



CANBERRA

February 17, 2016

U.S. Nuclear Regulatory Commission
Attn: Document Control Desk
Washington, DC 20555-0001

cc:
Greg Galletti, Acting Chief,
Electrical Vendor Inspection Branch
Division of Construction Inspection
and Operational Programs
Office of New Reactors

Subject: Reply to a Notice of Nonconformance

Docket No: 99901461
Reference NRC Inspection Report No. 99901461/2015-201
Nonconformance 99901461/2015-201-01
Nonconformance 99901461/2015-201-02
Nonconformance 99901461/2015-201-03

Dear Sir/Madam:

Canberra Industries Inc., CT has reviewed Nonconformance 99901461/2015-201-01, Nonconformance 99901461/2015-201-02 and Nonconformance 99901461/2015-201-03 and is enclosing responses to said nonconformances.

Should there be any questions or need for additional information, CANBERRA will be pleased to provide the same. I may be contacted by phone at (203) 639-2209, or by email at michael.byram@canberra.com.

Sincerely yours,

Canberra Industries Inc.

Michael R Byram
Manager Quality Assurance, North America

Attachment: Response to Notice of Nonconformance

Distribution: JB Koehl, Doug Bellfy, Audrey Carmichael, John Tamburro, Xavier Humel,
James Wrobel, Dominique Grandemange, Shelia Webb, Bertrand Duban

IED9
NRD

Nonconformance 99901461/2015-201-01

Criterion III, "Design Control," of Appendix B to Title 10 of the Code of Federal Regulations (10 CFR) Part 50 states, in part, that "Measures shall also be established for the selection and review for suitability of application of materials, parts, equipment, and processes that are essential to the safety-related functions of the structures, systems and components."

Canberra procedure, M07-0-2, "Commercial Grade Dedication Plan Process," Revision G, section 6.7.5, states, "Commercial grade items designated for installation or installed in seismically or environmentally qualified equipment or in locations which require such qualification shall include the selection of appropriate critical characteristics and possible dedication of the service required to maintain the qualification of the component or equipment."

Contrary to the above, as of November 6, 2015, Canberra failed to establish adequate measures for the selection and review for suitability for purchase order PO 00185091, for a CAM skid manual flow control mod kit, PO 00185167, for a time delay relay, and PO 00191479, for an electrical AC motor pump. Specifically, POs 00185091, 00185167, and 00191479 are essential to the safety-related functions of the structures, systems and components and Canberra failed to identify and verify all the appropriate critical characteristics for these POs and failed to ensure that the components met/enveloped the applicable qualification reports as required by the POs. Examples of some of the critical characteristics that were not identified or verified in these POs included: material composition and material strength; weight of components; dielectric strength; current capacity; operating current; startup current; insulation resistance; and overall dimensions. Therefore, all three POs that had seismically, environmental or electromagnetic interference (EMI)/electromagnetic compatibility (EMC) qualified related items were not appropriately verified or evaluated.

This issue has been identified as Nonconformance 99901461/2015-201-01.

(1) The reason for the noncompliance, or if contested, the basis for disputing the noncompliance.

CANBERRA Response:

CANBERRA acknowledges Nonconformance 99901461-2015-201-01.

Despite adequate verification of functional characteristics at standard conditions, these Commercial Grade Dedication Plans for spare parts did not identify nor verify critical characteristics required to maintain seismic qualification over the full range of conditions that could be assumed for a typical mild environment. The Commercial Grade Dedication Plans incorrectly stated that there were no requirements for seismic qualification, despite such need being specified on the customer Purchase Order. One of the Commercial Grade Dedication Plans selected characteristics from the manufacturer's component specification as being critical to the safety function, when in fact they were not needed for the intended use. The root cause of this non-conformance was inadequate training and qualification of personnel and then assigning both preparation and approval responsibility to a portion of the organization that was unfamiliar with the design and qualification of the systems where the spare parts were to be used.

(2) The corrective steps that have been taken and the results achieved.

CANBERRA Response:

CANBERRA has taken the following corrective action steps:

- a) Internal Corrective Action Request, CAR # 1511-MB940948 initiated 11/05/2015. Evaluation confirmed the non-conformance, identified root causes, short term containment actions and long term corrective actions.

- b) About two months prior to the NRC audit, CANBERRA had reorganized responsibilities for preparation and approval of Commercial Grade Dedication Plans to an experienced RMS nuclear systems engineer and the manager of RMS products design engineering. Immediately following the audit, CANBERRA sought reviews of active Commercial Grade Dedication Plans from third-party personnel who were qualified within the Nuclear Industry to review/approve Commercial Grade Dedication Plans. Formal training was conducted by the third-party for all CANBERRA personnel involved with preparation, review and approval of Commercial Grade Dedication Plans in accordance with ASME NQA-1 2009 and EPRI 3002002982 (Revision 1 to EPRI NP-5652 and TR-102260). CANBERRA has now assigned a technically diverse four-person team to prepare (or revise) each Commercial Grade Dedication Plan, with review by the experienced RMS nuclear systems engineer, and approval by the 3rd party qualified approver.
- c) CANBERRA submitted 10CFR21 INTERIM report to the NRC and to the licensee who received materials for the three Purchase Orders that were identified in this non-conformance. CANBERRA is actively working with the licensee to resolve the 10CFR21 interim report to facilitate a resolution.
- d) All existing un-shipped orders and new orders for safety-related products, spare parts and services have been subjected to more thorough technical and quality assurance review to prevent shipment with similar Commercial Grade Dedication Plan deficiencies as identified in this non-conformance. CANBERRA has begun investigating whether any other previously shipped orders had similar deficiencies.

(3) The corrective steps that will be taken to avoid noncompliance.

CANBERRA Response:

CANBERRA will take the following additional steps to avoid non-compliance:

- a) CANBERRA procedures for Commercial Grade Dedication Plans will be revised to provide more guidance on responsibilities, scope, and best practices, including following processes described in EPRI 3002002982.
- b) CANBERRA will improve the training and qualification program for personnel preparing, reviewing, and approving Commercial Grade Dedication Plans, and select personnel involved with proposal, contract review, and shipment/conformance controls of safety related items or services.

(4) The date when your corrective action will be completed.

CANBERRA Response:

These activities shall be completed no later than September 30, 2016.

Nonconformance 99901461/2015-201-02

Criterion III, "Design Control," of Appendix B to 10 CFR Part 50 states, in part, "The design control measures shall provide for verifying or checking the adequacy of design, such as by the performance of design reviews, by the use of alternate or simplified calculational methods, or by the performance of a suitable testing program. The verifying or checking process shall be performed by individuals or groups other than those who performed the original design, but who may be from the same organization. Where a test program is used to verify the adequacy of a specific design feature in lieu of other verifying or checking processes, it shall include suitable qualifications testing of a prototype unit under the most adverse design conditions."

Canberra procedure, M07-0-2, "Commercial Grade Dedication Plan Process," Revision G, section 6.2.2, states in part that "Dedication shall be performed on commercial items or services as required. Services may also require dedication. Examples of "services" requiring dedication are: b. Test and Qualification testing."

Contrary to the above, as of November 6, 2015, Canberra failed to verify the adequacy of design by a suitable testing program. Specifically, Canberra did not dedicate the commercial services offered by TUV for EMI and/or EMC testing that supported safety-related qualification activities.

This issue has been identified as Nonconformance 99901461/2015-201-02.

(1) The reason for the noncompliance, or if contested, the basis for disputing the noncompliance.

CANBERRA Response:

CANBERRA acknowledges Nonconformance 99901461-2015-201-02.

The reason for the noncompliance is that CANBERRA failed to realize that services performed by an OSHA-designated Nationally Recognized Testing Lab require commercial grade dedication. We assumed the quality controls would be in place to provide reasonable assurance that the safety function of the equipment tested by TUV would not be adversely affected. TUV SUD America, Plymouth MI, maintains an A2LA accreditation.

(2) The corrective steps that have been taken and the results achieved.

CANBERRA Response:

- a) Internal Corrective Action Request, CAR # 1511-MB512155 initiated 11/05/2015
- b) Developed CGDP for TUV SUD America Plymouth MI. for EMI/RFI (EMC) testing/qualification services.
- c) Review purchase order and testing requirements provided by CANBERRA to TUV
- d) Execute Commercial Grade Dedication on all future safety qualification testing performed by TUV SUD America Plymouth MI.
- e) Assess previous purchase orders for impact placed with TUV SUD America Plymouth MI.
Result: all previous services were executed under their A2LA and ISO 17025 program.

(3) The corrective steps that have been taken to avoid noncompliance.

CANBERRA Response:

- a.) Commercial Grade Dedication developed for EMC / EMI Services performed by TUV SUD America, Plymouth, MI
- b.) Planned execution of CGDP for EMC / EMI Services performed by TUV SUD America, Plymouth, MI
- c.) CANBERRA now has a clear understanding, that an NRTL service must be dedicated if the service is associated with safety-related equipment and could adversely affect the function of safety-related equipment.

(4) The date when your corrective action will be completed.

CANBERRA Response:

All corrective actions are targeted for completion by the end of the 2nd quarter 2016

Nonconformance 99901461-2015-201-03

Criterion IX, "Control of Special Processes," of Appendix B to 10 CFR Part 50 states, in part, "Measures shall be established to assure that special processes, including welding, heat treating, and nondestructive testing, are controlled and accomplished by qualified personnel using qualified procedures in accordance with applicable codes, standards, specifications, criteria, and other special requirements."

Canberra procedure, M09-0-1, "Control of Production Processes," Revision H, section 6.3.1, states in part that the special process, "Wave Soldering," shall be performed using qualified procedures in accordance with specified requirements. Section 6.3.2 states, in part that "Special processes shall be controlled by instructions, procedures, drawings, checklists, travelers, or other appropriate means," and "Conditions necessary for accomplishment of the process shall be included. These conditions shall include proper equipment, controlled parameters of the process, specified environment, and calibration requirements."

Contrary to the above, as of November 6, 2015, Canberra failed to assure that the wave soldering special process is controlled and accomplished using qualified procedures in accordance with applicable codes, standards, specifications, criteria, and other special requirements. Specifically, Canberra failed to correctly measure solder temperature in accordance with test equipment specifications, thus inducing potential latent failure modes.

This has been identified as Notice of Nonconformance 99901461-2015-201-03.

(1) The reason for the noncompliance, or if contested, the basis for disputing the noncompliance.

CANBERRA Response:

CANBERRA acknowledges Nonconformance 99901461-2015-201-03.

All testing activities were performed with properly calibrated and verified testing equipment in accordance with documented CANBERRA preventative maintenance requirements as detailed in CANBERRA Work Instruction "Wave Solder Machine PM Work Instructions." However, the alternate method utilized for temperature measurement by CANBERRA was not identical with recommended test equipment specifications by the manufacturer of the solder machine.

(2) The corrective steps that have been taken and the results achieved.

CANBERRA Response:

CANBERRA has taken the following corrective action steps

- a) Internal Corrective Action Request, CAR # 1511-MB613462 initiated 11/09/2015
- b) Stop Wave Solder Process - completed 11/06/2015
- c) Purchase new thermocouple probe, Fluke Thermocouple model 80TK ID #009109 and Fluke immersion probe ID # 009110 - completed 11/09/2015
- d) Calibrate Fluke probe- completed 11/10/2015
- e) Assess current state - completed 11/10/2015

Measured solder temperature with new calibrated probe, utilizing manufacturer's recommended methodology. Fluke probe indicates 247.7 C versus wave solder machine display indication of 247 C.

(Measurements across the entire temperature range were also taken, as described in "Assess Past State," below.)

Examined functioning and condition of old thermocouple (which takes readings at the wave solder machine junction box). The old thermocouple was in good condition and showed no degradation of performance.

The machine has a separate safety thermocouple which prevents the wave motor operation when the solder temperature is less than 240 degrees. It also has an over temp of 300 degrees.

IPC 610 inspection criteria are used to review our PCB's during the manufacturing process. These inspection criteria would detect over temp related defects. Based on this information CANBERRA has assessed solder temperature control is not an issue.

f) Assess past state - completed 11/13/2015

The low temperature shutoff prevents machine operation with solder below 240 degrees and has been verified. The over temp condition has never been observed during the life of this machine. The old thermocouple shows no degradation.

A correlation study has been conducted to assess current state of measurement system utilized verses past measurement system utilization. Analysis of the measurements taken through both measurement methods demonstrates agreement of the two methods within 1.2 C° maximum over the recommended solder temperature range. All readings are well within Manufacturer's process temperature limits.

g) Risk assessment on previous products - 11/14/2015

Based on our process review of the current and past states we have assessed the risk to quality to our PCB's is non-existent.

The following criteria were used for the basis of the above assessment to previous and current manufactured product.

- IPC 610 inspection criteria, by certified inspectors and technicians, are used to review our PCB's during and after the manufacturing process.
- The variation between the current method of measurement (Calibrated probe) and the old method of measurement (thermocouple reading at junction box) is within 0.5149 % or 1.2 C° across the acceptable operating range.

Based on these indicators CANBERRA has assessed and determined that there is no risk to the quality of our solder process, past or present state, due to the temperature measurement of the solder.

(3) The corrective steps that have been taken to avoid noncompliance.

CANBERRA Response:

CANBERRA has revised Work Instruction, "Wave Solder Machine PM Work Instructions", to reflect manufacture's recommended methodology utilizing calibrated probe method.

Completed 11/13/2015.

(4) The date when your corrective action will be completed.

CANBERRA Response:

These activities have been completed. Completion Date 11/20/2015.