



UNITED STATES
NUCLEAR REGULATORY COMMISSION

REGION III
2443 WARRENVILLE ROAD STE 210
LISLE, ILLINOIS 60532-4352

SEP 30 2010

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

Dear Dr. Gupta:

Enclosed is Amendment No. 42 renewing your NRC Material License No. 24-21362-01 in accordance with your request.

Please note that as discussed with Regis Greenwood of your staff, your NRC license has been renewed with a 1 year expiration date of October 31, 2011. A 1 year expiration date was issued primarily as a result of air effluent, public dose, and ALARA issues that were identified by the Center for Nuclear Waste Regulatory Analyses (CNWRA) during a July 2010 site visit to evaluate ARC's air effluent system. The results of their review were described in a report dated September 16, 2010 (enclosure 2). Be advised that your letter dated September 30, 2010, in which you committed to addressing the issues that are described in the report through an amendment to your NRC license no later than the expiration date of the license, has been incorporated as a requirement in license condition number 21.B.

In parallel with the CNWRA report, please note that we are continuing our review of your May 25, 2010, response to questions that we had regarding ARC's use of the Gaussian dispersion equation that was used to calculate ground level concentrations due to air effluents released from the new stacks that ARC installed to service buildings 100, 200, and 300. We will communicate the results of our review in the near future.

The NRC also felt that a 1 year expiration date was appropriate at this time given the recent inspection history at ARC. Specifically, NRC inspection activities have identified issues that include, but are not limited to, problems with contamination control in restricted and unrestricted areas, a trend which illustrates a gradual increase in calculated public dose from air effluents from 2005 to present, concerns over ARC's implementation of an effective ALARA program, and unresolved inspection issues including, for example, the characterization of contamination of on-site soil.

Also as a result of the outstanding issues described above, please be aware that we have not approved the new annex building for the use of iodine-125 at this time. Authorization for the annex building may be reconsidered after such time that ARC has demonstrated a marked improvement in the implementation of its Radiation Protection Program (RPP).

Please note that both the RPP and Standard Operating Procedures (SOP) are tied down in your license. ARC is not authorized to modify its RPP or SOP's without first applying for and receiving an amendment to its NRC license. In addition, ARC must also apply for and receive an amendment to its license to add authorized users, change the RSO, or modify existing or add new facilities.

However, we have approved your request for flexibility to modify forms that are attached to the SOP's as long as they contain the required information that is described in the relevant SOP.

Lastly, based on communications with Mr. Greenwood and confirmed in a follow-up letter to us dated September 22, 2010, it is our understanding that ARC is currently working on supplemental procedures to your license and will be submitting the following documents to our office no later than the end of the calendar year 2010: 1) a program for auditing the storage of surface contaminated objects (ref. SOP-29); 2) expanded emergency procedures that address items 8.3.1 and 8.3.2 of your RPP; and 3) an overall inventory program for tracking all radioactive waste generated at ARC.

Please review the enclosed document carefully and be sure that you understand all conditions. If there are any errors or questions, please notify the U.S. Nuclear Regulatory Commission, Region III office at (630) 829-9887 so that we can provide appropriate corrections and answers.

Please be advised that your license expires at the end of the day, in the month, and year stated in the license. Unless your license has been terminated, you must conduct your program involving byproduct materials in accordance with the conditions of your NRC license, representations made in your license application, and NRC regulations. In particular, note that you must:

1. Operate in accordance with NRC regulations 10 CFR Part 19, "Notices, Instructions and Reports to Workers; Inspections," 10 CFR Part 20, "Standards for Protection Against Radiation," and other applicable regulations.
2. Notify NRC, in writing, within 30 days:
 - a. When the Radiation Safety Officer permanently discontinues performance of duties under the license or has a name change; or
 - b. When the mailing address listed on the license changes.
3. In accordance with 10 CFR 30.36(b) and/or license condition, notify NRC, promptly, in writing, and request termination of the license:
 - a. When you decide to terminate all activities involving materials authorized under the license; or
 - b. If you decide not to complete the facility, acquire equipment, or possess and use authorized material.
4. Request and obtain a license amendment before you:
 - a. Change Radiation Safety Officers;
 - b. Order byproduct material in excess of the amount, or radionuclide, or form different than authorized on the license;
 - c. Add or change the areas of use or address or addresses of use identified in the license application or on the license; or
 - d. Change ownership of your organization.

5. Submit a complete renewal application or termination request at least 30 days before the expiration date of your license. You will receive a reminder notice approximately 90 days before the expiration date. Possession of byproduct material after your license expires is a violation of NRC regulations. A license will not normally be renewed, except on a case-by-case basis, in instances where licensed material has never been possessed or used.

In addition, please note that NRC Form 313 requires the applicant, by his/her signature, to verify that the applicant understands that all statements contained in the application are true and correct to the best of the applicant's knowledge. The signatory for the application should be the licensee or certifying official rather than a consultant.

You will be periodically inspected by NRC. Failure to conduct your program in accordance with NRC regulations, license conditions, and representations made in your license application and supplemental correspondence with NRC will result in enforcement action against you. This could include issuance of a notice of violation, or imposition of a civil penalty, or an order suspending, modifying or revoking your license as specified in the General Statement of Policy and Procedure for NRC Enforcement Actions. Since serious consequences to employees and the public can result from failure to comply with NRC requirements, prompt and vigorous enforcement action will be taken when dealing with licensees who do not achieve the necessary meticulous attention to detail and the high standard of compliance which NRC expects of its licensees.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter and the enclosed license will be available electronically for public inspection in the NRC Public Document Room or from the Publicly Available Records (PARS) component of NRC's document system (ADAMS). The NRC's document system is accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html> (the Public Electronic Reading Room).

Sincerely,



Kevin G. Null
Materials Licensing Branch

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

Enclosure: 1) Amendment No. 42
2) CNWRA report dated September 16, 2010