



UNITED STATES  
NUCLEAR REGULATORY COMMISSION

REGION IV  
612 EAST LAMAR BLVD, SUITE 400  
ARLINGTON, TEXAS 76011-4125

March 8, 2011

Department of Health and Human Services  
Food and Drug Administration  
National Center for Toxicological Research  
ATTN: Danny Forbush  
Radiation Safety Officer  
3900 NCTR Road  
Jefferson, AR 72079

SUBJECT: LICENSE AMENDMENT

Please find enclosed Amendment Number 14 to NRC License Number 03-15093-01 **removing Items 6.B., 7.B., 8.B., and 9.B. from the license, as requested. In addition, please note that License Condition 26 has been removed since you are no longer required to comply with the requirements of the "Order Imposing Increased Controls" (ADAMS Accession Number ML053130183) published in the Federal Register on December 1, 2005 (70 FR 72128); and with the "Order Imposing Fingerprinting and Criminal History Records Check Requirements for Unescorted Access to Certain Radioactive Materials" (fingerprinting Order) (ADAMS Accession Number ML073230738) published in the Federal Register on December 13, 2007 (70 FR 70901). However, please note that if and whenever you amend your license to include radionuclides in quantities of concern, you are required to complete implementation of said requirements by the first day that radionuclides in quantities of concern are possessed at or above the limits specified "Table 1: Radionuclides of Concern" contained within the fingerprinting Order, and notify, in writing, the Director, Office of Federal and State Materials and Environmental Management Programs, U.S. NRC, Washington, DC, 20555, when you have completed these requirements.**

NRC's Regulatory Issue Summary (RIS) 2005-31, provides criteria to identify security-related sensitive information and guidance for handling and marking of such documents. This ensures that potentially sensitive information is not made publicly available through ADAMS. The RIS may be located on the NRC Web site at: <http://www.nrc.gov/reading-rm/doc-collections/gen-comm/reg-issues/2005/>. Additionally, the link for frequently asked questions may be located at: <http://www.nrc.gov/reading-rm/sensitive-info/materials.html>. Pursuant to NRC's RIS 2005-31, the enclosed materials license will not be made publicly available.

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 the enclosed document carefully and be sure that you understand all conditions. If there are any errors or if you have any questions, contact me at 817-860-8132.

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;
  - b. Order byproduct material in excess of the amount, radionuclide or form authorized on the license;
  - c. Add or change the areas or address(es) of use identified in the license application or on the license, except for areas of use where byproduct material is used only in accordance with either 10 CFR 35.100 or 35.200; or
  - d. Change the name or ownership of your organization.
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/reading-rm/doc-collections/enforcement/>.

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NRC no longer publishes the NRC Rules and Regulations loose leaf supplements. However, an electronic version of the NRC's regulations is available on the NRC Web site at [www.nrc.gov](http://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).

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 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/*

Jacqueline D. Cook, Senior Health Physicist  
Nuclear Materials Safety Branch B

Docket: 030-08559  
License: 03-15093-01  
Control: 574036

Enclosures: As stated