

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: 08/19/2015			
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.

*** UPDATE AT 1507 EDT ON 8/19/2015 ***

The following, in part, was received from Asco Valve, Inc. via fax:

"On December 15, 2014, ASCO Valve Inc. (ASCO) issued an interim report to the USNRC. The interim report was issued because ASCO was awaiting additional information from Steris and was not able to complete their evaluation of Ref B within the 60 day time limit. A December 19, 2014 update from Steris contained no additional substantive information. Although further information from Steris was not received, ASCO has since received the

IEI9
NRR

'Industry Guidance Position Paper Responding to the 2014 Steris 10 CFPR Part 21', from the NUGEQ [Nuclear Utility Group on Equipment Qualification].

"ASCO has completed the review and calculated the minimum radiation exposure applied during qualification of ASCO nuclear qualified products at Steris. Based on this review, ASCO has determined that the minimum dose is less than what was originally reported in the ASCO qualification reports. ASCO is in the process of updating our reports and revising our certifications.

"Since ASCO is not able to determine what, if any impact these reduced radiation dose levels will have on the qualification testing of safety related equipment, we are forwarding this information to allow for a review of applicable qualification documentation and reports."

Notified R1DO (DeFrancisco), R2DO (Heisserer), R3DO (Riemer), R4DO (Hay), and Part 21 Group (email).



ASCO Valve, Inc.
1561 Columbia Highway
Aiken, SC 29801
USA

FAX COVER

T (803) 641-9200
F (803) 641-9290
www.asconumatics.com

Date:	August 19, 2015
Send to:	NRC Document Control Desk
Attention:	
Office location:	
Fax number:	301-816-5151

From:	Bob Royer
Office location:	

TOTAL PAGES, INCLUDING COVER: 5

Comments:

Please see attached letter. Please contact me directly at 803-641-9394 if there are any problems with receipt of this document.

The Information contained in this facsimile message is intended for the sole confidential use of the designated recipients and may contain confidential information. If you have received this information in error, any review, dissemination, distribution or copying of this information is strictly prohibited. If you are not the intended recipient of this message, or if this message has been addressed to you in error, please immediately alert the sender by fax and then destroy this message and its attachments.



ASCO Valve, Inc.
1561 Columbia Highway
Aiken, SC 29801
USA

T (803) 641-9200
F (803) 641-9290
www.asconumatics.com

August 19, 2015

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

Subject: Final evaluation of Steris Part 21 for impact on ASCO Nuclear Qualified Safety related products.

References:

- A. ASCO Valve Inc. Interim Report - Potential Part 21 Notification dated December 15, 2014
- B. Steris Isomedix Services letter, "Whippany NJ NRC Inspection Findings", dated June 18, 2014
- C. Steris Isomedix Services letter, "Whippany NJ NRC Inspection Findings", dated December 19, 2014
- D. NUGEQ Industry Guidance Position Paper – Responding to the 2014 Steris 10 CFR Part 21 – Rev. 0 dated June 2015

On December 15, 2014, ASCO Valve Inc. (ASCO) issued an interim report to the USNRC – Ref. A. The interim report was issued because ASCO was awaiting additional information from Steris and was not able to complete their evaluation of Ref. B within the 60 day time limit. A December 19, 2014 update from Steris (Ref. C) contained no additional substantive information. Although further information from Steris was not received, ASCO has since received the "Industry Guidance Position Paper Responding to the 2014 Steris 10 CFR Part 21" – Ref. D, from the NUGEQ.

Using the guidance and instructions contained in Ref D, ASCO has completed the review and calculated the minimum radiation exposure applied during qualification of ASCO nuclear qualified products at Steris. Based on this review, ASCO has determined that the minimum dose is less than what was originally reported in the ASCO qualification reports. See the attached Summary of Affected Qualification Reports. Based on that information, ASCO is in the process of updating our reports and revising our certifications.

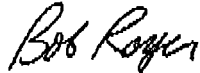
Since ASCO is not able to determine what, if any impact these reduced radiation dose levels will have on the qualification testing of safety related equipment, we are forwarding this information to allow for a review of applicable qualification documentation and reports.

ASCO
NUMATICS

Listed below are the affected ASCO qualification reports along with the originally reported radiation dose levels and the revised levels. Note that these levels are for the radiation aging and DBE radiation levels.

If you have any questions or would like to discuss further, please e-mail Bob Royer (robert.royer@emerson.com) or Mike Adase (michael.adase@emerson.com).

Best Regards,



Bob Royer
Technical Service Supervisor
ASCO Valve, Inc.

Cc: Areva NP Inc.

Nuclear Utility Group on Equipment Qualification (NUGEQ)

Summary Table

NP Series:

Project / Report	Tested Period	Products	Total Variation	Original Radiation Dose in Report	Revised Radiation Dose	Revised Qualification level (10% margin applied)
AQR-68061	July, 2000	NP8262; 8210; V012 (check valve)	8.95%	0.51Mrads	0.46Mrads	0.41Mrads
AQR-67368	Dec., 1980 to Feb., 1981	206-380; 206-381; 206-832; 208-266; 208-448; NP8314; 8316; 8317; 8320; 8321; 8323; 8344	9.17%	23Mrads for aging	21Mrads for aging	19Mrads for aging
			9.26%	182Mrads for DBE	165Mrads for DBE	149Mrads for DBE
AQR-67484	Dec., 1981 to April, 1982	NP8342 (AC & DC; Single & Dual solenoid)	9.17%	1500Rads & 21Mrads (NP8342 only) for aging	1400Rads & 19Mrads (NP8342 only) for aging	1260Rads & 17Mrads (NP8342 only) for aging
			9.53%	182Mrads for DBE	164Mrads for DBE	148Mrads for DBE
AQR-21678/TR	July, 1977 to Dec., 1977	206-381; NP8316; NP8320; NP8321; NP8323; NP8344	9.17%	50Mrads for aging	46Mrads for aging	41Mrads for aging
			9.26%	150Mrads for DBE	137Mrads for DBE	123Mrads for DBE

NS Series:

Project / Report	Tested Period	Products	Total variation	Original Radiation Dose in Report	Revised Radiation Dose	Revised Qualification level (10% margin applied)
AQR-21691	Feb., 1992 to Dec., 1992	NS8300;/8302;8314; 8316;8320;8321	9.17%	20Mrads for aging	19.28Mrads for aging	17Mrads for aging
			9.35%	180Mrads for DBE	168Mrads for DBE	151Mrads for DBE

Temperature/ Pressure Switches:

Project / Report	Tested Period	Products	Total variation	Original Radiation Dose in Report	Revised Radiation Dose	Revised Qualification level (10% margin applied)
AQR-101083 Note: there were more data in cert, but it was not in report main body.	Jan., 1983 to Dec., 1983	Pressure Switches	9.17%	0.53 or 0.63Mrads for aging 18.7 or 23.85Mrads for DBE	0.48 or 0.57Mrads for aging 17.0 or 21.7Mrads for DBE	0.43 or 0.51Mrads for aging 15 or 20Mrads for DBE
AQR-020184	Jan., 1983 to Jan., 1984	Temperature Switches	9.17%	0.63Mrads for aging 33Mrads for DBE	0.57Mrads for aging 30Mrads for DBE	0.51Mrads for aging 27Mrads for DBE

NT series:

Project / Report	Tested Period	Products	Total variation	Original Radiation Dose in Report	Revised Radiation Dose	Revised Qualification level (10% margin applied)
35115	April, 2011 to May, 2011	NT8316ZM	8.95%	40Mrads	32.8Mrads	29.5Mrads

Scram Solenoid Pilot valve (SSPV):

Project / Report	Tested Period	Products	Total variation	Original Radiation Dose in Report	Revised Radiation Dose	Revised Qualification level (10% margin applied)
35119	August, 2012	SSPV	8.95%	Group A-4.6Mrads Group B-20.7Mrads	Group A -4.1Mrads Group B-18.6Mrads	Group A -3.7Mrads Group B-16.7Mrads