



UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION IV
1600 E. LAMAR BLVD
ARLINGTON TX 76011-4511

October 4, 2017

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Radiation Safety Officer
Department of Health and Human Services
Food and Drug Administration
National Center for Toxicological Research
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Jefferson, AR 72079

SUBJECT: LICENSE RENEWAL

Please find enclosed Amendment Number 17 to NRC License Number 03-15093-01 renewing this license in its entirety as requested. Please note that the license expiration date has been extended from 10 years to 15 years in accordance with revised NRC licensing guidance. Also note that this license no longer authorizes radioactive materials in quantities of concern and therefore the markings "Official Use Only – Security-Related Information" have been removed from this license.

An environmental assessment for this action is not required since this action is categorically excluded under 10 CFR 51.22(c)(14)(v). You should review this license carefully and be sure that you understand all conditions. You can contact me at 817-200-1189 if you have any questions about this license.

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.

NRC expects licensees to conduct their programs with meticulous attention to detail and a high standard of compliance. Because of the serious consequences to employees and the public that can result from failure to comply with NRC requirements, you must conduct your radiation safety program according to the conditions of your NRC license, representations made in your license application, and NRC regulations. In particular, note that you must:

1. Operate by NRC regulations 10 CFR Part 19, "Notices, Instructions and Reports to Workers: Inspection and Investigations," 10 CFR Part 20, "Standards for Protection Against Radiation," and other applicable regulations.
2. Notify NRC in writing of any change in mailing address.

3. By 10 CFR 30.36(d) 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 whether at the entire site or any separate building or outdoor area;
 - b. If you decide not to acquire or possess and use authorized material; or
 - c. When no principal activities under the license have been conducted for a period of 24 months.
4. Request and obtain a license amendment before you:
 - a. Change Radiation Safety Officers; or
 - b. Order byproduct material in excess of the amount, radionuclide or form authorized on the license.
5. Submit a complete renewal application or termination request at least 30 days before the expiration date on your license. You will receive a reminder notice approximately 90 days before the expiration date. Possession of radioactive material after your license expires is a violation of NRC regulations.

In addition, please note that NRC Form 313 requires the applicant, by 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. Since the NRC also accepts a letter requesting amendment of an NRC license, the signatory for such a request should also be the licensee or certifying official rather than a consultant.

NRC will periodically inspect your radiation safety program. Failure to conduct your program according to NRC regulations, license conditions, and representations made in your license application and supplemental correspondence with NRC may result in enforcement action against you. This could include issuance of a notice of violation; imposition of a civil penalty; or an order suspending, modifying, or revoking your license as specified in the NRC Enforcement Policy. The NRC Enforcement Policy is available on the following internet address:
<http://www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html>.

An electronic version of the NRC's regulations is available on the NRC Web site at www.nrc.gov. Additional information regarding use of radioactive materials may be obtained on the NRC Web site at <http://www.nrc.gov/materials/miau/mat-toolkits.html>. This site also provides the link to the toolbox for updated information on the revised regulations for naturally-occurring and accelerator-produced radioactive materials (NARM).

K. Daniel

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

Thank you for your cooperation.

Sincerely,

/RA/

Roberto J. Torres, M.S., Senior Health Physicist
Materials Licensing and Inspection Branch

Docket: 030-08559
License: 03-15093-01
Control: 600605

Enclosure: As stated