

December 4, 2008

Mr. John Dekleine
Quality Assurance Director
Enertech
2950 Birch Street
Brea, CA 92821

SUBJECT: NRC INSPECTION REPORT NO. 99901377/2008-201 AND NOTICE OF
NONCONFORMANCE

Dear Mr. Dekleine,

On September 15-18, 2008, U.S. Nuclear Regulatory Commission (NRC) inspectors conducted an inspection at the Enertech facility in Brea, California. The enclosed report presents the details of that inspection.

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

During this inspection, the NRC found that the implementation of your QA program failed to meet certain NRC requirements which are discussed in the enclosed Notice of Nonconformance (NON) and NRC Inspection Report. Specifically, deficiencies were noted in the following activities: 1) failure to adopt effective commercial grade dedication procedures; 2) failure to provide adequate training for the use of sampling plans in commercial grade dedication activities; 3) failure to provide adequate traceability for tested items; 4) failure to maintain adequate document control; and 5) failure to provide adequate oversight of contractors and subcontractors. These nonconformances are cited in the enclosed NON, and the circumstances surrounding them are described in the enclosed report. You are requested to respond to the nonconformances and should follow the instructions specified in the enclosed NON when preparing your response.

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 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 2
Division of Construction Inspection
& Operational Programs
Office of New Reactors

Docket No. 99901377

Enclosures:

1. Notice of Nonconformance
2. Inspection Report No. 99901377/2008-201 and Attachment

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.

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/RA/

John A. Nakoski, Chief
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DATE	11/21/2008		12/4/2008		11/21/2008		12/4/2008	
OFFICE	NRO/DCIPCQVP	E	NRO/DCIPCQVP	E	NRR/DE/EQVB	E	NRO/DE/CIB1	E
NAME	JN for GGalletti		MConcepcion		JN for PPrescott		EReichelt	
DATE	12/4/2008		11/21/2008		12/4/2008		11/20/2008	

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NOTICE OF NONCONFORMANCE

Enertech
2950 Birch Street
Brea, CA 92821

Docket Number 99900378
Inspection Report Number 2008-201

Based on the results of a Nuclear Regulatory Commission (NRC) inspection conducted on September 15-18, 2008, of activities performed at Enertech's facility in Brea, California, it appears that certain activities were not conducted in accordance with NRC requirements.

- A. Criterion V, "Instructions, Procedures, and Drawings," of Appendix B to 10 CFR Part 50, states, in part, that "activities affecting quality shall be prescribed by documented instructions, procedures, or drawings, of a type appropriate to the circumstances and shall be accomplished in accordance with these instructions, procedures, or drawings."

Enertech Operating Procedure (EOP) 3140, "Procedure for the Dedication of Commercial Grade Items/Services," Revision AB, dated July 31, 2008, provides the methods for the dedication of commercial grade items and/or services used in nuclear safety applications.

Contrary to the above, as of September 18, 2008:

Enertech failed to provide adequate procedural guidance in EOP 3140 for dedication of commercial grade items. Specifically:

- EOP 3140 did not include the appropriate 10 CFR 21.3 definitions applicable to the dedication of commercial grade items. The NRC inspectors noted that the procedure did not include the correct definitions for "commercial grade item," "basic component," "dedication," and "critical characteristics," as defined in 10 CFR Part 21.
- EOP 3140 did not incorporate the restrictions to EPRI 5652, "Guideline for the Utilization of Commercial-Grade Items in Nuclear Safety-Related Applications," dated June 1988, as stated in Generic Letter (GL) 89-02, "Actions to Improve the Detection of Counterfeit and Fraudulently Marketed Products," dated March 21, 1989. The NRC inspectors noted that the procedure did not include the restrictions contained in GL 89-02. Specifically, Enertech's implementation of Method 2 did not include controls for the acceptance of items from suppliers with undocumented commercial quality control programs. In addition, the procedure did not include controls for accepting items from distributors consistent with GL 89-02.
- EOP 3140 did not provide adequate guidance for the dedication ("upgrade") of raw material. Subsection 7.9 of EOP 3140 states that "in case of 'upgrading' raw material, a CGI dedication need not be performed, since it is understood that the critical characteristic is the type of material, verifiable by testing, as deemed appropriate by engineering." EOP 3310, "Procedure for the Preparation of the Routing," Revision Q, dated September 12, 2008, provides criteria for handling raw material and states that "'upgrading' of raw material from commercial grade to 'safety-related' could be done by either testing using the XRF alloy analyzer to

confirm material type, or by performing a hardness test to verify the material's tensile strength." The NRC inspectors determined that this process is CGI dedication, not part of the routing process, and should have been described in EOP 3140.

- EOP 3140 did not provide adequate guidance for the development of sampling plans consistent with known industry standards. The NRC inspectors determined that Enertech's sampling plan methodology was inconsistent with the guidance described in EPRI 7218, "Guideline for Sampling in the Commercial-Grade Item Acceptance Process," dated January 1999, for the use of normal, reduced, or tightened sampling plans.

These issues have been identified as examples of Nonconformance 99901377/2008-201-01.

- B. Criterion III, "Design Control," of Appendix B to 10 CFR Part 50, states, in part, that "applicable regulatory requirements and the design basis are correctly translated into specifications, drawings, procedures, and instructions." It also states 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."

Criterion VIII, "Identification and Control of Materials, Parts, and Components," of Appendix B to 10 CFR Part 50, states, in part, that "measures shall be established for the identification and control of materials, parts, and components, including partially fabricated assemblies. These measures shall assure that identification of the item is maintained by heat number, part number, serial number, or other appropriate means, either on the item or on records traceable to the item."

Subsection 3.3.4.2 of Enertech's QAM states, in part, that "adequacy of the design shall be verified by independent design review, alternate calculations, qualification testing, or any combination of these methods."

Section 8.0 of Enertech's QAM states, in part, that this section "establishes controls for identification of items to provide requirements that assure traceability."

Contrary to the above, as of September 18, 2008:

Certain dedication packages reviewed did not include adequate traceability for items tested using the XRF alloy analyzer. The NRC inspectors noted that the dedication plan for two packages for pressure switches and relief valves did not provide adequate traceability to the items selected for test. The NRC inspectors also identified inconsistencies between test results using the XFR alloy analyzer in that some test result sheets were traceable to the test piece and others were not.

This issue has been identified as Nonconformance 99901377/2008-201-02.

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

Subsection 2.3.6 of Enertech's Quality Assurance Manual (QAM), Revision 14, states, in part, that "The Director of Quality Assurance promotes and maintains effective indoctrination and training for personnel performing or managing activities affecting quality. Training and indoctrination shall be conducted in accordance per the applicable Enertech Operating Procedure (EOP) and documented using a Training Record form. Each Department Manager is responsible for the training of individuals within their department to assure proficiency is established and maintained to this QA Manual and applicable EOP."

Contrary to the above, as of September 18, 2008:

Enertech did not conduct adequate training for the use of sampling plans in commercial grade dedication activities due to inadequate procedural guidance contained in EOP 3140, "Procedure for the Dedication of Commercial Grade Items/Services," Revision AB, dated July 31, 2008. The NRC inspectors inquired about the training activities conducted by Enertech to ensure that responsible individuals maintain proficiency on dedication activities, including implementation of sampling plans as discussed in EPRI 7218, "Guideline for Sampling in the Commercial-Grade Item Acceptance Process," dated January 1999. EOP 3140 did not include an adequate set of controls for sampling plans consistent with EPRI 7218. The NRC inspectors learned that no classroom type training with a training record form had been conducted on EPRI 7218; only self-study training of EOP 3140.

This issue has been identified as Nonconformance 99901377/2008-201-03.

- D. Criterion VI, "Document Control," of Appendix B to 10 CFR Part 50, states, in part, that "measures shall be established to control the issuance of documents, such as instructions, procedures, and drawings, including changes thereto, which prescribe all activities affecting quality. These measures shall assure that documents, including changes, are reviewed for adequacy and approved for release by authorized personnel and are distributed to and used at the location where the prescribed activity is performed."

Subsection 6.8.2 of EOP 3140, states, in part, that all dedications shall be documented in the Dedicated Product/Service Log, which is identified in the EOP as Attachment 3140-3.

EOP 3120, "Procedure for Identification, Release, and Revision of Design Documents," Revision R, dated July 30, 2008, provides specific instructions for identification, preparation, release, and revision of design documents. Subsection 6.2.1 states, in part, that document numbers for design documents generated by Enertech shall be obtained from the Drawing Number Register (DNR) (identified as attachment 3120-1) in the Document Control Department.

EOP 3502, "Preparing and Controlling the Engineering Drawing Change Order," Revision M, dated July 31, 2008, provides specific instructions for the use, preparation and distribution of the Engineering Drawing Change Order (ECO). Section 6.3 identifies that the ECO will document changes to CAD drawings. These changes to design and drawings shall be circulated through the checking/approval cycle so that the drawing will have original signatures only for that latest revision. Subsection 6.3.3 states that after

the checking/approval cycle, the file update described in EOP 3120 for Filing of Design Document shall be performed.

Subsection 6.5.4 of Enertech EOP 8072, "Procedure for Receiving Inspection," Revision R, dated August 1, 2008, states, in part, that when specified by codes, standards or specifications that include specific identification or traceability requirements (such as identification or traceability of the item to applicable specification and grade of material; heat, batch, lot, part or serial number; or specified inspection, test or other records), the Quality Control Inspector shall verify during Quality Control inspection that all requirements are met. Instructions for inspection of each product form [i.e. castings, forgings/bar, plate, etc.] are maintained in a Receiving Inspection Check List Log in QA (Attachment 8072-1).

Contrary to the above, as of September 18, 2008:

- The Enertech Dedicated Product/Service log located in the inspection area was different from the applicable log currently identified in EOP 3140. Subsection 6.8.2 of EOP 3140 states that all dedications shall be documented in the Dedicated Product/Service Log, (identified as Attachment 3). Additionally, there was no revision control (i.e., Rev. A) on the Attachment in the EOP.
- Enertech did not have the DNR identified as Attachment 3120-1 as required by the latest revision of EOP 3120. Subsection 6.2.1 of EOP 3502 states that "document numbers are obtained from the Drawing Number Registrar (DNR) (identified as attachment 3120-1) and should be located in the Document Control Department." While reviewing the latest revision of the EOP, it was found that there was no Attachment 3120-1 in the EOP.
- As required by EOP 3502, Enertech did not have the ECO in the Design Document File or in the Master File for a specific production order. EOP 3502 provides instructions for the use, preparation and distribution of the ECO. Subsection 6.3.3 of EOP 3502 states that "after the checking/approval cycle, the file update described in EOP 3120 for Filing of Design Document shall be performed." Design Report MA22149 identified ECO 5-16415 dated February 28, 2008, that was not in the design document file.
- Enertech has implemented an electronic database (BAAN) to record instructions for inspections of each product form. However, EOP 8072 still requires maintaining the Receiving Inspection Check List Log (Attachment 8072-1), and Enertech did not adequately revise EOP 8072 to reflect the implementation of the BAAN database.

These issues have been identified as examples of Nonconformance 99901377/2008-201-04.

- E. Criterion VII, "Control of Purchased Material, Equipment and Services," of Appendix B to 10 CFR Part 50, states, in part, that "the effectiveness of the control of quality by contractors and subcontractors shall be assessed by the applicant or designee at intervals consistent with the importance, complexity, and quantity of the product or services."

Subsection 7.3.2.2 of Enertech's QAM states that non-code suppliers not on the Approved Suppliers List (ASL) may be selected for forming and machining operations when the dimensional requirements for the forming and machining operations can be verified at receipt and the material identification has not been removed by these operations.

EOP 8072, "Procedure for Receiving Inspection," Revision R, dated August 1, 2008, Subsection 6.5.1, states, in part, that safety-related items can be procured from a supplier not on the ASL. Subsection 6.5.2 states that safety-related components may be machined by suppliers not on the ASL.

Contrary to the above, as of September 18, 2008:

Enertech procedural controls governing purchased material, equipment, and services do not always require the assessment of the effectiveness of contractors and subcontractors control of quality and allows for purchase of safety-related components and services from suppliers without such assessment. QAM Subsection 7.3.2.2 states that non-code suppliers not on the ASL may be selected for forming and machining operations when the dimensional requirements for the forming and machining operations can be verified at receipt and the material identification has not been removed by these operations. Furthermore, Subsection 6.5.1 of EOP 8072, states that safety-related items can be procured from a supplier not on the ASL and Subsection 6.5.2 of EOP 8072 states that safety-related components may be machined by suppliers not on the ASL. Specifically, EOP 8072 allows Enertech to procure safety-related items from suppliers not included on the ASL for these situations.

This issue has been identified as Nonconformance 99901377/2008-201-05.

**U.S. NUCLEAR REGULATORY COMMISSION
OFFICE OF NEW REACTORS
DIVISION OF CONSTRUCTION INSPECTION AND
OPERATIONAL PROGRAMS**

VENDOR INSPECTION REPORT

Docket No.: 99901377

Report No.: 99901377/2008-201

Vendor: Enertech
2950 Birch Street
Brea, CA 92821
(714) 528-2301

Vendor Contact: John Dekleine
Quality Assurance Director
RDeKleine@curtisswright.com

Nuclear Industry: Enertech is a Division of the Curtiss-Wright Flow Control Company. Enertech is a major supplier of safety-related ASME Code valves, safety-related pumps (including spare parts, upgrades, maintenance, etc.), large bore and pipe support snubbers, pneumatic actuators, motors, safety-related instrumentation, diagnostic and test equipment, service and repair, and engineering services to the nuclear power industry.

Inspection Dates: September 15-18, 2008

Inspection Team: Richard McIntyre NRO/DCIP/CQVB Lead Inspector
Yamir Diaz-Castillo NRO/DCIP/CQVB
Michael Morgan NRO/DCIP/CQVB
Greg Galletti NRO/DCIP/CQVP
Milton Concepcion NRR/DCIP/CQVP
Paul Prescott NRR/DE/EQVB
Eric Reichelt NRO/DE/CIB2

Approved By: /RA/ 12/04/2008

John A. Nakoski, Chief
Quality & Vendor Branch 2
Division of Construction Inspection
& Operational Programs
Office of New Reactors

Date

EXECUTIVE SUMMARY

Enertech
99901377/2008-201

The purpose of this inspection was to verify the implementation of the Enertech's quality assurance (QA) program and the program under Title 10, Part 21, "Reporting of Defects and Noncompliance," of the *Code of Federal Regulations* (Part 21). The U.S. Nuclear Regulatory Commission (NRC) inspectors reviewed selected portions of Enertech's QA and 10 CFR Part 21 controls established and implemented to meet the regulations set forth in Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants," to 10 CFR Part 50, "Domestic Licensing of Process and Utilization Facilities," and 10 CFR Part 21, respectively. The NRC conducted the inspection at the Enertech facility in Brea, California.

The following were the NRC inspection bases:

- Appendix B to 10 CFR Part 50
- 10 CFR Part 21

The NRC inspectors implemented Inspection Procedure (IP) 43002, "Routine Inspections of Nuclear Vendors;" IP 43004, "Inspection of Commercial-Grade Dedication Programs;" and IP 36100, "Inspection of 10 CFR Part 21 and 50.55(e) Programs for Reporting Defects and Nonconformance" during the conduct of this inspection.

There were no previous NRC inspections performed at Enertech's facility prior to this inspection. The results of the inspection are summarized below.

With the exception of the areas described below, the NRC inspectors concluded that Enertech's QA policies and procedures were in compliance with the applicable requirements of 10 CFR Part 21 and Appendix B to 10 CFR Part 50 and that Enertech personnel were implementing these policies and procedures effectively.

Instructions, Procedures, and Drawings

The NRC inspectors issued Nonconformance 99901377/2008-201-01 for Enertech's failure to adopt effective commercial grade dedication procedures. Specifically, Enertech's procedure for commercial grade dedication did not include the following guidance: 1) Appropriate 10 CFR 21.3 definitions applicable to the dedication of commercial grade items, 2) appropriate restrictions to EPRI 5652 as stated in GL 89-02, 3) adequate guidance for the dedication ("upgrade") of raw material, and 4) adequate guidance for the development of sampling plans consistent with known industry standards.

Design Control

The NRC inspectors issued Nonconformance 99901377/2008-201-02 for Enertech's failure to provide adequate traceability for tested items in dedication packages as part of Enertech's commercial grade dedication process.

Quality Assurance Program – Training and Qualification

The NRC inspectors issued Nonconformance 99901377/2008-201-03 for Enertech's failure to provide adequate training for the use of sampling plans in commercial grade dedication activities due to inadequate procedural guidance contained in EOP 3140, "Procedure for the Dedication of Commercial Grade Items/Services."

Document Control

The NRC inspectors issued Nonconformance 99901377/2008-201-04 for Enertech's failure to effectively implement and maintain quality assurance procedures associated with document control. EOP 8072 requires that instructions for inspection of safety-related and ASME code items and services are maintained in a Receiving Inspection Check List Log in QA. The Receiving Inspection Check List Log in QA is no longer maintained, and as of July 2005, was replaced with the use of an electronic database (BAAN). This process change was adequately captured in a revision to the QA Manual but was not adequately incorporated into EOP 8072.

Control of Purchased Material, Equipment, and Services

The NRC inspectors issued Nonconformance 99901377/2008-201-05 for Enertech's failure to provide adequate oversight of contractors and subcontractors by allowing the purchase of safety-related components and services from suppliers without an assessment of the effectiveness of the supplier's quality controls.

REPORT DETAILS

1. 10 CFR Part 21 Program

a. Inspection Scope

The Nuclear Regulatory Commission (NRC) inspectors reviewed Enertech's policies and implementing procedures that govern the 10 CFR Part 21 program to verify compliance with the requirements of 10 CFR Part 21, "Reporting of Defects and Noncompliances." In addition, the NRC inspectors evaluated the 10 CFR Part 21 postings and a sampling of Enertech's purchase orders (POs) for compliance with the requirements of 10 CFR 21.6, "Posting Requirements," and 10 CFR 21.31, "Procurement Documents," respectively. Specifically, the NRC inspectors reviewed the following policies and procedures established by Enertech:

- Enertech Quality Assurance Manual (QAM), Section 4, "Procurement Document Control," 4th Edition, Revision 14, dated August 13, 2008.
- Enertech Operating Procedure (EOP) 8200, "Employee Non-Discrimination Rights, and Reporting Requirements Concerning Defects & Noncompliance", Revision "L", dated July 2, 2008.
- EOP 8160, "Procedure for Corrective Action", Revision "Q", dated April 28, 2008.
- EOP 8150, "Processing of Nonconforming Material Reports", Revision "V", dated August 1, 2008.

b. Observations and Findings

b.1 Postings

The NRC inspectors evaluated Enertech's compliance with the posting requirements of 10 CFR 21.6. The NRC inspectors found that Enertech 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 current copy/revision of Enertech EOP 8200, and a notice which included the name and telephone number of Enertech's 10 CFR Part 21 contact: Enertech's Quality Assurance (QA) Director.

b.2 10 CFR Part 21 Procedure

EOP 8200 outlines the procedure and responsibilities to identify, control, document, and resolve conditions used for the reporting of defects and noncompliance discovered at Enertech or products returned by customers. During the review of the procedure, the NRC inspectors noted that this procedure contained adequate guidance to meet the regulatory requirements of 10 CFR Part 21.

Section 7.10 of EOP 8160 states that corrective action requests (CARs) will be trended quarterly and during this trend assessment CARs will be evaluated for 10 CFR Part 21 applicability. The NRC inspectors further noted that Subsection 6.8.5(f) of EOP 8150 provides instructions for the initial evaluation of defects during the preparation of an Enertech Nonconforming Material Reports (NMRs) and that during the preparation of the NMRs, an initial

assessment of Part 21 applicability is presented. Sections 6.4 and 6.5 of EOP 8200 provide additional guidance/instruction for the discovery of the defect, and further evaluation of the nonconformance/defect for possible 10 CFR Part 21 processing. Subsection 6.5.1 of EOP 8200 states that a Part 21 evaluation file will be established by Enertech's QA Director and Subsection 6.5.4 of the EOP states that the General Manager of Enertech will be approached for final approval and concurrence if a defect has been determined to be potentially reportable.

The NRC inspectors discussed Enertech's 10 CFR Part 21 program with Enertech's QA Director, one of Enertech's QA Engineers and two of Enertech's Product Engineers. The NRC inspectors determined that EOP 8160 and 8150 contained adequate procedural guidance to initiate Enertech's 10 CFR Part 21 process when a CAR or NMRs evaluation determined that a reportable defect exists. The NRC inspectors also determined that Enertech's staff was knowledgeable about the conditions that would warrant a 10 CFR Part 21 evaluation.

b.3 10 CFR Part 21 Implementation

The NRC inspectors requested copies of records of 10 CFR Part 21 evaluations that Enertech had completed. The inspectors discovered that Enertech management had performed only one potential 10 CFR Part 21 evaluation as a result of an identified deviation. The evaluation completed on April 7, 2005, determined that the issue, a product assessment/evaluation inconsistent with Enertech procedures, did not present a substantial safety hazard (SSH) and that a further evaluation of the issue was not required. The issue was therefore removed by Enertech management from any further 10 CFR Part 21 considerations.

b.4 Purchase Orders (POs)

The NRC inspectors reviewed four Enertech and Enertech Supplier POs and verified that Enertech had implemented a program consistent with the requirements described in 10 CFR 21.31 regarding specifying the applicability of 10 CFR Part 21 in its POs for basic components.

Subsection 4.3.2(H) of Enertech's QAM requires POs to contain 10 CFR 21 requirements as appropriate. Enertech 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. All reviewed POs contained the above 10 CFR Part 21 provision.

c. Conclusions

The NRC inspectors concluded that Enertech's program requirements for 10 CFR Part 21 were consistent with the regulatory requirements of 10 CFR Part 21 and were being effectively implemented.

2. Commercial Grade Item Dedication

a. Inspection Scope

The NRC inspectors reviewed Enertech's QA policies and implementing procedures that govern the dedication of commercial grade items (CGIs) for use in safety-related applications to verify compliance with applicable regulatory requirements. Specifically, the NRC inspectors reviewed the following procedures established by Enertech:

- EOP 3140, “Procedure for the Dedication of Commercial Grade Items/Services,” Revision AB, dated July 31, 2008.
- EOP 3310, “Procedure for the Preparation of the Routing,” Revision Q, dated September 12, 2008.

The NRC inspectors also reviewed several dedication packages, including dedication plans, the criteria for the selection of critical characteristics, the basis for sampling plan selection, and the selection of verification methods to verify effective implementation of the Enertech’s commercial grade items (CGIs) dedication process.

b. Observations and Findings

EOP 3140 provides the details and instructions describing the authority, responsibilities, and methods to be implemented by Enertech to dedicate and control CGIs in safety-related applications. The NRC inspectors noted that EOP 3140 provided adequate controls for dedication activities, including CGI evaluation criteria, procurement controls, acceptance/rejection criteria consistent with safety function, material traceability controls, and controls for receipt inspection and test activities.

During the review of EOP 3140, the NRC inspectors noted that the procedure did not include the correct definitions for “commercial grade item,” “basic component,” “dedication,” and “critical characteristics,” as defined in 10 CFR Part 21. This omission is significant since the terms “basic component” and “dedication” embody the regulatory process that, once effectively implemented, culminates in a successful CGI dedication program. This issue is an example of a failure to adopt effective dedication procedures and has been identified as part of Nonconformance 99901377/2008-201-01.

The NRC inspectors confirmed that Enertech implements the methods contained in EPRI 5652, “Guideline for the Utilization of Commercial Grade Items in Nuclear Safety-Related Applications,” dated June 1988, for dedication activities. EPRI 5652 provides four methods of accepting a CGI, including: Method 1, “Special Tests and Inspection;” Method 2, “Commercial Grade Survey of Supplier;” Method 3, “Source Verification;” and Method 4, “Acceptable Supplier/Item Performance Record.” Enertech implements Methods 1, 2, and 3 for the verification of critical characteristics in EOP 3140. However, the NRC inspectors noted that the procedure did not include the restrictions contained in Generic Letter (GL) 89-02, “Actions to Improve the Detection of Counterfeit and Fraudulently Marketed Products,” dated March 21, 1989. Specifically, Enertech’s implementation of Method 2 did not include controls for the acceptance of items from suppliers with undocumented commercial quality control programs. In addition, the procedure did not include controls for accepting items from distributors consistent with GL 89-02. This issue is another example of a failure to adopt effective dedication procedures and has been identified as part of Nonconformance 99901377/2008-201-01.

The NRC inspectors performed a sample review of dedication plans to verify adequate implementation of the dedication process. The following dedication plans were reviewed:

- Air Piston Actuator; Purchase Order No.: 116129-1; Production Order No.: 632854.
- Potentiometer; Purchase Order No.: 114591-1; Production Order No.: MR40908.
- Bridge Rectifiers; Purchase Order No.: 114882; Production Order No.: MR31182.
- Pressure switch; Purchase Order No.: 114568-4; Production Order No.: MR40958.

- Pressure switches; Purchase Order No.: 114568; Production Order No.: MR32493.
- Impellers; Purchase Order No.: 115718-1; Production Order No.: 603725.
- Relief valve; Purchase Order No.: 201689; Production Order No.: 632926.
- Relief valve cartridge; Purchase Order No.: 201689; Production Order No.: 632926.

In discussions with Enertech responsible personnel, the NRC inspectors learned that Enertech utilized sampling plans for the verification of critical characteristics in the majority of their dedication plans. The NRC inspectors reviewed the procedural guidance related to the use of sampling plans for dedicated items and noted that EOP 3140 referred to EPRI 7218, "Guideline for Sampling in the Commercial-Grade Item Acceptance Process," dated January 1999, for lot formation and sampling plan methodology. The NRC inspectors also noted that Subsection 7.12 of EOP 3140 only provided guidance related to lot formation by incorporating selective criteria from EPRI 7218. Specifically, EOP 3140 provided guidance for the use of normal, reduced, or tightened sampling plans based on the established traceability of items supplied by one or multiple manufacturers. However, during the review of several dedication packages and the discussion of their content with responsible Enertech personnel, the NRC inspectors determined that these criteria needed to be combined with other qualitative factors to ensure adequate selection and implementation of sampling plans. Specifically, the NRC inspectors noted the following:

- The selection of a specific sampling plan did not consider factors such as safety significance of the item, adequacy of supplier controls, complexity of the item, and performance history of the item.
- Sampling plans did not establish their applicability to destructive tests or inspections or nondestructive tests or inspections, nor did it refer to the respective Tables in EPRI 7218 that provide recommendations for sampling plan sample size.
- There is no guidance to provide an engineering justification in cases where a lot or batch is rejected and the dedication plan needs to be revised to change the sampling plan. This is important to assure that the basis for the selection of a sampling plan remains valid after rejection of a lot and/or batch has occurred. Although the NRC inspectors were able to interview responsible personnel and confirm that once an item is found defective, the complete lot is rejected or test and/or inspections are performed on 100% of the items in a lot, this was not captured in EOP 3140.

Enertech's sampling practice for dedicating commercial grade items needs to include appropriate engineering involvement, provide adequate qualitative factors, and should be consistent with the guidance described in EPRI 7218 to ensure that all parts supplied as basic components for use in nuclear safety-related applications conform to the applicable procurement specification requirements. These issues are examples of a failure to adopt an effective dedication program and have been identified as part of Nonconformance 99901377/2008-201-01.

The NRC inspectors reviewed the guidance provided in EOP 3140 for the dedication of raw material. Subsection 7.9 of EOP 3140 states that "in case of 'upgrading' raw material, a CGI dedication need not be performed, since it is understood that the critical characteristic is the type of material, verifiable by testing, as deemed appropriate by engineering." The NRC inspectors inquired about this statement and learned that EOP 3310 provided criteria for handling raw material. Specifically, Subsection 6.4.11 of EOP 3310 states that 'upgrading' of

raw material from commercial grade to 'safety-related' could be done by either testing using the XRF alloy analyzer to confirm material type, or by performing a hardness test to verify the material's tensile strength. After several discussions with Enertech's responsible personnel, the NRC inspectors determined that this upgrading process is CGI dedication, not part of the routing process, and should have been described in EOP 3140. For dedication of raw material, verification of material type and heat treatment are critical characteristics that should be verified; however, in absence of a specific safety function and application, this 'upgrading' process described by Enertech does not provide reasonable assurance that the dedicated material will perform adequately in service. Additional engineering evaluation is needed to ensure that the critical characteristics selected for acceptance (which could include design, material, and performance characteristics) provide reasonable assurance that the item will perform its intended safety function. This issue is an example of a failure to adopt effective dedication procedures and has been identified as part of Nonconformance 99901377/2008-201-01.

While reviewing dedication packages, the NRC inspectors noted that the dedication plan for two of the packages selected for review did not provide adequate traceability to the items selected for test. The NRC inspectors also identified inconsistencies between test results using the XFR alloy analyzer in that some test result sheets were traceable to the test piece and others were not. Specifically, the NRC inspectors identified this issue with dedication packages for pressure switches and relief valves. The NRC inspectors also learned that the XRF alloy analyzer can be programmed to provide traceability to the tested component; however, this was not consistently performed by the Enertech's personnel responsible for testing. This issue is being identified as Nonconformance 99901377/2008-201-02.

The NRC inspectors requested to review training activities conducted by Enertech to ensure that responsible individuals maintain proficiency on dedication activities, including implementation of sampling plans as discussed in EPRI 7218. After discussions with Enertech's responsible personnel, the NRC inspectors learned that no classroom training had been conducted on EPRI 7218; only self-study training of EOP 3140 was required. As identified by the NRC inspectors above, EOP 3140 did not include an adequate set of controls for sampling plans consistent with EPRI 7218. Although during interactions with Quality Control inspectors (QCIs) and project managers the NRC inspectors noted that personnel involved with sampling plans demonstrated adequate knowledge of sampling activities, the NRC inspectors concluded that Enertech did not provide adequate training for the performance of commercial-grade dedication due to inadequate procedural guidance contained in EOP 3140 related to sampling plans. This issue has been identified as Nonconformance 99901377/2008-201-01.

c. Conclusions

Except for the issues identified in Nonconformances 99901377/2008-201-01, 99901377/2008-201-02, and 99901377/2008-201-03, the NRC inspectors determined that Enertech's program requirements for the commercial grade dedication process are consistent with regulatory requirements and were being effectively implemented.

3. Design Control

a. Inspection Scope

The NRC inspectors reviewed Enertech's QA policies and implementing procedures that govern the design control activities that relate to software and hardware to verify compliance with the requirements of Criterion III, "Design Control," of Appendix B to 10 CFR Part 50. Specifically,

the NRC inspectors reviewed the following policies and procedures established by Enertech:

- Enertech QAM, Section 3, “Design Control,” 4th Edition, Revision 14, dated August 13, 2008.
- EOP 3110, “Procedure for the Development of Design Inputs,” Revision R, dated July 31, 2008.
- EOP 3115, Procedure for the Presentation of Engineering Calculations and Analysis,” Revision G, dated July 31, 2008.
- EOP 3120, “Procedure for Identification, Release, and Revision of Design Documents,” Revision R, dated July 30, 2008.
- EOP 3170, “Procedure for Design Verification,” Revision P, dated July 31, 2008.
- EOP 3502, “Preparing and Controlling the Engineering Drawing Change Order,” Revision M, dated July 31, 2008.

The NRC inspectors also reviewed a sample of design documentation packages to verify effective implementation of Enertech’s design control requirements.

b. Observations and Findings

Section 3 of Enertech’s QAM describes the requirements for order acceptance, verification and control of design activities and documentation used for Enertech’s products. The design process includes activities to translate design inputs into design documents that are used to construct the item when directed by the Project Leader consistent with applicable EOPs. Subsection 3.2 of the QAM identifies the responsibilities and authority to implement the design process.

During the review of a sample of design documentation packages for specific projects, the NRC inspectors verified that the process implemented by Enertech is consistent with relevant industry standards. In addition, the NRC inspectors interviewed Enertech personnel to ensure that activities they performed are commensurate with their responsibilities. These packages included:

- Design Report MA22501, Revision 0, dated September 20, 2007
Enertech 6 inch - 150ANSI 150 Type DRV-Z Nozzle Check Valve
Enertech Project No. 39008 for Constellation Energy Calvert Cliffs Nuclear Power Plant
PO 420771, Assembly Drawing – MD22059 Rev. C, Nozzle Check Valve 6” Class 150
DRV-Z.
- Design Report MA22149, Revision 0, dated December 28, 2007
Enertech 12 inch – Class 150 Model 815L Wafer-Sphere Valve
Enertech Project No. 340005 – project for progress Energy Shearon Harris Nuclear
Plant, PO 00320498, Assembly Drawing – MD22230 Rev. A, Outline and Assembly
Drawing 12 inch Class Wafer-Sphere Butterfly Valve.

EOP 3502 provides instructions for the use, preparation, and distribution of the Engineering Drawing Change Order (ECO). Section 6.3 of EOP 3502 identifies that the ECO will document changes to CAD drawings and that changes to the design and drawings shall be circulated through the checking/approval cycle so that the drawing will have original signatures only for that latest revision. Subsection 6.3.3 of EOP 3502 states that “after the checking/approval cycle, the file update described in EOP 3120 for Filing of Design Document shall be performed.” During the review of design report MA22149, the NRC inspectors identified that ECO 5-16415 dated February 28, 2008 had been issued. When the NRC inspectors requested the ECO and the reason for the change, the ECO was not located in the design document file. Personnel responsible for the control of design documentation confirmed that the file had not been scanned into the system. This issue is an example of a failure to maintain design document control and has been identified as part of Nonconformance 99901377/2008-201-04.

Subsection 6.2.1 of EOP 3502 states that “document numbers are obtained from the Drawing Number Registrar (DNR) (identified as Attachment 3120-1) and should be located in the Document Control Department.” The NRC inspectors determined that there was no Attachment 3120-1 in the latest version of EOP 3502. This issue is another example of a failure to maintain design document control and has been identified as part of Nonconformance 99901377/2008-201-04.

During the review of the Dedicated Product/Service Log (identified as Attachment 3140-3 in EOP 3140) located in the shop inspection area, the NRC inspectors determined that this log was different from the log required by the latest revision of the EOP 3140. Subsection 6.8.2 of EOP 3140 states that all dedications shall be documented in the Dedicated Product/Service Log (Attachment 3140-3). This log was not being utilized in the shop inspection area. This issue is another example of a failure to maintain design document control and has been identified as part of Nonconformance 99901377/2008-201-04.

c. Conclusions

Except for the issues identified in Nonconformance 99901377/2008-201-04, the NRC inspectors concluded that Enertech’s program requirements for design control are consistent with the regulatory requirements of Criterion III of Appendix B to 10 CFR Part 50. Based on the limited sample of design documentation reviewed, the NRC inspectors also determined that Enertech’s QAM and associated design control procedures were being effectively implemented.

4. Control of Purchased Material, Equipment and Services

a. Inspection Scope

The NRC inspectors reviewed Enertech’s QA policies and implementing procedures that govern the control of purchased material, equipment, and services to verify compliance with the requirements of Criterion VII, “Control of Purchased Material, Equipment, and Services,” of Appendix B to 10 CFR 50. Specifically, the NRC inspectors reviewed the following policies and procedures established by Enertech:

- Enertech QAM, Section 4, “Procurement Document Control,” 4th Edition, Revision 14, dated August 13, 2008.
- Enertech QAM, Section 7, “Control of Purchased Items and Services,” 4th Edition, Revision 14, dated August 13, 2008.

- Enertech QAM, Section 18, “Audits,” 4th Edition, Revision 14, dated August 13, 2008.
- EOP 6003, “Procedure for the Preparation of the Purchase Requisition,” Revision G, dated July 31, 2008.
- EOP 6004, “Purchase Order Processing,” Revision J, dated July 31, 2008
- EOP 8180, “Audit Planning and Procedure,” Revision O, dated October 4, 2007.
- EOP 8072, “Procedure for Receiving Inspection,” Revision R, dated August 1, 2008.

The NRC inspectors also reviewed a sample of receipt inspection reviews and reports from surveillances that Enertech conducted of its suppliers to verify the quality of the material, equipment, and services they supply. In addition, the NRC inspectors reviewed Enertech’s approved supplier’s list (ASL) to verify that listed vendors were qualified according to Enertech specifications and that the list was maintained up-to date.

b. Observations and Findings

b.1 Policies and Procedures for Vendor Qualification

Subsection 7.2.2 of Enertech’s QAM states that the QA Director is responsible for the approval of receiving inspection, supplier QA programs, surveys and audits of suppliers, and for control of approved suppliers. Subsection 7.3.1.1.1 of Enertech’s QAM identifies two methods for the initial evaluation and qualification of vendors: 1) direct evaluation (on-site survey) of their facilities for initial capability and 2) a review of the supplier’s current quality records. Initial qualification of a supplier is performed by a survey while subsequent qualifications are performed by audits.

Enertech is a member of the Nuclear Industry Assessment Committee (NIAC), which consists of companies who supply goods and services to the nuclear industry based on a quality program that meets the requirements of Appendix B to 10 CFR Part 50 or ASME NQA-1 (1989), and accept 10 CFR Part 21. NIAC develops and maintains procedures and processes necessary to plan, guide, and share supplier evaluations (audits) with its members. Enertech uses NIAC audits to support the qualification and maintenance of suppliers. Once a NIAC audit is received, Enertech’s QA Director reviews the audit for completeness and adequacy, evaluates the audit report in accordance with Enertech’s QA program and the appropriateness of the scope, and approves the audit report as the basis for including the vendor on the ASL. The QA Director’s review and acceptance is documented in an Assessment Evaluation Form.

Subsection 7.3.4.2 of Enertech’s QAM requires ASME Accredited Material Organizations and Certificate Holders to be surveyed or audited triennially provided an annual performance assessment is conducted. Subsection 7.3.4.3 of Enertech’s QAM requires material organizations qualified by Enertech to be initially surveyed prior to adding the organization to the ASL and are evaluated annually and audited triennially. Subsection 7.3.4.4 of Enertech’s QAM requires vendors who provide ASME Code mechanical assembly services and safety related items and services (excluding material) to be audited triennially. Annual performance assessments are documented in a report generated by the QA Director and are completed through a review of the results of previous source and receiving inspections.

EOP 8180 contains detailed instructions on the performance and planning of internal and external audits. This procedure sets forth the minimum requirements for audit plans, checklists, reports, and audit conduct, and requires that audit plans be prepared prior to each audit and include an audit checklist to be used for the audit. Reports must be written within 30 days of audit completion and include the following information: 1) objective of the audit, 2) description of the items selected for the audit, 3) input criteria for the audit basis, 4) summary of the process evaluated, and 5) a conclusion related to the effectiveness of the vendor's QA program implementation. The QA Director is required to review and accept the audit results prior to placing the vendor on the ASL.

The NRC inspectors identified an issue regarding the potential use of suppliers not listed on the ASL that provide basic components and services to Enertech. Specifically, Enertech QAM Subsection 7.3.2.2 states that non-code suppliers not on the ASL may be selected for forming and machining operations when the dimensional requirements for the forming and machining operations can be verified at receipt and the material identification has not been removed by these operations. Furthermore, Subsection 6.5.1 of EOP 8072, states that safety-related items can be procured from a supplier not on the ASL. Subsection 6.5.2 of EOP 8072 states that safety-related components may be machined by suppliers not on the ASL. In response to the finding, Enertech initiated a review of supplier orders to determine if, in fact, any supplier not currently on the ASL was used to procure basic components or services for Enertech. At the conclusion of the inspection, the Enertech staff had not completed this review. Enertech's required to assess the effectiveness of any supplier's quality controls before the purchase of safety-related components and services. This issue to allow procurement of safety related items from suppliers not on Enertech's ASL has been identified as Nonconformance 99901377/2008-201-05.

b.2 Review of Vendor Audit Reports

For a sample of audit reports that Enertech conducted of its suppliers, the NRC inspectors verified that Enertech adequately evaluated the vendor's compliance with the applicable requirements of Appendix B to 10 CFR Part 50, 10 CFR Part 21, and ASME Boiler and Pressure Vessel Code Section III, "Rules for Construction of Nuclear Facility Components." The following audit reports from Enertech suppliers were reviewed:

- Energy Steel & Supply
- Energy & Process Corporation
- Emerson Process Management
- METSO Automation

The NRC inspectors verified that Enertech had approved the vendor's corrective actions for any findings issued and that the approval was documented in a Vendor Evaluation Report. The NRC inspectors also verified that audit check lists were prepared and completed for the audit and contained sufficient objective evidence to support the conclusions made by Enertech. The NRC inspectors also verified that the scope of supply identified in Enertech's ASL was consistent with the materials supplied to Enertech by each vendor in the sample population.

b.3 Maintenance of the Approved Supplier's List

Subsection 4.3.4 of Enertech's QAM states that the ASL shall be developed and maintained by the QA Director in accordance with Section 7 of the Enertech QAM. Since the ASL is an

electronic database, a reference only copy of the current database is printed quarterly and retained in the QA files. Subsection 7.3.3 of Enertech's QAM states that employees have read-only access to the ASL database and any updates to the database will be performed by the QA Director when a change is required. In addition, the QA Director is responsible for reviewing surveys and audits results performed by other auditors prior to addition and deletion of suppliers from the ASL. The NRC inspectors verified listings from the ASL database and cross-referenced the information with applicable audits furnished by Enertech.

b.4 Review of Purchase Orders

Requirements for the preparation of purchase specifications are provided in Section 4 of Enertech's QAM and in EOPs 6003 and 6004. The procedures contain guidance for purchase specification content, such as requiring the ASME Code class, component type, scope of work, technical requirements, QA program requirements (Appendix B to 10 CFR Part 50), and requirements for reporting and approving the disposition of nonconformances (10 CFR Part 21), if applicable. The NRC inspectors determined that these procedures provide sufficient guidance to ensure that the necessary technical, quality, and administrative requirements are imposed on the vendors supplying to Enertech.

The NRC inspectors reviewed a sample of POs to determine whether the requirements identified in the procedures were imposed on applicable purchasing documents. The following POs were reviewed:

- POs 115774 and 116075 for a seal kit and actuator from Emerson Process Management
- PO 116290 for studs and nuts from Energy & Process Corporation
- PO 116327 for a valve body plate from Energy & Process Corporation

In addition to other quality requirements imposed depending on the items or services being procured, all of the POs included clauses invoking the provisions of 10 CFR Part 21 and requiring the vendor to conduct the work under its Appendix B to 10 CFR 50 QA Program.

b.5 Auditor Training and Qualification

Subsection 2.3.8.1 (b) of Enertech's QAM defines the minimum requirements for the training and qualification of auditors and lead auditors. The NRC inspectors reviewed a sample of Lead Auditor Qualifications and confirmed that auditing personnel had completed all required training and maintained qualification and certification in accordance with Enertech's policies and procedures.

c. Conclusions

Except for the issue identified in Nonconformance 99901377/2008-201-05, the NRC inspectors concluded that Enertech's program requirements for the control of purchased material, equipment, and services are consistent with the requirements of Criterion VII of Appendix B to 10 CFR Part 50. Based on the records reviewed, the NRC inspectors concluded that Enertech's reports for evaluations of its suppliers contained sufficient objective evidence to support the qualification and requalification of the vendors by Enertech. The NRC inspectors also concluded that the requirements set forth in customer design documents were effectively translated into purchase specifications and that purchase specification requirements were successfully verified by Enertech through source and receipt inspections.

5. Control of Special Processes

a. Inspection Scope

The NRC inspectors reviewed Enertech's QA policies and implementing procedures that govern the control of special processes to verify compliance with the requirements of Criterion IX, "Control of Special Processes," of Appendix B to 10 CFR Part 50. Specifically, the NRC inspectors reviewed the following policies and procedures established by Enertech:

- Enertech QAM, Section 9, "Control of Processes," 4th Edition, Revision 14, dated August 13, 2008.
- EOP 5002, "Filler Metal Issue and Control," Revision E, dated October 5, 2007.
- EOP 5005, "ASME Code and Safety Related Welding Qualifications," Revision C, dated October 3, 2007.

The NRC inspectors also reviewed a sample of welding procedure specifications (WPS) with the supporting procedure qualification records (PQRs) to verify compliance with Section IX of the ASME Code and effective implementation of such requirements.

b. Observations and Findings

Section 9 of Enertech's QAM describes the system used to control special processes for the fabrication of ASME Section III Code items. It also describes; 1) the process for preparation, issue, distribution, and implementation of shop travelers for manufacturing operations, 2) the general welding process requirements and limitations, and 3) the controls in place for performance of non-destructive examination (NDE) activities and for qualification and certification of NDE personnel.

The NRC inspectors verified that Enertech's manufacturing process used shop travelers as the method for controlling shop production activities. The shop travelers incorporate witness and hold points for the customer, authorized nuclear inspector, (ANI), Enertech Quality Control (QC), as applicable, and identifies the applicable drawings, material specifications, work instructions, and procedures applicable to the manufacturing operation activity being performed. The NRC inspectors concluded that the shop traveler serves to assure that the fabrication activities are accomplished in accordance with specified requirements and conducted in the correct operational sequence.

Welding

EOP 5005 establishes the specific instructions for the qualification and certification of welding procedures and performance qualification of welding processes in accordance with the requirements of ASME Section IX and customer contracts.

The following WPS with supporting WPS were reviewed for compliance with Section IX of the ASME Code:

- WPS PA 99628, Revision D, dated August 10, 2007, ASME Welding Procedure Specification. Base Materials P-1 to P-1 using the Gas Metal Arc Welding (GMAW) process. PQR PA 99671, Rev. B, GMAW P-1 to P-1, welder: Mike Carlo.
- WPS PA 98061, Revision F, dated August 28, 2002, ASME Welding Procedure Specification. Base Materials P-1 to P-1 using the Gas Tungsten Arc Welding (GTAW) process. PQR PA98062, GTAW P-1 to P-1, welder: John Harper.

The following production welding and NDE was reviewed:

- Production Order 632448, Drawing No. D4953 – Discharge Head
Welding Procedure PA99628, Revision D, GMAW P-1 to P-1
Welding Procedure PA 98601, Revision F, GTAW P-1 to P-1
Welder PQR: PA98159 Revision B (GTAW) and MA20578 (GMAW).
- Production Order 632698, Drawing No. B5961 – 8 inch Bottom Column Assembly
Welding Procedure PA99628, Revision D, GMAW P-1 to P-1
Welder PQR: MA20578
- Production Order 632234, Drawing No. B8063 – 6 inch Bottom Column Assembly
Welding Procedure PA99628, Revision D, GMAW P-1 to P-1
Welder PQR: MA20578.

The NRC inspectors found that all welding on ASME Code materials and fabrication of ASME Code items is performed by qualified welders in accordance with approved welding procedure specifications (WPS). Each welder is qualified in accordance with the requirements of Enertech's QAM and ASME Section III and Section IX, "Welding and Brazing Qualifications."

As a result of the review of the documentation related to welding activities performed on production orders, the NRC inspectors confirmed that the welding material Certificate of Material Test Reports (CMTRs) complied with purchase and material specification requirements and verified completion of sign off of all required shop traveler, QC customer, and ANI witness or hold points.

Control of Weld Material

EOP 5002 establishes the method for storage, control, and accountability for weld filler materials used for welding on ASME Code projects. This procedure applies to all filler metal purchased for use on ASME Code and jobs that require welding (including repair welding and hardfacing) to pressure retaining components, where welding is performed by Enertech.

The NRC inspectors performed a review on the issuance and control of ASME filler material. A review of the filler metal storage area was found to meet the requirements set forth in Enertech's QAM Section 9 and EOP 5002. Additionally, the filler metal issuance log was properly documented and the log sheet was properly maintained.

The NRC inspectors verified Enertech's process for welding material control through direct

interview of personnel and review of welding material control activities. Enertech employs the use of a Welding Material Control Log to control welding material. The weld filler metal issue and control is in accordance with EOP 5002. The filler metal is released by the Stock room Clerk.

The NRC inspectors verified the implementation of this process for the withdrawal and release of covered electrodes and flux from the welding crib. The NRC inspectors verified that the welding material was controlled using the Filler Metal Issuance Log and the correct heat/lot number of the welding material was identified on the Filler Metal Issuance Log released by the Stock room Clerk.

Nondestructive Examination (NDE)

The NRC inspectors verified on a small sample that all NDE of ASME Code materials and fabrication of ASME Code items were performed consistent with Enertech's QA program requirements and were conducted by personnel who had been qualified and certified.

c. Conclusions

The NRC inspectors concluded that Enertech's program requirements for control of special processes are consistent with the regulatory requirements of Criterion IX of Appendix B to 10 CFR Part 50. Based on the limited sample of records reviewed, the NRC inspectors concluded that the Enertech QAM and associated fabrication and special process procedures were being effectively implemented by qualified personnel, using qualified equipment and processes.

6. Inspection

a. Inspection Scope

The NRC inspectors reviewed Enertech's QA policies and implementing procedures that govern inspection activities to verify compliance with the requirements of Criterion X, "Inspection," of Appendix B to 10 CFR Part 50. Specifically, the NRC inspectors reviewed the following policies and procedures established by Enertech:

- Enertech QAM, Section 10, "Inspection" 4th Edition, Revision 14, dated August 13, 2008.
- EOP 6005, "Receipt of Material," Revision O, dated July 31, 2008.
- EOP 8071, "Standard Visual Inspection Procedure for Materials," Revision G, dated August 20, 2007.
- EOP 8072, "Procedure for Receiving Inspection," Revision R, dated August 1, 2008.
- EOP 8101, "In-Process, Assembly and Final Inspection of Items," Revision M, dated April 28, 2008.

The NRC inspectors also reviewed a sample of production orders, inspection record sheets, source inspections, and observed inspection activities at the Enertech manufacturing facility to verify effective implementation of such requirements.

b. Observations and Findings

Enertech's QAM establishes controls for inspection operations performed to assure conformance of the product to the applicable procedures, the ASME Code, and customer requirements. The scope of inspection applies to inspection activities performed in-house, field locations, and at supplier facilities for material, parts, and items. Specific categories of inspections performed by Enertech technicians and prescribed in quality procedures include: receiving, in-process, pre-assembly, and final inspections.

b.1 Receiving Inspection

EOP 6005 describes the process for receiving inspections. This procedure requires performance of receipt inspections on all incoming material to assure all of the requirements of the POs have been met. Initial receipt inspection confirms that the material delivered is consistent with the supplier's documentation, all required paperwork, such as CMTRs or Certificates of Conformance are included, and the shipment is free of any signs of shipping damage that may affect the quality of the components being received. Other characteristics include, but are not limited to, configuration, identification, dimensional, physical characteristics, and cleanliness. Documented results of this inspection, including the item quantity, receiver number, lot number, and receipt date, as applicable, are recorded in the Enertech Receiving Inspection Record (electronic database).

EOP 8072 further defines the requirements for inspection of purchased items to assure that items, parts, materials, and services purchased from suppliers are inspected upon receipt by qualified personnel using requirements identified in Enertech POs. This procedure applies to ASME code, safety-related, and commercial or industrial raw materials, parts, items, and services. The procedure requires the QCI to visually inspect code and safety-related items for damage, cleanliness, identification verification, and conformance to the purchase order. The QCI is further required to inspect the received item in accordance with specified drawings, procedures, or other documents, or requirements as stated on the purchase order. When dimensional inspection is performed as part of the receipt inspection, the results are required to be documented on an Inspection Record Sheet and attached to the Production Order Package after completion of the inspection.

The NRC inspectors observed receipt inspection of two pieces of ASME code bar stock. The inspectors observed the Enertech receipt inspector verify dimensional aspects of the bar, identify item heat no. and part no., and verify existence of a certificate of test and CMTR for chemical and physical analyses for each specimen. The NRC inspectors also verified a sample of production order packages to assess whether the receipt portions of the packages were adequately completed by the Enertech receipt inspector in accordance with the written procedural requirements.

During the review of completed Inspection Records Sheets associated with several production order packages, the NRC inspectors verified that all Inspection Record Sheets were completed with required dimensional information recorded and included inspection equipment identification and calibration information, as required by procedure.

The NRC inspectors identified a concern with the Enertech process for acceptance of safety-related and ASME code items and services. Specifically, Subsection 6.5.4 of EOP 8072, states, in part, that when specified by codes, standards or specifications that include specific identification or traceability requirements (such as identification or traceability of the item to

applicable specification and grade of material; heat, batch, lot, part or serial number; or specified inspection, test or other records), the QCI shall verify during QC inspection that all requirements are met. Instructions for inspection of each product form [i.e. castings, forgings/bar, plate, etc.] are maintained in a Receiving Inspection Check List Log in QA. Contrary to this requirement, the Receiving Inspection Checklist Log is no longer maintained, and as of July 2005, was replaced with the use of an electronic database (BAAN). This process change was adequately captured in a revision to the QAM but was not adequately incorporated into the EOP 8072 procedure. In response to this finding, Enertech issued CAR 1904 to address the inconsistency between the EOP procedure and the current practice. This issue has been identified as an example of nonconformance 99901377/2008-201-04.

b.2 Visual Inspection

EOP 8071 defines the controls for the visual inspection of materials (e.g., castings, forgings, bar, plate, sheet, strip). This procedure establishes the requirements for direct and remote visual inspection performed by the QCI.

Section 6.2 of EOP 8071 provides the requirements for verifying adequate inspection lighting at the source location where inspection activities are performed. The procedure states, in part, that the QCI is responsible for assuring adequate artificial or natural lighting prior to performing visual inspection activities. A guideline for determining adequate lighting may include the use of a fine line reference card, where a 1/32 inch wide line is drawn on a 18 percent neutral gray background card which is placed in the area of inspection. If the line is distinct and visible the area is considered adequately illuminated for inspection activities.

Subsection 7.6.1 of EOP 8071 requires that all visual inspections be recorded on the appropriate commodity checklist (i.e.: casting, forgings and bars, plate, sheet, strip, fasteners and fittings). Visual inspection reports shall be attached to the receiving inspection documentation or production order, and retained by the QA department for permanent record storage. The procedure contains a specific visual inspection form for each type of commodity.

The NRC inspectors verified that the QCIs were aware of the lighting requirement and observed the QCI use the fine line reference card to verify adequate lighting in inspection area. The NRC inspectors verified that all equipment documentation and information related to visual cards were present in the inspection location and the QCI inspectors were cognizant of the instructions and use of the cards.

During the review of completed visual inspection forms for each commodity type, the NRC inspectors verified that each acceptance criteria was addressed and properly recorded and signed by the QCI responsible for the activity.

b.3 In-Process and Final Inspections

Section 10 of Enertech's QAM defines the general requirements for the performance of In-process, pre-assembly, and final inspections. It includes provisions to ensure that parts and material shall be dimensionally and visually inspected in accordance with the Production Order and the applicable drawings and/or procedures and that the results of inspections shall be documented appropriately.

EOP 8101 further described the Enertech requirements associated with the performance of inspections, other than initial receipt inspection, to be conducted by the QCI. The procedure is

applicable to all ASME code and safety-related activities associated with Enertech products.

The NRC inspectors observed the Enertech QCIs performing inspections on a variety of materials and components during fabrication and commercial grade dedication activities. Specific inspection activities observed where associated with the following materials and items: 1) lubrite bronze bushings, 2) commercial relief valve dedication, 3) lubricant dedication, and 4) liquid penetrant examination on valve bodies.

The NRC inspectors observed that Enertech's QCIs adequately identified the items being inspected, verified the items in accordance with required documentation, and recorded all visual, dimensional, or other inspection information on the required inspection verification sheets. Additionally, the NRC inspectors verified that the QCIs identified and documented all Material and Testing Equipment (M&TE), verified equipment calibration status, and verified all M&TE scale and precision were consistent with procedural requirements prior to use.

b.4 Source Inspection

EOP 8074 defines the requirements for performance of source inspections and witness of activities at Enertech supplier locations. The procedure provides the instructions for initiating, completing and distributing the Source Inspection Record form. The Enertech inspector uses the Source Inspection Record form to document objective evidence that the specific attributes being evaluated were acceptable as well as to describe the activities inspected or witnessed.

The NRC inspectors verified that the Enertech inspectors adequately completed the source inspection checklists, including witnessing relevant fabrication processes and verifying required pre-requisites including commodity code requirements, shipping, storage and handling, and item traceability methodology. The NRC inspectors verified that the Source Inspection Records contained all pertinent production order information and testing records; that item traceability was adequately identified and that objective evidence of each was documented.

b.5 Inspector Training and Qualification

During the review of the training and qualification records for the QCIs, the NRC inspectors verified that the inspectors had completed all the required training on the Enertech policies and procedures governing their inspection-related responsibilities (i.e., approximately 20 procedures). The NRC inspectors also verified that the QCI's had completed indoctrination and training on the M&TE used during inspection activities, including but not limited to, the Fourier Transform Infrared (FTIR) analyzer (for material identification), XRF analyzer, force gages, and durometer. The NRC inspectors confirmed that each QCI had successfully completed a qualification examination, an annual eye examination, and an annual evaluation of inspector proficiency for inspection and dedication activities.

c. Conclusions

Except for the issue identified in Nonconformance 99901377/2008-201-04, the NRC inspectors concluded that Enertech's program requirements for inspection are consistent with the regulatory requirements of Criterion X of Appendix B to 10 CFR Part 50. Based on the limited sample of inspection documents reviewed, the NRC inspectors also determined that Enertech's QAM and associated inspection procedures were being effectively implemented.

7. Test Control

a. Inspection Scope

The NRC inspectors reviewed Enertech's QA policy and implementing procedures that govern test control activities to verify compliance with the requirements of Criterion XI, "Test Control," of Appendix B to 10 CFR Part 50. Specifically, the NRC inspectors reviewed the following policies and procedures established by Enertech:

- Enertech QAM, Section 11, "Test Control," 4th Edition, Revision 14, dated August 13, 2008.
- Enertech Test Procedure MA 21360, "Relief Valve Test Procedure," Revision B, dated June 24, 2005.
- Enertech Test Procedure MA 21662, "Liquid Penetrant Procedure," Revision D, dated June 6, 2008.
- CGI Dedication Procedure C4365S, Revision H, dated March 20, 2007.

The NRC inspectors observed several in-process tests conducted by Enertech personnel and reviewed a sample of previously completed test reports to verify adequate implementation of QAM requirements and specific test procedures governing the activities. Specific test activities observed or reviewed included: (1) pressure testing of relief valves in accordance with Test Procedure MA 21360, (2) liquid penetrant testing of pump shaft assembly in accordance with MA 21662, and (3) testing of lubricant.

b. Observations and Findings

Section 11 of Enertech's QAM establish controls for testing operations performed to assure conformance of the product to the design and procurement specifications, including any ASME Code requirements relevant to the product. The scope of testing includes any prototype qualification tests, production tests, proof tests, and functional tests performed by Enertech. This section also defines the requirements for documentation of test activities including: 1) identification of all test equipment; 2) providing detailed objective acceptance criteria; 3) records and reporting requirements; and 4) test personnel qualification requirements.

b.1 In-Process Testing

The NRC inspectors observed that Enertech staff adequately verified and documented: 1) all test prerequisites including equipment, materials, and test conditions (such as ambient temperature, and testing fluid condition) necessary for testing; 2) performed examination and recorded relevant examination information on non-destructive examination report log including material, heat code, dwell time, cleaner/remover, the specific test procedure used, all test and calibration equipment identification and date of last calibration, and final test results; and 3) the test fixture was correct, pressure gages adequate in range and precision, test procedure and CGI dedication plan were reviewed, and acceptance criteria were adequately identified. The NRC inspectors observed testing of a sample of cartridge relief valves in accordance with test procedure MA21360 and dedication procedure C4365S. Both pressure testing and set pressure activities were performed on all nine valves in the lot. The NRC inspectors observed

that the Enertech technicians used the “egg-carton” method (i.e., placing each component in a cell of an egg-carton fixture) for sample identification in accordance with the testing procedures. Each pressure value was placed in an individual bag and labeled sequentially to match the CGI dedication procedure after testing was completed. The NRC inspectors did not identify any issues with the testing observed; however as part of the review of the valve dedication package, the NRC inspectors noted that the dedication package did not contain adequate justification for the test sample size selected. Specifically, the vendor had chosen to destructively test a single valve from the sample lot to verify proper materials of construction were used. Although the vendor stated that the sample size was based on prior history with the valve supplier, the specific objective criteria supporting the sample size selected was not documented in the dedication package. This is an example of nonconformance 99901377/2008-201-01 regarding sample plan determination.

b.2 Test Documentation

Subsection 11.3.3 of Enertech’s QAM, “Test Documentation,” states the requirements for recording test activities. The QAM requires that test results be documented on a Test Data Sheet or alternate form specified in the test procedure and shall as a minimum, identify the item tested, date of test, test or data recorded, type of observation performed, and the results and acceptability of the tests. The QAM also requires identification of any action taken in connection with any deviations noted, including identification of the person evaluating test results and any M&TE used in the testing.

During the review of a sample of test procedures and completed test reports for recently completed production and dedication orders, the NRC inspectors verified that the test reports adequately captured the information required by the test procedure and individual purchase order requirements.

c. Conclusions

Except for the issue identified in Nonconformance 99901377/2008-201-03, the NRC inspectors concluded that Enertech’s program requirements for test control are consistent with the regulatory requirements of Criterion XI of Appendix B to 10 CFR Part 50. Based on the limited sample of test control documents reviewed, the NRC inspectors also determined that Enertech’s QAM and associated test control procedures were being effectively implemented.

8. Control of Measuring and Test Equipment

a. Inspection Scope

The NRC inspectors reviewed Enertech’s QA policies and implementing procedures that govern the control of M&TE to verify compliance with the requirements of Criterion XII, “Control of Measuring and Test Equipment,” of Appendix B to 10 CFR Part 50. Specifically, the NRC inspectors reviewed the following policies and procedures established by Enertech:

- Enertech QAM, Section 12, “Control of Measuring and Test Equipment,” 4th Edition, Revision 14, dated August 13, 2008.
- EOP 8120, “Calibration and Control of Measuring Test Equipment,” Revision P, dated August 1, 2008.

The NRC inspectors also reviewed a sample of equipment calibration procedures, calibration records, calibration extension records, and calibration recall schedules to verify compliance with the requirements for implementing controls of measuring and test equipment.

b. Observations and Findings

EOP 8120 contains methods used to calibrate, identify and control M&TE at Enertech. The procedure is applicable to all equipment used for acceptance of tests and inspections. Subsection 6.7.5.2 of the EOP states that if an instrument is set aside and not calibrated, the Calibration Technician (CT) or QCI shall affix an "out of service" label to the item. In a discussion with the CT, he clarified that once an instrument is set aside, not calibrated, and labeled as being "out of service," such instrument is located in one of two places: inside a file cabinet's drawer identified as "Out of Service" inside the calibration laboratory or in the bottom shelf of a cabinet located in the shop floor. The NRC inspectors noted two micrometers that were out of service without any label attached to them inside the file cabinet located in the calibration laboratory. Furthermore, while performing an in-process walk-through of the shop floor, the NRC inspectors noted a volumetric leak monitor stationed in the Production Weld Shop. The equipment had a calibration tag which identified that the last calibration was performed in 9/30/1987 and was due to be calibrated in 9/30/1988. There was no "out of service" label identified on the equipment and it was not stored in a non-conformance area or segregated from the rest of the testing equipment. Enertech took immediate action to address both issues prior to the conclusion of the inspection by affixing an "out of service" label to both micrometers and by removing the volumetric leak monitor from the shop floor.

The NRC inspectors verified that M&TE sampled had appropriate calibration stickers and current calibration dates, including calibration due date, and that records were available for review. The NRC inspectors verified that M&TE utilized in the laboratory was calibrated using procedures traceable to known industry standards. Calibration records indicated the calibration procedure to be used, as found/as left conditions, accuracy required, date of calibration and due date for recalibration, and the applicable National Institute of Standards and Technology (NIST) traceable reference equipment used in the calibration.

The NRC inspectors also visited Enertech's calibration laboratory and verified that appropriate environment controls are maintained as required by EOP 8120.

c. Conclusions

The NRC inspectors concluded that Enertech's program requirements for M&TE are consistent with the regulatory requirements of Criterion XII of Appendix B to 10 CFR Part 50. Based on the limited sample of calibration records reviewed, evaluation of controls established within the vendor's calibration laboratory, and observation of a sample of testing activities performed by the vendor, the NRC inspectors also determined that Enertech's QAM and associated M&TE procedures were being effectively implemented. The NRC inspectors did not identify any issues in this area.

9. Nonconforming Materials, Parts or Components

a. Inspection Scope

The NRC inspectors reviewed Enertech's QA policies and implementing procedures that govern the control of nonconformances to verify compliance with the requirements of Criterion

XV, "Nonconforming Materials, Parts, or Components," of Appendix B to 10 CFR Part 50. Specifically, the NRC inspectors reviewed the following policies and procedures established by Enertech:

- Enertech QAM, Section 15, "Control of Nonconformances," 4th Edition, Revision 14, dated August 13, 2008.
- EOP 8150, "Processing of Nonconforming Material Reports", Revision "V", dated August 1, 2008.
- EOP 8200, "Employee Non-Discrimination Rights, and Reporting Requirements Concerning Defects & Noncompliance", Revision "L", dated July 2, 2008.

The NRC inspectors also reviewed ten NMRs initiated during the past six months. These NMRs were primarily the result of deficiencies identified by Enertech's customers and by internal audits/inspections performed by Enertech personnel.

b. Observations and Findings

Section 15.0 of Enertech's QAM defines the measures to identify nonconformances, and to produce, track, and close NMRs. Enertech's nonconformance program is a closed-loop system that starts with the identification and documentation of the nonconformance and continues through the verification of actions that are to be taken to further investigate and then identify the root cause of the nonconformance. Section 15 of the QAM and EOP 8150 of Enertech's program includes provisions to address 1) problems identified to Enertech by its customers, 2) problems identified as a result of an internal or external audit, 3) problems that present frequently produced and similar NMRs or CARs, or 4) problems that are considered significant by Enertech management. EOP 8150 and EOP 8160 include provisions for the reporting of defects and possible and subsequent initiation of a 10 CFR Part 21 evaluation in accordance with EOP 8200 as appropriate.

Enertech's QA Department is responsible for issuing NMRs in response to an identified defect or deficiency from a variety of sources such as the discovery of such a defect/deficiency from an: 1) internal product inspection, 2) employee's discovery, 3) internal or "third-party" external audit, 4) customer audit/inspection, 5) customer's receipt inspection, 6) customer's returned product, or 7) customer's telephone call or memorandum describing such a defect/deficiency. As stated in Section 15 of Enertech's QAM, Subsection 15.2.1, all Enertech employees are responsible to identify real or potential problems and bring them to the attention of Enertech's QA Department.

The NRC inspectors noted that in the ten NMRs reviewed: 1) identified nonconformances were dispositioned in accordance with Enertech's approved procedures; 2) an appropriate technical justification was presented for each disposition; 3) adequate action was taken by Enertech in regard to the nonconforming material/item; and 4) all identified nonconformances, as appropriate, were subjected to a 10 CFR Part 21 assessment/ evaluation. The NRC inspectors also noted that the NMRs contained the appropriate review and disposition by Enertech personnel.

c. Conclusions

The NRC inspectors concluded that Enertech's program requirements for the control of nonconformances are consistent with the regulatory requirements of Criterion XV of Appendix B to 10 CFR Part 50. Based on the limited sampled of NMRs reviewed, the NRC inspectors determined that the Enertech's QAM and associated nonconformance procedure were being effectively implemented.

10. Corrective Actions

a. Inspection Scope

The NRC inspectors reviewed Enertech's QA policies and implementing procedures that govern the control of corrective actions to verify compliance with the requirements of Criterion XVI, "Corrective Action," of Appendix B to 10 CFR Part 50. Specifically, the NRC inspectors reviewed the following policies and procedures established by Enertech:

- Enertech QAM, Section 16, "Corrective Action," 4th Edition, Revision 14, dated August 13, 2008.
- EOP 8160, "Procedure for Corrective Action," Revision "Q," dated April 28, 2008.

The NRC inspectors also reviewed 17 CAR's initiated in 2006, 2007, and 2008. These CARs were primarily the result of deficiencies identified by Enertech's customers and by external audit findings.

b. Observations and Findings

Section 16.0 of Enertech's QAM defines the measures to generate, track, and close CARs. Enertech'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. Enertech's QA Department is responsible to issue CARs in response to an identified problem from a variety of sources such as product inspection, an internal or external quality system audit, a customer audit, customer product surveillance, or customer returned product. All Enertech employees are responsible to identify real or potential problems and bring them to the attention of Enertech's QA Department.

Section 7.7 of EOP 8160 states that CARs that are found to be open for more than 30 business days of issuance shall require immediate additional actions by the QA Director to address prompt corrective actions. EOP 8160 also contains provisions for an extension of completion dates should circumstances beyond the control of Enertech become apparent; i.e., required actions by the customer are not received by Enertech, the corrective actions are usually complex, or investigations are required by Enertech to fully complete the CAR.

The NRC inspectors reviewed CARs generated by Enertech on its products in 2006, 2007, and 2008. The NRC inspectors noted that all but one of the CARs had been completed by their assigned completion dates. One CAR had exceeded its originally scheduled completion date by one month; however, since its originally scheduled completion date could not be met for circumstances beyond the control of Enertech, this schedule was extended by about one month by the Director of QA. The NRC inspectors found that actions taken by the Director of QA were fully appropriate for this CAR. The NRC inspectors did not identify any findings in this area.

c. Conclusions

The NRC inspectors concluded that Enertech's program requirements for corrective actions are consistent with the regulatory requirements of Criterion XVI of Appendix B to 10 CFR Part 50. Based on the limited sample of CARs reviewed, the NRC inspectors determined that the Enertech QAM and associated corrective action procedures were being effectively implemented. The NRC inspectors did not identify any issues in this area.

11. Entrance and Exit Meetings

On September 15, 2008, the NRC inspectors discussed the scope of the inspection with Stan Miller, General Manager of Enertech; John Dekleine, Enertech QA Director and other Enertech management staff.

On September 18, 2008, the NRC inspectors presented the inspection results and observations during an exit meeting with Stan Miller, Enertech General Manager; John Dekleine, Enertech QA Director and other Enertech management staff.

ATTACHMENT

1. PERSONS CONTACTED

Ararat Torosyan	Director of Operations
Avi Shelcoviz	Director of Technology Manufactured Products
John Dekleine	Quality Assurance Director
Tad K. Gray	Director of Customer Service & Process Improvement
Bill Stick	Senior Quality Control Inspector
Jose Samuel Rivera	Quality Control Inspector, Calibration Technician
Saul Toledo	Quality Assurance Engineer
Carlos Sahagun	Product Engineer
Kennie McCanless	Product Engineer
Joey Tressler	Material Handler
Dale Surber	Technician

2. INSPECTION PROCEDURES USED

Inspection Procedure 43002, "Routine Inspections of Nuclear Vendors."

Inspection Procedure 43004, "Inspection of Commercial-Grade Dedication Programs."

Inspection Procedure 36100, "Inspection of 10 CFR Part 21 and 50.55(e) Programs for Reporting Defects and Nonconformance."

3. LIST OF ITEMS OPENED, CLOSED, AND DISCUSSED

<u>Item Number</u>	<u>Status</u>	<u>Type</u>	<u>Description</u>
99901377/2008-201-01	Opened	Nonconformance	Criterion V
99901377/2008-201-02	Opened	Nonconformance	Criterion III and VIII
99901377/2008-201-03	Opened	Nonconformance	Criterion II
99901377/2008-201-04	Opened	Nonconformance	Criterion VI
99901377/2008-201-05	Opened	Nonconformance	Criterion VII