



**UNITED STATES
NUCLEAR REGULATORY COMMISSION**
REGION I
2100 RENAISSANCE BLVD.
KING OF PRUSSIA, PA 19406-2713

November 2, 2016

Brian Baker, Director
Department of Health and Human Services
Food and Drug Administration
Winchester Engineering and Analytical Center
109 Holton Street
Winchester, MA 01890-1197

**SUBJECT: DEPARTMENT OF HEALTH AND HUMAN SERVICES, FOOD AND DRUG
ADMINISTRATION, LICENSE RENEWAL, MAIL CONTROL NO. 591011**

Dear Mr. Baker:

This refers to your request for renewal of your NRC license. Enclosed with this letter is the license. Please review the license carefully and be sure that you understand and fully implement all the conditions of the license. If there are any errors or questions, please contact me at 610-337-5040 or via electronic mail at Elizabeth.Ullrich@nrc.gov so that appropriate corrections or answers can be provided.

Please note that the molybdenum-99 and technetium-99m are now listed on rows D and E of the license. They are in secular equilibrium so they are listed in the same amount. This is a change from the format of the previous license where they were listed on a single row (row J) to indicate this fact. In addition, many other changes were made to the license authorizations during this renewal. If any of the new authorizations are incorrect due to our misunderstanding of the changes, please let us know.

An environmental assessment for this action was not required, since this action is categorically excluded under 10 CFR 51.22(c)(14).

Please be advised that your license expires at the end of the day in the month and year stated in the license. Until your license has been terminated, you must conduct your program in accordance with the conditions of your 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 and Investigations," 10 CFR Part 20, "Standards for Protection Against Radiation," and other appropriate regulations.
2. Notify NRC in writing 30 days in advanced of any change in mailing address.
3. In accordance with 10 CFR 30.36(d), notify NRC promptly, in writing, within 60 days 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, 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 (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 of your license. You will receive a reminder notice approximately 60 days before the expiration date. Possession of byproduct material after your license expires is a violation of NRC regulations.

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 NRC Enforcement Policy. The NRC Enforcement Policy is available at:

<http://www.nrc.gov/reading-rm/doc-collections/enforcement/>.

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).

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/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 be aware that, as a holder of an NRC license, you may be subject to the NRC's licensing and inspection fees in accordance with 10 CFR Part 170, and annual fees in accordance with 10 CFR Part 171. If you have any questions concerning the fee requirements, please contact the License Fee and Accounts Receivable Branch at (301) 415-7544.

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/

Betsy Ullrich, Senior Health Physicist,
Commercial, Industrial, R&D
and Academic Branch
Division of Nuclear Materials Safety
Region I

No. License No. 20-08361-01
Docket No. 030-04675
Mail Control No. 591011

Enclosure:
Amendment No. 44

cc: Edmond J. Baratta, Radiation Safety Officer

Please be aware that, as a holder of an NRC license, you may be subject to the NRC's licensing and inspection fees in accordance with 10 CFR Part 170, and annual fees in accordance with 10 CFR Part 171. If you have any questions concerning the fee requirements, please contact the License Fee and Accounts Receivable Branch at (301) 415-7544.

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/

Betsy Ullrich, Senior Health Physicist,
Commercial, Industrial, R&D
and Academic Branch
Division of Nuclear Materials Safety
Region I

No. License No. 20-08361-01
Docket No. 030-04675
Mail Control No. 591011

Enclosure:
Amendment No. 44

cc: Edmond J. Baratta, Radiation Safety Officer

DOCUMENT NAME: [G:\WBL Documents\WBL License Cover Letter\L20-08361-01.591011.NonP.docx]

ML16326A193

SUNSI Review Complete: E. Ullrich

After declaring this document "An Official Agency Record" it will be released to the Public.

To receive a copy of this document, indicate in the box: "C" = Copy w/o attach/encl "E" = Copy w/ attach/encl "N" = No copy

OFFICE	RI:DNMS	N					
NAME	E Ullrich /BU/						
DATE	11/2/16						

OFFICIAL RECORD COPY