

December 23, 2009

Mr. Ken Gould, Quality Assurance Manager
Namco Controls Corporation
2100 West Broad Street
Elizabethtown, NC 28337

SUBJECT: NRC INSPECTION REPORT NO. 99900378/2009-201 AND NOTICE OF
NONCONFORMANCE TO NAMCO CONTROLS CORPORATION

Dear Mr. Gould:

On October 29–30, 2009, the U.S. Nuclear Regulatory Commission (NRC) staff conducted a follow-up inspection at the Namco Controls Corporation (Namco) facility in Elizabethtown, NC. The purpose of the inspection was to review the implementation of corrective actions described in your June 23, 2008, and August 8, 2008, letters in response to the NRC's Notice of Violation (NOV) and Notice of Nonconformance (NON) dated May 27, 2008.

Based on the results of this inspection, the NRC inspectors determined that the corrective actions taken by Namco in response to the findings contained in NRC Inspection Report 99900378/2008-201 were effectively implemented.

During this follow-up inspection, the NRC inspectors identified one new nonconformance. Specifically, the NRC inspectors found that you failed to annotate the calibration records for measuring and test equipment that had gone beyond their recalibration dates, as required by Calibration Procedure Manual 000, "Calibration System Manual." Specifically, caliper CAL-8 and multimeter 43851245 went beyond their recalibration dates, and you did not record these instances in your calibration database or files. In response to this nonconformance, you issued Corrective Action Request 09-020, dated October 30, 2009. The enclosed NON cites this nonconformance to Criterion XII, "Control of Measuring and Test Equipment," 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 the subject inspection report details the circumstances surrounding it.

Please provide a written explanation or statement within 30 days of this letter in accordance with instructions specified in the enclosed NON.

In accordance with 10 CFR 2.390, "Public Exemptions, Requests for Withholding," the agency will make a copy of this letter and its enclosures available electronically for public inspection in the NRC Public Document Room or from the NRC's Agency wide Documents Access and Management System (ADAMS), accessible at <http://www.nrc.gov/reading-rm/adams.html>. To the extent possible, your response should not include any personal privacy, proprietary, or safeguards information so that it can be made available to the public without redaction. If personal privacy or proprietary information is necessary to provide an acceptable response, then please provide a bracketed copy of your response that identifies the information that should be protected and a redacted copy of your response that deletes such information. If you request that such material 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 will create an unwarranted invasion of personal privacy or provide the information required by 10 CFR 2.390(b) to support a request for withholding confidential commercial or financial information). If safeguards information is necessary to provide an acceptable response, please provide the level of protection described in 10 CFR 73.21, "Requirements for the Protection of Safeguards Information."

Sincerely,

/RA for/

Richard A. Rasmussen, Chief
Quality and Vendor Branch 2
Division of Construction Inspection
and Operational Programs
Office of New Reactors

Docket No.: 99900378

Enclosures:

1. Notice of Nonconformance
2. Inspection Report No. 99900378/2009-201

claim (e.g., explain why the disclosure of information will create an unwarranted invasion of personal privacy or provide the information required by 10 CFR 2.390(b) to support a request for withholding confidential commercial or financial information). If safeguards information is necessary to provide an acceptable response, please provide the level of protection described in 10 CFR 73.21, "Requirements for the Protection of Safeguards Information."

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DATE	12/23/09	12/23/09	12/23/09
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NAME	TFrye	RRasmussen (DSinks for)	
DATE	12/23/09	12/23/09	

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NOTICE OF NONCONFORMANCE

Ken Gould, Quality Assurance Manager
Namco Controls Corporation
2100 West Broad Street
Elizabethtown, NC 28337

Docket No: 99900378
Inspection Report No.: 2009-201

On October 29–30, 2009, the U.S. Nuclear Regulatory Commission (NRC) conducted an inspection at the Namco Controls Corporation (Namco) facility in Elizabethtown, NC. Based on the results of the inspection, the NRC inspectors found that Namco had not conducted certain activities in accordance with the NRC requirements that were contractually imposed upon it by NRC licensees.

Criterion XII, “Control of Measuring and Test Equipment,” 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 “measures shall be established to assure that tools, gages, instruments, and other measuring and test devices used in activities affecting quality are properly controlled, calibrated, and adjusted at specified periods to maintain accuracy within necessary limits.”

Section XII, “Control of Measuring and Test Equipment,” of the Namco Qualified Products Quality Control Manual describes the requirements for the calibration, identification, and control of measuring and test equipment (M&TE).

Namco Calibration Procedure Manual (CPM) 000, “Calibration System Manual,” Revision Y, provides for the identification, calibration, and control of M&TE. Section 9.0 of CPM-000 contains requirements for out of calibration conditions. Section 9.3 requires the inspector to annotate the calibration record for M&TE out of calibration or beyond its recalibration date.

Contrary to the above, as of October 30, 2009, Namco failed to annotate the calibration records for nuclear product M&TE beyond its recalibration date. Specifically, caliper CAL-8 and multimeter 43851245 went beyond their recalibration dates, and Namco failed to record these instances in its calibration database or files.

This issue has been identified as Nonconformance 99900378/2009-201-01.

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 Richard A. Rasmussen, Chief, Quality and Vendor Branch 2, Division of Construction Inspection and Operational Programs, Office of New Reactors, within 30 days of the date of the letter transmitting this Notice of Nonconformance. This reply should be clearly marked as a “Reply to a Notice of Nonconformance” and should include for each noncompliance: (1) the reason for the noncompliance, or if contested, the basis for disputing the noncompliance; (2) the corrective steps that have been taken and the results achieved; (3) the corrective steps that will be taken to avoid noncompliances; and (4) the date when your corrective action will be completed. Where good cause is shown, consideration will be given to extending the response time.

ENCLOSURE 1

Because your response will be made available electronically for public inspection in the NRC Public Document Room or from the NRC's document system (ADAMS), to the extent possible, it

should not include any personal privacy, proprietary, or safeguards information so that it can be made available to the public without redaction. ADAMS is accessible from the NRC Website at <http://www.nrc.gov/reading-rm/adams.html>. If personal privacy or proprietary information is necessary to provide an acceptable response, then please provide a bracketed copy of your response that identifies the information that should be protected and a redacted copy of your response that deletes such information. If you request withholding of such material, you must specifically identify the portions of your response that you seek to have withheld and provide in detail the bases for your claim of withholding (e.g., explain why the disclosure of information will create an unwarranted invasion of personal privacy or provide the information required by 10 CFR 2.390(b) to support a request for withholding confidential commercial or financial information). If safeguards information is necessary to provide an acceptable response, please provide the level of protection, described in 10 CFR 73.21.

Dated at Rockville, Maryland, this 23rd day of December 2009.

EXECUTIVE SUMMARY

Namco Controls Corporation
99900378/2009-201

The purpose of this inspection was to review the Namco Controls Corporation (Namco) corrective action activities described in Namco's response letters dated June 23, 2008, and August 8, 2008. The U.S. Nuclear Regulatory Commission (NRC) conducted the inspection at the Namco facility in Elizabethtown, NC.

The NRC based its inspection on the following:

- Title 10 of the *Code of Federal Regulations* (10 CFR) Part 21, "Reporting of Defects and Noncompliance"
- Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants," to 10 CFR Part 50, "Domestic Licensing of Production and Utilization Facilities"

The NRC staff implemented Inspection Procedure 43002, "Routine Inspections of Nuclear Vendors," dated October 3, 2007, and Inspection Procedure 36100, "Inspection of 10 CFR Part 21 and 50.55(e) Programs for Reporting Defects and Nonconformance," dated October 3, 2007, during the conduct of this inspection.

The NRC conducted a previous inspection at Namco's facility in Lancaster, SC, in April 2008. During that inspection, the NRC inspectors identified two violations and seven nonconformances. A summary of each is included below:

- Violation 99900378/2008-201-01 was issued because Namco Standard Practice (NSP) Procedure 60-0012, "Reporting of Defects per 10 CFR Part 21," Revision F, issued August 2007, failed to provide appropriate guidance for determining, through an evaluation, that the identified deviation was a defect or a failure to comply associated with a substantial safety hazard as required by the regulation. Furthermore, NSP Procedure 60-0012 failed to provide for verification that the NRC had actually received a facsimile sent by Namco by calling the NRC Operations Center to verify receipt of the facsimile, as required by 10 CFR Part 21. Section 1 of this report further discusses this issue.
- Violation 99900378/2008-201-02 was issued because Namco issued three purchase orders (POs) for nuclear-qualified parts to EGS, Inc., and issued two POs for material testing services to Applied Technical Service, Inc., without specifying that the provisions of 10 CFR Part 21 applied. Section 2 of this report further discusses this issue.
- Nonconformance 99900378/2008-201-03 was issued because Namco's sampling practice for dedicating commercial-grade items did not provide reasonable assurance that all items received from its suppliers would conform to specification requirements. Specifically, Namco's commercial-grade survey process failed to verify that its suppliers' quality assurance (QA) programs provided for the control of critical characteristics. Additionally, Namco did not identify and formally impose the applicable supplier's

program and procedures necessary to control the identified critical characteristics in its procurement documents. Section 3 of this report further discusses this issue.

- Nonconformance 99900378/2008-201-04 was issued because Namco's external audit reports for suppliers of nuclear material, equipment, and services failed to provide sufficient objective evidence to support the auditor's conclusions that suppliers have programs that meet the requirements of Appendix B to 10 CFR Part 50. Section 4 of this report further discusses this issue.
- Nonconformance 99900378/2008-201-05 was issued because Namco failed to provide current and historical calibration records sufficient to support calibration activities for measuring and test equipment (M&TE) used for nuclear products. Specifically, historical calibration records for a selection of M&TE were unavailable at the time of the April 2008 NRC inspection. Additionally, Namco's external audit reports for two commercial calibration suppliers did not provide objective evidence to support the qualifications of the suppliers and the accuracy and adequacy of the M&TE calibrated by the suppliers. Section 5 of this report further discusses this issue.
- Nonconformance 99900378/2008-201-06 was issued because Namco closed four corrective action reports without objective evidence indicating that it had completed all the corrective actions. Section 6 of this report further discusses this issue.
- Nonconformance 99900378/2008-201-07 was issued because Namco had received and accepted a PO from a customer and had subsequently issued an associated Certificate of Compliance that inaccurately reflected the material number. This action was not in compliance with Namco's design control program. Section 7 of this report further discusses this issue.
- Nonconformance 99900378/2008-201-08 was issued because the NRC inspectors found several examples of Namco's failure to follow procedures associated with its document control program. Specifically, Namco did not (1) provide formal identification of controlled documents, (2) provide accurate revision numbers of its revision records, (3) maintain a list of controlled copies of its documentation, (4) appropriately file the latest approved revisions of documents, and (5) maintain a master copy of its quality forms in its records storage area. Section 8 of this report further discusses this issue.
- Nonconformance 99900378/2008-201-09 was issued because Namco failed to provide training for all of its quality department associates and because it did not document required training of its preassembly and assembly personnel in accordance with its procedures. Section 9 of this report further discusses this issue.

During this October 2009, inspection, the NRC inspectors concluded that the corrective actions taken by Namco in response to the NOV's and the NON's contained in NRC Inspection Report 99900378/2008-201, were effectively implemented and were in compliance with the applicable requirements of 10 CFR Part 21 and Appendix B to 10 CFR Part 50, with the exception of the areas described below.

The NRC inspectors identified Nonconformance 99900378/2009-201-01 to address the staff's concern with the M&TE controls at Namco. Specifically, Namco failed to annotate the calibration records for nuclear product M&TE that went beyond their recalibration dates, as

required by Namco Calibration Procedure Manual (CPM) 000, "Calibration System Manual," and, in part, by Criterion XII, "Control of Measuring and Test Equipment," of Appendix B to 10 CFR Part 50. Therefore, this issue has been identified as NON 99900378/2009-201-01 and is further discussed in Section 5 of this report.

Following the NRC inspectors' identification of this finding, Namco prepared Corrective Action Request 09-020, dated October 30, 2009, to initiate corrective actions to revise CPM-000.

REPORT DETAILS

1. VIOLATION 99900378/2008-201-1

a. Inspection Scope

The NRC inspectors reviewed Namco Control Corporation's (Namco) corrective action records, quality assurance (QA) program, implementing procedures, training records, and additional documents, as applicable, which were associated with the corrective actions Namco had implemented in response to Violation 99900378/2008-201-01 to verify compliance with the requirements of 10 CFR Part 21.

Within the scope of this area of the inspection the NRC inspectors reviewed the following procedures, records, and other documents:

- Namco Corrective Action Request (CAR) 08-015, dated April 24, 2008
- Namco Root Cause Analysis Quality Form (QF) 102, Revision B, dated February 2, 2009
- Namco Test Plan for Flaking Plating on Part EA184-4100, dated April 7, 2009
- Namco 10 CFR Part 21 Evaluation Committee Meeting Minutes for CAR 08-036, dated September 23, 2008
- Namco NSP Procedure 60-0012, "Reporting of Defects per 10 CFR Part 21," Revision G, dated April 29, 2008

b. Observations and Findings

During the April 2008 inspection, the NRC inspectors identified Violation 99900378/2008-201-01 as a result of Namco's failure to provide appropriate guidance in NSP 60-0012 to perform an evaluation in order to determine if a deviation could create a substantial safety hazard (SSH) had it remained uncorrected. Additionally, Violation 99900378/2008-201-01 was issued because NSP 60-0012 failed to provide appropriate guidance for verification that the NRC Operations Center received a facsimile of a Part 21 issue, as required by 10 CFR Part 21. Namco initiated CAR 08-015 to address Violation 99900378/2008-201-01 and identified actions to prevent recurrence

The NRC inspectors reviewed CAR 08-015 to verify that it addressed reportability in accordance with 10 CFR Part 21. The NRC inspectors noted that the CAR addressed the issue of NRC facsimile receipt confirmation and contained corrective actions regarding the training of designated evaluation committee personnel pertaining to the details contained in the revised procedure.

The NRC inspectors also reviewed Revision G to NSP 60-0012, and noted that Namco had added a step which provided greater direction and guidance to Namco's 10 CFR Part 21 evaluation committee. The NRC inspectors further noted that the revision also added Step 5.5, which specified Namco's responsibility to call the NRC in order to confirm delivery of all facsimiles.

The NRC inspectors sampled the implementation of the corrective actions by reviewing the referenced test plan, which Namco used to determine 10 CFR Part 21 reportability for an identified potential defect. The NRC inspectors noted that the test plan contained adequate information for allowing Namco's assigned evaluation committee to conduct a thorough assessment of the issue. The NRC inspectors also reviewed a newly created quality form, QF 102, which was used by Namco's evaluation committee to assess a potential SSH for "flaking plating." The NRC inspectors noted that the evaluation committee determined that the issue was not reportable.

The NRC inspectors also reviewed the referenced evaluation committee meeting minutes to assess CAR 08-036. The minutes provided details on Namco's use of clear room-temperature vulcanizing (RTV) sealant versus a normally applied white sealant and allowed for a thorough assessment of 10 CFR Part 21 reportability by Namco's evaluation committee. The committee determined that the issue was reportable. The NRC inspectors noted that Namco had performed all other 10 CFR Part 21 evaluation follow-up actions, including confirmation of a facsimile that Namco sent to the NRC.

c. Conclusions

The NRC inspectors concluded that Namco adequately implemented the corrective actions specified in their letter to the NRC dated June 23, 2008 and in CAR 08-015. Therefore, Violation 99900378/2008-201-01 is closed.

2. VIOLATION 99900378/2008-201-02

a. Inspection Scope

The NRC inspectors reviewed Namco's corrective action documents, training records, and additional documents associated with corrective actions that Namco implemented in response to Violation 99900378/2008-201-2.

Within the scope of this area of the inspection, the NRC inspectors reviewed the following procedures, records, and other documents:

- Namco Response Letter to the NRC, Appendix A, Item B, dated June 23, 2008
- Namco Response Letter to the NRC, Appendix A, Item A, dated August 8, 2008
- NRC Letter, "Namco's Response to U.S. Nuclear Regulatory Commission Inspection Report 99900378/2008-201, Notice of Violations and Notice of Nonconformance," dated July 29, 2008
- Namco CAR 08-016, dated April 24, 2008
- Namco PO PJS0834, dated June 9, 2008
- Namco PO PCO161367, dated April 28, 2009
- Namco PO PTA5373, dated August 27, 2009

- Namco PO PJS1073, dated August 14, 2008
- Namco PO PTA5409, dated September 6, 2009
- Namco QF 113, "Nuclear Qualified Purchase Order Quality Assurance Requirement (QAR) P-003," Revision A, issued March 2009
- Namco QF 114, "Outside Source Material Evaluation to NAMCO TS001 Requirements QAR's P-005," Revision A, issued March 2009
- Namco QF 101, "Training Sign-Off Sheet for Nuclear Purchase Orders," Revision A, issued February 2008

b. Observations and Findings

During the April 2008 NRC inspection, the NRC inspectors identified Violation 99900378/2008-201-02 because Namco issued three POs for nuclear-qualified parts to EGS, Inc. (EGS), and they issued two POs for material testing services to Applied Technical Service, Inc. (ATS), without specifying that the provisions of 10 CFR Part 21 applied. Both EGS and ATS are Namco qualified suppliers of nuclear material, equipment, and services under Appendix B to 10 CFR Part 50.

Namco initiated CAR 08-016 to address Violation 99900378/2008-201-02 and to identify actions to prevent recurrence. Accordingly, Namco revised QARs P-003 and P-005 and incorporated them into Namco's purchasing system. Namco also revised the above referenced QF 113 and QF 114 to state that 10 CFR Part 21 is applicable. The NRC inspectors sampled the implementation of the corrective actions by reviewing QF 113 and QF 114 to verify that Namco had incorporated the appropriate requirements of 10 CFR Part 21. The NRC inspectors also reviewed a sample of POs that Namco issued since the April 2008 inspection to verify that they had actually translated the revised QARs into the POs. The NRC inspectors found that 10 CFR Part 21 was appropriately applied to all POs that Namco had sent to the P-003 and P-005 suppliers.

The NRC noted in its July 29, 2008, letter to Namco that they failed to address training to familiarize affected individuals with the new requirements implemented as part of their corrective actions. Namco's August 8, 2008, supplemental reply letter stated that training was conducted with all affected individuals. The NRC inspectors sampled the implementation of these subsequent corrective actions by reviewing a training record for purchasing entities and a training record for a purchaser who was new to his position since the time of the procedure change. The NRC inspectors also interviewed a Namco purchaser and quality engineer and confirmed that personnel understood the requirements of 10 CFR Part 21.

c. Conclusions

The NRC inspectors concluded that Namco adequately implemented the corrective actions specified in their letters to the NRC dated June 23, 2008 and August 8, 2008 and in CAR 08-016. Therefore, Violation 99900378/2008-201-02 is closed.

3. NONCONFORMANCE 99900378/2008-201-03

a. Inspection Scope

The NRC inspectors reviewed Namco's corrective and preventive actions associated with Nonconformance 99900378/2008-201-03. Specifically, the NRC inspectors reviewed Namco's procurement and purchasing documents and acceptance process of commercial-grade items (CGIs) for use as basic components to verify compliance with 10 CFR Part 21.

Within the scope of this area of the inspection, the NRC inspectors reviewed the following procedures, records, and other documents:

- Namco Response Letter to the NRC, Appendix B, Item A, dated June 23, 2008
- Namco Response Letter to the NRC, Appendix A, Item B, dated August 8, 2008
- NRC Letter, "Namco's Response to U.S. Nuclear Regulatory Commission Inspection Report 99900378/2008-201, Notice of Violations and Notice of Nonconformance," dated July 29, 2008
- Namco CGI Survey Checklist QF 107, Revision 5, issued May 2008
- Joslyn Clark Controls, Inc./Namco PO PMA3855 (Kerek Industries, Inc.), Revision 00, dated September 19, 2008
- Danaher Industrial Controls/Namco PO PTJ0076 (Newcomb Spring of Carolina), Revision 00, dated March 6, 2009
- Danaher Industrial Controls/Namco PO PRM1379 (Calibration Solutions, Inc.), Revision 00, dated June 1, 2009
- Danaher Industrial Controls/Namco PO PTA5352 (Stratford Metal Finishing), Revision 00, dated August 12, 2009
- Namco Qualified Products QCM, Section VII, "Control of Purchased Material and Services," Revision M, issued June 2007
- Namco Qualified Products QCM, Section IV, "Procurement Document Control," Revision M, issued June 2007
- Namco Quality Control Procedure QCP 002, Inspection and Dedication, Revision O, issued July 2009.

b. Observations and Findings

During the April 2008 NRC inspection, the NRC inspectors identified Nonconformance 99900378/2008-201-03 because Namco's sampling practice for dedicating CGI did not provide reasonable assurance that all items received from its suppliers would conform to specification requirements. The NRC inspectors also issued this Nonconformance because Namco did not identify and formally impose the suppliers' programs/procedures that were to be used to control

identified critical characteristics in its procurement documents. Namco addressed this Nonconformance 99900378/2008-201-03 by revising the referenced QCP 002 and producing the referenced Namco CGI Survey Checklist QF 107.

The changes to QCP 002 included 1) clarifications to the procurement process including calibration services, 2) requirements for material testing, 3) requirements for independent laboratory testing, 4) requirements for critical characteristics, and 4) information for conducting receipt inspection destructive testing (i.e., bend and elongation tests).

The NRC inspectors reviewed QF 107, Namco's newly created CGI survey checklist. The inspectors concluded that the checklist appropriately covered the regulatory requirements and met the requirements of Namco's referenced QCMs.

c. Conclusions

The NRC inspectors concluded that Namco adequately implemented the corrective actions specified in their letters to the NRC dated June 23, 2008 and August 8, 2008. Therefore, Nonconformance 99900378/2008-201-03 is closed.

4. NONCONFORMANCE 99900378/2008-201-04

a. Inspection Scope

The NRC inspectors reviewed Namco's corrective action records, implementing procedures, and additional documents associated with Nonconformance 99900378/2008-201-04. Specifically, the NRC inspectors reviewed Namco's auditing procedures and recently performed Namco audit records and documents.

Within the scope of this area of the inspection, the NRC inspectors reviewed the following procedures, records, and other documents:

- Namco Response Letter to the NRC, Appendix B, Item B, dated June 23, 2008
- Namco CAR 08-017, dated April 24, 2008
- ATS Audit Report, conducted June 3–4, 2008
- Tool & Gage House, Inc., Audit Report, conducted June 10, 2008
- Calibration Solutions, Inc., Audit Report, conducted June 27, 2008
- Namco QF 46, "New or Revised Procedure Training," Revision C, issued December 2006
- Namco Qualified Products Quality Control Manual (QCM) Section VII, Control of Purchased Material and Services, Revision M, issued June, 2007
- Namco Qualified Products QCM, Section XVIII, "Audits," Revision M, issued June 2007

- NSP Procedure 60-0006, "Guidelines for Auditing Quality Systems," Revision L, issued August 2007

b. Observations and Findings

During the April 2008 NRC inspection, the NRC inspectors identified Nonconformance 99900378/2008-201-04 for Namco's failure to provide sufficient objective evidence in its external audit reports for its suppliers of nuclear material, equipment, and services to support the auditors' conclusions that the audited suppliers had programs that met the requirements of Appendix B to 10 CFR Part 50.

Namco initiated CAR 08-017 to address Nonconformance 99900378/2008-201-4 and to identify actions to prevent a recurrence. CAR 08-017 and Namco's reply dated June 23, 2008, to this Nonconformance stated that, although the suppliers met the requirements of Appendix B to 10 CFR Part 50, the audit reports could be improved. The NRC inspectors further noted that Namco had changed its standard to use NUPIC-type checklists for its audit and CGI survey reports.

The NRC inspectors sampled the implementation of the corrective actions by reviewing audit reports for suppliers of materials, equipment, and services identified on Namco's qualified suppliers list as listed on the previous page. The NRC inspectors confirmed that the auditors documented the results of the referenced audits using a NUPIC-style audit checklist for ATS and a commercial-grade calibration services checklist for Tool & Gage House, Inc., and Calibration Solutions, Inc. The NRC inspectors found that these checklists were completed with sufficient detail to support the auditors' conclusions. The inspectors further noted that Namco's audit process met its current guidance in NSP Procedure 60-0006 and the requirements of Appendix B to 10 CFR Part 50.

c. Conclusions

The NRC inspectors concluded that Namco adequately implemented the corrective actions specified in their letter to the NRC dated June 23, 2008. Therefore, Nonconformance 99900378/2008-201-04 is closed.

5. NONCONFORMANCE 99900378/2008-201-05

a. Inspection Scope

The NRC inspectors reviewed Namco's corrective action records, implementing procedures, and additional documents associated with Nonconformance 99900378/2008-201-05. Specifically, the NRC inspectors reviewed Namco's procedures/guidance documents associated with their control of measuring and test equipment (M&TE) that are used for their nuclear products.

Within the scope of this area of the inspection, the NRC inspectors reviewed the following procedures, records, and other documents:

- Namco Response Letter to the NRC, Appendix B, Item C, dated June 23, 2008
- Namco CAR 08-017, dated April 24, 2008

- Namco CAR 08-018, dated April 24, 2008
- Namco CAR 09-020, dated August 30, 2009
- Calibration Procedure Manual (CPM) 000, "Calibration System Manual," Revision Y, dated April 14, 2009
- Excel spreadsheets for the calibration of bench micrometer BM-2, pin gage sets PGS-3A and PGS-5, caliper CAL-8, and micrometer MDC-1
- Calibration Solutions, Inc., Certificates of Calibration for multimeter ID43851245, dated March 24, 2009, and Hi-Pot ID1223, dated August 20, 2008
- Flowserve, Inc., PO 87201 for EA170 and EA180 switches, Assembly Inspection Record QF 24A, Revision I, dated September 15, 2009
- Tool & Gage House, Inc., Audit Report, conducted June 10, 2008
- Calibration Solutions, Inc., Audit Report, conducted June 27, 2008

b. Observations and Findings

During the April 2008 NRC inspection, the NRC inspectors identified Nonconformance 99900378/2008-201-05 because they found that Namco failed to provide current and historical calibration records that were sufficient to support its calibration activities for measuring and test equipment (M&TE). Specifically, the NRC inspectors noted that historical calibration records for selected M&TE were unavailable at the time of the April 2008 inspection. Nonconformance 99900378/2008-201-05 was also issued because the NRC inspectors found that Namco's external audit reports of two commercial calibration suppliers were not thorough. The audits of Tool & Gage House, Inc., and Calibration Solutions, Inc., did not provide objective evidence to support the qualifications of the suppliers and the accuracy/adequacy of M&TE calibrated by these calibration service suppliers.

Namco initiated CAR 08-018 to address the lack of calibration records to support M&TE calibration elements of Nonconformance 99900378/2008-201-05 and to identify actions to prevent recurrence. CAR 08-018 and Namco's reply dated June 23, 2008, to Nonconformance 99900378/2008-201-05 stated that the database was used as the quality record for internal calibrations and that Namco procedure CPM-000 required more detail to provide adequate guidance.

The NRC inspectors reviewed CAR 08-028 and noted that Namco identified the cause of Nonconformance 99900378/2008-201-05 as the overwriting of previous M&TE records with new calibration records. The NRC inspectors sampled the implementation of the corrective actions for CAR 08-018 and noted that Namco's CPM-000 was revised to require that an electronic or printed record be filed for maintenance of prior calibration records. The NRC inspectors further noted that external calibration records were being maintained with a supplier-provided Certificate of Calibration.

Namco also initiated CAR 08-017 to address the inadequate external audit report elements of Nonconformance 99900378/2008-201-05 and to identify actions to prevent recurrence. CAR

08-017 and Namco's reply dated June 23, 2008, to Nonconformance 99900378/2008-201-05 stated that the checklist was missing as a result of human error and that the quality manager should have identified this error.

The NRC inspectors sampled the implementation of the corrective actions for CAR 08-017, and noted that Namco expedited scheduling of subsequent audits for the two referenced suppliers and performed the audits before the required timeframe of three years. Furthermore, the NRC inspectors noted that Namco had changed its standard to use a NUPIC-style commercial-grade calibration services checklist for future audit reports for calibration service suppliers. The NRC inspectors reviewed the two referenced supplier audit reports for commercial-grade calibration services and noted that these audit reports contained the NUPIC-style checklists and were completed with sufficient detail to support the Namco-contracted auditors' satisfactory findings.

During this follow-up inspection, the NRC inspectors toured Namco's production shop and reviewed a sample of calibration records for its M&TE. The selected M&TE included, (1) a bench micrometer BM-2, (2) pin gage sets PGS-3A and PGS-5, (3) caliper CAL-8, (4) micrometer MDC-1, (5) multimeter ID43851245, and (6) Hi-Pot ID1223.

The NRC inspectors noted that the selected M&TE had affixed labels indicating the current calibration status. The NRC inspectors also noted that the historic calibration records dating back to the previous NRC inspection were available in either Namco's database or in its hardcopy files. However, the NRC inspectors also noted that two of the selected tools—the caliper and the multimeter—had lapses in their calibration history. Namco's quality manager informed the NRC inspectors that Namco had allowed some the M&TE calibrations to expire during a recent consolidation of its facilities and that Namco had properly marked and segregated those tools.

The NRC inspectors noted that Namco's CPM-000, Section 9.1, Revision Y, included requirements for M&TE that are found to be out of calibration or beyond their recalibration dates. Section 9.3 of CPM-000 stated that Namco's inspector shall annotate the record for M&TE identified in Section 9.1 with an appropriate status code. After questioning by the NRC inspectors, Namco's quality manager told the inspectors that Namco had not been routinely using this step in its procedure. During the exit meeting, Namco informed the NRC inspectors that it had initiated CAR 09-020 to address this NON.

Namco concluded, in CAR 09-020, that out-of-calibration tools had not been used during the calibration lapses because Namco calibration verification records document the current calibration status during production. The NRC inspectors sampled the use of a calibration verification record contained in the referenced assembly inspection record for Flowserve, Inc., PO 87201 for EA180 limit switches, dated September 15, 2009. The inspectors concluded that the calibration for the M&TE used for these products were within the appropriate timeframes.

c. Conclusions

The NRC inspectors concluded that Namco adequately implemented the corrective actions specified in their letter to the NRC dated June 23, 2008 and in CARs 08-017 and 08-018. Therefore, Nonconformance 99900378/2008-201-05 is closed.

The NRC inspectors found that Namco failed to properly annotate the calibration records for nuclear product M&TE that went beyond their required recalibration dates. This failure was

contrary to Namco's calibration system manual and to the requirements of Appendix B to 10 CFR Part 50. Therefore, Nonconformance 99900378/2009-201-01 was issued.

6. NONCONFORMANCE 99900378/2008-201-06

a. Inspection Scope

The NRC inspectors reviewed Namco's corrective actions, implementing procedures, and additional documents associated with Nonconformance (NON) 99900378/2008-201-06.

Within the scope of this area of the inspection, the NRC inspectors reviewed the following procedures, records, and other documents:

- Namco Response Letter to the NRC, Appendix B, Item D, dated June 23, 2008
- Namco CAR 07-062, dated November 2, 2007
- Namco CAR 07-068, dated December 12, 2007
- Namco CAR 07-069, dated December 12, 2007
- Namco CAR 08-001, dated January 15, 2008
- Namco CAR 08-015, dated April 24, 2008
- Namco CAR 08-036, dated September 22, 2008
- Namco Qualified Products QCM, Section XVI, "Corrective Action," Revision N, issued March 2009
- NSP Procedure 60-0011, "Corrective Action Requests," Revision H, issued March 2009

b. Observations and Findings

During the April 2008 NRC inspection, the NRC inspectors identified Nonconformance 99900378/2008-201-06 because they found that Namco closed four CARs without objective evidence indicating that it had completed the identification and documentation of conditions adverse to quality, causes of the conditions, and specific corrective actions taken.

The NRC inspectors sampled the implementation of Namco's corrective actions by reviewing newly issued CARs 08-015 and 08-036. The NRC inspectors noted that these CARs contained descriptions of conditions adverse to quality, causes of the conditions, interim actions required, and corrective actions necessary to prevent a recurrence. The NRC inspectors further noted that response dates for completion of the CARs were within a prescribed 30-day time period.

The NRC inspectors also reviewed NSP procedure 60-0011, Revision G, and noted a new step requiring a determination for 10 CFR Part 21 evaluation and notification when processing a CAR. The NRC inspectors noted that Namco's quality manager and engineering representative were assigned the responsibility of making the Part 21 determination. The NRC inspectors further noted that all of the reviewed CARs, issued after June 2008, adhered to guidance

contained in NSP procedure 60-0011 and that all of the CARs contained appropriate objective evidence.

c. Conclusions

The NRC inspectors concluded that Namco adequately implemented the corrective actions specified in their letter to the NRC dated June 23, 2008. Therefore, Nonconformance 99900378/2008-201-06 is closed.

7. NONCONFORMANCE 99900378/2008-201-07

a. Inspection Scope

The NRC inspectors reviewed Namco's corrective action records, implementing procedures, and additional documents associated with Nonconformance 99900378/2008-201-07. Specifically, the NRC inspectors reviewed Namco's procedures and other documents associated their processing of customer POs, receipt of components/parts and their handling of certificates of compliance (CoCs).

Within the scope of this area of the inspection, the NRC inspectors reviewed the following procedures, records, and other documents:

- Namco Response Letter to the NRC, Appendix B, Item E, dated June 23, 2008
- Namco CAR 08-014, dated April 23, 2008
- Namco QF 101, "Training Sign-Off Sheet for NSP 10-0001, NSP 60-0016, and NSP 60-0008," issued March 2009
- Weir PO 225316 and the associated Certificate of Compliance, dated March 18, 2008, and May 7, 2008, respectively
- Flowserve, Inc., PO 87201 and the associated Certificate of Compliance, dated September 15, 2009
- PPL Corporation (PPL) PO 467887 and the associated Certificate of Compliance, dated September 15, 2009
- NSP Procedure 10-0001, "Customer Purchase Order Entry," Revision M, issued July 2009
- NSP Procedure 60-0008, "Issuing Certificates of Conformance or Compliance (CoC)," Revision H, issued March 2009
- NSP Procedure 60-0016, "Processing Customer Order[s] for Qualified Products," Revision E, issued March 2009

b. Observations and Findings

During the April 2008 NRC inspection, the NRC inspectors identified Nonconformance 99900378/2008-201-07 because Namco improperly addressed an order and request that was received from Weir Valves & Controls (Weir). Specifically, the order required the use of an RX465 M-type glass-filled phenolic contact carrier for testing of Namco's limit switches. During the April 2008 inspection, the NRC inspectors discovered, in a Namco Qualification Test Report, that Namco had actually qualified their limit switches using an RX865 M-type glass-filled phenolic contact carrier rather than the requested RX465 carrier.

Namco initiated CAR 08-014 to address Nonconformance 99900378/2008-201-07 and to identify actions to prevent recurrence. The NRC inspectors noted that CAR 08-014 and Namco's June 23, 2008, reply to Nonconformance 99900378/2008-201-07 indicated that the conflicting material numbers were described as typographical errors. In the CAR, Namco documented that they confirmed with Weir that the mistake was a typographical error and also described actions to correct the documentation.

The NRC inspectors sampled the implementation of Namco's corrective actions by reviewing the revised PO 225316 and the associated CoC. The NRC inspectors verified that the correct material number was assigned. Additionally, the NRC inspectors reviewed Flowserve, Inc.'s POs 87201 and PPL PO 467887, and the associated CoCs to further verify that order requirements were properly translated. The NRC inspectors did not find any other discrepancies.

CAR 08-014 indicated that Namco had conducted training associated with the issue and associated with NSP Procedures 10-0001, 60-0016, and 60-0008. The NRC inspector also noted that Namco performed a random audit of 25 other POs to verify that there were other discrepancies. Namco did not find any other discrepancies.

c. Conclusions

The NRC inspectors concluded that Namco adequately implemented the corrective actions specified in their letter to the NRC dated June 23, 2008 and in CAR 08-014. Therefore, Nonconformance 99900378/2008-201-07 is closed.

8. NONCONFORMANCE 99900378/2008-201-08

a. Inspection Scope

The NRC inspectors reviewed Namco's corrective actions, implementing procedures, and additional documents associated with Nonconformance 99900378/2008-201-08. Specifically, the NRC inspectors reviewed Namco's procedures and other documents associated their document control program and, in particular, handling of controlled documents and revisions.

Within the scope of this area of the inspection, the NRC inspectors reviewed the following procedures, records, and other documents:

- Namco Response Letter to the NRC, Appendix B, Item F, dated June 23, 2008
- Namco Response Letter to the NRC, Appendix A, Item C, dated August 8, 2008

- NRC Letter, “Namco’s Response to U.S. Nuclear Regulatory Commission Inspection Report 99900378/2008-201, Notice of Violations and Notice of Nonconformance,” dated July 29, 2008
- Namco QCP 009, “Control of Forms,” Revision C, dated July 7, 2009
- Namco Qualified Products QCM, Section VI, “Document Control,” Revision N, issued March 2009
- NSP Procedure 60-0013, “Control of Quality Program Documents,” Revision F, issued May 2008
- NSP Manual, Table of Contents, Revision Record, Revision BJ, issued July 2008

b. Observations and Findings

During the April 2008 NRC inspection, the NRC inspectors identified Nonconformance 99900378/2008-201-08 because Namco’s document control program was inadequate and failed to meet prescribed standards, procedures, and regulations. Specifically, Namco did not (1) provide formal identification of controlled documents, (2) provide accurate revision numbers of its revision records, (3) maintain a list of controlled copies of its documentation, (4) appropriately file the latest approved revisions of documents, and (5) maintain a master copy of its quality forms in its records storage area.

The NRC inspectors reviewed Namco’s response letters dated June 23, 2008, and August 8, 2008; sampled the implementation of Namco’s corrective actions; and noted the following:

- (1) The formal identification issue occurred because Section 8.4.2 of NSP Procedure 60-0013 required an assignment of unique numbers to quality manuals that were provided to organizations outside of Namco in order to designate these manuals as controlled copies. NSP Procedure 60-0013 further required controlled copies of its quality manuals to be located in a storage area within its designated inspection area. As a corrective action, Namco stamped its controlled documents as “controlled”. Namco also revised NSP Procedure 60-0013 in order to include clear guidance on the use of its controlled stamp. The NRC inspectors confirmed Namco’s corrective actions by reviewing a random selection of Namco’s controlled documents and by verifying the prescribed NSP procedure 60-0013 guidance changes had be implemented.
- (2) Namco classified the inaccurate revision numbers as human performance issues. Namco corrected its revision records to match existing procedure revision levels. The NRC inspectors further noted that Namco also reviewed the revision records to ensure that they matched each individual procedure. The NRC inspectors confirmed Namco’s corrective actions by comparing a random selection of individual procedure revision numbers with the revision record levels reflected in the NSP Manual table of contents.
- (3) Namco did not maintain a list of controlled copies for some of it’s documents because Namco stated that its current practice is to use the table of contents contained in their NSP Manual as the list. Namco further stated that guidance contained in NSP Procedure 60-0013 did not match their current practice. The NRC inspectors reviewed the NSP Manual and confirmed, by sample, that Namco had listed its controlled

documents. The NRC inspectors also confirmed that the quality manager maintained a separate list of Namco controlled documents and that the manager's list was identical to the list on file. The NRC inspectors further confirmed that the lists were stored both internally and externally to Namco's Elizabethtown facility.

- (4) Namco reviewed each filing of superseded hardcopy revisions of NSP documents and classified them as human performance issues. The NRC inspectors confirmed Namco's corrective actions by noting that only the latest approved revisions are filed and that superseded revisions were routinely destroyed. Namco currently performs such actions for both its electronically stored and hardcopy stored and filed documents.
- (5) Namco reviewed each failure to maintain master copies of its QFs as required by QCP 009 and classified them as human performance issues. Namco contended that the new quality manager had overlooked this procedural requirement. Namco proposed, as a corrective action, to create and store a master copy of the QFs in its records storage area and to also create a separate list of controlled documents that its quality manager would maintain. The NRC inspectors confirmed that Namco produced and stored a master copy of the QFs in Namco's records storage area. They also confirmed that Namco's quality manager maintained a separate list of controlled documents.

c. Conclusions

The NRC inspectors concluded that Namco adequately implemented the corrective actions specified in their letters to the NRC dated June 23, 2008 and August 8, 2008. Therefore, Nonconformance 99900378/2008-201-08 is closed.

9. NONCONFORMANCE 99900378/2008-201-09

a. Inspection Scope

The NRC inspectors reviewed Namco's corrective action records, implementing procedures, and additional documents associated with Nonconformance 99900378/2008-201-09. Specifically, the NRC inspectors reviewed a revised Namco training procedure and required training documentation

Within the scope of this area of the inspection, the NRC inspectors reviewed the following procedures, records, and other documents:

- Namco Response Letter to the NRC, Appendix B, Item G, dated June 23, 2008
- Namco Response Letter to the NRC, Appendix A, Item D, dated August 8, 2008
- NRC Letter, "Namco's Response to U.S. Nuclear Regulatory Commission Inspection Report 99900378/2008-201, Notice of Violations and Notice of Nonconformance," dated July 29, 2008
- Namco CAR 08-023, dated April 24, 2008
- Namco QF 46, "New or Revised Procedure Training," Revision C, issued December 2006

- Namco QF 47, “Nuclear Awareness Training,” Revision D, issued July 2006
- Namco QF 44, “Inspector Qualifications,” Revision C, issued April 2008
- Namco QF 101, “Training Signoff,” Revision A, issued February 2008
- Namco QF 106, “Training Record,” Revision A, issued April 2008
- NSP Procedure 60-0009, Procedure for Personnel Training and Qualification, Revision M, issued March, 2009.

b. Observations and Findings

During the April 2008 NRC inspection, the NRC inspectors identified Nonconformance 99900378/2008-201-09 because they found that Namco’s procedure NSP 60-0009 only identified training and qualification requirements for assembly, inspection, quality testing, and audit personnel but did not provide for the training of all quality department associates. Namco’s QCM required such training. The NRC inspectors also noted that certain pre-assembly and assembly personnel did not have their required training documented. This documentation is also a requirement found in NSP 60-0009.

Namco initiated CAR 08-023 to address Nonconformance 99900378/2008-201-09 and to identify actions to prevent recurrence. Namco’s reply to Nonconformance 99900378/2008-201-09, dated June 23, 2008 and the CAR attributed this Nonconformance to recordkeeping issues that had been corrected. However, the NRC further noted that Namco did not thoroughly address the discrepancy between the Namco’s QCM and NSP 60-0009 in the NRC letter dated July 29, 2008. Accordingly, Namco’s subsequent supplemental reply to the NON, dated August 8, 2008, indicated that Namco had revised the procedure to include all quality department personnel.

The NRC inspectors sampled the implementation of Namco’s corrective actions by reviewing NSP 60-0009 to verify that Namco had incorporated training and qualification requirements for all quality personnel into the procedure. The NRC inspectors noted that Namco had revised NSP 60-0009 to define minimum qualification requirements for personnel whose activities affect qualified products.

The NRC inspectors also reviewed the training records for the Namco staff referenced in CAR 08-023. The NRC inspectors reviewed samples of the training documentation for six personnel who work on qualified products and for a contracted Namco supplier auditor. The NRC inspectors verified that Namco had properly documented the required training as complete. The NRC inspectors did not find any other significant training documentation issues.

c. Conclusions

The NRC inspectors concluded that Namco adequately implemented the corrective actions specified in their letters to the NRC dated June 23, 2008 and August 8, 2008 and in CAR 08-023. Therefore, Nonconformance 99900378/2008-201-09 is closed.

10. ENTRANCE AND EXIT MEETINGS

On October 29, 2009, the NRC inspectors discussed the scope of the inspection with Ken Gould, Namco Quality Manager; Robert Charles, Senior Quality Engineer; and Namco personnel. On October 30, 2009, the NRC inspectors presented the inspection results and observations during an exit meeting with Ken Gould, Robert Charles, and Namco personnel. A list of entrance/exit meeting attendees is included as an attachment to this report.

ATTACHMENT

1. ENTRANCE/EXIT MEETING ATTENDEES AND KEY PERSONS CONTACTED

NAME	ORGANIZATION	TITLE	ENTRANCE	EXIT	INTERVIEWED
Ken Gould	Namco	Quality Manager	√	√	√
Troy Carson	Namco	Supervisor	√	√	
Robert Charles	Namco	Senior Quality Engineer	√	√	√
David Donovan	Namco	Senior Development Engineer	√	√	√
Tammy Johnson	Namco	Customer Service	√	√	
Mark Prehar	Namco	Senior Buyer—Purchasing	√	√	√
James Robbins	Danaher	Business Systems Leader	√	√	
Jenny Dowless	Namco	Quality Inspector			√
Lacy Brewer	Namco	Assembler			√
Michael Morgan	NRC	Lead Inspector	√	√	
Garrett Newman	NRC	Inspector	√	√	
Richard Rasmussen	NRC	CQVB Branch Chief	√	√	
Robert (R.K.) Wild	NRC	OIG Audit Manager	√	√	

2. INSPECTION PROCEDURES USED

Inspection Procedure 36100, “Inspection of 10 CFR Part 21 and 10 CFR 40.55(e) Programs for Reporting Defects and Noncompliance”

Inspection Procedure 43002, “Routine Inspections of Nuclear Vendors”

3. LIST OF ITEMS OPEN, CLOSED, AND DISCUSSED

<u>Item Numbers</u>	<u>Status</u>	<u>Type</u>	<u>Description</u>
99900378/2008-201-01	Closed	NOV	10 CFR 21.21
99900378/2008-201-02	Closed	NOV	10 CFR 21.31
99900378/2008-201-03	Closed	NON	10 CFR Part 50, Appendix B, Criterion III
99900378/2008-201-04	Closed	NON	10 CFR Part 50, Appendix B, Criterion VII
99900378/2008-201-05	Closed	NON	10 CFR Part 50, Appendix B, Criterion XII
99900378/2008-201-06	Closed	NON	10 CFR Part 50, Appendix B, Criterion XVI
99900378/2008-201-07	Closed	NON	10 CFR Part 50, Appendix B, Criteria III and IV
99900378/2008-201-08	Closed	NON	10 CFR Part 50, Appendix B, Criterion VI
99900378/2008-201-09	Closed	NON	10 CFR Part 50, Appendix B, Criterion II
99900378/2009-201-01	Opened	NON	10 CFR Part 50, Appendix B, Criterion XII