

November 18, 2008

Mr. Robert Payton, V.P.
Quality Assurance
Energy Steel & Supply Company
3123 John Conley Drive
Lapeer, MI 48446-2987

SUBJECT: NUCLEAR REGULATORY COMMISSION INSPECTION REPORT
99901098/2008-201, NOTICE OF VIOLATION AND NOTICE OF
NONCONFORMANCE TO ENERGY STEEL AND SUPPLY COMPANY

Dear Mr. Payton:

On July 21-25, 2008, the U.S. Nuclear Regulatory Commission (NRC) conducted an inspection at the Energy Steel and Supply Company (ESSC) facility in Lapeer, Michigan. The enclosed report presents the results of that inspection.

This was a limited scope inspection that focused on assessing ESSC'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 ESSC's overall quality assurance or 10 CFR Part 21 programs.

During the inspection, the NRC inspector found that the implementation of ESSC'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 ESSC QA program requirements in the areas of design control; control of purchased material, equipment, and services; inspections; 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 ESSC's 10 CFR Part 21 program identified that ESSC did not adopt appropriate procedures for the evaluation of deviations to meet the requirements of 10 CFR Part 21. This violation is cited in the enclosed Notice of Violation, and the circumstances surrounding it 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 of Violation when preparing your response. The NRC will use your response,

R. Payton

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in part, to determine whether further enforcement action is necessary to ensure compliance with regulatory requirements.

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

Docket No. 99901098

Enclosures:

1. Notice of Violation
2. Notice of Nonconformance
3. Inspection Report No. 99901098/2008-201

R. Payton

-2-

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

Docket No. 99901098

Enclosures:

1. Notice of Violation
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3. Inspection Report No. 99901098/2008-201

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DATE	10/22/2008	11/17/2008	11/18/2008	11/17/2008	11/18/2008	11/17/2008	11/18/2008	11/18/2008

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NOTICE OF VIOLATION

Energy Steel & Supply Company
3123 John Conley Drive
Lapeer, MI 48446-2987

Docket Number 99901098
Inspection Report Number 2008-201

Based on the results of a Nuclear Regulatory Commission (NRC) inspection conducted July 21-25, 2008, of activities performed at the Energy Steel & Supply Company (ESSC) facility at Lapeer, Michigan, 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.

Contrary to the above, as of July 25, 2008, ESSC Standard Operating Procedure (SOP) Q-15.1, "Reporting of Defects Procedure (10 CFR Part 21 Evaluation and Reporting)," Revision 3, did not provide adequate procedural guidance to meet the requirements of 10 CFR Part 21. SOP Q-15.1 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 issue is identified as Violation 99901098/2008-201-01.

This is a Severity Level IV violation (Supplement VII of the Enforcement Manual).

Pursuant to the provisions of 10 CFR 2.201, ESSC is hereby required to submit a written statement or explanation to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, DC 20555-0001 with a copy to John A. Nakoski, 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 99901098/2008-201-01" and should include: (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.

ENCLOSURE 1

Because your response will be made available electronically for public inspection in the NRC Public Document Room or from the NRC's document system (ADAMS), 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 18th day of November 2008.

NOTICE OF NONCONFORMANCE

Energy Steel & Supply Company
3123 John Conley Drive
Lapeer, MI 48446-2987

Docket Number 99901098
Inspection Report Number 2008-201

Based on the results of a Nuclear Regulatory Commission (NRC) inspection conducted on April 21-25, 2008, at the Energy Steel & Supply Company (ESSC) facility at Lapeer, Michigan, it appears that certain activities were not conducted in accordance with NRC requirements that were contractually imposed upon ESSC by NRC licensees.

- A. Criterion III, "Design Control," of Appendix B to 10 CFR Part 50, states, in part, that measures shall be established to assure that applicable regulatory requirements and design basis as specified for those structures, systems, and components shall be correctly translated into specifications, drawings, procedures, and instructions. It further states that design changes, including field changes, shall be subject to design control measures commensurate with those applied to the original design and be approved by the organization that performed the original design.

Section 3.2, "Order Entry," of ESSC Nuclear Quality Assurance Program (NQAM) Issue No. 3, Revision 2, dated April 23, 2008, states, in part, that upon receipt of customer purchase orders for welded fabrications and Code items requiring Code Data Reports and NS-1 Certificate of Conformance (CoC) for welded supports, and CoC for non welded supports, the Contract Review Committee reviews the contracts to assure sufficient design information and instructions have been provided to fabricate or manufacture the item in accordance with Client/Customer Purchase order and the Code. The reviews shall be documented on the Contract Review Form (F-272) by signature and date entered by each reviewer.

Additionally, subsection 3.2.1.3 of the NQAM states that changes or revisions to the Customer Purchase Order shall require the same review process as the original. Section 3.3, "Design Control", subparagraph 3.3.2.2 of NQAM states, in part, that the Contract Review Committee assures that the order is in agreement with the quote package, and assures that the quality requirements are correctly stated and agreed to by ESSC.

Standard Operating Procedure (SOP) Q3.1, "Contract Review Procedure," Revision 0, states, in part, that customer quotes and customer contracts for ASME Safety Related NPT Fabrications and non-ASME safety related complex welded fabrications shall be reviewed by the Customer Review Committee. The ESSC Contract Review Committee, consisting of Welding Engineer, Sales, Vice President QA, and Project Manager/Engineering, shall document their review of the customer quotation and customer contracts on Request for Quote/Contract Review Form (F-272).

ESSC SOP Q3.2, "Design Control of ASME Section VIII Division 1 Pressure Vessels," Revision 1, dated July 15, 2002, and SOP Q3.3, "Design Control of Designed Component Fabricated by ESSC," Revision 0, dated August 11, 1999, establish the measures used to control design changes originated by external organization.

Section 4.0 of SOP Q3.3, "Design Control of Customer Designed Components Fabricated by ESSC," Revision 0, dated August 11, 1999, states, in part, that revision made by external organization shall be reviewed by ESSC Engineering, and the evaluation shall be documented on an Engineering Change Notice (ECN) along with the disposition of the affected completed or partially completed fabricated components or sub-assemblies.

Section 5.0 of SOP Q3.3, states, in part, that Engineering and Quality Assurance shall determine if a Traveler revision or a Traveler supplement is required, based on the scope of the design change and the effect of the design change on the fabrication process. It further states Engineering will evaluate the effect of the ECN on work-in-process, or work that is partially completed (sub-assemblies), and provide a disposition of the completed, partially completed, or work-in-process items. The ECN shall be approved / concurred by the Project Manager/Engineering, the Welding Engineer, and the Vice President QA.

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

1. ESSC failed to document in the Contract Review Form (F-272) the review by the Contract Review Committee and the acceptance of the revisions to the PO RLLA19846 related to ESSC Job No. 34185 for an ASME safety related discharge head.
2. ESSC failed to document on the ECN (F-310, Revision 1 dated August 9, 1999) the Engineering and Quality Assurance evaluation of the effect of the ECN on existing fabrication / sub-assemblies for ECN No. 104, 105, 120, 122, 124, 156, 166, 176, and 183.

These issues have been identified as Nonconformance 99901098/2008-201-02.

- B. 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 7.8, "Material Dedication (10 CFR Part 21 Dedication)" of the ESSC's NQAM, Issue No. 3, Revision No. 2, dated April 23, 2008, states, in part, that a commercial grade material to be dedicated to safety-related (Q-2) shall be tested for compliance to the specification in accordance with a material dedication procedure meeting the EPRI NP-5652 document as endorsed by the NRC.

Section 7.8 of the NQAM further states that "Critical characteristics of the material to be verified through the dedication process shall be identified as either all the critical

requirements of the material specification (when the material specification is referenced alone without identified critical characteristics) or those identified by the customer as the critical characteristics to be verified”.

ESSC SOP Q7.2, “Material Dedication Procedure,” Revision 7, dated July 25, 2001, states that “Non-standard items to be dedicated which the customer has not identified the critical characteristics or those for which the critical characteristics are not identified in the description of the item requires the additional approval of competent engineering approval.”

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

1. ESSC SOP Q7.2 does not provide sufficient detail to adequately identify critical characteristics and perform commercial grade dedication activities that will meet EPRI NP-5652.
2. ESSC’s commercial grade survey performed at Falk Corporation in support of replacement parts for a Falk coupling failed to verify that Falk’s quality program included processes, such as material traceability and lot/batch controls, for the control of critical characteristics to support the dedication plan with sampling practice.

These issues have been identified as Nonconformance 99901098/2008-201-03.

- C. Criterion VII, “Control of Purchased Material, Equipment and Services,” of Appendix B to 10 CFR Part 50 states, in part, that measures to assure that purchased material, equipment and services conform to procurement documents include provisions for examination of products upon delivery.

Section 7.6 of the NQAM states that all material received shall be inspected for conformance to purchase order requirements.

Contrary to the above, as of July 25, 2008, ESSC failed to effectively implement a receipt inspection for examinations and measurements that should be used to verify an item’s compliance to specified requirements. For example:

1. ESSC’s failed to identify during receipt inspection that a wrong item was received and after acceptance ESSC shipped the item to its costumer.
2. ESSC failed to identify during receipt inspection that a Mitutoyo Precision Reference Specimen calibrated by an ESSC subcontractor was not properly labeled, including the sticker and dates.

These issues have been identified as Nonconformance 99901098/2008-201-04.

- D. Criterion X, “Inspection,” of Appendix B to 10 CFR Part 50, states, in part, that a program

for inspection of activities affecting quality shall be established to verify conformance with the documented instructions, procedures, and drawings for accomplishing that activity. Criterion X further states, in part, that examinations, measurements, or test of material or products processed shall be performed for each work operation where necessary to assure quality.

Section 10.7 of the NQAM states that final inspection of fabricated items, materials, and products shall verify conformance of the item, material or product to the customer requirements as specified by ESSC Traveler and/or procedure instructions.

Contrary to the above, as of July 25, 2008, ESSC failed to establish procedure instructions that would include guidance for the performance of a final inspection before an item is shipped to its customer.

This issue has been identified as Nonconformance 99901098/2008-201-05.

- E. Criterion XVI, "Corrective Action," of Appendix B to 10 CFR Part 50 states, in part, that measures shall be established to assure that conditions adverse to quality, such as failures, malfunctions, deficiencies, deviations, defective material and equipment, and nonconformances are promptly identified and corrected.

Section 16.0 of the NQAM states that the purpose of the corrective action program is to assure that conditions adverse to quality are promptly identified and followed through to correction and completion with sufficient action to preclude repetition.

ESSC SOP Q-16.1, "Nonconformance and Corrective Action Reporting Procedure", Revision 2, Paragraph 5.2.2, states that corrective action reports that are found to be open for more than 30 business days of issuance shall require immediate additional actions to address prompt corrective actions.

Contrary to the above, as of July 25, 2008, four ESSC corrective action reports (CPAs) – CPA-1031, CPA-1028, CPA-1027, and CPA-1024 – were found to exceed the 30 business day time frame without documenting the justification of the extension of the completion dates.

This is identified as Nonconformance 99901098/2008-201-06.

- 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 6, "Document Control," of the NQAM requires that the NQAM Table of Contents to be signed by the Vice President, Quality Assurance, indicating authorship, review, and approval. It also states that Q procedures are controlled documents and that controlled

copies of procedures are not issued control numbers. Section 6 also states that the Q procedures index is the controlled document.

In addition, Section 6 states that Department Managers are responsible for assuring that only controlled Quality Procedures are utilized in the performance of quality functions and that implementation procedures for compliance may be described in the QA Manual or in separate implementing procedures. Section 6 also states that the Vice President, Quality Assurance, or President is responsible for review and approval of Q procedures and that signatures indicating review and approval are to be documented on the first page of the Q procedure.

Section 6 states that forms may be revised, but if a change “does not delete or reduce the aspect” of the form, it is not required to update the NQAM (a controlled document) with the revised form. Section 5 of SOP Q6.0, “Document Control Procedure,” states that forms are maintained in the Forms Book located in the QA Department and that only after a form is complete is it considered a “controlled document”.

Contrary to the above, as of July 25, 2008, ESSC failed to provide an adequate and consistent process for the preparation, review, approval, revision, issuance and control of documents affecting quality, including Q procedures and forms. For example:

1. ESSC failed to document the preparation, review, and approval of some Q procedures, such as SOPs Q1.0, Q3.1, and Q5.1. In addition, SOP Q6.0 does not adequately address the review, approval, distribution, revision, and control of quality forms.
2. ESSC NQAM and Q procedures failed to reference adequate quality documents and make reference to obsolete and uncontrolled documents. Specifically, SOP Q5.1 includes references to the Q-2 Nuclear QA Manual and Form F-273. Q-2 Nuclear QA Manual is an obsolete document.
3. ESSC failed to consistently control the hard copies of forms available in the Forms Book and electronic forms available on the ESSC network. In addition, the available revisions were not always consistent between the sources. Specifically, F-119A, Revision 8, was in the Forms Book, but Revision 9 was available electronically. Additionally, Revision 4 of F-193a was in the Forms Book, but Revision 5 was available electronically.

These issues have been identified as Nonconformance 99901098/2008-201-07.

- G. Criterion II, “Quality Assurance Program,” of Appendix B to 10 CFR Part 50, states, in part, that the quality assurance program shall take into account the need for special controls, and skills to attain the required quality. In addition Criterion II states, in part, that the quality assurance program shall provide for indoctrination and training of personnel performing activities affecting quality as necessary to assure that suitable proficiency is achieved and maintained.

Section 2.6.4 of the NQAM states that test personnel shall be qualified in accordance with ESSC SOP Q2.1, "Quality Inspector Qualification." Qualification shall be documented on the ESSC QA/QC Inspector Qualification Record.

Section 1.1 of procedure Q2.1, "Quality Inspector Qualification Procedure", delineates the requirements for qualification of ESSC personnel who perform quality inspection and testing activities and states that the procedure is intended to conform to the requirements of NQA-1, including supplements 2S-1 and Appendix 2A-1 as applicable to the scope of ESSC. Section 2.1 states that the procedure applies to personnel who perform quality inspections and surveillance activities, including testing activities. Section 4 specifies adequate qualification documentation, including indoctrination, training, determination of initial capability, performance evaluation, certification renewal, education, experience, and examination.

Contrary to the above, as of July 25, 2008, ESSC failed to qualify and document qualifications of testing personnel.

This is identified as Nonconformance 99901098/2008-201-08.

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 John A. Nakoski, 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 18th day of November 2008.

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

VENDOR INSPECTION REPORT

Report No: 99901098/2008-201

Organization: Energy Steel & Supply Company
3123 John Conley Drive
Lapeer, MI 48446-2987

Vendor Contact: Mr. Robert Payton
V.P., Quality Assurance

Nuclear Industry: Energy Steel and Supply Company (ESSC) is a long standing nuclear supplier of safety related products and services including ASME code materials to both the domestic commercial nuclear power industry and abroad. They maintain multiple active ASME certification stamps. Their core product lines in support of nuclear power plants have been in steel and pipe, but they have expanded their supply scope by partnering with various original equipment manufactures (OEM) to manufacture replacement safety related parts, components and services.

Inspection Dates: July 21-25, 2008

Inspection Team Leader: Aida Rivera-Varona, NRO/DCIP

Inspectors: Dan Pasquale, NRO/DCIP
Michael Morgan, NRO/DCIP
Rahsean Jackson, RII/CIP
Raju Patel, NRO/DCIP (in-training)
Donna Sinks, NRO/DCIP (in-training)

Observers: John Nakoski, NRO/DCIP
Takeshi Yamasaki, Foreign Assignee

Approved By:	<u>IRA/</u>	<u>11/18/2008</u>
	John A. Nakoski, Chief Quality & Vendor Branch 2 Division of Construction Inspection & Operational Programs Office of New Reactors	Date

EXECUTIVE SUMMARY

Energy Steel & Supply Company
99901098/2008-201

The purpose of this inspection was to verify that Energy Steel & Supply Company (ESSC) implemented an adequate quality assurance program that complies with the requirements of Appendix B to 10 CFR Part 50. The inspection also verified that ESSC implemented a 10 CFR Part 21 (Part 21) program that met NRC regulatory requirements. The NRC inspectors reviewed selected portions of the Quality Assurance (QA) program and Part 21 controls that ESSC had established and implemented to meet the regulations set forth in Part 21. The inspection was conducted at ESSC's facility in Lapeer, Michigan.

The NRC inspection bases were:

- 10 CFR Part 21, "Reporting of Defects and Noncompliance."
- Appendix B to 10 CFR Part 50, "Quality Assurance Program Criteria for Nuclear Power Plants and Fuel Reprocessing Plants."

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

There were no previous NRC inspections performed at ESSC's facility in Lapeer, Michigan, prior to this inspection.

The NRC inspectors reviewed ESSC's QA program and implementation activities for the control of purchased material, equipment, and services; inspections; special processes such as welding and non-destructive examination (NDE); procurement document control; and corrective action and nonconformance activities. The inspection team also evaluated ESSC's implementation of 10 CFR Part 21 for evaluating deviations and reporting of defects that could create a substantial safety hazard. The results of the inspection are summarized below.

The NRC inspectors found that ESSC Standard Operating Procedure (SOP) Q-15.1, "Reporting of Defects Procedure (10 CFR Part 21 Evaluation and Reporting)," generally incorporated the requirements of 10 CFR 21.21. However, as presented in the report details, the NRC inspectors identified as Violation 99901098/2008-201-01 that ESSC SOP Q-15.1 did not provide adequate 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.

The NRC inspectors found that ESSC order entry and design control program requirements are consistent with the regulatory requirements of Criterion III of Appendix B to 10 CFR 50. However, as part of Nonconformance 99901098/2008-201-02, the NRC inspectors identified that ESSC design control program failed to document the review of customer purchase orders and its changes or revisions on Contract Review Form (F-272). Also as part of Nonconformance 99901098/2008-201-02, the NRC inspectors identified that ESSC's design control program failed to document in the Engineering Change Notice, the Engineering and QA

evaluation for the need of a Traveler revision or a Traveler supplement requirement, based on the scope of the design change and the Engineering evaluation on the effect of the ECN on work-in-process, work that is partially completed (sub-assemblies), or any completed work.

With the exception of the issues identified in Nonconformance 99901098/2008-201-03, the NRC inspectors found that ESSC's dedication program requirements are consistent with the regulatory requirements of Criterion III of Appendix B to 10 CFR Part 50. Elements of the ESSC commercial grade dedication process that contributed to the issuance of Nonconformance 99901098/2008-201-03 included: 1) ESSC SOP Q7.2 failed to provide guidance to identify and dedicate items other than raw materials (e.g., plate, sheet, pipe, angle iron, bar stock); and 2) ESSC'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 to support the practice of including sampling in the dedication plan for dedicating commercial grade item from Falk Corporation.

The NRC inspectors identified in Nonconformance 99901098/2008-201-04 that ESSC failed to effectively implement a receipt inspection to verify an item's compliance to specified requirements. In addition, the NRC inspectors identified in Nonconformance 99901098/2008-201-05 that ESSC failed to establish procedure instructions that would include guidance for the performance of a final inspection before an item is shipped to customer. Except for the issues identified in Nonconformance 99901098/2008-201-04 and Nonconformance 99901098/2008-201-05, the NRC inspectors found that ESSC control of purchased material, equipment, and services and inspection program requirements are consistent with the regulatory requirements of Criterion VII and Criterion X of Appendix B to 10 CFR Part 50, respectively.

The inspectors identified Nonconformance 99901098/2008-201-06 that four ESSC corrective action reports (CPAs) – CPA-1031, CPA-1028, CPA-1027, and CPA-1024 – exceeded the 30 business day time frame and did not include a documented justification of the extension of the completion dates. Except for the issue identified in Nonconformance 99901098/2008-201-06, the NRC inspectors concluded that ESSC's corrective action program is consistent with the regulatory requirements of Criterion XVI of Appendix B to 10 CFR Part 50.

The NRC inspectors identified, through a review of ESSC's quality documents, that ESSC failed to develop and implement an adequate document control process consistent with the regulatory requirements of Criterion VI of Appendix B to 10 CFR Part 50, as well as ESSC's NQAM and Q procedure. In particular, the NRC inspectors found that ESSC failed to have adequate controls for procedures and forms that are used to control and document processes affecting quality, including Q procedures and quality forms. In addition, the NRC inspectors found that the Q procedures make reference to obsolete documents. The NRC inspectors found that ESSC was inconsistent in the manner in which it controls forms. The majority of the forms in the Forms Book were not referenced in the Forms Book, Welding Program Manual, or Q procedures. There were inconsistencies between the revisions of the forms in the Forms Book and the forms in electronic format. These issues are identified in Nonconformance 99901098/2008-201-07.

Except for the issue identified in Nonconformance 99901098/2008-201-08, the NRC inspectors concluded that ESSC is ensuring that personnel are trained and qualified in accordance with governing documents and that training and qualification documentation is completed. Nonconformance 99901098/2008-201-08 identifies ESSC's failure to ensure that its testing personnel are fully qualified and that adequate documentation was prepared to support the qualifications.

REPORT DETAILS

1. 10 CFR Part 21 Program

a. Inspection Scope

The NRC inspectors reviewed Energy Steel & Supply Company (ESSC) 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 inspectors evaluated the 10 CFR Part 21 postings for compliance with the requirements of 10 CFR 21.6, "Posting Requirements." The NRC inspectors reviewed four purchase orders (POs) and evaluated whether ESSC 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.

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

- Section 15 of the ESSC Nuclear Quality Assurance Manual (NQAM), Issue No. 3, Revision 2, dated April 23, 2008.
- ESSC Standard Operating Procedure (SOP) Q-15.0, "Nonconformance Reporting Procedure," Revision 0, dated April 18, 2008.
- ESSC SOP Q-15.1, "Reporting of Defects Procedure (10 CFR Part 21 Evaluation and Reporting)," Revision 3, dated July 17, 2008.
- ESSC SOP Q-16.1, "Nonconformance and Corrective Action Reporting Procedure," Revision 2, dated April 21, 2008.
- ESSC NC-1408, "9366733 – Zurn Part No. 83176," dated April 21, 2008.
- ESSC NC-1407, "9366733 – Zurn Part No. 83176," dated April 21, 2008.
- ESSC NC-1400, "0032038542 3 – Cage, Valve," dated April 14, 2008.
- ESSC NC-1400, "0032038540 3 – Stem, Lower Valve," dated April 14, 2008.

b. Observations and Findings

b.1 Postings

The NRC inspectors evaluated whether ESSC had complied with the posting requirements of 10 CFR 21.6. The NRC inspectors found that ESSC 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, ESSC SOP Q-15.1, and a memorandum which included the names and telephone numbers of ESSC's 10 CFR Part 21 contacts - ESSC's President and ESSC's Vice President of Quality Assurance (QA). The NRC inspectors did not identify any findings in this area.

b.2 10 CFR Part 21 Procedure

ESSC SOP Q-15.1 outlines the procedure and responsibilities to identify, control, document, and resolve conditions used for the reporting of defects and noncompliance discovered at ESSC 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. Step 6.4.1 of ESSC SOP Q-15.1 provides for the evaluation of defects during the preparation of an ESSC Nonconformance Report. Step 6.4.1.1 of the procedure further states that the evaluations shall be performed in accordance with 10 CFR Part 21 paragraph 21.21 (a) (1) and that the President and/or the Vice President of QA shall be informed after completion of the evaluation. The originator of the Nonconformance Report and either the President or Vice President of QA are to determine the reportability; however, the procedure failed to define and describe a determination of a substantial safety hazard (SSH).

ESSC SOP Q-15.0 defines the measures to generate, track, and close nonconformance reports (NCs). In addition, Step 4.5.3 of ESSC SOP Q-15.0 contains procedural guidance to evaluate all NCs for 10 CFR Part 21 program applicability and to use ESSC SOP Q-15.1 when performing this evaluation.

The NRC inspectors discussed ESSC's 10 CFR Part 21 program with the President of ESSC, ESSC's QA/QC Quality Manager and ESSC's Nuclear Sales Engineer and inquired as to how a condition adverse to quality, identified in ESSC's nonconformance program, would be evaluated under their 10 CFR Part 21 program. The inspectors determined that both ESSC SOP Q-15.0 and ESSC SOP Q-15.1 contained adequate procedural guidance to initiate the 10 CFR Part 21 process when an NC is opened, and that ESSC's staff was knowledgeable about the conditions that would warrant a 10 CFR Part 21 evaluation. However, the NRC inspectors further determined that neither ESSC SOP Q-15.0 nor ESSC SOP Q-15.1 contained adequate provisions for the evaluation, as defined in 10 CFR Part 21, of deviations and failures to comply associated with SSHs.

The NRC inspectors found that both ESSC SOP Q-15.0 and ESSC SOP Q-15.1 did not provide adequate guidance on how ESSC management was to determine, through their evaluations, that an identified deviation was in fact a defect associated with a SSH. As a result, the NRC inspectors found that ESSC's 10 CFR Part 21 program did not adopt appropriate procedures, pursuant to 10 CFR 21.21(a). This is identified as Violation 99901098/2008-201-01. ESSC initiated Corrective Action Program (CAP) report 1037 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 that ESSC had completed. The inspectors discovered that ESSC management had performed only one 10 CFR Part 21 evaluation. The evaluation concluded that the item was a Non-Part 21 item and was therefore removed from any further Part 21 considerations. The NRC inspectors did not identify any findings in this area.

b.4 Procurement Documents

ESSC's NQAM, Section 4, "Procurement Document Control," Step 4.4.2.10, states, in part, that POs will contain requirements for reporting and approving the disposition of nonconformances. ESSC 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 POs reviewed contained the above 10 CFR Part 21 provision. The NRC inspectors did not identify any findings in this area.

c. Conclusions

The NRC inspectors found that ESSC's postings of Part 21 requirements met the requirements

presented in 10 CFR 21.6(a). In addition, ESSC SOP Q-15.1 generally incorporated the requirements of 10 CFR 21.21. However, as presented above, the NRC inspectors found that ESSC SOP Q-15.1 did not provide adequate guidance to determine through an evaluation that the identified deviation is a defect or failure to comply associated with a SSH as required by the regulation. This is identified as Violation 99901098/2008-201-01. Except for the issues identified in NOV 99901098/2008-201-01, the NRC inspectors concluded that ESSC's 10 CFR Part 21 program requirements are consistent with regulatory requirements.

2. Design Control

a. Inspection Scope

The NRC inspectors reviewed ESSC policies and procedures governing the implementation of ESSC's order entry and design control program to verify compliance with the QA requirements of Criterion III, "Design Control," of Appendix B to 10 CFR Part 50. The NRC inspection team reviewed a sample of three completed design packages for components originally designed, fabricated, and supplied by an Original Equipment Manufacturer (OEM) certified as an ASME N stamp supplier and in accordance with a nuclear QA program meeting the requirements of Appendix B to 10 CFR Part 50.

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

- ESSC NQAM, Issue No. 3, Revision 2, dated April 23, 2008.
- ESSC SOP Q3.1, "Contract Review Procedure," Revision 0, dated August 16, 1996.
- ESSC SOP Q3.4, "Contract Review Procedure – APV Parts," Revision 0, dated April 10, 2001.
- ESSC Form F-279, "Contract Review Checklist," Revision 9, dated March 07, 2005.
- ESSC SOP Q3.2, "Design Control of ASME Section VIII Division 1. Pressure Vessels," Revision 1, dated July 15, 2002.
- ESSC SOP Q3.3, "Design Control of Customer Designed Components Fabricated by ESSC," Revision 0, dated August 11, 1999.
- ESSC Job No. 33213 for two EKJ04A and EKJ04B, Replacement Emergency Diesel Generator Lube Oil Heat Exchanger, Type EDG, ITT American Standard, ASME Section III, Class 3, 1974 Edition, Summer 1976 Addenda.
- ESSC Job No. 32389 for three replacement Model 303-6C-40LL Heat Exchanger Type Heat Flow, ASME Section III, Class 3.
- ESSC Job No. 32408 for two type EKJ03A and EKJ03B, Intercooler Heat Exchanger ASME Section III Cl. 3 1977 Edition, No Addenda and TEMA Class R.
- ESSC Job No. 34185 for Discharge Head.
- Design report MPR-3079, "ASME Code Design Report and Seismic Qualification Report for Wolf Creek Lube Oil Heat Exchanger Section III- Class 3," Revision 2, dated January 24, 2008.
- Design report MPR-2932, "ASME Code Design Report and Seismic Qualification Report for Intercooler Water Heat Exchangers Section III- Class 3," Revision 1, dated September 23, 2006.
- ESSC Engineering Change Notice (ECN) 216 for Job No. 34185.
- ESSC ECN 153 for Job No. 33213.
- ESSC drawing 1561, "Letdown Cooler Assembly," ESSC part number N32389, Revision 1, dated April 27, 2006.

- ESSC drawing 1561A “Casing Shell,” Revision 1, dated March 23, 2006.
- ESSC drawing 1642A, “Heat Exchanger Assembly”, ESSC part number N33213, Revision 1, dated December 20, 2007.

b. Observations and Findings

b1. Order Entry

ESSC NQAM Section 3.2 describes the process for receiving customer orders and initiating activities necessary to fulfill applicable ASME Code and contract requirements. Upon receipt of customer POs for ASME safety related fabrication and/or non-ASME safety related/complex welding fabrication, the POs are reviewed and approved by the Contract Review Committee. The Contract Review Committee, which consists of the Project Manager/ Engineering, Welding Engineer, Sales, and the Vice President of QA, reviews the purchase order to verify that sufficient design information has been provided to fabricate/manufacture the item in accordance with client purchase specifications and the Code, and documents this review on a Contract Review Form (F-272). The Contract Review Form includes the following information: the item ordered, customer purchase number, applicable QA regulatory codes and standards, customer requirements, applicable Code paragraph and ESSC procedures and documents, and a summary of the Contract Review Committee’s review of documents that describe the order.

When exceptions are taken to customer PO requirements, these exceptions are communicated to the customer, and written customer approval is received before initiating fabrication/ manufacture of the order. Changes or revisions to customer POs receive the same level of review as the original PO.

The NRC inspectors evaluated ESSC implementation of the order entry measure by sampling four POs, including PO 51554, PO 7336440, PO 733664 and PO 737566. The NRC inspectors verified that quality and technical requirements for the sample of job orders were adequately translated in accordance with ESSC’s procedure for controlling design input, design reports, drawings, and travelers. However, the NRC inspectors observed that PO reviews by the Contract Review Committee were not satisfactorily documented. The NRC inspectors determined that Contract Review Form for PO 733664 was missing Project Manager/Engineering, Sales, and the Welding Engineer review signatures.

The NRC inspectors reviewed work-in-process order for ESSC Job No. 34185, issued for customer PO RLLA19846, for an ASME safety related discharge head and found that the Contract Review Form documented the review of purchase order RLLA19846 but did not document any subsequent revisions to the PO.

Further, during the inspection, the ESSC Vice President of QA provided the NRC inspectors with an internal e-mail memo related to Contract Review Form. The memo contained a new ESSC policy for stapling the Contract Review Form to the cover of each Customer PO “QA File Copy,” that includes all revisions to customer POs. The memo further stated that Traveler was not to be authorized until the “Contract” had been formally accepted through the Contract Review Form. The memo was presented as an abbreviated method for implementing the new policy through signature of personnel from ESSC QA and Engineering departments, without issuing a corrective action to address the discrepancies as required by the NQAM. The NRC inspectors determined that the abbreviated method essentially bypassed ESSC policies and procedures for controlling the order entry process. This issue was identified as a contributing element in the issuance of Nonconformance 999-01098/2008-201-02.

b.2. Design Control

Design Document Review

ESSC SOP Q3.2 and SOP Q3.3 establish the process for the translation of design requirements into design documents. The NRC inspectors reviewed completed design packages for PO 737566, PO 51554, and PO 7336440. The NRC inspectors verified that a sample of customer requirements, such as PO requirements, design specifications, and drawings, were correctly translated into ESSC job travelers, procedures, design output documents, and fabrication drawings. Further, the NRC inspectors verified that design inputs were translated into design output documents. The NRC inspectors did not identify any issue in this area.

Design Responsibility

ESSC NQAM Section 3.3.3 states that design work may be subcontracted to a qualified and approved design organization maintained on the ESSC Approved Vendors List (AVL). ESSC retains the responsibility for the component design and achievement of structural integrity through review and approval of Design Reports and Load Data Sheets by the Vice President of QA and the Project Manager. ESSC NQAM Section 3.3.3 also describes the responsibilities for the Vice President of QA, the Project Manager and the designated Registered Professional Engineer (RPE) involved in various steps of the design control.

The NRC inspectors reviewed a sample of completed design packages in which the actual design function was subcontracted out to MPR Associates, a qualified Design Organization included in the ESSC AVL.

Through an evaluation of PO 13043, PO 13045, and PO 14258, issued to MPR Associates for Engineering Services, the NRC inspectors evaluated ESSC's controls for the transfer of design inputs to the design organization for final design documents. The NRC inspectors verified that the POs stated the scope of work; translated customer requirements and design specification and drawings, Code requirements, OEM inputs; and were approved by the ESSC Vice President of QA, Sales Manager, and the Project Manager.

The NRC inspectors also reviewed the design reports for PO 737566, PO 51554, and PO 7336440 to verify ESSC implementation of design responsibility. The NRC inspectors noted that the design reports were certified and approved by the designated RPE and reviewed by the ESSC Vice President of QA and the Project Manager/Engineering. The NRC inspectors reviewed the qualification records for the RPE, verified that the RPE's qualifications met the requirements of ASME Section III, Appendix XXIII, and verified that the qualification records were reviewed every three years by the ESSC Vice President of QA. The NRC inspectors found the sample of design reports reviewed to be acceptable, and ESSC controls for design reports had been effectively implemented.

Design Process and Design Verification

ESSC NQAM Section 3.3.5 addresses the selection by the design organization's engineers of design methods, materials, parts, equipment, and processes that are essential to the component. The Project Engineer provides the RPE with the required design input documents that are necessary for the design output documents needed (specifications, drawings, and procedures). The RPE is responsible for reviewing and approving design analysis and the final design report.

ESSC SOP Q3.2 establishes the design verification testing requirements. The NRC inspectors reviewed a sample of three completed design reports for heat exchangers and determined that the design reports incorporate design analysis reports, design calculation reports, hand calculations, and finite element analysis. Each report was signed by the preparer, checker/reviewer and approved by the RPE. The NRC inspectors verified that the reports were checked by individuals independent of the engineering function responsible for performing the calculations. Further, the NRC inspectors determined that the design packages included verification tests that consisted of eddy current examination and hydrostatic tests. The NRC found the design process to be effectively implemented.

Interface Control

ESSC NQAM Section 3, subparagraph 3.3.11, "Interface Control," establishes the implementation for the identification and control of design interfaces. The Project Manager/Engineering is responsible for identifying, controlling, and documenting design interfaces, both internal and external, among participating design organizations.

The NRC inspectors reviewed a sample of three job orders, Job Nos. 33213, 32408, and 32389 to evaluate ESSC implementation of these measures. The NRC inspectors noted that the job order packages included several transmittal documents used to document customer approval of drawings, design changes, non-conformance dispositions, and procedure approvals. The NRC inspectors found the interface control to be effectively implemented.

Design Change Control

ESSC NQAM Section 3, subparagraph 3.3.10 describes that the Project Manager with the assistance of the designated RPE is responsible for assuring that the changes to ESSC final designs, including field changes, are justified and subject to the same design control measures applied to the original design.

ESSC SOP Q3.2 and SOP Q3.3 establish the measures used to control design changes, originated by external organizations. Section 4.0 of SOP Q3.3 states that revision made by external organizations shall be reviewed by ESSC Engineering, and the evaluation shall be documented on Engineering Change Notice (ECN) along with the disposition of the affected completed or partially completed fabricated components or sub-assemblies.

ESSC SOP Q5.1 describes the method for control of revisions to drawings through the ECN process. Section 5.0 of SOP Q5.1 states that Engineering and QA shall determine if a Traveler revision or a Traveler supplement is required, based on the scope of the design change and the effect of the design change on the fabrication process. In addition, the procedure instructs Engineering to evaluate and determine if the ECN affects any completed, partially completed, or work-in-process components and, if found to have an effect on the component, to provide a disposition action.

The NRC inspectors reviewed a sample of three completed job packages, Job Nos. 33213 and 32408 and Job No. 32389 that included changes to the design and drawings. The NRC inspectors noted that ECN 153 for Job No. 33213 did not show complete evaluation performed by Engineering and QA as required by SOP Q5.1. The ECN did not reflect that a determination was made for the need of a Traveler revision or Traveler supplement, in addition to the evaluation of the effect of ECN on any completed, partially completed, or work-in-process components.

The NRC inspectors noted that ECN 158 for Job No. 33213 was issued to revise drawing 1642E sheet 2 to correct 0.500" maximum dimension per NC 1358. The ECN stated to rework Job No. 33213; however, the NRC inspectors noted that the design review check box was not appropriately marked. Upon further investigation, the NRC inspectors found that the NC-1358 disposition approval by the customer was for the design organization to revise the design report and evaluate the effect of the change in dimension on design calculation. The NRC inspectors reviewed more samples documented in the ECN logbook maintained by the Computer Aided Drafting (CAD) Engineer. The ECN logbook indicated similar inconsistencies in ECN No. 104, 105, 120, 122, 124, 156, 166, 176, 183 and 183 where neither the check boxes for the engineering evaluation for the effect on existing fabrication / sub-assemblies nor the check boxes for Engineering and QA evaluation for Traveler revision or Traveler supplement requirement were checked. This inconsistency identifies that ESSC failed to effectively implement the design change controls. This issue was identified as a contributing element in the issuance of Nonconformance 99901098/2008-201-02.

c. Conclusion

The NRC inspectors concluded that ESSC order entry and design control program requirements are consistent with the regulatory requirements of Criterion III of Appendix B to 10 CFR 50. However, the NRC inspectors found that ESSC failed to document the review of customer purchase orders and its changes or revisions on Contract Review Form (F-272). Also ESSC failed to document in the ECN the Engineering and QA evaluation for a Traveler revision or a Traveler supplement requirement, based on the scope of the design change and the effect of the design change on the fabrication process and the Engineering evaluation on the effect of the ECN on work-in-process, or work that is partially completed (sub-assemblies) and determine if the ECN affects any completed, partially completed or work-in-process components. These issues are identified as part of Nonconformance 99901098/2008-201-02.

3. **Control of Purchased Material, Equipment, and Services**

a. Inspection Scope

The NRC inspectors reviewed ESSC's NQAM and related implementing Quality Assurance procedures that govern the control of purchased material, equipment, and services. The NRC inspectors reviewed a sample of POs pertaining to safety related items, a selection of sub-supplier audits, and the ESSC AVL related to Safety Related-ASME (Q-1) and Safety Related Appendix B (Q-2) suppliers to determine compliance with Appendix B to 10 CFR Part 50, Criterion IV, "Procurement Document Control," and Criterion VI, "Control of Purchased Material, Equipment, and Services."

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

- ESSC NQAM, Issue No. 3, Revision No. 2, dated April 23, 2008.
- ESSC SOP Q7.1, "Receipt Inspection Procedure," Revision 3, dated August 04, 1995.
- ESSC SOP Q7.4, "Approved Vendors List Control Procedure", Revision 2, dated December 04, 1997.
- ESSC SOP Q18.2, "External Audit Procedure", Revision 2, dated November 10, 2005.
- ESSC Approved Vendors List (AVL) dated July 21, 2008.

- ESSC Safety Related Purchase Order (PO) 15288, dated November 07, 2007, to Quasar Industries, Rochester Hills, Michigan, for L.O. Cooler Heat Exchanger baffle plates-Job Nos. 33213-C4-A, 33213-C4-B, 33213-C4-C.
- ESSC Safety Related PO 15879, dated April 02, 2008, to Diversified Machine Components, Eastlake, Ohio, for 45 ea charging pump suction valves for APV pump, APV p/n APV035622.
- ESSC Supplier Audit Report No. 3115-0801, Lambert Macgill Thomas, Inc (LMT Test) Swainsboro, Georgia. Audit dates: April 1-2, 2008.
- ESSC Supplier Audit Report No. V0510 (NIAC) of MPR Associates, Alexandria, Virginia, performed by Invensys TRICONEX. Audit dates: August 18-19, 2005.

b. Observations and Findings

The NRC inspector verified the compliance of each sampled PO with the applicable requirements of Appendix B to 10 CFR Part 50, including: appropriate control, accurate transference of technical and quality requirements specified on the licensee's order, accurate transference of 10 CFR Part 21 requirements to the sub-supplier, and ESSC sub-suppliers audits to verify that each sub-supplier had an appropriate QA program. The NRC inspectors also verified that exceptions to, or revisions of, technical and quality requirements of these POs were processed using the same controls as applied to the initial PO. Additionally, the NRC inspectors verified an ESSC fabrication drawing that had been submitted with the corresponding PO by ESSC to their sub-supplier as the technical specification, and concluded that the licensee's initial technical and quality requirements had been accurately transferred to the sub-supplier in the drawing. The NRC inspectors found that all the QA requirements were adequately reflected in the sample POs. The inspectors did not identify any issues in this area.

The NRC inspectors found that for the majority of the POs reviewed, the AVL correctly identified the sub-supplier as qualified 10 CFR Part 50, Appendix B, authorized to provide nuclear material, equipment, and services to ESSC and was consistent with the conclusions of the supplier's audit. However, NRC inspectors noted that ESSC commercial PO 13491 was issued to the sub-supplier with quality requirements that were inconsistent with a purchasing restriction posted in the AVL. This item is discussed in further detail in Section 4, "Commercial Grade Dedication," of this inspection report.

Based on the review of the external audit reports, the NRC inspectors noted that ESSC's audit process includes the use of a formal checklist and the documentation of the objective evidence to substantiate the audit results. Additionally, the NRC inspectors verified that none of the audits had exceeded 3 years from the last audit and that all were within their expiration due dates. The NRC inspectors identified that the ESSC Vice President of Quality Assurance performed the duties of lead auditor for the audits reviewed and that his qualification to perform these activities was verified as current. The inspectors did not identify any issues in this area.

c. Conclusion

The NRC inspectors determined through a review of selected POs, ESSC's AVL and external audits to sub-suppliers that ESSC is implementing a process for the control of purchased material, equipment and services consistent with the regulatory requirements of Criterion VII of Appendix B to 10 CFR Part 50. The NRC inspectors concluded that policies and procedures governing the control, issuance and revision of safety significant POs and ESSC's effectiveness in implementing these requirements were adequate to satisfy the applicable requirements of

Appendix B to 10 CFR 50 and 10 CFR Part 21.

4. Commercial Grade Dedication

a. Inspection Scope

The inspectors reviewed ESSC's QA policies and procedures that governed commercial grade dedication activities to determine compliance with Appendix B to 10 CFR Part 50, with regard to the procurement and acceptance of commercial-grade items (CGIs) for use as basic components in accordance with 10 CFR Part 21.

The inspectors also reviewed ESSC's process for dedicating CGIs to verify it meets the applicable portions of Appendix B to 10 CFR Part 50 and that it provides reasonable assurance that CGIs will perform their intended safety function. Specifically, the inspectors reviewed the applicable portions of ESSC NQAM and the related SOPs. In addition, the inspectors evaluated a representative sample of ESSC's commercial grade dedication packages, associated sub-supplier commercial grade surveys and reviewed the adequacy and implementation of the ESSC AVL for commercial grade suppliers (Q4).

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

- ESSC NQAM, Issue No. 3, Revision No. 2, dated April 23, 2008.
- ESSC AVL, dated July 21, 2008.
- ESSC SOP Q7.1, "Receipt Inspection Procedure," Revision 3, dated August 4, 1995.
- ESSC SOP Q7.2, "Material Dedication Procedure," Revision 7, dated July 25, 2001.
- ESSC SOP Q7.4, "Approved Vendors List Control Procedure," Revision 2, dated December 4, 1997.
- ESSC SOP Q18.2, "External Audit Procedure," Revision 2, dated November 11, 1995.
- ESSC Drawing 1642-a, "Heat Exchanger Assembly," P/N N33213.
- ESSC PO 11780 to The Falk Corporation, Auburn Hills, MI for two Shaft Couplings, p/n1015G10, dated November 30, 2004.
- ESSC PO 13491 to The Falk Corporation, Auburn Hills, MI for a gasket/shim set, p/n 7-967061-01, dated June 29, 2006.
- ESSC PO 15214 to The Cassie Alaro Group, Grand Blanc, MI 48438 for 1 A36 baffle plate, 16 ea 3/8" x 20' steel rods, 16 lot of 1/2" OD x .035 wall and 0.430 ID plate steel, dated November 05, 2007.
- ESSC PO15878 to Alloy Cast Products, Inc, Kenilworth, NJ 07033 for 10 ea Charging Pump discharge valve seats for APV pump, APV p/n 036713, dated April 02, 2008.
- ESSC Supplier Audit Report No. 0340-0101, The Falk Corporation, Milwaukee, WI 53208. Audit dates: 10/2-3/01.

b. Observations and Findings

b.1 Identification of Critical Characteristics

ESSC NQAM Section 7.8 contains the programmatic guidance for performing CGDs in accordance with 10 CFR Part 21. This section states that a commercial grade material to be dedicated shall be tested for compliance to the specification in accordance with a material dedication procedure meeting the EPRI NP-5652 document as endorsed by the NRC. The

NQAM further states that “Critical characteristics of the material to be verified through the dedication process shall be identified as either all the critical requirements of the material specification (when the material specification is referenced alone without identified critical characteristics) or those identified by the customer as the critical characteristics to be verified”.

ESSC’s implementing instructions for commercial grade dedications are found in ESSC SOP Q7.1 and ESSC SOP Q7.2. The content of these procedures is written to apply to simple, raw material dedications (e.g., bar stock, round stock, flat stock, etc.), where the critical characteristics are published in corresponding ASTM material specifications. When commercial grade dedications of more complex items are needed, the ESSC procedures simply state that “Non-standard items to be dedicated which the customer has not identified the critical characteristics or those for which the critical characteristics are not identified in the description of the item requires the additional approval of competent engineering personnel.”

During discussions with ESSC personnel, ESSC indicated that it did not have access to the safety related function of each part that they supply, and as such identification of the critical characteristics for acceptance was coordinated with its customers. ESSC SOPs Q7.1 and Q7.2 indicate that ESSC will submit a commercial grade dedication plan to the customer for their approval prior to performing a dedication of complex parts, components or structures. These ESSC procedures do not provide the guidance necessary to assure that the dedication plans are prepared to adequately assure that the critical characteristics are identified and verified. This issue was identified as a contributing element in the issuance of Nonconformance 999-01098/2008-201-03.

b.2 Commercial Grade Surveys

ESSC routinely performs commercial grade surveys in support of the dedication program. The emphasis of these surveys is to assess the effectiveness of the sub-supplier’s program for controlling lot/batch/heat traceability to support the sampling in the dedication plan.

The NRC inspectors reviewed a commercial grade survey that ESSC performed at Falk Corporation in support of replacement parts for a Falk coupling. The NRC inspectors noted that the survey and checklist on file were incomplete and unsigned. When questioned by the NRC inspectors, the ESSC Vice President of Quality Assurance indicated that ESSC had determined, while performing the survey, that the sub-supplier’s program was incapable of providing the required level of quality assurance to support the commercial grade survey. Further, the NRC inspectors’ review of the Falk’s AVL entry resulting from the failed survey noted that the AVL correctly indicated that restrictions had been applied for this supplier. The restrictions indicated that a Method 2 dedication (commercial grade survey) of this vendor would not be allowed, and a Method 1 dedication would be required.

The NRC inspectors then reviewed the associated commercial grade dedication package for the subject coupling and to verify that test and inspection (Method 1) for dedication had been performed. The NRC inspectors found that although a Method 1 was performed, the dedication plan still allowed a sample for testing with an acknowledgement of a commercial grade survey. As stated before, restrictions had been applied for this supplier, based on failed commercial grade survey. This issue was identified as a contributing element in the issuance of Nonconformance 99901098/2008-201-03.

c. Conclusion

With the exception of the issues identified in Nonconformance 99901098/2008-201-03, the NRC inspectors concluded through a review of ESSC's commercial grade dedication process that the program requirements are consistent with the regulatory requirements of Criterion III of Appendix B to 10 CFR Part 50. Elements of the ESSC's commercial grade dedication process that contributed to the issuance of Nonconformance 99901098/2008-201-03 where: 1) ESSC SOP Q7.2 failed to provide guidance to identify and dedicate items other than raw materials (e.g., plate, sheet, pipe, angle iron, bar stock) and 2) ESSC'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 to support a dedication plan that included sampling for dedicating commercial grade items from Falk Corporation.

6. Control of Special Processes

a. Inspection Scope

The NRC inspectors reviewed ESSC's Welding Program Manual (WPM) and applicable implementing procedures for the control of special processes to assess compliance with the requirements of Criterion IX, "Control of Special Process," of Appendix B to 10 CFR Part 50. The NRC inspectors also reviewed the written practice for ESSC subcontractors who perform activities that are considered special processes. The NRC inspectors reviewed the following QA documentation and procedures of ESSC WPM:

- WM-GR, "Welding Program," Revision 3, dated August 11, 2005.
- WM-VT, "Visual Inspection of Welds," Revision 8, dated August 11, 2005.
- WM-REC, "Records," Revision 2, dated November 24, 1997.
- WM-GWS-1, "General Welding Standards – ASME," Revision 4, dated August 11, 2005.
- WM-FMC, "Filler Metal Control," Revision 3, dated September 9, 2005.
- Traveler, Job# 34250-B, Revision 0, for a pipe support assembly, (PO# 356246).

b. Observations and Findings

The NRC inspectors directly observed ESSC staff implementing these procedures during in-process Visual Inspections (VT) of root welds. These VTs were related to pipe support assemblies for traveler Job No. 34250-B. Nondestructive testing (NDT), heat treating, and special welding, if required, are performed by an ESSC subcontractor. The written practice for these contractors was reviewed to verify the contractor's procedure and employees' training, qualifications and certifications to perform NDT functions. The filler material storage area was also inspected and found to meet the requirements of the procedure.

The NRC inspectors noted that ESSC performs minimal activities that qualify as special process. Magnetic particle test (MT) and liquid penetrant test (PT) were the only qualified special processes performed by ESSC during the time of the inspection. The NRC inspectors directly observed an MT conducted by ESSC staff. While observing the test, the NRC inspectors verified that the procedure used to conduct the test met the requirements of ASME section V. The inspectors did not identify any finding in this area.

c. Conclusions

The NRC inspectors concluded that ESSC Special Process program is consistent with the regulatory requirements of Criterion IX of Appendix B to 10 CFR Part 50. Based on the sample of QA documents and activities reviewed, the NRC inspectors also determined that ESSC's Special Process program controls and procedures were effectively implemented.

6. Inspection

a. Inspection Scope

The NRC inspectors reviewed ESSC's NQAM and applicable implementing procedures for the inspection of activities affecting quality to assess compliance with the requirements of Criterion X, "Inspections," of Appendix B to 10 CFR Part 50. The NRC inspectors observed a sample of in-process inspections and reviewed a sample of completed inspection records. The NRC inspectors also reviewed a sample of PO documents to verify that specified design requirements were properly translated into inspection requirements and appropriate acceptance criteria. The NRC inspectors reviewed sections of the NQAM and associated implementing procedures to verify that ESSC maintains a program that effectively controls inspections used to verify components conform to required specifications. The NRC inspectors reviewed the following QA documentation and ESSC Quality Program procedures:

- ESSC SOP Q5.2, "Development & Control of ESSC Shop Travelers," Revision 0, dated March 1, 2004.
- ESSC SOP Q13.1, "Packaging and Shipping Procedure," Revision 3, dated October 3, 1994.
- ESSC SOP Q7.1, "Receipt Inspection Procedure," Revision 3, dated August 4, 1995.
- Traveler, Job# 34582, Revision 0, Lot Tag# 36408, for a pipe 3" S40 SA312 Type 304, (PO# 34700153024).
- Nonconformance (NC) Report # 1407, for a Worm Gear Box, dated April 21, 2008.
- NC# 1447, for a Receive / MT Profilometer Set-up, dated July 23, 2008.

b. Observations and Findings

The inspectors directly observed a receipt inspection by ESSC QC staff, related to Job# 34582. The NRC inspectors verified that the material was inspected in accordance with requirements specified in Q7.1. The NRC inspectors noted that characteristics to be inspected and inspection methods were correctly specified and that inspection results were properly documented. Although SOP Q7.1 properly defines methods to identify and inspect characteristic of simple components, the NRC inspectors noted that procedure SOP Q7.1 does not effectively provide methods of examinations and measurements that should be used to verify an item's compliance to specified requirements. This observation was supported by NC# 1407, which was written to address ESSC's failure to identify the wrong part was accepted during receipt inspection and shipped to its customer after final inspection. In addition, during the observation of a test conducted by ESSC staff, the NRC inspectors identified that a Mitutoyo Precision Reference Specimen calibration sticker was not properly labeled – ESSC asset number PRS001. The calibration and labeling of this specimen are conducted by an ESSC subcontractor and should be properly inspected upon receipt by ESSC, including the sticker and dates. ESSC drafted NC# 1447 to address this issue. This issue is identified as an example of an inadequate receipt inspection procedure that affects the control of purchased material, equipment, and services as

described in Nonconformance 99901098/2008-201-04.

In addition, during the review of ESSC procedures for inspections, the NRC inspectors noted the absence of a procedure in the program that describes the process for performing a final inspection. This issue is identified as an example of an inadequate inspection program as described in Nonconformance 99901098/2008-201-05.

c. Conclusions

Except for the issues identified in Nonconformance 99901098/2008-201-04 and Nonconformance 99901098/2008-201-05, the NRC inspectors concluded that ESSC's inspection program is consistent with the regulatory requirements of Criterion X of Appendix B to 10 CFR Part 50. Based on the sample of QA documents and activities reviewed, the NRC inspectors also determined that ESSC's inspection program controls and procedures were effectively implemented.

7. Test Control

a. Inspection Scope

The NRC inspectors reviewed ESSC's NQAM and applicable implementing procedures for the control of tests that are performed to demonstrate the applicable item will perform satisfactorily in service. This evaluation was conducted to assess ESSC's compliance with the requirements of Criterion XI, "Test Control," of Appendix B to 10 CFR Part 50. The NRC inspectors reviewed a sample of completed hydrostatic test records and calibration records for pressure gauges used during the hydro tests. The NRC inspectors reviewed the following QA documentation and ESSC Quality Program procedures:

- ESSC SOP Q12.0, "Control of Measuring and Test Equipment," Revision 1, dated April 23, 2004.
- ESSC SOP Q11.1, "Hydrostatic Testing Procedure," Revision 2, dated January 10, 2000.
- Form F-154, "Hydrostatic Test Data Sheet", Revision 0, dated February 9, 1997, related to Job# 33544 conducted on November 8, 2007.
- Calibration log for the Hydrostatic test gauge # PG008.

b. Observations and Findings

ESSC SOP Q11.1 provides the requirements for Hydrostatic test under ESSC's testing program. Based on the review of a sample of hydro test results, the NRC inspectors determined that completed tests were accomplished in accordance with quality procedures. The NRC inspectors also determined that calibration records for pressure gauge used for hydrostatic tests were in accordance with quality procedure Q12.0. The inspectors also noted the water quality certifications met the requirements of procedure Q11.1. The NRC inspectors did not identify any issues in this area.

c. Conclusions

The NRC inspectors concluded that ESSC's test control program is consistent with the regulatory requirements of Criterion XI of Appendix B to 10 CFR Part 50. Based on the limited

sample of records reviewed and activities observed, the NRC inspectors also determined that ESSC's NQAM and associated testing procedures were effectively implemented.

8. Nonconformance

a. Inspection Scope

The NRC inspectors reviewed the policies and procedures governing the implementation of ESSC's nonconformance program to assess ESSC's compliance with the requirements of Appendix B to 10 CFR Part 50, Criterion XV, "Nonconformance." NRC inspectors reviewed eight NC's initiated during the past six months. These NCs were primarily the result of deficiencies identified by ESSC's customers and by internal audits and inspections performed by ESSC.

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

- ESSC NQAM, Issue 3, Revision 2, dated April 23, 2008.
- ESSC SOP Q-15.0, "Nonconformance Reporting Procedure", Revision 0, dated April 18, 2008.
- ESSC SOP Q-15.1, "Reporting of Defects Procedure (10 CFR Part 21 Evaluation and Reporting)", Revision 3, dated July 17, 2008.
- NC-1434, "Weld Repair Elbow 30" 90 degree SR BW", dated June 23, 2008.
- NC-1425, "Gage Block Set GB004 (81 Pc Mitutoyo Ceramic Gage)", dated May 8, 2008.
- NC-1408, "9366733 – Zurn Part No. 83176", dated April 21, 2008.
- NC-1407, "9366733 – Zurn Part No. 83176", dated April 21, 2008.
- NC-1400 "0032038542 3 – Cage, Valve", dated April 14, 2008.
- NC-1399 "0032038540 3 – Stem, Lower Valve", dated April 14, 2008.
- NC-1392 "STEEL – Plate 4.25" X 96.00" X 260.00", dated March 27, 2008.
- NC-1358 "NCR 1358 – Rework Floating Channels", dated January 10, 2008.

b. Observations and Findings

ESSC SOP Q-15.0 defines the measures to identify nonconformances, and to produce, track, and close NCs. ESSC'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, when problems are identified as a result of: 1) an internal or external audit; 2) problems that present frequently produced and similar NCs; or 3) problems that are considered significant by ESSC management. Provisions exist in the program and within ESSC SOP Q-15.0 to proceed with ESSC SOP Q-16.1 corrective actions. ESSC's program using ESSC SOP Q-15.0 also contains provisions for the reporting of defects and possible and subsequent initiation of a 10 CFR Part 21 evaluation in accordance with ESSC SOP Q-15.1.

ESSC's QA Department is responsible for issuing NCs 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 6) customer's telephone call or memorandum describing such a defect/deficiency. As stated in Section 15 of ECCS's NQAM, all ECCS employees are responsible for identifying real or

potential problems and bringing them to the attention of ECCS's QA Department.

The NRC inspectors reviewed eight NCs generated by ESSC during the previous six months of 2008. The NRC inspectors noted that in these eight NCs: 1) identified nonconformances were dispositioned in accordance with ESSC's approved procedures; 2) an appropriate technical justification was presented for each disposition; 3) adequate action was taken by ESSC in regard to the nonconforming material/item; and 4) all identified nonconformances, if appropriate, were subject to a 10 CFR Part 21 assessment/evaluation. The NRC inspectors also noted that all of the eight reviewed NCs contained the appropriate review and disposition by ESSC personal tasked with such a review and disposition. ESSC personal tasked with review/disposition is described in ECCS SOP Q-15.0. The NRC inspectors did not identify any findings in this area.

c. Conclusions

The NRC inspectors determined that the nonconformance program requirements are consistent with the regulatory requirements of Criterion XV of Appendix B to 10 CFR Part 50. Based on the limited sample of records reviewed the NRC inspectors also determined that ESSC's nonconformance program was effectively implemented.

9. Corrective Action

a. Inspection Scope

The NRC inspectors reviewed the policies and procedures governing the implementation of ESSC's corrective action program to assess ESSC's compliance with the requirements of Appendix B to 10 CFR Part 50, Criterion XVI, "Corrective Action." NRC inspectors reviewed eight corrective action reports (CPA's) initiated during the previous four months of 2008. These CPAs were primarily the result of deficiencies identified by ESSC's customers and by external audit findings.

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

- ESSC NQAM, Issue 3, Revision 2, dated April 23, 2008.
- ESSC SOP Q-16.1, "Nonconformance and Corrective Action Reporting Procedure", Revision 2, dated April 21, 2008.
- CPA-1031 "Failure to Follow P.O. Requirements", dated May 19, 2008.
- CPA-1027 "Multiple Document Failures", dated May 8, 2008.
- CPA-1024 "NC 1407 & 1408", dated May 2, 2008.
- CPA-1022 "Material Marked Incorrectly", dated April 20, 2008.
- CPA-1018 "NC 1392 Follow Up with ArcelorMittal", dated May 1, 2008.
- CPA-1013 "NC1374 – Weld Failures", dated March 17, 2008.
- CPA-1026 "Metrology Lab Environment Monitoring", dated May 8, 2008.
- CPA-1028 "Job #32389 Documentation Discrepancies", dated May 4, 2008.

b. Observations and Findings

ESSC SOP Q-16.1 defines the measures to generate, track, and close CPAs. ESSC'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. ESSC's QA Department is responsible to issue CPAs 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 ECCS employees are responsible for identifying real or potential problems and bringing them to the attention of ECCS's QA Department.

ESSC SOP Q-16.1 further states that CPAs that are found to be open for more than thirty (30) business days of issue without schedule or reason shall require immediate additional actions to address prompt corrective actions.

The NRC inspectors reviewed CPAs generated by ESSC on its products during the previous four months of 2008. The NRC inspectors noted that of the eight CPAs reviewed only two had been completed by the assigned completion date and two others had their assigned completion dates extended. The remaining four had not been completed by their assigned completion dates nor had their originally assigned completion dates been extended. These four incomplete CPAs exceeded their assigned completion dates by over six weeks and were still open at the time of the inspection.

ESSC SOP Q-16.1 also contains provisions for an extension of completion dates should circumstances beyond the control of ESSC become apparent, e.g., required actions by the customer are not received by ESSC or usually complex investigations are required by ESSC to fully complete the CPA. While ESSC could justify the extension of the completion dates, it could not provide a reason to the NRC inspectors for why this provision was not used.

During the review of the CPAs, the NRC inspectors noted that the two completed CPAs were dispositioned in a timely manner and that proposed corrective actions were well-documented. The NRC inspectors also noted that the two CPAs that had extended completion dates provided sufficient and documented justification for their due date extensions. The NRC inspectors further noted that the four overdue/incomplete CPAs (CPA-1031, CPA-1028, CPA-1027, and CPA-1024) were related to document processing issues and that their assigned completion dates could also have been justified and extended in accordance with ESSC SOP Q-16.1 requirements dealing with timeliness. The failure to document the justification for extending the completion dates is identified as a failure to follow ESSC's corrective action program requirements and a failure to process corrective actions in a timely manner. This issue is identified as Nonconformance 99901098/2008-201-06. ESSC initiated CPA-1449 to address this issue.

c. Conclusions

Except for the issue identified in Nonconformance 99901098/2008-201-06, the NRC inspectors concluded that ESSC's corrective action program is consistent with the regulatory requirements of Criterion XVI of Appendix B to 10 CFR Part 50. Based on the sample of QA documents reviewed, the NRC inspectors also determined that ESSC's corrective action program was not adequately implemented in accordance with ESSC's requirements since ESSC failed to process corrective actions in a timely manner. This issue is identified as Nonconformance 99901098/2008-201-06.

10. Document Control

a. Inspection Scope

The NRC inspectors examined the documents governing ESSC's document control processes to evaluate the adequacy of its program for meeting the requirements of Criterion VI, "Document Control," of Appendix to 10 CFR Part 50. These documents establish the measures to assure that the correct documents are used for activities affecting quality. The documents included the quality assurance manual, WPM, quality implementing procedures, and forms. In addition, the NRC inspectors verified the storage of associated records to assure that records are stored in a manner that meet the requirements of Criterion XVII, "Records", of Appendix B to 10 CFR Part 50. The NRC inspectors also examined forms and controlled documents to verify overall implementation and effectiveness of ESSC's control of manuals, procedures, and forms.

Within the scope of this area of the inspection, the NRC inspectors examined the following documents:

- Nuclear Quality Assurance Manual, Issue 3, Revision 2, dated April 23, 2008.
- Welding Program Manual, Revision 13, dated September 9, 2005.
- Quality Assurance Q Procedures manual, Table of Contents, Revision 39, dated July 21, 2008.
- ESSC SOP Q1.0, Revision 0, "Quality Policy Deployment", dated August 14, 1996.
- ESSC SOP Q2.4, Revision 0, "Registered Professional Engineer Qualification Procedure", dated May 20, 2002.
- ESSC SOP Q3.1, Revision 0, "Contract Review Procedure", dated August 16, 1996.
- ESSC SOP Q5.1, Revision 2, "Development and Control of ESSC Drawings", dated May 2, 2005.
- ESSC SOP Q6.0, Revision 0, "Document Control Procedure", dated August 16, 1996.
- ESSC SOP Q7.1, Revision 3, "Receipt Inspection Procedure", dated August 4, 1995.
- ESSC SOP Q7.4 Revision 2, "Approved Vendor List Control", dated December 4, 1997.
- ESSC SOP Q17-1, Revision 1, "QA Records Maintenance", dated April 9, 1997.
- ESSC Forms Book.
- Form F-119A, "Nonconformance Report Form."
- Form F-154, "Production Inspection Report."
- Form F-193a, "Document Transmittal."
- Form F-273, "ESSC Shop Drawings."
- Southern California Edison Supplier Audit Report ESSC-1-08, June 6, 2008, Finding No. 1 (CAR S-2003).

b. Observations and Findings

b.1 Manuals and Procedures

The NQAM consists of 19 sections and one appendix. Section 6 of the NQAM states that the following documents are placed under document control: NQAM, Q procedures, WPM, Drawings, AVL, and revisions to these documents. Procedure Q6.0 addresses the NQAM, company policies, standard operating procedures, codes, regulations, quality standards, material standards and specifications, and forms; it does not address specifically the WPM, which is to be placed under document control in the same manner as the Quality Procedures Manual, as stated in the NQAM.

The NRC inspectors found that a controlled copy of the NQAM was issued to the Authorized Nuclear Inspector Supervisor, and a controlled copy of the NQAM is maintained in the Auditor's Workbook. The NRC inspectors also found that the NQAM Issuance Control Log was current and contained the required information. Controlled copies (with issuance numbers) of the NQAM are issued to in-house personnel. External controlled copies of the NQAM are issued and transmitted as required, and receipt acknowledgement is provided. The NQAM Table of Contents includes correct revision levels and dates of each section that is included in the NQAM. Q procedures are provided in the Auditor's Workbook and in other controlled sets. The WPM consists of 13 sections, each of which was signed by an independent preparer, reviewer, and approver. Master distribution logs are maintained by the QA Department.

The NRC inspectors examined several types of documents and determined that ESSC has an inadequate process to control the preparation, review, approval, revision, issuance, and control of processes affecting quality. The NQAM, Section 6, subsection 6.4.3.3 requires that the NQAM Table of Contents be signed by the Vice President of Quality Assurance, indicating authorship, review, and approval. A single person signing for authorship, review and approval does not provide for independence of these three processes from one another. In addition, the NQAM, Section 6, subsection 6.5.1.4, states that signatures indicating review and approval are required to be documented on the first page of the Q procedure. Contrary to this requirement, the NRC inspectors found that some Q procedures do not include the reviewer signature, such as SOPs Q1.0, Q3.1, and Q5.1. Furthermore, the NQAM, Section 6, subsection 6.5.4 states that the Vice President of Quality Assurance, or President is responsible for review and approval of Q procedures. The NRC inspectors found that SOP Q2.4 was prepared and reviewed by the Vice President, Quality Assurance, and approved by the President. ESSC failed to have a process that provides for independent review.

The NRC inspectors also noted that obsolete and uncontrolled documents are referenced in the NQAM and Q procedures. Specifically, SOP Q5.1 includes references to the Q-2 Nuclear QA Manual and Form F-273. Q-2 Nuclear QA Manual is an obsolete document. Form F-273 is not listed in Appendix A of the NQAM (see additional information regarding the use of forms in section b.2 below) and, therefore, is not controlled.

The issues above are examples of the ESSC's failure to have an adequate document control process for manuals and procedures, thus affecting the quality of ESSC's document control program. These issues are identified as Nonconformance 99901098/2008-201-07.

b.2 Quality Forms

ESSC uses different forms to document quality activities. However, the NRC inspectors found that Sections 5 and 6 of the NQAM and SOP Q6.0 do not adequately address the review, approval, distribution, revision, and control of these forms. The forms listed in Appendix A of the NQAM are referenced in the NQAM and Q procedures. However, the NRC inspectors found that the majority of the forms in the Forms Book, located in the QA Department as directed by SOP Q6.0, are not referenced in the NQAM, the WPM, or the Q procedures. Specifically, form F-154, "Production Inspection Report," used during the implementation of SOP Q7.1, is not referenced in Q7.1. Section 7 of the NQAM does provide a reference to F-154, but there are multiple versions of F-154 (e.g., F-154a, F-154b) that are to be used for various types of materials being inspected for conformance to the PO. In addition, the NRC inspectors were informed by the Vice President of Quality Assurance that the current forms also were available electronically in a folder on the ESSC computer network. The NRC inspectors noted that this

availability is not reflected in the NQAM or SOP Q6.0. The NRC performed a comparison of the form revisions in the Forms Book and the form revisions available electronically and determined that there were inconsistencies. Specifically, F-119A, Revision 8, was in the Forms Book, but Revision 9 was available electronically. Additionally, Revision 4 of F-193a was in the Forms Book, but Revision 5 was available electronically.

The NRC inspectors determined that Sections 5 and 6 of the NQAM and SOP Q6.0 are not consistent in their approach to controlling forms. According to Section 6.0, subsection 6.4.4 of the NQAM, forms may be revised, but if a change “does not delete or reduce the aspect” of the form, it is not required to update the NQAM (a controlled document) with the revised form. SOP Q6.0 states that forms are maintained in the Forms Book. However, the NRC inspectors noted that Section 5 of the NQAM states that ESSC forms, when completed, are considered records in accordance with Section 17, “Quality Assurance Records.” Contrary to Section 5 of the NQAM, SOP Q6.0, subsection 5.6, states that only after a form is complete is it considered a “controlled document.” When a form is completed it becomes a record under Section 17, as is stated correctly in the NQAM. The current revision of a form, prior to inclusion of specific information, should be the controlled document.

The issues above are examples of the failure to have an adequate document control process for forms, thus affecting the quality of ESSC’s document control program. These issues are identified as Nonconformance 99901098/2008-201-07.

b.3 Document Storage Room

The NQAM, Section 6, subsection 6.10.3 states that copies of obsolete revisions of documents controlled by this section are maintained as archive files in accordance with Section 17 of the NQAM. The NQAM, Section 17, subsection 17.7.1, states that records are stored in fireproof containers or record vaults and that QA records may be stored in fireproof cabinets in the QA Department or in one of two approved protective storage vaults at ESSC.

SOP Q17-1, section 8.1 states that records shall be stored in facilities meeting the minimum requirements of NQA-1, including Supplement 17S-1 for a “Single Storage Facility”, except as modified by ASME Section III NCA-4000. Section NCA-4134.17, “Quality Assurance Records”, section (a), “General,” states that “the provisions of NQA-1, Basic Requirement 17 and Supplement 17S-1, shall apply, except that the requirements for classification and facility in 17S-1, 4.4 are not applicable. Such records shall be classified and maintained as required by this section.” NQA-1, Supplement 17S-1, subsection 4.4.1, “Single Storage Facility,” (c), states that “doors, structure and frames, and hardware shall be designed to comply with the requirements of a minimum 2 hr fire rating.”

The NRC inspectors found that SOP Q17-1, as written, took exception to storing records in a facility that has a 2-hour fire rating. Therefore, the NRC inspectors determined that procedure Q17-1 by itself would not adequately meet the NQA-1 required fire rating for storage facilities. In addition, the NRC inspectors noted that the Document Storage room window contains a label stating a 1-hour fire rating, and the labels for its door and frame each state a 1 ½-hour fire rating. Both the window and the door/frame do not meet NQA-1 requirements. The NRC inspectors informed the President of ESSC that the fire rating of the Document Storage room did not meet NQA-1 requirements.

The ESSC President and NRC inspectors examined the architectural drawings of the building, and it was determined that the drawings clearly stated that the Document Storage room was to

be 2-hour fire rated. Subsequent to construction of the Document Storage room, it was not verified that fire protection requirements were met. The President immediately notified the builder who, in turn, contacted the door supplier and window supplier. The door supplier acknowledged that, with the choice between a 1 ½- or 3-hour fire rated door and frame, it made the decision to use the 1 ½-hour fire rated door and frame in lieu of the 3-hour fire rated door and frame. The builder stated in an email to the President that it was attempting to replace the existing door within about two days with a 2-hour or greater fire rated door. Additionally, ESSC contacted the window supplier, and it acknowledged that it did not supply the 2-hour fire rated window, as required. The supplier indicated that it would take eight to ten weeks get a replacement window that meets the 2-hour fire rating, and ESSC asked the supplier to expedite the process. On 7/24/2008 ESSC initiated nonconformance report NC-1448, which identified these two issues.

Therefore, the NRC considers these two records storage issues (procedural and storage room inadequacies) as a non-cited nonconformance because of the immediate actions taken by ESSC to remedy these two specific issues.

c. Conclusions

The NRC inspectors concluded, through a review of ESSC's quality documents, that ESSC failed to develop and implement an adequate document control process consistent with the regulatory requirements of Criterion VI of Appendix B to 10 CFR Part 50, as well as ESSC's NQAM and Q procedure. In particular, the NRC inspectors found that ESSC failed to have adequate controls for procedures and forms that are used to control and document processes affecting quality, including Q procedures and quality forms. In addition, the NRC inspectors found that the Q procedures make reference to obsolete documents. The NRC inspectors found that ESSC is inconsistent in the manner in which it controls forms. The majority of the forms in the Forms Book are not referenced in the Forms Book, WPM, or Q procedures. There are inconsistencies between the revisions of the forms in the Forms Book and the forms in electronic format. These issues are identified in Nonconformance 99901098/2008-201-07.

In addition, the NRC inspectors found that ESSC failed to provide adequate protection of records consistent with Criterion XVII of Appendix B to 10 CFR Part 50. ESSC Q17-1 does not meet NQA-1 requirements for storage of records. As a result of procedural inadequacies and failure to verify that the proper Document Storage room components were installed, ESSC records are not being protected appropriately. ESSC immediately initiated internal nonconformance report NC-1448 to address these issues.

11. Training and Qualification

a. Inspection Scope

The NRC inspectors examined the documents governing ESSC's training and qualification processes to evaluate the adequacy of its program for meeting 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. These documents establish the measures to assure that ESSC personnel and selected external personnel are indoctrinated, trained and qualified to perform activities affecting quality. The NRC inspectors also examined completed records that provide evidence of indoctrination and training of personnel to verify implementation and effectiveness of ESSC's training and qualification program. Records examined included qualification records, training attendance records, ESSC memoranda, examinations, and welder recertification

documentation.

Within the scope of this area, the NRC inspectors examined the following documents:

- Nuclear Quality Assurance Manual, Issue 3, Revision 2, dated April 23, 2008.
- ESSC SOP Q2.1, Revision 2, "Quality Inspector Qualification Procedure", dated June 10, 2008.
- ESSC SOP Q2.2, Revision 1, "QA Specialist Training and Qualification Procedure", dated February 14, 2005.
- ESSC SOP Q2.3, Revision 2, "Auditor and Lead Auditor Qualification Procedure", dated June 10, 2008.
- Form F-180, "QA/QC Inspector Qualification Record"
- Form F-276-IX, "Welder Performance Qualification Record (WQ) ASME IX"
- Form F-277, "Welder Continuity Log"
- Form "Active Welder Summary Sheet" (no form number)
- Form "Lead Auditor Certification (NQA-1/N45.2.23)" (no form number)
- Form F-295, "NDE Personnel Certification Record"
- Practical Examination Checklist
- General Examination Specific Examination

b. Observations and Findings

The NRC inspectors examined four ESSC documents pertinent to training and qualification. Section 2 of the NQAM and SOP Q2.1, Q2.2, and Q2.3 describe minimum requirements for the indoctrination, qualification, and training of personnel performing activities affecting quality.

Section 2 of the NQAM includes: 1) general responsibilities for qualification and training, 2) general requirements for all personnel performing quality functions, 3) additional requirements for QA personnel (including those in the QA and QC Departments, 4) lead auditors, 5) contract QA inspectors, and 6) Registered Professional Engineers. Section 9 addresses qualification of NDE personnel and welding personnel.

Three ESSC procedures address additional training and qualification requirements. SOP Q2.1 requires documentation of indoctrination and training of ESSC employees performing inspection and testing activities (including formal training and on the job training), experience, education, prior training and test results, eye examinations (if applicable), annual performance evaluations, and certification renewals. Additionally, there are three levels (i.e., I, II, and III) of qualification, each higher level requiring additional education, experience, capabilities, and responsibilities. All ESSC inspection personnel are required to complete written examinations that contain questions pertinent to the discipline of qualification. SOP Q2.2 provides for additional reading, training, and examination requirements for personnel performing QA activities related to the Work Order process. SOP Q2.3 includes additional experience, qualification and training requirements of auditors and lead auditors, including maintenance of qualification.

A selection of ESSC qualification and training records was examined by the NRC inspectors to determine if ESSC adequately implements the NQAM and Q procedures. The majority of these records are maintained by the Vice President of Quality Assurance in separate files for each employee. Additionally, the Vice President of Quality Assurance maintains a separate binder, arranged chronologically, of training attendance records and selected training materials for the current calendar year. Past training records examined by the NRC inspectors revealed that

training by the Vice President of Quality Assurance is presented regularly on revisions to the NQAM. Discussions between an NRC inspector and the Vice President of Quality Assurance indicated that, since ESSC is growing, it intends to create a database to track training and qualification for each person to help ensure that ESSC meets all requirements.

The NRC inspectors examined several qualification and training folders for ESSC personnel holding a variety of positions. The President issues the Statement of Policy (part of the NQAM), qualifies the Lead Auditor, approves Q procedures, and is ultimately responsible for ESSC's QA program. The NRC inspectors examined the qualifications of the Lead Auditor and determined that they were current in accordance with SOP Q2.3 requirements. The April 14, 2008, recertification of the Lead Auditor was documented on a form that reflected the 10 point credit system of NQA-1, Appendix 2A-3. This recertification included documentation of education, experience, professional accomplishments, audit communications skills, audit training courses, audit participation, and original N45.2.23 written and oral examination in 1987. Examination of the Lead Auditor's file by the NRC Inspectors revealed that the Lead Auditor has participated in eight vendor audits since January 2008.

A sampling of training and qualification records required by SOP Q2.1 was examined by the NRC inspectors for other ESSC personnel. The following records (form F-180 and other file records) for a QC Inspector/QA Specialist were examined and were determined to be current and to adequately document: education, experience, prior training and test results, eye examination, and re-evaluation. This person is also qualified for Level II welding - Visual test, mechanical, and QA. The NRC inspectors also examined form F-180 for a QA/QC Inspector, who was initially qualified in July 2007 in Q1, Q2, Q3 visual weld inspections; mechanical/ dimensional inspections; and document review and approval. In May 2008, qualification was upgraded to include Level II NDE MT testing and PT testing. The NRC inspectors examined complete documentation for the PT certification, including: form F-295; Lambert, MacGill, and Thomas, Inc. Practical Examination Checklist; Liquid Penetrant Level II General Examination; and Liquid Penetrant Level II Specific Examination. The NRC inspector determined that the documents fully supported the 2008 qualification upgrade.

Records for welding qualification were examined by the NRC inspectors. Form F-277 and the "Active Welder Summary Sheet" for a welder were examined by the NRC inspectors and found to be current. Several F-276-IX forms documented qualification of a welder for various welding processes, for example, FCAW (flux core) and GMAW (gas metal).

The NRC inspectors determined that additional training and qualification requirements are necessary for testing personnel and are described in the NQAM and Q procedures. Section 2.6.4 of the NQAM states that test personnel shall be qualified in accordance with ESSC Quality SOP Q2.1. The NRC inspectors also determined that this qualification is to be documented on Form F-180.

SOP Q2.1 states in Section 1.1 that the Scope of the procedure includes ESSC personnel who perform quality inspection and testing activities. This section also delineates the requirements for qualification of ESSC personnel who perform quality inspection and testing activities and states that the procedure is intended to conform to the requirements of NQA-1, including supplement 2S-1 and Appendix 2A-1 as applicable to the scope of ESSC. Section 2.1 states, in part, that the procedure applies to quality inspections and surveillance activities, which include inspections and "ESSC testing activities". Section 4 of the procedure addresses General Requirements for inspection personnel, which, in accordance with Applicability, includes personnel who conduct testing activities. These general requirements address qualification

documentation, including indoctrination, training, determination of initial capability, performance evaluation, certification renewal, education, experience, and examination. Section 4.5 requires written certification on ESSC form F-180. Section 5 requires documentation of qualification for levels I, II, and III personnel, each which perform increasing levels of responsibility and capability.

Discussions among the NRC inspectors and the Vice President, Quality Assurance revealed that ESSC does not qualify all testing personnel and document such qualifications. According to ESSC personnel, some technicians set up and conduct tests at the direction of the ESSC inspector. SOP Q2.1 states that it is required that technical personnel who set up and conduct tests are qualified, at a minimum, at Level II. An inspection is an activity independent from the activity being observed. Since the ESSC testing personnel may be directed by the QA/QC Inspector during a test, the NRC inspectors determined that there is no independence of the inspector from the testing. ESSC failed to ensure that its testing personnel are fully qualified and that adequate documentation was prepared to support the qualifications. This is identified as Nonconformance 99901098/2008-201-08.

c. Conclusions

The NRC inspectors determined that the NQAM and SOPs Q2.1, Q2.2, and Q2.3 adequately address requirements of 10 CFR 50, Appendix B and of NQA-1, Basic requirement 2 and Supplement 2S-3 and Appendix 2A-3. ESSC maintains individual personnel files that include documentation of training and qualification. The ESSC Vice President of Quality Assurance conducts or schedules periodic training to ensure that ESSC personnel are informed of changes to documents that describe quality affecting processes. Personnel qualification documentation is completed and maintained for the Lead Auditor and the QC Inspector/QA Specialists. The NRC inspectors determined that recertification of the Lead Auditor and the QA/QC inspectors are current and the NDE and welding qualifications are maintained and current.

However, ESSC failed to ensure that its testing personnel are fully qualified and that adequate documentation was prepared to support the qualifications. This is identified as Nonconformance 99901098/2008-201-08.

Except for the issue identified in Nonconformance 99901098/2008-201-08, the NRC inspectors concluded that ESSC is ensuring that personnel are trained and qualified in accordance with governing documents and that training and qualification documentation is completed. The NRC inspectors also determined that ESSC training and qualification requirements are consistent with the regulatory requirements of Criterion XI of Appendix B to 10 CFR Part 50.

12. Exit Meeting

On July 21, 2008, the inspectors presented the inspection scope and findings during an exit meeting with Lisa Rice, ESSC President, Robert Paton, Vice President Quality Assurance and ESSC personnel.

ATTACHMENT

1. PERSONS CONTACTED

L. Rice, President, Energy Steel and Supply Company
R. Paton, Vice President Quality Assurance
W. Kirt, Quality Assurance/Quality Control Supervisor
D. Johnson, Quality Assurance/Quality Control Technical Services Manager
T. Shepard, Manufacturing Manager
A. Valentine, Nuclear Sales Engineering Manager
W. Waters, Sales Manager
M. Ajo, Document Control Coordinator
T. Guthrie, Inspector

2. INSPECTION PROCEDURES USED

Inspection Procedure (IP) 43002, "Routine Vendor Inspection,"

IP 36100, "Inspection of 10 CFR Parts 21 and 50.55(e) Programs for Reporting Defects and Noncompliance"

IP 43004, "Inspections of Commercial-Grade Dedication Programs."

3. LIST OF ITEMS OPENED, CLOSED, AND DISCUSSED

<u>Item Number</u>	<u>Status</u>	<u>Type</u>	<u>Description</u>
99901098/2008-201-01	Open	NOV	Inadequate procedure for the evaluation of deviations – 10 CFR 21.21(a)
99901098/2008-201-02	Open	NON	Design control program failed to: (1) document the review of customer purchase orders and its changes or revisions on Contract Review Form (F-272), and (2) document in the Engineering Change Notice the Engineering and QA evaluation.
99901098/2008-201-03	Open	NON	Dedication program failed to include adequate basis to substantiate the sampling plans for verifying critical characteristics.
99901098/2008-201-04	Open	NON	Failure to effectively implement a receipt inspection to verify an item's compliance to specified requirements.
99901098/2008-201-05	Open	NON	Failed to establish guidance for the performance of a final inspection.
99901098/2008-201-06	Open	NON	ESSC failed to follow their corrective action program requirements and failed to process and correct conditions adverse to quality in a timely and prompt manner.

99901098/2008-201-07	Open	NON	Failure to provide process for the preparation, review, approval, revision, issuance and control of documents affecting quality, including quality procedures and quality forms.
99901098/2008-201-08	Open	NON	Failure to qualify and document qualifications of testing personnel.