March 28, 2012

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

SUBJECT: NRC INSPECTION REPORT NO. 99900271/2012-201, NOTICE OF VIOLATION AND NOTICE OF NONCONFORMANCE

Dear Mr. Bumgarner:

From January 30 to February 3, 2012, the U.S. Nuclear Regulatory Commission (NRC) conducted an inspection at the Rosemount Nuclear Instruments, Inc. (RNII) facility in Chanhassen, MN. The enclosed report presents the results of the inspection.

This limited scope inspection focused on assessing RNII's compliance with the provisions of Title 10 of the *Code of Federal Regulations* (10 CFR) Part 21 "Reporting of Defects and Noncompliance," and selected portions of Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants," to 10 CFR Part 50, "Domestic Licensing of Production and Utilization Facilities." This technically-focused inspection specifically evaluated RNII's implementation of quality activities associated with the design, procurement, manufacture, and testing of pressure transmitters with an emphasis on the 1154H and 3051N pressure transmitter product lines. The enclosed inspection report presents the results of this inspection. This NRC inspection report does not constitute NRC endorsement of your overall quality assurance (QA) or 10 CFR Part 21 programs.

The NRC inspection team performed a limited scope inspection with an emphasis on 1154H and 3051N pressure transmitters. Even though the NRC inspection did not identify issues in all areas reviewed, the number of deficiencies identified is not indicative of a fully effective QA program. In the response to the enclosed Notice of Violation and Notice of Nonconformance, RNII should document the results of the extent of condition and determine if there are any effects on components that have been shipped.

Based on the results of this inspection, the NRC has determined that two Severity Level IV violations of NRC requirements occurred. The NRC evaluated the violations in accordance with the agency's Enforcement Policy, which is available on the NRC's Web site at http://www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol/html. The violations are cited in the enclosed Notice of Violation (Notice), and the circumstances surrounding them are described in the inspection report because NRC inspectors identified that RNII failed to meet the requirements set forth in 10 CFR Part 21 for identifying defects and failures to comply associated with substantial safety hazards.

You are required to respond to this letter and should follow the instructions in the enclosed Notice when preparing your response. If you have additional information that you believe the NRC should consider, you may provide it in your response to the Notice. The NRC will use your response, in part, to determine if further enforcement action is necessary to ensure compliance with regulatory requirements.

In addition, during this inspection, NRC inspectors found that implementation of your QA program failed to meet certain NRC requirements contractually imposed on you by your customers or NRC licensees. Specifically, the inspection team determined that RNII was not implementing aspects of its design control, procurement/supplier control, and manufacturing control programs consistent with regulatory requirements. These nonconformances are cited in the enclosed Notice of Nonconformance (NON), and the enclosed inspection report describes in detail the circumstances surrounding them.

Please provide a written explanation or statement within 30 days of this letter in accordance with the instructions specified in the enclosed NON. We will consider extending the response time if you show good cause for us to do so.

In accordance with 10 CFR 2.390, “Public Inspections, Exemptions, Requests for Withholding,” of NRC's "Rules of Practice," a copy of this letter, its enclosures, and your response will be made available electronically for public inspection in the NRC Public Document Room or from the NRC’s document system Agencywide Documents Access and Management System (ADAMS), 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.”

Sincerely,

/RA/

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

Docket No.: 99900271

Enclosures:
As Stated

In addition, during this inspection, NRC inspectors found that implementation of your QA program failed to meet certain NRC requirements contractually imposed on you by your customers or NRC licensees. Specifically, the inspection team determined that RNII was not implementing aspects of its design control, procurement/supplier control, and manufacturing control programs consistent with regulatory requirements. These nonconformances are cited in the enclosed Notice of Nonconformance (NON), and the enclosed inspection report describes in detail the circumstances surrounding them.

Please provide a written explanation or statement within 30 days of this letter in accordance with the instructions specified in the enclosed NON. We will consider extending the response time if you show good cause for us to do so.

In accordance with 10 CFR 2.390, "Public Inspections, Exemptions, Requests for Withholding," of NRC's "Rules of Practice," a copy of this letter, its enclosures, and your response will be made available electronically for public inspection in the NRC Public Document Room or from the NRC's document system Agencywide Documents Access and Management System (ADAMS), 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."

Sincerely,

/RA/

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

Docket No.: 99900271

Enclosures: As Stated

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DATE	3/21/2012	3/22/2012	3/26/2012	3/26/2012	3/22/2012
OFFICE	NRO/DCIP/CAEB	NRO/DCIP/CEVB			
NAME	TFrye	RRasmussen			
DATE	3/27/2012	03/28/2012			

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NOTICE OF VIOLATION

Rosemount Nuclear Instruments, Inc.
Emerson Process Management
8200 Market Blvd.
Chanhassen, MN 55317-9685

Docket Number 99900271
Inspection Report No. 99900271/2012-201

Based on the results of a U.S. Nuclear Regulatory Commission (NRC) inspection conducted January 30 to February 3, 2012, of activities performed at Rosemount Nuclear Instruments, Inc. (RNII), two violations of NRC requirements were identified. In accordance with the NRC Enforcement Policy, the violations are listed below:

A. 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).

B. 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).

Pursuant to the provisions of 10 CFR 2.201, "Notice of Violation," RNII is hereby required to submit a written statement or explanation to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, DC 20555-0001, with a copy to the Chief, Construction Electrical Vendor Branch, Division of Construction Inspection and Operational Programs, Office of New Reactors, within 30 days of the date of the letter transmitting this Notice of Violation (Notice). This reply should be clearly marked as a "Reply to a Notice of Violation" and should include: (1) the reason for the violation, or, if contested, the basis for disputing the violation or severity level; (2) the corrective steps that have been taken and the results achieved; (3) the corrective steps that will be taken to avoid further violations; and (4) the date when full compliance will be achieved. Your response may reference or include previous docketed correspondence, if the correspondence adequately addresses the required response. Where good cause is shown, the NRC will consider extending the response time.

If you contest this enforcement action, you should also provide a copy of your response, with the basis for your denial, to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001.

Because 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, it 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 withholding of such material, you must specifically identify the portions of your response that you seek to have withheld and provide in detail the bases for your claim of withholding (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.”

In accordance with 10 CFR 19.11, you may be required to post this Notice within two working days of receipt.

Dated this 28th of March 2012.

NOTICE OF NONCONFORMANCE

Rosemount Nuclear Instruments, Inc.
Emerson Process Management
8200 Market Blvd.
Chanhassen, MN 55317-9685

Docket Number 99900271
Inspection Report No. 99900271/2012-201

Based on the results of a U.S. Nuclear Regulatory Commission (NRC) inspection conducted on January 30 to February 3, 2012, of activities performed at Rosemount Nuclear Instruments, Inc. (RNII), it appears that certain activities were not conducted in accordance with NRC requirements, which are contractually imposed upon RNII by your customers or by NRC licensees.

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.

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.

Please provide a written statement or explanation to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, DC 20555-0001 with a copy to the Chief, Construction Electrical Vendor Branch, Division of Construction Inspection and Operational Programs, Office of New Reactors, within 30 days of the date of the letter transmitting this Notice of Nonconformance. This reply should be clearly marked as a "Reply to a Notice of Nonconformance" and should include for each noncompliance: (1) the reason for the noncompliance, or if contested, the basis for disputing the noncompliance; (2) the corrective steps that have been taken and the results achieved; (3) the corrective steps that will be taken to avoid noncompliances; and (4) the date when your corrective action will be completed. Where good cause is shown, the NRC will consider extending the response time.

Because your response will be made available electronically for public inspection in the NRC Public Document Room or from the NRC's document system Agencywide Documents Access and Management System (ADAMS), accessible from the NRC Web site at http://www.nrc.gov/reading-rm/adams.html, to the extent possible, it 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 withholding of such material, you must specifically identify the portions of your response that you seek to have withheld and provide in detail the bases for your claim of withholding (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."

Dated this 28th day of March 2012.

U.S. NUCLEAR REGULATORY COMMISSION
OFFICE OF NEW REACTORS
DIVISION OF CONSTRUCTION INSPECTION AND OPERATIONAL PROGRAMS
VENDOR INSPECTION REPORT

Docket No.:	99900271
Report No.:	99900271/2012-201
Vendor:	Rosemount Nuclear Instruments, Inc. 8200 Market Blvd. Chanhassen, MN 55317
Vendor Contact:	Ms. Duyen Pham, Quality Manager Phone: (952) 949-5363 duyen.pham@emerson.com
Nuclear Industry:	Rosemount Nuclear Instruments, Inc. (RNII) scope of supply for the nuclear industry includes design, engineering, manufacturing and supply of pressure transmitters, differential pressure transmitters, trip/calibration systems, signal conditioners, spare and replacement parts and repair services. RNII is a supplier of analog and digital pressure transmitters for the Watts Bar Unit 2 completion project.
Inspection Dates:	January 30 – February 3, 2012
Inspection Team Leader:	George Lipscomb, NRO/DCIP/CEVB
Inspectors:	Daniel Pasquale, NRO/DCIP/CEVB Eugene Huang, NRO/DCIP/CEVB Louis Dumont, RG-II/DCI/CIB1 Brent Clarke, NRO/DCIP/CMVB
Approved by:	Richard A. Rasmussen, Chief Electrical Vendor Branch Division of Construction Inspection and Operational Programs Office of New Reactors

EXECUTIVE SUMMARY

Rosemount Nuclear Instruments, Inc.
99900271/2012-201

The U.S. Nuclear Regulatory Commission (NRC) conducted this inspection to verify that Rosemount Nuclear Instruments, Inc. (RNII) implemented an adequate quality assurance (QA) program that complied with 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.” The inspection team also verified that RNII implemented a program under 10 CFR Part 21, "Reporting of Defects and Noncompliance," that meets the NRC’s regulatory requirements. This technically-focused inspection specifically evaluated RNII’s implementation of quality activities associated with the design, procurement, manufacture, and testing of pressure transmitters with an emphasis on the 1154H and 3051N pressure transmitter product lines. The 1154H is an analog transmitter that is designed, manufactured, and tested by RNII while the 3051N is a digital transmitter that is commercially dedicated. These product lines were identified because both are anticipated to be used in new reactor construction and are already in use in the operating fleet. This inspection was conducted at RNII’s manufacturing facility in Chanhassen, MN.

The following regulations served as the bases for this NRC inspection:

- Appendix B to 10 CFR Part 50
- 10 CFR Part 21

The inspectors used Inspection Procedure (IP) 43002, “Routine Inspections of Nuclear Vendors,“ dated April 25, 2011; IP 43004, “Inspection of Commercial-Grade Dedication Programs,“ dated April 25, 2011; and IP 36100, “Inspection of 10 CFR Part 21 and 50.55(e) Programs for Reporting Defects and Noncompliance,” dated April 25, 2011, to conduct this inspection.

No other NRC inspections of RNII have occurred in the last twelve years.

The results of this inspection are summarized below.

10 CFR Part 21

The NRC inspection team concluded that RNII is not effectively implementing its program consistent with the requirements of 10 CFR Part 21. The NRC inspection team identified Violation 99900271/2012/201-01 for failure to report defects within 60 days of discovery and Violation 99900271/2012/201-02 for failure to evaluate a deviation potentially associated with a substantial safety hazard.

Design Control

The NRC inspection team concluded that RNII is not effectively implementing its design control program consistent with the regulatory requirements of Criterion III, “Design Control,” of Appendix B to 10 CFR Part 50. Based on a broad sample of quality activities evaluated, the inspectors determined that activities supporting design control for the environmentally-qualified 1154H pressure transmitter were inconsistent with requirements.

The inspectors identified failures relating to both RNII programmatic controls (i.e. policies and procedures relating to all products) and implementation of design controls specifically for the 1154H transmitter. The inspectors did not fully evaluate the effect of these deficiencies on other RNII product lines.

The NRC inspection team identified Nonconformance 99900271/2012-201-03 for multiple failures to meet the regulatory requirements of Criterion III, "Design Control," of Appendix B to 10 CFR Part 50:

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

- 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 transmitters.

- 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, the NRC inspection team identified three instances in which RNII failed to limit access to records associated with test data, the Nuclear Suppliers List (NSL), and the Parts Classification List (PCL).

Manufacturing Control

The NRC inspection team identified Nonconformance 99900271/2012-201-04 because RNII used cleaning chemicals containing ammonium chloride to clean keyboards, work services and other items within the nuclear component assembly area without procedural controls or

evaluation of the potential detrimental effect on electronic circuit boards and metallic components.

With the exception of the nonconformance, the inspectors determined that RNII has established a program that adequately controls fabrication in accordance with the regulatory requirements of Criterion V, “Instructions, Procedures, and Drawings,” of Appendix B to 10 CFR Part 50. Based on the sample reviewed, the inspectors determined that RNII is effectively implementing these control processes during sensor module subassembly activities.

Test Control

With the exception of Nonconformance 99900271/2012-201-03, the NRC inspection team concluded that RNII has established a test control program consistent with the regulatory requirements of Criterion XI, “Test Control,” of Appendix B to 10 CFR Part 50. Based on the sample reviewed, the inspectors determined that RNII is effectively implementing these control processes during sensor module Temp Comp testing and the Model 1152 final assembly temperature coefficient test. Additionally, the inspectors determined the Model 1154H pressure transmitter specification related to inaccuracies induced because of operating temperature changes was appropriately controlled through the final assembly temperature coefficient test.

Nonconformance and Corrective Action

With the exception of NOV 99900271/2012-201-02, the NRC inspection team determined that, for the samples inspected, RNII adequately implemented procedures to control materials, parts or components that do not conform to requirements in accordance with Criterion XV, “Nonconforming Materials, Parts or Components,” of Appendix B to 10 CFR Part 50.

The NRC inspection team was unable to assess the effectiveness of the current RNII corrective action program (a system known as the Corrective Action Preventive Action system), because the program was not in place for a sufficient period of time.

Transmitter Accuracy Basis

The NRC inspection team selected the Model 1154H pressure transmitter catalog-specified temperature accuracy tolerance as a specification for inspection. The inspection team verified this accuracy specification through design, production, and final testing, and also inspected the temperature coefficient test on a final assembled pressure transmitter. No findings of significance were identified.

REPORT DETAILS

1. 10 CFR Part 21

   a. Inspection Scope

   The U.S. Nuclear Regulatory Commission (NRC) reviewed various policies, implementing procedures, and records that govern and document the Rosemount Nuclear Instruments, Inc. (RNII) program under Title 10 of the *Code of Federal Regulations* (10 CFR) Part 21, "Reporting of Defects and Noncompliance," to verify compliance with regulatory requirements. An emphasis was placed on reviewing Part 21 notifications, records, nonconformances and corrective actions associated with the Model 1154H and Model 3051N pressure transmitters. These product lines were selected because these transmitters are expected to be used in new reactor construction and are already in use in the operating fleet.

   Additionally, the NRC inspection team evaluated the 10 CFR Part 21 postings for compliance with the requirements of 10 CFR 21.6, "Posting Requirements."

   Within the scope of this area of the inspection, the inspectors reviewed the following documents:

   - RNII Quality Manual, Document No. D9000115, Revision AB, dated January 1, 2011
   - MKT-1620-1, "10 CFR Part 21 Notification Checklist," Revision AE, dated October 22, 2010
   - QA-1620-1, "Additional Part 21 Notifications," Revision AC, dated June 3, 2010
   - OP 1620, "Implementation of 10 CFR Part 21," Revision AG, dated October 22, 2010
   - OP 1610, "Corrective Action," Revision AF, dated February 2, 2010

   Additionally the inspectors reviewed the Potential Deviation/Failure to Comply Issue Log, Part 21 Meeting Notebooks, and the following corrective actions and 10 CFR Part 21 notifications:

   - CAR 20107031, 710 Trip Unit resistors, initiated October 13, 2010
   - CAR 20106952, Flange surface rust (315X), initiated August 10, 2010
   - CAR 20106951, Flange surface rust (115X), initiated August 17, 2010
   - CAR 20106781, Drop to 50% yield 315X hydro testing, initiated June 21, 2010
   - CAPA 000063, 710 Trip Unit resistors, initiated October 13, 2010

- 10 CFR Part 21 Notification, Model 3051N Pressure Transmitters, dated July 12, 2010

- 10 CFR Part 21 Notification, Model 1152 Differential Pressure Transmitters with Output Code "L" 10-50 mA electronics, dated December 2, 2010

- 10 CFR Part 21 Notification, Model 1153 Series B, 1154 and 1154 Series H Pressure Transmitters, dated September 6, 2011

b. Observations and Findings

b.1 Postings

The NRC inspection team verified that RNII had posted notices that included (1) a copy of Section 206 of the Energy Reorganization Act of 1974, (2) a copy of 10 CFR Part 21, and (3) a description of the RNII procedure that implements the regulation.

b.2 10 CFR Part 21 Procedures and Implementation

The NRC inspection reviewed 10 CFR Part 21 notifications with an emphasis on the Model 1154H and Model 3051N pressure transmitter product lines. It was observed that several notifications appeared to exceed the 60-day reporting requirement of 10 CFR 21.21(a)(1). Consequently, RNII instructions and implementing procedures for reporting defects and the responsibilities, timelines, and actions for identifying and evaluating deviations and failures to comply were reviewed. Those instructions and implementing procedures included the RNII Quality Manual (QM), OP 1620, MKT-1620-1, and QA-1620-1.

The inspection team identified a disparity between the definitions of "discovery" in 10 CFR 21.3 and RNII OP 1620. The regulation in 10 CFR 21.3, "Definitions," defines "discovery" as, "the completion of the documentation first identifying the existence of a deviation or failure to comply potentially associated with a substantial safety hazard within the evaluation procedures discussed in 21.21(a)." RNII OP 1620 defines "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."

Further, the inspection team identified that RNII MKT-1620-1 contains a time-based checklist for 10 CFR Part 21 notifications that is based on the latter (incorrect) determination of discovery.

These issues are considered more than minor because they contributed to three notifications not being made within the 60-day reporting requirement defined in 10 CFR 21.21(a)(1).

As a result of the above deficiencies, Violation 99900271/2012-201-01 is issued for failure to meet the 60-day reporting requirement of 10 CFR 21.21(a)(1) 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

The inspection team also noted that there is no process connection between the current RNII corrective action program and the 10 CFR Part 21 program. Additionally, the inspectors found minutes from quarterly and special Part 21 committee meetings were used to track evaluations of deviations and failures to comply in order to identify defects and failures to comply associated with substantial safety hazards. However, the minutes from the May 26, 2011 Part 21 committee meeting included "conclusions" related to failed resistors that specifically 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 evaluation was never conducted and the relevant corrective actions were closed on May 26, 2011.

As a result of the above deficiency, Violation 99900271/2012-201-02 is issued for failure to evaluate a deviation potentially associated with a substantial safety hazard associated with resistor failures (CAPA 000063/CAR 20107031, dated October 13, 2010).

RNII created nonconformance reports NC0000681, NC0000675, and NC0000678, dated February 2, 2012, related to these violations.

c. Conclusions

The NRC inspection team concluded that RNII is not effectively implementing its program consistent with the requirements of 10 CFR Part 21. The NRC inspection team identified Violation 99900271/2012/201-01 for failure to report defects within 60 days of discovery and Violation 99900271/2012/201-02 for failure to evaluate a deviation potentially associated with a substantial safety hazard.

The NRC inspection team concluded that for the evaluated sample, RNII met the 10 CFR Part 21 posting requirements.

2. Design Control

a. Inspection Scope

The Model 1154H analog pressure transmitter is currently used in the operating fleet. Additionally, both the Model 1154H and Model 3051N digital pressure transmitter are scheduled to be employed in new nuclear reactor construction. As a result, the NRC inspection team reviewed RNII's policies and procedures governing the implementation of its design control process with an emphasis on these transmitters, to verify compliance with Criterion III, "Design Control", of Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel reprocessing Plants, " to 10 CFR Part 50, "Domestic Licensing of Production and Utilization Facilities." In addition, the NRC inspection team reviewed 1154H and 3051N component design and design modifications and impact on environmental qualification. The NRC inspection team also discussed the design control program with RNII's management and technical staff to

determine if they were implementing their process in accordance with the above requirements. Within the scope of this area of the inspection, the inspectors reviewed the following documents:

- Document No. D2001019, "Model 3051N Qualification Report," Revision C, dated September 30, 2011
- MPR-2789, "Critical Digital Review of the Model 375 Field Communicator: A support tool for use with HART communications devices," Revision 0, dated June 17, 2005
- MPR-3558, "A Critical Digital review of the Emerson Model 475 Field Communicator: A support tool for use with HART and foundation communicator devices," Revision 1, dated June 6, 2011
- Document No. 1001453, "Generic Qualification of the Rosemount 3051N Pressure Transmitter for Nuclear Safety Applications," dated April 2001
- Document No. 03051-2316, "Interco Inspection 3051N," Revision AG, dated September 29, 2011
- Document No. D8700096, "Qualification Report for Rosemount Model 1154 Series H Pressure Transmitter," Revision 1, dated July 19, 2000
- Document No. D2009016, "Rosemount 1153 Series B, 1153 Series D, 1154 and 1154 Series H Sensor and Linearity Diode replacement," Revision A, dated April 19, 2010
- Document No. D9900005, "Qualification Report for Output Code R OP Amp Replacement," Revision B, dated April 4, 2001
- Travel Card Template, "Model 1154, Serial #JNN," Revision January 19, 2012
- RNI 1050062, "Reformat To Improve Individual Board Tracking," Revision AP, dated March 3, 2011
- ECO-RNI 1050001, "Design Improvement Change," dated January 6, 2011
- TCA-RNI 1050001, "Technical Change Authorization—Substitution of two 10Kohm span thermistors in place of one 20kohm thermistor," dated January 6, 2011
- RNII Survey N2011-S-05, "Stainless Foundry and Engineering," dated January 10, 2011
- OP 1120, "Production Software Control," Revision AF, dated July 15, 2011
- OP 0310, "Design Development," Revision AD, dated January 26, 2012
- OP 0320, "Nuclear Product Baseline Documentation and Revision Control," Revision AD, dated June 4, 2010
- OP 0340, "Engineering Change Orders," Revision AG, dated October 30, 2009

- OP 0410, “Procurement Document Control,” Revision AH, dated January 20, 2012
- OP 0510, “Manufacturing Procedures,” Revision AH, dated February 25, 2010
- OP 0720, “Control of Purchased Safety-Related Components,” Revision AJ, dated January 23, 2012

b. Observations and Findings

Section 3, “Design Control” of the RNII QM describes the process and controls used during the design process. RNII uses Operating Procedures (OPs) and the Engineering Change Order (ECO) process to implement design changes and design verification and validation.

The NRC inspection team reviewed the 1154H pressure transmitter temperature effect and seismic specifications to verify that design qualification reports, test results and calculations encompassed the nuclear specifications. The inspectors reviewed a sample of Technical Change Authorizations (TCAs) and ECOs to verify that RNII implemented its design change process to evaluate design changes against the original qualifications and specifications.

The NRC inspection team noted that RNII uses 115X Amplifier functional test software on its procured circuit boards to verify the function and acceptance criteria for the design of its transmitters. The software outputs two text files that hold the supporting data necessary to either reject or accept the circuit board. The NRC inspection team discovered that these files are stored on a shared network drive that is accessible by a computer with a generic/shared (i.e., open to all personnel) login. The text file data can be altered, changed, or deleted without traceability. The NRC inspection team also discovered that the Nuclear Supplier List (NSL) and the Parts Classification List (PCL) were also stored on the shared drive without controlled access. The NSL is used to track approved nuclear suppliers and the PCL categorizes safety-related components as well as each component’s critical characteristics.

The inspectors determined the text file data, the NSL, and the PCL are quality records that are used in the design of RNII transmitters and are required to be controlled under Appendix B to 10 CFR Part 50. Failure to protect quality records that are used to control the design of RNII transmitters is the first deficiency cited in Nonconformance 99900271/2012-201-03.

RNII created nonconformance reports NC000682 and NC000684, dated February 2, 2012, in response to this issue.

c. Conclusions

Based on the design modification sample reviewed, the NRC inspection team determined that RNII is implementing its design modifications ECO process in accordance with regulatory requirements. However, the nonconformance identified above is one example of RNII not adequately implementing its design control program

consistent with the regulatory requirements of Criterion III of Appendix B to 10 CFR Part 50.

3. Software Design Control

a. Inspection Scope

The NRC inspection team reviewed software documention including the software requirements document, and the validation plan and approval document for the 601TT4000 software testing associated with multiple product lines including the Model 1154H to verify that RNII production and testing software was designed in accordance with Criterion III, of Appendix B to 10 CFR Part 50. In addition, the NRC inspection team interviewed RNII technical staff to determine whether proper design control was implemented during the production of the 601TT4000 software. This software is used as part of a temperature coefficient final acceptance test of a transmitter related to nuclear safety. Within the scope of this area the NRC inspection team reviewed the following documents:

- RNII Quality Manual, Document No. D9000115, Revision AB, dated January 1, 2011
- OP 1120, "Production Software Control," Revision AF, dated July 15, 2011
- Software Requirements Document for the 601TT4000 software, undated
- "Temperature Coefficient Test System Validation Plan and Approval," dated June 3, 2008

b. Observations and Findings

During the evaluation of RNII test controls, the NRC inspection team determined software was critical to the RNII Model 1152 transmitter testing observed during the inspection. As a result, the inspectors assessed if RNII software controls met the requirements of Criterion III of Appendix B to 10 CFR Part 50 as specifically applied to 601TT4000 test software used during temperature coefficient testing.

The inspectors noted that Section 2.3 of the RNII QM stated that the RNII quality management system met the requirements of ASME NQA-1-1994, "Quality Assurance Program Requirements for Nuclear Facilities," to satisfy the requirements of Appendix B to 10 CFR Part 50. Additionally, the inspectors noted Subpart 2.7 "Software Verification and Validation Document" of ASME NQA-1 1994 states that software verification documentation shall be organized in a manner that allows traceability to both the software requirements and the software design.

During an evaluation of 601TT4000 test software control, the inspectors found that the software requirements document was not reviewed and approved, and that software design verification activities were not traceable to specific requirements. The inspectors determined review and approval of software design requirements and traceability of verification activities back to specific software requirements are key programmatic elements of software design control. This is considered more than minor because software testing cannot detect all software errors, and programmatic software controls

during the various software development phases are required to provide additional assurance of correct software execution.

Failure to implement adequate software design controls is the second deficiency cited in Nonconformance 99900271/2012-201-03 related to inadequate design control.

RNII created nonconformance report NC000677, dated February 2, 2012, in response to this issue.

c. Conclusions

The NRC inspection team determined that RNII failed to adequately verify or check the adequacy of design for the 601TT4000 software used during the temperature coefficient testing. Specifically, the software requirements document did not have the required reviews and approvals and software requirements were not traceable to the test plan for software design verification.

4. Procurement/Supplier Control

a. Inspection Scope

The NRC inspection team reviewed RNII procurement and supplier control processes and their effect on the Model 1154H and Model 3051N pressure transmitter product lines to determine if controls were in compliance with the requirements of Appendix B to 10 CFR Part 50. Specifically, the inspection evaluated the effectiveness of RNII to ensure requirements were met throughout the processes and were passed to sub-suppliers. The inspectors selected a sample of purchase orders that NRC licensees issued to RNII for basic components and then evaluated RNII control processes including the procurement of replenishment items from sub-suppliers. Within the scope of this area of the inspection, the inspectors reviewed the following documents:

- RNII Quality Manual, Document No. D9000115, Revision AB, dated January 1, 2011
- OP 0410, “Procurement Document Control,” Revision AH, dated January 20, 2012
- OP 0710, “Selection and Approval of Suppliers,” Revision AJ, dated January 20, 2012
- OP 0720, “Control of Purchased Safety-Related Components,” Revision AJ, dated January 23. 2012
- OP 0730, “Receiving Inspection,” Revision AF, dated January 25. 2012
- OP 1910, “Order Control and Contract Administration,” Revision AJ, dated June 10, 2010

Additionally, the inspectors reviewed the following RNII documents to verify implementation of procurement/supplier controls:

- TVA (Watts Bar) Purchase Order No. 151 Release 322, Revision 1, dated June 18, 2009, P/N 3051ND3A02B1AH2B2

- TVA (Watts Bar) Purchase Order No. 151 Release 324, Revision 0, dated July 15, 2009, P/N 1154DH4RC (Modified for use with Swagelock fittings US NPT)
- Nuclear Traveler JNQ0002563, P/N 3152ND4A2F1E2Q6Q8 P4P8T1W1, Shop Order No. 3090656

- Rosemount Drawing No. 03154-0110, "Screw, 6-32 Captive," dated July 30, 2002

- Rosemount Drawing No. N10485, "Fluid, Silicone: Dimethyl Siloxane," dated August 31, 2004

- Rosemount Drawing No. N95158, "Part Number RN55, Resistor, Fixed, Metal Film: 1/10 W," dated August 29, 2007

b. Observations and Findings

b.1 Order Entry

The NRC inspectors assessed multiple examples of RNII's order entry and order exception processes, and determined them to be satisfactory. There were no observations or findings noted in these areas.

b.2 Sub-supplier Purchase Orders

The inspectors reviewed orders by licensees for 1154H transmitters, which were qualified for operation under seismically extreme, environmentally harsh accident conditions. The inspectors found multiple instances of RNII's established commercial grade dedication program failing to provide reasonable assurance that specified quality standards included in design documents were being effectively controlled. These instances are discussed in detail as follows:

- Control of critical characteristics: While reviewing documentation relating to the purchase of the silicone oil used in the transmitter, the inspectors noted that RNII utilized different silicone oils for different transmitter environmental qualifications. The inspectors noted contradictions in RNII's PCL related to the safety classification of the silicone oil for the 1154H pressure transmitter. Specifically, a Receiving Inspection Report (IR) generated in an earlier version of RNII's purchased material control program, listed both the viscosity and dielectric properties of the oil as critical characteristics of acceptance. In the current PCL process, however, the oil's dielectric properties were omitted, and only the oil's viscosity was identified as a critical characteristic for acceptance. RNII could not provide documentation or justification for this change.

  Additionally, the inspectors reviewed an integrated circuit board (ICB). The ICB serves as the platform for the operational amplifier for the 1154H transmitter and is an RNII-engineered item, manufactured to an RNII-controlled fabrication detail that includes design specifications for the discrete components used to populate the ICB. One discrete component reviewed was a small (6-32) "captive screw" with a passive safety function to retain the seismically-qualified ICB securely within the operational amplifier's housing. The inspectors noted that the screw's material of construction

was omitted as a critical characteristic of the mounting device. The inspectors consider this more than a minor issue because the material of construction is essential to ensuring that the ICB remains intact during and after a seismic event.

- Material substitutions: The inspectors noted during reviews of a RNII controlled electrical drawing, associated with a component installed on an ICB, that the drawing contained the following statement: "Higher reliability or tighter tolerance devices meeting all other drawing requirements may be substituted for standard devices as called out by the drawing." However, because RNII is performing commercial grade dedication of this commercially supplied product dedicated via the commercial survey method, they need to understand and evaluate all changes to ensure the validity of the dedication. This is considered more than minor because RNII could not provide justification that material substitutions made by their commercial supplier were ever evaluated as equivalent to the originally specified components.

- Conformance to environmental qualification parameters: The inspectors noted that RNII did not ensure that the silicone oil being installed in their transmitters was the identical product qualified in the component's Equipment Qualification Report. The inspectors verified that RNII does not sample the oil at receipt inspection, nor do they require documentation similar to a Certified Material Test Report (CMTR) or Certificates of Compliance/Conformance from suppliers attesting to the authenticity of the oil. The inspectors also identified that RNII does not inspect or audit their supplier's method of verifying the authenticity of this oil during their commercial grade survey of the vendor. This is considered more than minor because these activities provide assurance that the delivered component continues to conform to the established component qualification. Without this assurance, requalification testing of the component is necessary.

The NRC inspection team included these three instances of a failure to establish a commercial grade dedication program that provides reasonable assurance that specified design control standards are effectively controlled as the third, fourth, and fifth examples cited in Nonconformance 99900271/2012-201-03.

RNII created nonconformance report NC000683, dated February 2, 2012, in response to these issues.

c. Conclusions

Based on the samples reviewed and with the issuance of Nonconformance 99900271/2012-201-02 in the area of Design Control, the inspectors determined that RNII's current commercial grade dedication and supplier control processes do not satisfy the regulatory requirements set forth in Appendix B to 10 CFR Part 50.

5. Manufacturing Control

a. Inspection Scope

The NRC inspection team reviewed RNII procedures and observed manufacturing activities, with emphasis on the Model 1154H and Model 3051N pressure transmitters, to determine if RNII manufacturing controls were in compliance with the regulatory requirements of Criterion V, "Instructions, Procedures, and Drawings," of Appendix B to

10 CFR Part 50. Specifically, the inspectors observed and interviewed RNII manufacturing personnel during in-process fabrication of the sensor module subassembly, and compared the observed manufacturing activities to the related procedures. Within the scope of this area of the inspection, the inspectors reviewed the following documents:

- RNII Quality Manual, Document No. D9000115, Revision AB, dated January 1, 2011
- OP 0510, "Manufacturing Procedures," Revision AH, dated February 25, 2010
- OP 0810, "Product Identification and Traceability," Revision AD, dated January 27, 2012
- OP 0810, "Product Identification and Traceability," Revision AC, dated December 4, 2008
- OP 1010, "Inspection," Revision AC, dated April 28, 2011
- OP 1120, "Production Software Control," Revision AF, dated July 15, 2011
- Manufacturing Procedure No. 01152-3067, "Temp Comp Procedure," Revision AM, dated May 23, 2011
- Inspection Procedure No. 01152-3062, "Inspection, Sensor Module," Revision AM, dated November 10, 2010
- Nuclear Traveler T01153-0218 Template, "Traveler, Sensor Oil Fill," Revision BV, dated May 21, 2008
- Nuclear Traveler T01154-0004 Template, "Traveler, Module Subassembly," Revision BY, dated July 19, 2011
- Travel Card Template, "Model 1154, Serial #JNN," Revision January 19, 2012
- Travel Card Template, "3051N," Revision February 14, 2011
- Oracle BOM for Part No. 01154-0004-0042, Revision AG, February 2, 2012

Additionally the inspectors reviewed the following in-process production samples to verify implementation of manufacturing controls:

- Nuclear Traveler T01154-0004, Sensor Module Serial No. 4773853
- Nuclear Traveler T01154-0004, Sensor Module Serial No. 4773862
- Temp Comp Datasheet, Run 5, Sensor Module Serial No. 4773853, dated February 1, 2012
- Temp Comp Datasheet, Run 5, Sensor Module Serial No. 4773862, dated February 1, 2012

b. Observations and Findings

During the observation of manufacturing activities, the inspectors found that the manufacturing personnel were knowledgeable of the fabrication procedures, and their fabrication activities met NRC requirements.

During inspection of manufacturing activities, the inspectors noted that RNII production personnel used cleaning chemicals containing ammonium chloride to clean keyboards, work surfaces and other items within the nuclear component assembly area. Ammonium chloride is corrosive and in some situations can cause deterioration of electronic circuit boards and cracking of stainless steel. RNII did not evaluate the potential detrimental effect of this chemical and did not define procedural controls or other precautions on this chemical's use in the nuclear assembly area. The inspectors considered this concern more than minor because of the potential for latent corrosion induced failures that may not be detected.

Consistent with Criterion XIII, "Handling, Storage and Shipping," of Appendix B, and RNII Quality Manual, Section 13.1, the inspectors noted that RNII was required to ensure that handling measures prevent component damage or deterioration during the fabrication process. As a result of this deficiency, the NRC inspection team identified Nonconformance 99900271/2012-201-04 for use of ammonium chloride within the nuclear component assembly area without procedural controls or evaluation of potential detrimental effects on electronic circuit boards and metallic components.

RNII created nonconformance NC000679, dated February 2, 2012, related to this issue.

c. Conclusions

With the exception of the nonconformance identified above, the NRC inspection team determined that RNII has established a program that adequately controls fabrication in accordance with the regulatory requirements of Criterion V of Appendix B to 10 CFR Part 50. Based on the sample reviewed, the inspectors determined that RNII is effectively implementing these control processes during sensor module subassembly activities.

6. Test Control

a. Inspection Scope

The NRC inspection team reviewed operating and manufacturing procedures and test plans with an emphasis on the Model 1154H and Model 3051N pressure transmitters to determine if RNII test controls were in compliance with the regulatory requirements of Criterion XI, "Test Control" of Appendix B to 10 CFR Part 50. Within the scope of this area of the inspection, the inspectors reviewed the following documents:

- RNII Quality Manual, Document No. D9000115, Revision AB, dated January 1, 2011
- OP 1110, "Test Control," Revision AC, dated December 3, 2009

- OP 1120, “Production Software Control,” Revision AF, dated July 15, 2011
- OP 1210, “Metrology,” Revision AE, dated January 25, 2012
- OP 1410, “Inspection, Test and Operating Status,” Revision AD, dated January 19, 2012
- “Temperature Coefficient Test System Validation Plan and Approval,” dated June 3, 2008
- Manufacturing Procedure No. 01152-3067, “Temp Comp Procedure,” Revision AM, dated May 23, 2011
- Manufacturing Procedure No. 01154-3443, “Temp Coefficient Test,” Revision AK, dated August 11, 2011

Additionally the inspectors reviewed the following in-process test activities to verify implementation of test controls:

- Nuclear Traveler T01154-0004, Sensor Module Serial No. 4773745
- Nuclear Traveler T01154-0004, Sensor Module Serial No. 4777761
- Temp Comp Datasheet, Run 7, Sensor Module Serial No. 4773745, dated February 2, 2012
- Temp Comp Datasheet, Run 5, Sensor Module Serial No. 4777761, dated February 2, 2012
- Travel Card, “Model 1152,” Revision December 12, 2011, Transmitter Serial No. JNQ0002984

b. Observations and Findings

The NRC inspection team observed and interviewed RNII manufacturing personnel during sensor module Temp Comp testing and the Model 1152 final assembly Temp Coefficient Test, and compared the observed testing activities to the related procedures. The Model 1152 final assembly Temp Coefficient Test was observed because it was on the work schedule and was considered representative of similar tests for the Model 1154H. The inspectors found that the manufacturing personnel were knowledgeable of the testing procedures and their testing activities appropriately implemented RNII test control requirements. The inspectors noted that both tests were software controlled with software derived pass/fail criteria (minimal personnel interpretation).

The inspectors evaluated the Model 1154H pressure transmitter specification for temperature induced inaccuracies through the various subassembly and final component tests (see Section 8 for additional information on the accuracy basis portion of the inspection). The inspectors learned that the final assembly Temp Coefficient Test was a software driven test program that directly measured the specification and provided

pass/fail indications to test personnel (minimal personnel interpretation). The inspectors also noted the Temperature Coefficient Test System Validation Plan documented the basis for the temperature coefficient test and the initial test case validation.
The inspectors found that the manufacturing personnel followed control procedures during the observed testing. However, the inspectors found software programmatic deficiencies related to the software used during transmitter testing observations. Specifically, the NRC inspection team identified Nonconformance 99900271/2012-201-02, in part, because the software requirements document used for temperature coefficient testing did not have the required reviews and approvals and software requirements were not traceable to the test plan for software design verification. Section 3 (Software Design Control) provides a detailed discussion of this deficiency.

c. Conclusions

With the exception of the software design control deficiency included with Nonconformance 99900271/2012-201-03, the NRC inspection team concluded that RNII is effectively implementing its test control program consistent with the requirements of Criterion XI of Appendix B to 10 CFR Part 50. Based on the sample reviewed, the inspectors determined that RNII is effectively implementing these control processes during sensor module Temp Comp testing and the Model 1152 final assembly Temp Coefficient Test. Additionally, the inspectors determined that the Model 1154H pressure transmitter specification related to inaccuracies induced by operating temperature changes was appropriately controlled through the final assembly Temp Coefficient Test.

7. Nonconformance and Corrective Action

a. Inspection Scope

The NRC inspection team reviewed several nonconformance and corrective action documents with an emphasis on the 1154H and 3051N pressure transmitter product lines to verify that procedures have been established and implemented for controlling materials, parts or components that do not conform to the requirements of Criterion XV, "Nonconforming Materials, Parts or Components," of Appendix B, to 10 CFR Part 50, and correcting conditions adverse to quality in accordance with Criterion XVI, "Corrective Action," of Appendix B to 10 CFR Part 50. Also, the NRC inspection team interviewed RNII personnel to determine that they were implementing procedures in accordance with the above requirements. Within the scope of this area the NRC inspection team reviewed the following documents:

- OP 1510, "Nonconforming Material Control," Revision AG, dated April 28, 2011
- OP 0730, "Receiving Inspection," Revision AF, dated January 25, 2012
- OP 1610, "Corrective Action," Revision AF, dated February 2, 2010
- OP 1620, "Implementation 10 CFR Part 21," Revision AG, dated October 22, 2010
- QA-1620-1, "Additional Part 21 Notifications," Revision AC, dated June 3, 2010

- QA-1510-2, “Advance Deviation Request,” Revision AC, dated August 2, 2010
- MR-23739, dated January 31, 2012
- MR-23575, dated January 16, 2012
- MR-23479, dated January 7, 2012
- MR-22688, dated September 29, 2011
- ADR No 014806, dated January 27, 2010
- Discrepancy Report, “Failed TempCo” (TF7116/ TF5802), dated January 12, 2010
- Discrepancy Report, “Wrong Electronic Housing Part Number Recorded on Travel and,” dated November 30, 2009
- CAR SCA-2152, “Loctite Used on Heat Sink,” initiated April 18, 2011
- CAR 2196, “Tepro Resistor Failures,” initiated June 20, 2011
- CAR 20107031, “710 Trip Unit Resistors,” initiated October 13, 2010

b. Observations and Findings

b1. Nonconformance

The NRC inspection team found RNII captures nonconformances in multiple formats including: Material Reviews (MR), Discrepancy Reports (DR), and Advance Deviation Requests (ADR). The inspectors reviewed a sample of MRs, DRs, and ADRs with emphasis on nonconformances associated with the 1154H or 3051N pressure transmitters. Specifically, the inspectors selected a sample of four MRs to assess the quality of receipt inspections and to evaluate dispositions of potential nonconforming materials, plus two DRs and an ADR to assess if technical discrepancies were appropriately controlled and resolved.

The inspectors noted one nonconformance was not evaluated for 10 CFR Part 21 applicability as required by regulation and RNII procedure. This deficiency is cited in NOV 99900271/2012-201-02 and is discussed in detail in Section 1 (10 CFR Part 21) of this report. No other issues of significance were noted in the area of nonconformance.

b2. Corrective Action

The NRC inspection team found that in 2011 RNII completed a transition to a new corrective action tracking and disposition system. The legacy system uses CARs and the new system uses CAPA reports. The inspectors reviewed a sample of CARs with emphasis on corrective action reports associated with the 1154H or 3051N pressure transmitters. Specifically, the inspectors selected a sample of two corrective action documents that were tracked under the CAR system and found no issues of significance. The inspectors found a representative sample of CAPA system corrective

action dispositions could not be selected because the new system had not been in place for a sufficient period of time.

c. Conclusions

With the exception of the failure to evaluate a nonconformance for 10 CFR Part 21 applicability associated with NOV 99900271/2012-201-02, the NRC inspection team determined, that for the samples inspected, RNII adequately implemented its procedures to control materials, parts, or components that do not conform to requirements in accordance with Criterion XV of Appendix B to 10 CFR Part 50.

The NRC inspection team was unable to assess the effectiveness of the current RNII corrective action program, because the new CAPA tracking and disposition system had not been in place for a sufficient period of time.

8. Transmitter Accuracy Basis

a. Inspection Scope

The NRC inspection team sampled the controls and tests used by RNII to ensure the accuracy of their pressure transmitters from design through manufacture and testing. Because of its planned use in new reactor construction and current use in the operating fleet, the Model 1154H pressure transmitter was selected for inspection. Specifically, the temperature accuracy of the Model 1154H was selected as an inspected characteristic. The following documents were reviewed:

- OP 1110, “Test Control,” Revision AC, dated December 3, 2009
- OP 1120, “Production Software Control,” Revision AF, dated July 15, 2011
- “Temperature Coefficient Test System Validation Plan and Approval,” dated June 3, 2008
- Manufacturing Procedure No. 01154-3443, “Temp Coefficient Test,” Revision AK, dated August 11, 2011
- Travel Card Template, “Model 1154, Serial #JNN,” Revision January 19, 2012
- Document No. D8700096, “Qualification Report for Rosemount Model 1154 series H pressure transmitter,” Revision 1, dated July 7, 2000
- Catalog Document 00809-0100-4631, Rosemount 1154 Series H Reference Manual, Revision BA, dated April 2007
- Catalog Document 00813-0100-4631, Rosemount 1154 Series H Product Data Sheet, Revision BA, dated April 2007

b. Observations

The inspection team noted that the RNII product catalog listed the specification for temperature effect on the Model 1154H pressure accuracy as follows: "All ranges plus or minus (0.75% of upper range limit + 0.5% span) per 100 F (55.6 C) ambient temperature change between 40 F (4.4 C) and 200 F (93.3 C)." The inspectors also learned that the final assembly temperature coefficient test used to verify this accuracy was a software-driven test that directly measured the specification. The inspection team verified this accuracy specification through design, production, and final testing, and it inspected the temperature coefficient test on a final assembled pressure transmitter.

c. Conclusions

The NRC inspection team concluded that the temperature accuracy specification of the Model 1154H pressure transmitter was appropriately controlled. No findings of significance were identified.

9. Entrance and Exit Meetings

On January 30, 2012, the inspectors presented the inspection scope during an entrance meeting with Mr. Marc Bumgarner, RNII Vice President and General Manager, and other RNII personnel. On February 3, 2012, the inspectors presented the inspection results during an exit meeting with Mr. Bumgarner and other RNII personnel.

ATTACHMENT

1. PERSONS CONTACTED AND NRC STAFF INVOLVED:

Name	Title	Affiliation	Entrance	Exit	Interviewed
Marc Bumgarner	Vice President and General Manager	RNII	X	X	
Duyen Pham	QA Manager	RNII	X	X	X
Michele McDonald	Operations Manager	RNII	X	X	
Jeff Chivers	Director of Engineering	RNII	X	X	X
Nathan Schukei	Quality Engineer	RNII	X	X	X
Michael Schaepkens	Quality Engineer	RNII	X	X	X
Russell McDaniel	Manufacturing Systems Engineer	RNII	X	X	X
Brian Kocher	Design Engineer	RNII	X	X	X
Annie Larson	Supply Quality Engineer	RNII	X	X	X
Tracy Kaluzniak	Customer Care Manager	RNII	X	X	
Heidi Williams	Materials Manager	RNII	X	X	
Gerard Hanson	Value Chain Director	RNII	X	X	
Erin Irmiter	Manufacturing Systems Manager	RNII	X	X	
Daniel Flatten	Quality Engineer	RNII	X	X	
Brian Sofen	Electrical Design Engineer	RNII			X
Nate Wader	Design Engineer	RNII			X
Dan Norberg	Principle Design Engineer	RNII			X
Kori Reagan	Project Engineer	RNII			X
Alex Mejorada	Manufacturing Specialist	RNII			X
Yai Chanthalakeo	Production Operator	RNII			X
Thoa Doan	Production Operator	RNII			X
Robert Jopp	Production Operator	RNII			X
Chris Victor	Projects Engineer	RNII			X

Name	Title	Affiliation	Entrance	Exit	Interviewed
Richard Rasmussen	Branch Chief, CEVB	NRC		X	
George Lipscomb	Inspection Team Leader	NRC	X	X	
Daniel Pasquale	Inspection Team Member	NRC	X	X	
Eugene Huang	Inspection Team Member	NRC	X	X	
Louis Dumont	Inspection Team Member	NRC	X	X	
Brent Clarke	Inspection Team Member	NRC	X	X	

2. INSPECTION PROCEDURES USED:

IP 36100, "Inspection of 10 CFR Parts 21 and 50.55(e) Programs for Reporting Defects and Noncompliance"

IP 43002, "Routine Inspections of Nuclear Vendors"

IP 43004, "Inspection of Commercial-Grade Dedication Programs"

3. ITEMS OPENED, CLOSED, AND DISCUSSED :

Item Number	Status	Type	Description
99900271/2012-201-01	Opened	NOV	10 CFR 21.21(a)
99900271/2012-201-02	Opened	NOV	10 CFR 21.21(a)
99900271/2012-201-03	Opened	NON	App. B, Criterion III
99900271/2012-201-04	Opened	NON	App. B, Criterion XIII

4. ACRONYMS USED:

ADR	Advance Deviation Request
ASME	American Society of Mechanical Engineers
BOM	Bill of Materials
CAPA	Corrective Action Preventive Action
CAR	Corrective Action Report
CCV	Critical Characteristics Verification
CEVB	Construction Electrical Vendor Branch
CFR	Code of Federal Regulations
CMTR	Certified Material Test Report
CMVB	Construction Mechanical Vendor Branch
CIB1	Construction Inspection Branch 1
DCI	Division of Construction Inspection
DCIP	Division of Construction Inspection and Operational Programs
DR	Discrepancy Report
ECO	Engineering Change Order
FAT	Final Acceptance Test
ICB	Integrated Circuit Board
IP	Inspection Procedure
IR	Inspection Report
MR	Material Review
NON	Notice of Nonconformance
NQA-1	Nuclear Quality Assurance - 1
NRC	(U.S.) Nuclear Regulatory Commission
NRO	Office of New Reactors
NSL	Nuclear Supplier List
OP	Operating Procedure
PCL	Parts Classification List
P/N	Part Number
PO	Purchase Order
QA	Quality Assurance
QM	Quality Manual
RG-II	Region II, U.S. Nuclear Regulatory Commission
RNII	Rosemount Nuclear Instruments, Inc.
SQE	Supplier Quality Engineer
TCA	Technical Change Authorizations
TVA	Tennessee Valley Authority