



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

March 24, 2022

Jose E. Aponte, Radiation Safety Officer  
STERIS Isomedix Puerto Rico, LLC  
d/b/a STERIS Applied Sterilization Technologies  
P.O. Box 415  
State Road 690, km 1.7  
Vega Alta, PR 00692

SUBJECT: STERIS ISOMEDIX PUERTO RICO, LLC - NRC INSPECTION NO.  
03030578/2022-001 AND NOTICE OF VIOLATION

Dear Mr. Aponte:

This letter refers to the special inspection conducted on March 10 - 14, 2022, that was limited to the requirements for the submission of a Decommissioning Funding Plan (DFP) at a frequency of three years or at the time of renewal of your license. Within this area, the inspection consisted of selected examination of when the last time a DFP was submitted (September 17, 2018) and the receipt of your most current submission (March 3, 2022).

Based on the results of this inspection, the NRC has determined that a Severity Level IV violation of NRC requirements occurred. The violation was evaluated in accordance with the NRC Enforcement Policy. The current Enforcement Policy is included on the NRC's Web site at <https://www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html>. The violation is cited in the enclosed Notice of Violation (Notice) because the violation was identified by the NRC.

The NRC has concluded that information regarding: (1) the reason for the violation; (2) the corrective actions that have been taken and the results achieved; and (3) the date when full compliance was achieved is already adequately addressed on the docket and include: The licensee has believed that the three-year submittal interval started with the acceptance date of the DFP (April 10, 2019) rather than the submittal date (September 17, 2018). The licensee stated that they would change their calendar system so that the proper date was entered. The licensee submitted a DFP for License Number 52-24994-01 to the Commission by e-mail on March 8, 2022, and achieved full compliance on that date. Therefore, you are not required to respond to this letter unless the description herein does not accurately reflect your corrective actions or your position. In that case, or if you choose to provide additional information, you should follow the instructions specified in the enclosed Notice.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy 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 document 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 safeguards information so that it can be made available to the Public without redaction.

J. Aponte

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If you have any questions regarding this matter, please contact Steven Courtemanche of my staff at 610-337-5075 or via electronic mail at [Steven.Courtemanche@nrc.gov](mailto:Steven.Courtemanche@nrc.gov) .

Thank you for your cooperation.

Sincerely,

Christopher Cahill, Chief  
Commercial, Industrial, R&D  
and Academic Branch  
Division of Radiological Safety and Security  
Region I

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

Enclosure:  
Notice of Violation

cc w/ enclosure  
David Jackson, CIH, Senior Radiation Safety Manager  
Commonwealth of Puerto Rico

STERIS ISOMEDIX PUERTO RICO, LLC - NRC INSPECTION NO. 03030578/2022-001  
AND NOTICE OF VIOLATION DATED MARCH 24, 2022

DISTRIBUTION:  
OE, RI

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OFFICE	RI:DRSS	RI:DRSS			
NAME	SCourtemanche (src)	CCahill (cgc)			
DATE	03/23/2022	03/24/2022			

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## **NOTICE OF VIOLATION**

STERIS Isomedix Puerto Rico, LLC  
Vega Alta, PR

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

During an NRC inspection conducted on March 10 - 14, 2022, a violation of NRC requirements was identified. In accordance with the NRC Enforcement Policy, the violation is listed below:

10 CFR 30.35(e)(2) requires, in part, that the licensee submit, at the time of license renewal and at intervals not to exceed three years, the decommissioning funding plan with adjustments as necessary to account for changes in costs and the extent of contamination.

Contrary to the above, as of March 8, 2022, the licensee failed to submit, at the time of license renewal and at intervals not to exceed three years, the decommissioning funding plan with adjustments as necessary to account for changes in costs and the extent of contamination. Specifically, the licensee submitted, on September 11, 2018, an adjustment to its decommissioning funding plan by means of a document dated September 7, 2018. An adjustment to the decommissioning funding plan dated March 3, 2022, was not received until March 8, 2022; an interval exceeding three years.

This is a Severity Level IV violation (Enforcement Policy Section 6.3).

The NRC has concluded that information regarding the reason for the violation, the corrective actions taken and planned to correct the violation and prevent recurrence and the date when full compliance will be achieved is already adequately addressed on the docket. However, you are required to submit a written statement or explanation pursuant to 10 CFR 2.201 if the description therein does not accurately reflect your corrective actions or your position. In that case, or if you choose to respond, clearly mark your response as a "Reply to a Notice of Violation," and send it to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555 with a copy to the Regional Administrator, Region I, within 30 days of the date of the letter transmitting this Notice of Violation (Notice).

If you contest this enforcement action, you should also provide a copy of your response to the Director, Office of Enforcement, United States Nuclear Regulatory Commission, Washington, DC 20555-0001. Under the authority of Section 182 of the Act, 42 U.S.C. 2232, any response which contests an enforcement action shall be submitted under oath or affirmation.

Your response will be placed in the NRC Public Document Room (PDR) and on the NRC Web site. To the extent possible, it should, therefore, not include any personan June of 2018 I privacy, proprietary, or safeguards information so that it can be made publically available without redaction. However, if you find it necessary to include such information, you should clearly indicate the specific information that you desire not to be placed in the PDR, and provide the legal basis to support your request for withholding the information from the public.

In accordance with 10 CFR 19.11, you may be required to post this Notice within two working days of receipt.

Dated This 23rd day of March 2022