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August 24, 2012

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

Subject: Rosemount Nuclear Instruments, Inc. Reply to NRC Request for Clarification Docket 99900271

References: 1) NRC Inspection Report 99900271/2012-201
2) RNII Reply to NRC Inspection Report No. 99900271/2012-201, dated May 11, 2012
3) NRC Request for Clarification dated July 1, 2012

Rosemount Nuclear Instruments, Inc. ("**RNII**") hereby responds to the aforementioned letter from the Nuclear Regulatory Commission ("NRC") dated July 1, 2012, requesting clarification of information provided by RNII in its Reply to NRC Inspection Report No. 99900271/2012-201, dated May 11, 2012.

The structure of the response is separated into three sections to address the Request for Clarification pertaining to:

- Section 1 – Quality Records
- Section 2 – Software
- Section 3 – Commercial Grade Dedication

The appendices include more detailed supplemental information.

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

Sincerely,

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

Appendix A: 601TT4000 Software Documentation (Emerson Confidential)
Appendix B: 611AT Software Additional Software Documentation Example (Emerson Confidential)
Appendix C: CAPA-NC0000677
Appendix D: Design Study DS-RNII-2012-018 Resistor and Capacitor Tolerance, Temperature Coefficient, and Reliability Analysis (Emerson Confidential)
Appendix E: Design Study DS-RNII-2012-040 Assessment of Commercial Grade Dedication of 1150 Series Sensor Fill Fluid (Emerson Confidential)
Appendix F: Draft Technical Evaluation for Commercial Grade Dedication Template
Appendix G: CAPA-NC000683

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

Section 1
Reply to NRC Request for Clarification Related to Quality Records

Section 1 sets forth the reply of Rosemount Nuclear Instruments, Inc. ("**RNII**") to the following excerpt from the NRC's Request for Clarification dated July 1, 2012, relative to Inspection report 99900271/2012-201.

> *"Please clarify information provided in your response to these three response sections to NON 99900271/2012-201-03 as follows:*
>
> 1) *'Failure to establish measures that would preclude unauthorized access to quality records associated with the design control process' – please provide the evaluation of extent of condition (as requested in the cover letter of IR 99900271/2012-201.) Your response should include an analysis of potential uncontrolled access to other quality records (examples include, but are not limited to: design records, testing records, procurement records, training records). Your response should provide sufficient detail to allow inspectors to conclude that modifications and deletions to these records have been and will be controlled. It appears from your explanation that only the three inspector identified examples were evaluated."*

RNII's Response

For quality records, an evaluation of extent of condition and an analysis of effects on components that have shipped with respect to NON 99900271/2012-201-03 and RAI dated July 20, 2012, were completed. The quality records were reviewed for uncontrolled access, modifications, and deletions. Table 1 summarizes the type of documents reviewed, the control methods, and the results of the evaluation.

The review consisted of an evaluation based upon the records defined in RNII Operating Procedure 1710 Record Requirements. Each record type was reviewed and a matrix was created to identify potential gaps in control. The review team included engineering and quality representatives.

RNII's evaluation concluded that adequate controls are in place to preclude unauthorized access, modification and deletions. All electronic files are backed-up on a daily basis and can be retrieved if needed, but with controlled access. In the course of the evaluation RNII also identified areas where controls could be improved to provide further assurance of quality record integrity.

Table 1: Records Review Summary

Record Description	Control Method for access (while in process)	Control Method to prevent modification	Control Method to prevent deletion	Notes/Result
Production Documentation	Travel cards are typically handled by instrument builders, inspectors, and engineers. Throughout production, the manufacturing and inspection procedures define who is authorized to signoff at each step. At Final Inspection, inspectors verify that the required signoffs have been completed. This ensures that only authorized personnel have handled the travel cards.	Once a product ships, the production documentation is scanned and stored in a read-only electronic documentation storage system (hereinafter called Filenet). The original hard copies are stored at a secure offsite location. Access to offsite files requires a manager level signoff. Once files are uploaded into Filenet, files cannot be modified since it is a read-only system.	Only assigned Filenet system administrators can delete files once they are stored in Filenet. For the offsite files, they are only deleted with quality manager approval.	Controlled
Training Records	General training records are stored in the Human Resources database (called PeopleSoft). Employees and supervisors have read-only access to these records.	The training records can only be modified by authorized human resource administrators.	The training records can only be deleted by authorized human resource administrators.	Controlled
Procurement Records	Purchase orders are issued to suppliers using an Oracle business system. Only authorized Materials personnel can issue purchase orders.	Once a purchase order is entered into Oracle, only authorized Materials personnel can modify the purchase orders.	Once a purchase order is entered into Oracle, only authorized Materials personnel can cancel or close the purchase order. However, the purchase order cannot be deleted.	Controlled

Engineering Test Files & Product Qualification Files	The responsible engineer controls access to the specific test files. Working files are not released until a cross functional review is completed.	Once the files are reviewed, approved and released, files may be stored on a controlled network drive, at an offsite location, in Filenet, or in the RNII office area. Only authorized RNII personnel have access to the network folders. Permission for access to the RNII network folders requires approval by the RNII vice president / general manager. Only authorized personnel can modify the files. Access to offsite files requires a manager level signoff. Once files are uploaded into Filenet, files cannot be modified since it is a read-only system.	Only authorized RNII personnel have access to the network folders. Permission for access to the RNII network folders requires approval by the RNII vice president / general manager. Only authorized personnel can delete the files. For the offsite files, they are only deleted with quality manager approval. Only assigned Filenet administrators can delete files once they are stored in Filenet.	Controlled As a continuous improvement action, hard copies will be moved to the offsite location or scanned and uploaded into Filenet.
Engineering Change Orders (ECOs)	The ECO originator creates and routes the ECO in a content server system (called Stellent). Only the originator can modify the ECO before it is implemented. System permissions are used to control viewing, modifying, loading and any other access method for all Stellent documents (per form #F64608).	Once an ECO is routed, the ECO approvers can either Approve or Reject the ECO. The approvers cannot modify the ECO.	The ECO history is read-only. System users cannot delete files.	Controlled

Production Software Documentation	The responsible engineer controls access to the specific software documentation. Working files are not released until a cross functional review is completed.	Once the files are reviewed and approved, files may be stored on a controlled network drive or in the RNII office area. Only authorized RNII personnel have access to the network folders. Permission for access to the RNII network folders requires approval by the RNII vice president / general manager. Only authorized personnel can modify the files. Further electronic access is limited to RNII's Software Engineering Group.	Only authorized RNII personnel have access to the network folders. Permission for access to the RNII network folders requires approval by the RNII vice president / general manager. Only authorized personnel can delete the files. Further electronic access is limited to RNII's Software Engineering Group.	Controlled As a continuous improvement action, hard copies will be moved to the offsite location or scanned and uploaded into Filenet.
Receiving Inspection Records	The records are in an Oracle business system and access is limited to the receipt inspectors.	Once receipt inspection information is entered into Oracle, only assigned Oracle administrators can modify the records.	Once receipt inspection information is entered into Oracle, only assigned Oracle administrators can delete the records.	Controlled
Product Certificates	The responsible engineer and/or documentation coordinator controls access to the certificates.	Once the certificates are issued to be included in a customer shipment, an electronic copy is stored in Filenet. Once files are uploaded into Filenet, files cannot be modified since it is a read-only system.	Only assigned Filenet administrators can delete files once they are stored in Filenet.	Controlled

Section 2
Reply to NRC Request for Clarification Related to Software

Section 2 sets forth the reply of Rosemount Nuclear Instruments, Inc. ("**RNII**") to the following excerpt from the NRC's Request for Clarification dated July 1, 2012, relative to Inspection report 99900271/2012-201.

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

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

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

RNII's Response

An evaluation has been completed of extent of condition and analysis of effects on components that have been shipped with respect to NON 99900271/2012-201-03 and RAI dated July 20, 2012. The evaluation included an assessment of the adequacy of software verification shown in Table 2. This list includes what RNII has categorized as "Level 1" and "Level 2" software which performs in-process or final acceptance testing. As a result of this evaluation it has been determined that all production software has been adequately tested and approved and therefore the quality of all shipped components is reasonably assured.

To implement continuous improvement, RNII Operating Procedure OP 1120 Production Software Control was updated on May 8, 2012, to require a separate approved software requirements document and clear links between the approved software requirements document and the verification test plan.

Prior to May 2012, the software requirements, throughout the different phases of the software development cycle, were not documented in a consistent format. The requirements may have been included in a validation test plan as an attribute or feature, a specification control drawing that defined the specific product performance requirements and/or a description of the revision changes to the software. The software was developed based upon the requirements, but a separately approved requirements document was not always created.

For the 601TT4000 software, the Software Requirements Document and Manufacturing Station Validation Plan and Approval are provided in Appendix A. The validation plan includes a subset of the tests that were conducted when an additional oven chamber was added. For reference, in the validation plan, the corresponding requirement ID has been noted in red text.

An additional example of the software verification documentation is shown in Appendix B, which is the Validation Plan and Approval for a revision that was made to the 611AT Software.

Table 2: Software Review Summary

RNII Internal Software ID	**Software Description**	**Documented Requirements (Input)**	**Test Plan (Development)**	**Documented Results (Implementation)**
601AT	Amplifier CCA Test Station	01153-0188 (Model 1150 Series CCA Functional Test Specifications)	601AT1030.pdf (Validation Plan and Approval)	601AT1030.pdf (Validation Plan and Approval)
601CS	Calibration Software (PCPII)	Maintained by Test Fixture Software System	601CS3120.pdf (Software Verification and Validation)	601CS3120.pdf (Software Verification and Validation)
601FL	Final Line (ZDSII)	Maintained by Test Fixture Software System	601FL1170.pdf (Software Verification and Validation)	601FL1170.pdf (Software Verification and Validation)
601LN	Linearity	601LN200 Requirements.doc	601LN200.pdf (Validation Plan and Approval)	601LN200.pdf (Validation Plan and Approval)
601PC	Part Number Converter	None – Requirements document will be created with next release of software	601PC2030.pdf (Validation Plan and Approval)	601PC2030.pdf (Validation Plan and Approval)
601ST	Post-Processing Software	01152-1086 (Spec Drawing T1858)	601ST110.pdf	601ST110.pdf

601TC	Temperature Compensation	None – Requirements document will be created with next release of software	601TC111,pdf (Validation Plan and Approval)	601TC111,pdf (Validation Plan and Approval)
601TT	Temperature Coefficient Test	601TT4000.pdf (Software Requirements Document)	601TT4030.pdf (Software Validation Plan and Approval)	601TT4030.pdf (Software Validation Plan and Approval)
601TU	Trip Unit (710)	601TU200 Trip Unit Test Software Documentation.pdf	601TU2050.pdf (Validation Plan and Approval)	601TU2050.pdf (Validation Plan and Approval)
602DR	Data Retriever	None	None	None
602HP	Hydrostatic /Pneumatic Test	602HP Hydrostatic Software Requirements Document Rev AC.docx	602HP3000.pdf (Validation Plan and Approval)	602HP3000.pdf (Validation Plan and Approval)
611AT	Amplifier CCA Test Station	03154-0099 (Model 3150 Series CCA Functional Test Specifications)	611AT100.pdf (Validation Plan and Approval)	611AT100.pdf (Validation Plan and Approval)
611CF	MSCF (Maximum Span Correction Factor)	None – Requirements document will be created with next release of software	611CF1000.pdf (Software Validation Plan and Approval)	611CF1000.pdf (Software Validation Plan and Approval)
611CV	3150 Module CV	Software Definition.pdf System Requirments.pdf	611CV1100.pdf (Validation Plan and Approval)	611CV1100.pdf (Validation Plan and Approval)
611MP	Module Performance Test (3150 MPT)	03154-0300 (Module Drawing)	611MP1080.pdf (Software Validation)	611MP1080.pdf (Software Validation)
611RS	Resistor Select	03154-0300 (Module Drawing)	611RS2000.pdf (Software Validation)	611RS2000.pdf (Software Validation)
612UH	3150 Ultrasonic Oil Height	612UH114 Requirements Document.pdf	612UH1400.pdf (Validation Plan and Approval)	612UH1400.pdf (Validation Plan and Approval)
GMS App	GMS App (Global Manufacturing System Application)	Maintained by Test Fixture Software System	QA-0740-17 ICPA	QA-0740-17 ICPA
PC Scope	1150 Oil Height Set	None	Ultrasonic Oil Height Test Data Files	Ultrasonic Oil Height Test Data Files

During the software review, the following documentation gaps were identified, however there is no impact on shipped product based upon the nature of gaps described below:

- 602DR (Data Retriever) – The Data Retriever software is used to retrieve test results from the Temperature Coefficient Test Stations. The Data Retriever is used as an engineering tool, and is also used by Quality Inspectors to verify that transmitters passed the Temperature Coefficient Test. This software was found not to have documentation showing that it completed any formal validation testing or went through a formal approval process. It has been determined that this gap in our process does not have the potential to have had any negative impact on shipped product, as it is strictly a "viewer" and does not have the ability to edit or modify actual test data results. The Temperature Coefficient Test data has been periodically compared to the data that the Data Retriever software displays and confirmed to be correct.
    - Corrective Action: The documentation for the Data Retriever Software will be created by December 2012.
- PC Scope (1150 Oil Height Set) – This is a purchased piece of "off the shelf" software from an outside supplier. This software was found not to have documentation showing that it completed any formal validation testing or went through a formal approval process. It has been determined that this gap in our process does not have the potential to have had any negative impact on shipped product. There is extensive documentation in the Ultrasonic Oil Height Test Data File that contains test data including capability studies and correlation studies that validate the Ultrasonic Oil Height Measurement System (which includes the PC Scope software) meets its intended function. Downstream manufacturing tests of the product where performance is verified also have not indicated a problem with the software.
    - Corrective Action: OP1120 will be updated to clarify the requirement that purchased software must meet the same requirements for validation as internally developed software.
- Part Number Converter (PC601), Temperature Compensation (601TC), MSCF (611CF) – These 3 applications do not have their software requirements documented in a separate document. However, in all three cases the requirements are implicitly documented within the Validation Test Plan and Approval documents through the revision change descriptions, and as attributes or features that were verified during testing. It has been determined that this software has been adequately tested and approved.
    - Corrective Action: Requirements documents for these applications will be created prior to the release of the next revision of the software.

Continuous Improvement Plan: As we complete future revisions to production software there will be a more phased approach to software development. There will be at least three phases to the development process. The deliverable from each phase will include a reviewed and approved document.

1. Input Phase; define the requirements (Deliverable = approved Requirements Document)
2. Development Phase, design and develop the software (Deliverable = approved Test Plan)
3. Implementation Phase, release the software for use (Deliverable = approved Test Results)

As requested in the RAI letter, CAPA-NC0000677 is included in Appendix C.

Section 3
Reply to NRC Request for Clarification Related to Commercial Grade Dedication

Section 3 sets forth the reply of Rosemount Nuclear Instruments, Inc. ("**RNII**") to the following excerpt from the NRC's Request for Clarification dated July 1, 2012, relative to Inspection report 99900271/2012-201.

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

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

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

   Further, regarding verification of the fill oil used in transmitters. During the inspection the inspectors understood that there were multiple oils used in your transmitters and the selection of the oil was based upon the service application. As such, the inspectors remain concerned that your commercial grade dedication process for the oil adequately verifies the fill oil has the identical characteristics to the oil environmentally qualified for 'harsh' environment. We understand that you test your transmitters over their normal range of operation as part of the manufacturing process. However, the conditions of the 'harsh environment' are not simulated during your current testing. Given that the oil is a commercial product, and as such may be subject to changes without your awareness, please clarify how your dedication process provides reasonable assurance that the fill oil used during manufacturing will have equivalent performance with the fill oil used during baseline qualification. This would include meeting any baseline requirements for radiation, aging, seismic, and extended temperature and

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

In this section, the response is structured as follows:

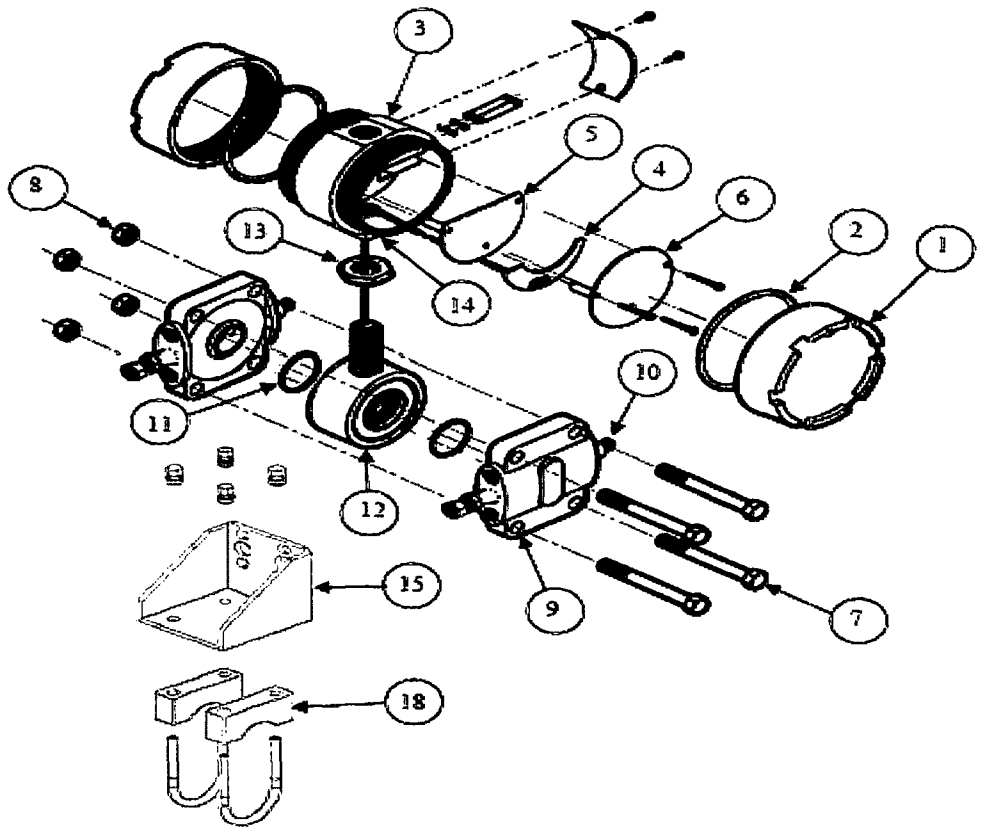
A. Commercial grade extent of condition evaluation, additional review for specific items
    a. Transistors used in the amplifier boards of Models 1152, 1153B/D, 1154/H, and 3152N
    b. Model 710 Trip Unit bipolar semiconductor devices
    c. Models 1152, 1153B/D, 1154/H, and 3152N carbon steel mounting bolts
    d. Model 1159 remote seal lower housing bolts
    e. Model 3051N mounting hardware
B. Additional passive component information
C. Additional oil fill fluid information
D. Continuous Improvement Plan Summary

RNII's Response

A. <u>Commercial Grade Extent of Condition Evaluation:</u>

An evaluation of extent of condition and analysis of effects on all dedicated commercial grade components that have shipped was completed. All nuclear qualified transmitter base model numbers including 1152, 1153B/D, 1154, 1154H, 3051N, and 3152N were evaluated along with 710 Trip Units and 1159 Remote Seals. This includes gage, absolute, and differential variants of the transmitter base models.

Based upon a review of the bill of materials for all of the above referenced products, an engineering assessment was completed to determine whether or not acceptable controls are in place to ensure that an item will perform its intended safety function under normal and accident conditions. This assessment included the effects of radiation, seismic and vibration, and high temperature steam as referenced in the baseline qualification documentation for each base model. Figure 1: 1154 Exploded View, is an example of the typical items included in a transmitter bill of materials.



Exploded View of the Rosemount 1154.

Item	Description	Item	Description
1	Electronics Cover	10	Valve Stem
2	O-ring for Electronics Cover	11	Process Seal
3	Electronics Housing Assembly	12	Sensor Module
4	Header Assembly Board	13	Module Lock Nut
5	Calibration Board	14	Housing Set Screw
6	Amplifier Board	15	Panel Mounting Bracket
7	Flange Bolt	16	Mounting Bolt (not shown)
8	Flange Nut	17	Mounting Washer (not shown)
9	Process Flange	18	Pipe Mount Hardware

Figure 1: 1154 Exploded View

Dedication activities for the majority of items reviewed were deemed sufficient to provide reasonable assurance that the item will perform its intended safety function under normal and accident conditions. The following subset of five items warranted further review:

- Transistors used in the amplifier boards of Models 1152, 1153B/D, 1154/H, and 3152N
- Model 710 Trip Unit bipolar semiconductor devices
- Models 1152, 1153B/D, 1154/H, and 3152N carbon steel mounting bolts
- Model 1159 remote seal lower housing bolts
- Model 3051N mounting hardware

a. Transistors used in the amplifier boards of Models 1152, 1153B/D, 1154/H, and 3152N:
During the engineering assessment, transistor radiation performance was identified as a critical characteristic which does not have a defined acceptance method in RNII's dedication process. RNII's commercial grade dedication program verifies the part number, manufacturer, and circuit operation with the transistor during normal conditions and at elevated temperatures. It does not include routine radiation testing to monitor potential gain degradation. However, this concern is significantly mitigated by multiple successful qualification tests utilizing the same transistors.

During these qualification tests, which included radiation exposure, there were no indications that any transistors caused any failures or anomalies. A summary of the radiation qualification testing is shown in Table 3. In addition, there are no indications that transistors are causing failures during the functional tests under normal operating conditions or at elevated temperatures. A review of the customer field returns data also supports this conclusion.

Extent of Condition Conclusion:
Based on 1) historical consistency in the use of specific component part numbers and manufacturers, 2) no anomalies during historical product qualification test programs including irradiation up to 122 Mrads, 3) lack of any indication that the transistors are causing failures during functional testing at both normal and elevated temperatures, and 4) lack of indication of customer field returns caused by the transistors, RNII concludes that there is not a significant safety risk related to the radiation performance of devices currently installed in the field.

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Description	Qualification Report	Qualification Report Date	Qualification Test Samples	Accident Test Conditions					Summary of Test Results
IEEE Qualification Report: Sensor and Linearity Diode Replacement for Model 1153 Series B, 1153 Series D, 1154 and 1154 Series H Pressure Transmitters	D2011019	25-Apr-12	Four (4) 1154DH5RA Three (3) 1154DP5RA Four (4) 1153DB5RA	Dose Rate	1153 Series B		1154 and 1154 Series H		Pass
				Time	Time	TID	Time	TID	
				2 Mrad/hr	2 hours	4 Mrad	2 hours	4 Mrad	
				1.5 Mrad/hr	4 hours	6 Mrad	4 hours	6 Mrad	
				1 Mrad/hr	14.4 hours	14.4 Mrad	100.5 hours	100.5 Mrad	
				Total	20.4 hours	24.4 Mrad	106.5 hours	110.5 Mrad	
Qualification Report for Output Code R Op Amp Replacement	D9900005	3-Apr-01	Three (3) 1154DP5RA Eleven (11) 1154DH5RA Three (3) 1153DB5RA One (1) 1154DP5RAN0037 One (1) 1154DH5RAN0037 One (1) 1153DB5RAN0037	Dose Rate	1153 Series B		1154 and 1154 Series H		Pass
				Time	Time	TID	Time	TID	
				2 Mrad/hr	2.3 hours	5.02 Mrad	2.3 hours	5.14 Mrad	
				1.5 Mrad/hr	4 hours	6.50 Mrad	4 hours	6.33 Mrad	
				1 Mrad/hr	12.7 hours	14.19 Mrad	95.4 hours	110.97 Mrad	
				Total	18.98 hours	25.71 Mrad	101.7 hours	122.44 Mrad	
Qualification Report for Rosemount Model 1154 Series H Pressure Transmitter	D8700096	26-Oct-88	Three (3) 1154DH4RA Three (3) 1154DH5RA Three (3) 1154DH6RA Five (5) 1154SH9RA	Dose Rate			Time	TID	Pass
				2.07 Mrad/hr			2 hours	4.14 Mrad	
				1.5 Mrad/hr			4 hours	6 Mrad	
				1.2 Mrad/hr			45.5 hours	54.6 Mrad	
				1.05 Mrad/hr (post LOCA)			54.3 hours	59.09 Mrad	
				Total			107.8 hours	116.99 Mrad	
KTA Qualification Report of Rosemount 3152K Transmitters for EPR™	D2009011	3-Mar-10	One (1) 3152KD1A3F0A1C4W1 One (1) 3152KD2B2F4B2C4T1W1 One (1) 3152KG3A2F0E2T1W1 One (1) 3152KD3A2F0A1W1 One (1) 3152KD4A3F4A1C4T1W1 One (1) 3152KA5A2F3B3C4W1 One (1) 3152KG6B2F3E2C4W1 One (1) 3152KD2B2F4B2C4T1W1 One (1) 3152KD4A3F4B1C4T1W1 One (1) 3152KG6A2F3E2C4W1	Dose Rate			Time	TID	Pass
				0.0215-0.296 Mrad/hr			262.8 hours	5.65-7.77 Mrad	
IEEE Qualification Report of Rosemount 3152N Pressure Transmitters	D2010015	15-Dec-10	One (1) 3152ND1A3F3A1E3W1 One (1) 3152ND2B2F3E2T1W1 One (1) 3152ND3B2F3A1T1C3E6W1 One (1) 3152NA6B2F3A2E6W1 One (1) 3152ND4A3F3A1T1C3W1 One (1) 3152NA5A2F3E3C3W1D3 One (1) 3152NG6B2F3A1W1	Dose Rate			Time	TID	Pass
				0.134 Mrad/hr			7.83 hours	1.05 Mrad	
				0.545 Mrad/hr			10.1 hours	5.5 Mrad	
KTA Qualification Report of Rosemount 1152 Series G Transmitters for EPR™	D2011004	7-Sep-11	One (1) 1152DP4N22PBT1856 One (1) 1152HP7N92PMT1856 w/pipe mount One (1) 1152GP9N22PBT1856	Dose Rate			Time	TID	Pass
				0.0239-0.296 Mrad/hr			262.8 hours	6.28-7.77 Mrad	
KTA Qualification Report of Rosemount 1154 Series G Transmitters for EPR™	D2012002	20-Apr-12	One (1) 1154DP4RAN0144 One (1) 1154HP7RBN0144 w/pipe mount One (1) 1154GP9RAN0144	Dose Rate			Time	TID	Pass
				0.0237-0.278 Mrad/hr			262.8 hrs	6.24-7.31 Mrad	
				nominal 0.076 Mrad/hr			>400 hrs	31.43 Mrad	

Table 3: Radiation Qualification Testing Summary

Continuous Improvement Plan:
To provide further assurance that the installed transistors will perform their intended safety function when exposed to radiation, RNII will implement routine gain testing of irradiated parts similar to qualification conditions. In addition, for each new transistor lot, a sample of parts will be decapsulated and analyzed to inspect the die. If the geometry of the die remains unchanged, the radiation effects on the transistor performance should also remain unchanged. The expected implementation of this additional testing will begin by December 2012.

b. Bipolar semiconductor components used on the Model 710 Trip Units:
During the engineering assessment, bipolar semiconductor component radiation performance was identified as a critical characteristic which does not have a defined acceptance method in RNII's dedication process. These components include transistors, an operational amplifier, and a timer integrated circuit. RNII's commercial grade dedication program verifies the part number, manufacturer, and circuit operation with the bipolar semiconductor component during normal conditions. It did not include routine radiation testing to monitor potential performance degradation.

There are no indications that these components are causing failures during the functional tests under normal operating conditions. A review of the customer field returns data also supports this conclusion.

Similar components are used in applications requiring 100X higher radiation levels; however, these specific part numbers are not tested nor are there recent qualification tests that can be used to provide additional assurance that the components will perform their safety related function.

Extent of Condition Conclusion:
Based on 1) historical consistency in the use of specific component part numbers and manufacturers, 2) historic radiation performance of similar components using the same bipolar semiconductor processing technology at significantly higher radiation levels, and 3) lack of any indication that devices installed for extended durations have experienced susceptibility to operating radiation levels, RNII concludes that there is not a significant safety risk related to the radiation performance of devices currently installed in the field.

Continuous Improvement Plan:
To provide further assurance that these devices will perform their intended safety function when installed on circuit card assemblies, RNII will first conduct an analysis to determine the sensitivity of the circuit with respect to radiation effects of each device. Periodic radiation testing will be

implemented for each bipolar semiconductor component if deemed necessary by the analysis. The analysis will be completed by October 2012.

c. Models 1152, 1153B/D, 1154/H, and 3152N Carbon Steel Mounting Bolts:
During the engineering assessment, tensile strength was identified as a critical characteristic which does not have a defined acceptance method in RNII's dedication process. The mounting bolts are included as an accessory to the transmitter when ordered by a customer. Tensile strength measurements are documented on the material certificates provided by the manufacturer; however a supplier survey is not conducted.

RNII has been performing periodic third party chemical composition verification on the bolts per SAE J429 and there have not been any failures. If the material properties are acceptable per the SAE J429 standard, this provides reasonable assurance that the mechanical properties are unchanged.

During several qualification tests, which included seismic test conditions, there were no indications that the carbon steel mounting bolts caused failures or anomalies. A summary of the seismic qualification testing is shown in Table 4. A review of the customer field returns data did not identify any carbon steel mounting bolt related issues.

Extent of Condition Conclusion:
Based on 1) historical consistency in third party material test results, 2) no anomalies during historical seismic testing programs (noted in Table 4), and 3) lack of any indication that transmitters in the field have experienced mounting bolt failures, RNII concludes that there is not a significant safety risk for the mounting bolts currently installed in the field.

Continuous Improvement Plan:
To provide further assurance that the tensile strength requirements are met, hardness testing will be implemented on a sample basis at receipt inspection. Hardness testing is an acceptable method to verify tensile strength per ASTM A370. The expected implementation of this additional testing will begin by October 2012.

Description	Qualification Report	Qualification Report Date	Qualification Test Samples	Accident Test Conditions		Summary of Test Results
Qualification Report for Rosemount Model 1154 Series H Pressure Transmitter	D8700096	26-Oct-88	Three (3) 1154DH4RA Three (3) 1154DH5RA Three (3) 1154DH6RA Five (4) 1154SH9RA	Horizontal Zero Period Acceleration (ZPA)	Vertical ZPA	Pass
				8.5g ZPA	5.2g ZPA	
KTA Qualification Report of Rosemount 3152K Transmitters for EPR™	D2009011	3-Mar-10	One (1) 3152KD3A2F0A1W1 One (1) 3152KA5A2F3B3C4W1 One (1) 3152KD2B2F4B2C4T1W1	Safe Shutdown Earthquake (One tri-axial, 30s min)	Operating Basis Earthquake (5 tri-axial, 30s min)	Pass
				8.5g ZPA	5g ZPA	
IEEE Qualification Report of Rosemount 3152N Pressure Transmitters	D2010015	15-Dec-10	One (1) 3152ND1A3F3A1E3W1 One (1) 3152ND2B2F3E2T1W1 One (1) 3152NA6B2F3A2E6W1 One (1) 3152ND4A3F3A1T1C3W1 One (1) 3152NA5A2F3E3C3W1D3 One (1) 3152NG6B2F3A1W1	Safe Shutdown Earthquake (One tri-axial, 30s min)	Operating Basis Earthquake (5 tri-axial, 30s min)	Pass
				8.5g ZPA	5.95g ZPA	
KTA Qualification Report of Rosemount 1152 Series G Transmitters for EPR™	D2011004	7-Sep-11	One (1) 1152DP4N22PBT1856 One (1) 1152HP7N92PMT1856 w/pipe mount One (1) 1152GP9N22PBT1856	Safe Shutdown Earthquake (One tri-axial, 30s min)	Operating Basis Earthquake (5 tri-axial, 30s min)	Pass
				8.5g ZPA	5g ZPA	
KTA Qualification Report of Rosemount 1154 Series G Transmitters for EPR™	D2012002	20-Apr-12	One (1) 1154DP4RAN0144 One (1) 1154HP7RBN0144 w/pipe mount One (1) 1154GP9RAN0144	Safe Shutdown Earthquake (One tri-axial, 30s min)	Operating Basis Earthquake (5 tri-axial, 30s min)	Pass
				8.5g ZPA	5g ZPA	

Table 4: Seismic Qualification Testing Summary

d. Model 1159 Remote Seal Housing Bolts:
During the engineering assessment, tensile strength was identified as a critical characteristic which does not have a defined acceptance method in RNII's dedication process. Tensile strength measurements are documented on the material certificates provided by the manufacturer; however a supplier survey is not conducted.

In April 2011 RNII modified its commercial grade dedication program to include periodic third party chemical composition verification on bolts per ASTM A193 and there have not been any failures. If the material properties are acceptable per the ASTM A193 standard, this provides reasonable assurance that the mechanical properties are unchanged.

The supplier includes material certificates including chemistry and mechanical test results with the shipments which provide additional assurance the mechanical properties are unchanged. A review of the customer field returns data did not identify any 1159 remote seal housing bolt related issues.

Extent of Condition Conclusion:
Based on 1) lack of any indication that remote seal housing bolts have experienced failures in the field, and 2) procurement drawing specifies material chemistry and dimensional requirements, RNII concludes that there is not a significant safety risk for the housing bolts currently installed in the field.

Continuous Improvement Plan:
To provide further assurance that the tensile strength requirements are met, hardness testing will be implemented on a sample basis at receipt inspection. Hardness testing is an acceptable method to verify tensile strength per ASTM A370. The expected implementation of this additional testing will begin by October 2012.

e. Model 3051N Mounting Hardware:
During the engineering assessment, material composition and tensile strength were identified as critical characteristics which do not have defined acceptance methods in RNII's dedication process. This hardware includes bolts, brackets, and washers. The commercial grade dedication activities for 3051N (documented in RNII report D2000055) do not include material testing or require material certificates for mounting hardware.

RNII surveys the supplier including the procurement processes. If the supplier changes the drawing (such as dimensions, materials, etc), RNII is notified of the design change. RNII design and quality engineers review the changes and assess whether they impact existing qualifications. RNII Document D2011005 details these engineering reviews. A review of the customer field returns data did not identify any 3051N mounting hardware related issues.

Extent of Condition Conclusion:
Based on 1) design controls on procurement requirements, and 2) lack of any indication that transmitters in the field have experienced mounting hardware failures, RNII concludes that there is not a significant safety risk for the mounting hardware currently installed in the field.

Continuous Improvement Plan:
To provide further assurance that the material remains unchanged, material testing will be implemented as a part of the quarterly material tests and D2000055 will be updated to reflect this requirement. To provide further assurance that the tensile strength requirements are met, hardness testing will be implemented on a sample basis at receipt inspection. Hardness testing is an acceptable method to verify tensile strength per ASTM A370. The expected implementation of this additional testing will begin by October 2012.

B. Additional passive component information:

Passive electrical devices are considered by RNII to be safety related items and are subject to 10CFR 50 Appendix B. As part of RNII's commercial grade dedication process for circuit card assemblies (CCAs), all "passive electrical components" are verified during receipt inspection. With each CCA shipment, a supplier traceability report is provided which includes the RNII part number, manufacturer's part number, the manufacturer's name, and manufacturer lot or date code. An inspector reviews the report against the controlled bill of materials and the approved supplier listed on the component drawings. If any discrepancies are identified, the supplier quality engineer is notified and a material review is conducted to determine the disposition of the parts.

For acceptability of material substitutions, RNII has performed an engineering analysis of the effects of substituting parts with improved functional, physical, and performance characteristics and/or specifications (i.e. tighter tolerance, lower temperature coefficient, higher voltage rating, etc). These parts are manufactured by the same manufacturer and produced under the same part family/series. They have the same material of construction, same production facility, same manufacturing process and controls; and the same marking / identification method. A detailed analysis and justification of every part and application is documented in Design Study DS-RNII-2012-018 (Appendix D).

RNII's commercial grade dedication activities for these components provide reasonable assurance that the passive electrical components will perform their safety related function during normal and accident conditions. These activities include verification of part number and manufacturer at receipt inspection, in-circuit testing at the CCA supplier, and performance testing at elevated temperatures. Additionally, no customer reported field failures have been identified due to substitute parts with improved function, physical, and performance characteristics and/or specifications.

C. **Additional Oil Fill Fluid Information:**

Reasonable assurance that the fill fluid used during manufacturing will have the equivalent performance with the fill fluid used during the baseline qualification has historically been achieved by verification of key characteristics during receiving inspection coupled with special controls implemented by RNII to filter and condition the silicone oil during the sensor fill process.

Receiving inspection process has historically included verification of approved manufacturer, product description, color of oil, and verification of viscosity (including supplier certification of viscosity and independent third party testing).

In RNII manufacturing, special steps are taken to prepare the silicone oil for use as a sensor fill fluid. The oil is filtered to remove insoluble contaminants larger than 5 microns, and special conditioning steps are used to remove soluble gases. These processing steps ensure that contaminants, which might affect safety function, are removed prior to sensor fill. Special tests are then performed at module and transmitter levels to verify the system (including effect of sensor fill fluid) is performing as expected.

Special tests on the sensor and module assemblies include ultrasonic oil height measurement which ensures optimum fill volume; temperature effects testing (beyond normal operating range) which confirms fill quality and equal fill volumes; linearity testing to confirm electrical performance of the sensor cell (including fill fluid); and overpressure testing which provides second check on fill quality and equal fill volumes. Temperature effects and linearity are also checked at final assembly to confirm the pressure transmitter performs as expected.

Although the historical approach does not directly detect changes to formulation, the layered methodology (receipt inspection, filtering & conditioning, performance verification) assures that the silicone oil has the critical characteristics necessary to perform its safety function.
For additional details refer to Appendix E – Design Study DS-RNII-2012-040 Assessment of Commercial Grade Dedication of 1150 Series Sensor Fill Fluid.

Extent of Condition Conclusion:
Based on 1) historical consistency of receipt inspection activities, including verification of manufacturer's part number, expected color and independent third-party viscosity testing, 2) historical consistency in filtering and conditioning of silicone oils prior to sensor fill, 3) verification of expected sensor performance at specified points within the manufacturing process, and 4) recently completed qualification of pressure transmitter Models 1152, 1153 and 1154 (noted in Table 3 & 4), RNII concludes that there is not a significant safety risk related to use of

silicone oil as sensor fill fluid under normal operating and accident conditions for devices currently installed in the field.

Continuous Improvement Plan:
To enhance existing manufacturing processes and functional verification testing, and to provide capability to detect contaminants or changes to formulation/use of additives prior to start of manufacturing process, RNII implemented Fourier Transform Infrared Spectrometry (FTIR) and dielectric testing at receipt inspection in May 2012.

D. Continuous Improvement Plan Summary:

While RNII believes that the current commercial grade dedication program provides reasonable assurance that dedicated parts will perform their intended safety function, improvements are being made to enhance the program. As part of our continuous improvement activities, RNII is developing more consistent processes to document technical evaluations for identifying the critical characteristics for acceptance. In particular, documentation of the basis for the technical evaluations requires improvement. The enclosed draft "Technical Evaluation for Commercial Grade Dedication" template (Appendix F) will be used to consolidate the dedication information. All safety related items in current production will be reviewed and updated to this new format.

As requested in the RAI letter, CAPA-NC000683 is included as Appendix G.

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Appendix A: 601TT4000 Software Documentation

Appendix Removed Due to Proprietary Nature of Material

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Appendix B: 611AT Software Additional Software Documentation Example

Appendix Removed Due to Proprietary Nature of Material

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Appendix C: CAPA-NC0000677

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Nonconformance # NC000677 Created by Schukei, Nathan on Feb 2, 2012 3:58:35 PM

Closed

Basic Access Control **All Tabs**

Basic

Last Comment

Schukei, Nathan, Jun 27, 2012 9:05:44 AM, Draft:
This NCR was created as a part of the NRC inspection and required the update of OP 1120 to clarify the V&V process. The OP is updated and the NCR is now closed.

Nonconformance Number
NC000677

Attachment(s)

Initiator Division : Site
RNII : RTC-RNII (Chanhassen, MN)

Nonconformance Due Date
Jul 27, 2012

Initiator Department / Functional Area
RNII : Quality

Nonconformance Type
Audit

Action Type
Preventive

Subject
Clarifications to Software Test Requirements in OP 1120

Problem Description
During NRC Inspection on 2/2/2012 it was identified that:
Section 4.5-4.7 of OP1120af does not detail a process for a phased review and approval of the Software Test Requirements and Verification of Results. Quality and Engineering review is conducted at the end of the process; however, expectations are for a more systematic review.

CAPA Decision

Is Root Cause Analysis (DMAIC) Required?
- ○ Yes, CAPA (DMAIC) is required
- ◉ No, CAPA (DMAIC) is not required
- ○ Not Sure if CAPA (DMAIC) is required

Resolution

Is Resolution Required?
◉ Yes ○ No

Create/Assign Action Item?
◉ Yes ○ No

Action Item Link(s)
Implementation - Review and Update OP1120 # ACTION001341 (Completed)

Resolution
Review and Update OP1120

Access Control

Phase Tracking

Assigned To	Phase	Submitted Date	Due Date	Completed Date
Schukei, Nathan	Draft	Feb 2, 2012	Feb 2, 2012	Jun 27, 2012
	Closed	Jun 27, 2012		Jun 27, 2012

Additional Document Security

Managers	Editors	Readers
	Schukei, Nathan	

Last Edited by Schukei, Nathan on Jun 27, 2012 9:05:44 AM

'Save' / 'Save & Close' does not route the document. Please use the phase tracker at the top of the page if you are intending to route.

Action Item # ACTION001341 Created by Schukei, Nathan on Feb 2, 2012 4:12:02 PM

Completed

Action Item | Access Control | All Tabs

Last Comment

Irmiter, Erin, Jun 27, 2012 9:02:39 AM, Open:

Activity Number
ACTION001341

Document Links
Nonconformance #NC000677 (Closed)

Action Type	Subject	Due Date
Audit	Review and Update OP1120	Jun 30, 2012

Description
Update OP1120 to clarify requirements for timing of reviews and approvals for Production Software Control.

Assign Action Item To
Irmiter, Erin

Attachments

☐ Action Item Verification Required

Action Taken

OP 1120 was updated in May 2012 (refer to revision AG).

Attachments

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Appendix D: Design Study DS-RNII-2012-018 Resistor and Capacitor Tolerance, Temperature Coefficient, and Reliability Analysis

Appendix Removed Due to Proprietary Nature of Material

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Appendix E: Design Study DS-RNII-2012-040 Assessment of Commercial Grade Dedication of 1150 Series Sensor Fill Fluid.

Appendix Removed Due to Proprietary Nature of Material

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Appendix F: Draft Technical Evaluation for Commercial Grade Dedication Template

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Technical Evaluation for CGD

Title: Critical characteristics for		Document No: CGI-1150-	Revision:	Date:
Prepared by: Design Engineer	*signature*	Approved by: Quality Engineer	*signature*	
Model:	Component/Commodity:			

I. Background/Purpose
II. References
III. Part Numbers
IV. Safety Function
V. Critical Characteristics and Acceptance Methods
VI. Revision History

I. Background/Purpose:

The purpose of this document is to define the critical characteristics for acceptance and identify the appropriate acceptance methods for the specified items, which are utilized in Rosemount Nuclear Class 1E safety-related products. Critical characteristics are those identifiable and measurable attributes/variables of a commercial grade item, when verified, provide reasonable assurance that the item received is the item specified.

The signatures above indicate that technical review was completed in accordance with applicable Operating Procedures. Changes to data contained in this document must be approved by cognizant Supplier Quality Engineer and Design Engineer.

II. References:

- 10CFR50 Appendix B, Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants
- 10CFR21, Reporting of Defects and Noncompliance
- D9000115, RNII Quality Manual
- OP 0720, Control of Purchased Safety-Related Components
- EPRI Guidelines: NP-5652, EPRI-TR-102260
- Applicable drawings and BOMs
- Applicable First Article Inspection results (on file in RNII)
- Applicable Commercial Grade Survey Results (on file in RNII)

III. Part Numbers

The following part numbers are addressed by this technical review:

Part Number	Description

Part Number	Description

IV. Safety Function

The safety function of the specified item / commodity is:

V. Critical Characteristics and Acceptance Methods

The following items have been identified as critical characteristics for acceptance. Verification of these characteristics provides reasonable assurance that the item received is the item specified and the item will perform its intended safety function. Additional information regarding general acceptance criteria can be found on drawings, BOMs, collection plans (receipt inspection procedures) and CGI survey results.

Item	Critical Characteristics for Acceptance	Acceptance Method (Method 1 – Inspection & Test Method 2 – Supplier Survey Method 3 – Source Surveillance)	Additional Notes
1			
2			
3			
4			
5			
6			
7			
8			
9			
10			

VI. Revision History

All changes to this document require justification to ensure the baseline qualification is maintained.. Refer to Design Study, TCA, ECO, etc, as appropriate, for detailed results from supporting tests or analyses.

Rev	Date (mm/dd/yyyy)	Change Description	Justification for Changes to Critical Characteristics
		Initial release or brief summary of change	

Additional Data

When necessary

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Appendix G: CAPA-NC000683

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Nonconformance # NC000683 Created by Bumgarner, Marc on Feb 2, 2012 5:41:09 PM

Draft | Approval | Reassign | Closed

Basic | Access Control | All Tabs

Last Comment

Nonconformance Number
NC000683

Attachment(s)

Initiator Division : Site
RNII : RTC-RNII (Chanhassen, MN)

Nonconformance Due Date
Mar 30, 2012

Initiator Department / Functional Area
RNII : Quality

Nonconformance Type
Audit

Action Type
Preventive

Subject
Commercial grade dedication program lacks clear documentation and auditable links

Problem Description
There needs to be clear evidence of how we identify critical characteristics and then clear documentation on which commercial grade dedication method that we employ. If we choose method 2 and survey a supplier, we need a method to ensure that they do not change the system that we last surveyed (i.e. quality manual revision).

CAPA Decision

Is Root Cause Analysis (DMAIC) Required?
- ○ Yes, CAPA (DMAIC) is required
- ◉ No, CAPA (DMAIC) is not required
- ○ Not Sure if CAPA (DMAIC) is required

Resolution

Is Resolution Required?
◉ Yes ○ No

Create/Assign Action Item?
◉ Yes ○ No

Create Action Item

Action Item Link(s)
Implementation - Commercial grade dedication program lacks clear documentation and auditable links # ACTION001346 (Completed)
Implementation - Update OP 720 and Part Classification List # ACTION001702 (Completed)

Resolution

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Action Item # ACTION001346 Created by Bumgarner, Marc on Feb 2, 2012 5:46:37 PM

Completed

Action Item Access Control All Tabs

Last Comment

Pham, Duyen, May 8, 2012 11:41:52 AM, Open:

Activity Number
ACTION001346

Document Links
Nonconformance #NC000683 (Draft, Bumgarner, Marc, due 02 Feb 2012)

Action Type
Audit

Subject
Commercial grade dedication program lacks clear documentation and auditable links

Due Date
Mar 30, 2012

Description
See NC000683

Assign Action Item To
Pham, Duyen

Attachments

☐ Action Item Verification Required

Action Taken

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

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

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

Attachments

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Action Item # ACTION001702 Created by Bumgarner, Marc on Jul 19, 2012 11:01:37 AM

Completed

Action Item Access Control All Tabs

Last Comment

Pham, Duyen, Jul 20, 2012 10:43:36 AM, Open:

Activity Number
ACTION001702

Document Links
Nonconformance #NC000683 (Draft, Bumgarner, Marc, due 02 Feb 2012)

Action Type	Subject	Due Date
Audit	Update OP 720 and Part Classification List	Jul 20, 2012

Description
Update OP 720 and Part Classification List

Assign Action Item To
Pham, Duyen

Attachments

☐ Action Item Verification Required

Action Taken

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

The OP was updated on 5/8/12 and the PCL was updated on 4/19/2012.

Attachments

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