Part 21 (PAR) Event # 50359

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| **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:** | 02/03/2016 |
| **Region:** | 3 | **Docket #:** | |
| **City:** | MOUNT VERNON | **Agreement State:** | Yes |
| **County:** | | **License #:** | |
| **State:** | IL | | |

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| **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 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
NRR

"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)

* * * UPDATE FROM NUTHERM INTERNATIONAL, INC. AT 1658 EST ON 2/3/16 * * *

The following information is summarized from the information received from Nutherm International, Inc. via fax:

Nutherm has completed their evaluation of past equipment qualifications and identified that the following U.S. facilities may be impacted: Cooper Nuclear Plant, Oconee Station, J.A. Fitzpatrick Station, Point Beach Nuclear, Brunswick Nuclear, Susquehanna Nuclear and Electric Power Research Institute.

Nutherm has notified the affected facilities.

Notified R1DO (Rogge), R2DO (Musser), R3DO (Kozak), R4DO (Pick) and the Part 21 group via email.

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Nutherm International, Inc.
www.nutherm.com

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

February 3, 2016

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

Attention: Document Control Desk

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

Reference: 1) Letter Thomas Sterbis to NRC dated 8/1/2014 – Event No. 50359 - Log Number 2014-56-00 Potential Issue Regarding Incorrect Industrial Radiation Dose
2) Industry Guidance Position Paper: Responding to the 2014 Steris 10CFR Part 21, IEEE/NUGEQ, Revision 0, dated June 2015
3) Letter Thomas Sterbis to NRC dated 8/31/2015 - Event No. 50359 - Log Number 2014-56-01 Update on Potential Issue Regarding Incorrect Industrial Radiation Dose

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 Reference 1) above that Nutherm would conduct 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 now complete.

In addition to the customer identified in Reference 3), Nutherm has identified other customers where there is a potential impact to the conclusions of the equipment qualification. Nutherm does not have the capability to perform further evaluations to determine if a defect exists.

The customers were identified as follows:

Nebraska Public Power District – Cooper Nuclear Station
Duke Energy – Oconee Station
Entergy Nuclear – Fitzpatrick Station
NextEra Point Beach - NextEra Energy Point Beach Nuclear
Progress Energy - Brunswick Nuclear Plant
PGS Enrique Maria Hierro S.L. - C.N. Cofrentes
Talen Energy, LLC - Susquehanna Nuclear Station
Electric Power Research Institute

In all cases where a customer identified a minimum irradiation dose, the dose received met the customer's TID requirement but did not meet the customer's TID requirement with the 10% IEEE 323 margin.

In accordance with the requirements of 10CFR Part 21.21 these customers have been notified regarding this issue to allow them to evaluate this deviation or failure to comply.

Nutherm has completed its review of all potentially impacted work and considers this issue closed with regards to the Part 21 review.

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.

Sincerely,
**NUTHERM INTERNATIONAL, Inc.**

Wade Bowlin
Chairman of the Board

WB/abs