

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

June 23, 2008

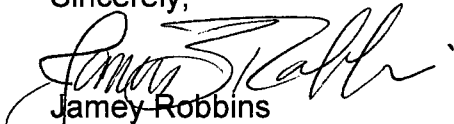
Subject: Reply to Notice of Violation
Reply to Notice of Nonconformance


Reference: NRC Report 99900378/2008 - 201

Namco Controls, Inc.'s reply to the Notice of Violation and Notice of Nonconformance is attached. Appendix A provides our response to the Notice of Violation. Appendix B provides our response to the Notice of Nonconformance.

As indicated in the appendices, Namco is committed to resolve these issues to prevent future nonconformance in this area.

Sincerely,


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Plant Manager
Namco Controls


Ken Gould
Quality Manager
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cc: John A Nakoski, Chief
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IEC
PSME

Appendix A

The purpose of this document is to provide a response to the NCR violations as defined in the inspection conducted April 21-25, 2008, at the Namco Controls facility in Lancaster, South Carolina.

A. Notice of Violation 9900378/2008-201-01

Namco Standard Practice (NSP) 60-0012, "Reporting of Defects Per 10 CFR Part 21, " did not provide adequate procedural guidance to meet the requirements of 10 CFR Part 21:

1. NSP60-0012 did not provide guidance to determine through an evaluation that the identified deviation is a defect or failure to comply associated with a substantial safety hazard as required by the regulation.
2. NSP 60-0012 did not provide for verification that the facsimile has been received by calling the NRC Operations Center as required by the regulation.

Reason for the violation

1. The intent of NSP60-0012 was that it met the requirements. It stated that the evaluation committee determines Part 21 reporting applicability. However, it did not provide the level of detail that is required.
2. Human error resulted in an oversight in that the procedure did not state that Namco must call the NRC to verify that the fax was received.

Corrective Action

Procedure NSP60-0012 was updated to include:

1. details of the steps the evaluation committee uses to determine Part 21 applicability
2. the statement that Namco must call the NRC to verify that the fax was received

Corrective Action to Prevent further Violations

Training was conducted with all affected persons.

Date for Full Compliance

Full compliance was achieved on June 4, 2008, as indicated by the sign off on the revised procedure.

B. Notice of Violation 9900378/2008-201-02

Namco issued purchase orders for material without specifying that the provisions of 10 CFR Part 21 apply.

Reason for the violation

1. The intention was there but the wording was insufficient. The purchase order stated " quality assurance program which complies with the applicable requirements of the following: CFR50, Appendix B, as applicable; CFR Part 21..."

Corrective Action

The purchase order requirements were modified to state that CFR Part 21 is applicable for purchase orders that are submitted to Appendix B suppliers.

Corrective Action to Prevent further Violations

The ordering system was updated to include the modified requirements.

Date for Full Compliance

Full compliance was achieved on June 10, 2008.

Appendix B

The purpose of this document is to provide a response to the NCR nonconformances as defined in the inspection conducted April 21-25, 2008, at the Namco Controls facility in Lancaster, South Carolina.

A. Notice of Nonconformance 9900378/2008-201-03

Namco's sampling practice for dedicating commercial grade items does not provide reasonable assurance that all items received from its suppliers would conform to the specification requirements:

1. Namco's commercial grade survey process failed to verify that the supplier's quality program included processes, such as material traceability and lot/batch controls, for the control of critical characteristics.
2. Namco did not identify and formally impose in procurement documents the applicable supplier's program/procedures to control the identified critical characteristics.

Reason for the nonconformance

1. The intention was that the supplier survey along with the dimensional inspection reports covered the requirements. Namco's supplier survey specifically asks "Does the supplier have established methods for maintaining material traceability and lot separation throughout processing?" The survey contained critical characteristics but they were not identified as such.
2. The intention was that the critical characteristics are identified on the purchase order. The purchase order has 11-13 quality requirements that apply to the order. However, the specific quality system number was not referenced on the purchase order.

Corrective Action

1. The supplier survey was changed to the NUPIC commercial grade survey checklist. This specifically states the critical characteristics that must be checked for each supplier.
2. The procurement documents will be changed to include the items are to be manufactured in accordance with the supplier quality system requirements.

Corrective Action to Prevent further nonconformances

1. The commercial grade survey was given to the auditors for use on all future supplier surveys.
2. The updated procurement documents are loaded into the system for use on all new purchase orders. The supplier's current quality system data is being loaded into the supplier database. Nine supplier surveys are scheduled to be completed with the new checklist by August 31, 2008.

Date for Full Compliance

1. Full compliance was achieved on May 2, 2008, as indicated by the addition of QF-107 (Commercial Grade Survey) in the quality forms manual.

2. Full compliance will be achieved by August 31, 2008.

B. Notice of Nonconformance 9900378/2008-201-04

Namco's external audit reports for suppliers of nuclear material, equipment, and services did not provide sufficient objective evidence to support the auditor's conclusions that audited suppliers have programs that meet the requirements of Appendix B to 10 CFR Part 50.

Reason for the nonconformance

The audit reports stated that the individual requirements were met for the various questions on the survey. However, Namco realized that the audit reports could be improved and made a change in contract auditors. A new contract auditing company was hired.

Corrective Action

The new contract auditing company has been in place since November 2007. The supplier survey was also changed to the NUPIC checklist which requires the auditor to include detailed procedure numbers and revisions.

Corrective Action to Prevent further nonconformances

The NUPIC checklist is now the Namco standard and has been in use since June 2008.

Date for Full Compliance

Full compliance was achieved on June 2, 2008 as all new audits are being performed using the NUPIC standard which is the Namco standard.

C. Notice of Nonconformance 9900378/2008-201-05

1. Namco could not provide current and historical calibration records sufficient to support calibration activities performed at Namco for measuring and test equipment used for nuclear products.
2. Namco external audit reports for commercial calibration suppliers did not provide a supplier audit checklist as objective evidence to support the qualifications of suppliers and the accuracy and adequacy of M&TE calibrated by those suppliers.

Reason for the nonconformance

1. The procedure needed more detail. The procedure stated that the database is the quality record. However, the database is overwritten once the device is calibrated. This is only for internal items calibrated by Namco.
2. The supplier audit reports did not have the survey checklist as required. This was a result of human error as the previous quality manager should not have accepted the report.

Corrective Action

1. Procedure CPM-000 was revised to include that historical data is maintained for internal calibrated items.
2. The surveys for the two calibration suppliers are being conducted before the required three year period.

Corrective Action to Prevent further nonconformances

1. Training on CPM-000 was conducted to all affected associates.
2. All supplier survey files were reviewed to see if any other audit reports were missing the checklist.

Date for Full Compliance

1. Full compliance was achieved on June 2, 2008, as shown on the procedure sign off.
2. Full compliance will be achieved by July 30, 2008, when the surveys for the two calibration suppliers are completed.

D. Notice of Nonconformance 9900378/2008-201-06

Namco closed four CARs without objective evidence that all actions were completed before closing the CAR.

Reason for the nonconformance

Objective evidence was available and was reviewed prior to closing the CARs. However, the CAR verification section did not contain enough detailed information to determine that the verification was done effectively.

Corrective Action

The four CARs were reviewed and the verifications were completed. More detail was added including the review of the training logs with the sign off date.

Corrective Action to Prevent further nonconformances

All CARs from the previous two years were reviewed and the verification was performed for any that did not have sufficient detail.

Date for Full Compliance

Full compliance was achieved on May 9, 2008.

E. Notice of Nonconformance 9900378/2008-201-07

Namco accepted the purchase order received from Weir Valves & Controls, USA, Incorporated, dated March 18, 2008, that included the use of RX465 M-type glass-filled phenolic contact carrier for the supply of 48 Type 740-50100 limit switches when Namco Qualification Test Report 180 qualified the EA740-series limit switches using RX865 M-type glass-filled phenolic contact.

Reason for the nonconformance

Human error was the reason for this nonconformance. The typo-graphical error was not caught.

Corrective Action

The supplier was immediately contacted and it was verified that there was a typo-graphical error. A revised PO was obtained and a new C of C was issued referencing the new PO with the correct material.

Corrective Action to Prevent further nonconformances

A random audit of 25 purchase orders was performed. The results were that this was an isolated case as no other issues were found. Training was performed for NSP10-0001, NSP60-0016, and NSP60-0008.

Date for Full Compliance

Full compliance was achieved on June 16, 2008.

F. Notice of Nonconformance 9900378/2008-201-08

1. Namco did not provide any formal identification, such as controlled number, on the second controlled hard copy of Namco's NSP procedures as required by NSP 60-0013, Section 8.4.2.
2. On the index of Quality Forms, the revision date for some of the quality forms did not match the revision date on the Revision Record of each form as required by NSP60-0013, Section 6.3.
3. Namco does not maintain a list of controlled copies as required by NSP60-0013, Section 4.2.6.
4. Namco had superseded hard copy versions of NSP documents filed in the same location with the latest approved revision contrary to NSP60-0013, Section 8.2.3, requirements.
5. Namco does not maintain a master copy of Namco's Quality Forms in the records storage area as required by QCP-009, Section 5.2.4.

Reason for the nonconformance

1. Section 8.4.2 of NSP60-0013 requires that the "Quality Manual provided to organizations outside of Namco shall be assigned a unique number to designate it as controlled". NSP 60-0013 states that controlled copies are located in the storage area and in the inspection area. Namco was meeting these requirements but also realized that the procedure could be improved.
2. Human error was the reason for the nonconformance.
3. The procedure did not match the current practice. The table of contents is used as the list.
4. Human error was the reason for the nonconformance. The old files had not been purged.

5. This nonconformance was due to human error. The new quality manager missed this requirement in QCP-009.

Corrective Action

1. The controlled documents were stamped as such.
2. The revision records were corrected to match the procedure revision levels.
3. NSP60-0013 was changed to state that the table of contents serves as the list of controlled documents for each manual. The procedure also states that there are two controlled manuals, one in the storage area and one in the inspection area.
4. The files were reviewed and the latest versions were placed in the file.
5. The master copy of the Quality Forms was placed in the storage area.

Corrective Action to Prevent further nonconformances

1. The procedure was changed to reflect the use of the controlled stamp.
2. All revision records were reviewed to ensure that they match the procedures.
3. Training was completed to all affected employees on the updated procedure.
4. The filing system in the storage area was cleaned up and the old revisions were either discarded or marked obsolete as stated in the procedure.
5. A file was created for the Quality Forms in the storage area.

Date for Full Compliance

1. Full compliance was achieved on April 30, 2008, as indicated by the procedure update and the documents were stamped controlled on June 20, 2008.
2. Full compliance was achieved on May 2, 2008, as indicated in the forms revision record.
3. Full compliance was achieved on April 30, 2008, as indicated by the procedure sign off.
4. Full compliance was achieved on May 5, 2008.
5. Full compliance was achieved on May 5, 2008.

G. Notice of Nonconformance 9900378/2008-201-09

1. NSP 60-0009 only identifies the training and qualifications requirements for assembly, inspection, quality test, and audit personnel. NSP60-0009 does not provide training for all Quality Department associates as required by Namco Qualified Products-Quality Manual.
2. Pre-assembly and assembly personnel did not have required training documented as being completed or performed as required by Section 5.0 of NSP60-0009.

Reason for the nonconformance

1. The training was conducted but the proper form was not used. This was a result of human error.
2. The training was completed and the records were available. However, the training records were not completely filled out.

Corrective Action

1. The training was conducted again and the correct sign off sheet was used.

2. The training for one associate was conducted and the training record was filled out completely. For the other associate, the missed date was added to the form.

Corrective Action to Prevent further nonconformances

1. The form was removed from the system. Now there is only one form.
2. The training form was revised to remove duplicate or obsolete sections.

Date for Full Compliance

1. Full compliance was achieved on May 2, 2008, as indicated by the training record.
2. Full compliance was achieved on April 28, 2008, as indicated by the training record.