



UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

January 27, 2020

Mr. Jeff Chivers
Director of Engineering and Quality
Rosemount Nuclear Instruments, Inc.
8200 Market Blvd
Chanhassen, MN 55317

SUBJECT: NUCLEAR REGULATORY COMMISSION VENDOR INSPECTION REPORT OF
ROSEMOUNT NUCLEAR INSTRUMENTS, INC. NO. 99900271/2019-201 AND
NOTICE OF NONCONFORMANCE

Dear Mr. Chivers:

From December 9 through December 12, 2019, the U.S. Nuclear Regulatory Commission (NRC) staff conducted an inspection at Rosemount Nuclear Instruments, Inc.'s (hereafter referred to as RNII) facility in Chanhassen, MN. The purpose of this limited-scope routine inspection was to assess RNII's compliance with 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 Program 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 the quality activities associated with the design, engineering, manufacturing, and supply of pressure transmitters, differential pressure transmitters, trip/calibration systems, signal conditioners, spare and replacement parts, and repair services. The enclosed report presents the results of the inspection. This NRC inspection report does not constitute NRC endorsement of RNII's overall quality assurance (QA) or 10 CFR Part 21 programs.

Based on the results of this inspection, the NRC inspection team found that the implementation of your QA program did not meet certain regulatory requirements imposed on you by your customers or NRC licensees. Specifically, the NRC inspection team determined that RNII was not fully implementing its QA program in the area of design and test control. The specific findings and references to the pertinent requirements are identified in the enclosures to this letter. In response to the enclosed Notice of Nonconformance (NON), RNII should document the results of the extent of condition review for this finding and determine if there are any effects on other safety-related components.

Please provide a written statement or explanation within 30 days of this letter in accordance with the instructions specified in the enclosed NON. This response should document the results from RNII's evaluation on the significance of the NON as requested above. 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 the NRC's "Rules of Practice," the NRC will make available electronically for public inspection

a copy of this letter, its enclosure, and your response through the NRC Public Document Room or from the NRC's Agencywide Documents Access and Management System, which is accessible at <http://www.nrc.gov/reading-rm/adams.html>. To the extent possible, your response (and if applicable), should not include any personal privacy, proprietary, or Safeguards Information (SGI) 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, 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 be 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 would 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 SGI 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,

Kerri A. Kavanagh, Chief */RA/*
Quality Assurance and Vendor Inspection Branch
Division of Reactor Oversight
Office of Nuclear Reactor Regulation

Docket No.: 99900271

EPID No.: I-2019-201-0069

Enclosures:

1. Notice of Nonconformance
2. Inspection Report No. 99900271/2019-201
and Attachment

SUBJECT:NUCLEAR REGULATORY COMMISSION VENDOR INSPECTION REPOT OF
ROSEMOUNT NUCLEAR INSTRUMENTS, INC. NO. 99900271/2019-201 AND
NOTICE OF NONCONFORMANCE Dated: January 27, 2020

DISTRIBUTION:

CMiller
RFelts
MYoung
ASakadales
ConE_Resource
Jeff.Chivers@Emerson.com
NRR_DRO_IQVB Distribution

ADAMS Accession No.: ML20024G416 *via e-mail

NRR-106

OFFICE	NRR/DRO/IQVB	NRR/DRO/IQVB	NRR/DRO/IQVB
NAME	DPark	PNatividad*	NSavvoir*
DATE	01/21/2020	01/21/2020	01/23/2020
OFFICE	NRR/DRO/IRAB	NRR/DRO/IQVB	
NAME	BHughes*	KKavanagh	
DATE	01/27/2020	01/27/2020	

OFFICIAL RECORD COPY

NOTICE OF NONCONFORMANCE

Rosemount Nuclear Instruments, Inc.
8200 Market Blvd
Chanhassen, MN 55317

Docket No. 99900271
Report No. 2019-201

Based on the results of a U.S. Nuclear Regulatory Commission (NRC) inspection conducted at the Rosemount Nuclear Instruments, Inc.'s (hereafter referred to as RNII) facility in Chanhassen, MN, from December 9, 2019 through December 12, 2019, RNII did not conduct certain activities in accordance with NRC requirements that were contractually imposed upon RNII by its customers or NRC licensees:

1. Criterion III, "Design Control," 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," states, in part, that "design control measures shall provide for verifying or checking the adequacy of design...by the performance of a suitable testing program."

Criterion XI, "Test Control," of Appendix B to 10 CFR Part 50 states, in part, that "the test is performed under suitable environmental conditions. Test results shall be documented and evaluated to assure that test requirements have been satisfied."

Contrary to the above, as of December 12, 2019, RNII failed to verify or check the adequacy of design by the performance of a suitable testing program and that the test was performed under suitable environmental conditions. Specifically, due to the way the 3159 nuclear qualified remote diaphragm seal and detector assemblies were mounted in the radiation chamber and the way that the associated radiation dose was measured, the test samples may have received significantly less radiation dose than what was called for in the test plan and captured in the analysis. Furthermore, portions of the test sample were shielded in the radiation chamber, and the thermoluminescent dosimeters used to measure the field were placed primarily on the test sample closest to the test source, resulting in a nonconservative dose delivered to the test sample. These two factors resulted in the test sample receiving less radiation dose than what was called for in the test plan and captured in the analysis performed to establish the accuracy specifications for the remote seal system.

This issue has been identified as Nonconformance 99900271/2019-201-01.

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, Quality Assurance and Vendor Inspection Branch, Division of Reactor Oversight, Office of Nuclear Reactor Regulation, 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 and the results achieved; (3) the corrective steps that will be to avoid further noncompliance; and (4) the date when the corrective action will be completed. Where good cause is shown, the NRC will consider extending the response time.

In accordance with 10 CFR 2.390, "Public inspections, exemptions, requests for withholding," of the NRC's "Rules of Practice," a copy of this letter, its enclosure(s), and your response will be made available electronically for public inspection in the NRC's Public Document Room or from the NRC's Agencywide Documents Access and Management System, which is 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 (SGI) so that the NRC can make it 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 be withheld, 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 would 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 SGI 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 27th day of January 2020.

**U.S. NUCLEAR REGULATORY COMMISSION
OFFICE OF NUCLEAR REACTOR REGULATION
DIVISION OF REACTOR OVERSIGHT
VENDOR INSPECTION REPORT**

Docket No.: 99900271

Report No.: 99900271/2019-201

Vendor: Rosemount Nuclear Instruments, Inc.
8200 Market Blvd
Chanhassen, MN 55317

Vendor Contact: Mr. Jeff Chivers
Director of Engineering and Quality
Email: Jeff.Chivers@emerson.com
Office: (952) 949-5377

Nuclear Industry Activity: Rosemount Nuclear Instruments, Inc.'s scope of supply for the nuclear power plants (operating and under construction) includes design, engineering, manufacturing, and supply of pressure transmitters, differential pressure transmitters, trip/calibration systems, signal conditioners, spare and replacement parts, and repair services.

Inspection Dates: December 9 - 12, 2019

Inspectors: Jeffrey Jacobson NRR/DRO/IQVB Team Leader
Nicholas Savvoir NRR/DRO/IQVB
Phil Natividad NRR/DRO/IQVB
Dong Park NRR/DRO/IQVB

Approved by: Kerri A. Kavanagh, Chief
Quality Assurance and Vendor Inspection Branch
Division of Reactor Oversight
Office of Nuclear Reactor Regulation

EXECUTIVE SUMMARY

Rosemount Nuclear Instruments, Inc.
99900271/2019-201

The U.S. Nuclear Regulatory Commission (NRC) staff conducted a routine vendor inspection at the Rosemount Nuclear Instruments, Inc.'s (hereafter referred to as RNII) facility in Chanhassen, MN, to verify that it had implemented an adequate quality assurance (QA) program that complies 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," and 10 CFR Part 21, "Reporting of Defects and Noncompliance." This NRC inspection team also evaluated RNII's corrective actions in relation to the findings identified in NRC inspection reports 99900271/2012-201 and 99900271/2013-201. Some of the specific activities observed by the NRC inspection team included the receipt inspection process in support of the commercial grade dedication of the 3150 pressure transmitter product lines. The NRC inspection team conducted the inspection on December 9 - 12, 2019. This was the third NRC inspection at RNII's facility in Chanhassen, MN.

This technically-focused inspection specifically evaluated RNII's implementation of quality activities associated with the design, engineering, manufacturing and supply of pressure transmitters, differential pressure transmitters, trip/calibration systems, signal conditioners, spare and replacement parts, and repair services.

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

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

During this inspection, the NRC inspection team implemented Inspection Procedure (IP) 43002, "Routine Inspections of Nuclear Vendors," dated January 27, 2017, IP 43004, "Inspection of Commercial-Grade Dedication Programs," dated January 27, 2017, and IP36100, "Inspection of 10 CFR Part 21 and Programs for Reporting Defects and Noncompliance," dated May 16, 2019.

With the exception of the nonconformance described below, the NRC inspection team concluded that RNII's QA policies and procedures comply with the applicable requirements of Appendix B to 10 CFR Part 50 and 10 CFR Part 21, and that RNII's personnel are implementing these policies and procedures effectively. The results of this inspection are summarized below.

10 CFR Part 21 Program

The NRC inspection team reviewed RNII's policies and implementing procedures that govern the implementation of its 10 CFR Part 21 program to verify compliance with 10 CFR Part 21. The NRC inspection team: (1) reviewed the 10 CFR Part 21 postings; (2) reviewed a sample of purchase orders (POs); and (3) verified that RNII's corrective action program provides a link to the 10 CFR Part 21 program. No findings of significance were identified.

Design Control

The NRC inspection team reviewed RNII's policies and procedures that govern the implementation of its design control program to verify compliance with the requirements of Criterion III, "Design Control" of Appendix B to 10 CFR Part 50. The NRC inspection team reviewed RNII's 3150 series pressure transmitter qualification reports that support multiple levels of environmental qualification (EQ). The NRC inspection team verified that adequate controls are in place to ensure EQ production and replacement parts are similar in form, fit, and function to those originally tested and qualified. The NRC inspection team identified one nonconformance associated with RNII's implementation of its design control program.

Nonconformance 99900271/2019-201-01 was issued for RNII's failure to verify or check the adequacy of design by the performance of a suitable testing program and that the test was performed under suitable environmental conditions. Due to the way the 3159 nuclear qualified remote diaphragm seal and detector assemblies were mounted in the radiation chamber and the way that the associated radiation dose was measured, the test samples may have received significantly less radiation dose than what was called for in the test plan and captured in the analysis. RNII entered this issue into their corrective action program under Corrective and Preventive Action (CAPA) No. 004435.

Commercial-Grade Dedication

The NRC inspection team reviewed RNII's policies and implementing procedures that govern the implementation of its commercial-grade dedication (CGD) program to verify compliance with the requirements of Criterion III and Criterion VII, "Control of Purchased Material, Equipment, and Services," of Appendix B to 10 CFR Part 50. The NRC inspection team reviewed a sample of CGD packages to verify that the process was being adequately implemented. The NRC inspection team also reviewed a sample of commercial-grade surveys and verified they contained the objective evidence necessary to demonstrate adequate control of the critical characteristics.

The NRC inspection team identified one minor issue related to traceability of commercial-grade items. Specifically, RNII conducted material critical characteristic verification through a commercial-grade survey of the manufacturer; however, the O-rings are procured through a distributor and material control at the distributor was not addressed. RNII's CGD method did not identify the verification of the distributor's process for correct handling of the supplied items as a critical characteristic. RNII initiated nonconformance No. 008722 to address this issue.

Oversight of Contracted Activities

The NRC inspection team reviewed RNII's policies and implementing procedures that govern the implementation of its supplier oversight program to verify compliance with the requirements of Criterion VII and Criterion XVIII, "Audits," of Appendix B to 10 CFR Part 50. The NRC inspection team verified a sample of POs and external audits that identified the audit scope and applicable checklist criteria before the initiation of the audit activity. No findings of significance were identified.

Manufacturing Control / Control of Special Processes

The NRC inspection team reviewed RNII's policies and implementing procedures that govern the special processes program to verify compliance with the regulatory requirements of Criterion

IX, "Control of Special Processes," of Appendix B to 10 CFR Part 50. The NRC inspection team observed soldering and in-process inspection of circuit boards, maintenance records, and training and qualification records. The NRC inspection team also observed the pressure transmitter lower module time response testing as a manufacturing/assembly step and the silicone fill fluid acceptance criteria testing. No findings of significance were identified.

Nonconforming Material, Parts, or Components and Corrective Action

The NRC inspection team reviewed the policies and procedures that govern the implementation of RNII's nonconformance program to verify compliance with the regulatory requirements in Criterion XV, "Nonconforming Materials, Parts or Components" and Criterion XVI, "Corrective Actions," of Appendix B to 10 CFR Part 50. The NRC inspection team reviewed RNII identified discrepancy reports (DRs) and a sample of CAPAs. The NRC inspection team also reviewed RNII's actions associated with its response to a Notice of Nonconformance (NON) contained in NRC Inspection Report 99900271/2012-201 and 99900271/2013-201. The NRC inspection team verified that RNII had taken adequate corrective actions to NONs 99900271/2012-201-03 and 99900271/2013-201-01. These two NONs are now considered closed. No findings of significance were identified.

REPORT DETAILS

1. 10 CFR Part 21 Program

a. Inspection Scope

The NRC inspection team reviewed Rosemount Nuclear Instruments, Inc.'s (hereafter referred to as RNII) policies and implementing procedures that govern the implementation of its Title 10 of the *Code of Federal Regulations* (10 CFR) Part 21, "Reporting of Defects and Noncompliance," program to verify compliance with the regulatory requirements. In addition, the NRC inspection team evaluated the 10 CFR Part 21 postings and a sample of RNII's purchase orders (POs) for compliance with the requirements of 10 CFR 21.21, "Notification of failure to comply or existence of a defect and its evaluation," and 10 CFR 21.31, "Procurement documents." The NRC inspection team also verified that RNII's nonconformance and corrective action procedures provide a link to the 10 CFR Part 21 program. For the five 10 CFR Part 21 evaluations performed within the past three years, the NRC inspection team verified that RNII had effectively implemented the requirements for evaluating deviations and failures to comply. The NRC inspection team verified that the notifications were performed in accordance with the requirements of 10 CFR 21.21, as applicable. RNII provided sufficient documentation to support their engineering judgements regarding potential 10 CFR Part 21 reportability over the period of the past three years.

The NRC inspection team also discussed the 10 CFR Part 21 program with RNII's management and technical staff. The attachment to this inspection report lists the documents reviewed by the NRC inspection team.

b. Observations and Findings

No findings of significance were identified.

c. Conclusion

The NRC inspection team concluded that RNII is implementing its 10 CFR Part 21 program in accordance with the regulatory requirements of 10 CFR Part 21. Based on the limited sample of documents reviewed, the NRC inspection team also determined that RNII is implementing its policies and procedures associated with the 10 CFR Part 21 program. No findings of significance were identified.

2. Design Control

a. Inspection Scope

The NRC inspection team reviewed RNII's policies and implementing procedures that govern the implementation of its design control program to verify compliance with the requirements of Criterion III, "Design Control" of Appendix B to 10 CFR Part 50.

The NRC inspection team reviewed the engineering evaluations and associated test reports to support the acceptability of a change in commercial suppliers for the silicon

dielectric fluid used within the transmitter module and the remote seal assembly. While the actual chemical formulation of the fluid from the old and new suppliers was stated as being the same, the NRC inspection team reviewed the testing that RNII performed to verify that the fluid performance and characteristics were not adversely impacted by the change in supplier and that the new supplier would not impact the overall qualification of the transmitters. The NRC inspection team also reviewed RNII's performance tests of the transmitters using fluid from the new supplier to verify the transmitter's performance.

The NRC inspection team also reviewed Technical Evaluation (TE)-315X-06-01, "Technical Evaluation of Silicone Oil Fill Fluid," Revision AC, dated December 29, 2017. The NRC inspection team verified that the technical evaluation appropriately captured the safety function of the component and established appropriate critical characteristics to be verified as part of commercial-grade dedication (CGD) process.

Environmental Qualification (EQ)

The NRC inspection team reviewed RNII's 3150 series pressure transmitter qualification reports that supports multiple levels of EQ. The RNII 3150s series pressure transmitter is an enhancement to RNII's 1150 series. The NRC inspection team ensured appropriate considerations were taken for the heat rise of internal electronic components and evaluated the basis for sample selection/grouping of models/sizes during qualification. The NRC inspection team verified that any activation energies used in the thermal aging analysis had a proper reference and were appropriate for the characteristic most associated with the safety function of the component. The NRC inspection team also verified that adequate controls are in place to ensure production and replacement parts are similar in form, fit, and function to those originally tested and qualified.

The NRC inspection team reviewed the basis for the activation energies used as an input to the thermal aging analysis for the 3155N pressure transmitters. The NRC inspection team identified that basing the thermal aging of the entire transmitter upon the lowest activation energy of the discrete electrical components was a conservative approach, particularly considering that such components are generally age insensitive at the temperatures in question. Also, RNII indicated that any resistance drift that might occur due to aging would likely be compensated for by periodic in situ calibration of the transmitter system. The NRC inspection team noted that as part of the thermal aging calculation, RNII utilized an internal heat rise of 6°F. The basis for and acceptability of the 6°F number is the subject of RNII's recent interim Part 21 notification as RNII has identified several components on the circuit cards where the temperature rise may exceed the assumed 6°F. RNII is currently evaluating the overall impact of the heat rise on the thermal aging analysis and is planning to update the 10 CFR Part 21 upon conclusion of its evaluation.

The NRC inspection team reviewed RNII document No. D2013009, "IEEE Qualification Report: Rosemount 3159 Remote Diaphragm Seal with 3150 Series Nuclear Pressure Transmitters," Revision B, dated January 28, 2015. The remote seal is used in conjunction with one of the 3150 series qualified transmitters and allows for a more remote connection of the process medium being measured. Because utilizing the remote seal in lieu of a direct connection to the transmitter may significantly affects the accuracy and response time of the installed transmitter, the NRC inspection team reviewed the RNII's testing to assess the accuracies and response time specifications

included in the Product Data Sheet 00813-0100-4859, "Rosemount 3159 Nuclear Qualified Remote Diaphragm Seal for Use with 3152N, 3153N, 3154N and 3155N," Revision AD, dated May 2019.

Seismic Qualification

The NRC inspection team reviewed seismic qualifications and pressure transmitter qualification report of the RNII 3154N series of pressure transmitters. The NRC inspection team reviewed five RNII seismic testing notice of anomalies that were documented and evaluated against the seismic qualification testing of the 3150 series pressure transmitters. The NRC inspection team reviewed five operating basis earthquake simulations, the seismic safe shutdown earthquake simulation, and the seismic random multi-frequency testing. The seismic test data was compared to monitor the specimens for degradation.

Electromagnetic Interference/Radio Frequency Interference (EMI/RFI) Testing

The NRC inspection team reviewed EMI/RFI qualification reports and PO requirements for the RNII's six 3150s pressure transmitters electromagnetic compatibility (EMC) test plan. The NRC inspection team reviewed RNII's EMC tests in accordance with NRC Regulatory Guide 1.180 Revision 1, "Guidelines for Evaluating Electromagnetic and Radio-Frequency Interference in Safety-Related Instrumentation and Control Systems" and MIL-STD-461E for conducted susceptibility, radiated susceptibility, conducted emission, and radiated emission testing.

The NRC inspection team reviewed the EMC assessment of circuit card assemblies used in 3152N, 3153N and 3154N, assessment of the effect of electrical design improvements on EMC performance, the voltage regulator circuit changes of the three resistors changes, and assessment of the P-spice simulation responses of the original and improved regulator designs. The NRC inspection team also reviewed the change in amplifier (op-amp) and printed wiring board laminate material. This change was due to discontinuance of the LM108 op-amp, design improvements, and passivation materials.

The NRC inspection team also discussed the design control program with RNII's management and technical staff. The attachment to this inspection report lists the documents reviewed by the NRC inspection team.

b. Observations and Findings

The NRC inspection team identified that the testing protocol that was implemented associated with the radiation testing portion of RNII's 3159 nuclear qualified remote diaphragm seal and 3150 series pressure transmitters did not verify the adequacy of the design. Specifically, due to the way the 3159 nuclear qualified remote diaphragm seal and detector assemblies were mounted in the radiation chamber and the way that the associated radiation dose was measured, the test samples may have received significantly less radiation dose than what was called for in the test plan and captured in the analysis. In addition, the NRC inspection team identified that the remote seal assemblies were installed in the test chamber in such a way that the capillary tubing was looped into multiple circles such that the loops on the outside would shield some of the other loops from the radiation field emitted from the test source. Also, the thermoluminescence dosimeters (TLDs) used to measure the field were placed primarily

on the outer loops closest to the test source, so the actual measured radiation would not have been indicative of the dose received by the loops farthest away from the source. The only non-metallic component of the seal assembly is the fluid encased in the capillary tubing, so it is this fluid that is the primary concern with respect to ensuring an accurate assessment of the applied radiation dose. Preliminary calculations performed by RNII during the inspection, showed that the shielding effects could be significant and could have resulted in a large percentage of the coil loops receiving less than the dose designated in the test plan. The overall impact of this on the stated accuracy numbers was indeterminate at the end of the inspection as margin may exist in other portions of the analysis. RNII entered this issue into their corrective action program under CAPA No. 004435.

The NRC inspection team identified these issues as an example of Nonconformance 99900271/2019-201-01 for RNII's failure to adequately qualify the design of the 3159 nuclear qualified remote diaphragm seal through suitable EQ testing under the most adverse design conditions to verify the adequacy of the design.

c. Conclusion

The NRC inspection team issued Nonconformance 99900271/2019-201-01 in association with RNII's failure to verify the adequacy of design by the performance of a suitable testing program and that the test is performed under suitable environmental conditions of a 3159 nuclear qualified remote diaphragm seal. As described above, the test sample received less radiation dose than what was called for in the test plan and in the accuracy specifications for the seal system. RNII initiated CAPA No. 004435 to address this issue.

3. Commercial Grade Dedication

a. Inspection Scope

The NRC inspection team reviewed RNII's policies and implementing procedures that govern the implementation of its CGD program to verify compliance with the regulatory requirements of Criterion III, "Design Control" and Criterion VII, "Control of Purchased Material, Equipment, and Services," of Appendix B to 10 CFR Part 50.

The NRC inspection team reviewed a sample of CGD plans, reports, associated POs, and commercial-grade surveys of several commercial suppliers on RNII's Approved Supplier List (ASL) to assess the different elements of the CGD program. The NRC inspection team verified that the technical evaluations documented the criteria for the identification of item functions, credible failure mechanisms/modes, selection of critical characteristics and acceptance criteria, the identification of verification methods, and justification of the sampling methodologies as applicable. Furthermore, the NRC inspection team reviewed the dedication packages, associated drawings and inspection reports to verify that the critical characteristics and acceptance methods were correctly specified, that the drawings and material specifications containing the associated acceptance criteria for each critical characteristic were referenced, and that the inspection reports adequately documented the acceptance of the critical characteristics to verify effective implementation of RNII's CGD processes.

The NRC inspection team reviewed RNII's CGD of the silicone oil fill fluid used in the 3159 nuclear qualified remote diaphragm seal. Part of this review included RNII's survey of the test center which was contracted to perform the radiation testing of the 3159 nuclear qualified remote diaphragm Seal. The NRC inspection team identified that RNII had appropriately identified and verified a set of critical characteristics that were appropriate for the service being provided.

The NRC inspection team also discussed the CGD program with RNII's management and technical staff. The attachment to this inspection report lists the documents reviewed by the NRC inspection team.

b. Observations and Findings

The NRC inspection team identified one minor issue related to traceability of commercial-grade items. Specifically, RNII conducts material critical characteristic verification through a commercial-grade survey of the manufacture, focusing on their ability to control the material formulation; however, the O-rings are procured through a distributor, and material control at the distributor is not addressed. The CGD did not identify the verification of the distributor's process for correct handling of the supplied items as a critical characteristic.

The NRC inspection team considered this a minor issue because the O-rings remain in OEM packaging, and as part of RNII's corrective action identified in Nonconformance (NC) No. 008722, they are considering performing a survey of the distributor. RNII also performs adequate sample material testing, durometer testing, etc. The distributor is certified as having an ISO 9000 program specifically for distributing materials. RNII orders the O-rings from only this distributor. The OEM and passes on appropriate OEM certifications to the distributor.

c. Conclusion

With the exception of the minor issue identified above, the NRC inspection team concluded that RNII is implementing its CGD in accordance with the regulatory requirements of Criterion III and Criterion VII of Appendix B to 10 CFR Part 50. Based on the limited sample of documents reviewed, the NRC inspection team also determined that RNII is implementing its policies and procedures associated with the CGD program. No findings of significance were identified.

4. Oversight of Contracted Activities

a. Inspection Scope

The NRC inspection team reviewed RNII's policies and implementing procedures that govern the implementation of its supplier oversight program to verify compliance with the requirements of Criterion VII and Criterion XVIII, "Audits," of Appendix B to 10 CFR Part 50.

The NRC inspection team verified a sample of POs included the scope of work, right of access to facilities, and extension of contractual requirements to sub-suppliers. The NRC inspection team also confirmed that the POs adequately invoked the regulatory requirements of Appendix B to 10 CFR Part 50 and 10 CFR Part 21.

The NRC inspection team verified a sample of external audits, as well as, prepared and approved plans that identified the audit scope and applicable checklist criteria before the initiation of the audit activity. The NRC inspection team confirmed that audit reports contained objective evidence of the review of the relevant quality assurance criteria of Appendix B to 10 CFR Part 50. In addition, the NRC inspection team confirmed that the qualified and approved suppliers performing safety related work for RNII were adequately listed on the ASL.

The NRC inspection team also discussed the oversight of contracted activities program with RNII's management and technical staff. The attachment to this inspection report lists the documents reviewed by the NRC inspection team.

b. Observations and Findings

No findings of significance were identified.

c. Conclusion

The NRC inspection team concluded that RNII is implementing its oversight of contracted activities program in accordance with the regulatory requirements of Criterion VII and Criterion XVIII of Appendix B to 10 CFR Part 50. Based on the limited sample of documents reviewed, the NRC inspection team also determined that RNII is implementing its policies and procedures associated with the oversight of contracted activities program. No findings of significance were identified.

5. Manufacturing Control / Control of Special Processes

a. Inspection Scope

The NRC inspection team reviewed RNII's policies and implementing procedures that govern the implementation of its manufacturing control program to verify compliance with the regulatory requirements of Criterion IX, "Control of Special Processes," of Appendix B to 10 CFR Part 50.

The NRC inspection team observed soldering and in-process inspection of circuit boards, maintenance records, and training and qualification records. The NRC inspection team also observed the pressure transmitter lower module time response testing as a manufacturing/assembly step and the silicone fill fluid acceptance criteria testing.

The NRC inspection team also discussed the control of special processes program with RNII's management and technical staff. The attachment to this inspection report lists the documents reviewed by the NRC inspection team.

b. Observation and Findings

No findings of significance were identified.

c. Conclusion

The NRC inspection team concluded that RNII is implementing its manufacturing control program in accordance with the regulatory requirements of Criterion IX of Appendix B to 10 CFR Part 50. Based on the limited sample of documents reviewed, the NRC inspection team also determined that RNII is implementing its policies and procedures associated with the manufacturing control program. No findings of significance were identified.

6. Nonconforming Materials, Parts, or Components and Corrective Action

a. Inspection Scope

The NRC inspection team reviewed RNII's policies and implementing procedures that govern the implementation of its nonconforming materials, parts, or components and corrective action program to verify compliance with the requirements of Criterion XV, "Nonconforming Materials, Parts, or Components," and Criterion XVI, "Corrective Action," of Appendix B to 10 CFR Part 50.

The NRC inspection team reviewed trending of discrepancy reports (DRs) generated during steps of the manufacturing process. Materials and commercial piece parts for CGD were inspected in a receiving area and discrepancies there were subject to Material Review reports generated, similar to DRs. In addition, the NRC inspection team verified there was a segregated nuclear procurement receipt and inspection area for nonconforming materials awaiting DR disposition.

The NRC inspection team reviewed RNII identified DRs that potentially affected quality beyond an individual instance of in-process error, or other issues with the potential for wider product-level nonconformances, were documented in NCs and CAPAs. The NRC inspection team's review of a sample of CAPAs provided sufficient documentation of actions to prevent recurrence of these potentially more significant quality issues, as well as documentation of preventive actions initiated due to RNII quality audits and self-improvement initiatives.

The NRC inspection team also discussed the nonconforming materials, parts, or components and corrective action programs with RNII's management and technical staff. The attachment to this inspection report lists the documents reviewed by the NRC inspection team.

b. Observations and Findings

b.1 Corrective Action Associated with Nonconformance No. 99900271/2012-201-03

Following a January 2012 NRC inspection of RNII, Nonconformance (NON) 99900271/2012-201-03 was issued for RNII's CGD program failing to provide reasonable assurance that specified quality standards in design documents were effectively controlled in three instances. The NRC conducted an inspection at RNII in November 2013. NON 99900271/2012-201-03 remained open because corrective actions for the CGD process were incomplete. During the current inspection, the NRC inspection team reviewed the corrective actions and CGD activities as implemented by RNII and observed no significant findings. The attachment to this inspection report lists

the documents reviewed by the NRC inspection team. Based on its review, the NRC inspection team closed Nonconformance 99900271/2012-201-03.

b.2 Corrective Action Associated with Nonconformance No. 99900271/2013-201-01

Following the November 2013 NRC inspection of RNII, NON 99900271/2013-201-01 was issued for RNII's failure to prescribe appropriate quantitative or qualitative acceptance criteria. Specifically, RNII failed to include requirements or acceptance criteria sufficient to verify critical characteristics necessary to assure that dedicated items will perform their intended safety functions in technical evaluations (TEs): (1) TE-Common-01-01, "Technical Evaluation of 3150 and 1150 Series Mounting Fasteners"; and (2) TE-315x-03-01, "Technical Evaluation of 3150 Series Pressure Retaining Flanges."

In its response dated February 28, 2014 (Agencywide Documents Access and Management System Accession No. ML14070A460), RNII stated that RNII issued an internal CAPA001525, which revised (1) RNII OP 0720, "Control of Purchased Safety-Related Components", (2) revised TE Template DES-0720-F1, (3) revised TE-Common-01-01 and TE-315x-03-01 and planned to review and update all their TEs.

The NRC inspection team reviewed the documentation that provided the objective evidence for the completion of the corrective actions. The NRC inspection team confirmed that the current revisions to OP 0720, the specific TEs TE-Common-01-01 and TE-315x-03-01, and a sampling of multiple TEs all provide adequate acceptance criteria for critical characteristics to perform the item's specified safety function. The attachment to this inspection report lists the documents reviewed by the NRC inspection team. Based on its review, the NRC inspection team has closed NON 99900271/2013-201-01.

No findings of significance were identified.

c. Conclusion

The NRC inspection team concluded that RNII is implementing its nonconforming materials, parts, or components and corrective action programs in accordance with the regulatory requirements of Criterion XV and Criterion XVI of Appendix B to 10 CFR Part 50. Based on the limited sample of documents reviewed, the NRC inspection team also determined that RNII is implementing its policies and procedures associated with the control of nonconforming materials, parts, or components and corrective action. No findings of significance were identified.

8. Entrance and Exit Meetings

On December 9, 2019, the NRC inspection team discussed the scope of the inspection with Mr. Jeff Chivers, Director of Engineering and Quality, and other members of RNII's management and technical staff. On December 12, 2019, the NRC inspection team presented the inspection results and observations during an exit meeting with Mr. Chivers, and other members of RNII's management and technical staff. The attachment to this report lists the attendees of the entrance and exit meetings, as well as those individuals whom the NRC inspection team interviewed.

ATTACHMENT

1. ENTRANCE/EXIT MEETING ATTENDEES

Name	Title	Affiliation	Entrance	Exit	Interviewed
Gerard Hanson	Vice President & General Manager	RNII	X	X	
Jeff Chivers	Director of Engineering & Quality	RNII	X	X	
Andrew Grimley	Senior Supplier Quality Engineer	RNII	X	X	X
Brian Kocher	Senior Principal Design Engineer	RNII	X	X	X
Craig Hanson	Quality Engineer	RNII	X	X	
Carter Brown	Quality Engineer	RNII	X	X	
Daniel Flatten	Project Quality Engineer	RNII	X	X	X
Nicole Ancel	Quality Specialist	RNII	X	X	
Russell McDaniel	Manufacturing Engineer	RNII	X		X
Felicia Marquez	Manufacturing Engineer	RNII			X
Blake Reoh	Receipt Inspector	RNII			X
Chuck Hunt	Principal Design Engineer	RNII			X
Tracy Kaluzniak	Materials Manager	RNII	X	X	
Ellen Aas	Technical Support Engineer	RNII	X		
Erin Irmiter	Director of Operations	RNII	X	X	
Paul Schmeling	Director of Sales & Business Development	RNII	X	X	
Christopher St. George	Global Customer Care Manager	RNII	X	X	

Name	Title	Affiliation	Entrance	Exit	Interviewed
Nathan Schukei	Business Development Manager	RNII	X	X	
Kerri Kavanagh	Branch Chief	NRC		X*	
Jeffrey Jacobson	Inspection Team Leader	NRC	X	X	
Nicholas Savvoir	Inspector	NRC	X	X	
Phil Natividad	Inspector	NRC	X	X	
Dong Park	Inspector	NRC	X	X	

* Present via telephone

2. INSPECTION PROCEDURES USED

Inspection Procedure (IP) 36100, "Inspection of 10 CFR Part 21 and Programs for Reporting Defects and Noncompliance," dated May 16, 2019.

IP 43002, "Routine Inspections of Nuclear Vendors," dated January 27, 2017.

IP 43004, "Inspection of Commercial-Grade Dedication Programs," dated January 27, 2017.

3. LIST OF ITEMS OPENED, CLOSED, AND DISCUSSED

Item Number	Status	Type	Description
99900271/2012-201-03	CLOSED	NON	Criterion III
99900271/2013-201-01	CLOSED	NON	Criterion V
99900271/2019-201-01	OPENED	NON	Criterion III Criterion XI

4. DOCUMENTS REVIEWED

Policies and Procedures

- OP 0210, "Quality Management System," Revision 3.0, dated December 4, 2017
- OP 0720, "Control of Purchased Safety-Related Components," Revision 3.0, dated February 13, 2018
- OP 0910, "Special Processes," Revision 2.0, dated January 26, 2018
- OPS-0910-1, "Special Process Plans," Revision 5.0, dated July 22, 2019
- OP 1510, "Nonconforming Material Control," Revision 4.0, dated November 22, 2017
- OP 1610, "Corrective Action," Revision 2.0, dated November 9, 2017
- OP 1620, "Implementation of 10CFR Part 21," Revision 3.0, dated July 16, 2018

- Document D2015009, "IEEE Qualification Report of Rosemount 3155N Pressure Transmitters for Post-Accident Monitoring Applications in Submergence Environments," Revision A, dated October 16, 2015.
- Document D2013009, "IEEE Qualification Report: Rosemount 3159 Remote Diaphragm Seal with 3150 Series Nuclear Pressure Transmitters," Revision B, dated January 28, 2015.
- Product Data Sheet 00813-0100-4859, "Rosemount 3159 Nuclear Qualified Remote Diaphragm Seal for Use with 3152N, 3153N, 3154N and 3155N," Revision AD, dated May 2019
- Technical Change Authorization TCA-RNI1052242, "Optimization of Bias Current in 3150 Oscillator Drive," Revision B, dated November 8, 2019
- Report: "Rosemount 3150 Series Pressure Transmitters, Activation Energy (Ea) Review," dated October 31, 2008
- Rosemount 3154N Nuclear Qualified Pressure Transmitter Product Data Sheet 00813-0100-48-54 Rev AF, August 2019
- Assessment of Circuit Card Assemblies used in 3152N, 3153N and 3154N Rosemount Nuclear Instruments, Inc. Document Number: D2013019 Revision A; June 27, 2013
- Test Report T56140-01- Electromagnetic Interference (EMI) Test Report on a Pressure Transmitter Model No. 3152 Revision A September 21, 2009
- Test Report T56140-02- Electromagnetic Interference (EMI) Test Report on a Pressure Transmitter Model No. 3153 Revision A September 21, 2009
- Test Report T56140-03- Electromagnetic Interference (EMI) Test Report on a Pressure Transmitter Model No. 3154 Revision A September 21, 2009
- Intertek Test Report No.101140653MIN-001 April 30, 2013
- Rosemount Test Plan for Supplement EMC Testing per US NRC 1.180 Revision 1 for Models 3152N and 3154N; Rosemount Report No. D2013013 Revision A; April 4, 2013

Design and Commercial-Grade Dedication Records

- Diffusion Pump Oil: Tetramethyl-Tetraphenyl Trisiloxane DWG No. N11981
- O-Rings, EPDM DWG No. N70001
- Collection Plan: N70001_R109_RNI, Last Updated Date: 6/13/2019
- Collection Plan: N11981_R103_RNI, Diffusion Pump Oil R103, Last Updated Date: 4/22/2019
- Technical Evaluation of 3159 Series Remote Seal, TE-3159-09-01, Revision: AE 05/22/2019
- TE-3159-09-01, "Technical Evaluation of 3159 Series Remote Seal", Revision AE, dated May 2, 2019
- TE-Common-01-01, "Technical Evaluation of 1150 and 3150 Series Mounting Fasteners", Revision AD, dated February 27, 2014
- TE-315X-03-01, "Technical Evaluation of 3150 Series Pressure Retaining Flanges", Revision AC, dated January 3, 2019
- TE-315X-02-06, "Capacitor, Tantalum, SMT", Revision AB, dated December 29, 2017
- TE-Service-13-02, "Technical Evaluation of Software Development", Revision AA, dated June 29, 2018
- TE-3155-04-04, "Technical Evaluation of 3155 Series Glassed Module Header", Revision AA, dated February 11, 2014
- TE-315X-06-01, "Technical Evaluation of Silicone Oil Fill Fluid", Revision AC, dated December 29, 2017

- Test Report for DBE Testing of RNII Pressure Transmitters Revision 3; September 30, 2013
- IEEE Qualification Test Report: Seismic Testing of Rosemount 3154 Pressure Transmitters No. K-115039-RA-0001 Revision 3; July 20, 2015
- IEEE Qualification Report of Rosemount 3154N Pressure Transmitters Document Nop. D2013003 Revision B; March 20, 2015
- Emails: Brian {Rosemount} to Dustin {Rosemount} September 27, 2011
- Certification of Calibration - Signal Generator (A2LA Cert. 1818.01)

Manufacturing Procedures

- Manufacturing Procedure 03154-3305, "Verify module time response meets specifications", Revision AK, dated July 20, 2019

Drawings

- Special Rework Procedure, Drawing No. 01153-3000, "Special Rework Specifications", Revision AK, dated December 5, 2019
- 03154-3130, Rev. AE Temperature Coefficient Test
- 03154-3302, Rev. BG Module Performance Test (MPT)
- 03154-3303, Rev. AR Temperature Compensation Procedure
- 90000833 – Rev. AT Oil Fill

Purchase Orders, Audit Reports, and Commercial-Grade Surveys

- PO 4252005862 Rev. No 0 Order date 5/13/2019
- PO Number: 4000012435 SO# 5648003
- Material Traceability Report, Sales Order Number 5648003, Printed on 9/20/2019
- RNII Survey N2012-S-14, RNII Commercial Grade Survey, June 29, 2012
- RNII Survey N2016-S-07, RNII Supplier Audit/Survey Report, September 23, 2016
- RNII Survey N2019-S-12, RNII Supplier Audit/Survey Report, October 11, 2019
- RNII Survey N2017-S-07, RNII Supplier Survey Report, August 7, 2017
- Purchase Order 4000012435 September 5, 2019 – component 3154NG
- Purchase Order 2001308 August 10, 2019
- Rosemount PO No. 4252001025 Revision 0, July 20, 2012 – seismic testing
- Rosemount PO No. 4252003275 Revision 0, July 10, 2015 – seismic testing

Nonconformance Reports

- Nonconformance #NC008722, NRC 2019: O-Ring Material Not Verified Through Distributor
- NC005033
- NC007246 (see CAPA003936)
- NC007788 (see CAPA004130)
- NC005452
- NC005000
- NC006634
- NC006176

Rework Travelers/Failure Analysis (FA) return materials authorization (RMA):

- FA1800098244 requested August 31, 2018
- FA1900103996 requested September 20, 2019
- FA1600089393 requested February 23, 2018
- Failure Analysis Report dated July 19, 2018 for FA1800096947 (model 3152)

10 CFR Part 21 Evaluations of Potential Deviations

- 2017-01 (CAPA003149)
- 2018-01 Reported to NRC March 15, 2018
- 2019-01 (CAPA003936)
- 2020-01 Interim Reported to NRC December 2019
- 2020-02 (CAPA004399)

Training Records

- Solder – Video Classroom Training on 8/14/2019