Part 21 (PAR)		Event #	50681
Rep Org: ASCO VALVE INCORPORATED	Notificati	ion Date / Time: 12/16/2014 09	0:01 (EST)
Supplier: STERIS ISOMEDIX SERVICES	Eve	ent Date / Time: 12/15/2014	(EST)
	Las	st Modification: 08/19/2015	
Region: 1	Docket #:		_
City: AIKEN Ag	reement 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

IE19 NIRR

'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).



FAX COVER

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

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:

Comments:

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

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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.



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 (<u>robert.royer@emerson.com</u>) or Mike Adase (<u>michael.adase@emerson.com</u>).

Best Regards,

Bob Royer

Technical Service Supervisor

ASCO Valve, Inc.

Bob Roger

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;	9.17%	23Mrads for aging	21Mrads for aging	19Mrads for aging	
		208-448; NP8314; 8316; 8317; 8320; 8321; 8323; 8344	9.26%	182Mrads for DBE	165Mrads for DBE	149Mrads for DBE
	Dec., 1981 to April, 1982	•	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-	AQR- July, 1977 to 206-381; NP8316; 21678/TR Dec., 1977 NP8320; NP8321; NP8323; NP8344	9.17%	50M rads for aging	46Mrads for aging	41M rads for aging	
21076/TR			9.26%	150Mrads for DBE	137Mrads for DBE	123Mrads for DBE

NS Series:

Project /	Tested Period	Products	Total	Original Radiation	Revised Radiation	Revised
Report			variation	Dose in Report	Dose	Qualification level
	1			1		(10% margin applied)
AQR-21691	Feb., 1992 to	NS8300;/8302;8314;	9.17%	20Mrads for aging	19.28Mrads for	17Mrads for aging
	Dec., 1992	8316;8320;8321			aging	
	1	•	9.35%	180Mrads for DBE	168Mrads for DBE	151Mrads for DBE
	<u> </u>					

Temperature/ Pressure Switches:

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

NT series:

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

Scram Solenoid Pilot valve (SSPV):

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