

May 27, 2010

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

Dear Dr. Gupta:

We have completed our review of American Radiolabeled Chemical's, Inc. (ARC) application for an amendment to NRC License Number 24-21362-01. In that amendment request you submitted revisions to ARC's Radiation Protection Program (RPP) and Standard Operating Procedures (SOP's).

Please note that in accordance with Mr. Regis Greenwood's request, we pulled the RPP and SOP's from your application for renewal and have processed these elements as an independent amendment request, which has been assigned Control Number 318694. You will also need to incorporate the final product (i.e., revised RPP and SOP's) into your license renewal as well. The Control Number for your license renewal is 318154. Below is a summary of our findings including requests for additional information.

General Comments

1. Our expectation is that ARC management and the Radiation Safety Committee (RSC) be directly involved in reviewing and certifying the RPP and SOP's prior to submitting proposed changes to the NRC for approval. Therefore, please identify by title, the member of ARC management who will perform this function, and confirm that the RSC will review and certify all proposed changes to the RPP and SOP's.
2. Describe the method that you will use to communicate revisions made to your RPP and current SOP's to ARC employees, and confirm that employees who are impacted by any changes will be trained in applicable revisions.
3. As a result of the recent discovery of contaminated soils on ARC property, and other existing contaminated items, e.g., the contaminated septic tank, please revise possession limits accordingly and re-evaluate your current financial assurance for decommissioning. Prepare a timetable for completion of the evaluation of the acceptability of your financial assurance and submit it for our review and tracking purposes. Submit an amendment to your current financial assurance if required, to account for any increase in decommissioning financial assurance.
4. Please develop and submit an index of SOP's. The index should indicate the title of the person who will be responsible for implementing the procedures. Please also confirm that a copy of each procedure will be provided to those individuals who will be

responsible for their implementation, that they will be trained on the procedures, and that the training will be documented.

5. Where applicable, SOP's should include references to other relevant SOP's. For example, radwaste compactor operators will need to be informed and trained in SOP-01 "Dry Solid Waste Compaction," but they would also need to be trained in other relevant SOP's, e.g., SOP-33 "Use of Protective Clothing and Equipment," SOP-03 "Air Monitoring Program," etc. Please review your SOP's and include relevant references to other applicable SOP's and confirm that workers will be trained in those referenced procedures.
6. In 2008 you requested approval of a modification to the ventilation and exhaust systems for buildings 100 (building 200 was tied into building 100) and 300. We issued a partial amendment, number 39, which addressed other requests but did not approve the facility modifications. In the March 13, 2009, cover letter accompanying the amendment we stated that we needed additional information. Specifically we had determined that the Gaussian dispersion equation should not have been used to calculate ground level concentrations due to effluent releases from the stacks. The effective stack heights of the buildings were less than 2.5 times the height of the building, therefore the plume exiting from the stack may be entrained into the wake behind the building. As a result of that review we requested that you resubmit your dose assessment based on building wake effect. To date, we have not received your response and have therefore not been able to complete a safety and compliance review.

In addition to responding to our March 13, 2009 letter, please resubmit the information regarding the modifications that were made to the ventilation and exhaust systems, in its entirety. Please describe in detail the modifications that were made to each building. Submit diagrams which illustrate the changes, and include a facility ventilation comparison of "before" and "after" the modifications were completed. For each fume hood in both buildings, include an evaluation of air flow (i.e., flow rate in volume of air per unit time) through the new system to the release point. Describe filtration systems and criteria for filter change out, locations of effluent sampling equipment, and procedures for determining concentrations of effluent released. Include diagrams of sampling systems relative to their location to release points and locations where samples are collected. Include procedures for conducting sample analysis and converting data collected to microcuries per milliliter in order to demonstrate compliance with 10 CFR Part 20 (ref. NUREG-1400 and Regulatory Guide 8.25).

Radiation Protection Program

1. Please revise your Radiation Protection Program (RPP) by including cross references to applicable SOP's.
2. Under item 1.1 of the RPP you indicated that authorized users will directly supervise the use of licensed materials. Direct supervision means that an authorized user will be physically present when materials are being used by another trained staff member who is not an authorized user. Please confirm your understanding of this, and that this is how your program will be implemented.

3. Item 2.1(a) states that unrestricted areas are defined as areas outside ARC's property line. Please identify how areas within ARC's property line are classified, i.e., either unrestricted, restricted, or controlled areas, and describes how restricted and controlled areas will be managed.
4. Clarify and describe in greater detail commitments found in item 10 of your application for renewal and Section 3 of your RPP pertaining to program oversight, periodic audits, and actions to address deficiencies identified during internal and contractor audits, as well as NRC inspection findings. Specifically, provide information regarding the following:
 - a. Expand Section 3.3.3.6 to include more detail. Address each program function to be audited, the frequency of audits based on safety significance, user and management responsibilities, the auditor name, the actions and required time-frames to resolve audit deficiencies, internal enforcement guidelines to address deficiencies, and the methodologies that will be used to ensure corrective actions were adequately implemented. The discussion of ARC's "Corrective Action Program" should be a stand-alone section of the RPP and supported by a directly-related SOP (ref. NRC Information Notice 96-28, "Suggested Guidance Relating to Development and Implementation of Corrective Action" for assistance in developing a corrective action program).
 - b. Describe in greater detail ARC's use of a third party auditor to perform audits of the RPP, which is discussed in Section 3.3.3.5 of the RPP, and Item 10 of your renewal application. Specifically, address the following:
 - (1) Include more detail on the commitment to use a third party auditor to review the RPP. Describe the scope of the review to be performed by the auditor, and the expected time commitment for the audit and program areas to be reviewed. Confirm that the auditor will issue a written report, and that ARC will provide a copy of the report to the NRC Region III office which will include a description of corrective actions that have been implemented, or planned. The NUREG-1556 series, Volume 12 contains a sample audit outline that may assist you in responding to this request.
 - (2) Discuss how you will address program deficiencies identified by the auditor. The discussion should indicate the timeframes that will be established to resolve issues and the documentation that will be generated to record the resolution of audit findings.
 - c. Please clarify statements made in Section 3.2.4.1, "Evaluations of New Uses of RAM," of your RPP and Item 6, "Purpose for which Licensed Material will be used," of your application for renewal. Item 6 of your application indicates that the use of licensed materials is limited to the synthesis of radiolabeled chemicals for distribution to persons authorized to receive the material. Please also confirm that in addition to requesting an amendment to your license for new uses and authorized users, ARC will also request an amendment for any changes to its RPP, SOP's, facilities and equipment, and decommissioning activities.

5. Please provide more detail on the minimum qualifications of the member of the RSC who will be from an outside company. In addition to the Chairman, please include the RSO as a member of the RSC and confirm that the RSO will be part of the quorum. Lastly, you stated that Committee membership included the Chairman, RSO, etc. However we also noted a reference made to a Vice Chairman being a member of the RSC. Describe the role of Vice Chairman on the Committee. Please note that the NRC and your license will only recognize one Chairman. Confirm also that the Chairman must be present and part of the quorum (ref. item 3.2.2).
6. Item 3.2.4.5 discusses "Personnel Classifications." It appears that ARC has designated three levels of radiation workers: a) authorized users (AU); b) Class 1 radiation workers; and c) Class 2 radiation workers. It also appears that both Class 1 and 2 radiation workers must work under direct supervision, and in the physical presence of, an authorized user who will be approved by the NRC through the amendment process. Please confirm our understanding of this. In addition, please address the following:
 - a. Provide more detail about Class 1 workers. Specifically, describe the types of job functions that these workers will perform and the minimum training and experience necessary for an individual to become a Class 1 worker. Also, clarify your statement that Class 1 workers will work under the direction of an AU, and that the physical presence of an AU is not necessary. Clarify how an AU will oversee a Class 1 worker, and discuss in greater detail the availability of an authorized user to indirectly oversee a Class 1 worker's use of radioactive material.
 - b. Provide examples of a Class 2 worker's job responsibilities/duties.
 - c. Clarify if there are approvals granted to other ARC personnel other than production-related personnel, e.g., maintenance and housekeeping personnel who work in restricted areas where licensed material is being used. We noted inferences made in your application that there are no maintenance activities which could be affected by work in radiological areas.
7. After an overall review of your RPP it is apparent that the RSO has been assigned numerous duties in addition to managing ARC's radioactive materials program and NRC license. Please provide a summary that details all of the RSO's duties and associated expected weekly time commitments to fulfill additional duties. Please also include an explanation as to how the RSO will be able to effectively fulfill the duties of the RSO (ref. item 3.3).
8. Item 3.3.3.9 states that the RSO will gather information and data needed by the President of ARC to determine corrective actions. Please explain why the RSC is not directly involved in collecting and reviewing data with regard to corrective actions that need to be taken. The RSC should be fully engaged in this process.
9. Item 3.3.5 makes reference to an Assistant RSO, but does not identify the individual, his/her qualifications, or duties. Please provide this information, and clearly state whether or not you are seeking approval for an ARC staff member to hold this position.

In addition, discuss in greater detail staffing availability to supervise your radiation protection program. Item 3.3.5 indicates that “when the RSO is not available for reasons such as illness or vacation, and there is no Assistant RSO, then the Radiation Safety Committee Chair shall function as the Alternate RSO and that routine radiation safety duties will be performed by an individual trained by the RSO.” Specifically address the following:

- a. Provide the job description and minimum qualifications and training for the individual who will be trained to perform the safety duties of the RSO in the RSO’s absence. Discuss the authority given to this person to stop or modify unsafe practices, and the ability to function in the event of an unplanned emergency involving an accidental release or spill of licensed materials.
 - b. Provide additional information regarding the maximum time frame this interim coverage will be allowed. Indicate steps for contacting the RSO in the event of an emergent situation.
 - c. Provide an estimate regarding the minimum staffing necessary to implement your radiation safety program. Currently it appears that you have two trained professional staff designated to oversee your program, but you have not indicated if there are additional staff, or the need for additional staff, to perform scheduled safety checks, audits, surveys, movement of waste, and other necessary radiation safety program duties.
 - d. The NRC needs to have a certain level of confidence that the person assuming the duties of the RSO in the RSO’s absence be knowledgeable in specific regulatory requirements, license tie-down commitments, required surveys, monitoring of employees, and have significant experience in dealing with off-normal issues, such as accidents and spills involving radioactive materials. Discuss other alternatives regarding coverage issues in times of the RSO’s absence, such as the use of a qualified radioactive materials contractor.
10. Revise item 4.1.6.1 to delete the reference to incineration. Incineration of licensed radioactive material requires specific authorization on an NRC license, and is currently not an approved form of waste disposal on your license.
 11. Define the dose levels and concentrations that are referenced in items 4.2.1 and 4.2.1.2.
 12. Define the term “unfinished forms” that is referenced in item 4.2.1.4(c).
 13. Item 4.2.1.6 describes specific action levels for contaminated areas and equipment, including a statement that decontamination will take place “at the next practical time” when these action levels are exceeded. Please define the term “next practical time” by providing a maximum timeframe and criteria for determining when decontamination will take place. Also, for times when you are not able to implement immediate corrective actions, please describe interim actions that will be taken that should include, for example, restricting and posting contaminated areas and equipment, informing personnel, etc.

14. Please modify Item 4.2.2.2 to clarify that restriction from work with “**any** radionuclide,” as opposed to a “**particular** radionuclide,” will be implemented when an individual has received a certain committed effective dose equivalent or committed dose equivalent to the thyroid.
15. Revise items 5.2.3, 5.2.6, 5.2.7.2, 5.2.7.3, and 5.2.9.1 to replace the word “should” with “shall.”
16. Please define how you determine the extent of training that an individual will receive at ARC based on his/her past experience and training with radioactive material, and their educational background. As written, this item is very non-specific and open for interpretation (ref. item 6.1).
17. Submit examples of written tests that will be provided as discussed in item 6.2.2. Describe the difference between written and oral tests, how you determine which will be given, provide an example of an oral test, and describe how you determine competency for both tests. Also, please clarify and ensure consistency between the commitments outlined in Item 8, “Training for Individuals Working in or Frequenting Restricted Areas,” and Item 6 of your RPP as follows:
 - a. Please revise your proposed refresher training cycle for Class 1 and 2 workers. Based on recent inspection findings, it appears appropriate to implement refresher training on a frequency that is less than the two and three years that you proposed (note that two different frequencies are specified in your documents). In keeping with current NRC guidance, refresher training should be provided on an annual basis. Also, include authorized users in refresher training. Please modify your program for refresher training accordingly.
 - b. Confirm that the refresher training is a formal presentation with structured, relevant topics. Provide a copy of the core refresher topics that will be provided, and include sections that address new and emergent issues such as NRC and licensee audit and inspection findings. Also confirm that attendees will sign an attendance sheet which will be maintained for NRC inspection.
 - c. Provide more detail regarding on-the-job training (OJT) in Item 8 of your renewal application and Section 6.3 of the RPP. Describe the minimum training time for each Class of user, documentation of OJT that will be maintained, and how ARC management will certify competency and completion of the OJT.
 - d. As requested in an NRC letter to you dated March 25, 2010, please respond to our request for more detail on your training program for vendors and non-production workers (ref. item 8 in your application for renewal and Section 6 of your RPP).
 - e. Regarding Section 6.4.2 “Training Outline” of your RPP, please describe in greater detail the time that will be allotted for each training topic, the training materials, e.g., handouts and reference materials that will be provided to the trainee, tests that will be administered per topic area, and a discussion regarding practical exercises, such as using survey meters for frisking and routine surveys,

donning protective clothing and using protective equipment, and responding to accidents and spills involving radioactive materials, etc. Confirm that trainees will sign a document that will be maintained in each employee's training file to certify completion of the training.

18. Modify your RPP to include ARC's Waste Management and Inventory Control Program. Please refer to Section 8.11 of NUREG 1556, Volume 11, and Appendix S, for specific guidance, and address the following:
- a. Describe a program that will ensure that proper training is provided for individuals who process radioactive waste, that waste-related procedures will be consistent with one another, and that ARC's inventory program will be sufficiently robust to monitor and track all materials under ARC's possession including waste that is being processed and in storage for disposal and/or decay.
 - b. For each of the following procedures, please provide additional information as noted below:
 - SOP-07 Liquid Waste Disposal Program
 - SOP-17 Decay-in-Storage Program
 - SOP-18 Liquid Waste Evaporation Program
 - SOP-19 Extended Interim-Storage of Low Level Waste (suspended)
 - SOP-29 Storage of Surface Contaminated Objects
 - SOP-32 Segregation of Dry Active Waste
- (1) Expand your SOPs to specify the individuals and their worker classification, i.e., authorized user, Class 1 or 2 worker, who are responsible for implementing each SOP. Also, your training program needs to discuss any additional specific training that is provided to the individuals performing these activities.
 - (2) Expand your procedures to include references to other relevant safety related SOPs, or modify each procedure individually to address radiation safety program requirements for monitoring the work areas, performing personal surveys, use of PCE, and actions to take in the event of an emergency or non-routine occurrence.
 - (3) Each procedure needs to include a discussion of processes that are necessary to ensure that radiological wastes are adequately inventoried, tracked, and controlled.
 - (4) Attach to each procedure the forms that will be used to record and document waste processing activities.
 - (5) Indicate the location of each storage and waste processing area. If the location and facilities are different from those currently tied down in your license, provide diagrams and schematics of the facilities. Submit your assessments for potential air borne exposure and contamination potential for personnel working in the vicinity of waste disposal processes.

Standard Operating Procedures (SOP)

1. **SOP-1: Dry Solid Waste Compaction Program**
 - a. Describe how hot waste containers are labeled (ref. item 1.3).
 - b. Describe how transport containers are labeled (ref. item 1.5).
 - c. Describe in more detail the training provided to individuals who will operate the compactor and confirm that they will be specifically designated and authorized to perform compaction activities. Include in the procedure a discussion regarding individual worker responsibility and communication requirements, such as emergency notifications, and when to contact the RSO (ref. item 2.0).
 - d. Describe protective clothing that compactor operators, e.g., chemists, technicians, etc., will wear when they are operating the compactor (ref. item 3.0).
 - e. Submit a description of the location of the compactor at your facility. Include diagrams of the location where the compactor is used, as well as a diagram of the ventilation system(s), including locations of air intake and exhaust points.
 - f. Describe the system in place to evaluate worker breathing zones for airborne radioactive material during compactor operation. Also include a description of any engineering controls that are in place to eliminate or mitigate airborne effluents in the area where the compactor is operated.
 - g. Describe post-compaction surveys that will be conducted in order to evaluate for removable contamination. Include types of surveys that will be conducted, instruments that will be used, and the frequency at which surveys will be performed. Include action levels and describe what actions will be taken should these levels be exceeded.
 - h. Confirm that workers who process, handle, or otherwise operate the compactor will be subject to ARC's routine bioassay program.
 - i. Submit a description of the limitations as to the types of material that can be compacted. For example, are there limitations with regard to types of radionuclides, chemical contaminants, etc., that may be present? Describe precautions that will be taken to you assure that workers will not be exposed to non-radiological hazards, or exposure will be controlled and minimized.
 - j. Describe your system for tracking quantities and types of radionuclides that are compacted and how you adjust your inventory.
2. **SOP-2: In Vitro Bioassay Program**
 - a. Your application did not include an attachment entitled "Counting Protocol 3." Please submit the attachment for our review (ref. item 4.2).

- b. Please include the records discussed in items 4.4 and 4.5 as an attachment to this procedure, and provide the attachment for our review.
 - c. Please clarify Item 5.2, "Chronic Exposures." It is not clear what you mean by "air concentrations that exist in excess of 50% of permissible."
 - d. Describe how you will take into consideration the varying biological half-lives of all the different radiological compounds that are manufactured at ARC when you evaluate staff for intake and internal dose.
 - e. Please identify the workers that will need to participate in this program.
 - f. Confirm that the RSO will document the basis for exposure evaluations, as well as corrective actions that are implemented. Also, confirm that the employee will be informed of the corrective actions (ref. item 5.1.2).
3. SOP-3: C-14 and H-3 Monitoring Program
 - a. Please incorporate a methodology and frequency for evaluating the effectiveness of the air sampling system and associated equipment.
 - b. This section refers to an "Attachment one" for a description of a sampler train. The attachment was not included with the SOP. Please submit a copy for our review. Conduct and submit an evaluation which demonstrates the air sampling needs for each specific operation involving licensed material. The description should discuss the sampler head locations and associated pumps along with a justification which demonstrates that the locations are representative of the radioactive material work hazard and air flow patterns. Also, describe the air sampling that will be performed during waste compaction activities. Provide specific air sampling frequencies for both routine and non-routine operations.
 - c. Submit an example of the spreadsheet sheet that is used to convert data collected to concentrations of radionuclides (ref. item 4.7).
4. SOP-4: HEPA and Pre-Filter Exchange Program

Please submit this procedure for our review. Based on the deposition of radioactive materials identified in the soils on ARC property and on the surface areas of buildings, it appears that particulate materials are being exhausted from ARC facilities. Thus, if you cannot justify the basis for not using these filters then you must implement their use. Please include a discussion of the types of materials (e.g., chemical form, half-life, etc.) and quantities which would trigger the need for HEPA and pre-filters.
5. SOP-5: Instrument Calibration Program
 - a. Regarding item 2, define what "production purposes" means. If the end user is using the meter to check for personal or immediate work area contamination as a "go" or "no go" test, these meters still need to have a limited calibration, including

constancy and response checks at specific frequencies. Provide a description of the tests for the production meters, or confirm that they will be incorporated into the routine calibration program. If this functional testing is to be done in-house, then please expand the procedure to address this calibration.

- b. The reference to approved NRC or Agreement State procedures is too general. NRC NUREG-1556 series, e.g., volumes 7 and 11, have acceptable model programs, which should be referenced. Alternatively, the in-house procedure should be expanded to ensure that all of the elements discussed in the NUREG-1556 series procedures have been addressed.
- c. With regard to the meters that are used for contamination surveys, please address the following:
 - Confirm that the mini-pulsar will be calibrated by a recognized vendor, and specify the calibration frequency;
 - Specify that traceable sources will be used for efficiency determinations;
 - Submit a copy of the meter calibration forms;
 - Discuss how you will keep track of calibration due dates; and
 - Discuss the types of meters and detectors that will be used, and include a discussion of detector surface areas and procedures for converting instrument data to disintegrations per minute.

6. SOP-6: Program for Picking up, Receiving, and Opening of Incoming Radioactive Materials

Please resubmit this procedure using NUREG-1556, volume 12, Item 8.10.3. The guidance that you used to draft this procedure, NRC Regulatory Guide 10.8, was designed for licensees with nuclear medicine programs, is outdated, and has been replaced by the NUREG-1556 series.

7. SOP-7: Liquid Waste Disposal Program

- a. Clarify what you mean when you stated that the sampling frequency for radioactive liquid waste will be conducted on an "as-needed" basis. Provide more definitive criteria with clear, established frequencies for taking samples (ref. item 3.0).
- b. Describe how you will ensure that wastewater is stirred thoroughly such that you obtain a representative sample for analysis (ref. item 4.2).
- c. In order to keep radioactive wastewater discharges at an ALARA level, please re-evaluate items 5.1 – 5.5 and set discharge limits to a percent that is lower than 100% of regulatory limits.
- d. Please submit the calibration procedure for your liquid scintillation counting instrument (ref. item 7.0).

- e. Please identify the workers who are authorized to perform liquid waste discharge activities. Also, please revise the procedure to include a short discussion on individual worker responsibility and communication requirements such as emergency notifications, and when to contact the RSO.
- f. During the last inspection it was noted that maintenance staff performed liquid waste disposal after receiving approval from the RSO. If maintenance staff will continue to perform these activities please develop and submit for our review, a checklist which the maintenance staff will follow to ensure that they conduct these activities in a safe manner.
- g. Describe the training which will be provided to the personnel who will discharge the waste into sanitary sewers and confirm that they are specifically designated and authorized to perform such activities. In addition to the basic radiation safety training, these personnel should have a separate module that focuses on specific additional training topics. For example, additional specialized training in the use of protective clothing, actions to be taken in the event of an unexpected accident or spill, when to restrict and post an area when waste disposal is taking place, and when to conduct surveys prior to and after disposal of radioactive materials, should be included.
- h. This procedure should point to/reference other procedures, such as SOP-16 "Radioactive Contamination Control Program", and SOP-33 "Use of Protective Clothing and Equipment", which would need to be implemented and followed in parallel.
- i. Please identify in this procedure any limitations on the types of materials to be placed in waste containers. Also, describe how you will evaluate and address hazards associated with chemicals that may be placed into the liquid storage containers which pose a hazard to workers.
- j. Include a discussion on how you will track and inventory bulk quantities of liquid radioactive wastes.
- k. Please identify all locations where radioactive waste will be stored.
- l. Submit the data sheets referenced in the procedure that will be used to track and record liquid waste storage and disposal.

8. SOP-08: Radioactive Waste Program

You indicated that this procedure is terminated, is redundant, and that the program described by this procedure is covered in more detail by SOP-01, SOP-07, and SOP-17. Multiple aspects of waste disposal are discussed in various SOP's, however neither the RPP or SOP's provide a singular, stand-alone radioactive waste program that discusses an overall storage and control program for inventory and tracking of radioactive waste. Please modify your RPP accordingly and include an SOP that addresses an overall radioactive waste program.

9. SOP-09: Hood Face Velocity Maintenance Program

- a. Describe the equipment that will be used to measure hood face velocity, and submit the procedure that will be used to calibrate the equipment, and include the frequency of calibration. Please use and reference applicable ANSI standards for fume hood checks and associated equipment operability tests.
- b. This procedure should point to/reference other procedures which would need to be implemented and followed such as SOP-03 "Air Monitoring," SOP-28 "Air Sampling Line Continuity," SOP-16 "Radioactive Contamination Control Program," and SOP-33 "Use of Protective Clothing and Equipment." The procedure should also include a description of how you will evaluate hood loading, i.e., placing of materials in the hood which could directly affect air flow into and out of the hood, and limit and monitor the placing and storage of other hazardous materials in hoods, e.g., flammables and explosives.
- c. Describe the measuring device that will be used to measure the hood face velocities, its calibration, and confirm that you will document the results of measurements made and calibrations performed.

10. SOP-12: In Vivo Bioassay Program

This appears to be a bioassay program specific for radioiodine which is independent of SOP-02. You stated that this procedure has been suspended until ARC begins using significant amounts of iodine-125. However, since your license currently authorizes 1.5 curies of iodine-125 and 100 millicuries of iodine-131, please reactivate this procedure and submit it for our review.

11. SOP-13: Iodine-125 Air Monitoring Program

You stated that this SOP has been suspended from use but would be reactivated in the event "ARC begins processing significant amounts of radio-iodines." However, since your license currently authorizes 1.5 curies of iodine-125, please submit this procedure for our review.

12. SOP-14: Phosphorous-32 Air Monitoring Program

You stated that this SOP has been suspended from use but would be reactivated in the event "ARC begins processing significant amounts phosphorous-32." However, since your license currently authorizes 1 curie each for both phosphorous-32 and -33, please submit this procedure for our review

13. SOP-15: Procurement and Use of Radioactive Materials

- a. Please revise item 1.2 to require that prior to ordering licensed material ARC staff will verify that possession limits will not be exceeded.

- b. In Item 2.1, please confirm that you will submit a request to the NRC for an amendment prior to implementing a proposed new use that the RSC has evaluated.
- c. In Items 2.2, 2.3, and 2.4, please confirm that you will maintain records of RSC reviews of new protocols and requests, proposed modifications to existing facilities, and proposed modifications to the RPP and SOP's. Also, confirm that you will request an amendment to your NRC license for any of these changes before implementation.

14. SOP-16: Radioactive Contamination Control Program

- a. Your references include old, outdated regulatory guides 8.21 and 1.86. Please review your procedure against current guidance in the NUREG-1556 series. Reference NUREG-1556, volume 11 as guidance for acceptable procedures.
- b. Item 2 states that areas and equipment are decontaminated "at the next practical time" when contamination levels exceed "action levels." Please provide specific criteria that clearly defines how you would determine when the "next practical time" would be. From our perspective, any level of contamination that exceeds an "action level" should require that some "action" be taken if decontamination is not required, e.g., isolate the area, notify personnel, etc. Identify the individual who will be responsible for decontaminating areas and equipment that exceed the "investigation levels." Describe relevant training that this individual will receive (ref. item 3.3).
- c. Define the areas/facilities that item 5.1 refers to with regard to the routine survey program for removable contamination. Also, describe what is meant by surveying material and equipment on an "as needed" basis.
- d. Please clarify and/or expand upon item 5.2.
- e. Define and describe "direct frisk surveys" that are discussed in item 5.3, and explain how they are used to determine total activity.
- f. Describe how wipe surveys that are taken in buffer zones assure that activity has been contained within restricted areas.
- g. Define the "action levels" that are referenced in item 6.5.
- h. In light of contamination that has historically been found on personal items released from the facility, please include a discussion of the survey program that you will employ in order to prevent future off-site release of contaminated personal items.
- i. Provide diagrams of the ARC facility which delineates restricted areas, buffer zones, and unrestricted areas.

- j. A statement was made that equipment removed from a restricted area will be surveyed on an "as needed" basis. Please define "as needed." Also, given the prevalence of contamination that is routinely found in restricted areas at ARC's facility, please revise this section to state that equipment removed from a restricted area will be surveyed in order to prevent spreading contamination from restricted areas to unrestricted areas. Furthermore, describe the type of surveys that will be conducted and actions that will be taken in the event you discover contaminated equipment.
- k. Provide copies of the forms which will be used to document surveys.

15. SOP-17: Decay-in-Storage (DIS) Program

In order to be consistent with current NRC policy on decay-in-storage of radioactive waste, you should modify item 1.0 to allow for the treatment of radioactive waste for decay to include radionuclides with half-lives up to 120 days. Please also include in your procedure a requirement that radiation labels be removed or defaced before disposal in ordinary trash. Also, describe the location where DIS waste will be stored for decay, as well as the security of the area to prevent unauthorized access.

16. SOP-18: Liquid Waste Evaporation Program

- a. Submit air effluent data from liquid evaporation operations for the CY 2009 to present and demonstrate that concentrations are within 10 CFR Part 20 limits, and that ARC is in compliance with 10 CFR Part 20.1301 (ref. item 1.2).
- b. Please identify the location of each hood that is used for liquid evaporation. Submit a diagram of each hood that illustrates its ventilation system, exhaust point, and air effluent sampling location. Include equipment descriptions and diagrams related to the liquid evaporation work as attachments to the SOP (ref. item 1.4).
- c. Describe in detail the personnel contamination surveys that will be conducted after an individual performs a liquid evaporation operation. Also include the equipment used, action levels that will be implemented, and a description of actions that will be taken if these levels are exceeded (ref. item 1.6).
- d. Identify the title of the workers who will perform the liquid evaporation work. Include a discussion of their responsibilities and communication requirements with the RSO, such as during emergency notifications, accidental spills, personnel contamination events, etc.
- e. Describe the training for those individuals who will perform the liquid evaporation and confirm that they are specifically designated and authorized to perform such activities. In addition to the basic radiation safety training, individuals performing liquid evaporation should receive training in the use of protective clothing, respiratory protection, breathing zone or general air sampling, actions to be taken in the event of an unexpected accident, spill, chemical reactions, or fire, etc.

- f. This procedure should point to/reference other procedures, which need to be implemented and followed such as SOP-03 "Air Monitoring", SOP-16 "Radioactive Contamination Control Program", SOP-33 "Use of Protective Clothing and Equipment", and Emergency Instructions and Procedures.
- g. Describe the size, volume, and construction of the transport containers. Movement of liquid materials in the containers from restricted areas through unrestricted areas to the liquid evaporation area should be limited. The transport containers should be break-resistant, and have securable lids that will not easily break or leak if the container is dropped or tipped.
- h. Please commit to analyzing and quantifying the liquid waste prior to pouring it into liquid evaporation pans. Confirm that records of this information will be maintained and incorporated into ARC's radioactive materials inventory program.
- i. In order to avoid build up of contamination within hoods where liquid evaporation procedures are conducted, please submit a procedure for decontaminating the pans and hoods that are used in the evaporation process.

17. SOP-19: Extended Interim Storage of Low Level Waste

An amendment to your license will be required prior to implementing a program for extended interim storage of low level radioactive waste. Please confirm that ARC will not institute extended interim storage of low level radioactive waste until it applies for, and receives, an amendment to its license authorizing this activity.

18. SOP-20: Glassware Decontamination Program

- a. In your objective you stated that this procedure applies to glassware contaminated with carbon-14 or hydrogen-3. Please indicate if this procedure would also apply to other radionuclides authorized on your license and if not, describe why not.
- b. Describe the criteria that must be met in order to determine whether or not waste material generated from glassware decontamination activities can be discharged. Describe how and where the waste will be discharged (ref. item 2.6).
- c. Confirm that you will generate and maintain records of wastewater that is discharged from glassware decontamination activities that includes, as a minimum, dates, concentrations, and radionuclides released.

19. SOP-21: Training and Dose Estimates for Non-ARC Personnel

Please confirm that this training pertains to non-ARC personnel/contractors who may be conducting non-licensed activities on ARC property. Please also address your training program for contractors who participate in licensed activities at ARC's facilities. Also, provide a detailed procedure with regard to control of non-ARC personnel on ARC facilities and escorted access by ARC staff.

20. SOP-23: Exhaust Stack Flow Rate Measurement Program

- a. Please revise this procedure to include provisions for conducting daily checks to verify stack flow rates, and conducting stack flow rate measurements, e.g., twice per year.
- b. Describe your program for verifying that exhaust flow rates are accurate and that flow meters/gauges are reading out correctly. Refer to and reference appropriate ANSI or other standards to support frequency of tests. Also, please include a discussion of actions that will be taken in the event flow meters reflect a significant change during operation.

21. SOP-24: Transportation of Radioactive Material Using Private Vehicles

Describe the average number of times per year that ARC personnel are involved in transporting packages using private vehicles. Also identify ARC employees that will be engaged in this activity, and describe the training that they will receive prior to being allowed to transport license material, as well as the frequency that this training will be provided.

22. SOP-25: Gamma Air Monitoring Program

Confirm that you do not release any gamma emitters to unrestricted areas and that you will develop and submit for NRC review and approval, a monitoring program for evaluating concentrations of gamma emitters before any are released. If gamma emitters are currently released, then please develop and submit procedures for monitoring both effluent and worker breathing zones.

23. SOP-26: Beta/Gamma TLD Monitoring Program

Confirm that in the event ARC determines that there is a need to monitor workers for external exposure, ARC will submit a request for an amendment to its NRC license requesting approval of this SOP.

24. SOP-27: Skin Dose Assessment Program

- a. Revise item 4.1 by replacing "should" interview, with "shall" interview.
- b. Revise item 5.3 to remove the reference to the RSO granting a waiver to restricting an individual from working if he/she exceeds the action level. Simply covering the exposed area (as discussed in your application) would not eliminate the possibility of receiving a skin dose to another area of the body. Please make a commitment that the RSO will determine the dose received and the cause of the exposure, as well as the corrective action(s) for all exposures that exceed action levels.
- c. Regarding item 4.4, please describe the probe and instrument that will be used. Also include a description of the procedure for calibrating the probe.

25. SOP-28: Air Sampling Line Continuity

- a. Provide the technical and scientific references used to develop the Air Sampling Line Continuity procedure. Provide ARC's evaluation and documentation demonstrating that the current system meets recognized standards. Provide diagrams and equipment specifications for all lines and samples.
- b. Describe a program for verifying by observation and measurements at a specified frequency that air flow rates and continuity are correct and meters/gauges are reading out correctly. Refer to appropriate ANSI or other standards to support frequency of tests. Also, please discuss actions that you will take should flow meters reflect a significant change during operation.
- c. Confirm that you will maintain records of these tests.

26. SOP-29: Storage of Surface Contaminated Objects

- a. Please describe in detail and incorporate into your procedure a methodology and criteria for segregating contaminated objects into each category so that items do not get mixed (ref. item 2.3).
- b. Identify the probe(s) that will be used to conduct the surveys described in item 3.1.1 and describe it's (their) capability to detect the radionuclides of interest.
- c. Describe in detail the content of the annual audit that will be conducted as stated in item 4.0.
- d. Please include a discussion of the characterization of surface contaminated materials prior to movement by personnel. ARC staff should survey and characterize these items prior to their movement. Describe how and by whom this will be done.
- e. Provide more detail on the unrestricted release limit based on 1000 dpm/100 cm². It is unclear if this is a total for both removable and fixed contamination, or not. The release must be based on both fixed and removable contamination, and should be a fraction of the limits for ALARA purposes. Please also confirm that direct surveys are being performed as well as wipe tests (ref. items 3.1 and 3.1.2).

27. SOP-30: Release of Equipment to Vendors

- a. Describe the probe that will be used to scan and survey equipment described in item 2.1. Demonstrate that the survey equipment (probe) that is used will be able to detect the radionuclides of interest.
- b. Provide a copy of the data sheet that will be used to record released equipment. Include the sheet as an attachment to the procedure.

28. SOP-31: Protocol for Packaging and Shipping Items to Japan

- a. Several sections throughout this procedure reference “results less than 200,” without units being specified. Please resubmit the procedure with the units specified.
- b. Submit an example of the labels that will be affixed to primary containers (ref. item 2.1.4).
- c. Please define JRIA (ref. item 2.1.9).
- d. Describe in detail the area surveys that will be conducted which are discussed in item 3.1.2.
- e. Attachments 1 and 2 were not included. Please submit copies for our review.

29. SOP-32: Segregation of Dry Active Waste

- a. Please explain how disposable gloves, shoe covers, and lab bench paper get into the cold trash (ref. item 2.2). Procedures should be revised to assure that items which are “hot” do not get into the “cold” trash. Please address this issue.
- b. Describe the probe that is coupled to the survey meter that is discussed in items 2.3, 3.3, 4.1, and 5.1 for conducting surveys.
- c. Include references to other procedures as applicable, and specify actions which would necessitate notification of the RSO and implementation of other emergency actions.

30. SOP 33: Use of Protective Clothing and Equipment

Define “twice background” for each meter, or indicate that this value will be determined by the user or radiation safety staff daily and noted on the unit. Also, background values should be evaluated and reduced if above an acceptable level, for example greater than 100 counts per minute. If the contamination levels in the change areas are too high, the frisk surveys might not be capable of detecting contamination on personnel exiting an area. Confirm that defective or contaminated meters will be replaced immediately upon being found to be defective or contaminated, and that you will immediately survey personnel who have left the area.

Emergency Procedures

Please expand the emergency actions discussed in Section 8.3.1 “Spill not involving contamination of individuals” and Section 8.3.2 “Spill involving contamination of individuals,” of the RPP. Please develop an SOP to assist in responding to emergency spills and incidents.

The RPP needs to be expanded to discuss the following:

- a. A classification scheme used to correlate emergency actions based on levels of contamination and potential exposure resulting from a spill or incident.
- b. Records that will be generated documenting the evaluation done prior to and following significant remediation actions.
- c. The training that will be provided to persons who will be responding to a spill or incident.
- d. Spill kits that will be maintained to limit the spread of contamination, as well as materials that will be used to post and restrict access to areas involving a spill or incident.
- e. Actions that will be taken to ensure that ARC employees will receive timely notification following the occurrence of a spill or incident in order to prevent contamination of personnel and off-site release.
- f. Follow-up actions that will be implemented to inform and train personnel of a spill or incident should be communicated to staff and included in training sessions. Actions should include: 1) information regarding the cause, 2) the associated risks, 3) the corrective actions, and 4) any lessons learned.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter will be available electronically for public inspection in the NRC Public Document Room or from the NRC's Agencywide Documents Access and Management System (ADAMS), accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>.

Please submit a response within 30 days of the date of this letter. In your response, please reference as additional information to Control Number 318694. Please contact me at 630-829-9854 if you have any questions.

Sincerely,

/RA/

Kevin G. Null
Materials Licensing Branch

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

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