



101 ARC Drive
Saint Louis, MO 63146 USA
Phone: 314-991-4545 or 800-331-6661
Fax: 314-991-4692 or 800-999-9925
Web: <http://www.arc-inc.com>
Email: arcinc@arc-inc.com

11 July 2014

U.S. Nuclear Regulatory Commission, Region III
2443 Warrenville Road, Suite 210
Lisle, IL 60532-4351

ATTN: Kevin Null

LICENSE No: 24-21362-01

SUBJECT: Request for amendment to RPP, SOP's 16, 29, 34

NRC,

In this letter you will find a request for amendments to the American Radiolabeled Chemicals, Inc (ARC) Radiation Protection Program; and SOP's 16, 29, and 34, with justification for making these requested changes.

The requested changes have been tracked using **red type** for text added, ~~striketrough~~ for text removed, and **red type/highlight** for changes made to SOP-29 as requested since the previous amendment request.

If you have any questions or require clarification on any of the attached information, you may contact our RSO directly at (314) 991-4545.

Sincerely

AMERICAN RADIOLABELED CHEMICALS, INC

A handwritten signature in black ink, appearing to read 'Surendra K Gupta', is written over a light blue horizontal line.

Surendra K Gupta, Ph.D.
President
American Radiolabeled Chemicals, Inc.

RECEIVED JUL 1 4 2014

Justification for amendment to license: 24-21362-01 in letter dated 11 July 2014

Radiation Protection Program

Pages: 31 and 32

Content changed: Item 4.2.1.6 (b) and (c)

Justification: SOP-16 was amended previously by the NRC. The RPP had different action levels for the same area, when compared to SOP-16. Due to the overlap of definitions with the RPP and SOP-16, the RPP has been changed to mimic SOP-16.

SOP-16 'Radioactive Contamination Control Program'

Page: 2

Content changed: Item 1.3.3.

Justification: The Building 300 garage is considered part of Building 300 laboratory and is therefore considered a contaminated area.

SOP-29 'Storage of Surface Contaminated Objects'

Page: All

Content changed: Objective; Item 1.1; Item 2.1; Item 2.2.3; Item 3.1; Item 3.3; Item 4.0; Item 5.0.

Justification: Objective; A more clear objective of this SOP was deemed necessary by the radiation safety committee due to the recent license violations involving said SOP.

Item 1.1; restricted areas include both contaminated and non-contaminated areas (example shipping vs. darkroom). Therefore it is unimportant where they got contaminated, just the fact that they are contaminated. The NRC requested that we explicitly write which items were to be considered temporary storage and an appropriate time frame associated with temporary.

Item 2.1; The NRC requested examples of how caution should be exercised when transferring items between buildings. Use of a secondary container has been approved for use in other SOP's and use of these transfer containers would be valid here as well.

Item 2.2.3; The SeaLand container is not always available and is only opened when weather permits and a justifiable amount of trash will be put inside, due to potential contamination issues. Items are first stored in a specified area, then put in the SeaLand all at once.

Item 3.1; This section specified release levels that were in conflict with release levels listed in the RPP and other SOP's. The release level was copied from these other sources for consistency.

Item 3.3; Magenta and yellow rope may not always be available or necessarily the best way to mark where items are going. ARC would like to be able organize and label areas in a manner deemed fit for the situation and materials being stored.

Item 4.0; The definition of SCO is vague. Anything with radioactive material on it would be considered SCO. This is a list of exempt items that do not need to be stored in Building 200 and for ease of access purposes may be stored in the main labs near the location they are used. This is done because items like tools may get lost in Building 200. If a tool was needed urgently it would require one to dress in full PPE, enter B100, walk to B200, find the tool and bring the contaminated tool out of a restricted area and into B300. The total time to retrieve the tool could be 30 minutes or more and in an urgent situation this is not acceptable. It also reduces the potential of contaminating a controlled area when being transferred between buildings.

Item 5.0; The NRC requested a definition of what 'timely disposition' meant.

SOP-34 'Surface Soil Sampling for Site Characterization'

Page: All

Content changed: Item 3.0; Item 5.2

Justification: The changes to SOP-34 were made at the request of the NRC.

ARC RADIATION PROTECTION PROGRAM

- (d) An item is in finished form when it has been packaged for shipping and all applicable DOT labels have been affixed, that is, the item is ready for presentation to the carrier.

Prior to this state, the radionuclide is in unfinished form

4.2.1.5 Permissible Levels of Surface Contamination

Any surface which has readily removable contamination in excess of permissible levels shall be decontaminated until reduced below the applicable levels.

4.2.1.6 ACTION LEVEL

At this level, areas and equipment are decontaminated at the next practical time if contamination is above the following levels.

NOTE:

For Contaminated Restricted Areas, this would be at the time of weekend cleaning.

For all others, decontamination will take place immediately, if possible, but not more than 24 hours shall elapse

Access to the area or item will be restricted during the cleaning. If the area or item cannot be cleaned immediately, it shall be posted commensurate with the level of contamination.

(a) Contaminated Restricted Areas

Tritium – 50,000 dpm/100 cm²
Carbon-14 – 10,000 dpm/100 cm²
Other β-γ - 10,000 dpm/100 cm²

(b) Non contaminated Restricted Areas and Controlled Areas

Total- 5,000 dpm/100 cm² average, not to exceed 150,000 for a single point, of which the Removable component is less than 1,000 dpm/100 cm² total

Goal – less than 1000 dpm/100 cm² total

(c) Unrestricted Areas

Total- 15,000 dpm/100 cm² average, not to exceed 15,000 for a single point, of which the removable component is less than 1,000 dpm/100 cm²

ARC RADIATION PROTECTION PROGRAM

Goal – 100 dpm/100 cm² each, fixed and removable and 100 cpm above background for direct survey.

4.2.1.6 INVESTIGATIVE LEVEL

At this level, areas and equipment are decontaminated immediately upon discovery if contamination is above the following levels.

- (a) If initial contamination levels exceed 10 times the action levels, attempt to determine the source and cause.
- (b) Document the results of the investigation and file the report in the Off-normal Occurrence File.
- (c) Decontaminate the area or equipment immediately.

4.2.1.7 STOP WORK LEVEL

This is the upper limit for contamination in ARC facilities. If any Investigation Level listed above is exceeded by a factor of 200, (NOTE: This is 2000 times the Action Level) all work in that lab building will stop until

- (a) The extent and cause of the contamination has been determined
- (b) All individuals have been shown to be non-contaminated
- (c) The contamination levels have been reduced to below the investigative level,
- (d) And the RSO has given permission to resume work

4.2.2 Precautionary Procedures

4.2.2.1 Requirements for Protective Outer Garments

- (a) Lab Coat – required for entering CAs
- (b) Safety glasses – required for entering CAs
- (c) Disposable gloves – required for entering CAs
- (d) Lab shoes – required for all work in CAs; see (i) and (j) below.

**AMERICAN RADIOLABELED CHEMICALS, INC.
STANDARD OPERATING PROCEDURE - SOP-16**

Supersedes: 7/27/2010
Approved by RSC: 7/11/2014
Approved by NRC: TBD

Page 2 of 6

SUBJECT: RADIOACTIVE CONTAMINATION CONTROL PROGRAM

1.3. Restricted Areas

Restricted Areas are further sub-divided into:

1.3.1. High Contamination Areas

Areas such as, but not limited to, inside fume hoods, inside bench top trays, inside the compactor enclosure; other areas as designated by the RSO.

1.3.2. Contamination Areas

1.3.2.1. Areas inside the laboratories not listed as High contamination areas.

1.3.2.2. Any area, no matter where located, where the following limits are exceeded:

Total – 5000 dpm/100 cm² average, not to exceed 15,000 for a single point

Removable – 1000 dpm/100 cm²

1.3.3. Non-contaminated Restricted areas

Areas such as, but not limited to, change areas, the shipping area, the ~~building 300 garage~~ or other areas designated by the RSO.

2.0 Action level

At this level, areas and equipment are decontaminated by maintenance personnel under supervision of the Radiation protection staff at the next practical (usually immediately, but in all cases within 24 hours time if contamination is above the following levels.)

2.1. Contaminated Restricted Areas

Tritium – 50,000 dpm/100 cm²

Carbon-14 – 10,000 dpm/100 cm²

**AMERICAN RADIOLABELED CHEMICALS, INC.
STANDARD OPERATING PROCEDURE - SOP-29**

Supersedes: 04/30/2008
Approved by RSC: 07/11/14
Approved by NRC: TBD

Page 1 of 3

SUBJECT: STORAGE OF SURFACE CONTAMINATED OBJECTS

OBJECTIVE: To ensure proper storage of surface contaminated objects (SCO) that ~~are not in use~~ can no longer be used. To ensure a timely disposal of items marked for decon or disposal. To ensure a safe and controlled location to store radioactive items that will be reused in the future.

RESPONSIBILITY: Radiation Safety Officer

REFERENCES: SOPs 16, 21, 33, 35, and 38

PROGRAM

1.0 Description

1.1. Surface contaminated objects (SCO) are pieces of equipment or objects that have become contaminated on their surfaces ~~by use in restricted areas~~. When no longer being used, these items are transferred to building 200 for temporary storage ~~or storage for future use~~. A decision is made by the Senior Chemist and the RSO on the future usefulness of the item prior to movement of the item. The possibilities are (1) reused sometime in the future (2) discarded as non radioactive waste (3) discarded as radioactive waste. ~~Items (2) and (3) are considered temporary storage SCO. Items marked as temporary storage should spend no longer than 12 months in the inventory. This 12 month time frame only applies to new items being brought to B200 and not to items listed on the SCO inventory as of June 2014.~~

2.0 Placing SCO in storage

2.1. Move the object/equipment to building 200 (~~roll-up door area~~). Exercise caution so that contamination does not spread from the object. ~~Examples of contamination control include using a transfer container or secondary container.~~

2.2. Depending upon the decisions made concerning the usefulness of the item

2.2.1. For possible future use – Place the item safely with other equipment being held for future use. As this equipment will be used in the future, take care not to damage or degrade the item.

2.2.2. For future decon and disposal – Place the item with other equipment being held for decon and disposal.

**AMERICAN RADIOLABELED CHEMICALS, INC.
STANDARD OPERATING PROCEDURE - SOP-29**

Supersedes: 04/30/2008
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Approved by NRC: TBD

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SUBJECT: STORAGE OF SURFACE CONTAMINATED OBJECTS

2.2.3. For disposal as radioactive waste – place the item in a cardboard box or with other items until they can be put in the SeaLand container for shipment as Rad Waste.

3.0 Removing SCO from storage

3.1. If an item is to be removed from storage for disposal as non-radioactive waste, it must be below the release level of: be surveyed and pass the release level of 1000 dpm/100 cm² total.

~~Survey prior to release must be done by a member of the Rad Safety organization~~

~~3.2.1 Scan the item with a GM survey meter and outline any areas where activity is detected.~~

3.1.1. 1,000 dpm/100 cm² for the sum of tritium and carbon-14.

AND

3.1.2. Less than 5,000 dpm average over the surface of the object, with no single reading greater than 15,000 dpm by direct scan with a survey meter.

NOTE: Survey meter reads in cpm, not dpm to find the limit in cpm, multiply the dpm limit by the meter efficiency (as a decimal fraction).

Example:

The limit is 5,000 dpm; the meter efficiency for C-14 is 4.3% (0.043)

5000 X 0.043 = 215

Therefore an average reading greater than 215 CPM above background exceeds the limit

3.2. If an item removed from storage cannot be cleaned satisfactorily, then dispose as radioactive waste.

3.3. Mark storage areas within building 200 with magenta and yellow rope with appropriate signage, other acceptable forms of signage include using a post or hanging signs on the wall.

**AMERICAN RADIOLABELED CHEMICALS, INC.
STANDARD OPERATING PROCEDURE - SOP-29**

Supersedes: 04/30/2008
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SUBJECT: STORAGE OF SURFACE CONTAMINATED OBJECTS

4.0 Exemptions

4.1. The following are not considered SCO and therefore not subject to this SOP. These items are excluded for various reasons. Items like tools are excluded because each lab has needs for tools that are intermittently used. It is not practical to store an item in building 200 and retrieve it each time it is needed. Spare parts can be very expensive and should be stored near the machine in use for urgent repairs. Glassware can be very delicate and break easily, repetitive transfers between buildings pose an increased risk of breaking expensive glassware as well contamination control issues.

4.1.1. Items like tools (i.e. screwdrivers, drills, nails, etc.)

4.1.2. Spare parts for items which are in current use

4.1.3. Machines which are in working order

4.1.4. Survey meters (GM meters)

4.1.5. Glassware, torches for sealing glass vials, etc.

5.0 Annual audits

The RSO shall perform annual audits to assure the timely disposition of items placed in storage. Timely disposition is approximately 12 months and only applies to new items added to the SCO inventory after June 2014.

**AMERICAN RADIOLABELED CHEMICALS, INC.
STANDARD OPERATING PROCEDURE - SOP-34**

Page 1 of 3

Supersedes: 8/23/13
Approved by RSC: 7/11/14
Approved by NRC: TBD

SUBJECT: Surface Soil Sampling for Site Characterization

- OBJECTIVE:** To determine the radioactive status and amount of accumulated radioactivity on the ARC site.
- RESPONSIBILITY:** Radiation Safety Officer
- PREREQUISITES:** The ARC License has been amended to permit site characterization
A sample plan has been prepared using VSP
The sample plan has been approved by the NRC
- REQUIRED EQUIPMENT:** Scale map of the site showing location of sample points.
Measuring tape at least 100" in length.
Suitable tools for digging to a six inch depth
Container for sorting and mixing soil sample
Sample containers capable of holding at least 50 gm of soil

PROGRAM

1.0 Purpose

- 1.1 To determine the radioactive status and amount of accumulated radioactivity on the ARC site.
- 1.2 To provide sufficient information to propose the time and type of any remediation which may be required.

2.0 Procedure

- 2.1 Location
 - 2.1.1 Transfer the sample location from the VSP print out to the scale site plan.
 - 2.1.2 Using the scale site plan and a 100' steel tape, locate the first sample point of the survey unit "on the ground".
 - 2.1.3 Mark the sample point with a flag or landscaper paint.
 - 2.1.4 Repeat for the remaining points of the survey unit.
 - 2.1.5 Repeat for each additional survey unit.

**AMERICAN RADIOLABELED CHEMICALS, INC.
STANDARD OPERATING PROCEDURE - SOP-34**

Supersedes: 8/23/13
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SUBJECT: Surface Soil Sampling for Site Characterization

2.2 Sampling

- 2.2.1 If necessary, loosen the soil at the sample point with a trowel or other digging implement.
- 2.2.2 Using the sampler rig to obtain a sample of the first 6 inches of soil.
- 2.2.3 Place the soil in a "clean" bucket. Remove all rocks, stones, twigs etc and discard. Stir the soil to remove any lumps. Repeat as necessary until the required sample size is obtained

(NOTE: Teledyne Brown, the analyst for ARC, requires a minimum of 50 grams. If the NRC is splitting sample, ORISE, the analyst for NRC requires 1 kilogram.)

- 2.2.4 Place the sample in an appropriate container, see note above. Label appropriately.
- 2.2.5 Clean the sampling tools of all visible dirt wash if necessary.
- 2.2.6 Clean the mixing bucket
- 2.2.7 Record the sample details on the chain of custody form.
- 2.2.8 Seal the sample container.
- 2.2.9 Repeat for each Sample point in the survey unit.
- 2.2.10 Package all the samples from this sample unit, with the chain of custody form for this sample unit in one box for shipment to the analytic lab.
- 2.2.11 Repeat 2.1 through 2.10 above for each additional survey unit

3.0 Disposition of Results

- 3.1 ~~Transmit a copy of~~ The raw results data **is maintained on file for examination purposes.** ~~to the Decommissioning Branch Region III, NRC~~
- 3.2 **The Decommissioning Branch, Region III, USNRC shall be informed if any sample exceeds four times the screening value.**

4.0 Remediation

**AMERICAN RADIOLABELED CHEMICALS, INC.
STANDARD OPERATING PROCEDURE - SOP-34**

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SUBJECT: Surface Soil Sampling for Site Characterization

- 4.1 Any proposed remedial actions must be submitted to the Decommissioning Branch Region III, NRC prior to taking any action.

5.0 Confirmatory Sampling

- 5.1 Site characterization sampling will be repeated at three-year intervals.
- 5.2 Results of sampling will be ~~submitted to the Decommissioning Branch~~ maintained for examination by Region III, NRC
- 5.3 Sampling may be discontinued if two successive results show no increase in soil contamination.

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TO **ATTN: KEVIN NULL**
U.S. NUCLEAR REGULATORY COMMISSION
2443 WARRENVILLE ROAD, SUITE 210
REGION III
LISLE IL 605324351

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