Namco Controls
2100 West Broad Street | Elizabethtown, NC 28337 | U.S.A.

December 29, 2016

U.S. Nuclear Regulatory Commission
Attn: Document Control Desk
Washington, DC 20555-0001

Terry W. Jackson, Chief
Quality Assurance Vendor Inspection Branch-1
Division of Construction Inspection
and Operational Programs
Office of New Reactors

Subject: Reply to a Notice of Non-conformance, Request for Additional Information
Docket No: 99901470
Reference NRC Inspection Report No. 99901470/2016-202
NON 99901470/2016-202-01

Dear Sir/Madam:
Namco Controls, has reviewed your request for additional information (letter dated December 2, 2016) regarding nonconformance 99901470/2016-202-01, and is enclosing response to said request.

Should there be any questions or need for additional information, Namco Controls will be pleased to provide the same. I may be contacted by phone at (910) 879-5489 or by email at joe.stack@sptech.com.

Sincerely yours,

30DEC2016

Joe Stack
Quality Assurance Manager
Namco Controls

Attachment: Namco Controls Response to NRC request for additional information

Distribution: K. Sutherby, J. Fuller, J. Borst, J. Kean, R. Pullenayegam, C. Clausen, S, Vanderslice

IE09
NRO

SUNSI review complete
1/25/17
Original

Namco Controls
NON Report No. 99901470/2016-202-01 Request for Additional Information

NRC request for additional information:

We have reviewed your letter and found that it is not fully responsive to addressing NON 99901470/2016-202-01.

Specifically:

Your response for NON 99901470/2016-202-01 states that "Until suppliers are approved for Method 2, material (and dimensional inspections) will follow the CGD Method 1 with enhanced EPRI sample size requirements." However, it is still not clear that Namco has established an engineering evaluation for the interim sampling plans chosen to verify material and dimensional critical characteristics.
Please provide a response within 30 days of this letter that explains your rational for the use of the enhanced EPRI sampling plan. The agency will consider extending the response time if you show good cause for us to do so.

Namco response to NON 99901470/2016-202-01, request for additional information:

Once it was discovered that material was being received from certain suppliers, even though their triennial surveys had expired, a cross-functional team (consisting of Quality, Design Engineering, and Manufacturing) was convened to develop an action plan/process to Commercial Grade Dedicate (CGD) these materials. There were several outputs from the team, the first being the generation of Corrective Action and Preventative Action (CAPA) 16-095 (Exhibit A). Two Containment Actions were deployed:

1. Remove all material from stock locations and quarantine in the Quality Lab
2. Develop a "Plan for Every Part" (PfEP)which included a Method for CGD which would be recorded Inspection Reports (IR) and applied to the Dimensional Inspection Record (DIR)

These two Containment Actions (CA) resulted in two distinctly separate outcomes:

- CA1 – Materials that were identified to have been received from suppliers with current surveys were returned to their production stock location. Materials that were identified to have been received from suppliers with expired surveys followed the PfEP process developed in CA2.
- CA2 – Control Document LP2016-2-DOC001 (Exhibit B) was developed which includes the Technical Justification for moving away from Mil-Std-105 S-1 and instead use EPRI *Guideline for Sampling in the Commercial-Grade Item Acceptance Process, TR-017218-R1 (January 1999).*

Further to CA2, each material receipt that fell into this category was written up on a unique IR and based on Engineering's and Quality's technical evaluation were processed for additional inspections (as required) per LP2016-2-DOC001. The inspections were performed per the DIR requirements and the LP2016-2-DOC001 Plan selected (refer to Exhibit B for Plan options and justifications).

Namco Controls' Quality Control Procedure QCP-002, *Inspection and Dedication*, Section 6.0 describes the process for Commercial Grade Dedication. In summary, this section informs that product from suppliers that are not 10CFR50 Appendix B approved will require CGD per one or more of the established four Methods. It also states that "Critical characteristics (are) identified during the technical evaluation (and) are verified during the acceptance process to provide reasonable assurance that the

item being accepted is capable of performing its intended safety-related function." Further on in Section 7.0 the procedure states "The critical characteristics for each part are located in the DIR." and that the DIR shall be developed by the Quality Manager (or Designee) and the Qualified Engineer "based upon engineering documents (such as Baseline Control Procedures, FMEA, drawings, etc.)..." Finally, the Namco Controls DIRs include all dimensions and material requirements found on any given drawing and as such automatically includes the critical characteristics.

Based on the above Namco Controls believed, at the time, that adequate Engineering Evaluation occurred during the transition from the AQL S-1 level to multiple sampling plans as specified in LP2016-2-DOC001. However, further conversations between Namco Controls and the NRC Inspection team (telecon 22Nov16) have helped us better understand that there are gaps in our evaluations and that more rigor needs to be applied to this portion of our CGD process.

A new CAPA (16-118) has been opened to address the process around CGD to include FMEA review and the identification of: critical characteristics, sampling plan selection, and CGD Method through technical evaluation.

Summary:

Now that we better understand the intent of NON 99901470/2016-202-01, and while we felt at the time we were addressing the requirements, we have initiated the development of an improved process for CGD.

A hard copy of this response has been mailed to the NRC Document Control Desk while a soft copy has been emailed to Aixa Belen (Aixa.Belen@nrc.gov) and Terry Jackson (Terry.Jackson@nrc.gov) .

Best regards,

30 DEC 2016

Joe Stack
Quality Manager

8D Problem Solving Form

CAPA No:	16-095	Open Date:	7/12/2016	Customer:	Various			Customer CAR No:	Not Applicable
Part No.	Not Applicable	Part Description:	Not Applicable	Reject Quantity:	Not Applicable	Mfg Cell No:	57	Value Stream:	Namco Nuclear

D1 TEAM

Name	Position
Jim Borst	QA Mgr.
Sam Vanderslice	Sr. QE Namco
Marta Rosa	Sr. QE
Jamie Kean	Dir. of Eng.
John Petty	Namco Ops.
Troy Carson	Namco ME

For nuclear safety related products, does this require a 10CFR50 Part 21 evaluation? Yes X No NA

D2 Problem Description

What, when, where found, how many, who found, product date codes, etc.

Commercial Grade Dedication (CGD) Method not clearly defined for each part and/or process whether from internal and/or external supplier.

D3 Containment Actions

Actions to contain the problem until C/A's are completed.

1. All Namco Nuclear material was pulled from stock location and quarantined in Quality Lab.
2. A Plan for Every Part (PEP), which included a Method for CGD, was developed by a cross-functional team (Quality, Engineering, and Manufacturing) and captured on Dimensional Inspection Reports (DIRs), Inspection Reports (IRs), Control Document LP2016-2-DOC001 to address all Namco Nuclear parts and assemblies.

D4 Root Cause of Problem

D4 Why? 1	D4 Why? 2	D4 Why? 3	D4 Why? 4	D4 Why? 5	D4 Root Cause of the Problem
Namco procedures did not specify where the Method requirement was to be captured.	Nuclear industry requirements do not specify where the Method of CGD is called out.	Existing DIRs is where this information should be captured, and while inspection requirements are defined, the actual Method to be employed is not called out.			*Clear statement of root cause including how root cause was verified.* The CGD Method is a requirement per QCP-002, but inspection documents (e.g. DIR) do not specify the Method to be used.

D4 Root Cause of Escape

D4 Why? 1	D4 Why? 2	D4 Why? 3	D4 Why? 4	D4 Why? 5	D4 Root Cause of the Escape
QCP-002, Inspection and Dedication, specifically Section 6, Commercial Grade Dedication Procedure, only Calibration services (6.4) identifies Method 2. Otherwise, this document does not specifically call out the Method to be used for purchased items. Although, it does allow for one or all of the four Methods to be used (6.3) to commercially dedicate the part.	Without documented Method requirement (save Calibration services) captured in inspection documents it leaves the Method open to interpretation.				*How did the defects escape the system? Where did the system fail?* Existing Namco documents do not specify which Method to use to CGD purchased parts.

D5 Permanent Corrective Actions	D6 Verify Implemented C/A's	D7 Actions to Prevent Recurrence	D7 Actions to Prevent Escape
Changes that resolve the concern for this circumstance, ie., Poke-Yoke, Tool fix etc.	*Objective, Quantitative evidence that C/A is effective. Show DATA Results.*	*(Actions to eliminate the potential recurrence of the concern for tomorrow's given environment and conditions on similar products (current and future).*	*Permanent Quality System changes to prevent recurrence of ESCAPE PATH.*
The DIRs will be updated to include the CGD Method requirement.	DIRs will be reviewed, on an on-going basis and will be updated with the proper Method to be used. Until such time that the DIR is updated we will continue to follow the containment action No. 2.	The DIR will be updated to include the CGD Method requirement.	Procedure QCP-002 will have the CGD section updated to address this issue.

Summary of Key Action items required to close this 8-D Action Item Description	Responsible Person	Due Date	Actual Complete Date	Status
Update QCP-002 to address CGD Method callout.	S. Vanderslice	8/31/2016		Not Started
Update DIRs to show Method required for each part.	S. Vanderslice	On-going		Not Started

Additional information / Digital Photos Etc.

Reference FR2016-2 Report Titled "COMMERCIAL GRADE DEDICATION, LAPSE IN SUPPLIER APPROVAL CONFORMANCE EVALUATION - FINAL REPORT"

Namco Controls
NON Report No. 99901470/2016-202-01 Request for Additional Information
Exhibit A

Exhibit B

Adjusted Sampling plans for suppliers that have not been surveyed within 36 months
Method 1: Commercial Grade Dedication

IR# _____

Technical Justification: The AQL S1 levels specified in the DIRs was based on surveys performed at the supplier location for justification of a special sampling plan (AQL S1) and to allow use of certificates of conformance for traceability and homogeneity. In the case that a survey was not performed in a timely manner a normal sampling plan must be used (EPRI TR-017218-R1). If a survey was not performed and the supplier had any NCR's in NAMCO's system a tightened plan must be used (EPRI TR-017218-R1). The following adjusted sampling plans are to be used based upon the disposition provided on Inspection Records (IRs). In the case that the adjusted sampling plan does not require any additional samples to be inspected the parts will be released to inventory. In all other cases parts will not be released until satisfactory completion of increased sample inspections.

Plan 1: Due to lack of or expired survey, sample size will be increased from AQL Level S1 to Normal Sampling Plan per EPRI TR-017218-R1 Table 2-1. Use chart to determine sample size based on lot size.

Plan 2: Due to lack of or expired survey and unacceptable performance, sample size will be increased from AQL Level S1 to Tightened Sampling Plan per EPRI TR-017218-R1 Table 2-1. Use chart to determine sample size based on lot size.

Plan 3: Due to lack of or expired survey, sample sizes for Destructive Testing will be increased from 1 sample per lot (Option 1) to use of Table 2-2 (Option 2) per EPRI TR-017218-R1 section 2.4.4 Use chart to determine sample size based on lot size.

Troy A Kloss
Qualified Engineer

6/9/16
Date

Jim Borst
Quality Manager

9 JUN 2016
Date