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

March 15, 2017

Jose E. Aponte, Maintenance Manager
STERIS Isomedix Puerto Rico, Inc.
dba STERIS Applied Sterilization Technologies
P.O. Box 415
State Road 690, km 1.7
Vega Alta, Puerto Rico 00692

SUBJECT: NRC INSPECTION REPORT NO. 03030578/2016002, STERIS ISOMEDIX
PUERTO RICO, INC., VEGA ALTA, PUERTO RICO SITE AND NOTICE OF
VIOLATION

Dear Mr. Aponte:

This letter refers to the inspection commenced on October 17, 2016, at your facility. This inspection examined activities conducted under your license as they relate to public health and safety and to confirm compliance with the Commission's rules and regulations, and with the conditions of your license. Within these areas, the inspection consisted of selected examination of procedures and representative records, observations of activities, and interviews with personnel. Additional information provided in your correspondence received on November 1, 2016, was also examined as part of the inspection. The findings were discussed with you at the conclusion of the inspection on March 2, 2017.

Based on the results of this inspection, the NRC has determined that two Severity Level IV violations of NRC requirements occurred. These violations were evaluated in accordance with the NRC Enforcement Policy, which is included on the NRC's Web site at (<http://www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html>). The violations are cited in the Notice of Violation (Notice, Enclosure 1), because they were identified by the NRC. Enclosure 2 provides a determination of severity level and a description of the corrective actions taken by STERIS Isomedix Puerto Rico, Inc. to address each violation.

The NRC has concluded that information regarding the reason for the violations and corrective actions taken and planned to correct the violations are adequately addressed in our records. Therefore, you are not required to respond to this letter unless the description of your corrective actions in Enclosure 2 does not accurately reflect your position. In that case, or if you choose to provide additional information, you should follow the instructions specified in the enclosed Notice.

Enclosures contain Sensitive Unclassified Non-Safeguards Information. Upon separation, this cover letter is DECONTROLLED.

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J. Aponte

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In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a public version of this letter and your response, if you choose to provide one, will be made available electronically for public inspection in the NRC Public Document Room or from the NRC's Agencywide Documents Access and Management System (ADAMS), accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>. To the extent possible, your response should not include any personal privacy, proprietary, or security-related information so that it can be made available to the Public without redaction. If security-related Information is necessary to provide an acceptable response, please mark the top of each page of your response, "Security-Related Information – Withhold Under 10 CFR 2.390."

In accordance with 10 CFR Part 19.11, you may be required to post this Notice within two working days. However, you are reminded to review your NRC security requirements that limit the release of information.

Current NRC regulations and guidance are included on the NRC's Web Site at www.nrc.gov; select **Nuclear Materials; Med, Ind, & Academic Uses**; then **Regulations, Guidance and Communications**. The current Enforcement Policy is included on the NRC's Web Site at www.nrc.gov; select **About NRC, Organizations & Functions; Office of Enforcement; Enforcement documents**; then **Enforcement Policy (Under 'Related Information')**. You may also obtain these documents by contacting the Government Printing Office (GPO) toll-free at 1-866-512-1800. The GPO is open from 8:00 a.m. to 5:30 p.m. EST, Monday through Friday (except Federal holidays).

If you have any questions regarding this matter, please contact Michael Reichard of my staff at 610-337-6945 or via electronic mail at michael.reichard@nrc.gov.

Thank you for your cooperation.

Sincerely,

/RA/

Blake Welling, Chief
Commercial, Industrial, R&D
and Academic Branch
Division of Nuclear Materials Safety
Region I

Docket No. 03030578
License No. 52-24994-01

Enclosures:

1. Notice of Violation (Non-Public)
2. Determination of Severity Level and
Description of Corrective Actions (Non-Public)

cc w/o Enclosures: Commonwealth of
Puerto Rico

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Docket No. 03030578
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- 1. Notice of Violation (Non-Public)
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cc w/o Enclosures: Commonwealth of Puerto Rico

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OFFICE	RI:DNMS	N	RI:DNMS	N			
NAME	Michael Reichard/mr		Blake Welling/bw				
DATE	3/2/17		3/15/17				

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