Part 21 (PAR) Event # 51621

Rep Org: HOMEWOOD PRODUCTS CORPORATION **Notification Date / Time:** 12/23/2015 11:15 (EST)
Supplier: NATIONAL TECHNICAL SYSTEMS, INC. FORM **Event Date / Time:** 12/21/2015 (EST)
Last Modification: 12/23/2015

Region: 1 **Docket #:**
City: PITTSBURGH **Agreement State:** Yes
County: **License #:**
State: PA

NRC Notified by: RICHARD MARTIN **Notifications:** JAMES NOGGLE R1DO
HQ Ops Officer: HOWIE CROUCH PART 21/50.55 REACTORS EMAIL
Emergency Class: NON EMERGENCY
10 CFR Section:
21.21(d)(3)(i) DEFECTS AND NONCOMPLIANCE

PART 21 REPORT - ERROR IN REPORTING THE VARIABILITY IN THE DOSE DELIVERED ON CERTIFICATE OF PROCESSING

The following information was received from Homewood Products Corporation via fax:

"Steris Isomedix Services measuring and test equipment used by NTS (Formerly Wyle Laboratories, Inc.) to determine the applied radiation dose did not account for all of the uncertainties involved, and therefore the actual radiation dose applied to components and reported to Homewood Products Corporation by Wyle Laboratories, could be less than the requested service condition dose."

The following information was received from Homewood Products Corporation as provided to them by National Technical Services, Inc. (formerly Wyle Laboratories, Inc.):

"The defect is an error in reporting the variability in the dose delivered or lack thereof on the Isomedix Certificate of Processing for the Whippany, NJ facility. The U.S. Nuclear Regulatory Commission (NRC) under 10 CFR Part 50, Appendix B issued a Notice of Nonconformance 99901145/2014-201-01 to Steris stating that the measuring and testing equipment used to determine the applied radiation dose reported on the Isomedix Certificate of Processing provided with each gamma irradiation run did not account for all the uncertainties involved (i.e. density of unrelated products in carriers, off-carrier locations within the irradiator, and Cobalt-60 source decay) and therefore the actual radiation dose applied to components could be less than requested as reported on the Certificate of Processing.

"Steris Isomedix Services completed an evaluation of the dose rate variability of items processed in off-carrier locations in the irradiator. Steris Isomedix Services Position Paper dated 4/27/15 states the overall variability (uncertainty) associated with gamma radiation exposures at their Whippany, NJ facility."

IE19
NMSS

The affected facilities have been notified of the non-conformance. They are:

Homewood Products Corporation, Pittsburgh, PA
Homewood Energy Services, Pittsburgh, PA

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Homewood Products Corporation

HPC HOMEWOOD PRODUCTS CORPORATION

PART 21 MATERIAL REVIEW BOARD EVALUATION FORM

Date of Discovery: 12/21/15	**Referenced Deficiency Document:** Attached NTS Letters

Description of Problem: Steris Isomedix Services measuring and test equipment used by NTS (Formerly Wyle Laboratories, Inc.) to determine the applied radiation dose did not account for all of the uncertainties involved, and therefore the actual radiation dose applied to components and reported to Homewood Products Corporation by Wyle Laboratories, could be less than the requested service condition dose.

Section 1: Screening:	**Yes**	**No**
Is the condition a failure to comply or a deviation i.e., • **a departure from the technical requirements included in a procurement document?** • **a departure from standard design certification or standard design approval?** **Explain:** The condition is a departure from the technical requirements in a procurement document and design certification.	X	☐

Section 2: Capability	**Yes**	**No**
Does the HPC have the capability to perform the evaluation to determine if a defect exists? *If no, the HPC Material Review Board Chairman shall inform the purchasers or affected licensees within five (5) working days so that the purchasers or affected licensees may evaluate the deviation or failure to comply.*	X	☐

Section 3: Evaluation	**Yes**	**No**
Is the condition a defect or failure to comply that results in a substantial safety hazard i.e., • **a significant deficiency in a final design?** • **a significant deviation from equipment performance specifications or qualifications?** • **a major degradation in performance of essential safety-related equipment?** • **a significant breakdown in any portion of the Quality Assurance Program?** **Explain:** Homewood Products Corporation will perform an evaluation to determine the impact on the five (5) motor qualification reports supplied to Homewood Products, and if the results are a substantial safety hazard. The evaluation will be completed within the 60 day period from the above discovery date.	X	☐

Section 4: Notifications Required	**Yes**	**Date**
HPC Quality Manager	X	12/21/15
Nuclear Regulatory Commission (NRC)	X	12/23/15
Customer		

Additional actions to be taken: (references)

HPC Attendee Review	**Organization**	**HPC Attendee Review**	**Organization**
Richard J. Martin	Quality Assurance	John Mikach	Engineering
Kevin Monaco	HES Marketing		

HPC Material Review Board Chair Approval Signature: Gary DeTrent	**Date:** 12/23/2015

NTS

Formerly Wyle Laboratories, Inc.

December 14, 2015

Homewood Products Corporation
820 Washington Blvd.
Pittsburgh, PA 15206

Attention: **QA Manager**

Subject: Pursuant to 10 CFR Part 21, this letter notifies Homewood Products of the existence of a reportable defect and its evaluation

Reference: Homewood Products Purchase Order No. N43333, Wyle Laboratories Job Number 55622

The defect is an error in reporting the variability in the dose delivered or lack thereof on the Isomedix Certificate of Processing for the Whippany, NJ facility. The U.S. Nuclear Regulatory Commission (NRC) under 10 CFR Part 50, Appendix B issued a Notice of Nonconformance 99901145/2014-201-01 to Steris stating that the measuring and testing equipment used to determine the applied radiation dose reported on the Isomedix Certificate of Processing provided with each gamma irradiation run did not account for all the uncertainties involved (i.e. density of unrelated products in carriers, off-carrier locations within the irradiator, and Cobalt-60 source decay) and therefore the actual radiation dose applied to components could be less than requested as reported on the Certificate of Processing.

Steris Isomedix Services completed an evaluation of the dose rate variability of items processed in off-carrier locations in the irradiator. Steris Isomedix Services Position Paper dated 4/27/15 states the overall variability (uncertainty) associated with gamma radiation exposures at their Whippany NJ facility.

Steris provided revised Component Irradiation Certification(s) that shows a revised minimum total delivered dose of 17.22 Mrad for Steris Process Run ID 30224A. The revised Steris certificate is attached.

Per the Wyle Laboratories Report 55622TR09, the stated required service condition dose is 18.25 Mrad.

The revised minimum total delivered dose does not envelop the stated service condition. The impact of this Part 21 on qualification is unknown. Please review this information to determine the impact of this defect on your application.

NTS

Formerly Wyle Laboratories, Inc.

December 14, 2015

If you have any questions, please feel free to contact me by phone (256) 716-4276, fax (256) 830-2109, or email megan.toomey@nts.com.

Sincerely,

National Technical Systems Huntsville
Formerly Wyle Laboratories, Inc.

Megan Toomey
Senior Contracts Manager

NTS

Formerly Wyle Laboratories, Inc.

December 14, 2015

STERIS
Isomedix Services

COMPONENT IRRADIATION CERTIFICATION

Prepared for Wyle Laboratories

Source Type: Cobalt 60 Gamma P.O. HSV0049082

Air Equiv. Required Dose (MRADS)	12.00
Rate Not to Exceed (MRADS / Hr.)	1.00

SPECIMENS:

Qty	Part No.	Serial No.	Description
1	N/A	N/A	75 hp Horizontal Motor
1	N/A	N/A	Chevron SRI-I Grease

DATA:

Total Delivered Dose (Air) MRADS:		Min	17.22	Max	22.88
Dose Rate (Air) MRADS / Hr:		Min	.30	Max	.88
Total Exposure Hours:		23.76			
Source Rotation	2 - WAY:		Turntable Rotation	None:	
Date In:	08/11/09	Date Out:		08/13/09	

DOSIMETRY:

Dosimeter Type	Harwell Red 4034 Perspex	Batch	KC
Calibration Date	01/20/09	Calibration Due Date	01/20/10
Readout Instrument:	Beckman DU-640	Serial No.:	4328387
Calibration Date	08/15/08	Calibration Due Date	08/18/09

Comments: Process Run #302224A / "Dose has been adjusted for a process variability of 9.4% in accordance with STERIS Isomedix Services Position Paper Appendix C (Rev 4/27/15)" / Revised Copy 11/03/15

ATTACHMENTS:

Worksheets:	N/A	Drawings:	N/A
Notice of Anomaly:		N/A	

Approved By: _____ **Title:** Sr. QS/RC Analyst **Date:** 11/03/15

Processing Location: STERIS Isomedix Services 9 Apollo Drive, Whippany, NJ 07981 Phone: 973-887-2754 Fax: 973-887-5591

The product run described above was processed in accordance with STERIS Isomedix Services Quality System requirements and the applicable requirements in ANSI/AAMI/ISO 11137. STERIS Isomedix Services facilities are in compliance with applicable state and federal regulations (FDA, NRC, EPA, and OSHA). STERIS Isomedix Services operates under a quality system which meets the requirements of the FDA QSR and ISO 13485:2003. STERIS Isomedix Services adheres to requirements provided through ANSI/AAMI/ISO 11137 and EN 552.

NTS

Formerly Wyle Laboratories, Inc.

December 14, 2015

Homewood Energy Services
820 Washington Blvd.
Pittsburgh, PA 15206

Attention: **QA Manager**

Subject: Pursuant to 10 CFR Part 21, this letter notifies Homewood Energy Services of the existence of a reportable defect and its evaluation

Reference: Homewood Energy Services Purchase Order No. N37223, Wyle Laboratories Job Number 51526

The defect is an error in reporting the variability in the dose delivered or lack thereof on the Isomedix Certificate of Processing for the Whippany, NJ facility. The U.S. Nuclear Regulatory Commission (NRC) under 10 CFR Part 50, Appendix B issued a Notice of Nonconformance 99901145/2014-201-01 to Steris stating that the measuring and testing equipment used to determine the applied radiation dose reported on the Isomedix Certificate of Processing provided with each gamma irradiation run did not account for all the uncertainties involved (i.e. density of unrelated products in carriers, off-carrier locations within the irradiator, and Cobalt-60 source decay) and therefore the actual radiation dose applied to components could be less than requested as reported on the Certificate of Processing.

Steris Isomedix Services completed an evaluation of the dose rate variability of items processed in off-carrier locations in the irradiator. Steris Isomedix Services Position Paper dated 4/27/15 states the overall variability (uncertainty) associated with gamma radiation exposures at their Whippany NJ facility.

Steris provided revised Component Irradiation Certification(s) that shows a revised minimum total delivered dose of 8.73 Mrad for Steris Process Run ID 29620. The revised Steris certificate is attached.

Per the Wyle Laboratories Report 51526TR05, the stated required service condition dose is 8.75 Mrad.

The revised minimum total delivered dose does not envelop the stated service condition. The impact of this Part 21 on qualification is unknown. Please review this information to determine the impact of this defect on your application.

If you have any questions, please feel free to contact me by phone (256) 716-4276, fax (256) 830-2109, or email megan.toomey@nts.com.

Sincerely,

National Technical Systems Huntsville
Formerly Wyle Laboratories, Inc.

Megan Toomey
Senior Contracts Manager

NTS

Formerly Wyle Laboratories, Inc.

December 14, 2015

STERIS-Isomedix Services
9 Apollo Drive
Whippany NJ 07981

STERIS-Isomedix Services

Component Irradiation Certification

CUSTOMER	Wyle Laboratories	P. O. #	H5V0034340
AIR EQUIV. REQUIRED DOSE (MRADS)		9.63	
RATE NOT TO EXCEED (MRADS/HR)		1.00	

SPECIMENS:

QTY	PART NO.	SERIAL NO.	DESCRIPTION
1	N/A	N/A	5 HP Motor
1	N/A	N/A	4 kV Motorette
1	N/A	N/A	Oil (3/4 full)

DATA:

SOURCE TYPE: COBALT-60 GAMMA					
TOTAL DELIVERED DOSE (AIR) MRADS:	MIN:	8.73	MAX:	12.37	
DOSE RATE (AIR) MRADS/HR:	MIN:	0.81	MAX	0.95	
TOTAL EXPOSURE HOURS.	11.9				
SPECIMEN ROTATION	2-WAY:	X	4-WAY:	NONE:	
DATE IN:	03/08/05		DATE OUT:	03/09/05	

DOSIMETRY:

DOSIMETER TYPE:	HARWELL PERSPEX	BATCH:	HK
	±6.5%	CALIBRATION DATE	10/21/04
READOUT INSTRUMENT:	Beckman DU-640-C		
SERIAL NO.:	4324039	CALIBRATION DATE	09/14/04
COMMENTS:	Irradiation Control #39620 / "Dose has been adjusted for a process variability of 9.4% in accordance with STERIS Isomedix Services Position Paper Appendix C (Rev 4/27/15)" / Revised Copy 11/06/15		

ATTACHMENTS:

WORKSHEETS:	N/A	DRAWINGS:	N/A
NOTICE OF ANOMOLY:		N/A	
AUTHORIZED SIGNATURE:			
TITLE:	Sr. OS/RC Analyst	DATE:	11/06/15

Form 1702.3N8
Revision: A
Effective Date: 08/18/03

NTS

Formerly Wyle Laboratories, Inc.

December 14, 2015

Homewood Products Corporation
820 Washington Blvd.
Pittsburgh, PA 15206

Attention: QA Manager

Subject: Pursuant to 10 CFR Part 21, this letter notifies Homewood Products of the existence of a reportable defect and its evaluation.

Reference: Homewood Products Purchase Order No. N42313, Wyle Laboratories Job Number 54067

The defect is an error in reporting the variability in the dose delivered or lack thereof on the Isomedix Certificate of Processing for the Whippany, NJ facility. The U.S. Nuclear Regulatory Commission (NRC) under 10 CFR Part 50, Appendix B issued a Notice of Nonconformance 99901145/2014-201-01 to Steris stating that the measuring and testing equipment used to determine the applied radiation dose reported on the Isomedix Certificate of Processing provided with each gamma irradiation run did not account for all the uncertainties involved (i.e. density of unrelated products in carriers, off-carrier locations within the irradiator, and Cobalt-60 source decay) and therefore the actual radiation dose applied to components could be less than requested as reported on the Certificate of Processing.

Steris Isomedix Services completed an evaluation of the dose rate variability of items processed in off-carrier locations in the irradiator. Steris Isomedix Services Position Paper dated 4/27/15 states the overall variability (uncertainty) associated with gamma radiation exposures at their Whippany NJ facility.

Steris provided revised Component Irradiation Certification(s) that shows a revised minimum total delivered dose of:

181.2 Mrad for Steris Process Run ID 27595.
176.4 Mrad for Steris Process Run ID 27608.
The revised Steris certificates are attached.

Per the Wyle Laboratories Report 54067TR08, the stated required service condition dose is 200.0 Mrad.

The revised minimum total delivered dose does not envelop the stated service condition. The impact of this Part 21 on qualification is unknown. Please review this information to determine the impact of this defect on your application.

NTS

Formerly Wyle Laboratories, Inc.

December 14, 2015

If you have any questions, please feel free to contact me by phone (256) 716-4276, fax (256) 830-2109, or email megan.toomey@nts.com.

Sincerely,

National Technical Systems Huntsville
Formerly Wyle Laboratories, Inc.

Megan Toomey
Senior Contracts Manager

NTS

Formerly Wyle Laboratories, Inc.

December 14, 2015

STERIS

COMPONENT IRRADIATION CERTIFICATION

Prepared for Wyle Labs

Source Type: Cobalt 60 Gamma P.O. # HSY00-42163

Air Equiv. Required Dose (MRADS)	200.0
Rate Not to Exceed (MRADS / Hr.)	1.0

SPECIMENS:

Qty	Part No.	Serial No.	Description
1	N/A	N/A	600 HP Motor
1	N/A	N/A	Mobile DTE Light Medium Oil

DATA:

Total Delivered Dose (Air) MRADS:		Min	181.20	Max	231.05
Dose Rate (Air) MRADS / Hr:		Min	0.627	Max	0.662
Total Exposure Hours:		318.98			
Static Rotation	2 - WAY:	*	Tumable Rotation	None:	
Date In:	8/1/2007	Date Out:		8/23/2007	

DOSIMETRY:

Dosimeter Type	Harwell Red 4034 Perspex	Batch	JM
Calibration Date	16Nov2006	Calibration Due Date	16Nov2007
Readout Instrument:	Beckman DU-640-C	Serial No.:	4126387
Calibration Date	08/24/06	Calibration Due Date	08/2007

Comments, Rotate 180 degrees at ½ dose. Run # 27595 / "Dose has been adjusted for a process variability of 9.4% in accordance with STERIS Isomedix Services Position Paper Appendix C (Rev 4/27/15)" / Revised Copy 11/05/15

ATTACHMENTS:

Worksheets:	N/A	Drawings:	N/A
Notice of Anomaly:		None	

Approved By: _____ **Title:** Sr. QS/RC Analyst **Date:** 11/05/15

Processing Location: STERIS Isomedix Services 9 Apollo Drive Whippany, NJ 07981 Phone: 973-887-2355 Fax: 973-887-0981

STERIS Isomedix Services' systems are designed to comply with applicable state and federal regulations (FDA, NRC, EPA, and OSHA). STERIS Isomedix Services' systems are operated under a quality system which meets the requirements of 21 CFR 820 (QSR) and ISO 13485:2003. STERIS Isomedix Services' sterilization processes are certified through ANSI/AAMI/ISO 11137 and EN 552

NTS

Formerly Wyle Laboratories, Inc.

December 14, 2015

STERIS

COMPONENT IRRADIATION CERTIFICATION

Prepared for Wyle Laboratories

Source Type: Cobalt 60 Gamma P.O. #HSV0043031

Air Equiv. Required Dose (MRADS)	200.00
Rate Not to Exceed (MRADS / Hr.)	1.00

SPECIMENS:

Qty	Part No.	Serial No.	Description
3	Project ID: AWG Lead Wires	N/A	Cables (24 gauge)
N/A	N/A	N/A	N/A

DATA:

Total Delivered Dose (Air) MRADS.	Min	176.40	Max	243.96
Dose Rate (Air) MRADS / Hr	Min	0.60	Max	0.66
Total Exposure Hours.	333.34			

Static Rotation	2 - WAY:	X	Turntable Rotation	Note:	
Date In:	10/30/07		Date Out:	11/24/07	

DOSIMETRY:

Dosimeter Type	Harwell Red 4034 Perspex	Batch	JM
Calibration Date	11/08/07	Calibration Due Date	11/08/08
Readout Instrument:	Beckman DU-640	Serial No.:	4326387
Calibration Date	08/25/07	Calibration Due Date	08/38/08

Comments: Process Run #276608 / "Dose has been adjusted for a process variability of 11.8 % in accordance with STERIS Isomedix Services Position Paper Appendix C (Rev 4/27/15)" / Revised Copy 11/10/15

ATTACHMENTS:

Worksheets.	N/A	Drawings	N/A
Notice of Anomaly		N/A	

Approved By: _____ Title: Sr. QS/RC Analyst Date: 11/10/15

Processing Location: STERIS Isomedix Services 9 Apollo Drive, Whippany, NJ 07981 Phone: 973-887-2754 Fax: 973-887-6691

NTS/RS Isomedix Services facilities are in compliance with applicable state and federal regulations (FDA, NRC, EPA, and OSHA). STS RIS Isomedix Services operates under a quality system which meets the requirements of 21 CFR 820 and ISO 13485:2003. STS RIS Isomedix Services adheres to requirements provided through ANSI/AAMI/ISO 11137 and EN 552.

PROC-00830 Form 3 Rev: 1 Eff Date: Aug8, 2007 Status: 07e. Completed: Multiple or Single Facility Page 1 of 1

NTS

Formerly Wyle Laboratories, Inc.

December 14, 2015

Homewood Energy Services
820 Washington Blvd.
Pittsburgh, PA 15206

Attention: **QA Manager**

Subject: Pursuant to 10 CFR Part 21, this letter notifies Homewood Energy Services of the existence of a reportable defect and its evaluation.

Reference: Homewood Energy Services Purchase Order Nos. N35384 and N35662, Wyle Laboratories Job Number 48955

The defect is an error in reporting the variability in the dose delivered or lack thereof on the Isomedix Certificate of Processing for the Whippany, NJ facility. The U.S. Nuclear Regulatory Commission (NRC) under 10 CFR Part 50, Appendix B issued a Notice of Nonconformance 99901145/2014-201-01 to Steris stating that the measuring and testing equipment used to determine the applied radiation dose reported on the Isomedix Certificate of Processing provided with each gamma irradiation run did not account for all the uncertainties involved (i.e. density of unrelated products in carriers, off-carrier locations within the irradiator, and Cobalt-60 source decay) and therefore the actual radiation dose applied to components could be less than requested as reported on the Certificate of Processing.

Steris Isomedix Services completed an evaluation of the dose rate variability of items processed in off-carrier locations in the irradiator. Steris Isomedix Services Position Paper dated 4/27/15 states the overall variability (uncertainty) associated with gamma radiation exposures at their Whippany NJ facility.

Steris provided revised Component Irradiation Certification(s) that shows a revised minimum total delivered dose of:

99.66 Mrad for Steris Process Run ID 22503 (4.0 kV Motorette).
99.66 Mrad for Steris Process Run ID 22503 (6.6 kV Motorette).
19.93 Mrad for Steris Process Run ID 22503 (10 hp Motor/Grease).
The revised Steris certificates are attached.

Per the Wyle Laboratories Report 48955TR04, the stated required service condition dose is either 100.0 Mrad or 20.0 Mrad.

The revised minimum total delivered dose does not envelop the stated service condition. The impact of this Part 21 on qualification is unknown. Please review this information to determine the impact of this defect on your application.

If you have any questions, please feel free to contact me by phone (256) 716-4276, fax (256) 830-2109, or email megan.toomey@nts.com.

Sincerely,

National Technical Systems Huntsville
Formerly Wyle Laboratories, Inc.

Megan Toomey
Senior Contracts Manager

NTS

Formerly Wyle Laboratories, Inc.

December 14, 2015

STERIS-Isomedix Services
9 Apollo Drive
Whippany NJ 07981

STERIS-Isomedix Services
Component Irradiation Certification

CUSTOMER	Wyle Laboratories	P. O. #	HSV0031928
AIR EQUIV. REQUIRED DOSE (MRADS)	110.00		
RATE NOT TO EXCEED (MRADS/HR)	1.00		

SPECIMENS:

QTY	PART NO.	SERIAL NO.	DESCRIPTION
1	N/A	N/A	4.0 kV Motorette
		N	
		A	

DATA:

SOURCE TYPE: COBALT-60 GAMMA					
TOTAL DELIVERED DOSE (AIR) MRADS:	MIN:	99.66	MAX:	140.73	
DOSE RATE (AIR) MRADS/HR:	MIN:	0.59	MAX	0.69	
TOTAL EXPOSURE HOURS:	186.44				
SPECIMEN ROTATION	2-WAY:	X	4-WAY:		NONE:
DATE IN:	06/14/04		DATE OUT:	06/29/04	

DOSIMETRY:

DOSIMETER TYPE:	HARWELL PERSPEX	BATCH:	HB
	66.3%	CALIBRATION DATE	02/04/04
READOUT INSTRUMENT:	Beckman DU-640-C		
SERIAL NO.:	4324039	CALIBRATION DATE	09/10/03
COMMENTS:	Irradiation Control Number 22503 / "Dose has been adjusted for a process variability of 9.4% in accordance with STERIS Isomedix Services Position Paper Appendix C (Rev 4/27/15)" / Revised Copy 11/06/15		

ATTACHMENTS:

WORKSHEETS:	N/A	DRAWINGS:	N/A
NOTICE OF ANOMOLY:		N/A	
AUTHORIZED SIGNATURE:			
TITLE:	Sr. QS/RC Analyst	DATE:	11/06/15

Form 1702.3NJ
Revision: A
Effective Date: 08/18/03

NTS

Formerly Wyle Laboratories, Inc.

December 14, 2015

STERIS-Isomedix Services
9 Apollo Drive
Whippany NJ 07981

STERIS-Isomedix Services

Component Irradiation Certification

CUSTOMER	Wyle Laboratories	P. O. #	HSV0031928
AIR EQUIV. REQUIRED DOSE (MRADS)	110.00		
RATE NOT TO EXCEED (MRADS/HR)	1.00		

SPECIMENS:

QTY	PART NO.	SERIAL NO.	DESCRIPTION
1	N/A	N/A	6.6 kV Motorette
		N	
		A	

DATA:

SOURCE TYPE: COBALT-60 GAMMA					
TOTAL DELIVERED DOSE (AIR) MRADS:	MIN:	99.66	MAX:	138.39	
DOSE RATE (AIR) MRADS/HR:	MIN:	0.60	MAX	0.69	
TOTAL EXPOSURE HOURS:	183.34				
SPECIMEN ROTATION	2-WAY:	X	4-WAY:		NONE:
DATE IN:	06/14/04		DATE OUT:	06/29/04	

DOSIMETRY:

DOSIMETER TYPE:	HARWELL PERSPEX	BATCH:	HB
	±6.5%	CALIBRATION DATE	02/04/04
READOUT INSTRUMENT:		Beckman DU-640-C	
SERIAL NO.:	4324039	CALIBRATION DATE	09/10/03
COMMENTS:	Irradiation Control Number 22503 / "Dose has been adjusted for a process variability of 9.4% in accordance with STERIS Isomedix Services Position Paper Appendix C (Rev 4/27/15)" / Revised Copy 11/06/15		

ATTACHMENTS:

WORKSHEETS:	N/A	DRAWINGS:	N/A
NOTICE OF ANOMOLY:		N/A	
AUTHORIZED SIGNATURE:			
TITLE:	Sr. OS/RC Analyst	DATE:	11/06/15

Form 1702.3NJ
Revision: A
Effective Date: 08/18/03

NTS

Formerly Wyle Laboratories, Inc.

December 14, 2015

STERIS-Isomedix Services
9 Apollo Drive
Whippany NJ 07981

STERIS-Isomedix Services

Component Irradiation Certification

CUSTOMER	Wyle Laboratories			P. O. #	HSV0031928
AIR EQUIV. REQUIRED DOSE (MRADS)			22.00		
RATE NOT TO EXCEED (MRADS/HR)			1.00		
SPECIMENS:					
QTY	PART NO.	SERIAL NO.		DESCRIPTION	
1	N/A	N/A		10 hp Motor	
1	N/A	N/A		Grease	
N/A	N/A	N/A		N/A	
DATA:					
SOURCE TYPE: COBALT-60 GAMMA					
TOTAL DELIVERED DOSE (AIR) MRADS:		MIN:	19.93	MAX:	27.88
DOSE RATE (AIR) MRADS/HR:		MIN:	0.38	MAX	0.44
TOTAL EXPOSURE HOURS:		57.9			
SPECIMEN ROTATION		2-WAY:	X	4-WAY:	NONE:
DATE IN:		06/14/14		DATE OUT:	06/18/04
DOSIMETRY:					
DOSIMETER TYPE:	HARWELL PERSPEX		BATCH:		HB
	±6.5%		CALIBRATION DATE		02/04/04
READOUT INSTRUMENT:			Beckman DU-640-C		
SERIAL NO.:	4324039		CALIBRATION DATE		09/10/03
COMMENTS:	Irradiation Control Number 22503 / "Dose has been adjusted for a process variability of 9.4% in accordance with STERIS Isomedix Services Position Paper Appendix C [Rev 4/27/15]" / Revised Copy 11/06/15				
ATTACHMENTS:					
WORKSHEETS:	N/A		DRAWINGS:		N/A
NOTICE OF ANOMOLY:			N/A		
AUTHORIZED SIGNATURE:					
TITLE:	Sr. QS/RC Analyst		DATE:		11/06/15

Form 1702.3NJ
Revision: A
Effective Date: 08/18/09

NTS

Formerly Wyle Laboratories, Inc.

December 14, 2015

Homewood Products Corporation
820 Washington Boulevard
Pittsburgh, PA 15206

Attention: **QA Manager**

Subject: Pursuant to 10 CFR Part 21, this letter notifies Homewood Products Corporation of the existence of a reportable defect and its evaluation.

Reference: Homewood Products Corporation Purchase Order No. N61979, NTS Project Number PR029808

The defect is an error in reporting the variability in the dose delivered or lack thereof on the Isomedix Certificate of Processing for the Whippany, NJ facility. The U.S. Nuclear Regulatory Commission (NRC) under 10 CFR Part 50, Appendix B issued a Notice of Nonconformance 99901145/2014-201-01 to Steris stating that the measuring and testing equipment used to determine the applied radiation dose reported on the Isomedix Certificate of Processing provided with each gamma irradiation run did not account for all the uncertainties involved (i.e. density of unrelated products in carriers, off-carrier locations within the irradiator, and Cobalt-60 source decay) and therefore the actual radiation dose applied to components could be less than requested as reported on the Certificate of Processing.

Steris Isomedix Services completed an evaluation of the dose rate variability of items processed in off-carrier locations in the irradiator. Steris Isomedix Services Position Paper dated 4/27/15 states the overall variability (uncertainty) associated with gamma radiation exposures at their Whippany NJ facility.

Steris provided revised Component Irradiation Certification(s) that shows a revised minimum total delivered dose of 32.98 Mrad for Steris Process Run ID 68005A (note the previous cert stated process run number 678005A which was incorrect). The revised Steris certificate is attached.

Per NTS Report PR029808-TR-14, the stated required service condition dose is 30.0 Mrad.

The revised minimum total delivered dose envelopes the stated service condition. Qualification of the component is maintained with reduced margin.

If you have any questions, please feel free to contact me by phone (256) 716-4358, fax (256) 830-2109, or email ronda.fisher@nts.com.

Sincerely,

National Technical Systems Huntsville
Formerly Wyle Laboratories, Inc.

Ronda L. Fisher

Ronda L. Fisher
Contracts Administrator II

NTS

Formerly Wyle Laboratories, Inc.

December 14, 2015

STERIS

COMPONENT IRRADIATION CERTIFICATION

Prepared for: National Technical Systems

Source Type: Cobalt 60 Gamma P.O. # PRPO016016-2

Air Equiv. Required Dose (MRADS)	36.40
Rate Not to Exceed (MRADS / Hr.)	1.00

SPECIMENS:

Qty	Part No.	Serial No.	Description
1	N/A	N/A	10 HP Electrical Motor

DATA:

Total Delivered Dose (Air) MRADS:		Min	32.98	Max	40.86
Dose Rate (Air) MRADS / Hr:		Min	0.847	Max	0.869
Total Exposure Hours:		42.98			
Static Rotation	2 - WAY:	Turntable Rotation: v		None:	
Date In:	06/25/14	Date Out:		06/28/14	

DOSIMETRY:

Dosimeter Type	Harwell Red 4034 Perspex	Batch	MW
Calibration Date	12/10/13	Calibration Due Date	12/10/14
Readout Instrument:	Beckman DU-640	Serial No.:	4324039
Calibration Date	08/07/13	Calibration Due Date	08/07/14

Comments: Process Run ID: 68005A / "Dose has been adjusted for a process variability of 9.4% in accordance with STERIS Isomedix Services Position Paper Appendix C (Rev 4/27/13)" / Revised Copy 11/13/15

ATTACHMENTS:

Worksheets:	N/A	Drawings:	N/A
Notice of Anomaly:		N/A	

Approved By: _____ Title: Sr. QS/RC Analyst Date: 11/3/15

Processing Location: STERIS Isomedix Services 9 Apollo Drive, Whippany, NJ 07981 Phone: 973-887-2754 Fax: 973-887-6591

The product run described above was processed in accordance with STERIS Isomedix Services Quality System requirements and the Customer approved process parameters. STERIS Isomedix Services facilities are in compliance with applicable state and federal regulations (FDA, NRC, EPA, and OSHA). STERIS Isomedix Services operates under a quality system which meets the requirements of the FDA QSR and ISO 13485:2003. STERIS Isomedix Services adheres to requirements provided through ANSI/AAMI/ISO 11137:2006.