Part 21 (PAR) Event # 50285

Rep Org: ITT ENGINEERING VALVES, LLC		**Notification Date / Time:** 07/18/2014 09:30	(EDT)
Supplier: STERIS ISOMEDIX SERVICES		**Event Date / Time:** 07/18/2014	(EDT)
		Last Modification: 07/18/2014	
Region: 1		**Docket #:**	
City: LANCASTER		**Agreement State:** Yes	
County:		**License #:** UNKNOWN	
State: PA			
NRC Notified by: S. T. DONOHUE	**Notifications:**	CHRISTOPHER CAHILL	R1DO
HQ Ops Officer: JOHN SHOEMAKER		GERALD MCCOY	R2DO
Emergency Class: NON EMERGENCY		PATTY PELKE	R3DO
10 CFR Section:		THOMAS FARNHOLTZ	R4DO
21.21(d)(3)(i) DEFECTS AND NONCOMPLIANCE		PART 21 GROUP	EMAIL

PART 21 REPORT - IMPROPER RADIATION TESTING OF BALL VALVE SEATS AND DIAPHRAGM SAMPLES

The following information was received from ITT Engineered Valves, LLC by facsimile:

ITT is submitting this report based on an NRC Inspection finding at Steris Isometric Services in Whippany, NJ, where samples may have received 3-9% less than the minimum target dosage specified during testing.

"ITT is in the process of determining how best to approach our customers with this information, and how to work with them to determine whether a defect as defined by 10 CFR Part 21 does exist. To that end, we are reviewing the impact of the variability on all projects that required radiated samples, particularly ball valve seats and diaphragms including the entire MI diaphragm product line, and what effect if any this will have on our results and conclusions. We are also reviewing any ongoing projects with radiated samples from Steris, and making the necessary adjustments."

Name and address of the individuals informing the Commission:

S. T. Donohue
ITT Engineered Valves, LLC
33 Centerville Road
Lancaster, PA 17603
stephen.donohue@itt.com
Senior Principal Engineer
(717) 509-2200

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NRR

ENGINEERED FOR LIFE

ITT Engineered Valves, LLC

33 Centerville Road
Lancaster, PA 17603
tel 717.509.2200

July 18, 2014

NRC Operations Center
Washington, DC
Fax 301-816-5151

Subject: Potential Part 21 Issue concerning radiation of sample diaphragms

Attachment: Steris Isomedix Services letter dated June 18, 2014.

In accordance with the requirements of 10 CFR Part 21, this letter notifies the NRC of a Potential Part 21 incident. ITT Engineered Valves, LLC (ITT) has received a letter from Steris Isomedix Services (Steris) with a notification of a Non Conformance (reference NRC report 99901445) concerning radiation services which were provided to ITT. The letter advised ITT that there should have been a higher allowance for variance in the amount of radiation applied to our Nuclear product line samples than was expected, with the end result that the actual applied radiation value may or may not have been as per the minimum specified by our purchase order. As a result, ITT's qualification testing may have been conducted on samples that received 3 to 9 percent less (or 3-9% more) than the minimum target dosage specified. Given the nature and scope of the amount of testing that we have performed over the years on various products, ITT is not yet certain whether a defect as defined in 10 CFR Part 21 does exist. However, due to the uncertainty ITT feels obligated to file this as a potential defect.

ITT is in the process of determining how best to approach our customers with this information, and how to work with them to determine whether a defect as defined by 10 CFR Part 21 does exist. To that end, we are reviewing the impact of the variability on all projects that required radiated samples, particularly ball valve seats and diaphragms including the entire M1 diaphragm product line, and what effect if any this will have on our results and conclusions. We are also reviewing any ongoing projects with radiated samples from Steris and making the necessary adjustments.

Per 10 CFR 21 policy guidelines, this initial notification will be followed by a written notification by August 15, 2014. In the meantime, please do not hesitate to contact me with any questions or issues regarding this matter.

Regards,

S. T. Donohue
stephen.donohue@itt.com
Senior Principal Engineer
ITT Engineered Valves, LLC

ATTACHMENT

STERIS
Isomedix Services

June 18, 2014

Re: Isomedix Service Whippany NJ NRC Inspection Findings

Dear Valued Customer:

As a valued Customer of STERIS Isomedix Services' gamma processing services, we want to make you aware of the results of an inspection recently conducted by the U.S. Nuclear Regulatory Commission (NRC) under 10 CFR) Part 50, Appendix B with respect to equipment qualification testing of nuclear safety-related components processed in off-carrier positions at the Whippany, New Jersey facility. The NRC issued a Notice of Nonconformance stating that the measuring and testing equipment used to determine the applied radiation dose reported to you on the Isomedix Certificate of Processing provided with each run did not account for all the uncertainties involved (i.e., density of unrelated products in carriers, off-carrier location within the irradiator and Cobalt-60 source decay) and therefore the actual radiation dose applied to components could be less than requested and as reported on the Certificate of Processing.

STERIS Isomedix Services has completed an evaluation of the dose rate variability of items processed in off-carrier locations in the irradiator. This evaluation determined that there may have been variability in readings as great as ± 5.1% of the dose delivered for components processed in off-carrier positions, depending on the location within the irradiator where the component was processed. As a result, the actual dose delivered to your component may have differed up to ± 5.1% from the value reported on the Certificate of Processing. This variability is in addition to the standard measurement uncertainty of the Red Perspex 4034 dosimetry system (± 6.5%) noted in all purchase quotations. Because Isomedix is unable to evaluate the affect this variation may have on the components processed, we are notifying you under the requirements of 10 CFR Part 21.

Isomedix strives to provide processing services in strict compliance with Customer specifications and Isomedix quality processes and procedures. We apologize for any inconvenience that this unique situation may have caused. If you have questions or require additional information, please contact me at (973) 887-2754 or Scott_Comstock@STERIS.com.

Very Truly Yours,

Scott Comstock
Plant Manager
STERIS Isomedix Services
9 Apollo Drive
Whippany, NJ 07981