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1 May 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

Gentlemen,

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 and ~~striketrough~~ for text removed.

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

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

RECEIVED MAY 02 2014

Justification for amendment to license: 24-21362-01

Radiation Protection Program

Pages: 31 and 32

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

Justification: SOP-16 was amended previously. The RPP, which had different action levels for the same area when compared to SOP-16, was not amended at the same time.

Due to the difference 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; References; Item 1.1; Item 2.2.3; Item 3.1; Item 4.0

Justification:

Objective – Clarify wording

References – Add SOP 30, Equipment Released

Item 1.1; Restricted areas includes both contaminated and non contaminated areas [example shipping (non-contaminated) vs. darkroom (contaminated)]. This change limits storage to items that have been used in contaminated areas.

Item 2.1; Building 200 was doubled in size in 2007 under the then existing “hybrid” license. The intent was: a) to have secure storage for items to be used again; b) store items which were to be decontaminated; c) store items to be shipped as radioactive waste; and d) provide a facility for decontamination of objects prior to release. Under the terms of the existing SOP it would be necessary to carry objects from the roll up door area to the decon facility for work and then back to the roll up door area at the end of the day. The operations listed above require the use of the entire building as originally intended. This SOP has been not been revised since its inception in the spring of 2008. Since that time, staffing has increased, the number of products has increased, and the volume of sales has doubled.

Item 2.2.3; The SeaLand container is not always available. When available, it is located out doors 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 and then put in the SeaLand all at once.

Item 3.1; This section originally specified the method in which decontamination should take place. It does not go into as much depth as SOP-30 'Release of Material' does. Therefore the instruction to follow SOP 30. This also prevents future incidents where one is amended but the other is not and therefore conflicting definitions occur.

Item 4.0; The definition of SCO is vague. Anything with radioactive material on it would be considered SCO. This is a list of items which are not considered to be SCO. This is done because items like tools may get lost in Building 200. If a tool was needed urgently in Building 300, 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.

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 ~~10,000~~ 15,000 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- 5,000 ~~1000~~ dpm/100 cm² average, not to exceed 15,000 ~~5,000~~ for a single point, of which the removable component is less than ~~500~~ 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
Reviewed by RSC: 2/21/2011

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SUBJECT: RADIOACTIVE CONTAMINATION CONTROL PROGRAM

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

Other β - γ - 10,000 dpm/100 cm²

2.2. Non-contaminated Restricted Areas

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

Supersedes: 04/30/2008
Approved by RSC: 04/28/2014

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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

RESPONSIBILITY: Radiation Safety Officer

REFERENCES: SOPs 16, 21, 30, 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 contaminated ~~restricted~~ areas. When no longer being used, these items are transferred to building 200 for ~~temporary~~ storage. 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

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.
- 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.
 - 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

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

Supersedes: 04/30/2008
Approved by RSC: 04/28/2014

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SUBJECT: STORAGE OF SURFACE CONTAMINATED OBJECTS

- 3.1. If an item is to be removed from storage for disposal as non-radioactive waste, it must comply with SOP-30 'Release of Material'. ~~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~~

- ~~3.1.1. Scan the item with a GM survey meter and outline any areas where activity is detected.~~

- ~~3.1.2. Wipe test the marked areas. Decon and rewipe until the areas are below the release level. Take a few random wipes at other locations.~~

- 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

4.0 Exemptions

- 4.1. The following are not considered SCO and therefore not subject to this SOP.

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

5.0 Annual audits

The RSO shall perform annual audits to assure the timely disposition of items placed in storage.

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

Supersedes: 8/23/13
Approved by RSC: 12/18/13
Approved by NRC:

Page 1 of 3

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
Approved by RSC: 12/18/13
Approved by NRC:

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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 by NRC Region III inspectors ~~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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Supersedes: 8/23/13
Approved by RSC: 12/18/13
Approved by NRC:

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 inspectors.
- 5.3 Sampling may be discontinued if two successive results show no increase in soil contamination.



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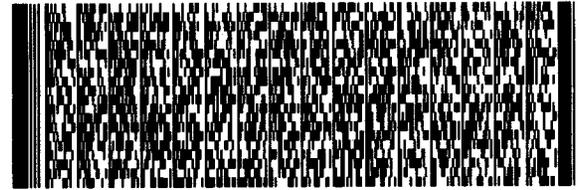
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