February 4, 2010

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

SUBJECT: NRC ROUTINE INSPECTION REPORT NO. 030-20567/09-04(DNMS) AND NOTICE OF VIOLATION – AMERICAN RADIOLABLELED 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 in-office review included receipt and review of information that was unavailable during the onsite inspection including, but not limited to, occupational dose information.

This inspection was an examination of activities conducted under your license as they relate to safety and compliance with the Commission's rules and regulations and with the conditions of your license. Within these areas, the inspection consisted of selected examination of procedures and representative records, observations of activities, and interviews with personnel.

Based on the results of the inspection, the NRC has determined that five Severity Level IV violations of NRC requirements occurred. The violations were 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 violations involve failure to: (1) enter the monitored individuals' weekly bioassay results into a spreadsheet to determine, for each monitored individual, the average weekly millirem dose, the quarterly millirem dose, and the running yearly millirem dose for each radionuclide; (2) post the roofs of some buildings, that were restricted areas, with signs worded, "Restricted Area, Authorized Personnel or Escorted Visitors Only;" (3) issue periodic notices or directives to make laboratory personnel aware of management's commitment to keep occupational exposures and exposures to other individuals within current As Low As Is Reasonably Achievable (ALARA) guidelines; (4) attempt to determine the source and the cause in response to several survey results that were greater than 10 times the statistically significant difference above background level; and (5) conduct a hands survey upon leaving a lab.

The violations are cited in the enclosed Notice of Violation (Notice) and the circumstances surrounding them are described in detail in the subject inspection report. Violations 1 through 4 are being cited in the Notice because they were identified by the inspectors. Violation 5 is being cited in the Notice because it is similar to a previously-identified violation.

You are required to respond to this letter and should follow the instructions specified in the enclosed Notice when preparing your response. For your consideration and convenience, an excerpt from NRC Information Notice 96-28, "Suggested Guidance Relating to Development and Implementation of Corrective Action," is enclosed. The NRC will use your response, in part, to determine whether further enforcement action is necessary to ensure compliance with regulatory requirements.

Furthermore, the NRC is concerned about American Radiolableled Chemicals' safety culture as it pertains to radiation surveys and contamination control. As discussed in Inspection Report No. 030-20567/09-03 (DNMS) and Section 3.2.e. of the subject inspection report, the inspectors identified several examples of a weak safety culture, including repeated cases of contaminated work stations, repetitive off-normal events involving the same personnel in the same areas with ineffective action to correct the behavior and/or conditions that produced the problems, and non-conservative decision-making regarding removal of booties used for contamination control.

As stated in the enclosed NRC Regulatory Issue Summary (RIS) 2005-18, "Guidance for Establishing and Maintaining a Safety Conscious Work Environment", a strong safety culture is described as the "necessary full attention to safety matters." A strong safety culture is also often described as having a "safety-first focus." Attributes include the safety-over-production principle, procedural adherence, and conservative decision-making. Therefore, in addition to responding to the violations cited in the Notice, the NRC is requesting that you provide specific actions that have been or will be taken to enhance American Radiolableled Chemicals' safety culture as it pertains to radiation surveys and contamination control. The enclosed RIS is provided for your consideration in developing your response to this concern.

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/readingrm/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/

Steven A. Reynolds, Director
Division of Nuclear Materials Safety

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

Enclosures:
1. Notice of Violation
2. Inspection Report 030-20567/09-04(DNMS)
3. Excerpt from NRC Information Notice 96-28
4. NRC Regulatory Issue Summary 2005-18

cc w/encls: Regis Greenwood, Radiation Safety Officer
State of Missouri

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Sincerely,
/RA/

Steven A. Reynolds, Director
Division of Nuclear Materials Safety

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

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cc w/encls: Regis Greenwood, Radiation Safety Officer
State of Missouri

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Letter to Surendra K. Gupta, Ph.D., from Steven A. Reynolds dated February 04, 2010.

SUBJECT: NRC ROUTINE INSPECTION REPORT NO. 030-20567/09-04(DNMS) AND NOTICE OF VIOLATION – AMERICAN RADIOLABLELED CHEMICALS

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NOTICE OF VIOLATION

American Radiolabeled Chemicals
St. Louis, Missouri

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

During a Nuclear Regulatory Commission (NRC) inspection conducted on November 16 through 20, 2009, violations of NRC requirements were identified. In accordance with the NRC Enforcement Policy, the violations are listed below:

A. 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 dated March 24, 2005, contains Standard Operating Procedure (SOP) – 02, "Invitro Bioassay Program" dated December 17, 2004. Item 4.5 of SOP-02 requires, in part, that for each occupationally exposed individual, the bioassay results are entered into his or her spreadsheet which provides the average weekly millirem, the quarterly millirem, and the running yearly millirem for each radionuclide.

Contrary to the above, from January 1 to November 20, 2009, the licensee failed to enter the monitored individuals' weekly bioassay results into a spreadsheet to determine, for each monitored individual, the average weekly millirem dose, the quarterly millirem dose, and the running yearly millirem dose for each radionuclide.

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

B. 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 February 8, 2005. The letter dated February 8, 2005, contains the licensee's Radiation Protection Program (RPP) dated October 21, 2004. Item 2.1 of the RPP states, in part, that a restricted area is any area access to which is controlled for radiation protection purposes, and the entrances to these areas are posted with signs worded, "Restricted Area, Authorized Personnel or Escorted Visitors Only."

Contrary to the above, as of November 20, 2009, the licensee failed to post the roofs of Buildings 100, 200, or 300, which were restricted areas, with signs worded, "Restricted Area, Authorized Personnel or Escorted Visitors Only."

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

C. 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 February 8, 2005. The letter contains the licensee's RPP dated October 21, 2004. Item 3.2.6 of the RPP states that the Radiation Safety Committee (RSC) issues periodic notices or directives to make laboratory personnel aware of management's commitment to

keep occupational exposures and exposures to other individuals within current As-Low-As-Reasonably-Achievable (ALARA) guidelines.

Contrary to the above, as of November 20, 2009, the licensee failed to issue periodic notices or directives to make laboratory personnel aware of management's commitment to keep occupational exposures and exposures to other individuals within current ALARA guidelines.

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

D. 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-16, "Radioactive Contamination Control Program" dated January 7, 2005. Item 3.3 of SOP-16 states that the action level for removable contamination surveys of unrestricted areas is, "any statistically significant difference above background." Item 5.0 of SOP-16 states, in part, that if initial contamination levels exceed 10 times the action levels, attempt to determine the source and the cause.

Contrary to the above, on May 11, July 15, September 4, and October 3, 2009, the licensee obtained results of removable contamination surveys of unrestricted areas that were greater than 10 times the statistically significant difference above background level and the licensee failed to attempt to determine the source and the cause.

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

E. 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 February 8, 2005. The letter contains the licensee's RPP dated October 21, 2004. Item 5.2.3.1 of the RPP states that individuals shall survey their hands upon leaving the laboratory.

Contrary to the above, on September 3, 2009, an individual failed to conduct a hands survey upon leaving a lab.

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, United States 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).

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

Dated this 4th day of February 2010

U.S. NUCLEAR REGULATORY COMMISSION

REGION III

Docket No.:	030-20567
License No.:	24-21362-01
Report No.:	030-20567/09-04(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 January 5, 2010
Preliminary Exit Meeting:	November 20, 2009
Final Exit Meeting:	January 5, 2010
Inspectors:	Andrew M. Bramnik, Health Physicist Robert G. Gattone, Jr., Senior Health Physicist
Approved By:	Tamara Bloomer, Chief Materials Inspection Branch Division of Nuclear Materials Safety

EXECUTIVE SUMMARY

American Radiolabeled Chemicals
NRC Inspection Report 030-20567/09-04(DNMS)

During a routine inspection, the inspectors identified five violations involving failure to: (1) enter the monitored individuals' weekly bioassay results into a spreadsheet to determine, for each monitored individual, the average weekly millirem dose, the quarterly millirem dose, and the running yearly millirem dose for each radionuclide; (2) post the roofs of some buildings, that were restricted areas, with signs worded, "Restricted Area, Authorized Personnel or Escorted Visitors Only;" (3) issue periodic notices or directives to make laboratory personnel aware of management's commitment to keep occupational exposures and exposures to other individuals within current ALARA guidelines; (4) attempt to determine the source and the cause in response to several survey results that were greater than 10 times the statistically significant difference above background level; and (5) conduct a hands survey upon leaving a lab. In addition to the violations, the inspectors identified a concern relative to the licensee's safety culture as it pertains to radiation surveys and contamination control.

The licensee's immediate corrective actions to prevent similar violations included: (1) entering individuals' weekly bioassay results into a spreadsheet to determine the average weekly millirem dose; the quarterly millirem dose, and the running yearly millirem dose for each radionuclide for year-to-date 2009; (2) committing to enter the individuals' weekly bioassay results into a spreadsheet; (3) providing the inspectors with each monitored individual's 2009 year-to-date bioassay dose for each radionuclide on November 24, 2009; (4) posting the signs on the roofs as required; (5) committing to issue notices or directives to make laboratory personnel aware of management's commitment to ALARA during quarterly safety meetings that include all licensee staff; (6) committing to comply with the procedure that requires actions in response to survey results that were greater than an action level; and (7) planning to re-train applicable staff regarding the need to conduct a hands survey upon leaving the laboratory.

The inspectors also identified two Open Items regarding issues associated with radiation surveys and bioassay. The inspectors continue to review issues associated with radiation surveys, including receipt and review of the inspectors' independent removable contamination survey results. The inspectors also continue to review issues associated with bioassay, including review of the licensee's method of determining radiation dose from bioassay samples.

Report Details

1 Program Overview

Licensed Activities and Inspection History

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 last 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 BettaBatt employees.

The NRC previously inspected the licensee from March 31 to April 1, 2009, with continued in-office review through June 9, 2009. The inspection included review of corrective actions taken for violations that were identified during an inspection conducted from January 22, 2008, through March 26, 2008, and involved failure to: (1) secure from unauthorized removal or limit access to licensed material in an aggregate quantity greater than 1000 times Appendix C to Title 10 Code of Federal Regulations (CFR) Part 20 limits; (2) comply with license conditions related to management oversight of the Radiation Protection Program, including a failure to conduct monthly meetings of the Radiation Safety Committee and a failure to implement timely and adequate corrective actions for issues identified during annual program reviews; (3) comply with license conditions related to radiological surveys; and (4) perform and document required investigations of contamination found in controlled and unrestricted areas. The violations were cited in a Notice of Violation and proposed imposition of a $6,500 civil penalty dated July 22, 2008.

In addition, the inspection conducted from March 31 to April 1, 2009, with continuing in-office review through June 9, 2009, included review of the licensee's implementation of the NRC's Confirmatory Action Letter (CAL) Number 3-08-002, dated February 21, 2008. The CAL documented short and long-term corrective actions associated with radiation safety program deficiencies, including contamination control, personnel training, and RSC activities. Based on the results of the inspection conducted from March 31 to

April 1, 2009, with continuing in-office review through June 9, 2009, the NRC issued a Notice of Violation to the licensee dated July 21, 2009, citing a violation involving failure to properly wear shoe covers in contaminated areas. In addition, the NRC issued a letter to the licensee dated July 28, 2009, stating that the licensee effectively addressed each of the issues documented in the CAL, resulting in CAL closure.

The NRC inspected the licensee June 24 through 25, 2003, to review corrective actions taken for violations that were identified during an inspection conducted March 19 and 20, 2002, and April 17 through 19, 2002, and involved deliberate failure to: (1) make surveys to comply with 10 CFR 20.1301, which limits the dose to members of the public; (2) perform required weekly removable contamination surveys in the restricted and unrestricted areas of Building 200; and (3) accurately record the results of required weekly fume hood face velocity measurements; and non-deliberate failure to conduct weekly removable contamination surveys in restricted and unrestricted areas as required. Each violation was cited in a Notice of Violation dated April 17, 2003, with proposed imposition of a $12,000 civil penalty for the three deliberate violations. The inspection conducted June 24 through 25, 2003, also included review of corrective actions taken for violations involving failure to limit the disposal of licensed material to authorized means that were identified during an inspection conducted December 10 and 11, 2002. No violations of NRC regulatory requirements were identified during the inspection conducted June 24 through 25, 2003.

2 Occupational Dose and Staff Communications

2.1 Inspection Scope

The inspectors reviewed the licensee's internal occupational dose assessment 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. In addition, the inspectors reviewed licensee communications with its staff by interviewing selected licensee staff, including the RSO; and reviewing selected documents, including postings of weekly bioassay results and NRC Form 3.

2.2 Observations and Findings

a. Occupational Dose

Between January 1 and November 20, 2009, the licensee determined the weekly radiation doses of individuals who were likely to receive greater than 10 percent of the annual radiation dose limits in 10 CFR Part 20.1201 based on bioassay sample analysis. During that period, the RSO placed the weekly bioassay results, which included the weekly radiation dose received for each individual, in a binder. However, the RSO did not enter the individuals' weekly bioassay results into a spreadsheet to determine, for each monitored individual, the average weekly millirem dose, the quarterly millirem dose, and the running yearly millirem dose for each radionuclide. In addition, the RSO did not determine, for each monitored individual, the average weekly millirem dose, the quarterly millirem dose, and the running yearly millirem dose for each radionuclide by other means. Therefore, the licensee could

not provide the 2009 average weekly millirem dose, quarterly millirem dose, or running yearly millirem dose for each radionuclide for any monitored individual until after the onsite inspection.

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 4.5 of SOP-02 requires, in part, that for each occupationally exposed individual, the bioassay results are entered into his or her spreadsheet which provides the average weekly millirem, the quarterly millirem, and the running yearly millirem for each radionuclide. The licensee's failure to enter the monitored individuals' weekly bioassay results into a spreadsheet to determine, for each monitored individual, the average weekly millirem dose, the quarterly millirem dose, and the running yearly millirem dose for each radionuclide between January 1 and November 20, 2009, is a violation of Condition 22 of the license.

As immediate corrective action to prevent a similar violation, the licensee entered the individuals' weekly bioassay results into a spreadsheet to determine, for each monitored individual, the average weekly millirem dose, the quarterly millirem dose, and the running yearly millirem dose for each radionuclide for year-to-date 2009. As long term corrective action to prevent a similar violation, the licensee committed to enter the individuals' weekly bioassay results into a spreadsheet to determine, for each monitored individual, the average weekly millirem dose, the quarterly millirem dose, and the running yearly millirem dose for each radionuclide. In addition, on November 24, 2009, the RSO provided the inspectors with each monitored individual's 2009 year-to-date bioassay dose for each radionuclide. The licensee reported that the highest radiation doses received by bioassayed individuals in 2008 and 2009 (through November 24, 2009) were 1080 millirem and 824 millirem, respectively. The results were well below regulatory dose limits.

The inspectors continue to review an issue associated with bioassay. The issue includes review of the licensee's method of determining radiation dose from bioassay samples. Therefore, the issue is an Open Item. Upon completion of the review of the Open Item, the conclusions will be documented in separate correspondence.

b. Staff Communications

The licensee had a contractor conduct a radiation survey of the roof of Building 100. As a result, fixed and removable hydrogen-3 and carbon-14 contamination was identified on the roof. The licensee determined that the roof contamination was from precipitation of licensed material that was released from an air effluent stack on the roof. Therefore, the licensee determined that the roof of Building 100 was a restricted area. The adequacy of the licensee's air effluent procedures and air effluent system is being reviewed by the NRC as part of the license renewal process. The licensee suspected that the roofs of Buildings 200 and 300 also had roof contamination; therefore, the licensee determined that the roofs of Buildings 200 and 300 were restricted areas. However, as of November 20, 2009, the licensee had not posted the roofs of Buildings 100, 200, or 300 with signs worded, "Restricted Area, Authorized Personnel or Escorted Visitors Only."

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 February 8, 2005. The letter contains the licensee's Radiation Protection Program (RPP) dated October 21, 2004. Item 2.1 of the RPP states, in part, that a restricted area is any area access to which is controlled for radiation protection purposes, and the entrances to these areas are posted with signs worded, "Restricted Area, Authorized Personnel or Escorted Visitors Only." The failure to post the roofs of Buildings 100, 200, or 300, which were restricted areas, with signs worded, "Restricted Area, Authorized Personnel or Escorted Visitors Only" is a violation of Condition 22 of the license.

As corrective action, the licensee posted the signs on the roofs of Buildings 100, 200, and 300 as required.

Topics discussed during RSC meetings included, among other things, approval of revised SOPs, review of area radiation survey results, discussion of NRC inspection findings, and discussion of bioassay results. However, the RSC did not issue periodic notices or directives to make laboratory personnel aware of management's commitment to keep occupational exposures and exposures to other individuals within current ALARA guidelines.

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 February 8, 2005. The letter contains the licensee's RPP dated October 21, 2004. Item 3.2.6 of the RPP states that the RSC issues periodic notices or directives to make laboratory personnel aware of management's commitment to keep occupational exposures and exposures to other individuals within current ALARA guidelines. The failure to issue periodic notices or directives to make laboratory personnel aware of management's commitment to keep occupational exposures and exposures to other individuals within current ALARA guidelines is a violation of Condition 22 of the license.

As corrective action, the licensee committed to issue notices or directives to make laboratory personnel aware of management's commitment to keep occupational exposures and exposures to other individuals within current ALARA guidelines during quarterly safety meetings that include all licensee staff.

The licensee provided its radiation workers with their 2008 radiation dose information using NRC Form 5 or an equivalent method. In addition, the licensee communicated weekly radiation worker bioassay results by posting them in the labs as a means for the licensee and its staff to monitor dose trends and take actions as needed to ensure that the doses were ALARA.

2.3 Conclusions

The inspectors identified three violations of Condition 22 of NRC License No. 24-21362-01 involving failure to enter the monitored individuals' weekly bioassay results into a spreadsheet to determine, for each monitored individual, the average weekly millirem dose, the quarterly millirem dose, and the running yearly millirem dose for each radionuclide; post the roofs of Buildings 100, 200, or 300, which were restricted

areas, with signs worded, “Restricted Area, Authorized Personnel or Escorted Visitors Only;” and issue periodic notices or directives to make laboratory personnel aware of management’s commitment to keep occupational exposures and exposures to other individuals within current ALARA guidelines. In addition, the inspectors identified an Open Item associated with bioassay.

3 Radiation Surveys and Contamination Control

3.1 Inspection Scope

The inspectors reviewed the licensee’s radiation survey and contamination control activities by interviewing the RSO and selected licensee staff, reviewing selected survey records, observing selected licensee staff conduct radiation surveys, and conducting independent removable contamination surveys.

3.2 Observations and Findings

a. Area Surveys

The licensee used SOP-16, “Radioactive Contamination Control Program” that included its area radiation survey protocol, including action levels. In approximately March 2008, the licensee revised SOP-16 to change the action level for removable contamination surveys of unrestricted areas from “any statistically significant difference above background” to “1000 disintegrations per minute (DPM) per 100 square centimeters,” and the licensee did not request a license amendment to incorporate the revised SOP into its license. The licensee considered “statistically significant difference above background” as a removable contamination survey result that was twice the background result. After the SOP revision, the licensee used “1000 DPM per minute per 100 square centimeters” as its action level for removable contamination surveys of unrestricted areas. SOP-16 required that, if initial contamination levels exceed ten times the action levels, the licensee will attempt to determine the source and the cause, document the results of the investigation, and file the report in the Off-Normal Occurrence file.

The licensee conducted removable contamination surveys of unrestricted areas weekly, including Building 400. The removable contamination surveys of unrestricted areas in Building 400 that were done on May 11, July 15, September 4, and October 3, 2009, included results that were greater than 10 times the statistically significant difference above background level and less than 10 times the 1000 DPM per 100 square centimeters level. For example, some of the results of surveys done on May 11, July 15, September 4, and October 3, 2009, were 4770, 4360, 4731, and 1651 DPM per 100 square centimeters, respectively. Since the licensee used 1000 DPM per 100 square centimeters as its action level for removable contamination surveys of unrestricted areas and the survey results were less than 10 times action level, the licensee did not attempt to determine the source and the cause.

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-16; "Radioactive Contamination Control Program" dated January 7, 2005. Item 3.3 of SOP-16 states that the action level for removable contamination surveys of unrestricted areas is, "any statistically significant difference above background." Item 5.0 of SOP-16 states, in part, that if initial contamination levels exceed 10 times the action levels, attempt to determine the source and the cause. The licensee's failure to attempt to determine the source and the cause in response to results of removable contamination surveys of unrestricted areas obtained on May 11, July 15, September 4, and October 3, 2009, that were greater than 10 times the statistically significant difference above background level is a violation of Condition 22 of the license.

As corrective action, the licensee committed to comply with SOP-16 dated January 7, 2005.

The inspectors continue to review issues associated with radiation surveys, including receipt and review of the inspectors' independent removable contamination survey results. Therefore, the issues are an Open Item. Upon completion of the review of the Open Item, the conclusions will be documented in separate correspondence.

b. Personal Contamination Surveys

The licensee required individuals to survey their hands upon leaving laboratories to prevent personal contamination and transfer of contamination to non-contaminated areas. To reduce contamination control problems, the licensee had trained applicable staff and the authorized users regarding the importance of conducting hand surveys prior to leaving the laboratories.

On September 4, 2009, an authorized user observed an individual preparing to leave a laboratory. Prior to the individual leaving the lab, the authorized user requested the individual to demonstrate how hands surveys were done. During the demonstration, contamination was found on the individual's hand. Licensee staff responded to the contamination by expanding the personal survey and identifying other contaminated areas, such as on the individual's the scalp. The licensee decontaminated the individual and monitored the effectiveness of the decontamination. In addition, the licensee conducted dose calculations to determine that the contamination resulted in a dose to the individual that was well below regulatory limits.

The licensee also conducted area surveys and identified contamination on the floor of the area where the individual had worked. The licensee decontaminated the area and conducted a post-decontamination survey to determine that decontamination was successful. The licensee determined that the personal contamination probably occurred on September 3, 2009. During its investigation of the cause of the personal contamination, the licensee identified that the individual had not conducted a hands survey upon leaving a lab on September 3, 2009.

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 February 8, 2005. The letter

contains the licensee's RPP dated October 21, 2004. Item 5.2.3.1 of the RPP states that individuals shall survey their hands upon leaving the laboratory. The failure to conduct a hands survey upon leaving a lab is a violation of Condition 22 of the license. The inspectors noted that this violation was similar to a violation that was cited in a Notice of Violation and proposed imposition of a $6,500 civil penalty dated July 22, 2008.

As corrective action to prevent a similar violation, the licensee planned to re-train applicable staff regarding the need to conduct a hands survey upon leaving the laboratory.

c. Independent Measurements

(1) Count Rate Radiation Surveys

The inspectors conducted independent ambient count rate and exposure rate surveys of selected areas using an NRC instrument (Ludlum Model 2403) affixed to a Ludlum Model 44-9 probe for count rate measurements or a Ludlum Model 44-38 probe for exposure rate measurements. A partial list of the survey results are listed below:

- Less than 50 Counts Per Minute (CPM) on the Building 200 garage door handle
- Less than 50 CPM on the handle of an empty Sealand container door handle
- Approximately 900 CPM on an exterior corner of an empty Sealand container - After the licensee decontaminated the area, the inspectors measured approximately 100 CPM at the affected area
- Less than 50 CPM on the ground near the exterior corner of an the empty Sealand container that measured approximately 900 CPM
- Less than 50 CPM on a Building 200 entrance door handle
- Approximately 150 CPM on top of a nitrogen tank near the garage door of Building 300
- Less than 50 CPM on a Building 300 entrance door handle
- Less than 50 CPM on a Building 100 entrance door handle
- 16000 CPM on a pair of safety glasses in a restricted, contamination area lab (The licensee placed the contaminated safety glasses in a radioactive waste receptacle)
- Less than 50 CPM on selected surfaces of Building 100 near a Personal Protection Equipment (PPE) de-gowning station and in a bathroom

- 1000 CPM on the handle of a safe in a restricted area of Building 300 (The licensee took actions to decontaminate the handle)

- 500 CPM on the dial of a safe in a restricted area of Building 300 (The licensee took actions to decontaminate the dial)

- 1500 CPM on the top of a safe in a restricted area of Building 300 (The licensee took actions to decontaminate the top of a safe)

- Less than 50 CPM on selected Building 400 surfaces

To assess the accuracy of the licensee's ambient count rate survey results, the inspectors conducted a comparative ambient count rate survey and determined that the licensee obtained the same result with one of its calibrated count rate instruments.

(2) Fume Hood Face Velocity Measurements

The inspectors conducted independent face velocity measurements of all of the fume hoods in Building 300 using an NRC anemometer (Alnor Model 9850). The results ranged from 100 to 200 feet per minute. To assess the accuracy of the licensee's fume hood face velocity measurements, the inspectors conducted a comparative fume hood face velocity measurement and determined that the licensee obtained the same result with one of its anemometers.

d. Contamination Control

The inspectors identified opportunities for improved contamination control. While observing a chemist demonstrate how he had removed PPE before leaving a laboratory and observing other licensee staff remove PPE before leaving labs, the inspectors noted that a chemist wore gloves to remove potentially contaminated booties and then used the same gloves to handle his street shoes that were worn in unrestricted areas. This resulted in potential contamination transfer from the gloves to the street shoes and unrestricted areas. The inspectors also identified that there were inconsistent methods used for removing PPE before leaving labs. The inspectors noted that there were no apparent licensee procedures for removing PPE before leaving labs. In response to the finding, the licensee began considering development of procedures for removing PPE before leaving labs.

The inspectors used a calibrated NRC survey instrument to conduct an independent count rate survey in a lab area where PPE removal occurred. The inspectors identified between 500 and 1500 counts per minute on a hook where lab coats were hung in a restricted, contaminated area. The lab coats that were on the hook were worn over street clothes that were eventually worn when transitioning from the restricted, contaminated area to unrestricted areas. This resulted in potential contamination transfer from the hook, to the lab coat, to the street clothes, and to unrestricted areas. In response to the finding, the licensee began considering actions to prevent contamination transfer from the hook, to the lab coat, to the street clothes, and to unrestricted areas.

The inspectors observed how a supervised user had exited a restricted, contaminated lab. The inspectors noted that the individual used a survey instrument positioned in the lab to conduct preliminary personal surveys to identify gross personal contamination prior to entering the area for PPE removal and hand surveys before leaving. The individual misread the survey instrument positioned in the lab by an order of magnitude. Specifically, the individual interpreted the actual 2000 to 2500 CPM reading as 200 to 250 CPM because the instrument was set on the "times ten" scale and the individual thought the scale was set on "times one." In addition, the inspectors questioned why the instrument was reading higher than expected. Therefore, the inspectors conducted an independent count rate survey of the area and identified that the hook used to hang the licensee's survey instrument probe read 4000 CPM. The inspectors noted that when the probe was removed from the contaminated hook, the licensee's instrument displayed a result that was indistinguishable from background. The licensee promptly decontaminated the hook.

The inspectors used a calibrated NRC survey instrument to conduct an independent count rate survey in the restricted shipping area of Building 300 and measured between 200 and 1000 CPM on the handles of four refrigerators. The licensee promptly decontaminated the handles.

The inspectors noted that a soap dispenser that was positioned near the boundary of a restricted, contaminated area and a non-contaminated area was used by some individuals that were positioned on the restricted, contaminated area and other individuals that were positioned on the non-contaminated area. This resulted in potential contamination transfer from the contaminated area to the non-contaminated area. In response to the finding, the licensee began considering actions to prevent contamination transfer from the contaminated area to the non-contaminated area via the soap dispenser.

e. Safety Culture Concern

The inspectors identified a concern about the licensee's safety culture, especially pertaining to radiation surveys and contamination control. Examples of the concern are included in Section 3.1.d. above. Below is a discussion of additional examples to support the concern.

Findings identified during a May 2009 audit of the content and implementation of the licensee's radiation protection program that was conducted by an outside consultant included, in part, that there was no root cause analysis or corrective actions taken regarding identified radiation protection problems; repeated cases of contaminated work stations and no evidence of corrective action taken by licensee management to address the problem; and based on repetitive off-normal events involving the same personnel in the same areas, the licensee's actions to remedy the problems were ineffective to correct the behavior and/or conditions that produced the problems. As of November 16, 2009, the licensee had not developed a formal root cause analysis procedure. In mid-2008 the RSO had initially proposed to the licensee's RSC a draft policy for consequences associated with failure to fully implement SOPs, and did so several times again during later RSC meetings; however, the policy had not been approved by the RSC.

The licensee has a history of performance problems associated with PPE use. During a tour of the licensee's facilities, the inspectors observed how licensee staff removed PPE upon leaving laboratories where licensed material was used. The PPE included, among other things, booties to prevent shoe contamination that could result in contamination spread to unrestricted areas. During discussions about PPE removal, the inspectors noted that the RSO stated that it was acceptable for staff to remove their booties with their bare hands. The inspectors informed the licensee that removal of booties with bare hands could result in hand contamination and subsequent contamination spread. In response, the RSO committed to ensure that licensee staff members use clean gloves to remove booties when leaving the laboratories.

While touring a laboratory where licensed material was used in Building 100, the inspectors noted that some of the absorbent paper used to contain contamination on work areas was torn, reducing its ability to contain contamination. During follow up, the inspectors identified that licensee maintenance staff usually replaced the absorbent paper every weekend; however, due to a shortage of maintenance staff, the absorbent paper had not been changed recently. In addition, the inspectors noted that licensee staff working in the lab did not take the initiative to replace the torn paper. In response to the finding, the licensee committed to change the absorbent paper promptly. In addition, the licensee had hired a new maintenance worker who was in training.

During review of the licensee's radiation survey activities, the inspectors noted that the licensee's existing radiation survey procedures had no process for ensuring that required area radiation surveys are completed during periods when applicable job positions are vacant. In addition, revised procedures included a new requirement to document the reason why required radiation area surveys are not completed, inferring that failure to complete required area surveys was routine and acceptable. These findings could lead to more licensee acceptance of failure to complete all required radiation surveys.

In approximately 2007, the RSO informed the licensee president about his very high workload and the need for more staff. However, it appears that the president did not respond to the RSO's concern until mid-June, 2009 when the licensee hired a new health physics technician, approximately two years after the RSO expressed his concern and approximately one year after the Alternate Radiation Safety Officer left the licensee's employ and was not replaced.

During discussions with the RSO regarding contamination control events, the RSO explained that handling high specific activity radioactive material results in a high potential for contamination control problems, in part, because very small volumes of radioactive material can be inadvertently expelled from work areas without the user's knowledge. This perspective can be a counter-incentive for increasing the rigor associated with identifying the cause of contamination control events and developing and implementing actions to prevent similar events.

3.3 Conclusions

The inspectors identified two violations of Condition 22 of NRC License No. 24-21362-01 involving failure to attempt to determine the source and the cause in response to area survey results that were greater than 10 times the action level; and conduct a hands survey upon leaving a lab. In addition, the inspectors identified a concern about the licensee's safety culture, especially as it pertains to radiation surveys and contamination control. The inspectors also identified an Open Item associated with radiation surveys.

4 Other Areas Inspected

4.1 Inspection Scope

The inspectors reviewed other areas of the licensee's radiation protection program by interviewing selected staff, observing licensed activities, observing demonstrations of how licensed activities had been or would be conducted based on scenarios posed by the inspectors, and reviewing selected records. Areas reviewed included survey instrument operability checks, radioactive spill response, security, and radiation dose reduction techniques.

4.2 Observations and Findings

Licensee staff conducted appropriate operability checks on survey instruments prior to conducting ambient count rate surveys. The staff used calibrated instruments to conduct the surveys. The licensee analyzed removable contamination survey samples with LSCs.

Selected licensee staff demonstrated proper techniques in response to radioactive spill scenarios posed by the inspectors. The selected staff demonstrated actions to properly contain the spill, decontaminate the affected area, identify personnel contamination, and dispose of radioactive waste generated by the decontamination.

The licensee secured licensed material from unauthorized access. The inspectors observed that licensed material was secured by being locked in a building or enclosure with the keys limited to authorized staff, or by being under surveillance by authorized persons who could prevent access to the material.

Licensee staff wore gloves, shoe covers, and lab coats when conducting licensed activities to protect against radioactive contamination. In addition, time, distance, and shielding were used to reduce radiation exposure.

4.3 Conclusions

The licensee effectively implemented other areas of its radiation safety program.

5 Exit Meeting

At the completion of the onsite inspection, the inspectors discussed the preliminary inspection findings in this report with licensee management during an exit meeting. The licensee did not identify any information reviewed during the inspection and proposed for inclusion in this report as proprietary in nature. A final telephone exit meeting was conducted on January 5, 2010.

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 January 5, 2010, for final exit meeting

LIST OF ACRONYMS USED

ALARA	As Low As Is Reasonably Achievable
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
PPE	Personal Protection Equipment
RPP	Radiation Protection Program
RIS	Regulatory Issue Summary
RSC	Radiation Safety Committee
RSO	Radiation Safety Officer
SOP	Standard Operating Procedure

Attachment