Part 21 (PAR) Event # 50681

Rep Org:	ASCO VALVE INCORPORATED	**Notification Date / Time:**	12/16/2014 09:01 (EST)
Supplier:	STERIS ISOMEDIX SERVICES	**Event Date / Time:**	12/15/2014 (EST)
		Last Modification:	12/16/2014
Region:	1	**Docket #:**	
City:	AIKEN	**Agreement State:**	Yes
County:		**License #:**	
State:	SC		

NRC Notified by:	BOB ROYER	**Notifications:**	JOHN ROGGE	R1DO
HQ Ops Officer:	JOHN SHOEMAKER		KATHLEEN O'DONOHUE	R2DO
Emergency Class:	NON EMERGENCY		AARON MCCRAW	R3DO
10 CFR Section:			NEIL OKEEFE	R4DO
21.21(a)(2)	INTERIM EVAL OF DEVIATION		PART 21 GROUP	EMAIL

INTERIM REPORT - POTENTIAL PART 21 NOTIFICATION

The following report was received via fax:

ASCO reviewed a Part 21 notification, received from Steris Isomedix Services, to see if the reported non conformance would impact qualification levels. Based on this review, ASCO determined that even if the radiation levels, applied to components, were lower than reported on the original certifications, the additional radiation dose added to meet the 10% margin suggested by IEEE 323 would envelope this variation. Therefore, the qualification levels listed in ASCO qualification reports would not be impacted. Based on this review, ASCO determined that it was not necessary to implement 10 CFR part 21 notifications since the reported qualification levels remain unchanged.

If you have any questions, you can contact Michael Adase at Michael.adase@emerson.com or 803-641-9345.

Note: The NRC has received reports from four (4) other Steris Isomedix customers concerning this issue; EN #50253, #50285, #50359, and #50434.

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IE19
NRR

EMERSON.
Industrial Automation

ASCO NUMATICS.

Facsimile

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To: NRC

No. of Pages *(including cover sheet)* 3

Company: NRC DOCUMENT CONTROL DESK

Fax Number: 301-816-5151

Date 12/16/2014

From: BOB ROYER, ASCO VALVE, INC.

Phone: 803-641-9394

Comments:

PLEASE SEE ATTACHED LETTER AND REFERENCE.

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December 15, 2014

Document Control Desk
U.S. Nuclear Regulatory Commission
Washington D.C. 20555-0001

Subject: Interim Report - Potential Part 21 notification

Reference A – Steris Isomedix Services Part 21 notification letter dated June 18, 2014

ASCO Valve Inc. was notified by Steris Isomedix Services on June 22 (Ref A) that the actual radiation dose applied to components may have differed by up to +/- 5.1 % from the value initially reported. ASCO valve has used Steris for radiation aging and radiation accident simulation for qualification testing of safety related solenoid valves, hydramotors and pressure and temperature switches.

ASCO reviewed this notification to see if the non conformance would impact our qualification levels. Based on this review, ASCO determined that even if the radiation levels were lower than reported on the original certifications, the additional radiation dose added to meet the 10% margin suggested by IEEE 323 would envelope this variation. Therefore, the qualification levels listed in ASCO qualification reports would not be impacted. Based on this review, ASCO determined that it was not necessary to implement 10 CFR part 21 notifications since the reported qualification levels remain unchanged.

During a recent meeting with Steris on October 29th, ASCO was advised that Steris will issue updated certifications that reflect the actual dose delivered. ASCO is working with Steris to obtain updated Certificates that incorporate the variability readings identified in Ref A. ASCO will update our qualification documents to include the updated certifications.

If we determine that the revised radiation levels result in a reduced qualification level beyond the 10% margin provided in the qualification report, we will update our reports and determine if a Part 21 notification in accordance with 10 CFR Part 21 is required.

If you have any questions, you can contact Michael Adase at Michael.adase@emerson.com or 803-641-9345.

Sincerely,

Bob Royer

Bob Royer
Technical Service Supervisor
ASCO Valve Inc.

ASCO numatics

(REF. A)

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
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Whippany, NJ 07981