prevent recurrence

Any bioassay result exceeding the guideline is reviewed by the RSC

Full compliance

ARC believes that we are in full compliance.

2. *Condition 22.8 of NRC License No. 24-21362-01, Amendments 38, 39, and 40\ requires, in part, that the licensee conduct its program in accordance with the statements, representations, and procedures contained in licensee letter dated March 24, 2005.*

One of the March 24, 2005, licensee letters includes Standard Operating Procedure (SOP) -16, "Radioactive Contamination Control Program." Item 1.0 of SOP-16 states, in part, that removable contamination surveys are required in Restricted, Controlled, and Unrestricted areas. Item 2.0 of SDP-16 states, in part, that the routine survey frequency for each type of survey is weekly. Item 2.1.1 of SOP-16 states that contamination area surveys are done at the "End of Week prior to cleaning, Last workday of the week, usually Friday." Item 2.1.2 of SOP-16 states that Contamination area surveys are done at the "Start of Week, after cleaning - usually Monday morning."

Contrary to the above, on November 28, 2008, May 15~ 2009, and October 9, 2009, the licensee failed to conduct contamination restricted area surveys in Buildings 100 and 300 at the end of the week prior to cleaning. On October 26, 2009, the licensee failed to conduct contaminated restricted area surveys in Buildings 100 and 300) at the start of the week after cleaning.

This is a Severity Level IV Violation (Section 6.7)

ARC Response

ARC agrees with the original finding.

Cause

ARC will treat each of the four occurrences separately.

1. November 28, 2008. We do not know why this survey was not done, or if done, no record exists.
   a) It is possible that the survey and the associated raw data (which are stapled together) was removed from the file and not returned.
   b) It is possible that the survey was done and the wipes not counted.
   c) It is possible the survey was not done due to an oversight.

2. May 15, 2009. We do not know why this survey was not done, or if done, no record exists.
   a) It is possible that the survey and the associated raw data (which are stapled together) was removed from the file and not returned.
   b) It is possible that the survey was done and the wipes not counted.
   c) It is possible the survey was not done due to an oversight.

3. October 9, 2009. Liquid Scintillation Counter failure. Priority of counting using the high background lab counter was given to surveys which could directly affect the public.
   a) Incoming and outgoing packages;
   b) Unrestricted areas
   c) Controlled areas

4. October 26, 2009. Illness of the (at that time) sole technician, and failure , on the part of the RSO, to back up the survey until the time that significant work had taken place in the labs. The purpose of this "Monday" survey being to determine the efficacy of the week end cleaning.

Corrective Action

All mandated surveys are done and verified as done by the RSO using a check list.
In the event of equipment failure, surveys are done as scheduled and counted after repair.
If necessary to use the lab counters, surveys take priority.

Action to prevent recurrence

In addition to the check list used by the RSO, surveys are verified by the Chair of the RSC.

Full Compliance

As no mandated surveys have been missed since October of 2009, ARC feels we are in full compliance at this time.