



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

January 10, 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, REQUEST FOR ADDITIONAL
INFORMATION REGARDING AMENDMENT OF EXEMPT DISTRIBUTION
LICENSE 32-31005-01E**

Dear Ms. Hoffman:

This letter refers to your amendment request dated December 16, 2016 (Agencywide Documents Access and Management System [ADAMS] Accession No. ML17332A031) for Exempt Distribution License 32-31005-01E. In reviewing your application, we have determined that additional information is required to complete our review. In order to continue our review, please address the issues listed below. This information is required by Title 10 of the *Code of Federal Regulations* (10 CFR) 30.14, "Introduction of byproduct material in exempt concentrations into products or materials, and transfer of ownership or possession: Requirements for license."

1. Please provide a copy of your radioactive material possession and use license issued by the State of North Carolina reflecting the name change of your company.
2. Please confirm that no changes were made to the product since the last amendment.
3. Provide the new label for the device indicating the new company name and the effective date of the label change.
4. Confirm that the Quality Assurance Program will remain the same for Sotera Health LLC.

We will continue our review upon receipt of this information. If we do not receive a reply from you within 30 calendar days from the date of this letter, we will assume that you do not wish to pursue your application.

Please be aware that upon your request, proprietary information submitted to the NRC may be withheld from public disclosure. To do this, you must follow the procedures in 10 CFR 2.390(b) including requesting withholding at the time the information is submitted and complying with the document marking and affidavit requirements set forth in 10 CFR 2.390 (b)(1).

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>.

If you have any questions, you may contact me at (301) 415-7640, or by e-mail at Shirley.Xu@nrc.gov. Any correspondence regarding your exempt distribution license should reference mail control number 601460.

Sincerely,

/RA/

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

Docket No. 030-37764
Mail Control No. 601759

STERIGENICS INTERNATIONAL LLC, REQUEST FOR ADDITIONAL INFORMATION
REGARDING AMENDMENT OF EXEMPT DISTRIBUTION LICENSE 32-31005-01E

Date: January 10, 2018

ML18010A259

OFFICE	MSTR/MSLB	MSTR/MSLB	MSTR/MSLB
NAME	Shirley Xu	D Weaver	SXu
DATE	1/10/2018	1/10/2018	1/10/2018

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