American Radiolabeled
Chemicals, Inc.

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23 August 2013

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

LICENSE No: 24-21362-01

ATTN: Kevin Null

SUBJECT: Conversation Record dated 8/21/2013

Gentlemen:

American Radiolabeled Chemicals, Inc (ARC) presents the attached information in response to your request dated 8/22/13.

If there are any questions, contact Regis A. Greenwood directly at the above numbers.

Sincerely

AMERICAN RADIOLABELLED CHEMICALS, INC

Surendra K Gupta, PhD.
President
American Radiolabeled Chemicals

Reply to Conversation Record dated 8/21/2013

Question 1

SOP-43 is attached for your review.

Contactor will be identified and measurement made before the end of September.

Question 2

ARC is presently purchasing a second SeaLand container. This will enable us to have a container at all times instead of waiting for the return of a single container.

Revisions to SOPs 29 and 41, to be submitted as an amendment after renewal will reclassify several classes off objects so that they will not be stored in the 200 garage.

Completion of the decon facility will enable ARC to decontaminate and release material instead of storing or treatment as waste. The plans, equipment list and an SOP for operation will be submitted for review.

Question 3

ARC reaffirms the commitments made in the letter dated 1 Nov 2011 concerning use of the building 300 Annex. For clarity, these commitments are repeated below.

This building was originally designed for use as a synthesis lab for labeling compounds with I-125, P-32, H-3, C-14 and S-35 in the amounts specified in the existing license. Do to the realization by ARC that the volume of these syntheses was not increasing, **this lab will not be used for production level synthesis of these compounds.**

The building contains four laboratory spaces, two to either side of a central hall way. Each set of two labs is trunked to a single exhaust blower.

It is ARC's intent to use the two labs in the front of the hall for "cold" chemical preparation. This will eliminate the present method of doing cold preps in the same lab as multi-Curie amounts of the various nuclides. This will remove the potential for cross contamination.

The two labs in the rear of the central hall will be used for purification and analysis of radiolabeled compounds and preparation of certificates of analysis. At present, these analyses are limited by: (a) the requirement to perform the

analysis in the same lab as production, (b)The necessity to ship samples to outside labs for analysis, and (c)The lack of space to install updated analytical equipment. **These labs will not be used for any production of radiolabeled compounds.**

The Annex is designed so that there is no direct connection between it and the production labs. That is, an individual, in order to leave production and go to analytics, will have to remove PCE and "frisk out" of the production lab, exit the production lab building, and enter the Annex. This will eliminate the possibility of wearing highly contaminated PCE into the analytic lab.

The normal sample size will vary with the nuclide and with the specific activity, however, the activity of an individual sample will be in the high microcurie/ low millicurie range.

It is envisioned that with samples in storage, samples in process and with dry and liquid waste, the total activity in the Annex will **normally** be less than 100 millicuries from all nuclides.

Question 4

We were unable to locate the term "general supervision" in the RPP version submitted with the Renewal Update. The section is repeated below for clarity.

3.2.4.5 Personnel Classifications

Authorized User

An AU is a person whose training and experience have been reviewed and approved by NRC, who is named on the license, and who uses or supervises the use of licensed material.

After review by the RSC, a license amendment request will be prepared and submitted to the Commission. The individual shall not be considered an Authorized User until the amendment is issued by the NRC.

The AU's primary responsibility is to ensure that radioactive material used in his or her particular lab or area is used safely and according to regulatory requirements The AU is also responsible to ensure that procedures and engineering controls are used to keep

occupational doses and doses to members of the public ALARA.

Workers

(a) Class 1 - Those individuals who may use, under the direction of an Authorized User radioactive materials within their area of responsibility. Direction by an AU does not require the physical presence of the AU, but responsibility remains with the AU.

(b) Class 2 - Those individuals who may use radioactive materials within their area of responsibility only under supervision by an AU, or by a Class 1 worker. This supervision requires the physical presence, on site, of the supervising individual.

The Committee may advise the upgrading of an individual from Class 2 to Class 1 under the following conditions:

a) The individual has been recommended for upgrade by the AU who has provided supervision.

b) The individual has demonstrated good radiation safety technique.

c) The individual has demonstrated good handling technique with RAM.

d) The individual has satisfactorily completed on-the-job training. The extent and content of the On the Job Training is at the discretion of the AU recommending upgrade.

Question 5

In the 2009 Audit note was made of the lack of "Root Cause Analysis" in the investigation of off normal occurrences. The report was discussed at an RSC meeting and root cause assigned to the RSO and Rad Protection Staff. It was noted in the 2010 Audit that investigations now contained root cause. Root Cause analyses are part of all investigations at this time.

Question 6

The RPP submitted with the update has been modified to include a definition of supervision. This modification is repeated below.

2.1.j Authorized User - An Authorized User (AU) is a person whose training and experience have been reviewed and approved by NRC, who is named on

the license, and who uses or supervises the use of, licensed material.

Supervision being defined as overseeing and directing without any connotation of location.

Duties of the RSC

3.2 Radiation Safety Committee

Function

The Radiation Safety Committee advises the President and the RSO on: (a) methods to control the procurement, use and disposition of radioactive materials; and, (b) proposed amendments to the License, and (c) **addressing issues that have been identified either internally by ARC employees , or through external organizations.**

Composition

The Committee is composed of a Chairman, the Radiation Safety Officer (Vice Chair of the Committee), and all of the Authorized Users. A quorum consists of half of the membership (or a simple majority if there are an odd number of members) one of whom must be the Chairman and one of whom must be the RSO.

Responsibility

The Radiation Safety Committee is responsible for advising the President and the RSO on means of complying with applicable NRC, DOT, and other Federal, State, and local regulations **and addressing issues that have been identified either internally by ARC employees , or through external organizations.**

AND

Reports or Responses to the Commission

The Committee reviews and gathers information and data needed by the President to determine corrective actions to be taken for reports or responses to the NRC.

Determines the circumstances causing exposures or levels of radiation or concentrations which require a report to the

Commission and any items of non-compliance noted during an inspection for determination of corrective actions.

Gathers information and data needed by the President to determine corrective actions to be taken for reports or responses to the NRC.

Addressing issues that have been identified either internally by ARC employees, or through external organizations

Question 7

Changed portions of RPP are quoted below

4.2.2.4 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. For unrestricted ,controlled, or non-contaaminated restricted areas this should take place immediately after the results are measured, follow up wipes are required. For contaminated areas, cleaning will take place over the weekend by the cleaning crew. Monday lab wipes will be considered follow up.

4.2.2.5 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.

Question 8

Changed portions of the RPP are quoted below.

9.1.1 Training

Individuals using the compactor are provided training in its operation and associated radiation protection principles. **Training will be based on the user manual provided by the manufacturer.**

Question 9

SOP-03 New Section 5

5.0 Calibration of Air Samplers

5.1 Equipment used

5.1.1 The F&J Mini-Calibrator purchased should be used. Consult the user manual on file in the RSO's office prior to performing calibrations.

5.1.2 Disconnect the air sample line from the inlet on the air sampler.

5.1.3 Place the Mini-Calibrator in series with the air sampler. Air flows on the calibrator from left to right.

5.1.4 The order of items the sampled air should pass through is; Stack air sample line; mini-calibrator; connector sample line; air sampler unit.

5.1.5 In order to maintain operating pressure, you must connect the stack sample line to the inlet of the mini-calibrator. Failure to connect the main stack line will result in skewed calibration.

5.1.6 After turning the calibrator on, set the air sampling unit to 4 different sampling rates, recording the flow display on the sampling unit as well as the corresponding calibrator flow. Settings of 60, 80, 100, 120 mL/minute is an example of 4 different sampling rates. The values should be between 60 and 150 mL/minute.

5.1.7 After changing the setting on the air sample unit, give approximately 5 minutes for the flow to equalize. The actual flow will fluctuate above and below for a few minutes, take display measurements after the flow has stopped fluctuating.

5.1.8 Calibration of the stack sample units should be performed annually.

Question 10

SOP-08

3.3.4.1 The RSO may designate individuals to perform any of the duties

listed in 3.3.3 or 3.3.4 above. The final responsibility for the designee's actions and the requirement for oversight of these actions remains with the RSO. As the persons available for use as RSO designee may vary from time to time, a table of the present personnel is included as Appendix A.

Appendix A is attached

Question 11

The bioassay procedure for I-125 is SOP-12, In Vivo Bioassay which will be re-activated. The SOP is attached.

Question 12

ARC confirms that revisions to SOPs 29 and 41, dealing with processing and storage of SCO will be submitted for review and approval following renewal of the ARC license.

Question 13

ARC confirms that revisions to SOP 34, dealing with surface soil sampling will be submitted for review and approval following renewal of the ARC license.

AMERICAN RADIOLABELED CHEMICALS, INC
STANDARD OPERATING PROCEDURE — SOP-43

Supersedes: new
Reviewed by RSC: 30July 2013
Approved by NRC: Pending
SUBJECT: Evacuation of Laboratories Due to Exhaust Failure

OBJECTIVE: This SOP outlines actions to be taken in the event of Exhaust blower failure.

This SOP will go into effect at the time license renewal is approved by Region III.

RESPONSIBILITY: Radiation Safety Officer or designee

PROCEDURE:

1.0 Immediate actions.

1.1 All personal shall evacuate the laboratory in question. Each chemist, before leaving, will place any operation in a safe condition.

1.2 The RSO or designee will, as far as practical, determine the cause

1.3 If the cause is not due to loss of utility power then direct the make-up air system for the laboratory in question to be shut down.

2.0 Duration of Evacuation

2.1 The laboratory without exhaust flow will remain out of service until flow is restored.

2.2 Entry into the laboratory for safety reasons, or to protect the public, or to prevent serious financial loss will be permitted by the RSO or designee on a case by case basis.

3.0 Return to operation

3.1 Start the exhaust blower.

3.2 After the exhaust blower has been operating for 15 to 20 minutes, start the make up air system.

3.3 After the make-up air system has been operating for 15 to 20 minutes, entry will be permitted.

3.4 The RSO or designee will measure the individual hood face velocity and determine if all hoods are within limits. 100 lfpm mandatory and 150 lfpm preferred.

Appendix A

Radiation Protection Program

PERSONS AVAILABLE FOR DESIGNATION TO FULFILL RSO DUTIES

Assistant RSO	any duty listed in 3.3.3 or3.3.4	4 year degree in Health Physics
Health Physics Tech	any duty listed in 3.3.3 or3.3.4	2 year degree in Nuclear Tech
Shipping Clerk	limited to shipping surveys and Shipping documents	4 years experience
Authorized Users	duties limited to Radiation Safety within their laboratories	

Approved by RSC: 4/22/99
Re-instated 8/22/2013
Approved by NRC

SUBJECT: INVIVO BIOASSAY PROGRAM

OBJECTIVE: The invivo bioassay program provides a means to estimate the committed dose equivalent to the thyroid received by ARC employees

RESPONSIBILITY: Radiation Safety Officer

PROGRAM

1.0 References: NUREG/CR-4884, Interpretation of Bioassay Measurements

General Reference Only: NRC Regulatory Guide 8.32
General Reference Only: NUREG-0938

2.0 Sampling frequency

The frequency for recorded thyroid burden measurements is on an as needed basis.

3.0 Requirement

Includes all individuals who work in restricted areas and who have processed or handled ^{125}I in amounts larger than 1 millicurie

4.0 Procedure

4.1 ARC employees shall have a thyroid burden measurement prior to start of work with I-125.

4.2 Corrections for efficiency and background are made to obtain results in net dpm

4.3 ARC employees shall have a thyroid burden measurement upon completion of work with I-125.

4.4 Corrections for efficiency and background are made to obtain results in net dpm

4.5 Net increase in dpm is obtained and converted to microcuries.

Approved by RSC: 4/22/99
Re-instated 8/22/2013
Approved by NRC

SUBJECT: INVIVO BIOASSAY PROGRAM

4.6 Conservatively assume that all of the intake occurred immediately following the initial measurement prior to work. Note the elapsed time between measurements.

4.7 Conservatively using ^{131}I as a surrogate, determine the fraction of the the intake remaining from the appropriate table in NUREG/CR-4884. Divide this fraction into the quantity obtained in 4.5 above. The result is the intake.

4.8 Conservatively divide the intake by 60 microcuries (the thyroid I-125 whole bodyAll) and multiply the resulting fraction by 5 rem to determine the dose from this intake.

5.0 Action Levels

5.1 Acute exposures

1. >100 mRem/week - the individual is restricted from work with ^{125}I which could result in an additional thyroid intake.

2. The individual shall remain restricted until the doserate falls below 50 mrem/week.

3. The RSO shall attempt to determine the cause of the uptake and to propose corrective actions to minimize a recurrence.

5.2 Quarterly exposures - Long or short-term (quarterly average mRem)

>300 mRem/quarter - the RSC reviews and identifies the primary sources of exposure in order to take possible corrective action to reduce exposures.

6.0 Calibration

Calibration is performed by third party calibration facility

7.0 Quality assurance.

Quality assurance is performed by counting available ^{125}I and/or ^{129}I reference standards. Results must be +-10% of the standard value.

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