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Process Management

Rosemount Nuclear Instruments, Inc.
8200 Market Boulevard
Chanhassen, MN 55317 USA

Tel 1 (952) 949-5210
Fax 1 (952) 949-5201

11 May 2012

United States Nuclear Regulatory Commission
Attn: Document Control Desk
Washington, DC 20555-0001

Subject: Reply to NRC Inspection Report NO. 99900271/2012-201 Notice of Violation and Notice of Nonconformance

References:
1) NRC Notice of Violation Docket Number 99900271/2012-201-01
2) NRC Notice of Violation Docket Number 99900271/2012-201-02
3) NRC Notice of Nonconformance Docket Number 99900271/2012-201-03
4) NRC Notice of Nonconformance Docket Number 99900271/2012-201-04
5) NRC Inspection Report 99900271/2012-201

Rosemount Nuclear Instruments, Inc. ("**RNII**") hereby responds to the aforementioned Notices of Violation and Notices of Nonconformance (Reference 1 through 4), dated March 28, 2012. Based upon the teleconference conducted on April 27, 2012, RNII's response deadline was extended until May 11, 2012. The violations and nonconformances were identified during the Nuclear Regulatory Commission's ("**NRC**") inspection (Reference 5) of RNII's Chanhassen, Minnesota facility, conducted January 30, 2012 – February 3, 2012 by inspectors Richard Rasmussen, George Lipscomb, Daniel Pasquale, Eugene Huang, Louis Dumont, and Brent Clark.

Attached, please find RNII's reply to References 1, 2, 3, and 4.

RNII appreciates the opportunity the Inspection Report gives us to continuously improve our Quality Assurance Program and products supplied to the nuclear industry and to ensure our compliance with NRC regulations.

Please contact me at (952) 949-5340 if you have any questions or need to discuss this matter further.

Sincerely,

Marc D. Bumgarner
Vice President & General Manager
Rosemount Nuclear Instruments, Inc.

Attachments

cc: Richard Rasmussen, Chief, Electrical Vendor Branch, Division of Construction Inspection and Operational Programs, Office of New Reactors, United States Nuclear Regulatory Commission, Washington, DC 20555-0001

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Attachment 1
Reply to NRC Notice of Violation
Docket Number 99900271/2012-201-01
NRC Inspection Report 99900271/2012-201

Attachment 1 sets forth the reply of Rosemount Nuclear Instruments, Inc. ("**RNII**") to the NRC's Notice of Violation dated March 28, 2012, relative to NRC Inspection Report 99900271/2012-201 (the "**Inspection Report**"), Notice of Violation **99900271/2012-201-01** (the "**Notice of Violation**").

The Notice of Violation
The Notice of Violation provides the following description of Violation-01:

> *"Title 10 of the Code of Federal Regulations (10 CFR) Section 21.21, "Notification of Failure To Comply or Existence of a Defect and Its Evaluation," paragraph 21.21(a)(1), requires, in part, "that each individual, corporation, partnership, dedicating entity, or other entity subject to the regulations in this part shall adopt appropriate procedures to evaluate deviations and failures to comply to identify defects and failures to comply associated with substantial safety hazards as soon as practicable, and, except as provided in paragraph (a)(2), in all cases within 60 days of discovery, in order to identify a reportable defect."*
>
> *Contrary to the above, as of February 3, 2012, RNII failed to complete 10 CFR Part 21, "Reporting of Defects and Noncompliance," notifications within the 60-day reporting requirement in the following three instances:*
>
> *(1) 10 CFR Part 21 Notification regarding Model 3051N Pressure Transmitters, dated July 12, 2010*
>
> *(2) 10 CFR Part 21 Notification regarding Model 1152 Differential Pressure Transmitters with Output Code "L" 10-50mA Electronics, dated December 2, 2010*
>
> *(3) 10 CFR Part 21 Notification regarding Model 1153 Series B, 1154 and 1154 Series H Pressure Transmitters, dated September 6, 2011*
>
> *This issue has been identified as Notice of Violation 99900271/2012-201-01.*
>
> *This is a Severity Level IV violation (Section 6.9.d of the NRC Enforcement Policy).*

RNII's Response

I. Reason for the Violation

At the time of the inspection, per RNII Operating Procedure OP 1620, "Implementation of 10 CFR Part 21," RNII defined discovery as the completion of the analysis/documentation first verifying the existence of a deviation or failure to comply potentially associated with a substantial safety hazard.

Based upon RNII's definition of discovery, the evaluation of whether a particular deviation or failure to comply created a substantial safety hazard would be completed within sixty (60) days from the date RNII verified the existence of a potential deviation or failure to comply that may result in a substantial safety hazard, otherwise an interim report would be issued. This definition of discovery has been utilized since OP 1620 was issued in 2003.

RNII's intent for defining discovery based upon verifying instead of identifying a potential deviation or failure to comply was to confirm by evidence that discovery had actually occurred. This intent was to establish a diligent approach in which RNII would only proceed with a full evaluation when confirmed evidence of a potential deviation or failure to comply was available. Since 2003, RNII's implementation of 10 CFR Part 21 has resulted in 13 Part 21 notifications.

RNII's issuing of notifications in the three instances noted in the Inspection Report was consistent with OP 1620 and based upon the definition of discovery as the completion of the analysis/documentation first verifying the existence of a deviation or failure to comply potentially associated with a substantial safety hazard. In reviewing the three notifications in the Inspection Report and the remaining 10 notifications made per this procedure, in all cases RNII met the 60-day reporting requirement offset forth in OP 1620.

II. Corrective Steps Taken and Results Achieved

During the NRC Inspection, RNII was made aware that the definition of discovery in OP 1620 was incorrect.

In response to this, RNII issued an internal Corrective Action Preventive Action (CAPA) NC000681. Pursuant to the CAPA, RNII took the following steps:

RNII Operating Procedure OP 1620, "Implementation of 10CFR Part 21," has been amended to change the definition of discovery from "the completion of the analysis/documentation first **verifying** the existence of a Deviation or Failure to Comply potentially associated with a substantial safety hazard" to "the completion of the analysis/documentation first **identifying** the existence of a Deviation or Failure to Comply potentially associated with a substantial safety hazard."

All current potential Part 21 investigations were reviewed to confirm that there are no other instances of missed sixty (60) day interim report requirements.

RNII Department Procedure DP MKT-1620-1, "10CFR Part 21 Notification Checklist," was reviewed to ensure consistency with the revision to OP 1620 noted above. This DP is a time-based checklist used by RNII when a notification is generated. No updates or revisions were required.

Additionally, RNII employees making the determination of Part 21 compliance requirements were made aware of the Notice of Violation and updated operating procedure. Updated OP 1620 has been released. Training of affected personnel was completed by May 11, 2012.

III. Corrective Steps That Will be Taken

As noted above, all outstanding actions have been completed.

IV. Date Full Compliance Achieved

The steps to improve the process have been implemented and RNII respectfully asserts that it is in full compliance as of the date of this reply.

Attachment 2
Reply to NRC Notice of Violation
Docket Number 99900271/2012-201-02
NRC Inspection Report 99900271/2012-201

Attachment 2 sets forth the reply of Rosemount Nuclear Instruments, Inc. ("**RNII**") to the NRC's Notice of Violation dated March 28, 2012, relative to NRC Inspection Report 99900271/2012-201 (the "**Inspection Report**"), Notice of Violation **99900271/2012-201-02** (the "**Notice of Violation**").

The Notice of Violation
The Notice of Violation provides the following description of Violation-02:

> *10 CFR 21.21(a)(1), requires, in part, "that each individual, corporation, partnership, dedicating entity, or other entity subject to the regulations in this part shall adopt appropriate procedures to evaluate deviations and failures to comply to identify defects and failures to comply associated with substantial safety hazards as soon as practicable, and, except as provided in paragraph (a)(2), in all cases within 60 days of discovery, in order to identify a reportable defect."*
>
> *Contrary to the above, as of February 3, 2012, RNII failed to evaluate a deviation associated with a potential safety hazard. Specifically, the effect of the deviation on a calibration unit was not evaluated as committed to in the minutes of a May 26, 2011, Part 21 Committee Meeting which stated, "R48 is used in the Calibration Unit. This will be evaluated to see if it has any impact on the 710's safety related function." This issue has been identified as Notice of Violation 99900271/2012-201-02.*
>
> *This is a Severity Level IV violation (Section 6.9.d of the NRC Enforcement Policy).*

RNII's Response

I. Reason for the Violation

The action noted in the May 26, 2011, Part 21 Committee Meeting was not completed due to an oversight by the assigned engineer, insufficient follow up to assure closure of this action item, and an incomplete description of the issue and action in the minutes of the May 26, 2011 Part 21 Committee Meeting.

The minutes should have stated, "Resistor (R48) is used in the calibration sequence of the master trip unit (MTU). This will be evaluated to see if it has any impact on the 710's safety related function during calibration." Upon further analysis, the only function of the resistor is to maintain loop continuity for the instrument providing a 4mA to 20mA input into the MTU when the MTU is selected for calibration. This allows for the calibration of the MTU without disruption to the 4 mA to 20 mA loop. By design, the resistor is disconnected from the safety related circuit by a relay during normal operation of the MTU and therefore cannot impact the safety function of the MTU. Additionally, the performance characteristics or reliability of this component are not significant in the successful calibration of the MTU as the resistor is not associated with the MTU calibration circuitry. Therefore, reduced performance characteristics or reliability of R48 does not adversely impact the 710 MTU safety function during normal operation or the calibration of the MTU.

II. Corrective Steps Taken and Results Achieved

In response to this violation, RNII issued internal Corrective Action Preventive Actions (CAPA) NC000675 and NC000678. Pursuant to these CAPAs, RNII took the following steps:

The action to evaluate if a failure of the resistor (R48) in the 710DU Master Trip Unit would impact the 710's safety related function when being calibrated is complete. It was concluded that there is no substantial safety hazard related to the potential failure of the resistor (R48) in this application during calibration.

The May 26, 2011 Part 21 Committee Meeting minutes were amended on February 3, 2012. As noted above, the reduced performance characteristics or reliability of R48 does not adversely impact the 710 MTU safety function during normal operation or the calibration of the MTU. This is documented in CAPA NC000675.

RNII Operating Procedure OP, "1620 Implementation of 10CFR Part 21," has been amended to clearly include the review of actions from previous meetings as part of the quarterly and special meetings. The procedure update also includes explicit instructions to add follow-up actions as a result of Part 21 Review Committee meetings to the CAPA system as needed. This is documented in CAPA NC000678.

Additionally, RNII employees making the determination of Part 21 compliance requirements were made aware of the Notice of Violation and updated operating procedure. Updated OP 1620 has been released. Training of affected personnel was completed by May 11, 2012.

III. Corrective Steps That Will be Taken

As noted above, all outstanding actions have been completed.

IV. Date Full Compliance Achieved

The steps to improve the process have been implemented and RNII respectfully asserts that it is in full compliance as of the date of this reply.

Attachment 3
Reply to NRC Notice of Nonconformance A
Docket Number 99900271/2012-201-03
NRC Inspection Report 99900271/2012-201

Attachment 3 sets forth the reply of Rosemount Nuclear Instruments, Inc. ("**RNII**") to the NRC's Notice of Nonconformance dated March 28, 2012, relative to NRC Inspection Report 99900271/2012-201 (the "**Inspection Report**"), Notice of Nonconformance **99900271/2012-201-03** (the "**Nonconformance-03**").

The Notice of Nonconformance
The Notice of Nonconformance provides the following description of Nonconformance-03:

"A. Criterion III, "Design Control," of Appendix B, "Quality Assurance Program 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," states, in part, that:

- *'Measures shall be established for the identification and control of design interfaces and for coordination among participating design organizations. These measures shall include the establishment of procedures among participating design organizations for the review, approval, release, distribution, and revision of documents involving design interfaces.'*

  Contrary to the above, as of February 3, 2012, RNII failed to establish measures that would preclude unauthorized access to quality records associated with the design control process, such that modifications or deletions of design documents were not controlled. Specifically, RNII failed to:

  (1) Limit access to test data results from the 115X Amplifier functional test
  (2) Limit access to the Nuclear Supplier List (NSL)
  (3) Limit access to the Parts Classification List (PCL).

- *'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.'*

  Contrary to the above, as of February 3, 2012, RNII failed to adequately verify or check the design for the 601TT4000 software used during temperature coefficient testing. Specifically, the software requirements document did not have required reviews and approvals and the requirements were not traceable to the test plan for software design verification.

- *'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,' and '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,' and 'Design changes, including field changes, shall be subject to design control measures commensurate with those applied to the original design and be approved by the organization that performed the original design unless the applicant designates another responsible organization.'*

Contrary to the above, as of February 3, 2012, RNII's commercial grade dedication program failed to provide reasonable assurance that specified quality standards in design documents were effectively controlled in the following three instances:

(1) RNII failed to perform a technical evaluation to justify a reduction in the critical characteristics of acceptance related to the dielectric qualities of the silicone oil used in its pressure transmitters.

Additionally, RNII failed to perform a technical evaluation to verify that a captive screw used to secure a printed circuit board in a safety-related, seismically-qualified transmitter, would perform its intended safety function. RNII listed the diameter, length and thread profiles as critical characteristics, but failed to identify or document the material of construction as a critical characteristic of acceptance.

(2) RNII failed to perform a technical evaluation to verify material substitutions made by a supplier of printed circuit boards. Specifically, the purchase documents for a commercial circuit board to be dedicated via the commercial survey method allowed the commercial vendor to substitute components without further RNII evaluation.

(3) RNII failed to perform a technical evaluation to verify that the unique silicone oil specified in the environmental qualification test reports for transmitters qualified for 'harsh environment' was the identical oil installed in the transmitter.

These issues have been identified as Nonconformance (NON) 99900271/2012-201-03."

RNII's Response to the following nonconformance noted in the NRC Inspection Report:

"A. Criterion III, "Design Control," of Appendix B, "Quality Assurance Program 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," states, in part, that:

'Measures shall be established for the identification and control of design interfaces and for coordination among participating design organizations. These measures shall include the establishment of procedures among participating design organizations for the review, approval, release, distribution, and revision of documents involving design interfaces.'

Contrary to the above, as of February 3, 2012, RNII failed to establish measures that would preclude unauthorized access to quality records associated with the design control process, such that modifications or deletions of design documents were not controlled. Specifically, RNII failed to:

(1) Limit access to test data results from the 115X Amplifier functional test
(2) Limit access to the Nuclear Supplier List (NSL)
(3) Limit access to the Parts Classification List (PCL)."

Reason for the Noncompliance

Historically RNII has controlled access to quality records associated with the design control process, such that modifications or deletions of design documents are limited to authorized RNII personnel. These records are segregated on a network drive which only authorized RNII personnel have access to. This access list is approved only by the Vice President.

Access to the Nuclear Supplier List (NSL), Parts Classification List (PCL), and the test data results from the 115X Amplifier functional test was not further controlled within RNII. The NSL and PCL are working documents primarily used by design engineers and supplier quality engineers. There was a gap in the oversight to further limit access within RNII.

The 115X Amplifier functional test data is collected on the production computer and then imported to a network drive and to a database on a weekly basis. Since these files are on a network drive, they are backed up on a daily basis which would allow for retrieval of a file if it was deleted. When setting up the storage of the test data, RNII did not take into consideration deliberate attempts to modify or delete the test data and further access controls were not implemented.

Subsequent to the inspection, further access controls within RNII have been implemented. Accordingly, RNII issued Corrective Action Preventive Action (CAPA) NC000682 and NC000684.

Corrective Steps Taken and Results Achieved
CAPA NC000682: Per RNII Operating Procedure OP 1120, "Production Software Control," engineering will ensure that software source code is protected from uncontrolled changes. This requirement was reviewed by the manufacturing support engineers. For a more effective implementation of this requirement, additional access restrictions have been added to the RNII network files for the 115X Amplifier functional test. Access to software source code and to software test results are now restricted to a subset of the RNII group (Manufacturing Support Engineers). This access list is approved by the Manufacturing Systems Manager.

To further preclude modifications or deletions of test results from the 115X Amplifier functional test, a revision to the software was made so that test results are written directly to a network location that is backed up on a daily basis. This eliminates the need for RNII to manually migrate the test results and mitigates the potential for any inadvertent loss of data.

CAPA NC000684: To further limit access to the NSL and PCL spreadsheets, password protection was added. A password is now required to edit these spreadsheets. Only the Quality Manager and Supplier Quality Engineers have access to edit these files. RNII Operating Procedure OP 720 "Control of Purchased Safety-Related Components" was updated to note that changes to the PCL can only be made by the quality manager or a supplier quality engineer.

Updated RNII OP 720 has been released. Training of affected personnel was completed by May 11, 2012.

Corrective Steps That Will be Taken
The actions noted above have been completed.

Date Full Compliance Achieved
The steps to improve the process have been implemented and RNII respectfully asserts that it is in full compliance as of the date of this reply.

RNII's Response to the following nonconformance noted in the NRC Inspection Report:

"A. Criterion III, "Design Control," of Appendix B, "Quality Assurance Program 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," states, in part, that:

. . . . . .

'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.'

Contrary to the above, as of February 3, 2012, RNII failed to adequately verify or check the design for the 601TT4000 software used during temperature coefficient testing. Specifically, the software requirements document did not have required reviews and approvals and the requirements were not traceable to the test plan for software design verification."

Reason for the Noncompliance
At the time of the inspection, RNII Operating Procedure OP 1120, "Production Software Control," required the creation of a software requirements document and test documentation. Per the procedure, the software requirements document did not require approval or review, whereas the test documentation did require approval.

Consistent with OP 1120, the verification of the design for the 601TT4000 software used during temperature coefficient testing included a software requirements document and an approved Manufacturing Station Validation Plan and Results. As identified in the NRC inspection report, requirements were not directly traceable to test documentation. Accordingly, RNII issued CAPA NC000677.

Corrective Steps That Will be Taken
CAPA NC000677: RNII Operating Procedure OP 1120 has been updated to require an approved and signed requirements document as well as a signed and approved Manufacturing Station Validation Plan and Results document. Furthermore, clarification has been added to ensure the Manufacturing Station Validation Plan and Results document tie directly to the requirements document.

Updated RNII OP 1120 was released. Training of affected personnel was completed by May 11, 2012.

Corrective Steps That Will be Taken
The actions noted above have been completed.

Date Full Compliance Achieved
The steps to improve the process have been implemented and RNII respectfully asserts that it is in full compliance as of the date of this reply.

RNII's Response to the following nonconformance noted in the NRC Inspection Report:

"A. Criterion III, "Design Control," of Appendix B, "Quality Assurance Program 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," 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,' and '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,' and 'Design changes, including field changes, shall be subject to design control measures commensurate with those applied to the original design and be approved by the organization that performed the original design unless the applicant designates another responsible organization.'

Contrary to the above, as of February 3, 2012, RNII's commercial grade dedication program failed to provide reasonable assurance that specified quality standards in design documents were effectively controlled in the following three instances:

(1) RNII failed to perform a technical evaluation to justify a reduction in the critical characteristics of acceptance related to the dielectric qualities of the silicone oil used in its pressure transmitters.

Additionally, RNII failed to perform a technical evaluation to verify that a captive screw used to secure a printed circuit board in a safety-related, seismically-qualified transmitter, would perform its intended safety function. RNII listed the diameter, length and thread profiles as critical characteristics, but failed to identify or document the material of construction as a critical characteristic of acceptance.

(2) RNII failed to perform a technical evaluation to verify material substitutions made by a supplier of printed circuit boards. Specifically, the purchase documents for a commercial circuit board to be dedicated via the commercial survey method allowed the commercial vendor to substitute components without further RNII evaluation.

(3) RNII failed to perform a technical evaluation to verify that the unique silicone oil specified in the environmental qualification test reports for transmitters qualified for 'harsh environment' was the identical oil installed in the transmitter."

Reason for the Noncompliance

RNII's approach to commercial grade dedication has been to employ an accepted industry methodology that includes special inspections and tests; commercial grade surveys; and source verification, either alone or in combination, depending on the item being evaluated. Within RNII's commercial grade dedication process, design engineering and supplier quality engineering identify the critical characteristics related to an item's safety related function, and establish the appropriate acceptance methods.

Additional confidence in the effectiveness of RNII's commercial grade dedication approach has been gained through the successful completion of three supplemental IEEE 323 qualification programs conducted on model 1153 and 1154 pressure transmitters, in addition to the baseline qualification. No anomalies were identified in any of these programs related to commercial grade components. These qualification programs are documented in Rosemount Reports D9600073, D9900005 and D2011019.

RNII has evaluated each of the examples listed in this nonconformance and has concluded that no safety hazards exist as a result of the issues identified. Specific information on each of the examples cited is provided below:

(1) Pertaining to the removal of dielectric properties as a critical characteristic of the sensor fill fluid:

To document the critical characteristics of the silicone based fluid in RNII's Part Classification List (PCL), a peer review was conducted between RNII design engineering and supplier quality engineering. This review did not include dielectric properties as a critical characteristic for acceptance of the fill fluid because the electrical properties of the fluid are verified during manufacturing test (as described below).

The peer review was noted in the PCL by the initials of the design engineer and the supplier quality engineer. As noted in the inspection report, further auditable documentation was not created for this technical evaluation. As described in the corrective steps taken and results achieved section, RNII Operating Procedure OP-0720 has been updated to improve auditable documentation related to the technical evaluation of critical characteristics.

Although the dielectric properties were removed as a critical characteristic of the fill fluid, all test and inspection methods used to provide reasonable assurance the fill fluid will perform acceptably when assembled into a sensor assembly have remained unchanged. Therefore, there was no reduction in the level of assurance achieved. Descriptions of methods used to verify acceptable hydraulic and dielectric characteristics are as follows:

a. Hydraulic characteristics
    i. Visual inspection of container marking and fluid color.
    ii. Viscosity measurement by a third party on every new manufacturer's batch lot.
    iii. Certification of viscosity with each batch/lot received.
    iv. Direct measurement during RNII manufacturing processes of sensor time response, linearity, high line pressure effects, and temperature effects. These tests are conducted on 100% of the sensors manufactured.

b. Dielectric characteristics
    i. Visual inspection of container marking and fluid color.
    ii. Direct measurement during RNII manufacturing processes of sensor linearity and temperature effects. These tests are conducted on 100% of the sensors manufactured.

c. Additionally, RNII's quality program requires the material to be purchased only from an approved supplier.

Pertaining to the lack of technical evaluation to verify that a captive screw used to secure a printed circuit board in a safety-related, seismically-qualified transmitter, would perform its intended safety function:

RNII's methods used to verify critical characteristics of the captive screw are described below.

a. Mechanical characteristics
   i. Visual inspection of the captive screw and associated packaging marking.
   ii. Measurement of diameter, length, and thread characteristics on a sample for every new manufacturer's batch lot received.
   iii. Assembly to the mating parts using a controlled torque value during RNII manufacturing processes.

b. Additionally, RNII's quality program requires the material to be purchased only from an approved supplier.

High confidence in the acceptability of the fastener to perform its safety function is obtained through this process. As RNII has not historically verified the material type through inspection and test, supplemental samples have been tested to ensure tensile strength met minimum design criteria. All samples tested exceeded minimum design criteria providing further confidence in the acceptability of the captive screws. As described in the corrective steps taken and results achieved section, RNII will verify material type during inspection moving forward.

(2) Pertaining to the lack of technical evaluation to verify material substitutions made by a supplier of printed circuit boards:

The supplier of printed circuit board assemblies procures components according to RNII controlled drawings. The technical evaluation of higher reliability or tighter tolerance devices is done by RNII when the component drawing is created or revised. This is documented in RNII's engineering change order (ECO) system. This type of substitution is limited to characteristics described by the manufacturer's part numbering scheme and may include component value tolerance, temperature coefficient, or specified reliability rating as dictated by the drawing. This type of substitution is limited to passive electrical components such as resistors and capacitors.

When a higher reliability or tighter tolerance device is substituted for a standard part, it is required that "all other drawing requirements" be met by the substitute component, including but not limited to the following:

a. same manufacturer as specified on the drawing;
b. same part family/series as specified on the drawing; and
c. all other requirements specified on the drawing.

For resistors and capacitors, parts manufactured by the same manufacturer and produced under the same part family/series will have the following common characteristics:

a. same materials of construction;
b. same production facility;
c. same manufacturing processes and controls; and
d. same marking/identification method.

As part of RNII's commercial grade item dedication of printed circuit board assemblies, RNII's survey of the supplier would include an evaluation of the supplier's incoming receipt inspection process to verify that the supplier is procuring parts per RNII's drawings. Historically an ongoing evaluation of allowed component substitutions for passive electrical components such as resistors and capacitors was not deemed necessary. As a result of the NRC inspection report, additional supplier controls and inspections are in the process of being implemented as described in CAPA NC000683.

(3) Pertaining to the lack of technical evaluation to verify the unique silicone oil specified in the environmental qualification test reports for transmitters qualified for 'harsh environment' was the identical oil installed in the transmitter:

Silicone fluid used in RNII pressure transmitters are commercially available products. Acceptance methods used by RNII for acceptance of silicone fluid are outlined in (1) above. It has been RNII's assessment that this process establishes reasonable assurance that the fill fluid used during manufacturing will perform consistent with the batch of fill fluid used in the baseline qualification. RNII acknowledges the feedback from this inspection and is taking action to improve the commercial grade dedication process as outlined in the section on corrective steps taken and results achieved. Specifically, RNII is implementing third party testing of fill fluid dielectric characteristics for each lot received.

Corrective Steps Taken and Results Achieved

(1) CAPA NC000683: RNII Operating Procedure OP 0720, "Control of Purchased Safety-Related Components," has been updated to include, in the future, the technical evaluation method used to establish the critical characteristics for acceptance as described in the Parts Classification List (PCL). The technical evaluation method may include, but is not limited to engineering change order (ECO), technical change authorization (TCA), documented design study, and/or peer review.

To further document the technical evaluation of the silicone fluid, RNII Design Study DS-RNII-2012-017 was created. Dielectric properties have been added to the PCL as a critical characteristic of the silicon fluid with reference to DS-RNII-2012-017.

To further document the technical evaluation of the captive screw, RNII Design Study DS-RNII-2012-016 was created. Material type has been added as a critical characteristic which will be evaluated at receiving inspection.

(2) To conduct an ongoing evaluation of allowed component substitutions for passive electrical components and further control changes at the supplier of printed circuit board assemblies, an update to RNII NPS-18, "Nuclear Procurement Specification for Circuit Card Assembly Requirements," has been initiated to require the supplier to include the component manufacturer's part number on the traceability reports submitted to RNII and also notify RNII if there are changes to their quality manual revision or to their manufacturing site location.

(3) To provide further assurance that the item received is the item specified for the silicone based fluid, on a going forward basis a third party evaluation of dielectric properties will be performed in addition to the viscosity measurements on a lot basis.

Updated OP 720 has been released. Training of affected personnel was completed by May 11, 2012.

Corrective Steps That Will be Taken
The remedial actions noted above have been completed.

The following additional continuous improvements are in the process of being implemented:

Once the update to NPS-18 is implemented, this will be communicated to RNII's circuit card assembly supplier.

RNII's receipt inspection collections plans are in the process of being updated to include a review of the manufacturer's part numbers on the traceability report to verify that the manufacturer's part numbers meet RNII drawing requirements and to include material type as a critical characteristic to be evaluated at receiving inspection.

RNII resistor and capacitor drawings with the allowable material substitutions note are in the process of being updated to clarify which manufacturer part numbers are acceptable.

Third party evaluation of dielectric properties will be performed on a going-forward basis.

The updates to NPS-18, the collection plans, and drawings will be completed by June 25, 2012.

Date Full Compliance Achieved
The remedial actions to improve the process have been implemented and RNII respectfully asserts that it is in full compliance as of the date of this reply.

Additional continuous improvements actions will be implemented by June 25.

Attachment 4
Reply to NRC Notice of Nonconformance B
Docket Number 99900271/2012-201-04
NRC Inspection Report 99900271/2012-201

This Attachment 4 sets forth the reply of Rosemount Nuclear Instruments, Inc. ("**RNII**") to the NRC's Notice of Nonconformance dated March 28, 2012, relative to NRC Inspection Report 99900271/2012-201 (the "**Inspection Report**"), Notice of Nonconformance **99900271/2012-201-04** (the "**Nonconformance-04**").

The Notice of Nonconformance
The Notice of Nonconformance provides the following description of Nonconformance-04:

> *"B. Criterion XIII, 'Handling, Storage and Shipping,' of Appendix B to 10 CFR Part 50 states, in part, that 'measures shall be established to control the handling, storage, shipping, cleaning and preservation of material and equipment in accordance with work and inspection instructions to prevent damage or deterioration.'*
>
> *RNII Quality Manual, Revision AB, Section 13.1, states, in part, that 'handling, storage, shipping, cleaning and preservation of equipment and materials are performed in accordance with established procedures, instructions and drawings in order to maintain conformity to requirements.'*
>
> *Contrary to the above, as of February 3, 2012, RNII failed to establish procedures and failed to evaluate the cleaning and preservation of equipment and materials to maintain conformity to requirements. Specifically, RNII used ammonium chloride within the nuclear component assembly area without procedural controls or evaluation of potential detrimental effect on electronic circuit boards and metallic components.*
>
> *This issue has been identified as Nonconformance 99900271/2012-201-04."*

RNII's Response

I. Reason for the Noncompliance

Disinfecting cleaning wipes were introduced to the facility in response to the increase of flu cases as a result of the 2009 A/H1N1 flu pandemic and were intended to minimize the spread of germs. Verbal and written instructions were provided to all employees to use these wipes to disinfect work stations, cart handles, and tools at the beginning of shifts and when returning from breaks. Since these wipes were not intended to clean or to come into contact with electronic circuit boards or metallic components, RNII did not evaluate the potential effects of these wipes on these items. To our knowledge, the wipes were not used in this manner.

II. Corrective Steps Taken and Results Achieved

In response to Nonconformance-04, RNII issued an internal Corrective Action Preventive Action (CAPA) NC000679. Pursuant to the CAPA, RNII took the following steps:

The disinfecting cleaning wipes were removed from the production area on February 16, 2012.

RNII Operating Procedure OP 1310, "Material Handling, Storage, and Shipping," has been updated to control chemicals which may come into contact with production hardware. Prior to using any new chemicals on the production floor, an engineering evaluation to prevent damage or deterioration of product will be completed using RNII Nuclear Production Chemical Review Form OP-1310-F1.

An evaluation to review the potential impact of using the wipes in the production area was completed and it concluded that there is no detrimental effect on the electronic circuit boards or metallic components. This evaluation is documented in an OP-1310-F1 form.

RNII has identified isopropyl alcohol (IPA) wipes which can be used as an acceptable disinfectant to help prevent the spread of gems. The evaluation of the suitability of the IPA wipes is also documented in an OP-1310-F1 form.

Updated OP 1310 and new form OP-1310-F1 have been released. Training of affected personnel was completed by May 11, 2012.

III. Corrective Steps That Will be Taken

As noted above, all outstanding actions have been completed.

IV. Date Full Compliance Achieved

The steps to improve the process have been implemented and RNII respectfully asserts that it is in full compliance as of the date of this reply.