

March 30, 2010

Surendra K. Gupta, Ph.D., President
American Radiolabeled Chemicals
101 ARC Drive
St. Louis, MO 63146

SUBJECT: NRC ROUTINE INSPECTION REPORT NO. 030-20567/10-01(DNMS) AND
NOTICE OF VIOLATION – AMERICAN RADIOLABELED CHEMICALS

Dear Dr. Gupta:

On November 16 through 20, 2009, the U. S. Nuclear Regulatory Commission (NRC) conducted a routine inspection at your St. Louis, Missouri facility, with continued in-office review through January 5, 2009. The results of the inspection were described in NRC Inspection Report No. 030-20567/09-04(DNMS) dated February 4, 2010.

As discussed in Section 2.2.a. of the NRC Inspection Report No. 030-20567/09-04(DNMS) dated February 4, 2010, the inspectors identified an Open Item pertaining to your method of determining radiation dose from bioassay samples. On March 22, 2010, an NRC inspector informed Regis Greenwood of your staff of the results of the NRC's evaluation of the Open Item, which is described in Section 2.2 of the attached report. As discussed, the NRC has completed its review of the Open Item and concluded that your method of determining radiation dose from bioassay samples is adequate. As such, the Open Item is closed.

As discussed in Section 3.2.a. of the NRC Inspection Report No. 030-20567/09-04(DNMS) dated February 4, 2010, the inspectors identified an Open Item pertaining to issues associated with radiation surveys. The review of this second Open Item is ongoing. The results of the second Open Item will be documented in separate correspondence.

Based on the results of the review of your bioassay program, the NRC has determined that a Severity Level IV violation of NRC requirements occurred. The violation was evaluated in accordance with the NRC Enforcement Policy. The current Enforcement Policy is included on the NRC's Web site at <http://www.nrc.gov/about-nrc/regulatory/enforcement/enforcement-pol.html>. The violation involves failure to restrict an individual from further work with radionuclides after the individual exceeded the 100 millirem bioassay action level for acute exposures until the individual's dose rate fell below the required level, 50 millirem per week, based on two consecutive samples.

The violation is cited in the enclosed Notice of Violation (Notice) and the circumstances surrounding it are described in detail in the subject inspection report. The violation is being cited in the Notice because it was identified by the inspectors.

You are required to respond to this letter and should follow the instructions specified in the enclosed Notice when preparing your response. The guidance in NRC Information

S. Gupta

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Notice 96-28, "Suggested Guidance Relating to Development and Implementation of Corrective Action," may be helpful. You can find the information notice on the NRC website at:

<http://www.nrc.gov/reading-rm/doc-collections/gen-comm/info-notices/1996/in96028.html>.

The NRC will use your response, in part, to determine whether further enforcement action is necessary to ensure compliance with regulatory requirements.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter, its enclosures, and your response, will be made available electronically for public inspection in the NRC Public Document Room or from the NRC's Agencywide Documents Access and Management System (ADAMS), accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>. To the extent possible, your response should not include any personal privacy, Proprietary, or safeguards information so that it can be made available to the Public without redaction.

Sincerely,

/RA/

Tamara E. Bloomer, Chief
Materials Inspection Branch

Docket No. 030-20567

License No. 24-21362-01

Enclosures:

1. Notice of Violation
2. Inspection Report 030-20567/10-01(DNMS)

cc w/encls: Regis Greenwood, RSO
State of Missouri

S. Gupta

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Enclosures:

1. Notice of Violation
2. Inspection Report 030-20567/10-01(DNMS)

cc w/encls: Regis Greenwood, RSO
State of Missouri

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NOTICE OF VIOLATION

American Radiolabeled Chemicals
St. Louis, Missouri

Docket No. 030-20567
License No. 24-21362-01

During a U.S. Nuclear Regulatory Commission (NRC) inspection conducted on November 16 through 20, 2009, with continued NRC review through March 22, 2010; a violation of NRC requirements was identified. In accordance with the NRC Enforcement Policy, the violation is listed below:

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)-02, "Invitro Bioassay Program" dated December 17, 2004. Item 5.1 of SOP-02 states that the bioassay action level for acute exposures is the sum of the dose rates for each radionuclide identified resulting in greater than 100 millirem per week, and the individual must be restricted from further work with radionuclides which could result in additional intake. Item 5.1.1. of SOP-02 states that the individual shall remain restricted from work with radionuclides until the dose rate falls below 50 millirem per week, based on two consecutive samples.

Contrary to the above, the licensee failed to restrict an individual from further work with radionuclides after the individual exceeded the 100 millirem bioassay action level for acute exposures until the individual's dose rate fell below 50 millirem per week based on two consecutive samples. Specifically, on January 19, 2009, an individual had a bioassay result of 119 millirem and the licensee restricted the individual from working with licensed material. However, the licensee authorized the individual to begin working with licensed material again on January 20, 2009, based on a subsequent bioassay result of 23 millirem.

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

Pursuant to the provisions of 10 CFR 2.201, American Radiolabeled Chemicals is hereby required to submit a written statement or explanation to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, DC 20555-0001, with a copy to the Regional Administrator, Region III, within 30 days of the date of the letter transmitting this Notice of Violation (Notice). This reply should be clearly marked as a "Reply to a Notice of Violation" and should include for each violation: (1) the reason for the violation, or, if contested, the basis for disputing the violation or severity level; (2) the corrective steps that have been taken and the results achieved; (3) the corrective steps that will be taken to avoid further violations; and (4) the date when full compliance will be achieved. Your response may reference or include previous docketed correspondence, if the correspondence adequately addresses the required response. If an adequate reply is not received within the time specified in this Notice, an Order or a Demand for Information may be issued as to why the license should not be modified,

suspended, or revoked, or why such other action as may be proper should not be taken. Where good cause is shown, consideration will be given to extending the response time. If you contest this enforcement action, you should also provide a copy of your response, with the basis for your denial, to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001.

Because your response will be made available electronically for public inspection in the NRC Public Document Room or from the NRC's Agencywide Documents Access and Management System (ADAMS), accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>, to the extent possible, it should not include any personal privacy, proprietary, or safeguards information so that it can be made available to the public without redaction. If personal privacy or proprietary information is necessary to provide an acceptable response, then please provide a bracketed copy of your response that identifies the information that should be protected and a redacted copy of your response that deletes such information. If you request withholding of such material, you must specifically identify the portions of your response that you seek to have withheld and provide in detail the bases for your claim of withholding (e.g., explain why the disclosure of information will create an unwarranted invasion of personal privacy or provide the information required by 10 CFR 2.390(b) to support a request for withholding confidential commercial or financial information). If safeguards information is necessary to provide an acceptable response, please provide the level of protection described in 10 CFR 73.21.

In accordance with 10 CFR 19.11, you may be required to post this Notice within two working days.

Dated this 30TH day of March 2010.

U.S. NUCLEAR REGULATORY COMMISSION

REGION III

Docket No.: 030-20567

License No.: 24-21362-01

Report No.: 030-20567/10-01(DNMS)

Licensee: American Radiolabeled Chemicals

Facilities: 100 and 104 ARC Drive
St. Louis, Missouri

Inspection Dates: November 16 through 20, 2009
Continued in-office review through March 22, 2010

Preliminary Exit Meeting: November 20, 2009

Final Exit Meeting: March 22, 2010

Inspectors: Andrew M. Bramnik, Health Physicist
Robert G. Gattone, Jr., Senior Health Physicist

Approved By: Tamara E. Bloomer, Chief
Materials Inspection Branch
Division of Nuclear Materials Safety

EXECUTIVE SUMMARY

American Radiolabeled Chemicals NRC Inspection Report 030-20567/10-01(DNMS)

On November 16 through 20, 2009, the U. S. Nuclear Regulatory Commission (NRC) conducted a routine inspection at the licensee's St. Louis, Missouri facility, with continued in-office review through January 5, 2009. The results of the inspection were described in NRC Inspection Report No. 030-20567/09-04(DNMS) dated February 4, 2010. The review of the licensee's method of determining radiation dose from bioassay samples was an Open Item. In addition, issues associated with radiation surveys was an Open Item.

On March 22, 2010, the NRC completed its review of the Open Item pertaining to the licensee's method of determining radiation dose from bioassay samples and concluded that its method is adequate. As such, the Open Item is closed. The Open Item regarding issues associated with radiation surveys remains under review by the NRC.

The inspectors identified a violation involving failure to restrict an individual from further work with radionuclides until the individual's bioassay dose rate fell below a required dose threshold.

The licensee stated that an immediate corrective action to prevent a similar violation included committing to follow the required procedure such that, if a bioassay sample is greater than 100 millirem per week, then the individual shall remain restricted from further work with radionuclides until the dose rate falls below 50 millirem in a week based on two consecutive samples.

Report Details

1 Program Overview

Licensed Activities and Inspection History

U.S. Nuclear Regulatory Commission (NRC) License No. 24-21362-01 authorizes American Radiolabeled Chemicals (licensee) to manufacture and synthesize radiolabeled chemicals for distribution to authorized persons. The licensee possessed approximately 10,000 curies of hydrogen-3 and 200 curies of carbon-14. Nearly 100 percent of the licensee's radioactive material was hydrogen-3 and carbon-14. Radiolabeled chemical synthesis involved use of high specific activity hydrogen-3 and carbon-14 labeled organic chemicals.

A Health Physics Technician reported to the licensee's Radiation Safety Officer (RSO). The RSO reported to the licensee's president who also served as the Chairman of the Radiation Safety Committee (RSC) and an authorized user. Three additional authorized users reported to the licensee's president.

The NRC completed a reactive inspection on January 21, 2010. The purpose of the inspection was to evaluate the licensee's activities relating to characterization of soils in outdoor areas of the site and to determine if the activities were conducted safely and in accordance with NRC requirements. As a result, the NRC issued a Notice of Violation dated February 18, 2010, citing three violations involving failure to: (1) identify and evaluate the associated hazards of known contamination in outdoor areas of the licensee's site; (2) require the use of protective clothing in a contaminated area; and (3) ensure adequate survey of an individual's hands after performing decontamination work in one of the production buildings. The inspectors also identified an Open Item that is under continuing NRC review regarding issues associated with authorized use of licensed materials.

The NRC previously inspected the licensee during a reactive inspection that was conducted on October 27 and 28, 2009, to review the circumstances surrounding a leaking hydrogen-3 source event. As a result, the NRC issued a Notice of Violation dated December 28, 2009, citing six violations involving: (1) unauthorized use of licensed material; (2) failure of the RSO to make a safety evaluation of the use of material; (3) failure of the RSC to make a safety evaluation of the use of material; (4) failure of the RSC to review a protocol for the handling of licensed material; (5) failure of the RSC to meet during the months of June and July of 2009; and (6) failure to provide adequate training to BetaBatt employees.

2 Bioassay Program

2.1 Inspection Scope

The inspectors reviewed the licensee's bioassay program by interviewing the RSO and reviewing selected records. The reviewed records included the licensee's, "Bioassay Program" dated July 14, 1999, Standard Operating Procedure (SOP) – 02, "Invitro Bioassay Program" dated December 17, 2004, selected bioassay result records, and Liquid Scintillation Counter (LSC) quench curves.

2.2 Observations and Findings

As stated in Section 2.2.a. of NRC Inspection Report No. 030-20567/09-04(DNMS) dated February 4, 2010, the review of the licensee's method of determining radiation dose from bioassay samples was an Open Item. The inspectors completed review of the licensee's method of determining radiation dose from bioassay samples and concluded that it was adequate. Therefore, the Open Item is closed.

During review of the licensee's method of determining radiation dose from bioassay samples, the inspectors determined that the licensee's "Bioassay Program" dated July 4, 1999, was adequate. For example, the program states that a 10-day effective half-life is used to conservatively estimate the doses derived from analysis of hydrogen-3 and carbon-14 bioassay samples. The licensee determined that the 10-day effective half-life for hydrogen-3 and carbon-14 is based, in part, on analyses of bioassay samples collected in relatively short time periods and an article published by a recognized health physics authority. In addition, the program included performing bioassays on Monday mornings prior to beginning work with radioactive materials to allow short half-life carbon-14 compounds to clear from the body, and correcting the Monday morning bioassay for decay to the previous Friday using a 10-day half-life.

The inspectors reviewed bioassay result records that included counts per minute (CPM), disintegrations per minute (DPM), and quench curve data for selected individuals. The inspectors used the information to determine the LSC's counting efficiency and how the quench curves affected counting efficiency to convert CPM to DPM. The inspectors also used the information to determine that the DPM results were adequately converted to units of radiation dose and that the licensee's use of a 10-day effective half-life for hydrogen-3 and carbon-14 was adequate.

The inspectors reviewed the licensee's dual level quench curves that were used to determine doses associated with bioassay samples containing hydrogen-3 and carbon-14. The inspectors verified the adequacy of the dual level quench curves by reviewing the licensee's results of counting its entire set of carbon-14 and hydrogen-3 quenching standards as bioassay samples using the dual level quench curves. The analytical sampling results of the entire set of carbon-14 quenching standards showed essentially the same carbon-14 dose results for the entire quenching standard set, which verified the accuracy of the carbon-14 quench correction. Likewise, the analytical sampling results of the entire set of hydrogen-3 quenching standards showed essentially the same hydrogen-3 dose results for the entire quenching standard set, which verified the accuracy of the hydrogen-3 quench correction.

During review of bioassay records, the inspectors noted that an individual had a bioassay result of 119 millirem on January 19, 2009, and, as required, the licensee restricted the individual from working with licensed material. Later on January 19, 2009, the licensee obtained another bioassay sample from the individual and the result was 65 millirem. On January 20, 2009, the licensee obtained another bioassay sample from the individual and the result was 23 millirem; therefore, the licensee authorized the individual to begin working with licensed material again.

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-02;

“Invitro Bioassay Program” dated December 17, 2004. Item 5.1 of SOP-02 states that the bioassay action level for acute exposures is the sum of the dose rates for each radionuclide identified resulting in greater than 100 millirem per week, and the individual must be restricted from further work with radionuclides which could result in additional intake. Item 5.1.1. states that the individual shall remain restricted from work with radionuclides until the dose rate falls below 50 millirem per week, based on two consecutive samples. The licensee’s failure to restrict an individual from further work with radionuclides until the individual’s dose rate fell below 50 millirem per week based on two consecutive samples after the individual exceeded the 100 millirem bioassay action level for acute exposures is a violation of Condition 22 of NRC License No. 24-21362-01.

The RSO misinterpreted that SOP-02 dated December 17, 2004, required that, if a bioassay sample indicates greater than 100 millirem in a week, then the individual would need to have another bioassay sample that is less than 50 millirem in a week before permitting the individual to resume working with licensed material again. Therefore, the RSO restricted the individual from working with licensed material on January 19, 2009, because one of the individual’s bioassay samples indicated greater than 100 millirem that day. The RSO subsequently authorized the individual to begin working with licensed material again on January 20, 2009, because a follow-up bioassay indicated less than 50 millirem.

As corrective action, the RSO committed to implement SOP-02 revision dated December 17, 2004, including the requirement that, if a bioassay sample is greater than 100 millirem per week, then the individual shall remain restricted from further work with radionuclides until the dose rate falls below 50 millirem in a week based on two consecutive samples.

2.3 Conclusions

The inspectors completed review of the Open Item regarding the licensee’s method of determining radiation dose from bioassay samples and determined that it was adequate. Therefore, the Open Item is closed. The inspectors identified a violation involving failure to restrict an individual from further work with radionuclides until the individual’s bioassay dose rate fell below a required dose threshold.

3 Exit Meeting

At the completion of the inspectors’ review of the Open Item regarding the licensee’s method of determining radiation dose from bioassay samples, an inspector discussed the inspection findings in this report with the RSO during a telephone exit meeting on March 22, 2010. The licensee did not identify any information reviewed during the inspection and proposed for inclusion in this report as proprietary in nature.

ATTACHMENT: SUPPLEMENTAL INFORMATION

SUPPLEMENTAL INFORMATION

PARTIAL LIST OF PERSONS CONTACTED

- Jerry Bone, Maintenance Technician
 - # Kamal Das, Ph.D., Vice President
 - # * Regis Greenwood, RSO
 - # Surendra Gupta, President
 - # April Jeffries, Health Physics Technician
 - # Erin Ray, Office Manager
 - Ganesh Sadras, Group Leader, Analytical Service
 - # Janardhanam Selvasekaran, Ph.D., Vice President
 - Jason Yu, Chemist
- # participated in onsite exit meeting on November 20, 2009
- * contacted by telephone on March 22, 2010, for telephone exit meeting

LIST OF ACRONYMS USED

CAL	Confirmatory Action Letter
CFR	Code of Federal Regulations
CPM	Counts Per Minute
DPM	Disintegrations Per Minute
LSC	Liquid Scintillation Counter
NRC	Nuclear Regulatory Commission
RSO	Radiation Safety Officer
SOP	Standard Operating Procedure