



UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION IV
611 RYAN PLAZA DRIVE, SUITE 400
ARLINGTON, TEXAS 76011-4005

August 15, 2007

Department of Health & Human Services
Food & Drug Administration
National Center for Toxicological Research
ATTN: Jennings E. Partridge
Radiation Safety Officer
3900 NCTR Road
Jefferson, Arkansas 72079

SUBJECT: LICENSE RENEWAL

Please find enclosed Amendment No. 12 to NRC License No. 03-15093-01. **The possession limit designation in Item 8.A has been changed based on our August 15, 2007 telephone conversation.**

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/faqlist.html>, then select "Withholding of Sensitive Information." Pursuant to NRC's RIS 2005-31, the enclosed materials license will not be made publicly available.

Please note that by License Condition 26 you are required to comply with the "Increased Controls for Licensees that Possess Sources Containing Radioactive Material Quantities of Concern" (IC) (ADAMS Accession No. ML053130364) published as "Attachment B" to the "Orders Imposing Increased Controls" (ML053130218) in the Federal Register on December 1, 2005 (70 FR 72128). This License Condition requires you to complete implementation of said requirements by the first day that radionuclides in quantities of concern are possessed at or above the limits specified in "Table 1: Radionuclides of Concern" found in the IC, 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 the requirements of this License Condition. Your response must be marked as "Withhold from Public Disclosure Under 10 CFR 2.390."

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, please contact me at 925-673-9646.

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/what-we-do/regulatory/enforcement/enforc-pol.pdf>.

The 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. To view these regulations, highlight "Electronic Reading Room" and choose "Regulations" on the drop down menu. An electronic version of the NUREG-1556 Series publications is also available on the NRC Web site. To view these guidance documents, highlight "Electronic Reading Room"; choose "Collections"; choose "NUREG-Series Pubs"; and select "Publications Prepared by the NRC Staff". Then, choose "NUREG-1556" from the table and select the appropriate volume(s) for your license type.

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

James L. Montgomery, Health Physicist
Nuclear Materials Licensing Branch

Docket: 030-08559
License: 03-15093-01
Control: 471413

Enclosures: As stated