

August 7, 2015

U.S. Nuclear Regulatory Commission
Electrical Vendor Inspector Branch
Division of Construction Inspection
And Operational Programs
Washington, DC 20555-0001

Subject: Reply to a Notice of Violation
Reference: Nuclear Regulatory Commission Vendor Inspection of Thermo
Fisher Scientific Report No. 99901460/2015-201-01, Reply to a
Notice of Violation
Attachments: Notice of Defect from Mirion IST dated March 3, 2015
CAR 15-006
Part 21 Notification to the NRC dated June 1, 2015

During the NRC Vendor Inspection starting on June 1, 2015, it was noted that Thermo Fisher Scientific was in violation of Title 10 of the *Code of Federal Regulations Part (10CFR) 21.21*, "Notification of failure to comply or existence of a defect and its evaluation". Per the NRC report Thermo Fisher Scientific (TFS),

"Section (d)(1) states, in part, that "A director or responsible officer subject to the regulations of this part or a person designated under Section 21.21(d)(5) must notify the Commission when he or she obtains information reasonably indicating a failure to comply or a defect affecting a basic component that is within his or her organization's responsibility and is supplied for a facility or an activity within the United States that is subject to licensing under part 50." Section (d)(3)(i) requires an initial NRC notification by facsimile or telephone within two days and section (d)(3)(ii) requires a written NRC notification within 30 days following receipt of the information by the director or responsible officer ... Contrary to the above, as of June 5, 2015, TFS failed to notify the NRC within both the initial two day and written 30 day time periods that a defect existed in a Power Range Detector (Part No. 201872-101, Serial No. 006) that was shipped to Palisades Nuclear Power Plant. The defect was documented in an evaluation dated March 24, 2015, and was conducted in response to written notification from a sub-supplier, Mirion Technologies IST, that an uncompensated ion chamber (PO No. M50426) used in the Power Range Detector had a potential defect and could fail under certain conditions ... This is a Severity Level IV violation (Section 6.9.d of the NRC Enforcement Policy)".

Mirion IST sent TFS a letter titled, *Notification of Potential Defect Under the Atomic Energy Act of 1954 and 10CFE Part 21* from, dated March 3, 2015. In it Mirion IST detailed that an Uncompensated Ion Chamber (UIC), Model NY-10419, Serial Number 143110, had a potential short between HV and Signal B that could present

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during a seismic event. Mirion IST assigned a 2.6% chance that this particular chamber had this defect.

On March 5 TFS Quality Assurance opened Corrective Action Request 15-006 to track and address the Mirion IST letter. It was determined that the UIC had been installed into a Power Range Detector, TFS Part Number 201872-101 Serial Number 006, and had been shipped to Entergy Operations, Inc. This detector is a safety related component.

One March 24, 2015, TFS sent a letter to Mirion informing them that the UIC in question had been issued to a safety related assembly.

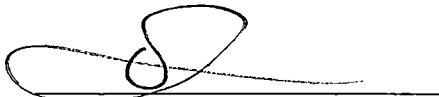
On June 2, 2015, TFS sent a letter to Entergy Operations, Inc., informing them of the possible defect. TFS identified the failure mode, and requested Entergy's preferred implementation. Entergy informed TFS that the detector was never installed. Entergy has since opted to return the detector. Once TFS receives the detector, the UIC will be removed and returned to Mirion IST.

On June 5, 2015, TFS sent an interim notification to the NRC. This has been given Event No. ML15162A027.

On July 1, 2015, TFS sent the Final Report to the NRC titled, *10 CFR Part 21 Notification of Power Range Detector Assembly – Final Report*. This has been given Event No. ML15187A031.

TFS failed to observe the requirement for prompt notification, the interim notification sent to the NRC on June 5 should have been sent no later than April 3, 2015. While TFS promptly performed an internal evaluation as to the impact of the potential defect of the UIC, this was not properly externally translated to the NRC.

TFS has since properly notified the NRC, and the customer, Entergy Operations, Inc. To address the breakdown in internal communications, the TFS NRC Reporting Official has been changed from the Global Commercial Leader, to the Technical Support Manager. The TFS Quality Procedure governing reporting of defects and noncompliance, as required by 10CFR Part 21, will be reviewed and revised by August 31, 2015.



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