



Engine Systems, Inc.

175 Freight Road
Rocky Mount, NC 27804

Telephone: (252) 977-2720
Fax: (252) 446-3830

Reply to a Notice of Nonconformance

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 Nonconformance dated 9th day of January 2007, Engine Systems is providing the following:

(1) Nonconformance 99901362/2006-201-02:

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."

Description of steps that have been or will be taken to correct this item:

This 26 week method was only used on a very limited number of components and only for the purposes of seismic qualification. ESI always performs 100% dimensional inspection and functional test (where applicable) of parts shipped. It has not been utilized since this issue was identified during the 13-16 Nov, 2006 NRC inspection.

This method was incorporated in the 2/22/06 revision to PSP-201 to establish lot control for select part numbers where numerous lots repeatedly passed seismic testing and were visually of the same design. The revision to PSP-201 was poorly worded and, as written, the 26 week method could be applied to any part number. This method was only utilized in a few instances for components with proven seismic capability and in each case the parts were visually inspected (although not formally documented) to determine similarity in design to a previous seismic test specimen. Dedication of these components was therefore not compromised. Internal Corrective/Preventive Action Report, CAR#: 2007-04, issued January 22, 2007.

Description of steps that have been or will be to prevent recurrence:

Revise procedure PSP-201 to delete the 26 week method and return to the previous method of lot control by date code and/or purchase order lot; or, perform a comparison analysis of a sample item with lot control against a previously qualified specimen. See attached revised sections from Procedure PSP-201; page 2 section 3.17, page 8 sections 6.2.3.4 and 6.2.4. Train all involved with the dedication process in the new revision of PSP-201.

Dates corrective action and preventive measures were or will be completed:

Completed and implemented February 2, 2007.

(2) Nonconformance 99901362/2006-201-03:

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.



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Description of steps that have been or will be taken to correct this item:

No interim containment is necessary. This does not affect the dedication process.

10CFR21 was changed after the original definition of commercial grade items was incorporated in the ESI dedication reports. Period reviews of 10CFR21 are not performed to identify changes and thus the old definition was still utilized in the dedication reports. Currently, the definition of a commercial grade item is not included in dedication procedure PSP-201. Internal Corrective/Preventive Action Report, CAR#: 2007-05, issued January 22, 2007.

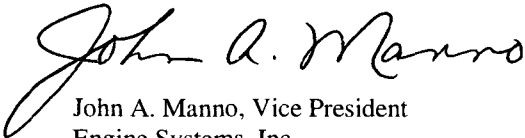
Description of steps that have been or will be to prevent recurrence:

Revise procedure PSP-201 to include the commercial grade item definition included in the current revision of 10CFR21. Any new dedication reports and those requiring revision will include the current definition. Dedication reports will not be revised solely to change the definition as this does not impact the dedication process. See attached revised sections from Procedure PSP-201; page 5 section 6.1.1. Also, add an item to future internal audit checklist to review the current revision of 10CFR21 to verify the current revision is posted within the facility and to determine if any procedural changes are necessary.

Dates corrective action and preventive measures were or will be completed:

Completed and implemented February 2, 2007.

Sincerely,



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

Enclosure: 1. Corrective/Preventive Action Report, CAR#: 2007-04.
 2. Corrective/Preventive Action Report, CAR#: 2007-05.
 3. Procedure PSP-201, Revision 11, dated 01/31/07, Dedication of safety Related Items;
 cover page, revision page, pages 2, 5 & 8.

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



Corrective/Preventive Action Report

Type:	Customer	Supplier	Internal	X	Health & Safety	Preventive	CAR #: 2007-04
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							
<p>Based on the results of a Nuclear Regulatory Commission (NRC) inspection conducted November 13 – 16, 2006, of activities performed at ESI, it appears that certain activities were not conducted in accordance with NRC requirements which were contractually imposed upon ESI by NRC licensees. (see attached Report 99901362/2006-201 and Notice of Nonconformance)</p> <p>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.</p> <p>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.</p> <p>Contrary to the above,</p> <p>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."</p> <p>This issue has been identified as Nonconformance 99901362/2006-201-02.</p>							
Part #: N/A		Part Description: NRC Audit Violation			Process Where Problem Discovered: ESI Documentation		
Order #: N/A		Qty Defective: N/A			Qty Returned: 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)							
This 26 week method was only used on a very limited number of components and only for the purposes of seismic qualification. ESI always performs 100% dimensional inspection and functional test (where applicable) of parts shipped. It has not been utilized since this issue was identified during the 13-16 Nov. 2006 NRC inspection.					Responsible Person	Target Date	Date Implemented
					Don Galeazzi	1/22/07	1/22/07
D4. Identify The Root Cause(s)							
This method was incorporated in the 2/22/06 revision to PSP-201 to establish lot control for select part numbers where numerous lots repeatedly passed seismic testing and were visually of the same design. The revision to PSP-201 was poorly worded and, as written, the 26 week method could be applied to any part number. This method was only utilized in a few instances for components with proven seismic capability and in each case the parts were visually inspected (although not formally documented) to determine similarity in design to a previous seismic test specimen. Dedication of these components was therefore not compromised.						Responsible Person	
						Don Galeazzi	
D5. Develop & Implement Permanent Corrective Action(s)							
Revise PSP-201 to delete the 26 week method and return to the previous method of lot control by date code and/or purchase order lot; or, perform a comparison analysis of a sample item with lot control against a previously qualified specimen. Train all involved with the dedication process in the new revision of PSP-201.					Responsible Person	Target Date	Date Implemented
					Don Galeazzi	2/2/07	2/2/07
D6. Analysis of Action (Link Solution; D3 – D5)							
Does this problem apply to similar and/or other products at:		This Site?	YES _____	NO <input checked="" type="checkbox"/>	Analyzed By: Don Galeazzi		
		External Site(s)?	YES _____	NO <input checked="" type="checkbox"/>			
Does this problem require a 10CFR Part 21 Evaluation?		YES _____	NO <input checked="" type="checkbox"/>				
D7. Verify Corrective Action							
PSP-201 revision 11 dated 01/31/07 is revised to delete the 26 week lot control method. Remaining verified.					Reviewed and Approved By: Vann Mitchell		
<div style="border: 1px solid black; padding: 5px; display: inline-block;"> FOR INFORMATION ONLY FEB 02 2007 ENGINE SYSTEMS, INC. </div>					D8. Closure		
					Date Closed: 2/2/07		



Corrective/Preventive Action Report

Type:	Customer	Supplier	Internal	X	Health & Safety	Preventive	CAR #:	2007-05
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, of activities performed at ESI, it appears that certain activities were not conducted in accordance with NRC requirements which were contractually imposed upon ESI by NRC licensees. (see attached Report 99901362/2006-201 and Notice of Nonconformance)

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 function 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.

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.

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

D2. Identify Problem Solving Team

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

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

D3. Develop Interim Containment Action(s)

No interim containment is necessary. This does not affect the dedication process.	Responsible Person	Target Date	Date Implemented
	Don Galeazzi	1/22/07	1/22/07

D4. Identify The Root Cause(s)

10CFR21 was changed after the original definition of commercial grade items was incorporated in the ESI dedication reports. Period reviews of 10CFR21 are not performed to identify changes and thus the old definition was still utilized in the dedication reports. Currently, the definition of a commercial grade item is not included in dedication procedure PSP-201.	Responsible Person
	Don Galeazzi

D5. Develop & Implement Permanent Corrective Action(s)

Revise PSP-201 to include the commercial grade item definition included in the current revision of 10CFR21. Any new dedication reports and those requiring revision will include the current definition. Dedication reports will not be revised solely to change the definition as this does not impact the dedication process. Also, add an item to the internal audit checklist to review the current revision of 10CFR21 to verify the current revision is posted within the facility and to determine if any procedural changes are necessary.	Responsible Person	Target Date	Date Implemented
	Don Galeazzi P. Stepantschenko	2/2/07	2/2/07

FOR INFORMATION ONLY

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

Does this problem apply to similar and/or other products at:	This Site?	YES _____	NO <input checked="" type="checkbox"/>	Analyzed By: 2007 Don Galeazzi
	External Site(s)?	YES _____	NO <input checked="" type="checkbox"/>	
Does this problem require a 10CFR Part 21 Evaluation?	YES _____	NO <input checked="" type="checkbox"/>	ENGINE SYSTEMS, INC.	

D7. Verify Corrective Action

PSP-201 is revised to include the definition of "Commercial Grade Item" as found in the Jan 1, 2004 revision of 10CFR21.3. The definition found in the previous revisions of PSP-201 and the dedication reports did not affect the dedication process or the products shipped. Revisions to dedication reports and new dedication reports from 2 Feb, 2007 forward have the revised definition as required by revision 11, dated 1/31/07 of PSP-210.	Reviewed and Approved By: Vann Mitchell
	D8. Closure Date Closed: 2/2/07

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.

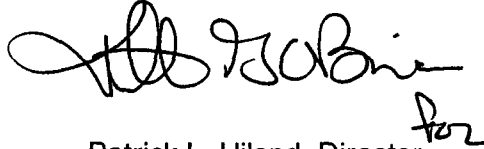
In addition, the NRC inspectors found that the implementation of your quality assurance program failed to meet certain NRC requirements imposed on you by your customers. Specifically, inadequate instructions were identified in ESI's procedures related to the dedication process, as required by Appendix 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,

A handwritten signature in black ink, appearing to read "Patrick L. Hiland". The signature is fluid and cursive, with a large initial "P".

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 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.