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August 26, 2013

United States Nuclear Regulatory Commission  
 ATTN: Document Control Desk  
 Washington, D.C. 20555-0001  
 Docket No.: 99900880

**Subject: Reply to NOTICE OF NONCONFORMANCE (99900880/2013-201)**

Reference: Letter, R. Rasmussen(NRC) to A. Fogle(NSPI) dated July 31, 2013,  
 "NRC Inspection Report No. 99900880/2013-201 and Notice of Nonconformance"

Dear Sirs,

Ultra Electronics, NSPI's reply to the Notice of Nonconformance is enclosed in Attachment-1.

The attachment to this letter addresses the reason for the noncompliance; corrective steps that have been taken and the results achieved to date; corrective steps that will be taken to avoid future noncompliance; and the date when all corrective actions will be complete.

As discussed in the attachment, some of the corrective actions have been completed and others are currently in progress. We believe that proper containments are in place and the stated corrective actions will prevent further nonconformance in these areas.

Regards,

Alan D. Fogle  
 Director of Quality Systems & Operational Excellence  
 Ultra Electronics-NSPI

Enclosure: Attachment-1

cc: Richard A. Rasmussen, Chief,  
 Construction Electrical Vendor Branch,  
 Division of Construction Inspection and Operational Programs,  
 Office of New Reactors



Instrumentation is  
 Inc.

Ultra Electronics,  
 Nuclear Sensors & Process

a business name of Weed Instrument Co.,

*Handwritten:* 1E09 NRO

## Attachment-1

### Reply to Notice of Nonconformance NRC NO. 99900880/2013-201.

Text from the Nuclear Regulatory Commission Inspection Report No. 99900880/2013-201 and Notice of nonconformance will appear in *italics* within the body of this response.

#### Observations and Findings

*"The NRC inspection team verified that Ultra Electronics was adequately implementing procedure Quality System Department Regulation (QSDR) 100-20.1, "Software Quality Assurance," to control the use of software. The NRC inspection team found during inspection of Ultra Electronics testing activities that in two cases, N9004 RTD Hysteresis Test and DTN-2070 Pressure Transmitter Temperature Compensation Test, Ultra Electronics used Lab View commercial software to run automated test processes. The Lab View software was programmed by Ultra Electronics to control, verify and document test parameters for the various test equipment used as part of the acceptance and documentation of test results. The NRC inspection team learned the software was considered safety-related under the Ultra Electronics software QA program, but noted it was not appropriately controlled under the current Software QA Program (as specified in Company Regulation 100-20.1, Revision 4) or by any other means to assure that the commercially purchased software would perform its safety-function associated with testing (e.g., assurance of test parameters and profiles were properly controlled).*

*Some verification was performed to validate resistance temperature calculations for the N9004 RTD Hysteresis Test, but there was no documented verification that the automated test profile and data recording software for the test were functional as designed. The observed testing was unmonitored by personnel and occurred over extended periods of time (12 or more hours). For the DTN-2070 Pressure Transmitter Temperature Compensation Test the test results are used to determine resistor changes to ensure accurate readings of the pressure transmitter through the range of its operations and to validate performance of the final transmitter. The NRC inspection team found through interviews with Ultra Electronics staff that the same software controls were used during design verification testing of the DTN-2070 Pressure Transmitter and N9004 RTD.*

*The NRC inspection team determined that Ultra Electronics did not appropriately control Lab View 3rd Party Software in accordance with released procedures and instructions or demonstrate by another means of verification (i.e. dedication or conducting tests not relying on the same software used for design) that the software was capable of performing its safety function as related to the testing of safety related components. Ultra Electronics stated at the exit meeting that they had entered the finding in their corrective action program. This issue is identified as Nonconformance 99900880/2013-201-01."*

### **The reasons for noncompliance, or if contested, the basis for disputing the noncompliance**

NSPI has over 30 years of experience providing safety related products to the domestic nuclear utility industry. That experience has allowed us to embed redundancy into our various control processes. In the cases mentioned in the nonconformance, there is an independent check during the manufacturing process that assures the automated test profile and data recording software is functioning as designed. This check supplements the resistance temperature calculation verification and report generation verification that was noted to be in place during the NRC Inspection. All DTN-2070 Pressure Transmitters and N9004 RTD's have the test profile and data recording results of the 3<sup>rd</sup> party Lab View software verified by an independent engineer at the time of testing. Any anomalies in the test profile or test record would be cause for investigation and rejection if appropriate.

ASME NQA-1a-2009 states that to utilize a Commercial Grade Item or service, controls shall be implemented to provide reasonable assurance that the item or service will perform its intended safety function. The combination of the existing verification activities and the in-process verification provides a reasonable assurance.

NSPI has reviewed this noncompliance for potential reportability in accordance with 10 CFR Part 21 and has concluded this noncompliance has no impact to delivered equipment and is not reportable for the reasons given above.

### **The corrective steps that have been taken and the results achieved to date**

NSPI has taken several steps to address the noncompliance as a containment action prior to the implementation of more permanent solutions. In general, the steps that have been taken are meant to remove the reliance of verification on in-process checks and to return it to a considered part of the software CGD process. Specifically,

- It has been confirmed that all safety related software has been validated according to an approved version of QSDR 100-20.1 except for the N9004 RTD and DTN2070 test profile and data acquisition software (Lab View).
- The Quality Systems Department Regulation (QSDR) 100-20.1 is currently being revised to incorporate a more robust Commercial Grade Dedication (CGD) process.
- A preliminary technical evaluation has been performed on the DTN2070 and N9004 RTD Test Profile and Data Acquisition software (Lab View) using the proposed CGD process.

### **The corrective steps that will be taken to avoid future noncompliance**

NSPI will take several steps to enhance the existing processes to be more in line with the expectation of the NRC.

- The QSDR 100-20.1 "Software Quality Assurance" regulation will be revised and released as a controlled document through NSPI's Quality Management System with a more robust CGD process and more stringent rules for the technical evaluation and classification of safety related software. This action is targeted to be completed by Q3-2013.
- All personnel who will be performing technical evaluations and safety classifications using the CGD process defined in QSDR 100-20.1 will be trained to the new procedure with their training records updated to reflect the training. This will be completed by Q4-2013.

- The DTN-2070 Pressure Transmitter Temperature Compensation test and the N9004 RTD Hysteresis test are targeted to be brought under full control under QSDR 100-20.1 by Q4-2013.
- NSPI will rededicate where necessary the remaining 3<sup>rd</sup> party safety-related software by Q4-2014. At a high level, this will be accomplished through the completion of a technical evaluation, the identification of the associated critical characteristics, the development of acceptance methods and the completion of acceptance testing.

**Date when all corrective actions will be completed**

Ultra Electronics, NSPI commits to having these actions completed no later than 12/31/2014.