July 14, 2011

Mr. Jeffery McConkey, Quality Assurance Manager
Flowserve Limitorque
5114 Woodall Road
Lynchburg, VA 24502

SUBJECT: FLOWSERVE LIMITORQUE RESPONSE TO NRC INSPECTION REPORT NO. 99900100/2011-201, NOTICE OF VIOLATION, AND NOTICE OF NONCONFORMANCE

Dear Mr. McConkey:

Thank you for your May 20, 2011, letter in response to the Notice of Violation (Notice) and Notice of Nonconformance (NON) that were discussed in the U.S. Nuclear Regulatory Commission (NRC) inspection report (IR) 99900100/2011-201.

We reviewed your letter and found that it was not responsive to some of the issues discussed in IR 99900100/2011-201.

Specifically, in the cover letter to IR 99900100/2011-201, we stated, in part, that Flowserve Limitorque relied "on multiple standards to define the QA requirements in the Quality Management System Manual (QMSM). The NRC inspection team noted that the QMSM was primarily written for adherence to International Standardization Organization (ISO) 9001:2000 provisions. In addition, the QMSM states, in part, that the manual "will also comply with the following: Title 10 of the *Code of Federal Regulations* (10 CFR) Part 21 and Part 50 Appendix B, NQA -1-1994, ATEX EN 13980:2002, IECEx and Military Specification MIL-I-45208A Amendment 1 – 1981 . . . ." However, the QMSM reviewed by the inspection team did not establish clear policies and guidance consistent with the requirements of Appendix B to 10 CFR Part 50." Accordingly, the NRC staff needs to understand what corrective actions Limitorque has taken or will be taking to address these issues. Please provide a response outlining any changes made to the Flowserve Limitorque QMSM to address these issues.

In addition, the inspection report cover letter stated, in part, that "the NRC inspection team performed a limited scope inspection. The deficiencies identified may affect other portions of Limitorque's 10 CFR Part 21 and Quality Assurance (QA) program that the NRC inspection team did not review. Therefore, Limitorque must extend its review, where applicable, beyond the specific examples identified by the NRC inspection team and apply corrective actions, as appropriate." In your response to IR 99900100/2011-201, Flowserve Limitorque did not address the impact of these issues on the overall QA program implementation and effectiveness (i.e., extent of condition). In addition, Flowserve Limitorque failed to identify those aspects of its QA or 10 CFR Part 21 programs for which it extended its review beyond the specific examples of the deficiencies identified by the NRC inspection team, the extent of its review, any additional deficiencies identified, and the corrective actions implemented.

Finally, your response did not adequately address certain specific Notice and NON issues identified during the subject inspection as described in the Enclosures to this letter. In preparing your response, you should follow the instructions specified therein. The NRC review of your

response will also determine whether further enforcement action is necessary to ensure compliance with regulatory requirements.

In accordance with 10 CFR 2.390 “Public Inspections, Exemptions, Requests for Withholding,” of the NRC's "Rules of Practice," a copy of this letter, its enclosure(s), and your response will be made available electronically for public inspection in the NRC Public Document Room or from the NRC’s Agencywide Documents Access and Management System (ADAMS), accessible from the NRC Web site at http://www.nrc.gov/reading-rm/adams.html. To the extent possible, your response should not include any personal privacy, proprietary, or safeguards information so that it can be made available to the Public without redaction. If personal privacy or proprietary information is necessary to provide an acceptable response, then please provide a bracketed copy of your response that identifies the information that should be protected and a redacted copy of your response that deletes such information. If you request that such material is withheld from public disclosure, you must specifically identify the portions of your response that you seek to have withheld and provide in detail the bases for your claim (e.g., explain why the disclosure of information will create an unwarranted invasion of personal privacy or provide the information required by 10 CFR 2.390(b) to support a request for withholding confidential commercial or financial information). If safeguards information is necessary to provide an acceptable response, please provide the level of protection described in 10 CFR 73.21 “Protection of Safeguards Information: Performance Requirements.”

Please contact Mr. Robert Prato at (301) 415-6035 or via electronic mail at robert.prato@nrc.gov, if you have any questions or need assistance regarding this matter.

Sincerely,

/RA/ Robert Prato for

Juan D. Peralta, Chief
Quality and Vendor Branch 1
Division of Construction Inspection
& Operational Programs
Office of New Reactors

Docket No.: 99900100

Enclosure:
As stated

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As stated

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OFFICE	NRO/DCIP/CQVA	R-II/DCI/CIB3	NRO/DE/SEB1	NRO/DCIP/CQVB	NRO/DCIP/CQVA
NAME	RPrato *	TSteadham*	TScarbrough *	DBollock *	FTalbot *
DATE	06/ /2011	06 / 20 /2011	06/14/2011	06 / 16 /2011	07/13 /2011
OFFICE	NRO/DCIP/CQVA	NRO/DCIP/CQVA	NRO/DCIP/CQVA/		
NAME	PCoco *	TKendzia	JPeralta		
DATE	06/21/2011	07/13/2011	07/14/2011		

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IR 99900100/2011-201-01 Notice

Violation 99900100/2011-201-01

The violation states, in part, that as of March 4, 2011, Flowserve Limitorque did not complete an evaluation and failed to prepare and submit in writing to the Commission an interim report within 60 days of discovery of an identified deviation or failure to comply potentially associated with a substantial safety hazard. Specifically, the US Nuclear Regulatory Commission (NRC) inspection team determined that Flowserve Limitorque had not completed its evaluation, nor prepared and submitted an Interim Report to the Commission for an ongoing Part 21 evaluation initially identified on September 28, 2010.

Flowserve Limitorque's response, stated that an "active Part 21 file was established and the appropriate evaluation was in process but Flowserve failed to file an interim report to the NRC commission as required after 60 days." For the corrective actions taken, Flowserve Limitorque stated that "Flowserve is still in the process of evaluation of the above potential Part 21 and is in the process of preparing an interim report to submit to the NRC commission by 6/3/11 or before. Flowserve has also retrained all members of the Part 21 committee to the requirements of Quality Assurance Program (QAP) 13.2 (Reporting of Defects for Safety related Equipment)."

The NRC noted that your interim report was dated June 3, 2011, 91 days after the NRC inspection team identified Flowserve Limitorque's failure to meet the 60 day reporting requirement under Title 10 of the *Code of Federal Regulations* (10 CFR) 21.21(a)(2) and as prescribed by quality procedure QAP 13.2. Please provide an explanation for exceeding the 60 day reporting requirement a second time after the NRC notified Flowserve Limitorque of its initial violation to 10 CFR 21.21(a)(2). The NRC will consider your response in determining the severity of the original violation.

Violation 99900100/2011-201-03

The violation states, in part, that "as of March 4, 2011, Limitorque issued procurement documents for basic components that did not impose the provisions of 10 CFR Part 21. Specifically, safety related material testing services were procured from an approved vendor without imposing 10 CFR Part 21 reporting requirements." For the corrective actions taken, Flowserve Limitorque stated that "blanket Purchase Requisition form has been revised as follows: *"Testing* shall be done in accordance with EXOVA Quality Assurance Manual, Revision 2, dated 2/1/10, 10CFR50 Appendix B, 10 CFR Part 21, and NQA-1. Also, revised QAP 6.1 appropriately to state requirements of safety related testing services."

The NRC reviewed your response to this violation and needs additional information regarding the changes made to Quality Assurance Procedure (QAP) 6.1 and how these changes address the violation. In addition, your response failed to identify any actions taken to determine the extent of condition, (i.e., impact of the omission of 10 CFR Part 21 requirements from previous procurement documents including the extent of your review any additional deficiencies identified, and the corrective actions implemented to prevent the potential for 10 CFR Part 21 reporting requirements not being imposed in other purchase orders for basic components.

Pursuant to the provisions of 10 CFR 2.201, "Notice of Violation," Flowserve Limitorque is hereby required to submit a written statement or explanation to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, DC 20555-001 with a copy to the Chief, Quality and Vendor Branch 1, Division of Construction and Operational Program, Office

of New Reactors, within 30 days of the date of the letter transmitting this Notice of Violation (Notice). This reply should be clearly marked as a "Reply to a Notice of Violation and should include for each violation: (1) the reason for the violation, or, if contested, the basis for disputing the violation or severity level, (2) the corrective steps that have been taken and the results achieved, (3) the corrective steps that will be taken, and (4) the date when full compliance will be achieved. Your response may reference or include previous docketed correspondence, if the correspondence adequately addresses the required response. Where good cause is shown, consideration will be given to extending the response time.

If you contest this enforcement action, you should also provide a copy of your response, with the basis for your denial, to the Director, Office of Enforcement, United States Nuclear Regulatory Commission, Washington, DC 20555-0001.

IR 99900100/2011-201-01 NON

Nonconformance 99900100/2011-201-04

The nonconformance states, in part, that “as of March 4,2011, Limitorque failed to establish measures to assure that applicable regulatory requirements and design basis are correctly translated into specification, drawings, procedures, and instructions; and failed to perform independent reviews of changes to software used in the manufacturing of safety related actuators. Specifically, Limitorque failed to develop guidance for when software reviews are to be performed and to independently verify changes to the "Configurator" software used in the design and assembly of safety related Limitorque actuators. For the corrective actions taken, Flowserve Limitorque stated that “Flowserve will add an additional step to the product configurator output for SMB and HBC nuclear product that will require the Engineer Change Notice (ECN) originator and another Engineer for verification. A signed scanned copy of this configuration output will be attached to the ECN. Quality Assurance Procedure (QAP) 5.1 has been revised accordingly.”

The US Nuclear Regulatory Commission (NRC) reviewed your response to this nonconformance and needs additional information regarding the changes made to QAP 5.1 and how these changes address the nonconformance. In addition, your response failed to identify any actions taken to identify the extent of condition (i.e., the impact of software reviews not being conducted to independently verify previous changes to the "Configurator" software used in the design and assembly of safety related Limitorque actuators) including the extent of your review, any additional deficiencies identified, and the corrective actions implemented. The extent of condition review needs to include at a minimum the “Center of Gravity” software, as well as any other safety related software in use today.

Nonconformance 99900100/2011-201-05

The nonconformance states, in part, that “as of March 4, 2011, Limitorque failed to impose the requirements of Appendix B to the Title 10 of the Code of Federal Regulation (10 CFR) Part 50 in documents for the procurement of safety related equipment and services. Specifically, Limitorque issued purchase orders (PO) 179913 and 183027 for the purchase of electrical motors for use in safety related actuators without imposing the requirement of Appendix B to 10 CFR Part 50. In addition, Limitorque used "open" POs to procure calibration services for safety related instrumentation and analyses of lubricants used in safety related actuators without imposing the requirement of Appendix B to 10 CFR Part 50.” For the corrective actions taken, Flowserve Limitorque stated that “Purchase note (POL 17) for procurement of safety related motors has been revised to state both 10 CFR 50 Appendix B and 10 CFR Part 21 are required. The *"open"* PO blankets for services have been revised to state the requirement of 10 CFR 50 Appendix B.”

The NRC reviewed your response to this nonconformance and was unable to identify any actions taken to address the extent of condition (i.e., the impact of past purchases and deliveries of electrical motors for use in safety-related actuators at NRC licensed facilities) including the extent of your review, any additional deficiencies identified, and the corrective actions taken to prevent similar errors from occurring in other safety related POs. In addition, your response did not address the potential that other blanket POs exist and whether the corrective actions taken apply to other blanket POs. Finally, your response did not address the potential for this condition to exist in non-blanket POs and the appropriate corrective actions to prevent similar conditions from occurring in non-blanket POs.

Nonconformance 99900100/2011-201-07

The nonconformance states, in part, that “as of March 4, 2011, Limitorque failed to establish measures to assure that the purchase of material, equipment, or services conformed to procurement documents. Specifically, Limitorque accepted material test reports for components and materials used in safety related actuators provided by a non Appendix B subcontractor. In addition, Limitorque failed to identify or reference acceptance criteria for receipt inspection to verify that purchased equipment conform to procurement documents. For the corrective actions taken, you stated that “[the laboratory performing the mechanical testing for Earle M. Jorgenson will be added to the Approved Vendors List (AVL) for the requirement of a "Commercial Grade Survey." The 2011 audit schedule will be revised to schedule this commercial grade survey. The appropriate survey check sheets will be developed. Also, Quality Control Procedure 10.5 has been revised to incorporate the acceptance criteria of the engineering drawings”.

The NRC reviewed your response and corrective actions for this nonconformance and notes that commercial grade surveys, in and of themselves are not sufficient for adding a testing laboratory to an AVL for mechanical testing of materials to be used in safety related applications. As described in Generic Letter 89-02, “Actions to Improve the Detection of Counterfeit and Fraudulently Marketed Products,” proper implementation of EPRI NP-5652, "Guideline for the Utilization of Commercial-Grade Items in Nuclear Safety-Related Applications (NCIG-07)," Acceptance Method 2, "Commercial-Grade Survey of Supplier," along with verification that the vendor has a documented commercial quality control program that is being effectively implemented establishes one method that satisfies the requirements of Appendix B to 10 CFR Part 50 for dedication of commercial-grade items. Combining commercial grade surveys with periodic verification of an effective, documented commercial quality control program will allow sampling of stock from each heat numbers versus full piece part verification of mechanical and chemical properties. Limitorque’s response to this noncomformance needs to confirm that the commercial grade dedicated process(es) are proceduralized and formally implemented for each commercial grade dedicated activity.

In addition, your response failed to identify any actions taken to identify the extent of condition (i.e., the impact of Flowserve Limitorque’s previous acceptance of material test reports for components and materials used in safety related actuators provided by a non Appendix B subcontractor), including the extent of your review, any additional deficiencies identified, and the corrective actions implemented.

Nonconformance 99900100/2011-201-08

The nonconformance states, in part, that “as of March 4,2011, Limitorque performed an external audit of an approved supplier on the Approved Vendors List for safety related components and services that did not evaluate the supplier's compliance with the requirements of Appendix B to 10 CFR Part 50. Specifically, in June 2009, Limitorque performed an audit of a qualified supplier of safety related actuator products and services including testing and calibration services. The audit evaluated the applicable requirements of International Standardization Organization 9001:2000 and International Standardization Organization/International Electrotechnical Commission 1725 for calibration services but did not include an evaluation of the applicable requirements for Appendix B to 10 CFR Part 50.”

For the corrective actions taken, you stated that Limitorque will “develop a *"Commercial* Grade Survey" checklist and re-audit to this new criteria.” The NRC reviewed your response to this nonconformance and was unable to identify any actions taken to identify the extent of condition,

(i.e., the impact of Flowserve Limitorque's failure to evaluate the supplier's compliance with the requirements of Appendix B to 10 CFR Part 50) including the extent of your review, any additional deficiencies identified, and the effectiveness of corrective actions implemented. Because this nonconforming condition existed for two years or more, Flowserve Limitorque needs to assess the impact of this nonconformance on equipment delivered for safety-related applications at NRC licensees. In addition, your assessment needs to determine why Flowserve Limitorque's implementation of its Quality Management System Manual allowed an external audit for a supplier of safety-related components and services to be conducted without verifying the supplier's compliance with the requirements of Appendix B to 10 CFR Part 50