

Enclosure 6 – Inspection Record

Region III Inspection Report No. 2011-001

License No. 24-21362-01

Docket No. 03020567

Licensee (Name and Address): American Radiolabeled Chemicals  
100 ARC Drive  
St. Louis, MO

Location (Authorized Site) Being Inspected: 100 ARC Drive  
St. Louis, MO

Licensee Contact: Regis Greenwood, RSO Telephone No. 314-991-4545 Priority: 5

Program Code: 03214

Dates of Last Inspection: August 2-6, 9 and 10, 2010

Dates of This Inspection: February 14-16, 2011, with continued in-office review through February 18, 2011

The in-office review included, in part, receipt and review of staff training records and information about licensee investigations of survey results that exceeded 10 times the licensee's action level.

Type of Inspection: ( ) Initial ( ) Announced (x) Unannounced (x) Routine ( ) Special

Next Inspection Date: 10/2011 ( ) Normal (x) Reduced

Justification for reducing the routine inspection interval:

The licensee has a history of poor performance and it needs to demonstrate sustained improved performance before it goes back to the routine five year inspection frequency.

Summary of Findings and Actions:

- ( ) No violations cited, clear U.S. Nuclear Regulatory Commission (NRC) Form 591 or regional letter issued
- ( ) Non-cited violations (NCVs)
- ( ) Violation(s), Form 591 issued
- (x) Violation(s), regional letter issued
- (x) Follow-up on previous violations

Inspector(s) (Name): Robert G. Gattone, Jr.

Date 3/15/11

(Signature) Robert G. Gattone, Jr.

Approved (Name): Tamara E. Bloomer

Date 3/15/11

(Signature) Tamara Bloomer

## PART I-LICENSE, INSPECTION, INCIDENT/EVENT, AND ENFORCEMENT HISTORY

### 1. AMENDMENTS AND PROGRAM CHANGES:

AMENDMENT #	DATE	SUBJECT
42	9/30/10	Renewal
43	10/14/10	Added possession incident to outdoor site construction and site beautification activities involving movement of site soils, radiological site characterization, collection and analysis of water and soil samples containing residual contamination

### 2. INSPECTION AND ENFORCEMENT HISTORY:

As a result of inspections conducted on October 27 and 28, 2009, with continued in-office review through December 4, 2009, and November 16 through 20, 2009, with continued in-office review through January 5, 2010, the licensee was cited for two Severity Level IV violations. The first violation involved failure to restrict an individual from further work with radionuclides until his dose rate fell below 50 millirem in a week based on bioassay results. The second violation involved failure to conduct contamination restricted area surveys in Buildings 100 and 300 at the end of the week prior to cleaning and failure to conduct contaminated restricted area surveys in Buildings 100 and 300 at the start of the week after cleaning. In addition, the NRC identified continued concern with the licensee's safety culture as it pertains to compliance with license requirements.

On October 19, 2010, the NRC completed its review of an Unresolved Item identified during a reactive inspection which concluded on January 21, 2010. The Unresolved Item pertained to contamination identified in outdoor areas of the site and modification of building exhaust systems. As a result, the licensee was cited for two Severity Level IV violations involving failure to: (1) make adequate surveys to demonstrate compliance with public dose limits of 0.1 rem per year to a member of the public from air effluents; and (2) calibrate the system's instruments and equipment that are used in the air effluent monitoring system to determine the volume of air passed through the system to demonstrate compliance with the public dose limit.

Based on an inspection conducted on August 2 through 6, 9 and 10, 2010, with continued in-office review through October 4, 2010, the licensee was cited for three Severity Level IV violations involving failure to: (1) conduct removable contamination surveys in controlled areas and contaminated areas at the end of the week prior to cleaning and at the start of the week after cleaning and conduct removable contamination surveys of "work areas" inside Restricted Contaminated Areas; (2) to stop use of fume hoods with face velocities that were less than 100 feet per minute; and (3) conduct an appropriate survey of radioactive materials in air effluents released to unrestricted and controlled areas to demonstrate compliance with dose limits to members of the public. In addition, the NRC identified several examples of a weak safety culture.

### 3. INCIDENT/EVENT HISTORY:

None

## PART II - INSPECTION DOCUMENTATION

### 1. ORGANIZATION AND SCOPE OF PROGRAM:

The NRC License No. 24-21362-01 authorizes the licensee to manufacture and synthesize radiolabeled chemicals for distribution to authorized persons. The majority of the licensee's radioactive material was hydrogen-3 and carbon-14. The licensee's radiolabeled chemical synthesis activities involved use of high specific activity hydrogen-3 and carbon-14 labeled organic chemicals and are conducted in the licensee Buildings 100, 200 and 300. Building 400 is the nearest publically occupied building to the licensee operational facilities and is located to the north of Building 300 and northeast of Buildings 100 and 200.

### 2. SCOPE OF INSPECTION:

Inspection Procedure(s) Used: 87125  
Focus Areas Evaluated: 03.01-03.07

The inspector reviewed the licensee's action taken regarding the following:

Violation of the tie down condition (an individual received a CEDE of at least 148 millirem (combined for hydrogen-3 and carbon- 14) and the licensee failed to restrict the individual from further work with radionuclides until his dose rate fell below 50 millirem in a week)

Violation of the tie down condition (failure to conduct contamination restricted area surveys in Buildings 100 and 300 at the end of the week prior to cleaning and failure to conduct contaminated restricted area surveys in Buildings 100 and 300 at the start of the week after cleaning)

Violation of the tie down condition (if contamination levels exceed 10 times the action levels, attempt to determine the source and cause and document the results of the investigation)

Authorization for excavation for a nitrogen storage tank foundation pad that was approved in Amendment No. 43 dated 10/14/10

Authorization for possession incident to outdoor site construction and site beautification activities involving movement of site soils, radiological site characterization, collection and analysis of water and soil samples containing residual contamination that was approved in Amendment No. 43 dated 10/14/10

License authorization granted on 7/6/10 for excavation to repair a natural gas leak under a driveway

Previously identified examples of a safety culture concern

Previously identified need for enhanced management involvement and oversight of the radiation safety program to ensure that the program is properly implemented

The licensee's status of having the RSO serve as such until a replacement is found

Violation of 10 CFR 20.1302(a) (failure to perform adequate surveys to identify the extent of contamination, levels of the on-going liquid effluent release, and the potential hazards associated with the radioactive material to ensure compliance with 10 CFR 20.1301 following the licensee's identification of contamination on the roof and soil)

Violation of the tie down condition (failure to prevent use of fume hoods with face velocities less than 100 feet per minute)

Violation of 10 CFR 20.1501 as it pertains to 10 CFR 20.1302(b)(1) involving failure to conduct reasonable surveys of radioactive materials in effluents released to unrestricted and controlled areas to demonstrate compliance with the public dose requirements

The inspector observed:

That the Building 300 stack and sand below it was fenced in

Required postings on the roof of Building 300

The newly installed nitrogen storage tank and the associated pad

Lab personnel conduct required ambient count rate surveys when exiting contaminated restricted areas

That the licensee received new air sampling bubblers that will be installed soon such that the current two bubbler air sampling trains will become three bubbler air sampling trains

That Building 400 air sampling equipment was in working order

That Building 400 air sampling equipment included new stainless steel lines

That selected fire extinguishers in Building 300 and the Building 300 Annex were fully charged with records that monthly checks were done timely

An authorized user demonstrate how he conducted whole body ambient count rate scans when exiting contaminated restricted areas

An authorized user demonstrate his knowledge of the action level for whole body ambient count rate scans when exiting contaminated restricted areas, and how he would respond if the action level is exceeded

A Health Physics Technician measure the face velocities of every fume hood in Building 100, and results were greater than 100 feet per minute

That the findings of a Building 100 tour conducted by the licensee's President and RSO were posted in Building 100

That the licensee grounded cabinets containing flammable material as corrective action taken in response to a finding associated with a Building 100 tour conducted by the licensee's President and RSO

An authorized user demonstrate how he doffed personal protective equipment (PPE)

A lab technician using carbon-14 while donning required PPE

A lab technician demonstrate how he would respond to a radioactive spill based on a scenario posed by the inspector

A lab technician demonstrate how he had disposed of radioactive liquid waste

The RSO demonstrate how the licensee determined that radioactive waste disposal to the sanitary sewer system was in accordance with NRC regulatory requirements

The inspector reviewed the following records:

Bioassay records generated between 9/1/10 and 2/7/11

"Daily Calendar Checklists" that were generated 1/1/11 through 2/11/11 and used to ensure that daily tasks were completed

Records of investigations of the source and cause of contamination levels that exceeded 10 times the action levels as a result of removable contamination surveys of restricted areas, dated 12/6/09, 12/7/09, 12/11/09, 8/25/10, 10/5/10, 11/1/10, 12/27/10, and 1/3/11

Records of beginning of the week area surveys dated 1/3/10, 1/4/10, 1/11/10, 1/18/10, 1/25/10, 2/1/10, 2/8/10, 2/15/10, 2/22/10, 3/1/10, 3/8/10, 3/15/10, 3/22/10, 3/29/10, 4/4/10, 4/12/10, 4/19/10, 4/26/10, 5/3/10, 5/1/10, 5/17/10, 5/24/10, 6/1/10, 6/7/10, 6/14/10, 6/21/10, 7/12/10, 7/6/10, 7/19/10, 7/26/10, 8/2/10, 8/8/10, 8/16/10, 8/23/10, 8/30/10, 9/7/10, 9/13/10, 9/20/10, 9/27/10, 10/4/10, 10/11/10, 10/18/10, 10/25/10, 11/1/10, 11/8/10, 11/15/10, 11/22/10, 11/29/10, 12/6/10, 12/13/10, 12/20/10, 12/27/10, 1/3/11, 1/10/11, 1/17/11, 1/24/11, 1/31/11, and 2/7/11

Records of end of the week area surveys dated 1/1/10, 1/9/10, 1/15/10, 1/22/10, 2/6/10, 2/13/10, 2/26/10, 3/5/10, 3/14/10, 3/19/10, 3/26/10, 4/2/10, 4/9/10, 4/16/10, 4/24/10, 4/30/10, 5/7/10, 5/14/10, 5/21/10, 5/28/10, 6/4/10, 6/11/10, 6/18/10, 6/25/10, 6/28/10, 7/2/10, 7/9/10, 7/16/10, 7/23/10, 7/30/10, 8/6/10, 8/13/10, 8/20/10, 8/27/10, 9/3/10, 9/10/10, 9/17/10, 9/24/10, 10/1/10, 10/8/10, 10/15/10, 10/22/10, 10/29/10, 11/5/10, 11/12/10, 11/19/10, 11/24/10, 12/3/10, 12/10/10, 12/17/10, 12/23/10, 12/31/10, 1/7/11, 1/15/11, 1/22/11, 1/28/11, and 2/5/11

Note dated 1/29/10 regarding the end of the week area surveys noting that several inches of snow had fallen and the temperature was 5 degrees Fahrenheit

Records of daily whole body scan surveys dated 11/15, 16, and 17/10, associated with excavation for a nitrogen storage tank foundation pad that was approved in Amendment No. 43 dated 10/14/10

Records of an ambient count rate survey of equipment used during the excavation for a nitrogen storage tank foundation pad dated 11/11, 12, 15/10, and 12/2/10

Records of training on SOP-37 dated 11/11/10, and 12/1/10 and 2/10/11, associated with excavation for a nitrogen storage tank foundation pad

Records of training for workers involved with excavation for a nitrogen storage tank foundation pad dated 11/11/10

Record of tarp surveys after soil removal dated 12/2/10, associated with excavation for a nitrogen storage tank foundation pad

Record of surveys of soil prior to disturbance dated 11/11/10, associated with excavation for a nitrogen storage tank foundation pad

Selected survey records of Buildings 100 and 300 roof rain water collected in barrels dated 8/31/10, 9/29/10, and 10/28/10

Selected survey records of Buildings 100 and 300 stacks and sands since 8/9/10

Water utility bills for 7/13/10 through 10/13/10

Record of the scoping ambient count rate survey of the work area prior to beginning work to repair a gas leak under a driveway dated 7/21/10, in accordance with an amendment that authorized this one time activity.

Record of the ambient count rate survey of tools and a back hoe that were used to repair a gas leak under a driveway dated 7/21/10

Records of workers' personal ambient count rate surveys after they exited the restricted area after performing work associated with repair of a gas leak under a driveway

Records of workers' training dated 7/21/10 prior to repair of a gas leak under a driveway

Records of wipe and ambient count rate surveys taken of the driveway associated with repair of a gas leak underneath it

Radiation Safety Committee (RSC) meeting minutes dated 1/26/11

Health Physics summary reports dated 1/8/10, 2/7/11, and 2/14/10

Records of monthly safety training records dated 9/10, 10/10, and 11/10

Records of sewer discharges of licensed material for 2009 and 2010

Records dated 1/25/11 of monthly ambient count rate surveys of street shoes and jackets

Record dated 1/27/11 of monthly ambient count rate surveys of cars

### 3. INDEPENDENT AND CONFIRMATORY MEASUREMENTS:

The inspector used a calibrated Ludlum Model 2403 survey instrument to measure: (1) < 50 counts per minute (CPM) on selected employee car door handles; (2) < 50 CPM on selected

Building 300 door knobs and banisters; (3) < 50 CPM on selected areas of the ground where a 90 degree downspout elbow directed roof rain water away from the opening of a collection barrel on the creek side of Building 300; (4) < 50 CPM on selected areas of the ground where a downspout had no hose connecting it to the opening of a rain water collection barrel on the creek side of Building 300; (5) < 50 CPM on selected areas of the ground where a large plastic 90 degree downspout elbow directed roof rain water away from the opening of a collection barrel on the side of Building 300; (6) < 50 CPM on selected areas of the ground where a 90 degree downspout directed roof rain water away from the opening of a collection barrel on the creek side of Building 300; (7) < 50 CPM on the whole body of a radiation worker who had just exited a contaminated restricted area; (8) < 50 CPM on selected surfaces in Building 100; and (9) 1500 CPM on a lab coat rack within a contaminated restricted area of Building 100.

#### 4. VIOLATIONS, NCVs, AND OTHER SAFETY ISSUES:

Condition 22 of NRC License No. 24-21362-01, Amendment No. 40, requires in part, that the licensee conduct its program in accordance with the statements, representations, and procedures contained in licensee letters dated March 24, 2005.

One of the March 24, 2005, licensee letters includes Standard Operating Procedure (SOP)-16, "Radioactive Contamination Control Program." Item 1.0 of SOP-16 states, in part, that removable contamination surveys are required in Restricted, Controlled, and Unrestricted Areas. Item 5.1 of SOP-16 states, "If contamination levels exceed 10 times the action levels, attempt to determine the source and cause." Item 5.2 of SOP-16 states "Document the results of the investigation and file the report in the Off-Normal Occurrence File."

Contrary to the above, the licensee investigated the source and cause of contamination levels that exceeded 10 times the action levels as a result of removable contamination surveys of restricted areas conducted on December 1, 15, and 19, 2009, and the licensee failed to document the results of its investigation.

As corrective action, the licensee committed to have more than one person look at all of the survey records to verify that all investigation records are done.

The inspector identified an Open Item involving a potential violation of 10 CFR 20.1501(a) (1) as it pertains to 10 CFR 20.1101(d). The NRC is continuing its review of the Open Item. Upon completion of the review, the results will be documented in separate correspondence.

The inspector observed the following examples indicating that the licensee did not ensure that down spouts used to channel rain water from the roofs of Buildings 100 and 300 drained into rain barrels:

Two Building 100 down spout hoses were misaligned with the openings on rain barrels

Two Building 300 downspouts had a 90 degree elbow that directed rain water away from the opening of a collection barrel

A Building 300 downspout had no hose connecting it to the opening of a rain water collection barrel

A Building 300 downspout had no hose connecting it to the opening of a rain water collection barrel and the barrel was lying horizontal on the ground

The licensee had not identified the aforementioned examples because it had not been sampling the rain water in the barrels during the winter due to frozen water in the downspouts and barrels. The inspector identified the examples when the temperature was above freezing and there was no frozen water in the downspouts and barrels.

In response to this finding, the licensee committed to do weekly checks to verify that all of the Building 100 and 300 down spouts have proper hardware configurations to drain water from the roofs to the rain barrels. In addition, the licensee committed to add the down spout hardware configuration checks to its weekly checklist form.

5. PERSONNEL CONTACTED:

+ Kamal Das, Ph.D., Vice President

#+^Regis Greenwood, RSO

#+ Surendra Gupta, President

+ April Birkholz, Health Physics Technician

+ Christina Lafser, Computer Specialist

John Larue, Laboratory Technician

+ Janardhanam Selvasekaran, Vice President

Don Tegeler, Accountant

Shin Yu, Chemist

Use the following identification symbols:

# Individual(s) present at entrance meeting

+ Individual(s) present at onsite preliminary exit meeting

^ Individual participating in the final telephonic exit meeting