

Part 21 (PAR)

Event # 50359

Rep Org: NUTHERM INTERNATIONAL, INC		Notification Date / Time: 08/01/2014 15:16 (EDT)	
Supplier: NUTHERM INTERNATIONAL, INC		Event Date / Time: 08/01/2014 (CDT)	
Last Modification: 08/13/2014			
Region: 3	Docket #:		
City: MOUNT VERNON	Agreement State: Yes		
County:	License #:		
State: IL			
NRC Notified by: ADRIENNE SMITH	Notifications: SILAS KENNEDY	R1DO	
HQ Ops Officer: JEFF ROTTON	GEORGE HOPPER	R2DO	
Emergency Class: NON EMERGENCY	CHRISTINE LIPA	R3DO	
10 CFR Section:	VIVIAN CAMPBELL	R4DO	
21.21(a)(2) INTERIM EVAL OF DEVIATION	PART 21	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



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

August 1, 2014

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

Attention: Document Control Desk

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

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.

Sincerely,
Nutherm International, Inc.

A handwritten signature in black ink, appearing to read 'Thomas A. Sterbis', enclosed within a hand-drawn oval.

Thomas A. Sterbis
President

TAS/abs

Fax

Nutherm **Ni** 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. Nuclear Regulatory Commission</u>	
Fax: <u>301 816 5151</u>	Pages including Cover: <u>2</u>
Phone: <u>301 816 5700</u>	Date: <u>8/1/14</u>
CC: _____	Nutherm Project No: <u>N/A</u>
	Customer Project No: <u>N/A</u>
Subject: <u>Potential IOEFR PART 21 Notification</u>	

If you have any questions on the above, call me at 618-244-6000. x 3034

