



UNITED STATES  
NUCLEAR REGULATORY COMMISSION  
WASHINGTON, D.C. 20555-0001

March 6, 2018

Sterigenics International LLC  
ATTN: Kathleen Hoffman  
Senior Vice President –  
Global Environmental, Health & Safety  
10811 Withers Cove Park Drive  
Charlotte, NC 28278

SUBJECT: STERIGENICS INTERNATIONAL LLC, AMENDED EXEMPT DISTRIBUTION  
LICENSE 32-31005-01E

Dear Ms. Hoffman:

This letter refers to your amendment request dated November 16, 2017 (Agencywide Documents Access and Management System [ADAMS] Accession No. ML17332A031) for Exempt Distribution License 32-31005-01E. Subsequently, we sent your letter dated January 10, 2018, requesting additional information. Due to the delay of incoming mail delivery, we did not receive your response letter dated February 9, 2018, until February 26, 2018. Therefore, we sent you a letter dated February 22, 2018, to discontinue our review. However, based on your response letter dated February 9, 2018, enclosed is an amended copy of your license.

You must distribute the products in accordance with the statements and representations contained in your applications, with enclosures thereto, and the information set out in your license. As a general rule, you must request and obtain an amendment to the license before you make changes or modifications to the information submitted to obtain them. You are also obligated to notify us promptly in writing should you decide to no longer distribute the product.

You must conduct your program involving radioactive materials in accordance with the conditions specified in your U.S. Nuclear Regulatory Commission (NRC) license, representations made in your license application, and other rules, regulations, and orders of the NRC, now or hereafter in effect, to include the following:

1. Comply with applicable NRC regulations in Title 10 of the *Code of Federal Regulations* (10 CFR Part 30), "Rules of General Applicability to domestic Licensing of Byproduct Material"; 10 CFR Part 32, "Specific Domestic Licenses to Manufacture or Transfer Certain Items Containing Byproduct Material"; and other applicable regulations.

NOTE: Licensees authorized to distribute or initially transfer products containing byproduct material must also possess a valid possession license issued either by NRC or an Agreement State(s) which authorizes possession and use of byproduct material.

2. Distribute only those products containing radioactive material which are specifically authorized in your license.
3. Notify the NRC in writing within 30 days of any change in mailing address.

4. In accordance with 10 CFR 30.33, 30.34 and 30.38, you must file appropriate documentation with the NRC prior to any changes to your organization; change in locations of distribution of products containing radioactive material, facilities, equipment, procedures; change in the contact person or the person responsible for the quality assurance program for licensed activities; or any other changes in your program which are contrary to the license conditions or representations made in your license application and any supplemental correspondence with the NRC.
5. Submit a complete renewal application or termination request at least 30 days before the expiration date on your license. You should receive a reminder notice approximately 60 days before the expiration date. Continued distribution of products containing radioactive material after your license expires is a violation of NRC regulations.
6. In accordance with 10 CFR 30.36, request termination of your license if you plan to permanently discontinue activities involving distribution of products containing radioactive material.

You will be periodically inspected by the NRC. Failure to conduct your program in compliance with NRC regulations, license conditions, and representations made in your license application and supplemental correspondence with the NRC may result in enforcement action(s) against you. This could include issuance of a notice of violation; proposed imposition of a civil penalty; or an order suspending, modifying, or revoking your license as specified in "General Statement of Policy and Procedures for NRC Enforcement Actions" (NUREG-1600).

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 "Agency Rules of Practice and Procedure," a copy of this letter will be available electronically for public inspection in the NRC Public Document Room or from the Publicly Available Records component of NRC's Agencywide Documents Access and Management System (ADAMS). ADAMS is accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>.

K. Hoffman

3

If you have any questions, you may contact me at (301) 415-7640, or by e-mail at [Shirley.Xu@nrc.gov](mailto:Shirley.Xu@nrc.gov). Any correspondence regarding your exempt distribution license should reference mail control number 602491

Sincerely,

**/RA/**

Shirley S. Xu  
Materials Safety Licensing Branch  
Division of Materials Safety, Security, State,  
and Tribal Programs  
Office of Nuclear Material Safety  
and Safeguards

Docket No. 030-37764  
Mail Control No. 602491

Enclosure:  
License 32-31005-01E

K. Hoffman

4

STERIGENICS INTERNATIONAL LLC, AMENDED EXEMPT DISTRIBUTION LICENSE  
32-31005-01E

Date: March 6, 2018

**ML18064A036**

|               |            |                |            |
|---------------|------------|----------------|------------|
| <b>OFFICE</b> | MSTR/MSLB  | MSTR/MSLB      | MSTR/MSLB  |
| <b>NAME</b>   | Shirley Xu | Deborah Weaver | Shirley Xu |
| <b>DATE</b>   | 3/6/2018   | 3/6/2018       | 3/6/2018   |

OFFICIAL RECORD COPY