July 9, 2013

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 renewal to NRC License Number 24-21362-01 and find that we will need the following additional information.

Items A. through D. address topics pertaining to historically-related licensing and inspection issues. The remainder of the letter addresses deficiencies identified in your renewal application, and is organized in a manner that follows the sections which appear in your application.

A. CNWRA Recommendations

As a result of a July 7 through 8, 2010, site visit by a representative of the Center for Nuclear Waste Regulatory Analyses (CNWRA) and staff from the NRC Region III office to evaluate ARC's air effluent system, issues were identified pertaining to air effluent, public dose, and ALARA, which were documented in a September 2010 report issued by CNWRA. The report was forwarded to you for your review.

The recommendations that were made by the CNWRA and described in the report were as follows:

1. The practice of averaging the four air sampling measurements taken at four locations on building 400 to obtain an average concentration should be reconsidered because the air that enters building 400 is not mixed. The CNWRA recommended that instead, each of the four locations be tracked separately and that each should be compared to the public dose limits in 10 CFR 20.1302 and 10 CFR 20.1101(d);

2. The CNWRA evaluated the appropriateness of designating building 400 as the representative location of the nearest member of the public. They recommended that a study that includes air sampling be conducted at the warehouse located south of the ARC facility at the closest air intake to ensure that doses do not exceed those measured at building 400. They also recommended that the study include sampling during each of the four seasons; and

3. Tritium and carbon-14 air concentrations measured at building 400 have historically been below the public dose limits, although they were found to be consistently close to the limit. The CNWRA recommended that ARC investigate modifying its handing procedures or use additional, cost-effective engineered controls to reduce radionuclide emissions from its facilities to keep exposures ALARA.

On September 30, 2010, you submitted a letter to our office which described a commitment that ARC would, among other things: (1) Propose changes to its RPP and SOP's to correct deficiencies brought to light by the CNWRA report; (2) Review the changes with Region III; and (3) Submit a license amendment request to institute the changes.

On September 8, 2011, you provided a response to the recommendations. However, we will need you to provide additional detail as follows. Each item below corresponds to the numbered recommendation that listed is above:

1. Identify when you started tracking the four sampling stations located on building 400 separately, and provide the assessments of public dose from each sampler since you instituted this change.

2. You did not address this issue. It was recommended that you conduct air sampling at the warehouse located south of ARC, and that the sampling be conducted each of the four seasons. In your response, you simply stated that ARC uses the COMPLY code which used 16 data points around the facility.

3. Describe the "production methods" that the chemists have implemented to address the recommendation that ARC modify its handing procedures or use additional, cost-effective engineered controls to reduce radionuclide emissions from its facilities to keep exposures ALARA. Please illustrate how and why these new/revised "production methods" have worked to reduce the calculated annual public dose, and commit to full implementation of these "production methods."

B. <u>Storage of Surface-Contaminated Objects (SCO)</u>

During the NRC inspection conducted from May through June 2013, the inspectors identified that the designated area for storage of SCO was exceeding capacity and that some SCO was apparently being stored in areas not authorized on the license.

Please describe plans to address the storage capacity issues for SCO, as well as plans for shipment of SCO items for final disposal.

C. <u>Building 300 Stack Blower</u>

During the NRC inspection conducted from May through June 2013, ARC's Radiation Safety Officer (RSO) informed the inspectors that ARC would document a procedure to evacuate building 300 labs if the building 300 stack blower would ever fail, and not allow lab re-entry until 30 minutes after the blower is restarted. The RSO stated that the

procedure would address the inspectors' concern about potential increased levels of radioactivity in the air of building 300 in the event of stack blower failure, which could result in increased internal radiation doses to laboratory personnel.

The RSO also informed the inspectors that ARC does not possess an instrument to measure the volume of air released from the building 300 stack per unit time; therefore, ARC sums the volume of air per unit time from each fume hood in building 300 to estimate the volume of air released from the building 300 stack per unit time. In addition, the RSO stated that ARC was planning to hire a contractor to directly measure the volume of air released from the building 300 stack per unit time.

Please submit a copy of the procedure that has been developed to address the inspectors' concerns about the potential impact on occupational radiation dose if the stack blower fails. Also, submit a timeline for following through on your plan to hire a contractor to directly measure the volume of air released from the building 300 stack per unit time.

D. Status of Building 300 Annex

Please confirm our understanding that building 300 annex is not currently being used to process and handle radioactive material. Since NRC approval of building 300 annex would be a significant undertaking, it would be preferable to conduct such a review as an action that would be separate from this license renewal application.

E. Radioactive Material

1. You did not include a request for authorization for iron-55 or iron-59. Please confirm that you no longer need authorization for these two nuclides and submit evidence that this material has been properly disposed of and that you do not possess these nuclides in any form.

2. We are in receipt of ARC's revised decommissioning financial assurance (DFA). It has been processed in by our office as a separate action and will be reviewed by our staff independently of your application for license renewal. Correspondence from us regarding your revised DFA will be addressed to you under separate letter.

F. Purpose For Which Licensed Material Will Be Used

Confirm that license number 24-21362-02E (exempt distribution) is still active and that you need to retain authorization to possess material under 24-21362-02 incident to distribution of labeled compounds under the exempt distribution license.

Provide an update and/or status on the authorization currently granted in items 9. A. and E. of your license related to outdoor site construction and beautification activities.

G. Individuals Responsible For Radiation Safety Program and Their Training and Experience

1. For Class 1 workers under the section “All Other Radiation Workers”, define what you mean by the statement that these workers may use radioactive material under “general supervision” of an authorized user.

2. For Class 2 workers under the same section, please define what you mean when you say that these workers may use radioactive material only under “direct supervision” of a Class 1 worker.

3. For Class 1 and 2 workers, a statement is made that both may use material “within their area of responsibility.” Please define what the “area or responsibility” is for both.

4. A process has been established whereby a Class 1 or 2 worker may receive a recommendation for a radiation worker upgrade if either “has demonstrated good handling techniques with radioactive materials and has satisfactorily completed on-the-job training.” Please describe criteria that will be used by an authorized user to determine when a Class 1 or 2 worker has met these expectations.

H. Training Program

1. Describe in detail the “radiation safety indoctrination” that is given to new employees by the RSO.

2. Describe in detail the “refresher training” that is given every year, and to whom the training is provided.

3. Provide examples of written exams that are given to evaluate the effectiveness of training.

I. Facilities and Equipment

1. For each building where radioactive material may be received, please describe (through the use of a diagram) where the receipt and storage areas are located.

2. Submit a diagram of buildings 100 and 200 which illustrates the ventilation (air supply and exhaust systems) and how the systems connect between the two buildings.

3. Describe filtration that is used for radioactive air effluent exhaust for all buildings. Describe how filters are checked for saturation, and submit filter change-out procedures.

4. Describe the minimum air flow that will be maintained for the radioactive air effluent exhaust systems.

5. Describe the ventilation systems for building 300 and 300 annex.

J. Audit Program

In your application you provided a brief statement committing to a third party audit program. Please describe in greater detail, the following: (1) The purpose and content of the audit; (2) How the results of the audit will be communicated to the RSO and Radiation Safety Committee (RSC) and; (3) ARC's process or program for addressing issues or areas of improvement that are identified by the auditor.

K. Radiation Protection Program

Item 2.1.j.: An authorized user is defined, in part, as someone who "directly supervises the use of licensed material." Define the term "directly supervises."

Item 3: Provide a list by name of the members of the RSC.

Describe the RSC's roles and responsibilities in reviewing the radiation protection program (RPP) and addressing issues that have been identified either internally by ARC employees, or through external organizations, e.g., the NRC or other regulatory agencies, external auditors, etc.

Item 3.3.3.5 Confirm that the results of the RSO's annual review of the RPP will be documented. Submit a copy of the report of the audit that was conducted by the RSO in 2012.

Identify who the third party auditor was for 2012 and who it will be for 2013. Describe their qualifications.

Describe the process for communicating results of the annual review conducted by the RSO and the yearly third party audit to the RSC. Describe the process that the RSC will use to address recommendations made from both the annual review and third party audit.

Item 3.3.3.7 Describe the content of the summary reports and the frequency at which they will be issued.

Item 3.3.3.8 Confirm that safety evaluations which the RSO makes of any new synthesis proposal, will be documented.

Items 3.3.4.5 & 6 Describe the content of on-the-job (OJT) training and confirm that it will be documented.

Item 3.3.4.8 Provide examples of the types of records that will be maintained with regard to the RPP.

Items 3.3.4.10 and 11 Confirm that the president of ARC has given the RSO the authority to stop operations that threaten safety or are not in compliance with NRC regulations or ARC's license.

Item 3.3.5 Confirm that the president of ARC has given the assistant RSO, in the absence of the RSO, stop work authority.

Item 3.3.6 Confirm that any of the RSO's duties which are performed by an outside consultant will only be performed under the direct supervision (i.e., with the RSO physically present on site) of the RSO.

Item 4.2.2.6 A statement is made in this section that areas and equipment will be decontaminated at the "next practical time" if contamination is above certain levels. Be more definitive as to what "next practical time" means. In order to avoid the accumulation of contaminated areas and equipment to the point at which it becomes out of control, please establish a "no later than" date/policy.

Item 5.2.3 Describe the types of the probes which will be used to perform personal contamination surveys.

Item 5.2.3.2 Describe instrumentation that will be used (including probes) for surveying items that will be taken from laboratories to prevent transfer of contamination. Define the threshold for determining when contaminated items can or cannot be transferred from contaminated to non-contaminated areas.

Item 5.7.2.3 Define "high energy beta emitter", and describe the types of beta shields that will be used.

Item 6.1 This item discusses ARC's training program. A statement is made that "the extent of training is dependent upon their experience and training with radioactive material and their educational background." Please establish and submit criteria that will be used to evaluate a person's previous experience and training with radioactive material in order to determine how much training he/she should receive at ARC. In addition, regardless of a person's previous experience and training, there must be a certain level of training that should be required for all employees.

Item 9.1.2 Submit a copy of your program for training employees in the use of the compactor. Confirm that, at a minimum, the manufacturer's instructions will be followed.

Item 9.2.7 Define the monthly and yearly limit values for each radionuclide that can be discharged as liquid waste.

Item 9.4.1.4 Identify the fume hoods in building 200 that are designated for waste evaporation. List the radionuclides that will undergo the evaporation process.

Item 9.4.1.2 Describe your program for monitoring air effluent that is released from non-aqueous liquid waste.

Item 9.4.1.6 Describe the personal contamination surveys that will be performed after an individual performs liquid waste evaporation operations.

Item 9.4.2.2 Describe the process for analyzing low level aqueous waste to determine if it may be discharged into the sanitary sewer.

L. **Standard Operating Procedures**

SOP-01 Dry Solid Radioactive Waste Compaction Program

Identify individuals by title, who can directly use the compactor and those who cannot.

Confirm that ARC has and will follow the manufacturer's instruction manual for the compactor.

Describe the criteria that will be followed for determining whether or not the floor area should be surveyed. Include a description of the types of surveys that will be performed (ref. 3.2.13).

Provide a list of radionuclides that can be compacted.

Describe the location of the compactor and associated air supply and exhaust systems, air effluent monitoring that will be conducted, and any exhaust filtration that exists.

SOP-02 In Vitro Bioassay Program

Submit a bioassay program for other radionuclides listed on your license, e.g., iodine-125, or provide justification for not including these nuclides in the program.

Describe the criteria for determining which ARC employees will be required to provide a urine sample each Monday (ref. 4.1).

Submit the counting protocol 3, which was not included with this SOP (ref. 4.2).

SOP-03 C-14 and H-3 Air Monitoring Program

Describe the procedure that will followed for calibrating the rotameter and the frequency at which it will be calibrated (ref. 1.1).

Describe how you will determine if an area may have concentrations exceeding 10% of permissible limits that would require air sampling, and describe your procedure for checking air sampling stations (ref 2.1).

Describe criteria that will be used to determine the frequency at which air sampling will be performed (ref 3.1).

Distinguish between continuous air sampling (ref 3.2) and intermittent air sampling (ref 3.3). Describe criteria that will be used to determine which will be implemented.

SOP-06 Program For Picking up and Receiving and Opening Incoming Radioactive Materials

Your action levels are provided in cpm per square area; however, NRC regulations are in dpm per square area. Provide action levels in dpm per square area, and describe the procedure for converting instrument readings (cpm) to activity (dpm) (ref 1.6).

Define what you mean by "higher than expected" (ref 2.7 & 2.1.3).

Describe the type of probe that will be used for surveying packages (ref 2.15).

SOP-07 Liquid Waste Disposal Program

Describe the training that maintenance personnel will receive in taking and analyzing samples safely and accurately (ref 4.0).

SOP-08 Radioactive Waste Program

Describe who, by title, will be authorized to use the compactor, and the details of the training that they will receive (ref 1.2.1).

Describe the probe that will be used to survey waste which is held for decay (ref 3.1.6).

Describe how non-aqueous liquid waste effluent that is released to an unrestricted area is monitored. Why and how can it be released to an unrestricted area? Describe specifically what unrestricted areas you are referring to (ref 4.1.2).

Item 4.2.2 makes a reference to RPP Section 3.3.4.12. The RPP stops at Section 3.3.4.11. If there is a section 3.3.4.12, please revise the RPP accordingly and submit the revision for our review.

SOP-10 ARC Shipping Program

Your action levels are provided in cpm per square area; however, NRC regulations are in dpm per square area. Provide action levels in dpm per square area, and describe the procedure for converting instrument readings (cpm) to activity (dpm) (ref 4.1.2 & 4.1.4).

SOP-12 In Vivo Bioassay Program

In your application you requested authorization for 1.5 curies of iodine-125 for manufacturing and synthesis of radiolabeled compounds, yet you stated that this SOP is no longer applicable and that it would be reinstated in the event that ARC begins processing significant amounts of radio-iodines. Unless you describe specific controls on the type and amount of unlabeled and labeled iodine-125 that can be processed by an individual at any one time, you must submit a bioassay program for iodine-125.

SOP-18 Liquid Waste Evaporation Program

Describe how effluent which is released to an unrestricted is monitored. Explain why and how effluent would be released to an unrestricted area from this process (ref 1.2).

Identify the fume hoods where this process will take place (ref 1.4), and describe the minimum fume hood flow rate that will be maintained and how you will verify the flow rate.

Describe filtration that is used for air effluent and the method and frequency for checking filters for saturation.

SOP-26 Beta/Gamma TLD Monitoring

Provide an assessment which demonstrates that occupational workers are not likely to exceed 10 percent of the yearly limit for whole body and extremity exposure to high energy beta emitters authorized on your license, and iodine-125.

SOP-29 Storage of Surface Contaminated Objects

In order to prevent long term storage of surface contaminated objects (SCO), please develop and submit a plan which will describe the timely disposition of objects that will not be re-used but will be discarded as radioactive waste. Also, describe a timeline for making decisions about SCO that is being held for potential future use. A plan should be developed to avoid holding SCO for too long of a period whereby you create a shortage of storage space and potential safety issues (ref 4.0).

SOP-30 Release of Material

Describe the probes that will be coupled to the GM meter to scan equipment (ref 2.1).

Confirm that action levels for the release of material will be based on liquid scintillation counter results from smears taken on the equipment, and not GM meter survey readings.

SOP-31 Protocol for Packaging and Shipping Items to Japan

Explain the significance of the action level of 200 counts for wipes that are taken on primary containers. What is the conversion to dpm? How does the value relate to background? What type of instrument is used to analyze the wipes? (ref 2.1.2.3 and 2.1.2.4; 2.2.5.3 and 2.2.5.4; 2.3.1.4 and 2.3.1.5; and 3.1.1).

SOP-32 Segregation of Dry Active Waste

This procedure includes action levels of 150 counts and 150 cpm for direct survey readings. Explain the significance in choosing these actions levels. How do they relate to background? What type of probe is used?

SOP-33 Use of Protective Clothing and Equipment

You have established a personal contamination survey action level of twice background for individuals who exit a restricted area. Our expectation is that individuals who exit any restricted area should be free of contamination after removal of protective clothing and that survey readings should be at background. Please provide an explanation why you have chosen a threshold that is twice background, or modify your procedure (ref 4.3).

SOP-34 Surface Soil Sampling for Site Characterization

Modify this procedure to include action levels and a description of the type of action that will be taken. Commit to submitting all of the raw data results to the NRC any time that you exceed a threshold and are required to perform an action. Please modify the procedure by committing to submit results of the surveys that indicate you exceeded a threshold, and include a description of the action that will be taken.

SOP-36 Excavation and Backfill of Soil Due to Gas Line Repair

It is our understanding that this was a procedure which was developed to address an issue with a leaking gas line that has since been repaired. This procedure appears to be no longer applicable. Please delete the procedure or provide justification why you would like it to remain active.

SOP-41 Inventory of Surface Contaminated Objects

Please modify the note under item 4.0 to state that the "analysis and labeling must take place prior to transport of the SCO to the processing facility."

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.

The NRC's Safety Culture Policy Statement became effective in June 2011. While a policy statement and not a regulation, it sets forth the agency's *expectations* for individuals and organizations to establish and maintain a positive safety culture. You can access the policy statement and supporting material that may benefit your organization on NRC's safety culture Web site at http://www.nrc.gov/about-nrc/regulatory/enforcement/safety-culture.html. We strongly encourage you to review this material and adapt it to your particular needs in order to develop and maintain a positive safety culture as you engage in NRC-regulated activities.

Please submit a response to this letter no later than August 1, 2013. In your response, please reference as additional information to Control Number 575968. You may contact me at (630) 829-9854 if you have any questions.

Sincerely,

/RA/

Kevin G. Null
Materials Licensing Branch
Division of Nuclear Materials Safety

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

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Kevin G. Null
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Docket No.: 030-20567
License No.: 24-21362-01

*See previous concurrence
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