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21 January 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 American Radiolabeled Chemicals reply to the Notice of Violation dated 28 December 2009

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

JE07
R.H.S.

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 October 27 and 28, 2009, with continued in-office review through December 4, 2009, six violations of the NRC requirements were identified

ARC does not contest the violations, with the exception of the violation labeled F, 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. *Item 9 of the NRC License Number 24-21362-01 on Amendment No. 39 limits the use of licensed material to the manufacture and synthesis of radiolabeled chemicals for distribution.*

Contrary to the above, during the week of January 12, 2009, the licensee failed to limit the use of licensed material to the manufacture and synthesis of radiolabeled chemicals for distribution. Specifically, the licensee supervised a research and development project that involved the incorporation of hydrogen-3 labeled beta-carotene into a battery device, which is not an authorized use on the license.

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

ARC Response

ARC agrees with the original finding.

Cause

The cause was belief on the part of the RSO and the RSC that performance of research and development is inherently part of the manufacture of labeled compounds.

Corrective Actions

All members of the RSC; the RSO; and company management have reviewed the license and are fully aware of the limitations of the ARC license.

Actions to prevent recurrence

ARC will no longer accept contracts for performing any type of research and/or development for outside parties.

Full compliance

ARC believes that full compliance has been achieved

- B. License Condition 22.B. on Amendment No. 39 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 a letter dated February 8, 2005, including the Radiation Protection Program (RPP), dated October 21, 2004.*

Item 3.3.3.8 of the licensee's RPP entitled "Administrative Duties as Radiation Safety Officer (RSO)" requires, in part, that the RSO make safety evaluations of proposed new uses of radioactive material including modifications of facilities, equipment, and procedures.

Contrary to the above, the RSO failed to make a safety evaluation of a proposed new use of radioactive material and related procedures. Specifically, no safety evaluations were conducted for BetaBatt's processing of several hundred curies of hydrogen-3 labeled beta-carotene during the week of January 12, 2009, for incorporation into a battery device.

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

ARC Response

ARC agrees with the original finding.

Cause

Belief, on the part of the RSO, that the informal evaluations performed prior to the work performed by BetaBatt in March 2004, October 2006, March 2008, were sufficient. At the time the RSO was not aware of the increase in the amount of activity that would be used in this session.

Corrective Action

ARC has required that all future safety evaluations be documented. Informal evaluations are no longer permitted.

Action to prevent recurrence

ARC has required that all future safety evaluations be documented. Informal evaluations are no longer permitted. Full details are required prior to the evaluation.

Full Compliance

ARC feels that full compliance has been achieved.

- C. *License Condition 22.B. on Amendment No. 39 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 a letter dated February 8, 2005, including the RPP', dated October 21, 2004.*

Item 3.2.4.1 of the licensee's RPP entitled "Evaluations of New Uses of Radioactive Material" requires, in part, that the Radiation Safety Committee (RSC) make safety evaluations of proposed new uses of radioactive material prior to the new use.

Contrary to the above, the RSC failed to make a safety evaluation of a new use of radioactive material prior to the new use. Specifically, the RSC did not conduct a safety evaluation of BetaBatt's proposed use of hydrogen-3 labeled beta carotene that occurred during the week of January 12, 2009, for incorporation into a battery device, prior to the new use.

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

ARC Response

ARC agrees with the original finding.

Cause

Belief, on the part of the RSC, that the informal evaluations performed prior to the work performed by BetaBatt in March 2004, October 2006, March 2008, were sufficient.

Corrective Action

ARC has required that all future safety evaluations be documented. Informal evaluations are no longer permitted.

Action to prevent recurrence

ARC has required that all future safety evaluations be documented. Informal evaluations are no longer permitted. Full details are required prior to the evaluation.

Full Compliance

ARC feels that full compliance has been achieved.

- D. License Condition 22.B. on Amendment No. 39 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 a letter dated February 8,2005, including the RPP, dated October 21,2004.

Item 3.2.4.2 of the licensee's RPP entitled "Evaluations of Written Protocols for Syntheses" requires, in part, that the RSC review protocols for the syntheses of radiochemicals and related operations involving the handling of licensed materials.

Contrary to the above, the RSC failed to review a protocol for the syntheses of radiochemicals and related operations involving the handling of licensed materials. Specifically, prior to the week of January 12, 2009, the RSC did not review a protocol for BetaBatt's research and development project that involved the handling of several hundred curies of hydrogen-3 labeled beta-carotene for incorporation into a battery device that occurred during the week of January 12, 2009.

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

ARC Response

ARC agrees with the original finding.

Cause

Belief, on the part of the RSC, that the informal evaluations performed prior to the work performed by BetaBatt in March 2004, October 2006, March 2008, were sufficient.

Corrective Action

ARC has required that all future safety evaluations be documented. Informal evaluations are no longer permitted.

Action to prevent recurrence

ARC has required that all future safety evaluations be documented. Informal evaluations are no longer permitted. Full details are required prior to the evaluation.

Full Compliance

ARC feels that full compliance has been achieved.

- E. License Condition 22.B. on Amendment No. 39 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 a letter dated February 8, 2005, including the RPP, dated October 21, 2004.*

Contrary to the above, during the months of June and July of 2009, the licensee failed to hold monthly meetings of the RSC.

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

ARC Response

ARC agrees with the original finding.

Cause

1. This period of time is the height of the vacation season, it was difficult at times to meet the requirements for a quorum.
2. After the inspections in 2008, the RPP and associated SOPs were extensively re-written as part of the corrective action. An amendment request submitted in March of 2008. By June-July of 2009, ARC had assumed that the revised RPP and SOPs were in effect. One provision of these change was to make RSC meeting mandatory at the quarterly level.

Corrective Action

Instead of having a fixed day of the month for the meetings and canceling if a quorum is not possible, meetings will be held on the first available day when a quorum is present

Action to prevent recurrence

Instead of having a fixed day of the month for the meetings and canceling if a quorum is not possible, meetings will be held on the first available day when a quorum is present

Full Compliance

As six months have passed with no meetings missed, ARC feels full compliance has been achieved.

F License Condition 22.B. on Amendment No. 39 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 a letter dated February 8, 2005, including the RPP, dated October 21, 2004.

Item 6.1 of the licensee's RPP entitled "Radiation Safety Training" requires, in part, that all individuals who use radioactive material, before the use of material begins, shall be issued a copy of the RPP, attend training specific to their duties, and that on-the-job training will augment the training session.

Contrary to the above, during the week of January 12, 2009, the licensee failed to provide three individuals who used radioactive material, training that was specific to their duties and responsibilities, a copy of the licensee's RPP, and on-the-job training.

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

ARC Response

ARC disagrees with the interpretation reached by the inspector.

Cause

There are two scopes of training in routine use at ARC. The first is for outside contractors brought in to repair or install equipment. This is covered by SOP 21 Contractor Training. The second is training for newly hire employees, this is covered by Item 6.1 of the RPP. The individuals covered by this inspection do not fit into either category. Non-routine training is tailored to the individual and the operation to be performed. A description of the training

received by BetaBatt personnel is attached to this reply. The RSO did not believe that training methods were limited to only those described in the RPP

Corrective Action

ARC will revise the RPP to allow for non-routine training requirements.

Action to prevent recurrence

Same as corrective action.

Full Compliance

When the revisions to the RPP are approved by Region III and the license is amended to reflect this.

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From: "Larry Gadeken" <larrygad@betabatt.com>
To: "S Gupta" <drgupta@arc-inc.com>; <regisgreenwood@arc-inc.com>; <janard@arc-inc.com>
Cc: "Ron Buchanan, PhD, CHP" <ron.buchanan@sbcglobal.net>
Sent: Tuesday, October 27, 2009 11:39 AM
Subject: Timeline for BetaBatt at ARC

Dr. Gupta,

A brief timeline of BetaBatt work at ARC follows:

March 2004 --- Purpose – R&D for NSF SBIR Phase I feasibility study. Participant – Larry Gadeken

Activity – Load 1 atm tritium gas (volume ~0.2 cc) into each of 4 Wafer Test Fixtures by Janard.

Training – A comprehensive safety meeting and review of ARC procedures was held by Regis for

Larry with Janard participating before lab entry.

October 2006 --- Purpose – R&D for NSF SBIR Phase II development project. Participants – Larry Gadeken and Jeff Clarkson, University of Rochester student

Activity – Janard prepared ~30 µl tritiated beta carotene (TBC). Larry attempted infiltration into ~5 3D porous silicon diodes. Jeff did support.

Training – Regis reviewed ARC procedures for Larry and Jeff and trained on radiation safety before lab entry. Janard gave a lab overview.

March 2008 --- Purpose – R&D for BetaBatt technology development. Participants – Larry Gadeken, Emory Garth and Ron Buchanan

Activity – Janard prepared ~100 µl TBC. Larry performed infiltration into ~12 3D porous silicon diodes. Ron and Emory supported box assembly.

Training – Regis reviewed ARC procedures for Larry, Emory and Ron and held radiation safety training before entry. Janard gave a lab overview.

January 2009 --- Purpose – R&D for BetaBatt technology commercialization. Participants – Larry Gadeken, Emory Garth and Ron Buchanan

Activity – Janard prepared ~500 µl TBC. Larry performed infiltration into ~50 3D porous silicon diodes. Ron and Emory supported box assembly.

Training – Regis reviewed ARC procedures and radiation safety training for Larry, Emory and Ron before entry.

Please let me know if you need more details or additional information.

Regards,
 Larry

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10/27/2009