

July 1, 2012

Mr. Marc Bumgarner, Vice President
and General Manager
Rosemount Nuclear Instruments, Inc.
8200 Market Blvd.
Chanhassen, MN 55317-9685

SUBJECT: ROSEMOUNT NUCLEAR INSTRUMENTS, INC. RESPONSE TO THE NUCLEAR
REGULATORY COMMISSION INSPECTION REPORT 99900271/2012-201,
NOTICE OF NONCONFORMANCE – REQUEST FOR ADDITIONAL
INFORMATION

Dear Mr. Bumgarner:

Thank you for your May 11, 2012, letter in response to the Notice of Nonconformance (NON) that was discussed in the subject U.S. Nuclear Regulatory Commission (NRC) inspection report (IR).

We reviewed your letter and found that it was not fully responsive to issues discussed in IR 99900271/2012-201.

Specifically, your response to NON 99900271/2012-201-03 did not provide adequate detail for the staff to conclude that your proposed corrective actions would meet the requirements of Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants," to Title 10 of the *Code of Federal Regulations* (10 CFR) Part 50, "Domestic Licensing of Production and Utilization Facilities."

Your response to NON 99900271/2012-201-03 addressed the NON in three separate sections:

- 1) failure to establish measures that would preclude unauthorized access to quality records associated with the design control process,
- 2) failure to adequately verify or check the design for the 601TT4000 software used during temperature coefficient testing, and
- 3) failure to provide reasonable assurance that specified quality standards in design documents were effectively controlled with RNII's commercial grade dedication program.

Please clarify information provided in your response to these three response sections to NON 99900271/2012-201-03 as follows:

- 1) "Failure to establish measures that would preclude unauthorized access to quality records associated with the design control process" – please provide the evaluation of extent of condition (as requested in the cover letter of IR 99900271/2012-201). Your

response should include an analysis of potential uncontrolled access to other quality records (examples include, but are not limited to: design records, testing records, procurement records, training records). Your response should provide sufficient detail to allow inspectors to conclude that modifications and deletions to these records have been and will be controlled. It appears from your explanation that only the three inspector identified examples were evaluated.

- 2) "Failure to adequately verify or check the design for the 601TT4000 software used during temperature coefficient testing" - please provide the evaluation of extent of condition and analysis of effects on components that have been shipped. Your response should include an assessment of potential inadequate verification for other testing software beyond the example provided by the inspection. If further examples are identified, please address the potential impacts on shipped products. It appears from your explanation that only the 601TT4000 software example was evaluated.

Additionally, clarify and provide supporting documentation relating to how software requirements will be traceable throughout all the different phases of the software development lifecycle. The corrective steps provided in your response fail to provide enough detail to resolve inspector identified software requirements traceability issues at both the programmatic level and for the specific 601TT4000 software case. Please include a copy of CAPA-NC000677 with your response.

- 3) "Failure to provide reasonable assurance that specified quality standards in design documents were effectively controlled with RNII's commercial grade dedication program" - please provide the evaluation of extent of condition and analysis of effects on components that have been shipped for failures in your commercial grade dedication process to perform technical evaluations. Your response should include an assessment of potential inadequate technical evaluations during commercial grade dedication activities for other dedicated commercial components. It appears from your explanation that only the inspector identified examples were evaluated.

Additionally, regarding verification of material substitutions made by a supplier of printed circuit boards (second instance in report), please clarify and provide supporting documentation regarding "passive electrical component" failures. It is unclear from your response if a failure of these "passive" devices would prevent the transmitter from performing its intended safety function. If so, these components are subject to the requirements of Appendix B to 10 CFR 50. If not, please provide any engineering evaluations/justification supporting your conclusions.

Further, regarding verification of the fill oil used in the transmitters. During the inspection the inspectors understood that there were multiple oils used in your transmitters and the selection of the oil was based on the service application. As such, the inspectors remain concerned that your commercial grade dedication process for the oil adequately verifies the fill oil has identical characteristics to the oil environmentally qualified for "harsh environment." We understand you test the transmitters over their normal range of operation as part of the manufacturing process. However, the conditions of the "harsh environment" are not simulated during your current testing. Given that the oil is a commercial product, and as such may be subject to changes without your awareness, please clarify how your dedication process provides reasonable assurance that the fill oil

used during manufacturing will have equivalent performance with the fill oil used during baseline qualification. This would include meeting any baseline requirements for radiation, aging, seismic, and extended temperature and pressure envelopes which are currently not tested as part of manufacturing. Please include your assessment of how your methodology would detect changes to the formulation, including changes in additives or the introduction of contaminants, that might impact the oil's performance in "harsh environment." Your response should provide sufficient detail to allow inspectors to conclude that your dedication of the current dielectric oil provides reasonable assurance that the oil has equivalent performance to the baseline qualification oil for the entire "harsh environment" qualification envelope. Please also provide a copy of CAPA-NC000683 with your response.

In accordance with Title 10 of the *Code of Federal Regulation* (10 CFR) 2.390 "Public Inspections, Exemptions, Requests for Withholding," of the NRC's "Rules of Practice," a copy of this letter, its enclosure(s), and your response will be made available electronically for public inspection in the NRC Public Document Room or from the NRC's Agencywide Documents Access and Management System, accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>. To the extent possible, your response should not include any personal privacy, proprietary, or safeguards information so that it can be made available to the Public without redaction. If personal privacy or proprietary information is necessary to provide an acceptable response, then please provide a bracketed copy of your response that identifies the information that should be protected and a redacted copy of your response that deletes such information. If you request that such material is withheld from public disclosure, you must specifically identify the portions of your response that you seek to have withheld and provide in detail the bases for your claim (e.g., explain why the disclosure of information will create an unwarranted invasion of personal privacy or provide the information required by 10 CFR 2.390(b) to support a request for withholding confidential commercial or financial information). If safeguards information is necessary to provide an acceptable response, please provide the level of protection described in 10 CFR 73.21 "Protection of Safeguards Information: Performance Requirements."

Please contact Mr. George Lipscomb at (301) 415-6838 or via electronic mail at George.Lipscomb@nrc.gov, if you have any questions or need assistance regarding this matter.

Sincerely,

/RA/

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

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Docket No. 99900271

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