Engine Systems, Inc.

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Reply to a Notice of Violation

U.S. Nuclear Regulatory Commission
Attn: Document Control Desk
Washington, D.C. 20555-0001

February 2, 2007

Dear Sir/Madam:

Based on the results identified during the November 13 -16, 2006 Nuclear Regulatory Commission (NRC) inspection and Notice of Violation dated 9th day of January 2007, Engine Systems is providing the following:

Violation 99901362/2006-201-01:
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.

Reason for violation:
Misinterpretation of the wording of 10CFR21. While ESI has been adequately identifying deviations and performing evaluations in accordance with 10CFR21 requirements, procedure QCP-301 did not include the process steps to accomplish this, it focused primarily on the reporting requirement of 10CFR21.

Corrective steps that have been taken and the results achieved:
As mentioned in the NRC Vendor Inspection Report 99901362/2006-201, ESI has adequately performed evaluations and notifications consistent with 10CFR21 requirements; therefore, interim containment action is not necessary. ESI will continue to evaluate all NCR's and Corrective/Preventive Action Reports (CAR's) to identify any deviation or non compliance that could create a substantial safety hazard. Any 10CFR21 issues are to be reported to the engineering manager for evaluation. If an evaluation is necessary, a CAR will be issued to initiate the evaluation process. Internal Corrective/Preventive Action Report, CAR#: 2007-03, issued January 22, 2007.

Corrective steps that will be taken to avoid further violations:
Revise QCP-301 to provide guidance to identify deviations and to evaluate if the deviation is associated with a substantial safety hazard. See attached revised Procedure QCP-301. Train all involved with the process on the revision to ensure that deviations are consistently identified and evaluated.

Date when full compliance will be achieved: February 16, 2007.

Sincerely,

John A. Manno

John A. Manno, Vice President
Engine Systems, Inc.

Enclosure: 1. Corrective/Preventive Action Report, CAR#: 2007-03.
2. Procedure QCP-301, Revision 17, dated 01/31/07; Control of Nonconforming Conditions and Corrective Actions and 10CFR21 Reportable Conditions.

cc w/encl: Director, Division of Engineering,
Office of Nuclear Reactor Regulation

IE09

Engine Systems, Inc.

Nuclear Parts & Service

Corrective/Preventive Action Report

Type:	Customer		Supplier		Internal	X	Health & Safety		Preventive		CAR #:	2007-03

Customer/Supplier:	NRC	**Contact:**	Patrick L. Hiland, Director Division of Engineering
Date Opened:	1/22/07	**RGA #:**	NRC Report 99901362/2006-201
Response Due Date:	1/31//07	**Issued By:**	Paul Stepantschenko

D1. Describe the Problem

Based on the results of a Nuclear Regulatory Commission (NRC) inspection conducted November 13 – 16, 2006, at 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: (see attached Report 99901362/2006-201 and Notice of Violation)

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.

Part #:	**Part Description:**	**Process Where Problem Discovered:**
N/A	NRC Audit Violation	ESI Documentation
Order #:	**Qty Defective:**	**Qty Returned:**
N/A	N/A	N/A

D2. Identify Problem Solving Team

Issued To (Team Leader): Don Galeazzi, Engineering Manager

Team members:	Department	Team members:	Department
1. Paul Stepantschenko		4.	
2. Vann Mitchell		5.	
3.		6.	

D3. Develop Interim Containment Action(s)

	Responsible Person	Target Date	Date Implemented
As mentioned in the NRC Vendor Inspection Report, ESI has adequately performed evaluations and notifications consistent with 10CFR21 requirements; therefore, interim containment action is not necessary. ESI will continue to evaluate all NCR's and CAR's to identify any deviation or non compliance that could create a substantial safety hazard. Any 10CFR21 issues are to be reported to the engineering manager for evaluation. If an evaluation is necessary, a CAR will be issued to initiate the evaluation process.	Don Galeazzi	1/22/07	1/22/07

D4. Identify The Root Cause(s)

	Responsible Person
Misinterpretation of the wording of 10CFR21 is the root cause of this issue. While ESI has been adequately identifying deviations and performing evaluations in accordance with 10CFR21 requirements, procedure QCP-301 did not include the process steps to accomplish this, it focused primarily on the reporting requirement of 10CFR21.	Don Galeazzi

D5. Develop & Implement Permanent Corrective Action(s)

	Responsible Person	Target Date	Date Implemented
Revise QCP-301 to provide guidance to identify deviations and to evaluate if the deviation is associated with a substantial safety hazard.	Don Galeazzi	2/2/07	1/31/07
Train all involved with the process on the revision to ensure that deviations are consistently identified and evaluated.	Don Galeazzi	2/16/07	

D6. Analysis of Action (Link Solution; D3 – D5)

Does this problem apply to similar and/or other products at:	**This Site?**	**YES** ____	**NO** ✔	**Analyzed By:**
	External Site(s)?	**YES** ____	**NO** ✔	Don Galeazzi
Does this problem require a 10CFR Part 21 Evaluation?		**YES** ____	**NO** ✔	

D7. Verify Corrective Action

QCP-301 revision 17 dated 01/31/07 includes the necessary criteria from 10CFR21 [illegible] includes the method of evaluation and report writing. CAR and NCR processes include the necessary 10CFR21 evaluation and this evaluation is documented on the forms used to document the processes. Completion of training to be verified after 2/16/07 and close date will be added.

Reviewed and Approved By: Vann Mitchell

D8. Closure

Date Closed:

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PROCEDURE
QCP-301

CONTROL OF NONCONFORMING CONDITIONS AND CORRECTIVE ACTIONS AND 10CFR21 REPORTABLE CONDITIONS

REVISION: 17 **DATE:** 01/31/07

PREPARED BY

1/31/07
DATE

APPROVED BY DEPARTMENT HEAD

1/31/07
DATE

APPROVED BY QUALITY DEPARTMENT

1/31/07
DATE

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REVISION	DATE	PAGE	PARA	DESCRIPTION
9	5/24/00	All	6.6	Incorporated requirements of EP-205 in section 6.6
10	8/2/00	2	5.5	Removed Procurement Manager, added Purchasing
		1	4.0	Changed reference from exhibit 3 to exhibit 1
		3	6.1	Added : Customer supplied material identified as nonconforming shall be identified on a NCR
11	10/16/02	All	All	Revised in it's entirety
12	10/24/02	1	5.1.2	Added "NCR"
			5.1.3	Changed noncompliance to nonconformance
		2	5.2.2	changed report to NCR and added(CAR)
			5.5	added "REPAIR"
		3	6.2.2.2	changed Procurement to Purchasing
		4	6.4	changed 6.4 and renumbered paragraphs added 6.4.6
		5	6.6.2.1	added Customer supplied towards end of sentence
13	3/21/03	4	6.5.2	Changed Manager – Nuclear Operations to Manager -Engineering
		5	6.6.1	Changed Manager – Nuclear Operations to Manager -Engineering
		3	6.3.2.2	Removed statement- If re-inspection is unsatisfactory the NCR shall be closed, a new NCR written, and the new Hold Tag applied.
		3	6.2.2.1	Added "when repair, rework or "accept as is" activities are involved."
		Exhibit 1	Exhibit 1	Revised flow chart
14	1/22/04	1	1.0 2.0 3.0	Added "(NRC)" Added "(Code of Federal Regulations)" Added "ORACLE-11i Documentation Manual"
		3	6.2	Changed NCR to Non Conformance Reports
		4	6.4 6.4.2,3,4 6.5.1	Added "Report" Added "Could be cause for corrective action" Added "or present the CAR's issues and actions to the Management Team"
14	01/22/04	Exhibit 1	Exhibit 1	Revised flow chart to detail ORACLE activities
		All	All	Reformatted and renumbered as required
15	7/30/04	1	1.0	Added "identification and tracking of Suspect / Counterfeit items"
		Exhibit 2	Exhibit 2	Added Trend Code R-14 Suspect / Counterfeit Items
16	4/11/06	Exhibit		Added Corrective/Preventive Action Form
		4	6.4	Revised to include Preventive Action
		5	6.5	Revised to include Preventive Actions

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REVISION	DATE	PAGE	PARA	DESCRIPTION
17	01/31/07	1		Added "AND 10CFR21 REPORTABLE CONDITIONS" to heading.
			1.0	In last sentence, replaced "nonconformances" with "defects and non-compliances" and added "in accordance with 10CFR21".
			5.1.3	Changed "defects and/or nonconformances" to "deviations and/or failures to comply". Added "that could create a substantial safety hazard".
		2	5.3	Changed "all occurrences" to "all reported occurrences" in last sentence and added "or designee".
			6.1.1	Added "electronically" in first sentence and "(Exhibit 4) in second sentence.
			6.1.4	Added OS&D definition.
		3	6.2	Changed paragraph heading from "Dispositions" to "Disposition and Routing of NCR's".
			6.2.1	Added: "and determine if the nonconforming condition requires a 10CFR21 evaluation. If it is determined that a 10CFR21 evaluation is required, the Manager - Engineering shall be notified and the evaluation shall be performed in accordance with 6.7.1. The NCR form shall be electronically dispositioned."
			6.2.2.1	Reworded to require engineering to disposition all NCR's so that 10CFR21 evaluations are considered.
			6.3	Changed paragraph heading from "Closure" to "Closure of NCR's". Deleted 6.3.1 since it was redundant to 6.3.2.
			6.3.1	Was 6.3.2. In 6.3.1.5, "Quality Assurance" was "The Manager, Quality Assurance or Designee".
		4	6.4.1	Added reference to Exhibit 3.
			6.4.4	Combined 6.4.4 through 6.4.7 into subparagraphs of 6.4.4.
			6.4.5	Was 6.4.8.
		6	6.6.2	In first sentence, changed "manager" to "person" and added "and determine if a 10CFR21 evaluation is required." Added last sentence to notify the engineering manager if a 10CFR21 evaluation is required.
			6.6.3	Changed "manager" to "person".
			6.6.4	In the first sentence, "Quality Assurance" was "Manager, Quality Assurance".
			6.6.5	In the first sentence, "Quality Assurance" was "Manager, Quality Assurance".
			6.6.6	Reworded to specify that Quality Assurance will close the CAR and update the log as to the its status.
		7	6.7	Revised this section in its entirety to address the following: a. Requirements for performing 10CFR21 evaluations and the reporting requirements if ESI does not have the capability to perform the evaluation. b. Include a procedure to perform 10CFR21 evaluations. c. Updated requirements for reporting 10CFR21 defects or failures to comply.
		8	8.0	Added 8.4, 8.5 & 8.6: Records and retention periods of 10CFR21 evaluations, 10CFR21 reports and purchasers of safety related components or services, respectively.
		9	9.4	Added Exhibit 4: Hold tag

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CONTROL OF NONCONFORMING CONDITIONS AND CORRECTIVE ACTIONS AND 10CFR21 REPORTABLE CONDITIONS

1.0 PURPOSE

The purpose of this procedure is to describe the methods used to identify, control, document and resolve conditions or items that do not conform to specified requirements, and the methods used to ensure significant conditions adverse to quality are promptly identified and corrected. This includes Trend Analysis evaluations to provide indications of conditions that are adverse to quality, identification and tracking of suspect / counterfeit items and also, the method of reporting defects and non-compliances to the Nuclear Regulatory Commission (NRC) in accordance with 10CFR21.

2.0 SCOPE

This procedure is applicable for all work and Quality Levels with the exception of 10CFR21 (Code of Federal Regulations) which is applicable to Nuclear work only.

3.0 REFERENCES

3.1 QAM-1, "Management Responsibility"

3.2 QAM-13, "Nonconformance Control"

3.3 QAM-14, "Corrective action"

3.4 QAM-16, "Quality Records"

3.5 PSP-108 "Material Receiving"

3.6 10CFR21, "Reporting of Defects and Noncompliance"

3.7 ORACLE-11i "Documentation Manual"

4.0 PREREQUISITES

None.

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5.0 RESPONSIBILITIES

5.1 All personnel are responsible for:

5.1.1 Identifying nonconforming conditions or items that do not conform to specified requirements.

5.1.2 Completing tasks, as required, by the Nonconformance Report (NCR) disposition.

5.1.3 All personnel have the responsibility to report known or suspected deviations and/or failures to comply associated with nuclear safety related materials, items, or services that could create a substantial safety hazard to the Manager - Engineering.

5.2 The Manager, Quality Assurance or Designee is responsible for:

5.2.1 Investigating reported nonconformance's when required.

5.2.2 Reviewing NCRs for completeness, accuracy, adverse affects on the quality system, approving recommended dispositions and initiating Corrective/Preventive Action Reports (CAR) when necessary.

5.2.3 Routing all CARs to senior management for information.

5.2.4 Verifying that corrective action has been completed and is satisfactory for all NCR's.

5.2.5 Performing a semi-annual review of nonconforming conditions for trend analysis and evaluating CAR's adverse trends.

5.2.6 Making the necessary report of defects and non-compliances to the Nuclear Regulatory Commission.

5.2.7 Trend and review suspect / counterfeit items identified during the year.

5.3 The Manager - Engineering or designee is responsible for recommending a disposition and providing instructions to correct the non-conforming condition when documented on a NCR. The disposition review includes 10CFR21 evaluations. The Manager - Engineering or designee is responsible for investigating all reported occurrences which appear to meet the conditions of Title 10CFR part 21 requirements for the reporting of defects and non-compliances.

5.4 The Purchasing agent is responsible for the purchase of replacement material and vendor contact in resolving discrepancy.

5.5 Customer Service / Project Manager or designee is responsible for obtaining customer approval when a NCR "ACCEPT AS IS" or "REPAIR" disposition is recommended which deviates from the original product specification.

6.0 PROCEDURE

6.1 Identification and Control of Nonconforming conditions.

6.1.1 All nonconformances for nuclear parts or service shall be electronically documented on a NCR. Nonconforming items shall be identified with a "Hold Tag" (Exhibit 4). If possible, items shall be placed in a segregated hold area. Complete descriptions shall be given with sketches and/or photographs attached, if necessary.

6.1.2 Hold Tags shall remain attached until an approved disposition is provided and corrective action is accomplished. Tags shall only be removed by the Quality Department.

6.1.3 Customer supplied material identified as nonconforming shall be identified and segregated when practical. These items will be identified by tag or red paint. Customer Service shall be notified when customer supplied material is outside the scope of supply or nonconforming by the use of a Condition Report or NCR.

6.1.4 Material identified as nonconforming during receiving by Shipping and Receiving personnel shall be documented on an Over, Short or Damage (OS&D) report as described in PSP-108, and segregated.

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6.2 DISPOSITION AND ROUTING OF NCR's

6.2.1 Engineering shall provide the recommended disposition, any instructions necessary to correct the nonconforming condition and determine if the nonconforming condition requires a 10CFR21 evaluation. If it is determined that a 10CFR21 evaluation is required, the Manager - Engineering shall be notified and the evaluation shall be performed in accordance with 6.7.2. The NCR form shall be electronically dispositioned.

NOTE:

"Rework" is completion or correcting the item to a drawing or specification, verification is required.
"Repair" must be accomplished to technical instructions, verification is required.
"Accept as is" must be provided with suitable technical justification.

6.2.2 Routing of the NCR to the appropriate department is as follows:

6.2.2.1 All NCR's shall be routed to Engineering for disposition in accordance with 6.2.1.

6.2.2.2 Purchasing Agent shall interface with the vendor if the disposition requires vendor contact, return of material, or new purchase.

6.2.2.3 Customer Service shall interface with the customer if customer approval and/or acceptance are required for NCRs pertaining to parts orders.

6.2.2.4 Project Manager / designee shall be used if customer approval and/or acceptance are required for NCRs pertaining to non-parts orders.

6.2.2.5 Quality shall be used if the part requires re-inspection or if the Purchasing Agent directs the material to be returned to the vendor or scrapped.

6.2.2.6 If the recommended disposition is not approved by the routed individual, the NCR shall be directed by the reviewing party to the responsible party with comments.

6.2.3 Disposition of OS&Ds will be in accordance with procedure PSP-108.

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6.3 CLOSURE OF NCR's

6.3.1 NCR's will be closed by Quality Department personnel as follows:

6.3.1.1 For "Accept-As-Is" disposition requiring customer approval, the NCR is closed when customer acceptance has been received and the Hold Tag is removed.

6.3.1.2 For "Repair or Rework" disposition, the NCR is closed when the item is re-inspected by Quality and is found to be acceptable and customer acceptance is received, when required.

6.3.1.3 If the disposition is "Scrap" or "Return to Vendor", the NCR will be closed when an acceptable replacement part is received and the material is placed in shipping for return to the vendor, or to be scrapped.

6.3.1.4 When closing the NCR, Quality Department personnel shall enter appropriate remarks such as "Repaired" or "Reworked", "Reinspected" and found to be Acceptable".

6.3.1.5 Quality Assurance will review, sign and date the closed NCR. A copy of the completed NCR will be filed in the sales order file.

6.4 CORRECTIVE/PREVENTIVE ACTION REPORT (CAR)

6.4.1 The Corrective/Preventive Action Report (Exhibit 3) process is a quality tool that acts as a vehicle for a cross-functional team to articulate thoughts and provides assurance to details of problems and long-lasting solutions. This method is used for solving customer complaints, supplier corrective actions, internal corrective actions, health and safety actions, and preventive actions.

6.4.2 A Corrective/Preventive action report may be generated:

6.4.2.1 As a method to address potential problems from occurring.

6.4.2.2 When management agrees that a problem is serious enough to warrant additional information/action.

6.4.3 Causes of detected (or potential) nonconformities should be promptly identified so that corrective action may be taken and recurrence (or occurrence) may be prevented. These causes may include the following;

6.4.3.1 failures, malfunctions or nonconformities in incoming materials, processes, tools, equipment or facilities in which products are processed, stored or handled, including the equipment and systems therein;

6.4.3.2 inadequate or non-existent procedures and documentation;

6.4.3.3 non-compliance with procedures;

6.4.3.4 inadequate process control;

6.4.3.5 poor scheduling;

6.4.3.6 lack of training;

6.4.3.7 inadequate working conditions;

6.4.3.8 inadequate resources (human or material);

6.4.3.9 inherent process variability.

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6.4.4 The following are also potential causes for Corrective/Preventive Action reports;

6.4.4.1 Failure to obtain appropriate approval before making changes to, or failure to follow approved organization, procedure or policy changes.

6.4.4.2 Failure to implement action to resolve deficiencies in a timely manner.

6.4.4.3 Failure to adhere to hold points identified on the "Process Control Documentation".

6.4.4.4 To evaluate a reported deviation or noncompliance to determine if it could create a substantial safety hazard in accordance with 10CFR21 requirements.

6.4.4.5 Adverse NCR trends. NCR's shall be reviewed twice a year for adverse trends. Corrective Action Reports shall be generated as required. This review shall be included in the Management Review.

NOTE:

Corrective action is not necessarily required for every occurrence of a nonconformance, but periodic analysis of patterns of nonconformance should be considered to uncover opportunities for process improvement.

6.4.5 CAR's are generated by the Quality Department which will maintain a log of issued CAR's and their status.

6.5 PREVENTIVE ACTIONS

6.5.1 Preventive actions may be documented and completed through the Corrective/Preventive Action Report process or as action items in the management review meeting. Analyzed data will be reviewed during management review meetings to determine courses of action to prevent future problems.

6.5.2 Information such as process and operations reviews, service reports, audit results, Quality Records, service reports, customer complaints and warranty claims shall be reviewed to detect and eliminate potential causes of nonconformities which affect product quality. Statistical techniques that may be used to establish, control and verify process and product conformance to support the need of preventive action may include, but not limited to:

6.5.2.1 Pareto charts, control charts, Cp and Cpk, effective yields, attribute data, DPK, DPPM, DPMO, trend analysis.

6.5.3 The applicable tools used to document and implement preventive actions will vary depending on the timing and scope of preventive action required. These tools may include, but not limited to:

6.5.3.1 Failure Mode Analysis, control plans, quality plans, Management reviews, continuous improvement meetings, data analysis and reporting, corrective/preventive action reports, preventive action requests, audits, 5S, Kaizen, Lean Manufacturing and 6 Sigma principles.

6.5.4 A preventive action plan may be formulated to the extent necessary as determined by Management and will include:

6.5.4.1 An action plan to prevent the failure mode identified

6.5.4.2 The estimated implementation date

6.5.5 Sources of Preventive action are established to detect, analyze, and eliminate potential causes of nonconformities. These sources may include, but not limited to:

6.5.5.1 Data relating to processes and operations which affect quality

6.5.5.2 Data received from customers and suppliers, as well as sources of information generated internally

6.5.5.3 Design data (verification, validation review), new product designs

6.5.5.4 Customer surveys, customer feedback; including returns and complaints

6.5.5.5 Quality records, calibration data, audit reports, training records

6.5.5.6 Process and Product measurement and monitoring, nonconformance reports

6.5.5.7 Corrective actions applied to other products or processes

6.5.5.8 Supplier evaluation data, audits, source inspection

6.5.5.9 Field performance data

6.5.5.10 Preventive maintenance of equipment data

6.5.5.11 Environmental, health and safety data

6.5.5.12 Safety and OSHA related concerns

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6.5.6 The conditions resulting from these causes may be revealed by analysis of the following:

6.5.6.1 inspections and test records;

6.5.6.2 nonconformity records;

6.5.6.3 observations during process monitoring;

6.5.6.4 audit observations;

6.5.6.5 field, service or purchaser complaints;

6.5.6.6 regulatory authority or customer observations;

6.5.6.7 observations and reports by personnel;

6.5.6.8 sub-contract problems;

6.5.6.9 management review results;

6.5.6.10 inherent process variability.

6.6 CORRECTIVE/PREVENTIVE ACTION EVALUATION AND REVIEW.

6.6.1 The Manager, Quality Assurance will submit copies of all Corrective/Preventive Action Reports to senior management or present the CAR's issues and actions monthly to the Management Team.

6.6.2 The responsible person identified on the CAR shall document the cause, the proposed corrective action and/or the preventative actions to preclude occurrence on the report and determine if a 10CFR21 evaluation is required. If the recommended action requires engineering evaluation, the report will be referred to the Manager - Engineering for concurrence. If it is determined that a 10CFR21 evaluation is required, the responsible person shall notify the Manager - Engineering and the evaluation shall be performed as per paragraph 6.7.2.

6.6.3 The responsible person shall implement the corrective actions and the preventive actions by the response due date or request in writing an extension from Quality Assurance.

6.6.4 Completed CARs will be reviewed by Quality Assurance for adequacy. Verifications of corrective actions to prevent reoccurrence may need to be performed to ensure adequate measures have been taken.

6.6.5 Unacceptable CARs shall be noted on the report and Quality Assurance shall state the reason for rejection. A second CAR will be generated and routed to the responsible person with a copy of the original attached. If appropriate response cannot be obtained or if the corrective action is not implemented in the specified time, the Manager - Quality Assurance shall order work stopped on the affected item(s) or activity by issuance of an NCR.

6.6.6 Acceptable CARs shall be noted in the appropriate block, signed and dated by Quality Assurance to close the CAR. Quality Assurance shall update the log as to the CAR status.

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6.7 REPORTING OF DEFECTS AND NONCOMPLIANCES (10CFR21).

6.7.1 All personnel have the responsibility to report a known or suspected *deviation* and/or *failure to comply* associated with nuclear safety related materials, items, or services to the Manager - Engineering. *Deviation* means a departure from the technical requirements included in a procurement document. *Failure to comply* means fails to comply with the Atomic Energy Act of 1954, as amended, or any applicable rule, regulation, order or license of the Commission relating to a substantial safety hazard.

6.7.2 The Manager – Engineering or designee shall:

6.7.2.1 Perform an evaluation of the reported deviation or failure to comply to determine if it could create a substantial safety hazard. This evaluation must be performed as soon as practicable, and in all cases within 60 days of discovery of the deviation or failure to comply, except as provided in 6.7.2.4. The evaluation shall include the following:

a. Request Quality Assurance to initiate a Corrective Action Report (CAR) in accordance with paragraph 6.4.

b. Determine the application of the component(s) affected by the deviation or failure to comply to determine if a safety related system is involved and if the deviation or failure to comply could prevent the system from performing its safety function and thus creates a substantial safety hazard. If so, the deviation is then considered to be a defect.

c. Identify the root cause and determine if the defect or failure to comply is an isolated incident or if a generic condition exists. Contact the component manufacturer, supplier, system designer, etc. as necessary for assistance.

d. If a generic condition exists, determine duration of the condition (affected date codes, lot numbers, serial numbers, etc.).

e. Review sales order history to identify users affected by the defect or failure to comply.

6.7.2.2 Ensure that, if an evaluation cannot be completed within sixty (60) days from discovery, an interim report is prepared and submitted to the NRC. This interim report must be submitted in writing within sixty (60) days of the discovery of the deviation or failure to comply. The interim report shall describe the deviation or failure to comply which is being evaluated and shall also state when the evaluation is to be completed.

6.7.2.3 Notify the Manager, Quality Assurance within five (5) working days after completion of the evaluation if the evaluation determines that the deviation or failure to comply could create a significant safety hazard.

6.7.2.4 Ensure that, if ESI does not have the capability to perform the evaluation, all affected users (purchasers) are notified within five (5) working days of this determination.

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6.7.2.5 Prepare a 10CFR21 report for the defect or failure to comply that could create a significant safety hazard. The report shall be controlled and distributed in accordance with procedure EP-813 and shall be submitted to the Manager, Quality Assurance immediately upon completion such that the notification requirements of paragraph 6.7.3.1 are satisified. As a minimum, the report shall include the following:

a. Identification of the activity or the basic component supplied within the United States which fails to comply or contains a defect.

b. Identification of the firm supplying the basic component which fails to comply or contains a defect.

c. Nature of the defect or failure to comply and the safety hazard which is created or could be created by such defect or failure to comply.

d. The date on which the information of such defect or failure to comply was obtained.

e. In the case of a basic component which contains a defect or fails to comply, the number and location of all such components in use at, supplied for, or being supplied for one or more facilities or activities.

f. The corrective action which has been, is being, or will be taken; the name of the individual or organization responsible for the action; and the length of time that has been or will be taken to complete the action.

g. Any advice related to the defect or failure to comply about the facility, activity, or basic component that has been, is being, or will be given to purchasers or licensees.

6.7.3 The Manager, Quality Assurance is responsible for:

6.7.3.1 Notifying the NRC of any reported defect or noncompliance that could create a significant safety hazard. Initial notification to the NRC shall be made within 2 days following notification from the Manager - Engineering of the defect or noncompliance. The initial notification shall be made by facsimile to the NRC Operations Center at (301) 816-5151 or by telephone at (301) 816-5100. This does not apply to interim reports described in paragraph 6.8.2.b.

6.7.3.2. Providing written notification to the NRC within 30 days following notification from the Manager - Engineering of the defect or noncompliance. Written reports shall be addressed to the NRC's Document Control Desk and shall be mailed to the U.S. Nuclear Regulatory Commission, Washington, DC 20555-01. The written report shall include the following:

a. Name and address of the individual or individuals informing the Commission.

b. The 10CFR21 report prepared in accordance with paragraph 6.7.2.5.

7.0 ACCEPTANCE CRITERIA

7.1 As defined in the body of this procedure.

8.0 RECORDS

8.1 Non-conformance Report (NCR).

8.2 Corrective Action Report (CAR).

8.3 Trend Analysis Report.

8.4 10CFR21 evaluations (retain for 5 years minimum after evaluation date).

8.5 10CFR21 reports (retain for 5 years minimum after notification date).

8.6 Purchasers of safety related components or services (retain for 10 years minimum after delivery date of component or service).

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9.0 FORMS

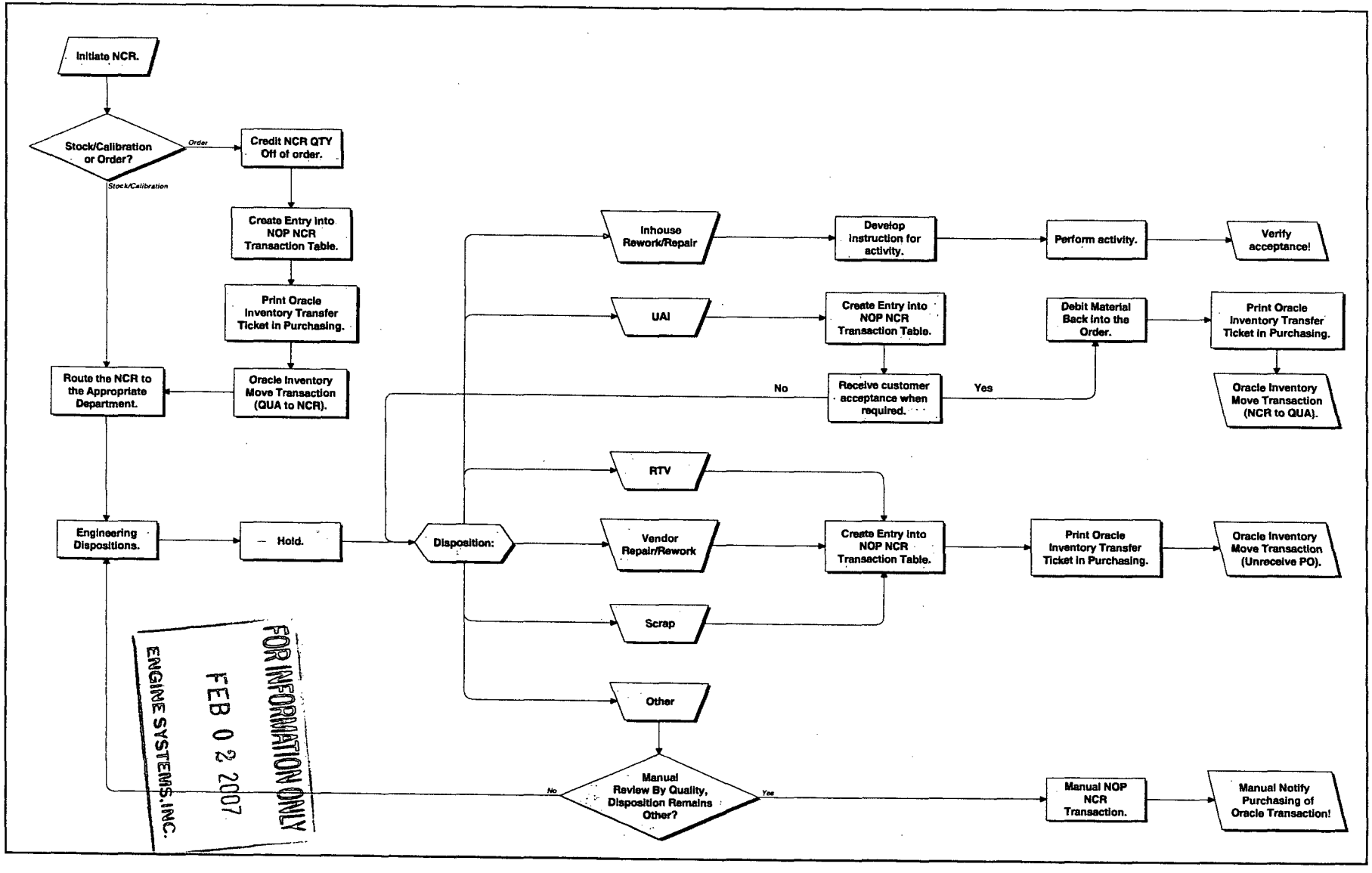
9.1 Exhibit 1, Flow chart for the processing NCR's.

9.2 Exhibit 2, Trend Analysis Attribute Key

9.3 Exhibit 3, CAR form

9.4 Exhibit 4, Hold tag

Processing Nonconformances



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Trend Analysis Attribute Key

ENGINEERING

E-01	DOCUMENT CONTROL
E-02	DESIGN
E-03	PROCEDURE

RECEIVING / DEDICATION

R-01	PURCHASE ORDER
R-02	CMTR / -C OF C
R-03	DIMENSIONAL
R-04	IDENTIFICATION
R-05	SHIPPING DAMAGE
R-06	MATERIAL
R-07	QUANTITY
R-08	UNAPPROVED SUPPLIER
R-09	SHELF LIFE
R-10	TEST ANOMALY
R-11	OXIDATION
R-12	WORKMANSHIP / WELDING
R-13	OTHER
R-14	SUSPECT / COUNTERFEIT ITEMS

STORAGE

S-01	LOSS OF TRACEABILITY
S-02	DAMAGE
S-03	LOSS OF CONTROL / PROTECTION
S-04	PREVENTIVE MAINTENANCE
S-05	OTHER

PRODUCTION / INSTALLATION

P-01	DRAWINGS / PROCEDURE
P-02	LOSS OF TRACEIBILTY
P-03	DAMAGE
P-04	DIMENSIONAL
P-05	LOCATION
P-06	MISSED HOLD POINTS
P-07	WELDING / BRAZING
P-08	NDE
P-09	TESTING ANOMALY
P-10	COATINGS
P-11	MARKINGS / IDENTIFICATION
P-12	WRONG MATERIAL TYPE OR SIZE
P-13	OTHER

CALIBRATION

C-01	LOSS OF EQUIPMENT
C-02	DAMAGE
C-03	MARKINGS
C-04	UNCALIBRATED TOOL
C-05	OTHER

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ENGINE SYSTEMS, INC.

LIFTING AND HANDLING

L-01	PROCEDURE
L-02	DAMAGE TO GEAR
L-03	OVERLOADING
L-04	OTHER

OTHER

X-01	OTHER

Engine Systems, Inc.

Nuclear Parts & Service

Corrective/Preventive Action Report

Type:	Customer		Supplier		Internal		Health & Safety		Preventive		CAR #:	

Customer/Supplier:		Contact:	
Date Opened:		RGA #:	
Response Due Date:		Issued By:	

D1. Describe the Problem

Part #:	Part Description:	Process Where Problem Discovered:
Order #:	Qty Defective:	Qty Returned:

D2. Identify Problem Solving Team

Issued To (Team Leader):

Team members:	Department	Team members:	Department
1.		4.	
2.		5.	
3.		6.	

D3. Develop Interim Containment Action(s)

	Responsible Person	Target Date	Date Implemented

D4. Identify The Root Cause(s)

	Responsible Person

D5. Develop & Implement Permanent Corrective Action(s)

	Responsible Person	Target Date	Date Implemented

D6. Analysis of Action (Link Solution; D3 – D5)

Does this problem apply to similar and/or other products at:	This Site?	YES ____ NO ____	Analyzed By:
	External Site(s)?	YES ____ NO ____	
Does this problem require a 10CFR Part 21 Evaluation?		YES ____ NO ____	

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D7. Verify Corrective Action

FEB 02 2007

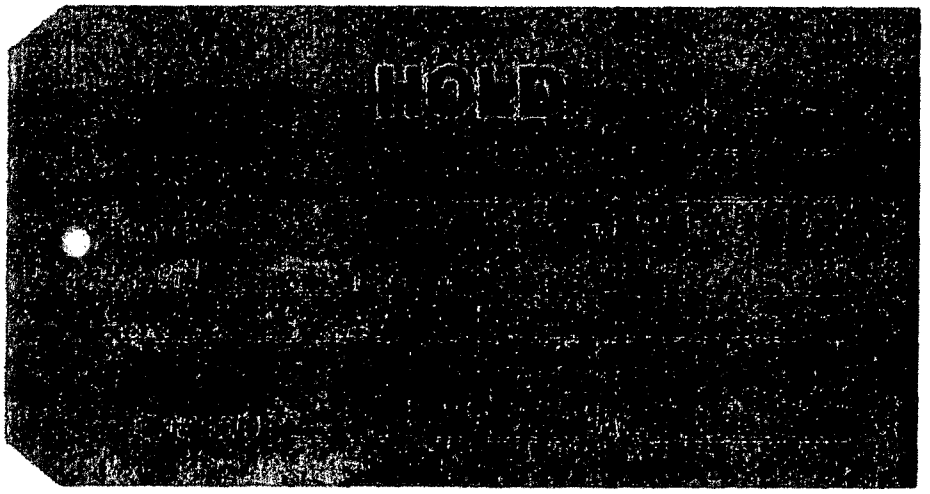
ENGINE SYSTEMS, INC.

Reviewed and Approved By:

D8. Closure

Date Closed:

Hold Tag



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FEB 0 2 2007
ENGINE SYSTEMS, INC.

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

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,

for

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

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

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.