

April 23, 2008

EA-08-126
EA-08-127

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

SUBJECT: NRC INSPECTION REPORT 030-20567/2008-001(DNMS) - AMERICAN
RADIOLABELED CHEMICALS, INC.

Dear Dr. Gupta:

This refers to the inspection conducted on January 22 through 25, and March 11 through 14, 2008, at the Saint Louis, Missouri, American Radiolabeled Chemicals, Inc. facility, with continued in-office review until March 26, 2008. The purpose of the inspection was to determine if licensed activities were conducted safely and in accordance with NRC requirements. Specifically, the inspection focused on: management organization and controls; radiation protection program activities; and actions taken in response to a February 21, 2008, Confirmatory Action Letter (CAL 3-08-002). At the conclusion of on-site inspections on January 25, and March 14, 2008, the NRC inspectors discussed the preliminary findings with you and members of your staff. On March 26, 2008, the inspectors completed an in-office review of information relating to your waste management program and conducted a telephone exit interview with your Radiation Safety Officer, Mr. Regis Greenwood.

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

Based on the results of this inspection, five apparent violations were identified and are being considered for escalated enforcement action in accordance with the NRC Enforcement Policy. The current Enforcement Policy is included on the NRC's Web site at www.nrc.gov/reading-rm/doc-collections/enforcement. The first apparent violation involved two examples of inadequate management oversight of the Radiation Protection Program. The examples included the failure to conduct Radiation Safety Committee meetings and the failure to implement timely and adequate corrective action in response to annual program reviews in accordance with license commitments. The second apparent violation involved four examples of a failure to comply with license commitments related to radiological surveys. The third apparent violation involved the failure to secure from unauthorized removal or limit access to licensed material pursuant to 10 CFR 20.1801. The fourth apparent violation involved two

examples of a failure to discharge licensed material into the sanitary sewer in accordance with 10 CFR 20.2003. The fifth apparent violation involved the failure to perform and document investigations of contamination in both controlled and unrestricted areas in accordance with license commitments.

In response to observations and findings from the first part of this inspection in January 2008, you committed to completing certain corrective actions in a February 8, 2008, letter to the NRC. These commitments were subsequently documented in a February 21, 2008, Confirmatory Action Letter issued to you from the NRC. Several of the Confirmatory Action Letter items were among the areas reviewed during the second part of this inspection in March, 2008. Open items from the Confirmatory Action Letter will continue to be reviewed by the NRC during future inspections.

Since the NRC has not made a final determination in this matter, a Notice of Violation is not being issued for this inspection finding at this time. In addition, please be advised that the number and characterization of apparent violations described in the enclosed inspection report may change as a result of further NRC review.

An open predecisional enforcement conference to discuss these apparent violations has been scheduled for May 20, 2008. This conference will be open to public observation in accordance with Section V of the NRC Enforcement Policy.

The decision to hold a predecisional enforcement conference does not mean that the NRC has determined that a violation has occurred or that enforcement action will be taken. This conference is being held to obtain information to assist the NRC in making an enforcement decision. This may include information to determine whether a violation occurred, information to determine the significance of a violation, information related to the identification of a violation, and information related to any corrective actions taken or planned to be taken. The conference will provide an opportunity for you to provide your perspective on these matters and any other information that you believe the NRC should take into consideration in making an enforcement decision. In presenting your corrective actions, you should be aware that the promptness and comprehensiveness of your actions will be considered in assessing any civil penalty for the apparent violation. The guidance in the enclosed excerpt from NRC Information Notice 96-28, "Suggested Guidance Relating to Development and Implementation of Corrective Action," may be helpful.

You will be advised by separate correspondence of the results of our deliberations on this matter. No response regarding these apparent violations is required at this time.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter, its enclosures, and your response, if you choose to provide one, will be made available electronically for public inspection in the NRC Public Document Room or from the NRC's document system (ADAMS), accessible from the NRC Web site at

S. Gupta

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<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/

Steven A. Reynolds
Director, Division of Nuclear Materials Safety

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

Enclosures:

- 1. Inspection Report 030-20567/2008-001(DNMS)
- 2. Excerpt from NRC Information Notice 96-28

cc: Regis Greenwood, Radiation Safety Officer
State of Missouri

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Letter to Surendra K. Gupta, Ph.D. from Steven A. Reynolds dated April 23, 2008.

SUBJECT: NRC INSPECTION REPORT 030-20567/2008-001(DNMS) - AMERICAN
RADIOLABELED CHEMICALS, INC.

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REGION III

Docket No.: 030-20567

License No.: 24-21362-01

Report No.: 030-20567/2008-001(DNMS)

Licensee: American Radiolabeled Chemicals, Inc.

Facility: Buildings 100, 200, 300, and 400

Location: 101 ARC Drive
St. Louis, Missouri

Inspection Dates: January 22 through 24, 2008
March 11 through 14, 2008
Continued in-office review through March 26, 2008

Exit Meeting: March 26, 2008 (conducted by telephone)

Inspectors: George M. McCann, Senior Health Physicist
Andrew M. Bramnik, Health Physicist

Approved by: Patrick L. Loudon, Chief
Decommissioning Branch, DNMS, RIII

EXECUTIVE SUMMARY
American Radiolabeled Chemicals, Inc.
NRC Inspection Report 030-20567/2008-001(DNMS)

This inspection evaluated the American Radiolabeled Chemicals, Inc. (ARC) routine radioactive materials program performance related to: management organization and controls; safety reports and audits; Radiation Safety Committee (RSC) and Radiation Safety Officer (RSO) activities, documentation, and implementation of radiation control procedures; security and control of licensed materials; waste disposal activities; the release of surface contaminated items; and the distribution and shipment of licensed materials.

The inspectors also evaluated corrective actions associated with Confirmatory Action Letter (CAL) No. 3-08-002, dated February 21, 2008. Specifically, during the first phase of the inspection, inspectors identified radiological contamination outside of the licensee's radiologically protected areas. Carbon-14 contamination was identified on workers' clothing, shoes, lunch boxes, and inside workers' vehicles. Immediate actions were initiated by the licensee's staff to characterize the extent of the contamination, conduct remedial activities as necessary, and implement changes to prevent recurrence. The CAL documented actions that had been taken to address these issues, and actions planned to be taken within specified time-frames.

The inspectors also evaluated the licensee's compliance with NRC decommissioning requirements relating to: tracking of current and past authorized radioactive material use locations, conducting and documenting radiological surveys necessary for unrestricted use of former use areas, decommissioning activities performed prior to the release of these areas, and maintaining required information important to the decommissioning of buildings or areas until the licensed site is released for unrestricted use. As part of the decommissioning review, the inspectors performed independent radiation measurements and collected soil samples in unrestricted areas of buildings and outdoor areas on the licensee's property. Based on NRC analysis results of the soil samples, which identified quantities of carbon-14 and hydrogen-3 in excess of NUREG-1757, Table B.2 "Interim Screening Values (pCi/g) of Common Radionuclides for Soil Surface Contamination Levels," the licensee committed to perform radiological characterization of the ARC site and not to perform any construction activities which could potentially disturb or release site soils to unrestricted areas adjoining the site.

American Radiolabeled Chemicals, Inc. is a manufacturing and distribution licensee. The ARC license authorizes the licensee to approve individuals as authorized users of licensed materials, and to manufacture, synthesize, and re-distribute radiolabeled chemicals for distribution to specific licensees. The ARC site occupies approximately four to five acres and contains four buildings (identified as 100, 200, 300, and 400).

Management Organization and Controls

- The NRC inspectors identified one apparent violation regarding management controls:

Failure to comply with license commitments as evidenced by the following examples:

- A. Failure to conduct Radiation Safety Committee meetings during the months of February, June, July, and September through December 2006, and January through October 2007 in accordance with the Radiation Protection Program; and

- B. Failure to implement timely and adequate corrective actions regarding items identified in annual program reviews in December 2004, June 2005, April 2006, and November 2007 in accordance with the Radiation Protection Program.

The inspectors also identified an Unresolved Inspection Item regarding the licensee's storage of potentially contaminated items in a location that is not approved by the license. (Section 1.0)

Radiation Protection Program

- The inspectors concluded that the licensee's bioassay monitoring results were in compliance with NRC occupational exposure limits. (Section 2.1)
- The inspectors identified one apparent violation regarding the licensee's radiological monitoring program:

Failure to comply with license commitments related to radiological surveys, as evidenced by the following examples:

- A. Failure to survey Building 200, a Controlled Area, in accordance with Standard Operating Procedure 16;
- B. Failure to conduct surveys that were reasonable to evaluate radiation levels, concentrations or quantities of radioactive material, and radiological hazards in accordance with the Radiation Protection Program; and
- C. Failure to ensure that employees survey their hands upon exiting the laboratory areas in accordance with the Radiation Protection Program.

The inspectors also identified one Unresolved Inspection Item regarding the implementation and adequacy of the licensee's site characterization efforts. (Section 2.2)

- The inspectors concluded that licensee failed to secure from unauthorized removal or limit access to licensed material, which is an apparent violation. (Section 2.3)
- The inspectors concluded that the licensee had monitoring programs for tracking air and liquid wastes discharges from its facilities. The licensee also had a program for monitoring and documenting potentially contaminated items released from its facilities. However, the inspectors identified one apparent violation:

Failure to discharge licensed materials to the sanitary sewer in accordance with 10 CFR 20.2003, as evidenced by two examples:

- A. In December 2007, the licensee discharged a concentration of licensed material at 108 percent of the monthly average concentration limit for carbon-14 listed in Table 3 of Appendix B to 10 CFR Part 20, and

- B. In December 2003, the licensee discharged a concentration of licensed material at 159 percent of the monthly average concentration limit for carbon-14 listed in Table 3 of Appendix B to 10 CFR Part 20;

The inspectors also identified an additional example of an apparent violation for failure to comply with license commitments related to radiological surveys, as evidenced by the licensee's failure to perform radiation surveys and complete required documentation prior to releasing gas nitrogen tanks on March 13, 2008, in accordance with Standard Operating Procedure 30. (Section 2.4)

- The inspectors identified one apparent violation concerning incident investigation and cleanup, as evidenced by the licensee's failure to perform and document investigations of contamination found in controlled and unrestricted areas.

The inspectors also identified one Unresolved Inspection Item regarding the appropriate implementation of the licensee's emergency spill procedures and actions conducted in response to two radioactive spills, which occurred at the time of the inspection. (Section 2.5)

Confirmatory Action Letter (CAL)

- The licensee initiated actions to resolve and address all CAL items. During the NRC preliminary exit meeting on March 14, 2008, the NRC acknowledged the licensee's request to extend the due date for a commitment involving the updating of Radiation Protection Program procedures. The licensee agreed to revise its procedures by April 30, 2008. (Section 3.0)

Report Details¹

1.0 Management Organization and Controls (88005)

a. Inspection Scope

The inspectors interviewed the licensee's Radiation Safety Officer (RSO), the Assistant Radiation Safety Officer (ARSO), members of the Radiation Safety Committee (RSC), and other ARC personnel to evaluate the licensee's compliance with NRC license and regulatory requirements pertaining to management oversight of licensed material programs. The inspectors reviewed and evaluated the licensee's procedures, practices, and documentation related to activities, duties, and responsibilities. The inspectors reviewed the licensee's annual program reviews, RSC meeting minutes, records maintained by the Radiation Safety Officer (RSO) as required by the license, Radiation Protection Program (RPP) manual dated October 21, 2004, Standard Operating Procedures (SOPs), and records of staff training.

b. Observations and Findings

Radiation Safety Committee and Radiation Safety Officer Oversight

The licensee's program is implemented and maintained by the RSO and ARSO. Each Laboratory Building has a designated Laboratory Supervisor. These supervisors are members of the licensee's RSC.

License Condition 22.B of Amendment No. 37 to ARC's license, dated July 25, 2006, required the licensee to implement its program in accordance with their RPP document. Section 3.2.5 of the RPP document specifies that the RSC must meet at least monthly, and under any of the following circumstances: (a) to fulfill the listed duties of the Committee, or (b) whenever any Committee member requests the Chairman or Vice Chairman to call a meeting at any time for any valid reason. The licensee maintained monthly RSC meeting minutes. The licensee's RSC met monthly except for the months of February, June, July, and September through December, 2006, and January through October, 2007. The licensee's failure to conduct RSC meetings during the months of February, June, July, September through December 2006, and January through October 2007, is an example of an apparent violation of license commitments (APV 03020567/08-01-01).

Annual Radiation Program Reviews

The inspectors reviewed the licensee's annual program reviews from December 2004, June 2, 2005, April 13, 2006, and November 2007. The reviews from 2005 and 2006 were conducted by an outside contractor. Issues that were routinely documented in the annual program reviews included: chemists not adhering to RPP requirements, no action levels being documented for air monitoring, no discussion of the number and locations of survey meters on site, production protocol documentation being outdated, and SOPs regarding both the release of equipment to vendors and the storage of surface contaminated objects not being followed. These program issues were generally repetitive in each annual report. The licensee's annual reviews and RSC meeting

¹ A List of acronyms used in the report is included at the end of the Report Details.

minutes contained little or no discussion regarding corrective actions implemented by the RSO or RSC. The reviews and minutes also contained little information regarding progress in correcting issues identified from the previous years' annual report. Additionally, little or no discussion was written concerning contamination control, facility modifications, or management oversight.

Section 3.2.1 of the RPP states that "the Radiation Safety Committee administers the Radiation Protection Program to assure control of the procurement, use and disposition of radioactive materials and assures that the Radiation Protection Program meets all requirements of the ARC Radioactive Materials License." Section 3.2.4.7 of the RPP further states that "the RSC establishes action levels to minimize the internal and external exposures of individuals in restricted areas and the release of radioactive material (RAM) to unrestricted areas. These action levels, which may be more restrictive than applicable Federal or State regulations, are reviewed at least annually and reduced where possible to achieve the ALARA commitment." Section 3.3.3.5 of the RPP states that the RSO "annually reviews and updates, as necessary, the Radiation Protection Program to assure compliance with established standards and procedures." Section 3.3.3.6 of the RPP further states that the RSO "audits radiation safety records periodically to assure compliance with the provisions of the RPP. Additionally, Section 3.3.4.7 of the RPP states the RSO "performs radiation safety surveys in accordance with Standard Operating Procedures and reviews the results to ensure compliance with NRC regulations."

The failure of the licensee to implement timely and adequate corrective actions to ensure compliance with NRC and license requirements and to prevent the recurrence of repetitive radiation program violations and weaknesses identified in annual program reviews in December 2004, June 2005, April 2006, and November 2007, is an example of an apparent violation of license commitments (APV 03020567/08-01-01).

Approved Locations of Use

During a follow-up review of licensee actions to address contamination control issues, the inspectors identified potentially contaminated items in the warehouse area of Building 400. The inspectors inquired about the quantity of contaminated material that was bought into Building 400, a building that is not identified as an approved location of use. The inspectors also inquired about the frequency of this occurrence. The inspectors will determine the overall scope of this issue during a future inspection. The licensee's storage of potentially contaminated items in a location that is not approved by the license is considered an Unresolved Item (URI 03020567/08-01-01) pending completion of the NRC's review.

c. Conclusion

The NRC inspectors identified one apparent violation regarding management oversight: Failure to comply with license commitments, as evidenced by two examples: A) Failure to conduct RSC meetings during the months of February, June, July, September through December, 2006, and January through October, 2007; and B) Failure to implement timely and adequate corrective actions regarding items identified in annual program reviews in December 2004, June 2005, April 2006, and November 2007. The inspectors also identified an Unresolved Inspection Item regarding the licensee's storage of potentially contaminated items in a location that is not approved by the license.

2.0 Radiation Protection Program (88035, 88045, 83890)

2.1 Bioassay Program

a. Inspection Scope

The inspectors interviewed the licensee's RSO and ARSO regarding the licensee's oversight and implementation of the bioassay program. The inspectors evaluated the employee bioassay program as outlined in the licensee's SOP-2, "In-vitro Bioassay Program."

b. Observations and Findings

The licensee collects employee urine samples weekly and analyzes them in-house using a calibrated liquid scintillation counter. The licensee bioassay reports for the months of January through March 2008 did not exceed NRC limits as specified in 10 CFR Part 20, Appendix B, "Annual Limits on Intake (ALIs) and Derived Air Concentrations (DACs) of Radionuclides for Occupational Exposure; Effluent Concentrations; Concentrations for Release to Sewerage."

c. Conclusion

The inspectors concluded that the licensee's bioassay monitoring results were in compliance with NRC occupational exposure limits.

2.2 Radiological Monitoring Program

a. Inspection Scope

The inspectors observed surveys being performed by the radiation safety staff and maintenance personnel during the performance of both routine work and work related to a spill of radioactive material. The inspectors observed personnel performing contamination detection surveys prior to exiting restricted production areas. The inspectors also observed laboratory personnel working with licensed materials, and evaluated the personnel's use of protective clothing and equipment. The inspectors performed independent radiation measurements. The inspectors collected wipe samples for removable surface contamination, in conjunction with the direct survey measurements in unrestricted areas of the licensee's production buildings. The inspectors also collected ten soil samples in outdoor areas on the licensee's site for radiological analysis. The inspectors performed radiological surveys in an on-site licensee sewer sampling pipe, and with the support of the St. Louis Municipal Sewer District, performed radiological surveys at the bottom of the nearest sewer manhole downstream from the licensee's site. The inspectors interviewed the licensee's radiation safety staff regarding the availability and appropriateness of current instrumentation, as well as methods used to calibrate the licensee's monitoring equipment.

b. Observations and Findings

Routine Radiation Safety Surveys

License Condition 22.B of Amendment 37 to ARC's license, dated June 25, 2006, required the licensee to implement its program in accordance with their SOPs. Section 2.0 of the licensee's SOP-16 "Radioactive Contamination Control Program," states, in part, that controlled areas are to be surveyed at the end of every week; at the start of every week; and daily (as conditions and manpower permit).

The inspectors reviewed the licensee's survey results for required twice-weekly controlled area surveys, and optional daily controlled area surveys for 2006, 2007, and 2008. The inspectors determined that, since 2006, the licensee had not conducted surveys in Building 200, a controlled area, in accordance with SOP-16. The inspectors noted that wipe surveys were only conducted in Building 200 on a weekly basis, at the end of every week, and not at the start of every week or daily in accordance with SOP-16. The licensee's failure to survey a Controlled Area in accordance with SOP-16 is an example of an apparent violation of license commitments (APV 03020567/08-01-02).

License Condition 22.B. of Amendment No. 37 to ARC's license, dated July 25, 2006, required the licensee to implement its program in accordance with their RPP document. Section 4.1.3 of the RPP, "Surveys and Monitoring" states, in part, that "surveys shall be made as are reasonable to evaluate radiation levels, concentrations or quantities of radioactive material (RAM), and radiological hazards."

The licensee collected wipes for removable contamination on a weekly basis in controlled areas on both Fridays and Mondays, collects wipes for removable contamination daily in controlled areas when possible, and collects wipes for removable contamination weekly in Building 400. The wipes for removable contamination involved the use of a dry filter paper collecting random samples in an area of approximately 100 cm². The licensee's radiation safety staff informed the inspectors that radiation survey meters were not used as part of the licensee's routine radiation surveillance program. The inspectors noted that the licensee did not include wet wipes or direct survey measurements to determine quantities of fixed or removable contamination.

Between January 23 and 25, 2008, the inspectors performed direct survey measurements using calibrated radiation survey meters, with detector probes sensitive to beta and gamma radiations, in unrestricted areas of the licensee's production and office buildings. The inspectors also collected wet and dry wipes to sample for removable contamination. Direct survey measurements were taken at each area where contamination wipes were collected. The surveys were in radiologically unrestricted areas, and included surveys in lunchrooms and offices. The survey results ranged from several hundred dpm/100 cm² to 142,000 dpm/100 cm².

The inspectors also surveyed associated items in those rooms, including chairs, tables, telephones, lunchboxes, employee's coats hanging on coat racks, and shoes. The contamination identified ranged from several hundred dpm/100 cm² to levels as high as 17,000 dpm/100 cm². Additionally, after receiving permission, the inspectors surveyed several of the employees' personal vehicles. Inspectors' surveys on employee vehicles

identified contamination levels ranging from several hundred dpm/100 cm² to 70,000 dpm/100 cm². The inspectors collected 18 wipes for removable contamination. The samples were sent to the NRC contract laboratory Oak Ridge Institute for Science and Education (ORISE) for analysis. The ORISE analyses for the samples indicated that levels of removable contamination ranged from a low of 300 to a high of 880 dpm/100 cm². The licensee's failure to conduct surveys that are reasonable to evaluate radiation levels, concentrations or quantities of RAM, and radiological hazards is an example of an apparent violation of license commitments (APV 03020567/08-01-02).

Personnel Monitoring

License Condition 22.B. of Amendment No. 37 to ARC's license, dated July 25, 2006, required the licensee to implement its program in accordance with their RPP. Section 5.2.3 of the licensee's RPP required that all individuals survey their hands upon leaving the laboratory.

On January 23, January 24, and March 12, 2008, the inspectors observed licensee employees exit the laboratories of Buildings 100 and 300 (restricted areas) without surveying their hands. The licensee's failure to ensure that employees survey their hands upon exiting the laboratory areas in accordance with the RPP is an example of an apparent violation of license commitments (APV 03020567/08-01-02).

Section 5.2.5 of the licensee's RPP required that all individuals shall wear shoe covers in contaminated areas. The purpose of this requirement was to prevent employees from transporting contamination out of the Controlled Area laboratories.

On January 23 and 24, 2008, the inspectors observed licensee personnel improperly wearing rubber shoe covers. Specifically, several licensee employees were observed wearing shoe covers with broken or bent heels, allowing personal shoes to scrape the floor. This improper wearing of the protective shoe covers negates the effectiveness of the covers in contamination control. The inspectors performed surveys on several employee personal shoes stored in unrestricted areas of the licensee facilities, and identified radiological contamination on both the outside and inside of the employees' shoes. The identified contamination ranged from a few hundred dpm/100 cm² to several thousand dpm/100 cm². The inspectors discussed this issue with the RSO and the RSC members. The licensee committed to taking corrective actions to address the matter. The use of shoe covers and other protective measures were discussed in a February 21, 2008, Confirmatory Action Letter (CAL 3-08-002), and are discussed in greater detail in Section 3.0 of this report.

Municipal Sanitary Sewers

On January 23, 2008, the inspectors performed independent radiation surveys in and around a stand-pipe between and behind Buildings 100 and 200, using calibrated NRC radiation survey instruments sensitive for the detection of alpha, beta, and gamma radiations. In the area immediately around the stand-pipe, the levels of detectable residual contamination ranged from just above the ambient background levels to approximately 1,000 dpm/100 cm². The inspectors also performed measurements in the sewer stand-pipe. The detectable residual contamination in the standpipe ranged from

ambient radiation background levels to a hot spot measurement of approximately 17,000 dpm/100 cm².

On January 24, 2008, the inspectors met with personnel from Metropolitan St. Louis Sewer District, St. Louis, Missouri. The Sewer District personnel identified the nearest sewer manhole off-site and down stream from the licensee's site (150N1-081S). The Sewer District personnel poured green colored dye down the sewer sampling stand-pipe between and behind Buildings 100 and 200. The dye was used to ascertain if the liquid wastes going through the stand-pipe led to the sanitary sewerage system or storm-water drains. The NRC inspectors and Sewer District inspectors observed the green dye flowing through the pipe below the off-site manhole, which verified that the licensee's liquid wastes were going to the municipal sanitary sewerage system and not the storm water drainage system.

The inspectors performed independent radiation surveys around and near the bottom of sewer manhole 150N1-081S, which was approximately 14 feet deep. The inspectors used calibrated NRC radiation survey instruments with detector probes sensitive for the detection of alpha, beta, and gamma radiations. The inspectors did not identify any radiation levels around the sewer pipe nor near the bottom of the manhole that were above ambient radiation levels.

Soil Contamination and Site Characterization

On January 23, 2008, the inspectors collected three soil samples in areas around the licensee's facility. These soil samples were sent to ORISE for analysis. ORISE reported to the NRC in a February 29, 2008, letter that carbon-14 was identified at levels of 19, 25, and 63 picocuries per gram (pCi/g); and that hydrogen-3 was identified in the samples at levels of 182, 484, and 525 pCi/g. The NRC unrestricted use concentrations for surface soils are specified in NUREG-1757, Table B.2 "Interim Screening Values (pCi/g) of Common Radionuclides for Soil Surface Contamination Levels." The screening values are 12 pCi/g for carbon-14 and 110 pCi/g for hydrogen-3. On March 12, 2008, the inspectors collected seven additional soil samples around the licensee's facility as a result of the identification of elevated levels of carbon-14 and hydrogen-3. These samples were sent to ORISE for analysis. Results of the samples will be reported in a separate letter to the licensee.

During an interim exit meeting on March 14, 2008, the inspectors discussed the elevated levels of carbon-14 and hydrogen-3 in the soil with the licensee. The licensee's management committed to perform characterization surveys of its site to ascertain the extent of contamination and any potential impacts. The licensee also committed to the NRC that no intrusive work or construction will be performed on the site until adequate radiological characterization has been performed.

In light of the contamination identified by the NRC in soil samples from around the licensee's facility, the licensee's program for site characterization remains under further NRC review. The implementation and adequacy of the licensee's site characterization is considered an Unresolved Item (URI 03020567/08-01-02) pending completion of the NRC's review.

Radiological Survey Instrumentation Calibration

The licensee possessed current calibration records for each survey meter. The licensee performed two types of survey meter calibrations: one for survey meters used for “regulatory purposes” and a different one for those used for “production purposes.” The meters that were used for regulatory purposes were calibrated by an outside calibration vendor. The meters used for production purposes were calibrated in-house by the licensee’s radiation safety staff. No issues were identified regarding the licensee’s instrument calibration processes.

c. Conclusion

The inspectors identified one apparent violation for failure to comply with license commitments referenced in License Condition No. 22.B of License No. 24-21362-01 as evidenced by three examples: A) the licensee’s failure to survey a controlled area in accordance with SOP-16; B) the licensee’s failure to conduct surveys that were reasonable to evaluate radiation levels, concentrations or quantities of RAM, and radiological hazards in accordance with the RPP; and C) the licensee’s failure to ensure that employees survey their hands upon exiting the laboratory areas in accordance with the RPP. The inspectors also identified one unresolved item regarding the licensee’s radiological monitoring program concerning the implementation and adequacy of the licensee’s site characterization efforts.

2.3 Security of Licensed Material in Storage

a. Inspection Scope

The inspectors interviewed the licensee’s personnel regarding NRC posting requirements. The inspectors toured the licensee’s site observing the types, quantities, and conditions of the licensee’s precautionary radiation signage. The inspectors also discussed security measures employed by the licensee to ensure control and security of licensed materials.

b. Observations and Findings

On January 23, 2008, the inspectors identified multiple unlocked and unsecured areas, such as a Sea Land shipping container, a door to Building 100, a door to the Building 300 shipping area, and the exterior garage door to the Building 200 radioactive waste storage and processing area. All these areas were properly posted with “Caution – Radioactive Material” signs, and were restricted by the licensee for the purposes of preventing access to licensed materials and preventing the spread of contamination. In addition to serving as the licensee’s waste storage and process facility, Building 200 also contained a compactor used for compacting contaminated dry waste, and hoods used for evaporation of contaminated liquid waste. The inspectors noted that the licensee took immediate corrective actions to close and lock these areas.

On March 11, 2008, inspectors identified that the exterior garage door to Building 200 was unlocked and unsecured a second time. The licensee took immediate corrective actions to close and lock this area. The inspectors inquired about the quantity of material that was present in Building 200. The licensee’s records indicated that a

significant quantity of material had been left unsecured. Specifically, a licensee evaluation performed on January 8, 2008, reported that 33 bottles of liquid waste in Building 200 contained 5.6 curies of carbon-14 and 2.6 curies of hydrogen-3. The licensee's radiation safety staff indicated that the material was in the same place for an unknown period of time prior to the NRC inspection.

The inspectors informed the licensee about the importance of security of licensed material during an interim exit meeting on January 25, 2008. Additionally, a February 21, 2008, Confirmatory Action Letter CAL No. 3-08-002, to licensee management addressed the security of licensed materials in the licensee's shipping area. The licensee's corrective actions are addressed below in Section 3.0 of this report. The licensee's failure to secure from unauthorized removal or limit access to licensed material is an apparent violation of 10 CFR Part 20, Section 20.1801 (APV 03020567/08-01-03).

c. Conclusion

The inspectors concluded that licensee failed to secure from unauthorized removal or limit access to licensed material, which is an apparent violation.

2.4 Radioactive Waste Management and Transportation Activities

a. Inspection Scope

The inspectors interviewed the RSO and ARSO regarding the licensee's disposal practices to determine if the licensee was in compliance with 10 CFR Part 20, Subpart K "Waste Disposal." The RSO and ARSO were also interviewed regarding methods for tracking discharges of air effluents and liquid waste to demonstrate compliance with 10 CFR Parts 20.1302, "Compliance with dose limits for individual members of the public;" and 20.2003, "Disposal by release into sanitary sewerage." The inspectors reviewed and evaluated the licensee's compliance with SOP-07, "Liquid Waste Disposal Program;" and Microsoft Excel spreadsheets used to track effluent discharges. The inspectors also observed the licensee's staff collect and analyze samples from liquid waste hold-up tanks.

b. Observations and Findings

The licensee collected weekly stack air samples to demonstrate compliance with 10 CFR Part 20, Appendix B, "Annual Limits on Intake (ALIs) and Derived Air Concentrations (DACs) of Radionuclides for Occupational Exposure; Effluent Concentrations; Concentrations for Release to Sewerage." The licensee's records for the period of January through March, 2008, did not identify any effluent discharges greater than the Part 20 limits.

License Condition 22.B of Amendment No. 37 to ARC's license, dated July 25, 2006, required the licensee to implement its program in accordance with their RPP document and their SOPs. Section 4.1.6.2 of the licensee's RPP document stated that radioactive material may be discharged to the sanitary sewerage providing the average monthly concentration does not exceed Part 20 limits. The licensee's SOP-07, "Liquid Waste Disposal Program," required that liquid radioactive waste disposals to the sanitary

sewerage must not exceed 100 percent of the monthly average concentration limit for radionuclides specified in Table 3 of Appendix B to 10 CFR Part 20.

As described in SOP-07, the licensee's radiation safety staff was to enter the type of material to be discharged into a Microsoft Excel table, along with the volume, and the activity. The licensee's Excel table was configured to automatically tabulate the total amount of radioactive material discharged for the current year, as well as the quantity and concentration of material that is discharged each month.

On January 23, 2008, the inspectors noticed that in several places the column labeled "Monthly Percent Permissible: carbon-14" in the above-referenced Excel tables was greater than 100 percent. The SOP-07 stated, in part, that "If at any time during the month the sum monthly percent permissible would exceed the 100 percent monthly limit, all or part of the radioactive liquid waste must be stored for future disposition." Although the Excel table indicated a monthly concentration limit in excess of 100 percent, the licensee staff continued to discharge liquid radioactive waste to the sanitary sewerage. The licensee explained that these instances were allowable and not in excess of the monthly limit because the computer program values for the monthly concentration limit had not been reset to 0 percent at the beginning of the month.

The inspectors observed the licensee correct the monthly values in the computer model. Once corrected, all of the months from 2003 through 2007 were less than 100 percent of the monthly concentration limit, except for the months of December 2007, and December 2003. The licensee discharged 108 percent of the allowable monthly concentration limit of carbon-14 during the month of December 2007; and during the month of December 2003, the licensee discharged 159 percent of the allowable monthly concentration limit of carbon-14. At no time was any annual limit for disposal of licensed material to the sanitary sewerage exceeded.

The licensee's failure to discharged licensed materials into the sanitary sewer in accordance with 10 CFR 20.2003(a) is considered an apparent violation, as evidenced by two examples: In December 2007, the licensee discharged a concentration of licensed material at 108 percent of the monthly average concentration limit for carbon-14 listed in Table 3 of Appendix B to 10 CFR Part 20, and in December 2003, the licensee discharged a concentration of licensed material at 159 percent of the monthly average concentration limit for carbon-14 (APV 03020567/08-01-04).

On March 13, 2008, the inspectors observed that a licensee vendor had removed six empty liquid nitrogen gas tanks from the garage area of Building 300, had loaded them onto his truck, and was preparing to leave the site. The inspectors performed direct radiation survey measurements using calibrated NRC survey instruments on three of the six tanks. All three tanks exhibited radioactive contamination levels greater than three times background levels. The inspectors collected wipes for removable contamination on the same three tanks. The wipes for removable contamination were counted by the RSO using the licensee's liquid scintillation counter. The values ranged from 3,800 to 18,550 dpm/100 cm² of carbon-14, and 3,200 to 119,375 dpm/100 cm² of hydrogen-3. Upon obtaining the results of the wipe samples, the RSO had the vendor unload all of the tanks, and instructed the licensee's maintenance staff to clean and decontaminate the tanks. The inspectors surveyed the truck driver's shoes, hands, and clothing, and did not identify any contamination above background radiation levels. The RSO indicated that he was under the impression that the tanks had been surveyed by license

personnel. The RSO was unable to locate either a survey record or vendor release form required by licensee procedure.

The licensee's SOP-30 "Release of Equipment to Vendors" required the licensee to survey and, if necessary, decontaminated equipment before released to vendors, if the material to be released exceeds the licensee's release limits. The licensee's release level is 1,000 dpm/100 cm² total for the sum of carbon-14 and hydrogen-3.

The licensee's failure to perform radiation surveys and document required information prior to releasing gas nitrogen tanks to a vendor on March 13, 2008, in accordance with SOP-30 is an example of an apparent violation of license commitments (APV 03020567/08-01-02).

c. Conclusion

The inspectors concluded that the licensee had active monitoring programs for tracking air and liquid wastes discharged from its facilities. The licensee also had a program for monitoring and documenting potentially contaminated items from its facilities. However, the inspectors identified one apparent violation for the licensee's failure to discharge licensed material to the sanitary sewer in accordance with 10 CFR Part 20.2003, with two examples. The inspectors also identified one example of an apparent violation for the licensee's failure to comply with license commitments as evidenced by the licensee's failure to survey and document required release information prior to the loading of six radiologically contaminated liquid nitrogen tanks onto a contractor vehicle.

2.5 Incident Investigation and Cleanup

a. Inspection Scope

The inspectors reviewed licensee survey records and evaluated the licensee's investigation into the cause and determination of the sources of contamination exceeding licensee's action limits. The inspectors also interviewed licensee personnel regarding actions to be performed when reporting and responding to radiological spills. The inspectors observed radiation safety staff respond to actual radiological spills and their actions to restrict access to, post, and decontaminate the area where the spill occurred.

b. Observations and Findings

The licensee collected wipes for removable contamination on a weekly basis in controlled areas on both Fridays and Mondays, collected wipe tests for removable contamination daily in controlled areas when possible, and collected wipe tests for removable contamination weekly in Building 400. The wipes for removable contamination involved the use of a dry filter paper "wipe" collecting random samples in an area of approximately 100 cm². The licensee's radiation safety staff informed the inspectors that radiation survey meters were not used as part of the licensee's routine radiation surveillance program. The inspectors noted that the licensee's survey program did not include measurements to determine quantities of fixed contamination, or wipes to ascertain the removable contamination fraction in areas where contamination had been detected.

License Condition 22.B of Amendment 37 to ARC's license, dated July 25, 2006, required the licensee to implement its program in accordance with their SOPs. Section 5.0 of SOP-16, "Radioactive Contamination Control Program," stated that "if [during the conduct of radiation surveys by ARC personnel] initial contamination levels are identified exceeding 10 times the action levels, [Health Physics personnel shall] attempt to determine the source and cause. The results of this investigation shall be documented and filed in the Off-Normal Occurrence File." The licensee's action level for contamination in controlled areas is 1,000 dpm/cm² total combined for carbon-14 and hydrogen-3. Ten times the contamination action level is 10,000 dpm/cm².

The inspectors identified multiple instances where the licensee detected contamination greater than 10 times the action levels in Buildings 100 or 300 and did not conduct an investigation, including on the following dates: November 19, 2007 (68,000 dpm/100 cm² total contamination), July 16, 2007 (98,000 dpm/100 cm²), and May 21, 2007 (11,000 dpm/100 cm²). The inspectors also identified multiple instances where the licensee detected contamination greater than 10 times the action levels in Building 400 (a radiologically unrestricted area, not listed as an approved location of use on the license) and did not conduct an investigation, including on the following dates: August 14, 2007 (11,500 dpm/100 cm² total contamination), January 30, 2007 (41,000 dpm/100 cm²), June 19, 2006 (13,000 dpm/100 cm²), and February 20, 2006 (26,000 dpm/100 cm²).

The licensee's failure to perform and document investigations of contamination found in controlled and unrestricted areas greater than 10 times the contamination action levels on June 19, 2006, February 20, 2006, January 30, 2007, November 19, 2007, July 16, 2007, May 21, 2007, and August 14, 2007 in accordance with SOP-16, is an apparent violation of license commitments (APV 03020567/08-01-05).

On March 11, 2008, the inspectors identified a spill of radioactive materials in an unrestricted area immediately outside the door leading into the liquid waste evaporation room of Building 200. On March 12, 2008, the inspectors identified a spill of radioactive material inside the Building 200 restricted area of the liquid evaporation room next to a ventilation hood used for evaporating liquids contaminated with radiological materials.

The spill outside the door to Building 200 appeared to be a green, dry, crusty material that was present in nine lines averaging one half inch in width and approximately 16 to 20 inches in length. The inspectors performed direct radiation measurements in the area of the spill and observed a maximum direct survey reading of 70,000 counts per minute. The inspectors estimated that there was 9,000,000 dpm/100 cm² in the area of the spill. After being informed about the spill by the inspectors, the RSO restricted the area of the spill, and directed the ARSO to decontaminate the area outside the door of Building 200. The ARSO started decontamination activities immediately without a pre-decontamination assessment. The second spill involved liquid waste that had spilled onto the floor from an evaporation pan in a hood located in Building 200. The inspectors performed a direct measurement in the area immediately above the spill and observed a maximum survey reading of 110,000 counts per minute. The inspectors estimated a surface contamination level of 13,200,000 dpm/100 cm². Since this was a liquid volume, the inspectors estimated that several hundred microcuries of licensed material might be present in the spill.

On March 12, 2008, the inspectors were informed by the RSO that he was unaware of both spills until the NRC inspectors informed him. Additionally, he was unable to obtain

any information from the licensee's staff regarding who may have caused the spills, or when or how the spills may have occurred. On March 12, 2008, the inspectors were informed by one of the building Supervisory Chemists, who was also a member of the RSC, that he had not been informed of the spill.

The licensee's implementation of its Emergency Spill Procedures regarding actions to evaluate and investigate sources and causes of spills, to determine the radiation exposure consequence prior to performing decontamination activities, and to notify personnel that a spill has occurred, remains under further NRC review. The full scope and adequacy of the licensee's implementation of its Emergency Spill and Incident Investigation Procedures is considered an Unresolved Item (URI 03020567/08-01-03) pending completion of the NRC's review.

The RSO indicated that a 30-day report pursuant to 10 CFR 20.2203, "Reports of exposures, radiation levels, and concentrations of radioactive material exceeding the constraints or limits," would be prepared and submitted to the NRC. The NRC received a copy of the licensee's report on April 10, 2008.

c. Conclusion

The inspectors identified one apparent violation regarding the failure to comply with license commitments as evidenced by licensee's failure to investigate and document levels of contamination exceeding 10 times the licensee's action levels in accordance with SOP-16. The inspectors also identified one unresolved inspection item regarding the appropriate implementation of the licensee's emergency spill procedures and actions conducted in response to two spills of radioactive material, which occurred at the time of the inspection.

3.0 Confirmatory Action Letter (CAL) Corrective Actions

a. Inspection Scope

The inspectors interviewed licensee management and staff, observed licensee activities involving the use of licensed materials, and evaluated the licensee's corrective actions to address four items outlined in the February 21, 2008, Confirmatory Action Letter (CAL) No. 3-08-002.

b. Observations and Findings

CAL Item 1: Contamination Outside Restricted Areas

- The licensee committed to complete contamination surveys of any company employee's personal property, including vehicles and homes would be surveyed, upon request.

The licensee had completed surveys of personal employee's items and automobiles by March 13, 2008. Additionally, three homes were surveyed. All contaminated items were either decontaminated below release limits or disposed of by the RSO as contaminated waste.

- The licensee committed to perform an upper-bound calculation of the potential dose to the most sensitive off-site individual by March 28, 2008.

The licensee completed an initial direct beta dose assessment using VARSKIN modeling, which indicated that the direct skin dose to an individual would be less than 1 mrem per year. During the March 14, 2008, interim exit meeting, the licensee agreed to provide a final assessment that included both direct and ingestion exposure pathways to the NRC by April 30, 2008.

- The licensee committed to increase the location and extent of contamination surveys to be completed in the Building 100 and 300 lunch rooms by February 4, 2008.

The licensee had increased the scope of the surveys of the kitchen areas, supplementing the wipe test surveys with direct survey meter measurements.

- The licensee committed to making a decision by February 25, 2008, as to whether the lunch rooms would be left open or permanently closed. If the decision was made to leave the lunch rooms open, the frequency and scope of surveys in those areas would be changed, as appropriate, to ensure any inadvertent spread of contamination was quickly identified. The licensee also committed to incorporating changes in the surveys for both lunch rooms into the SOPs by March 14, 2008.

The licensee did make a decision to continue the use of the lunchrooms. As indicated above, the scope of the surveys had been expanded to involve the periodic use of a survey meter. The frequency of surveys was essentially the same. The RSO indicated that ARC was going to continue to monitor the areas, and if other contamination controls such as personnel frisking, the use of new protective clothing, and emphasis on training are effective, then the company will allow the continued use of the lunchrooms.

The licensee revised a portion of the survey procedures. During the interim exit meeting on March 14, 2008, the NRC agreed to extend the procedure completion date until April 30, 2008, so that the licensee could complete revisions to the remainder of the survey procedures.

CAL Item 2: Training

- On February 6, 2008, the licensee's staff conducted refresher training for all but three chemists regarding the nature of contamination, controlling the spread of contamination, and proper survey techniques. One of the three individuals who were not available for the February 6, 2008, training was provided a one-on-one training session on February 11, 2008. The other two individuals were out of the country and would be trained by March 7, 2008, upon their return.

The licensee completed the training of the remaining two chemists on March 4, 2008.

CAL Item 3: Control of Contamination

- The licensee committed to purchase heavy cloth aprons and require them to be worn under lab coats. The licensee also committed to order sleeve protectors for the chemists, and would require their use by February 22, 2008. The licensee committed to have new, vinyl shoe covers in use by February 22, 2008, and that all workers would be

required to have separate lab shoes no later than March 18, 2008. These changes in the policy for laboratory attire would be addressed in the SOPs by March 14, 2008.

Licensee personnel were observed using the cloth aprons and sleeve protectors. Some licensee personnel had also employed other protective measures, such as wearing leg (pant cuff) protectors, placing aluminum foil along work benches to prevent transfer from contaminated benches and hoods, and labeling workers' chairs to enhance personal responsibility. Licensee personnel had purchased separate pairs of shoes for use in contaminated laboratory areas, and were required to wear those shoes underneath new rubber shoe covers.

- The licensee committed to designate desk areas in laboratories as contaminated. As a result of this change, workers were required to wear a separate lab coat when using the laboratory desks. The workers were trained in this change on January 25, 2008, and it was to be incorporated into the SOPs by March 14, 2008.

The licensee's approved users were observed using different colored laboratory gloves. The inspectors were informed that one color was for work with licensed materials, while the other was to be worn when working at the individual's desk. Due to difficulties and feedback from the licensee's staff, the use of multiple lab coats at desk areas was discontinued.

- The licensee committed to sending a total of 10 radiological survey meters and 13 probes for repairs, and ordering additional "pancake" probes. All survey instruments would be repaired or replaced by February 29, 2008.

The inspectors verified that all survey meters in use were in proper working order and had current calibration certificates.

- The licensee committed that future abnormal discharges of liquid radioactive waste would require the RSO to directly supervise the activity to ensure surveys before and after are acceptable, and that maintenance personnel wear appropriate clothing. This protocol would be addressed in the SOPs by March 14, 2008.

The licensee's RSO confirmed the above position, and the applicable SOP was modified to reflect the commitment. However, as indicated above, the NRC extended the deadline for successful completion of procedure revisions to April 30, 2008.

- The licensee committed to place a combination lock on the inner door to the shipping area where packages containing radioactive materials are received. This door would shut and lock automatically after someone passed through it, preventing workers from inadvertently leaving radioactive material unattended in an unlocked area. This change was completed by February 12, 2008.

The inspectors verified the installation and operation of the above lock. In addition, the licensee replaced all of the external door handles and locks with a similar-style electronic keypad controlled combination lock throughout the site. No modifications to external garage doors were made.

CAL Item 4: Radiation Safety Committee

- The licensee committed to resume weekly RSC meetings by February 5, 2008. The licensee confirmed that the RSC meetings are required monthly by license commitment. The licensee committed to conducting meetings weekly until corrective actions appear to be effectively in place, and will then reduce the meeting frequency as appropriate, and according to the SOPs.

The licensee provided copies of meeting minutes, attendees, and dates as proof of the above commitment.

c. Conclusions

The licensee initiated actions to resolve and address all CAL items. During the preliminary exit meeting on March 14, 2008, the licensee was allowed additional time to insure that all procedures are completed with sufficient quality. The licensee agreed to revise its procedures by April 30, 2008. All CAL items remain open and will be reviewed during future inspections.

4.0 Exit Meeting Summary

The NRC inspectors presented preliminary inspection findings to members of the facility management team following onsite inspections on January 25 and March 14, 2008. A final exit meeting was performed via telephone on March 26, 2008, with the ARC RSO. The licensee did not identify any documents or processes reviewed by the inspectors as proprietary. The licensee acknowledged the findings presented.

ATTACHMENT: SUPPLEMENTAL INFORMATION

SUPPLEMENTAL INFORMATION

PARTIAL LIST OF PERSONS CONTACTED

American Radiolabeled Chemicals, Inc.

S. Guupta, Ph.D., President, ARC ^ *

R. Greenwood, Radiation Safety Officer, ARC ^ *

N. Zheng, Assistant Radiation Safety Officer, ARC

J. Selvasekaran, Senior Scientist, Radiation Safety Committee Member, ARC *

K. Das, Ph.D., Senior Scientist, Radiation Safety Committee Member, ARC *

^ Present at interim Exit Meeting on January 25, 2008

* Present at interim Exit Meeting on March 14, 2008

INSPECTION PROCEDURES USED

IP 88005	Management Organization and Controls
IP 88035	Radioactive Waste Management
IP 88045	Effluent Control and Environmental Protection
IP 83890	Closeout Inspections and Surveys

ITEMS OPENED, CLOSED, AND DISCUSSED

<u>Opened</u>	<u>Type</u>	<u>Summary</u>
APV 03020567/08-01-01	APV	Failure to provide adequate management attention to ensure that licensed activities were conducted in accordance with the Radiation Protection Program.
APV 03020567/08-01-02	APV	Failure to comply with license commitments related to radiological surveys.
APV 03020567/08-01-03	APV	Failure to secure from unauthorized removal or limit access to licensed material.
APV 03020567/08-01-04	APV	Failure to discharge licensed material into the sanitary sewer in accordance with 10 CFR 20.2003.
APV 03020567/08-01-05	APV	Failure to perform and document investigations of contamination found in controlled and unrestricted areas.
URI 03020567/08-01-01	URI	Storage of contaminated items in a location that is not approved by the license.
URI 03020567/08-01-02	URI	Implementation and adequacy of the licensee's site characterization efforts.

URI 03020567/08-01-03 URI Implementation of licensee's Emergency Spill and Incident Response Procedures

Closed None

Discussed None

PARTIAL LIST OF DOCUMENTS REVIEWED

Licensee documents reviewed and utilized during the course of this inspection are specifically identified in the "Report Details" above.

LIST OF ACRONYMS USED

ADAMS	Agencywide Documents Access and Management System
APV	Apparent Violation
ARSO	Assistant Radiation Safety Officer
CFR	Code of Federal Regulations
DNMS	Division of Nuclear Material Safety
NRC	U.S. Nuclear Regulatory Commission
PDR	Public Document Room
pCi/g	picocuries per gram
RAM	Radioactive Material
RPP	Radiation Protection Program
RSC	Radiation Safety Committee
RSO	Radiation Safety Officer
SOP	Standard Operating Procedure
URI	Unresolved Item
VIO	Violation