

March 25, 2010

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

SUBJECT: REVIEW OF AMERICAN RADIOLABELED CHEMICALS AMENDMENT  
REQUEST TO EXCAVATE SOIL FOR CONCRETE PAD AND TO INSTALL  
NITROGEN LINES IN A PRODUCTION BUILDING (MAIL CONTROL  
NO. 318776)

Dear Dr Gupta:

The U.S. Nuclear Regulatory Commission (NRC) staff has completed an initial technical review of your amendment request. Your request seeks NRC approval to permit excavation for a foundation pad for the placement of a liquid nitrogen storage tank outside of your production Building 300, and to install nitrogen lines from the tank into the production building. Based on our review of the amendment request, NRC staff has identified the purpose, scope and justification for the request as follows:

Building 300 houses laboratories that label and analyze various byproduct materials, with hydrogen-3 and carbon-14 being the predominant long-lived materials used, i.e., greater than 120 day half-lives. The liquid nitrogen bulk storage tank would be used to supply liquid Nitrogen to the laboratories in Building 300 and in the future to the 300 Annex. The justification and statement of need for the amendment was that the installation of the pad and tank would eliminate the need for multiple smaller tanks that are stored inside the building and replaced on a regular basis by an outside vendor. By eliminating the smaller tank exchange, American Radiolabeled Chemicals (ARC) management believes a pathway with potential for transferring contamination to unrestricted areas and potentially to the public would be eliminated.

Please note that your license does not currently authorize the excavation of radioactively-contaminated soil. Unless and until the NRC approves your pending license amendment request, you are prohibited from excavating radioactively-contaminated soil for any purpose. If you have any questions, or if our understanding of your amendment request differs from your own, please contact me at (630) 829-9856.

This letter also acknowledges your request to modify ARC's radiation protection program (RPP) document and standard operating procedures (SOPs). These documents are currently being reviewed as a separate license amendment request (Mail Control No. 318694). While we have included in this letter a request for additional information (RAI) in regard to the construction of the concrete pad and installation of the nitrogen lines into the production building, there may also be additional RAIs pertinent to the reviews of your RPP and SOPs.

Please provide within 30 days from the date of this letter, written responses and documentation that address the following RAIs. When responding to our requests for information, please refer to Mail Control Number 318776.

- A. Submit a revised current SOP (or a new SOP) that addresses the preparation of specific work instructions (WIs) or radiation work permits (RWPs), and addresses radiological safety for construction, renovation, and site beautification projects to be performed in areas exceeding your unrestricted radiological limits. This SOP should be compatible with your radiation program procedure (RPP). The information and commitments detailed in your revised document should include, but not be necessarily limited to the following information:
1. A section that specifies clear references to other applicable ARC procedures that govern the work to be performed and as appropriate make reference to Sections of the RPP that provide additional clarifying detail;
  2. A section that clearly states the work to be performed, and that establishes the range and limitations of work that can be performed by ARC and contract personnel;
  3. A section that contains a description of each work area, including ARC's designation for each area's radiological classification. A section that diagrammatically portrays the work areas should be part of the WI and RWP with the radiological levels correlated to the diagram;
  4. A section specifying required safety actions, use of protective clothing and equipment (PCE), Occupational Health and Safety Administration (OSHA) safety considerations for use of PCEs, and work safety controls in construction areas;
  5. A section to confirm that the personnel have been instructed in the relevant procedures and limitations of the work instruction such as the use of an acknowledgment sign-off sheet. The discussion should include a commitment that copies of the WI or RWP will be provided to the workers or will be posted in the construction area;
  6. A section that documents the current radiological conditions in the area(s) where work will be performed. Confirm that the survey performed to establish radiological levels are relevant and current to the area where the work will be performed. Also, that the work area will be immediately resurveyed and work will be curtailed, if the area contamination levels have significantly increased changing the radiological classification for the area and necessary safety measures as a result of production activities, accidents or spills;
  7. A section that will be signed by the Radiation Safety Officer approving the WI or RWP prior to construction work being performed. Confirm that the WI or RWP will be developed sufficiently ahead of time so preparation and training of involved personnel can be satisfactorily completed. Also, discuss the review and concurrence of other ARC personnel necessary to ensure there will be an

appropriate level of management awareness and approval of work actions performed in contaminated areas;

8. Also, confirm that non-production work activities will be monitored and observed by a member of the ARC Health Physics staff. Additionally, discuss how WIs or RWPs will be modified if the work conditions change in a manner that the prescribed safety conditions or the radiological conditions of the WIs or RWPs are no longer relevant to the work being performed. Indicate what time limitations will be allowed before the WIs or RWPs will be reviewed and revised as appropriate; and
9. Provide an attachment to this SOP or another of your SOPs that will document the sign-in and sign-out and radiological frisking of personnel entering and exiting contaminated work areas.

B. Revise SOP-21, "Training and Dose Estimates for Non-ARC Personnel."

1. Confirm that this instruction is applicable to all workers regardless whether they are ARC or non-ARC personnel that perform non-production work activities in areas that exceed specified contamination trigger levels. This instruction should be applicable to individuals who are not authorized users or laboratory assistants actively doing research and preparing product for distribution.
2. Specify the individual(s) who will provide the training indicating their training and experience. Provide an expanded training outline, indicating the approximate time per topic, use of practical exercises, such as donning and removing PCEs. Also, provide a copy of handout materials that will be provided to the trainees for future reference. Confirm that trainees will be provided copies of pertinent SOPs, the RPP and other guidance or that a designated area will be established where individuals, production or contract workers, will have unfettered access to these documents.
3. Clarify in Section 2.1, that the training will be provided prior to the conduct of work, and that it is applicable to contaminated areas both inside and outside production buildings.
4. Ensure that the SOP specifies that instruction is provided to personnel regarding the purposes, conditions and limitations of work instructions (WIs) and radiation work permits (RWPs).
5. Regarding the instruction outline, describe in greater detail the safe work practices that will be provided to staff working in contaminated areas, such as:
  - Do not store food, drink or use personal effects in areas where licensed material is stored or used;
  - Do not eat, drink, smoke or apply cosmetics in any area where licensed material is stored or used; and

- Before leaving the work area, monitor hands, shoes, and clothing for contamination in a low-background area. Discuss what the individuals actions should be upon detecting personal contamination, e.g., use of SOP-33, “use of Protective Clothing and Equipment,” and SOP-16 “Radioactive Contamination Control Program.”
6. Describe in greater detail the actions to be followed in the event of an emergency or accident involving radiological materials and personal injury.

C. Revise SOP-30, “Release of Equipment to Vendors.”

The current procedure lacks sufficient detail to address and document the release surveys for the tools and equipment used for excavation of soils and the tools and equipment that will be used by the contractor to install the nitrogen lines in Building 300. Please address the following items:

1. Modify the SOP to ensure that it addresses non-radiochemical production work both inside and outside Production Buildings;
2. Confirm that the radiological direct surveys and tests for removable contamination will be performed and analyzed prior to the release of equipment;
3. Provide additional information that describes the tests for removable contamination in greater detail. Confirm that the test will be collected in areas where the probability of contamination is the greatest on equipment to be released. Also, that a sufficient number of tests will be collected and that the tests will be representative of the area surveyed. Specifically, expand the SOP or point to another SOP that defines the surface area of the equipment or tool to be evaluated for contamination. Information pertinent to this request can be found in NRC technical guidance documents, such as: Regulatory Guide 1.86, NUREG 1556 series and NUREG 1757, Vol. 2;
4. Provide a table of contamination action limits specific to the release of equipment and materials. This table can be incorporated into this SOP, or the SOP should point to another SOP or a RPP requirement that contains the appropriate information. Regardless, a specific table of values and the technical requirements for the conduct of these surveys must be provided with sufficient detail that NRC reviewers can make a finding that the procedure is adequate; and
5. Add a section to the SOP, and provide a copy of the survey document that will be completed prior to the release of equipment and materials. Each survey record should include the following:
  - drawing of the materials surveyed
  - list of items and equipment surveyed

- specific locations on the survey diagram where wipe test was taken
- ambient radiation levels with appropriate units
- contamination levels with appropriate units
- make and model number of instruments used
- background levels
- name of the person making the evaluation and recording the results and date.

D. Revise SOP-16, "Radioactive Contamination Control Program."

1. Expand the SOP reference section to specify clear reference to other SOPs that are applicable to the work to be performed. As appropriate references should be included that point to sections of the RPP that provide additional clarifying detail. Your current reference section has reference to Regulatory Guide 8.21; Regulatory Guide 1.86, and NUREG-1556 Vol. 12 Appendix P. The simple listing of these documents in your procedure does not provide clarity regarding what aspects of the guidance documents are applicable to your program. It is necessary to indicate that you have either adopted a specific reference in its entirety, or address what parts of the reference are to be enforced, or modify your SOP to incorporate guidance information you wish to implement and enforce as part of your radiation protection program guidance.

As noted above in this letter, it will be necessary that your RPP and other SOPs be modified to be consistent. The information and commitments requested for this SOP, once approved in your license will supersede other previously submitted documents that were tied down in Condition 22 of your license that discuss similar radiation program commitments.

2. Describe in greater detail SOP Section 1.1, "Unrestricted Areas." Clarify that this section applies to both indoor and outdoor areas.
3. Describe in greater detail SOP Section 1.2.2 "Contaminated Areas," that is discussed under Section 1.2 "Restricted Areas." Clarify that a contaminated area is any area exceeding the action limits regardless whether or not it is inside or outside the production buildings.
4. Expand SOP Section 2, "Action Level." This SOP commitment should ensure that personnel working in an area with measured contamination exceeding your specified action limits, and if the area is not immediately restricted until it is decontaminated, are immediately informed of the elevated levels and advised of interim actions and restrictions to be followed.

5. Revise SOP-16, and SOP-33 "Use of Protective Clothing and Equipment (PCE)" to ensure that the definitions of contaminated and restricted areas are logical and consistent with one another. Review of the definitions and application of contamination criteria in SOP-16 and SOP-33 appear to conflict with one another.
  6. Clarify that Section 4 "Stop Work" is applicable to both inside and outside ARC facilities. Discuss the level of management required to restart work in radiological areas after a stop work action has been implemented.
  7. Clarify and justify SOP Section 5.1 that indicates material and equipment are surveyed on an as needed basis. It is questionable that materials and equipment removed from an area with removable contamination would not warrant surveying.
  8. Expand and clarify SOP Section 5.9 "Unrestricted Areas." The present commitment is specific to unrestricted areas inside the production buildings. Based on recent NRC inspections, significant contamination in out-door areas of your site has been identified on asphalt drives, concrete, and soil areas that appear to have resulted from movement of contaminated waste and past spills, leakage of liquids from production exhaust stacks, and run-off from the production buildings. Include a Section or modify a Section of the current SOP that addresses the frequency of survey and the contamination action limits to be applied if different than the unrestricted area criteria.
  9. Expand SOP Section 6.5 to specify when decontamination in an area exceeding the limits will occur. Also, provide information regarding interim measures that will be taken to inform personnel that limits are being exceeded, and what protective measures will need to be implemented until the contamination levels have been reduced to acceptable levels.
  10. Submit the survey record referenced in Section 6.3 that will be used to document fixed and wipe test surveys.
  11. Clarify SOP Section 6.7 regarding the use of the survey meter. Typically, when collecting a wipe a direct measurement is performed, so that the ratio of fixed contamination to removable contamination (removable fraction) can be determined.
- E. Revise SOP-33, "Use of Protective Clothing and Equipment (PCE)."
1. Describe in greater detail and expand the actions to be implemented in SOP-33, Section 4.3, regarding monitoring of hands. Specifically, discuss what background levels on the radiation meters used to frisk for personal contamination are considered adequate to ensure proper monitoring of hands and face and clothing. During several NRC inspections, meters used for frisking personnel exiting contaminated areas were identified with contamination levels on the detector probes with levels that made questionable the employees ability to identify personal contamination on their hands and

clothing using a discrimination level of background. Discuss the actions that will be implemented daily to ensure the monitors are functioning appropriately and that personnel understand what background or reading on the meter will prompt additional decontamination and or notification of the RSO.

2. Describe in greater detail, the actions that will be implemented to ensure that personnel exiting contaminated areas clothing and other personal items are not contaminated. During previous NRC inspections, personnel clothing, safety glasses, shoes, coats, and personal items such as lunch boxes were identified with significant levels of contamination. It appears appropriate that your SOP be expanded to include frisking of clothing and exposed body parts such as the face, prior to exiting contaminated areas.
3. Describe the contamination action limit that will be used for evaluating employees' personal clothing and personal items. Also, discuss the actions to be taken if the action limit is exceeded.

F. SOP-34, "Surface Soil Sampling for Site Characterization."

1. Modify this SOP or develop another SOP that will allow ARC to perform both site characterization surveys for dose estimates, and other surveys for developing estimates for operational remediation activities.
2. Regarding the pad construction, discuss in greater detail the sampling that will be done prior to the excavation of the soil. What criteria will be used to determine if the soil will be used for back-fill or disposed of as radiological waste. For example, if the contamination in the soil appears to be generally uniform and less than the NRC NUREG-1757 Screening Values, it would appear to be reasonable that no restrictions would be necessary. However, if the soil contamination levels are not uniform and are greater than the screening values, then it appears to be appropriate that a work instruction would be developed and implemented. Clarify what levels will trigger certain actions, such as area restrictions, postings, and or waste disposal.
3. Expand the description of ARC's approach for monitoring and sampling the soil and related out-door media that will either be disturbed or remediated for operational purposes. ARC's sampling procedure and approach must define the bounds of the work to be performed, such as, but not necessarily be limited to activities like: soil and asphalt removal, landscaping, installation and or changes to utilities or production storage tanks, or other activities that would disturb the soil and increase the potential for release of radiological materials into the environment.

The description should discuss the number of samples to be collected per unit area, and how the sampling points inside the area to be sampled will be distributed within the sampling area, such that an average concentration for the soil can be derived. Provide the sampling and survey report that will document the survey work. Please include the map/grid description that will be used in conjunction with the report.

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- G. If soil is to be disposed of as radiological waste, discuss the method for characterizing the waste to meet DOT and vendor waste disposal criteria.
- H. Provide additional information regarding the local and State agencies that were contacted regarding construction work on the buildings and the construction of the pad for the nitrogen tank. Please, indicate what permits were needed and that local ordinances have been satisfied.

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>.

If you have any questions regarding this letter, please do not hesitate to contact me at (630) 829-9856.

Sincerely,

*/RA/*

George M. McCann, Senior Health Physicist  
Materials Control, ISFSI, and  
Decommissioning Branch

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

cc: R. Greenwood, RSO



S. Gupta

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