

Part 21 (PAR)

Event # 50359

<b>Rep Org:</b> NUTHERM INTERNATIONAL, INC	<b>Notification Date / Time:</b> 08/01/2014 15:16 (EDT)
<b>Supplier:</b> NUTHERM INTERNATIONAL, INC	<b>Event Date / Time:</b> 08/01/2014 (CDT)
	<b>Last Modification:</b> 08/31/2015
<b>Region:</b> 3	<b>Docket #:</b>
<b>City:</b> MOUNT VERNON	<b>Agreement State:</b> Yes
<b>County:</b>	<b>License #:</b>
<b>State:</b> IL	
<b>NRC Notified by:</b> ADRIENNE SMITH	<b>Notifications:</b> SILAS KENNEDY R1DO
<b>HQ Ops Officer:</b> JEFF ROTTON	GEORGE HOPPER R2DO
<b>Emergency Class:</b> NON EMERGENCY	CHRISTINE LIPA R3DO
<b>10 CFR Section:</b>	VIVIAN CAMPBELL R4DO
21.21(a)(2) INTERIM EVAL OF DEVIATION	PART 21 GROUP EMAIL

## POTENTIAL ISSUE REGARDING INCORRECT INDUSTRIAL IRRADIATION DOSE

The following information was received via facsimile:

Nutherm International, Inc. was notified by Steris Isomedix Services that the applied radiation dose reported on their Component Irradiation Certificates did not account for all uncertainties involved (i.e. density of unrelated products in carriers, off-carrier location within the irradiator and Cobalt-60 source decay). This issue was originally identified as part of NRC Inspection Report No. 99901445/2014-201.

"Nutherm International, Inc. is conducting an evaluation to determine whether a defect as defined by 10 CFR Part 21 exists. The impact of this failure to account for all uncertainties will be evaluated for all projects that required data from any sample irradiated by this supplier.

"At the conclusion of the evaluation, any customer impacted by this issue will be notified and the U.S. Nuclear Regulatory Commission will be notified in accordance with the requirements of 10 CFR Part 21.21.

"If you have any questions regarding this issue please do not hesitate to contact Adrienne Smith, Quality Assurance Manager at 618-244-6000, adrienne.smith@nutherm.com."

The supplier will update this report when the evaluation is complete. This event report was originally received by the NRC Operations Center on 08/01/2014

\*\*\* UPDATE AT 1727 ON 8/31/2015 FROM THOMAS STERBIS TO MARK ABRAMOVITZ \*\*\*

The following information was received via fax:

IE19  
NPO

"Nutherm has identified one customer where there is a potential impact to the conclusions of the equipment qualification that Nutherm does not have the capability to perform further evaluations to determine if a defect exists.

"Nutherm International, Inc. performed equipment qualification testing for SOR, Inc., Lenexa, KS under SOR, Inc. Purchase Order number 166984 which included irradiation performed by Steris Isomedix. Based on the location of the sample during the irradiation and the total variability for this location provided by Steris Isomedix, Nutherm has verified that the test specimens received a minimum irradiation dose that meets the customer's TID requirement but does not meet the customer's TID requirement with the 10 percent IEEE 323 margin.

"In accordance with the requirements of 10 CFR Part 21.21, SOR Inc. has been notified regarding this issue to allow them to evaluate this deviation or failure to comply."

Notified the R4DO (Werner), NMSS Events Resource (via e-mail), and the Part-21 Group (via e-mail)

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# Fax

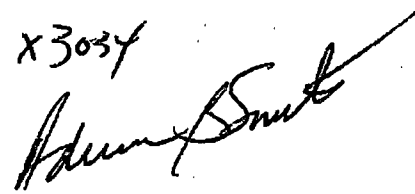
# Nutherm **NO**

INTERNATIONAL, INC.

501 SOUTH ELEVENTH STREET MT. VERNON, ILLINOIS 62864 PHONE 618-244-6000 FAX 618-244-6641

To:	<u>DOCUMENT CONTROL DESK</u>	From:	<u>ADRIENNE SMITH</u>
Company:	<u>U.S. NRC</u>		
Fax:	<u>301 816 5151</u>	Pages Including Cover:	<u>3</u>
Phone:	<u>301 816 5100</u>	Date:	<u>8/31/15</u>
CC:		Nutherm Project No:	<u>N/A</u>
		Customer Project No:	<u>N/A</u>
Subject:	<u>UPDATE ON POTENTIAL IOCFR PART 21 ISSUE</u>		

If you have any questions on the above, call me at 618-244-6000. X3034





501 South 11th Street Mount Vernon, IL 62864 Phone:618-244-6000 Fax:618-244-6641

August 31, 2015

U.S. Nuclear Regulatory Commission  
Washington, DC 20555-0001

Attention: Document Control Desk

Subject: Update on Potential 10 CFR Part 21 Issue Regarding Incorrect Industrial Irradiation Dose

Reference: Letter Thomas Sterbis to NRC dated 8/1/2014 – Event No. 50359 - Log Number 2014-56-00  
STERIS Isomedix Position Paper dated 4/27/2015  
Industry Guidance Position Paper: Responding to the 2014 Steris 10CFR Part 21, IEEE/NUGEO,  
Revision 0, dated June 2015

Nutherm International, Inc. was notified by STERIS Isomedix Services, Whippany, New Jersey that the applied radiation dose reported on their Component Irradiation Certificates did not account for all uncertainties involved (i.e. density of unrelated products in carriers, off-carrier location within the irradiator and Cobalt-60 source decay). This issue was originally identified as part of NRC Inspection Report No. 99901445/2014-201.

Nutherm notified the NRC in the letter referenced above that Nutherm is conducting an evaluation of all past equipment qualifications performed by Nutherm to determine, on a case by case basis, if any customer is impacted by this issue. This evaluation is currently ongoing.

Nutherm has identified one customer where there is a potential impact to the conclusions of the equipment qualification that Nutherm does not have the capability to perform further evaluations to determine if a defect exists.

Nutherm International, Inc. performed equipment qualification testing for SOR, Inc., Lenexa, KS under SOR, Inc. Purchase Order number 166984 which included irradiation performed by STERIS Isomedix.

Based on the location of the sample during the irradiation and the total variability for this location provided by STERIS Isomedix, Nutherm has verified that the test specimens received a minimum irradiation dose that meets the customer's TID requirement but does not meet the customer's TID requirement with the 10% IEEE 323 margin.

In accordance with the requirements of 10CFR Part 21.21 SOR, Inc. has been notified regarding this issue to allow them to evaluate this deviation or failure to comply.

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August 31, 2015

If you have any questions regarding this issue please do not hesitate to contact Adrienne Smith, Quality Assurance Manager at 618-244-6000 x3034, [adrienne.smith@nutherm.com](mailto:adrienne.smith@nutherm.com).

Sincerely,  
NUTHERM INTERNATIONAL, Inc.



Thomas Sterbis  
President

TAS/abs