

May 27, 2008

Mr. Ken Gould, Manager
Quality Assurance
Namco Controls, Inc.
2013 W. Meeting Street
Lancaster, South Carolina 29720

SUBJECT: NUCLEAR REGULATORY COMMISSION INSPECTION REPORT
99900378/2008-201, NOTICE OF VIOLATION AND NOTICE OF
NONCONFORMANCE TO NAMCO CONTROLS

Dear Dr. Gould:

On April 21-25, 2008, the U.S. Nuclear Regulatory Commission (NRC) conducted an inspection at the Namco Controls (Namco) facility in Lancaster, South Carolina. The enclosed report presents the results of that inspection.

This was a limited scope inspection that focused on assessing Namco's compliance with selected portions of Appendix B to Part 50 of Title 10 of the *Code of Federal Regulations* (10 CFR Part 50), "Quality Assurance Program Criteria for Nuclear Power Plants and Fuel Reprocessing Plants," and the provisions of 10 CFR Part 21, "Reporting of Defects and Noncompliance." This NRC inspection report does not constitute NRC endorsement of Namco's overall quality assurance or Part 21 programs.

During the inspection, the NRC inspector found that the implementation of Namco's Quality Assurance (QA) program failed to meet certain NRC requirements. Specifically, the dedication program failed to include adequate basis to substantiate the sampling plans for verifying critical characteristics to provide reasonable assurance that the dedicated items conform to the specification requirements. In addition, the NRC inspectors identified inadequate implementation of the Namco QA program requirements in the areas of control of purchased material, equipment and services, control of measuring and test equipment, corrective action, document control, and training. These nonconformances to the requirements of Appendix B to 10 CFR Part 50 are cited in the enclosed Notice of Nonconformance, and the circumstances surrounding them are described in the enclosed report. Please provide a written explanation or statement within 30 days of this letter in accordance with the instructions specified in the enclosed Notice of Nonconformance.

In addition, based on the results of this inspection, the NRC has determined that violations of NRC requirements occurred. Specifically, a review of Namco's 10 CFR Part 21 implementation identified that Namco did not adopt appropriate procedures to meet the requirements of 10 CFR Part 21, and issued purchase orders without specifying that the provisions of 10 CFR Part 21 apply to its suppliers. These violations are cited in the enclosed Notice of Violation and the circumstances surrounding them are described in detail in the subject inspection report.

You are required to respond to this letter and should follow the instructions specified in the enclosed Notice when preparing your response. The NRC will use your response, in part, to determine whether further enforcement action is necessary to ensure compliance with regulatory requirements.

K.Gould

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In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter, its enclosures, and your response will be made available electronically for public inspection in the NRC Public Document Room or from the NRC's document system (ADAMS), accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>. To the extent possible, your response should not include any personal privacy, proprietary, or safeguards information 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 is 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.

Sincerely,

/RA/

John A. Nakoski, Chief
Quality and Vendor Branch 1
Division of Construction Inspection
& Operational Programs
Office of New Reactors

Docket No. 99900378

Enclosures:

1. Notice of Violation
2. Notice of Nonconformance
3. Inspection Report No. 99900378/2008-201

NOTICE OF VIOLATION

Namco Controls, Inc.
2013 West Meeting Street
Lancaster, SC 29720

Docket Number 99900378
Inspection Report Number 2008-201

Based on the results of a Nuclear Regulatory Commission (NRC) inspection conducted April 21-25, 2008, of activities performed at the Namco Controls (Namco) facility at Lancaster, South Carolina, violations of NRC requirements were identified. In accordance with the NRC Enforcement Policy, the violations are listed below:

- A. Title 10, Section 21.21, "Notification of Failure to Comply or Existence of a Defect and Its Evaluation," of the Code of Federal Regulations (10 CFR 21.21), paragraph 21.21(a), requires, in part, that each individual, corporation, partnership, or other entity subject to 10 CFR Part 21, "Reporting of Defects and Noncompliance," shall adopt appropriate procedures to evaluate deviations and failures to comply associated with substantial safety hazards as soon as practicable.

In part, 10 CFR 21.21(d)(3)(i), requires that the responsible officer verify that the initial notification by facsimile has been received by calling the NRC Operations Center.

Contrary to the above, as of April 25, 2008, Namco Standard Practice (NSP) 60-0012, "Reporting of Defects Per 10 CFR Part 21," Revision F, did not provide adequate procedural guidance to meet the requirements of 10 CFR Part 21. For example:

1. NSP 60-0012 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.

This issue is identified as Violation 99900378/2008-201-01.

This is a Severity Level IV violation (Supplement VII).

- B. 10 CFR Part 21, Section 21.31, "Procurement Documents," requires, in part, that each individual, corporation, partnership, dedicating agency, or other entity subject to 10 CFR Part 21 shall ensure that each procurement document for a facility, or a basic component issued by him, her or it on or after January 6, 1978, specifies, when applicable, that the provisions of 10 CFR Part 21 apply.

Contrary to the above, as of April 25, 2008, Namco issued three purchase orders (PJS0606, dated April 17, 2008; PJS0497, dated March 7, 2008; and, PTA4612, dated January 24, 2008) for nuclear-qualified parts to EGS, Inc. (EGS) and two purchase orders (PCO132662, dated February 27, 2008; and, PCO132492, dated February 25,

2008) for material testing services to Applied Technical Service, Inc. (ATS) without specifying that the provisions of 10 CFR Part 21 apply. Both EGS and ATS are Namco-qualified 10 CFR Part 50, Appendix B, suppliers providing nuclear material, equipment, and services to Namco.

This issue has been identified as Violation 99900378/2008-201-02.

This is a Severity Level IV violation (Supplement VII).

Pursuant to the provisions of 10 CFR 2.201, Namco Controls is hereby required to submit a written statement or explanation to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, DC 20555-001 with a copy to the 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 Violation (Notice). This reply should be clearly marked as a "Reply to a Notice of Violation; 99900378/2008-201-01 and 99900378/2008-201-02" and should include for each violation: (1) the reason for the violation, or, if contested, the basis for disputing the violation or severity level, (2) the corrective steps that have been taken and the results achieved, (3) the corrective steps that will be taken to avoid further violations, and (4) the date when full compliance will be achieved. Your response may reference or include previous docketed correspondence, if the correspondence adequately addresses the required response. Where good cause is shown, consideration will be given to extending the response time.

If you contest this enforcement action, you should also provide a copy of your response, with the basis for your denial, to the Director, Office of Enforcement, United States Nuclear Regulatory Commission, Washington, DC 20555-0001.

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), accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>, 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. 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 this 27th day of May 2008.

NOTICE OF NONCONFORMANCE

Namco Controls
2013 W. Meeting Street
Lancaster, South Carolina 29720

Docket Number 99900378
Inspection Report Number 2008-201

Based on the results of a Nuclear Regulatory Commission (NRC) inspection conducted on April 21-25, 2008, at the Namco Controls (Namco) facility at Lancaster, South Carolina, it appears that certain activities were not conducted in accordance with NRC requirements that were contractually imposed upon Namco Controls by NRC licensees or other vendors.

- A. Criterion III, "Design Control," of Appendix B to 10 CFR Part 50, states, in part, that measures shall be established for the selection and review for suitability of application of materials, parts, equipment, and processes that are essential to the safety-related functions of the structures, systems and components.

Section VII, "Control of Purchased Material and Services," of the Namco Qualified Products-Quality Manual, Revision M, states that suppliers are chosen on the basis of their ability to satisfy the applicable requirements.

Section IV, "Procurement Document Control," of the Namco Qualified Products-Quality Manual states that the Purchasing Department shall issue purchase orders assuring that proper quality codes are referenced.

Quality Control Procedure (QCP)-002, "Inspection and Dedication," Revision M, defines the measures for inspection and dedication of commercial grade items used in Qualified Products. Section 8.0, "Sampling Procedures," of QCP-002 establishes the sampling procedures and plans for inspection of qualified products, including piece level parts and subassemblies. Inspection of piece level parts and subassemblies shall be performed in accordance with the applicable drawing, specifications, and the dimensional inspection report.

Contrary to the above, as of April 25, 2008, 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. Specifically:

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.

This issue has been identified as Nonconformance 99900378/2008-201-03.

- B. Criterion VII, "Control of Purchased Material, Equipment, and Services," of Appendix B to 10 CFR Part 50, states, in part, that measures shall be established to assure that purchased material, equipment, and services, whether purchased directly or through contractors and subcontractors, conform to the procurement documents. These measures shall include provisions, as appropriate, for source evaluation and selection.

Section VII, "Control of Purchased Material and Services," and Section XVIII, "Audits," of the Namco Qualified Products-Quality Manual state that suppliers are chosen on the basis of their ability to satisfy the applicable requirements. Only those suppliers approved by the Quality Department and appearing on the Qualified Suppliers List (QSL) may furnish material, parts, or services for Qualified Products.

Namco Standard Practice (NSP) 60-0005, "Qualification of Suppliers," Revision L, provides measures for approval and qualification of suppliers of products and services incorporated in Namco products. Section 7.4 of NSP60-0005 requires that for a supplier to be added to the QSL a satisfactory on-site evaluation (audit) of the supplier's quality program or process controls, as applicable, is completed.

NSP 60-0006, "Guidelines for Auditing Quality Systems," Revision L, defines the system for planning, conducting, and reporting quality system audits of the quality program at Namco and its suppliers. Section 5.0 of NSP60-0006 requires for the audits to be designed to provide confidence in the implementation of the quality program and assess the effectiveness of the program. Prepared checklists and applicable procedures shall be used as guidelines.

Contrary to the above, as of April 25, 2008, 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, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants."

This issue has been identified as Nonconformance 99900378/2008-201-04.

- C. Criterion XII, "Control of Measuring and Test Equipment," of Appendix B to 10 CFR Part 50, states, in part, that measures shall be established to assure that tools, gauges, instruments, and other measuring and testing 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 Manual describes the requirements for the calibration, identification, and of M&TE.

Namco procedure CPM-000, "Calibration System Manual," Revision X, provides for the identification, calibration, and control of M&TE. Section 13.0 of CPM-000 requires that calibration records shall be retained in accordance with applicable procedures.

NSP 60-0006, "Guidelines for Auditing Quality Systems," Revision L, defines the system for planning, conducting, and reporting quality system audits of the quality program at Namco and its suppliers. Section 5.0 of NSP60-0006 requires for the audits to be designed to provide confidence in the implementation of the quality program and assess the effectiveness of the program. Prepared checklists and applicable procedures must be used as guidelines.

Contrary to the above, as of April 25, 2008:

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

These issues have been identified as Nonconformance 99900378/2008-201-05.

- D. Criterion XVI states, in part, that identification of condition adverse to quality, the cause of condition, and the corrective action taken shall be documented.

Section XVI, "Corrective Action," of the Namco Quality Products-Quality Manual states that conditions adverse to quality shall be documented on a Corrective Action Requests (CAR) and processed in accordance with documented procedures.

NSP 60-0011, "Corrective Action Request," Revision F, defines the measure to generate, track and close CARs. Section 4.0 of NSP 60-0011 provides for the Quality Department to be responsible for issuing CARs, verifying implementation of actions taken, verifying the effectiveness of action taken, and maintaining the appropriate records and associated data. Section 6.0 of NSP 60-0011 requires that in the event that the actions taken are acceptable the CAR and the CAR log are annotated accordingly (i.e., CLOSED).

Contrary to the above, as of April 25, 2008, Namco closed four CARs (CAR 07-062, dated November 2, 2007; CAR 07-068, dated December 12, 2007; CAR 07-069, dated December 12, 2007; and, CAR 08-001, dated January 15, 2008) without objective evidence that all actions were completed before closing the CAR.

This is identified as Nonconformance 99900378/2008-201-06.

- E. Criterion III, "Design Control" of Appendix B to 10 CFR Part 50, states, in part, that measures shall include provisions to assure that appropriate quality standards are specified and included in design documents and that deviations from such standards are controlled.

Criterion IV, "Document Control," of Appendix B to 10 CFR Part 50, states, in part, that measures shall be established to control the issuance of documents which prescribe activities affecting quality.

NSP 10-0001, "Customer Purchase Order Entry," Revision E, provides a system to review, approve, accept and control customer PO requirements. Section 5.1 of NSP 10-0001 provides for the Nuclear Market/Customer Service Manager (NM/CSM), or his designee to be responsible for the review of all the customer specifications and PO requirements.

NSP 60-0016, "Processing Customer Order for Qualified Products," Revision E, requires the Quality Manager or his designee to review a customer's PO to assure that no discrepancies exist between Namco Standard Operating Procedure and customer requirements.

NSP 60-0008, "Issuing Certificates of Conformance or Compliance (CoC)," Revision H, establishes a system for issuing and controlling certificates of conformance (CoC). The Quality Manager is required to verify that the quality requirements are reasonable under Namco's QA program, review the CoC for correctness, completeness, and compliance with customer's PO, and document exceptions on Quality Form (QF)-35.

Contrary to the above, as of April 23, 2008, Namco accepted the purchase order (PO 225316, dated March 18, 2008) received from Weir Valves & Controls, USA, Incorporated that included the use of RX465 M-type glass-filled phenolic contact carrier for the supply of 48 Type EA 740-50100 limit switches when Namco Qualification Test Report 180 qualified the EA740-series limit switches using RX865 M-type glass-filled phenolic contact. In addition, Namco issued the CoC reflecting the use of RX465 M-type glass-filled phenolic contact carrier.

These issues have been identified as Nonconformance 99900378/2008-201-07.

- F. Criterion VI, "Document Control," of Appendix B to 10 CFR Part 50, states, in part, that measures shall be established to: 1) control the issuance of documents that prescribe activities affecting quality; 2) assure that documents, including changes, are reviewed for adequacy and approved for release by authorized personnel; and 3) assure that documents are distributed to and used at the location where the prescribed activity is performed.

Section VI, "Document Control," of the Namco Quality Products-Quality Manual states that the Quality Manager maintains a controlled copy list of the quality program documentation issued internally and externally.

NSP 60-0013, "Control of Quality Program Documents," Revision F, provides for the review, approval, and ownership of the Namco Standard Practice (NSP) documents, quality program forms, and the Namco Qualified Products-Quality Program Manual.

Sections 8.1.1.1 and 8.2.1.1 of NSP 60-0013 requires having only two sets of controlled hard copies of the Namco Qualified Products-Quality Program Manual and NSPs, respectively, in the printed form; the master hard-copy with original signatures in the document storage area and the second copy in the inspection area. In accordance with Section 8.4.2 of NSP60-0013, the second copy should be identified with a controlled copy or set number.

Section 6.3 of NSP 60-0013 requires having an Index of Quality Forms, controlled by version. The index must be authorized by the quality manager and contain the form name, form number, and revision level of each form. Section 6.2.4 of NSP 60-0013 provides for a "Record of revisions – A specific separate form that documents the revision history of the form and includes the revision date, revision level, and a brief description of the changes."

Section 4.2.6 of NSP 60-0013 requires the Quality Manager to maintain a list of all controlled copies of quality program documents issued internally and externally.

Section 8.2.3 of NSP 60-0013 requires that superseded versions of NSP documents and the NSP table of contents be marked superseded or obsolete and deleted from or moved to a secure location on the LAN. The hard copies must be discarded upon internal distribution of the approved replacement versions.

QCP-009, "Control of Forms," Revision C, provides for the preparation, issuance and control of Quality Forms (QF) used in the Namco quality system. Section 5.2.4 of QCP-009, requires that a controlled binder that includes a table of contents and a copy of the current version of each approved form should be maintained in the Quality Department in addition having to a masters forms tables of contents and forms in the Records Storage area.

Contrary to the above, as of April 25, 2008:

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 NSP 60-0013, Section 6.3.
3. Namco does not maintain a list of controlled copies as required by NSP 60-0013, 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 NSP 60-0013, 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.

These issues have been identified as Nonconformance 99900378/2008-201-08.

- G. Criterion II, "Quality Assurance Program," of Appendix B to 10 CFR Part 50, states, in part, that measures shall be established to provide for indoctrination and training of personnel performing activities affecting quality as necessary to assure that suitable proficiency is achieved and maintained.

Namco Qualified Products-Quality Manual states that Quality Department associates are trained in accordance with applicable Namco procedures.

NSP 60-0009, "Procedure for Personnel Training and Qualification," Revision F, defines minimum requirements for the indoctrination and training of personnel performing activities affecting quality. Specifically, Section 5.0, "Specialized Training and Qualification Requirements," of NSP 60-0009 establishes minimum qualifications requirements for: 1) Assembly personnel, 2) Inspection and Quality Test personnel, and 3) Lead auditors and auditors. In addition, Section 5.0 of NSP 60-0009 states that the qualification and proficiency of inspection, quality test, and audit personnel shall be reviewed and documented annually.

Contrary to the above, as of April 25, 2008:

1. NSP 60-0009 only identifies the training and qualifications requirements for assembly, inspection, quality test, and audit personnel. NSP 60-0009 does not provide for training of 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 NSP 60-0009.

These are identified as Nonconformance 99900378/2008-201-09.

Please provide a written statement or explanation to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, DC 20555-0001 with a copy to the Chief, Quality 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.

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 Web site 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 this 27th day of May 2008.

1.0 INSPECTION SUMMARY

The purpose of this NRC inspection was to review selected portions of the quality assurance (QA) and 10 CFR Part 21 controls that the Namco Controls (Namco) facility in Lancaster, South Carolina has implemented. Namco manufactures Limit Switches, Solenoids, Proximity Switches, Position Switches and special application products for commercial and industrial uses as well as a line of Nuclear Limit Switches and accessories. The Nuclear Limit Switches manufactured by Namco are used in safety-related application and, as a result, QA requirements were imposed on Namco by NRC licensees and other vendors. The NRC inspection focused on quality activities related to the manufacturing activities of the nuclear limit switches. The NRC inspection bases were:

- Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants," to Part 50 of Title 10 of the *Code of Federal Regulations*, and
- 10 CFR Part 21, "Reporting of Defects and Noncompliance."

1.1 VIOLATIONS

- Violation 99900378/2008-201-01 was identified and is discussed in Section 3.1 of this report.
- Violation 99900378/2008-201-02 was identified and is discussed in Section 3.1 of this report.

1.2 NONCONFORMANCES

- Nonconformance 99900378/2008-201-03 was identified and is discussed in Section 3.3 of this report.
- Nonconformance 99900378/2008-201-04 was identified and is discussed in Section 3.4 of this report.
- Nonconformance 99900378/2008-201-05 was identified and is discussed in Section 3.5 of this report.
- Nonconformance 99900378/2008-201-06 was identified and is discussed in Section 3.6 of this report.
- Nonconformance 99900378/2008-201-07 was identified and is discussed in Section 3.2 of this report.
- Nonconformance 99900378/2008-201-08 was identified and is discussed in Section 3.7 of this report.
- Nonconformance 99900378/2008-201-09 was identified and is discussed in Section 3.9 of this report.

2.0 STATUS OF PREVIOUS INSPECTION FINDINGS

There were no previous NRC inspections performed at Namco prior to this inspection.

3.0 INSPECTION FINDINGS AND OTHER COMMENTS

3.1 10 CFR PART 21 PROGRAM

a. Inspection Scope

The NRC inspectors reviewed the Namco policies and procedures governing the 10 CFR Part 21 program to assure those guidelines provided an adequate description of the process and implementation requirements described in 10 CFR Part 21, "Reporting of Defects and Noncompliances." In addition, the NRC inspector evaluated the 10 CFR Part 21 postings and reviewed a sample of purchase orders (POs) for compliance with the requirements of 10 CFR 21.6, "Posting Requirements," and 10 CFR 21.31, "Procurement Documents," respectively.

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

- Namco Qualified Products-Quality Manual, Revision M.
- Namco Standard Practice (NSP) 60-0012, "Reporting of Defects Per 10 CFR Part 21," Revision F.
- NSP 60-0019, "Control of Purchases," Revision F.
- NSP 60-0011, "Corrective Action Requests," Revision F.
- Namco Qualified Suppliers List (QSL).
- PO PJS0606, dated April 17, 2008.
- PO PJS0497, dated March 7, 2008.
- PO PCO132662, dated February 27, 2008.
- PO PCO132492, dated February 25, 2008.
- PO PTA4612, dated January 24, 2008.
- Corrective Action Request (CAR) 07-061, dated October 31, 2007.
- CAR 08-016, dated April 24, 2008
- CAR 08-022, dated April 24, 2008.

b. Observations and Findings

b.1 Postings

The NRC inspectors evaluated whether Namco had complied with the posting requirements of 10 CFR 21.6. The NRC inspectors found that Namco had posted notices that included a copy of Section 206 of the Energy Reorganization Act of 1974, a current copy of 10 CFR Part 21, a copy of Appendix B to 10 CFR Part 50, and a copy of NSP 60-0012. The NRC inspectors did not identify any findings in this area.

b.2 10 CFR Part 21 Procedure

NSP 60-0012 outlines the procedure and responsibilities to identify, control, document, and resolve conditions used for the reporting of defects and noncompliance discovered at Namco or products returned by customers. During the review of the procedure, the NRC inspectors noted that the procedure did not contain adequate guidance to meet certain requirements of the regulations. Section 4 of NSP 60-0012 provides for the evaluation of deviations by an Evaluation Committee comprised of the Director of Engineering, the Quality Assurance Manager, the Plant Manager, and the Nuclear Market Manager. The Evaluation Committee decides whether or not the deviation is a defect or failure to comply associated with a substantial safety hazard.

NSP 60-0011 defines the measures to generate, track, and close CARs. In addition, Section 6.1.2 of NSP 60-0011 contains procedural guidance to evaluate all CARs for 10 CFR Part 21 program applicability when a CAR is open.

The NRC inspectors discussed the Namco 10 CFR Part 21 program with the Quality Manager and inquired as to how a condition adverse to quality identified in the corrective action program would be evaluated under the 10 CFR Part 21 program. The inspectors determined that NSP 60-0011 contained adequate procedural guidance to initiate the 10 CFR Part 21 process when a CAR is opened, and that Namco staff was knowledgeable about the conditions that would warrant a 10 CFR Part 21 evaluation. However, the NRC inspectors determined that NSP 60-0012 did not contain adequate provisions for the evaluation, as defined in 10 CFR Part 21, of deviations and failures to comply associated with substantial safety hazards. The NRC inspectors found that the procedure did not provide guidance on how the Committee was determining through the evaluation that the identified deviation is a defect or failure to comply associated with a substantial safety hazard. As a result, the NRC inspectors found that Namco's Part 21 program did not adopt appropriate procedures pursuant 10 CFR 21.21(a) to evaluate deviations and failure to comply. This is identified as an example of failure to adopt appropriate procedure to comply with 10 CFR Part 21 requirements and is identified as part of Violation 99900378/2008-201-01. Namco initiated CAR 08-022 to address this issue.

Section 5 of NSP 60-0012 established the responsibilities and timeliness guidance to comply with the reporting requirements of 10 CFR Part 21. However, the procedure did not provide guidance to comply with the requirements of 10 CFR 21.21(d)(3)(i), which requires that the supplier is responsible for the verification that the initial notification by facsimile has been received by calling the NRC Operations Center. Therefore, the NRC inspectors found that Namco's 10 CFR Part 21 program did not adopt appropriate procedures pursuant 10 CFR 21.21(d)(3)(i). This is identified as an example of failure to adopt appropriate procedure to comply with 10 CFR Part 21 requirements and is identified as part of Violation 99900378/2008-201-01. Namco initiated CAR 08-022 to address this issue.

b.3 10 CFR Part 21 Implementation

In accordance with 10 CFR 21.21, the NRC inspectors requested copies of 10 CFR Part 21 records of evaluations and reports that Namco has completed. Namco has only performed one 10 CFR Part 21 evaluation as a result of CAR 07-061. CAR 07-061 was generated to capture the failure of Part EA740-80100 during a bench check. The problem was that one of the contact strips was turned in the horizontal position, and it should have been in the vertical position.

However, the switch was still operational. Because the switch was still operational, and the failure can be detected during final test the Evaluation Committee concluded that this was not reportable in accordance with 10 CFR 21.21. The NRC inspectors did not identify any findings in this area.

b.4 Procurement Documents

The NRC inspectors reviewed several POs and evaluated whether Namco had implemented a program consistent with the requirements described in 10 CFR 21.31 regarding specifying the applicability of 10 CFR Part 21 in POs for basic components.

Section IV, "Procurement Document Control," of Namco's Qualified Products-Quality Manual, states, in part, that qualified engineers shall ensure that the applicable regulatory requirements are specified in POs. Section 5.1, "Qualified Products," of NSP 60-0019, describes the Procurement Codes (P-codes) assigned to each supplier on the QSL. Namco imposes the requirements of 10 CFR Part 21 on its qualified suppliers having programs meeting the requirements of Appendix B to 10 CFR Part 50. These Appendix B suppliers are assigned P-codes of P-003 for nuclear qualified parts and services suppliers, and P-005 for laboratory testing suppliers.

On its QSL, Namco identified one supplier with a P-code of P-003, EGS, Inc. (EGS) located in Huntsville, Alabama, and one supplier with a P-code of P-005, Applied Technical Service (ATS) located in Marietta, Georgia. Both EGS and ATS are Namco-qualified 10 CFR Part 50, Appendix B, suppliers providing nuclear material, equipment, and services to Namco. Namco issued three POs (PJS0606, PJS0497, and PTA4612) for nuclear-qualified parts to EGS and two POs (PCO132662, and PCO132492) for material testing services to ATS without specifying that the provisions of 10 CFR Part 21 applied. The NRC inspectors concluded that in these cases Namco failed to impose the requirements of 10 CFR Part 21 on its Appendix B suppliers. This issue is identified as Violation 99900378/2008-201-02. During the inspection, Namco initiated CAR 08-016 to address this issue.

c. Conclusions

The NRC inspectors found that the Namco's postings of Part 21 requirements met the requirements in 10 CFR 21.6(a) and that NSP 60-0012 generally incorporated the requirements of 10 CFR 21.21. However, as noted above, the NRC inspectors found that NSP 60-0012 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. This is identified as Violation 99900378/2008-201-01.

As noted above, the NRC inspectors also found that Namco failed to impose the requirements of 10 CFR Part 21 on the POs to its Appendix B suppliers as required by 10 CFR Part 21. This is identified as Violation 99900378/2008-201-02.

Except for the issues identified in Violation 99900378/2008-201-01 and Violation 99900378/2008-201-02, the NRC inspectors concluded that Namco's 10 CFR Part 21 program requirements are consistent with the regulatory requirements.

3.2 Design Control

a. Inspection Scope

The NRC inspector reviewed the Namco Qualified Products-Quality Manual and implementing procedures that govern the design control process. In addition, the NRC inspectors reviewed the documentation of completed limited switches supplied to customers as basic components for use in safety-related applications to verify compliance with the program requirements and adequate implementation of those requirements.

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

- Namco Qualified Products-Quality Manual, Revision M.
- NSP 10-0001, "Customer Purchase Order Entry," Revision E.
- NSP 60-0016, "Processing Customer Order for Qualified Products," Revision E.
- NSP 60-0008, "Issuing Certificates of Conformance or Compliance (CoC)," Revision H.
- PO 10188084, dated March 26, 2008, issued to Namco for EA-170-11302 type limit switch rated for 125/600 volts alternating current, 125/250 volts direct current, and 20/15 amperes in a National Manufacturer's Association (NEMA) 4-type enclosure.
- PO 225316, dated March 18, 2008, issued to Namco by Weir Valves & Controls, USA, Incorporated – formerly Atwood & Morrill – for the supply of 48 Type EA 740-50100 limit switches for installation inside the containment of a nuclear power plant.
- PO 566546, dated December 6, 2007, issued to Namco by Henry Pratt Company for the supply of four Namco EA 750-2000 type limit switches and four adjustable offset limit switch levers identified as Catalog Number EL 130-64410.
- PO KO-08N020, dated February 22, 2008, issued to Namco by KTI Korea for the supply of six each Namco EA 170-31302 and EA 170-32302 type limit switches and 12 EL 010-5338 type levers.
- Qualification Test Report 180, Revision 1, dated December 1999, for the qualification of the EA740-series limit switches.
- CAR 08-014, dated April 23, 2008.

b. Observation and Findings

NSP 10-0001 provides a system to review, approve, accept and control customer PO requirements. Section 5.1 of NSP 10-0001 states, in part, that the Nuclear Market/Customer Service Manager (NM/CSM), or his designee will be responsible for review of all the customer specifications and PO requirements. In addition, Sections 5.2 and 5.3 of NSP 10-0001 states that Engineering and the Quality Manager, respectively, will be responsible for review and approval of any customer specification or requirement deemed necessary by the NM/CSM. Section 6.4.1 of the procedure requires the Quality Manager to complete the documentation for the customer orders for the product from the factory in accordance with NSP 60-0016.

NSP 60-0016 requires the Quality Manager or his designee to review a customer's PO to assure that no discrepancies exist between Namco Standard Operating Procedure and customer requirements. The review is intended to evaluate if the customers requirements can be met.

NSP 60-0008 establishes a system for issuing and controlling CoC. Subsection 3.1 of NSP 60-0008 states that it is the Namco's Policy that the CoCs issued to the customers are properly controlled to assure accuracy. Subsection 4.1.1 of NSP 60-0008 states that the NM/CSM or his designee is responsible for completing Part 1 of the two-part CoC. Furthermore, NSP 60-0008 requires NM/CSM to send the Quality Manager copies of the PO and the completed CoC Part 1 for review. The Quality Manager is required to verify that the quality requirements are reasonable under Namco's QA program, review the CoC for correctness, completeness, and compliance with customer's PO, and document exceptions on Quality Form (QF)-35.

The NRC inspectors reviewed four POs (PO 10188084, PO 225316, PO 566546, PO KO-08N020) issued to Namco to review the types of limit switches ordered and the specifications Namco had to meet to verify if the CoCs and associated records confirmed that the technical and quality requirements specified were met. During the review, the NRC inspector verified whether current drawings were used during the manufacturing and inspection process.

During the review of the POs, the NRC inspector noted that PO 225316 received from Weir Valves & Controls (Weir) included additional requirements, including the use of RX465 M-type glass-filled phenolic contact carrier. In the Qualification Test Report 180, Namco qualified the EA740-series limit switches using RX865 M-type glass-filled phenolic contact carrier. The NRC inspector requested the NM/CSM to provide documentation where RX465M glass-filled phenolic contact carrier was qualified to be used in this type of series. When questioned by the NRC inspectors, the NM/CSM realized that the purchase order received from Weir and the CoC issued by Namco did not reflect the correct material number. This issue was identified as Nonconformance 99900378/2008-201-07. Namco initiated CAR 08-014 to state that there was a typo-graphical error on PO 225316 received from Weir. Weir had referenced a contact block with RX465M material when it should have been RX865M. The corrective action for CAR 08-014 was to contact Weir and confirm that it was a typographical error on the PO and to verify that it should have read RX865M. Namco took action to address the issue prior to the conclusion of the inspection by contacting Weir and obtaining a revised PO and issue a revised CoC to Weir referencing the revised PO and the correct material.

c. Conclusion

The inspectors concluded that Namco's design control program requirements are consistent with the regulatory requirements of Criterion III of Appendix B to 10 CFR Part 50. However, as identified above, the NRC inspectors found an instance where a purchase order received and accepted from a customer, and the associated CoC issued by Namco did not reflect the correct material number affecting Namco's design control program. This issue was identified as Nonconformance 99900378/2008-201-07.

3.3 Commercial Grade Dedication

a. Inspection Scope

The NRC inspectors reviewed the Namco Qualified Products-Quality Manual, procedural guidance and the implementation process for commercial grade item dedication activities. Specifically, the NRC inspectors reviewed the implementing procedures, commercial grade

surveys, and dimensional inspection reports (DIRs) that govern Namco's implementation of commercial grade dedication activities.

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

- Namco Qualified Products-Quality Manual, Revision M.
- Quality Control Procedure (QCP)-002, "Inspection and Dedication," Revision M.
- Drawing EA 181-60010, "Contact Block Assembly"
- Commercial grade surveys performed by Namco for Brainin Advance Industries, dated December 21, 2006.
- Commercial grade surveys performed by Namco for Cuyahoga Molded Plastics, dated July 15, 2005.
- Commercial grade surveys performed by Namco for Fastener Tool and Supply, dated July 31, 2007.
- Commercial grade surveys performed by Namco for Kerek Industries LLC, dated March 21, 2005.
- Commercial grade surveys performed by Namco for Laystrom Manufacturing Co., dated July 26, 2006.
- Commercial grade surveys performed by Namco for Precision Metalsmiths, dated December 8, 2006.
- PO PJS0442 dated August 21, 2007, to Cuyahoga Molded Plastics, Cleveland, Ohio, for the supply of 7500 pieces Contact Block & Inserts identified as item EA 181-53031, Revision B.
- PO PDD0650 to Layston Manufacturing Company, Chicago, Illinois, dated July 19, 2007, for the supply of 2000 contact strip-as identified as item EA 186-83024.
- PO PJS0189, dated September 28, 2006, to Brainin Advance Industries, Attleboro, Massachusetts, for the supply of 500,000 pieces of contact-un-plated identified as item EA 742-12804.
- PO PDR 0947 dated July 17, 2007, to Fastener Tool & Supply Company, Solon, Ohio, for the supply of 100,000 pieces of screw-SEMs-8-32x0.38-CONE-NIPL-ELCO 680-08-35, identified as item EF 420-00013.
- CAR 08-017, dated April 24, 2008.

b. Observations and Findings

b.1 Policies and Procedures

Namco's Section IV, "Procurement Document Control," and Section VII, "Control of Purchased Material and Services," of the Namco Qualified Products-Quality Manual, and QCP-002, address the process steps for dedicating and accepting a commercial grade item.

As explained in 10 CFR Part 21 and as supplemented in Generic Letter (GL) 89-02, "Actions to Improve the Detection of Counterfeit and Fraudulently Marketed Products," dated March 21, 1989, and GL 91-05, "Licensee Commercial-Grade Procurement and Dedication Programs," dated April 9, 1991, the dedication process represents an acceptable method for providing reasonable assurance that a commercial grade item will perform its intended safety function. In this respect, dedication is an acceptable process for achieving an equivalent level of quality to

Appendix B to 10 CFR Part 50 with the dedicating entity assuming many of the responsibilities for ensuring quality and functionality of an item. In this context, the dedicating entity is required to identify and verify the critical characteristics and activities affecting the item's quality and safety function to assure they are adequately controlled and verified.

The NRC inspectors observed that Namco dedicates its limit switches in two stages. In the first stage, Namco dedicates the sub-components of the limit switches, purchased as commercial grade items, during receipt inspections. In the second stage, Namco dedicates the assembled limit switch during final inspection and tests.

b.2 Identification of Critical Characteristics

For limit switches that will be provided as basic components, the NRC inspectors noted that important attributes of sub-components procured as commercial grade items are identified in DIRs by Namco engineering personnel. In addition, the NRC inspectors noted that Namco's assembly inspection records (AIRs) lists all the attributes to be verified on the assembled limit switches. Namco verifies the attributes of the limit switch sub-components on a sample basis during receipt inspection and performs inspection and tests on all assembled limit switches. The NRC inspectors found that although these attributes are not identified in Namco's dedication process as critical characteristics, these attributes are consistent with guidance for the identification of critical characteristics to be verified for commercial grade items.

b.3 Commercial Grade Surveys

When sampling is used as part of the dedication process to verify critical characteristics (e.g., material composition), the commercial grade surveys performed by dedicating entities must identify the products and their critical characteristics in order to verify that the suppliers' commercial quality programs include processes, such as material traceability and lot/batch controls, for the control of the specified critical characteristics. The NRC inspectors noted that Namco's procedures for conducting commercial grade surveys did not include requirements to identify the products and their critical characteristics to verify that the commercial grade suppliers have the capabilities and processes to control the identified critical characteristics. Specifically, the verification of traceability and lot/batch control during the surveys provides assurance of the homogeneity of the product lots and provides the basis for sampling to verify critical characteristics. During the verification of critical characteristics, the sampling plans rely on those batch/lot controls to provide reasonable assurance that the commercial grade items not sampled during inspection also have the required chemical and physical properties required by the applicable material specification.

The NRC inspectors reviewed the commercial grade surveys performed by Namco for Brainin Advance Industries, Cuyahoga Molded Plastics, Fastener Tool and Supply, Kerek Industries LLC, Laystrom Manufacturing Co., and Precision Metalsmiths. During the review of these commercial grade surveys the NRC inspectors noted that Namco's commercial grade surveys failed to identify critical characteristics and to verify that these suppliers' quality programs included processes, such as material traceability and lot/batch controls, for the control of critical characteristics. As a result, the NRC inspectors concluded that Namco's sampling practice for dedicating commercial grade items does not provide reasonable assurance that all material and parts received and used in nuclear qualified products conform to the specification requirements. This is identified as an example of failure to adopt an appropriate dedication program and is

identified as part of Nonconformance 99900378/2008-201-03. Namco initiated CAR 08-017 to address critical characteristics on commercial grade surveys.

b.4 Commercial Grade Procurement Documents

When procuring commercial grade items, the dedicating entity can use a commercial grade survey to verify that the supplier's commercial quality program includes processes for the control of the critical characteristics. When supplier's controls are determined to be satisfactory during the commercial grade survey, the procurement document is expected to invoke those applicable controls as contract requirements by referencing the applicable program/procedures and revisions. Invoking the specific commercial suppliers' procedural controls assessed by Namco during the commercial grade surveys, provides assurance that the processes will be implemented during the manufacturing of the item and that the commercial supplier is controlling the items critical characteristics.

During review of Namco's purchase orders issued to commercial grade suppliers, the NRC inspectors noted that Namco did not identify and formally impose the applicable supplier's program/procedures to control the identified critical characteristics. This is identified as an example of failure to adopt an appropriate dedication program and is identified as part of Nonconformance 99900378/2008-201-03.

b.5 Commercial Grade Dedication of Purchased Sub-Components

The NRC inspectors reviewed a component drawing and associated documentation to determine if Namco had performed an adequate dedication on that component, including verification that the appropriate critical characteristics on each component had been adequately identified. Drawing EA 181-60010 is a CBA component used in the assembly of a LS-NVC-CW-R-W-QTR 155-NSP 60-type limit switch. The CBA has about 29 sub-components. The NRC inspectors sampled four sub-components (EA 181-53031, EA 186-83024, EA 742-12804, EF 420-00013) to determine if dedication of each item was adequately performed before the assembly of the component.

The NRC inspectors observed that Namco Engineering provided the required dimensions that were included in the DIRs for these components. The NRC inspectors verified that during receipt inspection, the Namco inspector verified, on a sample basis, the actual dimensions of the components specified in the DIRs. In addition, the NRC inspectors verified that the Namco inspector recorded the dimensions measured, the M&TE used, its unique identification number, and when it was last calibrated. During observation and review of the sampling activities conducted during receipt inspection, the NRC inspectors did not identify any findings. However, as noted previously, because of inadequate verification of the supplier's control of critical characteristics during Namco commercial grade surveys, sampling is not an acceptable approach for dedicating these components.

b.6 Commercial Grade Dedication of Assembled Limit Switches

The NRC inspectors reviewed an AIR to determine if Namco had performed an adequate dedication on the limit switch. The NRC inspectors observed that the AIR for the EA 180-31402 limit switch listed all the attributes to be verified on individual components before assembling the switch. The dimensions, including tolerances, the M&TE used to measure the dimensions, and

the various lubricants used, such as grease and oil, were listed in the AIR. The inspectors verified that the assembly personnel recorded the dimensions, the M&TE used, its unique identification number, and when it was last calibrated. After completing the assembly and installation of the top and bottom covers, the NRC inspectors observed that slow latch tests were performed to verify that the limit switch operates to the full trip position without indication of binding and is able to return from the full trip position to the initial/reset position. Switches that exhibit binding, hesitation, and fails to change state (open to close, or close to open) during the verification are rejected. As required by QCP-002, Namco performs tests on all assembled limit switches during final inspection.

Some other critical characteristics verified during the final inspection are the following:

- Visual configuration
- Pre-travel angle in degrees
- Differential travel angle
- Minimum torque during pre-travel in inch-pounds
- Insulation resistance
- Electrical load
- Contact transfer
- Performance testing

The NRC inspectors did not identify any findings in this area.

c. Conclusions

The NRC inspectors determined through a review of Namco's dedication process, that Namco is not adequately implementing a commercial dedication process in compliance with regulatory and industry guidance. Without verification during the commercial grade survey of applicable controls, such as material traceability and lot/batch controls, and not imposing such controls to commercial grade suppliers in procurement documents, Namco's sampling practice for dedicating commercial grade items does not provide reasonable assurance that all items received from its suppliers conform to the specification requirements. The NRC inspectors concluded that the approach in which Namco implements its dedication program does not assure the uniform quality of the basic components that Namco supplies for use in safety-related applications. As a result, there is insufficient justification and technical bases for accepting the results of Namco's dedication of commercial grade items for use in safety-related applications. This is identified as Nonconformance 99900378/2008-201-03.

3.4 Control of Purchased Material, Equipment, and Services

a. Inspection Scope

The NRC inspectors reviewed Namco's Qualified Products-Quality Manual and implementing procedures that govern the control of purchased material, equipment, and services. The NRC inspectors reviewed a sample of reports for audits of suppliers qualified by Namco as having programs that meet the requirements of Appendix B to 10 CFR Part 50. The inspector also reviewed a sample of reports for audits of commercial grade suppliers as discussed in Section 3.3 of this report.

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

- Namco Qualified Products-Quality Manual, Revision M.
- NSP 60-0005, "Qualification of Suppliers," Revision L.
- NSP 60-0006, "Guidelines for Auditing Quality Systems," Revision L.
- Audit report for EGS, dated August 8, 2007.
- Audit report for ATS, dated August 19, 2005.
- CAR 08-017, dated April 24, 2008.

b. Observations and Findings

Section VII, "Control of Purchased Material and Services," of Namco's Qualified Products-Quality Manual states, in part, that suppliers are chosen on the basis of their ability to satisfy the applicable requirements. This section also states that only those suppliers approved by the Quality Department and appearing on the QSL may furnish material, parts, or services for Qualified Products. Section XVIII, "Audits," of Namco's Qualified Products-Quality Manual states, in part, that internal and external quality system audits and surveys shall be planned and scheduled.

NSP 60-0005 states, in part, that a satisfactory on-site evaluation (audit) of the supplier's quality program or process controls must be completed. In addition, NSP 60-0006 states, in part, that its purpose is to define the system for planning, conducting, and reporting quality system audits of the quality program at Namco and suppliers. NSP60-0006 also states, in part, that the audits shall be designed to provide confidence in the implementation of the quality program and assess the effectiveness of the program.

EGS and ATS are identified on the Namco QSL as qualified 10 CFR Part 50, Appendix B, suppliers authorized to provide nuclear material, equipment, and services to Namco. The NRC inspector reviewed the audit reports for EGS and ATS to verify that the audits had been performed in accordance with procedural guidance and that EGS and ATS provided adequate controls for items and materials procured by Namco.

The NRC inspectors noted that both audit reports state in the conclusion that program formalities were reviewed and found to satisfactorily address the intent of 10 CFR 50 Appendix B and 10 CFR Part 21. However, based on the review of the audit reports, the NRC inspectors determined that the reports did not include sufficient objective evidence to support the auditor's conclusions with respect to the areas reviewed. The lack of objective evidence documented in the checklists providing a basis for the conclusions reached in the audit reports has been identified as Nonconformance 99900378/2008-201-04. Namco initiated CAR 08-017 to evaluate the extent of the condition and address this issue.

c. Conclusions

The NRC inspectors determined through a review of Namco's QSL and audit reports that Namco is not implementing a document control process consistent with the regulatory requirements of Criterion VII of Appendix B to 10 CFR Part 50. The NRC inspectors found that there is insufficient evidence indicating how Namco's auditor reviewed the implementation of the

quality assurance programs to assess the effectiveness of the programs and support the audit conclusions regarding the areas reviewed. As a result, there is insufficient evidence for adding audited suppliers to the Namco QSL as Appendix B suppliers. This issue is identified as Nonconformance 99900378/2008-201-04.

3.5 Control of Measuring and Test Equipment

a. Inspection Scope

The NRC inspector reviewed Namco's Qualified Products-Quality Manual and implementing procedures that govern the control of measuring and test equipment (M&TE), implementing procedures, and supporting quality records. The inspector reviewed a sample of M&TE calibrated by Namco calibration suppliers and M&TE calibrated by Namco at its facilities.

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

- Namco Qualified Products-Quality Manual, Revision M.
- CPM-000, "Calibration System Manual," dated August 2007.
- NSP 60-0005, "Qualification of Suppliers," Revision L.
- Audit report for The Tool and Gage House, dated September 22, 2006.
- Audit report for Calibration Solutions, Inc., dated March 3, 2007.
- CAR 08-017, dated April 24, 2008.
- CAR 08-018, dated April 24, 2008.

b. Observations and Findings

Section XII, "Control of Measuring and Test Equipment," of Namco's Qualified Products-Quality Manual states, in part, that calibration records shall be maintained on all equipment. Namco procedure CPM-000 identifies the minimum information required to be maintained for M&TE calibration records.

The NRC inspectors found that the M&TE sampled had appropriate calibration stickers and current calibration dates meeting applicable regulatory and procedural requirements. However, calibration records for M&TE calibrated by Namco at its facility for use on nuclear products were found to be insufficient. Specifically, historical calibration records for the following sample of M&TE, used to perform inspection of materials and products, were not available: Continuity Fixtures (ID NUC-001, NUC-002), Micro Balls (ID MB-1), Pin Gages (ID PGS-1, PGS-3), Torque Wrench (ID 2175), and Surface Plate (ID 157248). The Namco Quality Manager informed the NRC inspector that the only record of Namco-calibrated M&TE is a Microsoft Excel Spreadsheet. Each line of the spreadsheet represents a specific measuring or test equipment item. As measuring or test equipment items are calibrated, the prior calibration information is replaced by the new information.

Loss of historical M&TE calibration information prevents the ability to determine equipment performance trends. Furthermore, if measuring or test equipment performance is found to be unacceptable during calibration, loss of historical calibration records reduces the ability to take effective action regarding materials and products previously inspected using the unacceptable

equipment. This issue is identified as a failure to have appropriate calibration records affecting Namco's M&TE program and is part of Nonconformance 99900378/2008-201-05. Namco initiated CAR 08-018 to evaluate the extent of the condition and address this issue.

Section XII, "Control of Measuring and Test Equipment," of Namco's Qualified Products-Quality Manual states, in part, that only calibrated and controlled M&TE shall be used to determine product acceptance. NSP 60-0005 states, in part, that a satisfactory on-site evaluation (audit) of the supplier's quality program or process controls must be completed.

The NRC inspectors reviewed the qualification records (audit reports) for two Namco calibration services suppliers: The Tool and Gage House located in Charlotte, North Carolina, dated September 22, 2006; and, Calibration Solutions, Inc. located in Cornelius, North Carolina, dated March 3, 2007. The NRC inspectors noted that the audit reports did not contain an attached checklist or supportive documentation of the activities evaluated and conducted during the audit. The NRC inspectors requested the Quality Manager for the checklists. Namco was not able to provide supplier audit checklists for these calibration suppliers. As a result, there is insufficient information supporting the qualifications of Namco calibration suppliers and the accuracy and adequacy of M&TE used to accept commercial grade items for nuclear products. This issue is identified as a failure to have sufficient objective evidence on calibration audit reports affecting Namco's M&TE program and is part of Nonconformance 99900378/2008-201-05. Namco initiated CAR 08-017 to evaluate the extent of the condition and address this issue.

c. Conclusions

The NRC inspectors determined through a review of Namco's calibration records that Namco is generally implementing a M&TE process consistent with the regulatory requirements of Criterion XII of Appendix B to 10 CFR Part 50. However, as identified above, the NRC inspectors found that Namco could not provide historical calibration records for M&TE calibrated by Namco at its facility sufficient to support proper maintenance of M&TE used for inspecting nuclear products. Also, the NRC inspectors found that Namco could not provide sufficient objective evidence on calibration audit reports, such as supplier audit checklists for the qualification of its calibration suppliers. These issues are identified as Nonconformance 99900378/2008-201-05.

3.6 Corrective Action

a. Inspection Scope

The NRC inspectors reviewed the policies and procedures governing the implementation of the Namco corrective action program, and reviewed the corrective actions initiated during the past 24 months. These corrective actions were primarily the result of deficiencies identified by audits findings.

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

- Namco Qualified Products-Quality Manual, Revision M.
- NSP 60-0011, "Corrective Action Requests," Revision F.
- CAR log for nuclear products.

- CAR 07-061, dated October 31, 2007.
- CAR 07-062, dated November 2, 2007.
- CAR 07-068, dated December 12, 2007.
- CAR 07-069, dated December 12, 2007.
- CAR 08-001, dated January 15, 2008.
- CAR 08-009, dated March 31, 2008.
- CAR 08-011, dated April 3, 2008.
- CAR 08-019, dated April 24, 2008.

b. Observations and Findings

NSP 60-0011 defines the measures to generate, track, and close CARs. Namco's corrective action program is a closed-loop system that starts with the identification and documentation of a problem and continues through verification of the actions taken to eliminate the identified root cause. The Quality Department is responsible to issue CARs in response to an identified problem from a variety of sources such as product inspection, an internal quality system audit, a customer audit, customer product surveillance, or customer returned product. All Namco employees are responsible to identify real or potential problems and bring them to the attention of the Quality Department.

The inspectors reviewed CARs generated by Namco on nuclear products during the last 24 months. The inspectors noted that only seven out of 81 CARs generated in the 24-month period were still open. Only three of the 81 CARs had been opened based on returned products by customers. All three CARs were still opened. For two of them (CAR 08-009, and CAR 08-011), Namco is still waiting for the products to be returned, and the other (CAR 07-061) remains open for monitoring field returns to ensure that no other issues exist. Namco initiates a 10 CFR Part 21 evaluation on all returned products, including for CAR 07-061 as discussed in section 3.1 of this report.

During the review of the CARs, the NRC inspectors noted that some of the completed/closed CARs were dispositioned in a timely manner, and proposed corrective actions were generally well documented. However, the NRC inspectors found four closed CARs (CAR 07-062, CAR 07-068, CAR 07-069, and CAR 08-001) related to procedural guidance updates that required a corrective action to train personnel had been closed without objective evidence that all actions were completed before closing the CAR. This issue is a failure to follow requirements affecting the quality of Namco's corrective action program and is identified as Nonconformance 99900378/2008-201-06. Namco initiated CAR 08-019 to evaluate the extent of the condition and address this issue.

c. Conclusions

The NRC inspectors determined through a review of Namco's CARs that Namco's corrective action program requirements were adequately described in Namco's Qualified Products-Quality Manual and associated procedures. In addition, the NRC inspectors concluded that program requirements were consistent with the requirements for identifying and correcting conditions adverse to quality described in Appendix B to 10 CFR Part 50, Criterion XVI, "Corrective Actions." However, as identified above, the NRC inspectors determined that the corrective

action program was not adequately implemented in accordance with Namco's administrative requirements. This issue is identified as Nonconformance 99900378/2008-201-06.

3.7 Document Control

a. Inspection Scope

The NRC inspectors reviewed implementation of Namco's processes for document control for the supply of items and components subject to the regulations of Appendix B to 10 CFR Part 50. The NRC inspectors reviewed policies and procedures governing Namco's document control processes to verify the overall extent and effectiveness of its programs for meeting the requirements of Criterion VI, "Document Control," of Appendix B to 10 CFR Part 50. The NRC inspectors verified that Namco's quality related documents were developed, reviewed, approved, issued, used, and revised under an established program.

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

- Namco Qualified Products-Quality Manual, Revision M.
- NSP 60-0013, "Control of Quality Program Documents," Revision F.
- QCP-009, "Control of Forms," Revision C.
- NSP 60-0007, "Internal Document Control," Revision I.
- Master copy and controlled copy of the Qualified Products-Quality Manual.
- Master copy and controlled copy of the QCPs.
- CAR 08-020, dated April 24, 2008.
- CAR 08-021, dated April 24, 2008.
- CAR 08-022, dated April 24, 2008.

b. Observations and Findings

NSP 60-0013 provides for the review, approval, and ownership of the NSP documents, quality program forms, and the Namco Qualified Products-Quality Program Manual. Section 8.1.1.1 and 8.2.1.1 of NSP 60-0013 requires having only two sets of controlled hard copies of the Namco Qualified Products-Quality Manual and NSPs in the printed form; the master copy with original signatures is in the document storage area and the second copy in the inspection area. The NRC inspectors reviewed controlled hard copies of the Qualified Products-Quality Manual and of the NSP procedures to verify that they were being maintained in accordance with Namco's document control program. In accordance with Section 8.4.2 of NSP 60-0013, the second copy should be identified with a controlled copy or set number. The NRC inspectors observed that the second controlled hard copy of Namco's NSP procedures did not contain any formal identification such as a control number. This issue is an example of a failure to follow a procedure affecting the quality of Namco's document control program and is identified as Nonconformance 99900378/2008-201-08. Namco initiated CAR 08-020 to evaluate the extent of the condition and address this issue.

QCP-009 provides for the preparation, issuance and control of Quality Forms used in the Namco quality system. Section 5.2.4 of QCP-009 requires that a controlled binder that includes a table of contents and a copy of the current version of each approved form should be

maintained in the Quality Department in addition to having a masters form tables of contents and forms in the Records Storage area. When the NRC inspectors asked the Quality Manager for such copy, Namco's Quality Manager stated that there is only one controlled copy of the Quality Forms and no master copy exists in the records storage area, as required by QCP-009. This issue is another example of a failure to follow a procedure affecting the quality of Namco's document control program and is identified as Nonconformance 99900378/2008-201-08. Namco initiated CAR 08-021 to evaluate the extent of the condition and address this issue.

Namco's Qualified Products-Quality Manual states that the Quality Manager maintains a controlled copy list of the quality program documentation issued internally and externally. In addition, Section 4.2.6 of NSP 60-0013 requires that the Quality Manager maintains a list of all controlled copies of quality program documents issued internally and externally. The list is required to contain the controlled copy or set number, the designated holder, and the date issued. The NRC inspectors requested the Quality Manager for the list of controlled copies. Namco's Quality Manager was not able to produce such a list. This issue is another example of a failure to follow a procedure affecting the quality Namco's document control program and is part of Nonconformance 99900378/2008-201-08. Namco initiated CAR 08-020 to evaluate the extent of the condition and address this issue.

The NRC inspectors also reviewed a sample of NSPs, QCPs, and Quality Forms and observed that they were of the correct revision. Additionally, the NRC inspectors compared the master copy and controlled copy of the Qualified Products-Quality Manual, the QCPs, and a sample of NSP procedures and verified that both copies were equal to one another and that were the latest revision.

NSP 60-0013 requires that "Superseded versions of NSP documents and the NSP table of contents shall be marked superseded or obsolete and deleted from or moved to a secure location on the local access network (LAN). Section 8.2.3 of NSP 60-0013 requires that the hard copies must be discarded upon internal distribution of the approved replacement versions. The NRC inspectors observed that superseded hard copy versions of NSP documents were still filed in the same location with the latest approved revision. This issue is another example of a failure to follow a procedure affecting the quality of Namco's document control program and is part of Nonconformance 99900378/2008-201-08.

NSP 60-0013 requires that "An Index of Quality Forms, controlled by version, shall be prepared and indicate the latest approved version of each form. The index shall be authorized by the quality manager and contain the form name, form number, and revision level of each form." Section 6.2.4 of the same procedure states: "Record of revisions – A specific separate form that documents the revision history of the form and includes the revision date, revision level, and a brief description of the changes." The NRC inspector observed that in addition to having all the information required by procedure for the index, the index also included the date of the revision. The NRC inspectors identified that for some of the quality forms, the revision date on the index did not match the revision date on the Revision Record for each form. This issue is another example of a failure to follow a procedure affecting the quality of Namco's document control program and is part of Nonconformance 99900378/2008-201-08. Namco initiated CAR 08-021 to evaluate the extent of the condition and address this issue.

NSP 60-0007 establishes the system for distribution and control of engineering changes, Work Order Routings, Floor Job Instructions (FJIs), Inspection Reports (IRs) and DIRs. The NRC

inspectors reviewed a sample of Work Order Routings, FJIs, IRs, and DIRs to verify these documents had been reviewed and signed by quality personnel as required by NSP 60-0007. The NRC inspectors observed that both FJIs were reviewed and approved by quality personnel. However, the inspector noted that one FJI included the inspector signature, while the other FJI was initialized, with the date and the inspector's stamp. The NRC inspectors discussed this with the Quality Manager. The Quality Manager could not explain the reason for the difference on the review and approval of these FJIs. The NRC inspectors found that although the procedure lacks guidance on when the quality inspectors should sign the FJI and when they should be initialed, dated, and stamped, both FJIs were adequately revised and approved by the quality inspector. Even though not required, Namco initiated CAR 08-022 to address the issue of how quality inspectors should record their review, observation, or acceptance of internal documents such as FJIs.

c. Conclusions

The NRC inspectors determined through a review of Namco's quality program documents and procedures that Namco developed and is generally implementing a document control process consistent with the regulatory requirements of Criterion VI of Appendix B to 10 CFR Part 50 and industry guidance as well as Namco's quality program and implementing procedure guidance. However, as identified above, the NRC inspectors found several examples where Namco failed to follow procedures affecting Namco's document control program. These issues were identified as examples of Nonconformance 99900378/2008-201-08.

3.8 Handling, Storage, and Shipping

a. Inspection Scope

The NRC inspectors reviewed Namco's Qualified Products-Quality Manual and applicable implementing procedures to assess compliance with the requirements of Criterion XIII, "Handling, Storage and Shipping," of Appendix B to 10 CFR Part 50. The NRC inspectors reviewed sections of Namco's Qualified Products-Quality Manual and associated procedures to verify that Namco maintains a program that effectively controls the handling, storage, and shipping of items and components to prevent damage or deterioration.

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

- Namco Qualified Products-Quality Manual, Revision M.
- NSP 50-0001, "Packaging, Storage, and Shipping," Revision E.
- NSP 50-0002, "Preservation Packaging," Revision G.
- Namco instructions QF24A, "Assembly Inspection Record EA170/EA180 Limit Switches," Revision H.

b. Observations and Findings

Section XIII, "Handling, Storage, and Shipping," of Namco's Qualified Products-Quality Manual states, in part, that orders not requiring special packaging shall be packaged in accordance with documented procedures. The NRC inspector observed the assembly of two EA180-31402 Limit

Switches under work order 411585. Namco personnel used instructions QF24A to complete the assembly of the two limit switches. The NRC inspectors noted that the AIR specified the steps for assembling the limit switches, the inspection and test procedures, and the acceptance criteria. In the AIR, Step 12 of the Final Inspection provided instructions to perform the packaging of the limit switch in accordance with NSP 50-0002. During the packaging of one of the limit switches, the NRC inspector observed that the Namco inspector did not have the packaging procedure available at the location as required by Criterion VI, "Document Control," of Appendix B to 10 CFR Part 50. The NRC inspectors observed that the Namco employee was knowledgeable about the requirements of NSP 50-0002 and had properly packed the limit switch in accordance with the procedure. Further, Namco took action to address the issue prior to the end of the inspection by making the procedure available at the location of packaging. While this action was not documented in Namco's corrective action program, a nonconformance is not being cited because NSP 50-0002 was being effectively implemented and Namco took prompt and appropriate corrective action.

The NRC inspector verified the storage areas for nuclear grade material. The NRC inspector observed and assessed actual techniques being used for storage and their acceptability relative to Namco's NSP 50-0001 requirements. The NRC inspector did not identify any issue in this area.

c. Conclusions

The NRC inspector concluded that Namco's handling, storage, and shipping controls are consistent with the regulatory requirements of Criterion XIII of Appendix B to 10 CFR Part 50. Based on the limited sample of documents and activities reviewed, the NRC inspectors determined that Namco's Qualified Products-Quality Manual and associated handling, storage, and shipping procedures were effectively implemented.

3.9 Training and Qualification

a. Inspection Scope

The NRC inspectors reviewed Namco's policies and procedures for the indoctrination and training of personnel performing activities affecting quality to assess compliance with the requirements of Criterion II, "Quality Assurance Program," of Appendix B to 10 CFR Part 50 and to assure that proficiency was achieved and maintained.

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

- Namco Qualified Products-Quality Manual, Revision M.
- NSP 60-0009, "Procedure for Personnel Training and Qualification," Revision F.
- Quality Form 54, "Inspector Training Log."
- Quality Form 106, "Assembly Personnel Training for Qualified Products."
- CAR 08-023, dated April 24, 2008.
- CAR 08-024, dated April 24, 2008.

b. Observations and Findings

NSP60-0009 contains controls Namco has in place for the training and qualification of assembly, inspection, quality test, and audit personnel. Specifically, NSP 60-009 defines the minimum requirements for the indoctrination and training of personnel performing activities affecting quality, including assembly personnel, inspection and quality test personnel, and lead auditors and auditors. Training for assembly, inspection and quality test personnel consists of: 10 CFR Part 50 Appendix B; 10 CFR Part 21; Energy Reorganization Act Section 206, "Noncompliance," and Section 210, "Unresolved Safety Issues Plan;" Section 223(b), "Violation of Sections Generally," of the Atomic Energy Act; NSP 60-0012; and, an overview of the Namco Qualified Products-Quality Manual. In addition to these training requirements, lead auditors are trained on American National Standard Institute (ANSI) N45.2.23, "Qualification of Quality Assurance Program Audit Personnel for Nuclear power Plants," ANSI N45.2.12, "Requirements for Audit Team of quality Assurance Program for Nuclear Power Plants," and NSP 60-006, "Guidelines for Auditing Quality Systems." In addition, the procedure states that the qualification and proficiency of inspection, quality test, and audit personnel shall be reviewed and documented annually.

Namco currently has eight pre-assembly personnel, two assembly personnel, two inspection and quality test personnel, and three lead auditors. The NRC inspectors reviewed the files of assembly, inspection, quality test, and audit personnel and found several examples of personnel's required training not documented as being completed or performed as required by NSP 60-0009. Training regarding the Energy Reorganization Act, Sections 206 and 210 for pre-assembly personnel was not documented as being completed. In addition, one of the assemblers did not have training on the Assembly Functions documented as being completed per Quality Form 106. Furthermore, the backup assembler did not have the General Awareness training documented as completed per Quality Form 54. This issue is an example of a failure to follow a procedure affecting the quality of Namco's training and qualification of personnel and is identified as Nonconformance 99900378/2008-201-09. Namco initiated CAR 08-023 to evaluate the extent of condition and address this issue.

During the review of the lead auditors' records, the NRC inspectors observed that documentation supporting the lead auditors' annual re-qualification was not provided in the training file. The Namco Quality Manager indicated that the documentation was in his possession but not in the training files of the lead auditors. The Quality Manager was able to provide such documentation and the NRC inspectors reviewed the annual re-qualifications records and observed that the qualifications were in accordance with NSP 60-0009. Annual reviews were performed and documented, and the certification documented the required information. Namco initiated CAR 08-024 to address the issue of where the lead auditors' re-qualification records are located and to evaluate the extent of the condition.

Section 3.4 of Namco Qualified Products-Quality Manual, Quality Assurance Program, Section II, states, in part, that "Quality Department associates are trained in accordance with applicable Namco procedures." Procedure NSP 60-0009 only identifies the training and qualifications requirements for assembly, inspection, quality test, and audit personnel. The NRC inspectors observed a discrepancy between Namco Qualified Products-Quality Manual and procedure NSP 60-0009. Specifically, the NRC inspectors noted that NSP 60-0009 did not required training and qualification for all quality personnel as required by Namco Qualified Products-Quality Manual. This inconsistency is an example of inadequate procedure affecting Namco's

training and qualification of personnel and is identified as Nonconformance 99900378/2008-201-09. Upon further review of the training records for all quality personnel, the NRC inspectors identified that all Namco quality personnel have been trained in accordance with the Qualified Products-Quality Manual.

c. Conclusions

Except for the issue identified in Nonconformance 99900378/2008-201-09, the NRC inspectors concluded that the training requirements provided by Namco are consistent with the regulatory requirements of Criterion XI of Appendix B to 10 CFR Part 50. The NRC inspectors identified several examples where the personnel training and qualification process was not implemented in accordance with Namco policies and procedures. The NRC inspectors concluded that training had not been adequately identified, documented, and maintained as required by procedures.

4.0 MANAGEMENT MEETINGS AND PERSONNEL CONTACTED

4.1 ENTRANCE AND EXIT MEETINGS

In the entrance meeting on April 21, 2008, the NRC inspectors discussed the scope of the inspection, outlined the areas to be inspected, and established interfaces with the Namco Plant Manager, Quality Manager and staff. During the exit meeting on April 25, 2008, the NRC inspectors discussed the inspection findings and observations with the Namco Plant Manager, Quality Manager and staff.

4.2 PERSONNEL CONTACTED

Jamey Robbins	Plant Manager
Ken Gould	Quality Manager
Douglas Coe	Product Manager
Ray Lewis	Value Stream Manager
Sean C. Parker	Human Resources Manager
James Shupe	Buyer
David Donavan	Senior Development Engineer
Troy Carson	Product Specialist
Hollis Deason	Quality Inspector
Tina Osborne	Nuclear Builder
Tammy Johnson	Customer Service Manager
Sudhi Bangalore	Director, Product Development