

January 9, 2007

Mr. John A. Manno, Vice President
Engine Systems, Inc.
175 Freight Rd.
Rocky Mount, NC 27804

SUBJECT: NRC INSPECTION REPORT 99901362/2006-201, NOTICE OF VIOLATION
AND NOTICE OF NONCONFORMANCE

Dear Mr. Manno:

On November 13-16, 2006, U.S. Nuclear Regulatory Commission (NRC) completed an inspection at the Engine Systems, Inc. (ESI) facility in Rocky Mount, North Carolina. The enclosed report presents the results of that inspection.

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

During this inspection, it was found that the implementation of your quality assurance program failed to meet certain NRC requirements which are discussed in the enclosed Notice of Violation (NOV), Notice of Nonconformance (NON), and NRC Inspection Report. Specifically, a review of ESI's 10 CFR Part 21 implementation identified that ESI did not adopt appropriate procedures to evaluate deviations and failures to comply associated with substantial safety hazards as soon as practicable, as required by 10 CFR 21.21(b). The violation of 10 CFR Part 21 is cited in the enclosed NOV and the circumstances surrounding the NOV are discussed in the enclosed report. Please note that you are required to respond to this letter and should follow the instructions in the enclosed NOV when preparing your response. The NRC will use your response, in part, to determine whether further enforcement action is necessary to ensure compliance with regulatory requirements.

In addition, the NRC inspectors found that the implementation of your quality assurance program failed to meet certain NRC requirements imposed on you by your customers. Specifically, inadequate instructions were identified in ESI's procedures related to the dedication process, as required by Appendix B to 10 CFR Part 50. These nonconformances are cited in the enclosed NON, and the circumstances surrounding them are described in the enclosed report. You are requested to respond to the nonconformances and should follow the instructions specified in the enclosed NON when preparing your response.

In accordance with 10 CFR 2.390 of the NRC's "Public inspections, exemptions, requests for withholding," of 10 CFR Part 2, "Rules of Practice for Domestic Licensing Proceedings and Issuance of Orders," a copy of this letter, its enclosures and any associated correspondence

Mr. Manno

will be placed in the NRC's Public Document Room (PDR) 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.

Sincerely,

/ra/

Patrick L. Hiland, Director
Division of Engineering
Office of Nuclear Reactor Regulation

Docket No.: 99901362

Enclosure: 1. Notice of Violation
2. Notice of Nonconformance
3. Inspection Report No. 99901362/2006-201

cc w/encl: Mr. Paul Stepanschenko

Mr. Manno

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Sincerely,

Patrick L. Hiland, Director
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Docket No.: 99901362

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cc w/encl: Mr. Paul Stepanschenko

DISTRIBUTION:

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NAME	ARivera-Varona	GGalletti	RMcIntyre	PFPrescott	DThatcher	PHiland
DATE	12/21/2006	12/20/2006	12/20/2006	12/21/2006	12/22/2006	01/09/2007

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NOTICE OF VIOLATION

Engine Systems, Inc.
175 Freight Road
Rocky Mount, NC 27804

Docket Number 99901362
Inspection Report Number 2006-201

Based on the results of a Nuclear Regulatory Commission (NRC) inspection conducted November 13 - 16, 2006, at Engine Systems Incorporated (ESI), a violation of NRC requirements which were contractually imposed upon ESI by NRC licensees was identified. In accordance with the NRC Enforcement Policy, the violation is listed below:

10 CFR Part 21, Section 21.21, "Notification of failure to comply or existence of a defect and its evaluation," paragraph 21.21(a), requires, in part, each individual, corporation, partnership, or other entity subject to 10 CFR Part 21 shall adopt appropriate procedures to (1) evaluate deviations and failures to comply associated with substantial safety hazards as soon as practicable.

Contrary to the above, as of November 16, 2006:

ESI's 10 CFR Part 21 implementing procedure QCP-301, "Control of Nonconforming Conditions and Corrective Actions and 10CFR21 Reportable Conditions," Revision 16, dated June 28, 2006, was not appropriate in that it did not provide guidance to identify a deviation and to evaluate if the deviation was associated with a substantial safety hazard. Violation 99901362/2006-201-01.

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

Pursuant to the provisions of 10 CFR 2.201, "Notice of Violation," ESI is hereby required to submit a written statement or explanation to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555-0001, with a copy to the Director, Division of Engineering, Office of Nuclear Reactor Regulation, within 30 days of the date of the letter transmitting this Notice of Violation. This reply should be clearly marked as a "Reply to a Notice of Violation" and should include: (1) the reason for the violation, or, if contested, the basis for disputing the violation; (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.

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. Agency-wide Documents Access and Management System (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

ENCLOSURE 1

response that identifies the information that should be protected and a redacted copy of your response that deletes such information. If you request withholding of such material, you must specifically identify the portions of your response that you seek to have withheld and provide in detail the bases for your claim of withholding (e.g., explain why the disclosure of information will create an unwarranted invasion of personal privacy or provide the information required by 10 CFR 2.390(b) to support a request for withholding confidential commercial or financial information). If safeguards information is necessary to provide an acceptable response, please provide the level of protection, described in 10 CFR 73.21.

Dated at Rockville, Maryland this 9th day of January 2007.

NOTICE OF NONCONFORMANCE

Engine Systems, Inc.
175 Freight Road
Rocky Mount, NC 27804

Docket Number 99901362
Inspection Report Number 2006-201

Based on the results of a Nuclear Regulatory Commission (NRC) inspection conducted November 13-16, 2006, of activities performed at Engine Systems Inc. (ESI), it appears that certain activities were not conducted in accordance with NRC requirements which were contractually imposed upon ESI by NRC licensees.

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

The Program Implementation Section of the ESI Quality Assurance Manual, Fourth Edition, Revision 0, states, in part, that the Engine Systems Inc. Quality Program is implemented by means of the system defined in this manual and the following Implementing Procedures: Parts & Service Procedures (PSP) - contain the procedures for controlling the parts and service activities. Additionally, the ESI Quality Assurance Manual states that production and services shall be planned and carried out under controlled conditions.

Contrary to the above,

ESI was unable to provide any engineering justification for lot/batch control or a documented basis for allowing commercial grade items to be tested by establishing homogeneous lot/batch control tied to the 26-week time frame. Specifically, ESI procedure PSP-201, "Dedication of Safety Related Items," Revision 10, dated February 22, 2006, Section 6.2.4, stated that "all components having a manufacturer's date code within six months (26 weeks) from the date code of a test specimen part are considered to be from a homogeneous lot."

This issue has been identified as Nonconformance 99901362/2006-201-02.

2. 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.

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

ENCLOSURE 2

The Program Implementation Section of the ESI Quality Assurance Manual, Fourth Edition, Revision 0, states, in part, that the Engine Systems Inc. Quality Program is implemented by means of the system defined in this manual and the following Implementing Procedures: Parts & Service Procedures (PSP) - contain the procedures for controlling the parts and service activities.

Contrary to the above,

The Section II portion of the Dedication Procedure (part of PSP-201), for all the Dedication Reports, did not include the appropriate 10 CFR 21.3 definition for a commercial grade item when it applies to a nuclear power plant licensed pursuant to 10 CFR Part 50. The definition included in the ESI Dedication Reports (as part of the Commercial Grade Determination) related to commercial grade items as applied to facilities and activities other than nuclear power plants in 10 CFR 21.3.

This issue has been identified as Nonconformance 99901362/2006-201-03.

Please provide a written statement or explanation to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555-0001, with a copy to the Director, Division of Engineering, Office of Nuclear Reactor Regulation, 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: (1) a description of steps that have been or will be taken to correct this item; (2) a description of steps that have been or will be taken to prevent recurrence; and (3) the dates your corrective action and preventive measures were or 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. Agency-wide Documents Access and Management System (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 9th day of January 2007.

**U.S. NUCLEAR REGULATORY COMMISSION
OFFICE OF NUCLEAR REACTOR REGULATION
DIVISION OF ENGINEERING**

VENDOR INSPECTION REPORT

Report No: 99901362/2006-201

Organization: Engine Systems, Inc.
175 Freight Rd.
Rocky Mount, NC 27804

Vendor Contact: Mr. Paul Stepantschenko, Manager Quality Assurance
Engine Systems, Inc.
175 Freight Rd.
Rocky Mount, NC 27804
(252) 407-8592

Nuclear Industry: Engine Systems, Inc. (ESI) supplies emergency diesel generator equipment and replacement parts qualification services to the nuclear power industry.

Inspection Dates: November 13-16, 2006

Inspection Team Leader: Steven Dennis, DE/NRR

Inspector: Paul Prescott, DE/NRR

Inspector: Richard McIntyre, DE/NRR

Inspector: Aida Rivera-Varona, DE/NRR

Inspector: Greg Galletti, DE/NRR

Approved By:

Dale F. Thatcher
Quality & Vendor Branch A
Division of Engineering (DE)
Office of Nuclear Reactor Regulation (NRR)

Date

ENCLOSURE 3

1.0 INSPECTION SUMMARY

The purpose of this inspection was to review selected portions of the quality assurance (QA) and 10 CFR Part 21 (Part 21) controls that Engine Systems, Inc. (ESI) has established and implemented. The inspection was conducted at ESI's facility in Rocky Mount, North Carolina. The NRC inspection bases were:

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

1.1 VIOLATIONS

- Violation 99901362/2006-201-01 was identified and is discussed in Section 3.1 of this report.

1.2 NONCONFORMANCES

- Nonconformance 99901362/2006-201-02 was identified and is discussed in Section 3.3 of this report.
- Nonconformance 99901362/2006-201-03 was identified and is discussed in Section 3.3 of this report.

2.0 STATUS OF PREVIOUS INSPECTION FINDINGS

There were no previous NRC inspections performed at ESI's facility in Rocky Mount, North Carolina, prior to this inspection.

3.0 INSPECTION FINDINGS AND OTHER COMMENTS

3.1 10 CFR Part 21 Program

a. Inspection Scope

The inspectors reviewed the ESI policies and procedures governing the Part 21 program to assure those guidelines provided adequate description of the process and implementation requirements described in 10 CFR Part 21, "Reporting of Defects and Noncompliances."

b. Observations and Findings

b.1. Postings

The inspectors evaluated whether ESI had complied with the posting requirements of 10 CFR 21.6. The inspectors found that ESI had posted notices which included a copy of

Section 206 of the Energy Reorganization Act of 1974, a current copy of 10 CFR Part 21, and a note with the title of the responsible person and title and location of the procedure. The inspectors did not identify any findings in this area.

b.2. 10 CFR Part 21 Procedure

Procedure QCP-301, "Control of Nonconforming Conditions and Corrective Actions and 10CFR21 Reportable Conditions," Revision 16, established the procedures and responsibilities to identify, control, document, and resolve conditions or items that do not conform to specified requirements. Additionally, it established the methods used to ensure significant conditions adverse to quality are promptly identified and corrected. Section 6.7 of procedure QCP-301 described the procedure for reporting defects and noncompliances under Part 21.

The inspectors found that procedure QCP-301 also established the responsibilities and timeliness guidance to comply with the reporting requirements of Part 21. Procedure QCP-301 provided a list of different conditions that may require reporting in accordance with Part 21. However, the inspectors found that the procedure did not provide guidance to identify and evaluate deviations pursuant 10 CFR 21.21(a) to determine that any of the conditions existed. For example, the inspectors found that one condition that may require reporting in accordance with Part 21 was "a defect/deviation in structures, systems, components or parts." The inspectors did not find procedure guidance to determine how a deviation is identified and how an evaluation, as defined in 10 CFR 21.3, is performed to determine that the deviation could create a substantial safety hazard. Therefore, the inspectors found that ESI's Part 21 program did not adopt appropriate procedures pursuant 10 CFR 21.21(a) to evaluate deviations and failures to comply to determine if they could be associated with a substantial safety hazard. NRC Violation No.99901362/201-01 was identified in this area.

The inspectors also observed that procedure QCP-301 could provide more effective implementation of the other requirements of Part 21. For example, the procedure did not provide guidance to comply with the requirements of 10 CFR 21.21(b), which requires that if the supplier discovers a deviation or failure to comply and determines it is not capable of performing an evaluation to determine if a defect exists, the supplier shall inform the purchaser within five working days from that determination so that the purchaser may evaluate the deviation pursuant 10 CFR 21.21(a). ESI had guidance for the reporting of defects; however, this specific requirement was missing. Furthermore, the procedure did not provide definitions for key terms used (e.g., deviation, evaluation, and defect). These observations were subsequently addressed prior to the end of the inspection in a revision to the affected procedure.

b.3. 10 CFR Part 21 Program Implementation

The inspectors reviewed several Part 21 reports and evaluated whether ESI had implemented a program consistent with the requirements described in Part 21. The NRC inspectors verified that ESI's program included a method of identification, an adequate evaluation, and timely reporting.

Procedure QCP-301 described the process to control nonconforming conditions and corrective actions. The procedure established that nonconforming conditions found during dedication and/or quality processes are to be documented in a Nonconformance Report (NCR). In addition, Corrective Action Reports (CARs) are used to document and resolve customer complaints, internal corrective actions, health and safety actions, and preventive actions. The inspectors noted that the CAR form provided a method to screen for Part 21 applicability and evaluation.

The inspectors found that most of the Part 21 reports were generated as a result of a CAR. However, the inspectors found that the Part 21 reports did not provide consistency in the method of identifying and starting a Part 21 evaluation. For example, Part 21 report number 10 CFR 21 – 0092 “Turbine Governor Control,” dated February 10, 2006, was developed based on Service Bulletin #01365 received from Woodward in February 2006. The inspectors were not able to find in relevant documents reviewed the reason that initially prompted ESI to develop the Part 21 report (e.g., a CAR, or any other type of document). The inspectors noted that ESI had a method to screen for Part 21 applicability and evaluation through the CAR process. Additionally, the Engineering Manager pointed out that ESI includes a question in the NCR for applicability of the nonconformance to previous shipments, which ESI uses to screen for Part 21 applicability. However, the inspectors were not able to find in ESI’s QA program a procedure that described the CAR/NCR interface with the Part 21 applicability process and discussed this with ESI staff. The Engineering Manager stated the concern would be addressed when procedure QCP-301 is revised in response to the inspection finding.

The inspectors also noted that ESI had performed five Part 21 evaluations in the last two years. Four of the five evaluations were reportable. The inspectors' review of ESI’s evaluation that was found not to be reportable was determined to be consistent with Part 21 requirements. Additionally, the inspectors reviewed the Part 21 reports issued in the last two years and determined that ESI had adequately performed evaluations and notifications consistent with the requirements of Part 21.

c. Conclusions

The inspectors concluded that the ESI's Part 21 program implementation was generally acceptable with one exception. The exception was a violation of Part 21 for the lack of procedural guidance for the interface of the CAR and NCR process with the Part 21 program. This issue was identified as Violation No. 99901362/201-01.

3.2 CORRECTIVE ACTIONS

a. Inspection Scope

The inspectors reviewed the policies and procedures governing the implementation of the ESI corrective action program, and reviewed the corrective actions initiated during the past 24 months. These corrective actions were primarily the result of deficiencies identified by ESI with internal ESI processes, procedures, and materials associated with their commercial grade dedication activities.

b. Observations and Findings

b.1. Policies and Procedures Governing Corrective Actions

The inspectors reviewed ESI's policies and procedures governing the corrective action process to ensure an adequate description of the process and implementation requirements consistent with the requirements of Appendix B to 10 CFR Part 50, Criterion XVI, "Corrective Actions."

ESI Quality Assurance Manual, Fourth Edition, Revision 0, Section 14, "QAM-14 Corrective/Preventive Action," described the general requirements for the implementation of a corrective action program. The manual stated that procedures and practices provided assurance that conditions adverse to quality are promptly identified, documented, and corrected, or otherwise handled in accordance with established procedures. Corrective action followup and closeout procedures provide for assuring that corrective action commitments are implemented in a systematic and timely manner.

Procedure QCP-301, "Control of Nonconforming Conditions and Corrective Actions and 10CFR Part 21 Reportable Conditions," Revision 16, defined the specific requirements for the ESI corrective/preventive action system. The procedure outlined the basic activities associated with identification of a condition adverse to quality, evaluation and resolution of such conditions, and development of supporting documentation.

Section 6, "Procedure," of QCP-301, described the process used to identify and control nonconforming conditions, and included specific actions to be taken to identify and segregate nonconforming items, generation and implementation of NCRs, and closure of NCRs by the Quality Assurance Department.

Section 6.4, "Corrective/Preventive Action Report (CAR)," of QCP-301, described the CAR process as a method to address potential problems and as a tool to gather additional information and identify actions for serious problems. The procedure provided a list of potential causes for nonconformities such as material defects, non-compliance with procedures, lack of training, inadequate process control, inadequate resources, and inherent process variability. CARs can be written when periodic analysis of NCRs indicated a repetitive pattern or adverse trend for an issue.

Section 6.5, "Preventive Actions," of QCP-301, described potential sources of information that are routinely used to identify issues requiring preventive actions, and list the applicable tools that can be used to document and implement preventive actions. These tools included, but were not limited to, management reviews, failure modes analysis, control plans, CARs, audits, and data analysis and reporting.

Section 6.6, "Corrective/Preventive Action Evaluation and Review," of QCP-301, described the process for routing all CARs through the various departments that have responsibility for the identification, implementation, and disposition of all CAR activities.

QCP-700, "Quality Assurance Records," Revision 7, described the methods used to control the generation, validation, identification and storage of completed company records. The procedure defined the roles and responsibilities of company personnel

with regard to record management, classification of records as either commercial or nuclear safety-related, and the specific storage requirements for each. Attachment 1, of QCP-700, provided a detailed table of the various record types, procedures governing that record type, retention requirements, and location information. The procedure required that CARs shall be maintained for a period of at least three years.

The inspectors reviewed the implementing procedures governing ESI's corrective action program. The inspectors verified that the guidance was consistent with the requirements for corrective actions described in Appendix B to 10 CFR Part 50, Criterion XVI, "Corrective Actions," and contained the necessary elements to ensure conditions adverse to quality were identified, evaluated, and corrected in a timely manner.

The inspectors also reviewed all CARs generated by the vendor during the last 24 months. The inspectors noted that approximately 90 percent of the CARs generated in the 24-month period had been completed, all of the completed CARs were dispositioned in a timely manner, and detailed information regarding the characterization of the nonconforming conditions, proposed corrective actions, and documentation of the results of those actions, were generally well documented. Of the remaining open CARs, the inspectors did not identify any that were not being processed in accordance with the administrative controls governing the CAR process. In one instance, the inspectors observed that CAR package (2005-02, "Fuel Injector Shelf Life") was apparently voided without adequate justification provided in the supporting CAR package documentation. Based on further review by the inspectors, ESI provided documentation that verified the vendor had previously issued a service advisory (IB 05-11, "Long Term Storage of EMD Fuel Injectors," dated February 7, 2005) to all ESI customers with affected components. That service bulletin effectively addressed the issue identified in CAR 2005-02. As a result of this service advisory, any further actions associated with CAR 2005-02 were considered unnecessary. The inspectors agreed with the vendor's conclusions and the CAR package was supplemented with the additional documentation supporting closure of the CAR. The inspectors did not identify any findings in this area.

b.2. Management Review of Corrective Actions

Section 6.4, "Corrective/Preventive Action Report" of QCP-301, required that management perform a biannual review of NCRs to identify any adverse trends, and provided for the generation of CARs to address such adverse trends as deemed necessary.

The inspectors reviewed the 2004, 2005, and 2006 Monthly Management Meeting Reports to gain an understanding of how ESI's management review of the NCRs was implemented, and to confirm that ESI was performing an analysis of NCRs as required by QCP-301. The ESI management reviews are conducted monthly as a means of identifying areas for continued improvement and assessing the current adequacy of the NCR and CAR programs. The report was assembled by the quality organization and sources of information used in the report included, but were not limited to, analysis of NCR data, internal audits, and individual observations. The inspectors noted that each report contained an analysis of current NCRs and recommendations for addressing any adverse trends identified. From the sample reviewed, the inspectors verified that the vendor had generated a number of CARs to address adverse trends identified from the

Monthly Management Meeting Reports. The inspectors verified that those CARs were completed in a timely manner. The inspectors did not identify any findings in this area.

c. Conclusions

The inspectors determined that ESI's corrective action program requirements were adequately described in the ESI Quality Assurance Manual and the corrective action procedures, and were consistent with the requirements for identifying and correcting conditions adverse to quality described in Appendix B to 10 CFR Part 50, Criterion XVI, "Corrective Actions." The inspectors determined, that requirements to process and complete corrective actions were adequately implemented in accordance with ESI's administrative requirements.

3.3 Commercial Grade Dedication

a. Inspection Scope

The inspectors reviewed the ESI Quality Assurance Manual, procedural commitments and the implementation process for commercial grade item dedication activities. Specifically, the inspectors reviewed the procedures and dedication reports which govern the implementation of commercial grade dedication activities. Additionally, the inspectors reviewed a sample of ESI dedications of commercial grade items.

b. Observations and Findings

b.1. Commercial Grade Dedication Process

The inspectors reviewed ESI Procedure PSP-201, "Dedication of Safety Related Items," revision 10. The purpose of this procedure was to identify the requirements to be applied in the purchase, dedication, and documentation of items and material supplied as spare, replacement, and/or modification parts for use in nuclear safety-related systems and to establish methods to satisfy the requirements of Appendix B to 10 CFR Part 50, 10 CFR 50.49, and Part 21 with respect to the dedication of commercial grade items (CGIs). CGIs include spare, replacement, repair, renovated, and fabricated parts; subparts; subcomponents, components; or assemblies.

The ESI dedication process provided for selection, purchase, analysis, qualification, and application of CGIs for Class IE electrical equipment and safety-related mechanical equipment. The dedication process also established the documentation requirements to substantiate the engineering evaluation and verification of the CGI being used in safety-related applications.

ESI further stated that the dedication process involved analysis of the item's design, material and manufacture to assure that the replacement item is equivalent to the original and/or that the item will function properly when exposed to the environmental conditions at the installed location. To implement the above described dedication process, PSP-201 required that Dedication Engineering prepare a Dedication Report that includes all the information necessary to determine the equivalency of the replacement part. This information may include, but was not limited to the following:

- Component
- Supplier
- Parts breakdown
- Form
- Fit
- Safety function
- Failure mode analysis
- Critical characteristics
 - ▶ Part number
 - ▶ Size - dimensional data
 - ▶ Physical condition
 - ▶ Operability
 - ▶ Material / design control
 - ▶ Design environment
 - ▶ assembly / completeness
 - ▶ Seismic qualification
 - ▶ Shelf life
- Acceptance/Inspection criteria
- Testing activities and procedures
- Ongoing surveillance

Finally, supporting documentation such as customer purchase orders, design drawings, manufacturer's literature, calculations, dedication (receipt) inspection report, dedication inspection report and verification results, applicable test procedures, test results, and seismic or environmental test data, and the ESI issued safety-related certificate of conformance (provided to the customer) are maintained together as a document package to support the specific ESI customer's sales order.

During the review of PSP-201, the inspectors identified that sections 6.2.3 and 6.2.4 documented the requirements for lot control with respect to item sampling as part of dedication testing. Section 6.2.4 stated that, "all components having a manufacturers date code within six months (26 weeks) from the date code of a test specimen part are considered to be from a homogeneous lot." The inspectors were not aware of the use of specific time allowances for determining lot homogeneity of commercial grade items. Lot/batch control is defined in EPRI TR-017218-R1, "Guideline for Sampling in the Commercial Grade Item Acceptance Process" as units of a single type, grade, class, size, and composition, manufactured under essentially the same conditions and essentially the same time. ESI did not provide any engineering justification for lot/batch control or a documented basis for allowing commercial grade items to be tested by establishing homogeneous lot/batch control tied to the 26-week time frame. This issue is identified as Nonconformance 99901362/2006-201-02.

b.2. Implementation of the Commercial Grade Dedication Process

ESI developed dedication reports for nearly all items/components for which a commercial grade dedication is performed. The inspectors reviewed a sample of

dedication reports performed during the last four years and found the documents were thorough and provided proper guidance to perform an adequate dedication. All dedication reports listed: 1) the component and breakdown of associated parts, as applicable, to be dedicated; 2) a determination of commercial grade item applicability; 3) past operating experience; 4) shelf life determination; 5) seismic determination; 6) design environment; 7) the item's form, fit and function specifications; 7) failure mode analysis; 8) critical characteristics; 9) acceptance/inspection criteria; and 10) test/surveillance requirements.

The inspectors identified that the Section II, "Dedication Procedure," of all the dedication reports, did not include the appropriate 10 CFR 21.3 definition for a commercial grade item when it applied to a nuclear power plant licensed pursuant to 10 CFR Part 50. The definition included in the ESI Dedication Reports (as part of the commercial grade determination) related to commercial grade items as applied to facilities and activities other than nuclear power plants in 10 CFR 21.3. The inspectors also noted that this same out of date definition, as it relates to a nuclear power plant licensed pursuant to 10 CFR Part 50, was included in the Glossary Section of the ESI Quality Assurance Manual. This issue is identified as Nonconformance 99901362/2006-201-03.

The inspectors reviewed the associated documentation from a sample of items/components dedicated by ESI. The following is a brief overview of completed dedication reports for several items/components which ESI had processed, based on licensee purchase orders, reviewed by the inspectors.

- Dedication Report D-CES-0334104AERR-1 was conducted on August 29, 2002, for an Enterprise piston skirt repair and return. The ductile iron piston skirt was tin-plated. The inspectors noted the plating exceeded the specified thickness (.0005"). Actual measurements taken using a magnetic coating thickness meter indicated the thickness to be as high as .0011" on the piston skirt. The inspectors reviewed an engineering evaluation conducted by ESI that found the plating thickness acceptable for the following reasons: 1) the plating was considered a sacrificial coating that is designed for break-in; 2) the average thickness of the tin plating was .0006" - .0001"; 3) the final outside diameter remained within the specified tolerance; and 4) plating presence was considered more important than thickness. The staff found the engineering evaluation provided an adequate basis for acceptability of the piston skirt.
- Dedication Report D-EMD-8411355-1 was conducted in October 2003, for a Viking Fuel Oil pump and 120 VDC motor assembly from General Motors (GM) Electro-Motive Division (EMD). The inspectors reviewed all associated documentation for dedication of the pump and motor assembly. The inspectors also verified that ESI adequately processed a pump/motor assembly test failure due to motor seizure and initiated an NCR, as required by ESI's nonconformance and corrective action process. The inspectors did not identify any issues with this dedication report.
- Dedication Report SV-DRS-15 was conducted on September 8, 2005, for two Dresser ½" safety valves. The inspectors noted that the purchase order required a source verification during manufacture. The inspectors noted that the package

for the valves did not have the source surveillance report. The source surveillance report was subsequently located by ESI.

- Dedication Report D-CES-211P1149002-1 was conducted on April 2, 2004, for a lube oil keep-warm pump/AC motor assembled by ESI. The inspectors did not identify any issues with this dedication report.
- Dedication Report EC-WOOD-993543-1 was conducted on April 31, 2005, for a Woodward 505 digital governor. The inspectors did not identify any issues with this dedication report.
- Dedication Report D-ESI-107342260-1 was conducted in April 2006, for Haynes fuel injection pumps. The staff noted that the source surveillance report documented that 42 of the 44 fuel injection pumps had indications of cracking in the delivery valve outer diameter that was identified by a magnetic particle examination. The cause of the cracking was surface burning thought to be from a grinding operation conducted during machining. ESI elected to reject the fuel injection pumps with the cracking indications. New fuel injection pumps were manufactured. The inspectors found ESI's resolution of the cracking issue to be adequate.

c. Conclusions

The inspectors determined through a review of ESI's dedication process and implementation of dedication packages for several items/components, that ESI is generally implementing a commercial dedication process in compliance with regulatory and industry guidance as well as ESI quality program and implementing procedure guidance.

The inspectors identified ESI did not provide any engineering justification for lot/batch control or a documented basis for allowing commercial grade items to be tested by establishing homogeneous lot/batch control tied to the 26-week time frame. This issue is identified as Nonconformance 99901362/2006-201-02.

The inspectors also identified that the Section II portion of all the Dedication Reports reviewed, did not include the appropriate 10 CFR 21.3 definition for a commercial grade item when it applied to a nuclear power plant licensed pursuant to 10 CFR Part 50. The definition included in the ESI Dedication Reports (as part of the commercial grade determination) related to commercial grade items as applied to facilities and activities other than nuclear power plants in 10 CFR 21.3. The inspectors also noted that this same out of date definition, as it relates to a nuclear power plant licensed pursuant to 10 CFR Part 50, was included in the Glossary Section of the ESI Quality Assurance Manual. This issue is identified as Nonconformance 99901362/2006-201-03.

3.4 Supplier Audit/Survey Process and Implementation

a. Inspection Scope

The inspectors reviewed the ESI process and implementation of the external supplier audits, commercial grade surveys, and the source verification program. Specifically, the inspectors verified that the supplier audit program was consistent with the requirements of Appendix B to 10 CFR Part 50, Criterion VIII, "Control of Purchased Material, Equipment and Services." Additionally, the inspectors reviewed a sample of commercial grade surveys and source verification/surveillance reports.

b. Observations and Findings

b.1. Audit/Survey Process

The inspectors reviewed the ESI Procedure QAP-501, "Supplier Audits / surveys and Source Verifications," Revision 11. This procedure described the conduct of supplier audits / surveys, source verification and witnessing of required testing performed at suppliers' facilities. The inspectors also reviewed Procedure PCP-501, "Control and Maintenance of the Approved Supplier's List," Revision 11. This procedure was used to create and control the ESI Approved Supplier's List (ASL).

PCP-501 describes Quality Level I (QL-1) suppliers as those who can supply ASME Section III Code stamping and Code data reports. This was the highest level of control by ESI. QL-II was assigned to suppliers that implement an Appendix B to 10 CFR Part 50 QA program and accept Part 21 responsibilities for reporting defects and noncompliance. QL-III was assigned to suppliers that have been audited or assessed to supply commercial grade items. QL-IV was assigned to suppliers that provide commercial products or services. QAP-501 required that QL-I and QL-II suppliers be audited prior to placement on the ASL and every three years after. QL-III suppliers were required to be surveyed (commercial grade) prior to placement on the ASL.

During review of QAP-501 the inspectors observed that it was not clear as to the distinction between, and when to perform an audit /survey. The term commercial grade survey was not identified or used in either QAP-501 or PCP-501. ESI agreed that clarification would be beneficial and developed a draft revision of QAP-501 prior to the completion of the inspection that clearly identified the differences between an audit, a commercial grade survey and a source verification/surveillance.

The inspectors also noted that PCP-501 QL-I (ASME suppliers) and QL-II (Appendix B suppliers) had no requirement to conduct an annual evaluation of a supplier's QA program. An internal audit conducted in October 2006 has identified this issue and the inspectors reviewed the CAR that addressed this issue. The inspectors noted that ESI performed a biannual review of a supplier's performance that was trended in a monthly management report. The inspectors noted that ESI conducted an annual review of a supplier's quality assurance manual to review any changes to the quality assurance program requirements. Additionally, for ESI's major suppliers, audits were conducted on a more frequent basis than the triennial audit for evaluated suppliers that included a documented performance trend.

The inspectors reviewed PCP-501 for adequacy of procedural controls for commercial grade item component suppliers. Commercial grade surveys are considered an engineering function that should be conducted at a sufficient frequency to ensure that the process controls applicable to critical characteristics of the item/component procured continue to be effectively implemented. NRC staff guidance of factors to be considered in determining the frequency of commercial grade surveys include: 1) complexity of the item, 2) frequency of procurement, 3) receipt inspection, 4) item performance history, and 5) knowledge of change in the vendor's quality controls. As noted above, ESI did conduct audits at an appropriate frequency and trended performance. However, the inspectors observed that procedure PCP-501, Section 6.3, allowed all QL-III suppliers to be assessed or surveyed every three years without documented justification for this survey frequency and did not reflect actual ESI practice for the conduct of commercial grade surveys. ESI developed procedural guidance prior to the end of the inspection.

b.2. Implementation of the Audit /Survey Process

Commercial Grade Surveys

The inspectors reviewed the ESI ASL and chose QL-III suppliers for review of the commercial grade survey activities and report performed by ESI. The inspectors reviewed the results of three commercial grade surveys conducted by ESI. The commercial grade survey for The Gear Works (TGW) was conducted in April 2005. ESI utilized the Nuclear Procurement Issues Committee (NUPIC) checklist to perform the survey. TGW performed dimensional checks and inspection of gears. This was the extent of ESI's qualification of the vendor. Critical program elements of TGW's program that were reviewed included: 1) material control and traceability, 2) control of nonconformances and corrective action, 3) personnel training, 4) test control and documentation, and 5) measuring and test equipment control. ESI identified that TGW's corrective action program was apparently weak, due to the lack of documented corrective action reports. ESI subsequently required TGW to send all nonconformances to ESI for resolution.

The inspectors reviewed the results of the commercial grade survey for Markisches Werk of Halver, Germany that was conducted in April 2005. Markisches Werk manufactured intake and exhaust valves. The vendor was qualified for: 1) design control, 2) material control, 3) dimension checks, and 4) inspection and test controls. The three issues identified by ESI during the commercial grade survey were minor in nature and resolved prior to the end of the survey.

The inspectors reviewed the results of the commercial grade survey for GM EMD at LaGrange, IL that was conducted in October 2006. EMD supplied diesel engines and associated spare parts to ESI. ESI verified implementation of the EMD quality program related to specific controls for critical characteristics identified by ESI. EMD was qualified for: 1) design control, 2) material and traceability control, 3) manufacturing process control, 4) purchasing, 5) measuring and test equipment, and 6) test control. There were no findings identified by ESI during the commercial grade survey; however, several recommendations were made to EMD for the ESI scope of review.

Source Verifications

ESI performed numerous source verifications at suppliers in support of commercial grade dedication. QAP-501 required engineering to identify critical characteristics prior to performing verifications and that the results are documented in a manner to provide objective evidence that the critical characteristics were adequately verified. The inspectors reviewed the results for several source surveillance reports conducted by or for ESI for completeness and procedural compliance. A summary of the surveillance reports is given below:

- Surveillance Report No. 2005-41, dated May 23, 2005, was related to 40 fuel injectors that were rebuilt and tested to ESI procedure RCP-103, "Fuel Injector Rebuild/Test Procedure," Revision 7.
- Surveillance Report No. 2005-42, dated May 20, 2005, was related to the disassembly and as-found evaluation conducted for six fuel injector pumps.
- Surveillance Report No. 2005-49, dated June 14, 2005, was related to the disassembly and as-found evaluation conducted for one fuel injector pump.
- Surveillance Report No. 2005-50, dated June 29, 2005, was related to the rebuild and testing of 36 fuel injectors.
- Surveillance Report No. 2005-54, dated July 13, 2005, was related to the dimensional check of two cylinder head sub-covers.
- Surveillance Report No. 2005-55, dated August 10, 2005, was related to the testing, in accordance with the manufacturer's requirements, of (5) 10 horsepower and (4) 20 horsepower electric motors (3-phase/380VAC).
- Commercial Grade Survey No. 2005-57, dated August 11, 2005, was related to the dimensional and nondestructive examination inspections, after rework, for compliance with applicable repair procedures, of four pistons and two piston crowns.
- Surveillance Report No. 2005-64, dated November 8, 2006, was related to a functional test performed for a 160-ampere Legrand fuse. The test was performed in accordance with procedure TP-165-55, Revision 0. For each fuse, the current (amps), voltage across the fuse, and the time were appropriately recorded. The test and measurement equipment information was also documented.

c. Conclusions

The inspectors determined through a review of ESI's audit, commercial grade survey, and source verification process and review of a sample of commercial grade surveys and source verification surveillance reports, that ESI was generally implementing an audit, commercial grade survey and source verification process in compliance with

regulatory and industry guidance, and ESI's quality program and implementing procedure guidance.

4.0 MANAGEMENT MEETINGS AND PERSONNEL CONTACTED

4.1 Entrance and Exit Meetings

In the entrance meeting on November 13, 2006, the inspectors discussed the scope of the inspection, outlined the areas to be inspected, and established interfaces with ESI's vice president and several staff personnel. During the exit meeting on November 16, 2006, the inspectors discussed the inspection findings and observations with ESI's Vice President and staff.

4.2 Personnel Contacted

John Manno	Vice President, ESI
Paul Stepantschenko	Manager, Quality Assurance, ESI
Kevin Broussard	Quality Assurance, ESI
Chris Payne	Nuclear Governor Coordinator, ESI
Don Galeazzi	Engineering Manager, ESI
Vann Mitchell	Project Manager, ESI
John Kriesel	Mechanical Engineer, ESI