



Flow Control Division
Limatorque

TO: US Nuclear Regulatory Commission
Attn: Document Control Desk
Washington, D.C. 20555-001

FROM: Jeff McConkey

DATE: 5/20/2011

SUBJECT: Response to Notice of Violation's and Nonconformance's (99900100/2011-201)

Ref.: Notice of Violation's and Nonconformance's as stated in Nuclear Regulatory Commission Inspection report Number 99900100/2011-201; Flowserve-Limatorque Corporation

Attached are the Flowserve-Limatorque Corporation responses to the Notice of violations (NOV) described in the referenced report and Notice of Nonconformance's (NON), also stated in the report.

If you have questions or require further information, please contact me at 434-845-9738

Regards,

Jeff McConkey
Quality Assurance Manager

Cc: Juan Peralta, Chief
Quality and Vendor Branch 1
Division of Construction Inspection and Operational Programs
Office of New Reactors

Attachments

IED9
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Reply to Notice of Violation
NRC Inspection Report 99900100/2011-201; Flowserve

Violation VIO 99900100/2011-201-01

The Violation as stated in the referenced Notice of Violation (NOV) is as follows:

Title 10 of the *Code of Federal Regulations* (10 CFR) 21.21(a), "Notification of failure to comply or existence of a defect and its evaluation," requires, in part, that "[e]ach individual, corporation, partnership, or other entity subject to the regulations in this part shall adopt appropriate procedures to -- (2) [e]nsure that if an evaluation of an identified deviation or failure to comply potentially associated with a substantial safety hazard cannot be completed within 60 days from discovery of the deviation or failure to comply, an interim report is prepared and submitted in writing to the Commission. . . within 60 days of discovery of the deviation or failure to comply."

Quality Assurance Procedure (QAP), QAP 13.2, "Reporting of Defects for Safety Related Equipment," Revision 15, states, in part, that "[a]ny defect condition under evaluation which cannot be completed within 60 days from date of discovery shall be reported to the Nuclear Regulatory Commission (NRC) in the form of an Interim Report within 60 days."

Contrary to the above, as of March 4, 2011, 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 NRC inspection team determined that 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.

This issue has been identified as Violation 99900100/2011-201-01.

This is a Severity Level IV Violation (Section 6.5).

Reasons for the Violation

Flowserve failed to follow the established timeline in procedure QAP 13.2 "Reporting of Defects for Safety Related Equipment". 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.

Corrective Actions Taken

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 QAP 13.2 (Reporting of Defects for Safety related Equipment).

Actions to Avoid Future Violations

Flowserve will follow the requirements of existing procedure QAP 13.2. The Quality Assurance manager will also visually track any "open" Part 21 evaluation to make sure all timelines are adhered to and report to upper management as needed of the status.

Date of Full Compliance

Corrective actions will be completed by 6/3/11.

Reply to Notice of Violation
NRC Inspection Report 99900100/2011-201; Flowserve

Violation VIO 99900100/2011-201-02

The Violation as stated in the referenced Notice of Violation (NOV) is as follows:

10 CFR 21.21(a), requires, in part, that “[e]ach individual, corporation, partnership, or other entity subject to the regulations in this part shall adopt appropriate procedures to -- (1) [e]valuate deviations and failures to comply to identify defects and failures to comply associated with substantial safety hazards as soon as practicable . . . in order to identify a reportable defect or failure to comply that could create a substantial safety hazard, were it to remain uncorrected.”

QAP 13.2 states, in part, that “if during the review, Quality Assurance determines the condition is “Not Reportable” or “Not Applicable”, the basis for the decision shall be documented” in the Limatorque Corrective Action Requests (LCARs), and Audit Deficiency Notifications (ADNs). QAP 13.2 also states that Discrepant Material Reports (DMRs), Field Service Reports, Customer Reported Problems, LCARs, and ADNs /Audit Findings are the methods used by Limatorque to identify nonconforming conditions and deviations that need to be evaluated for reportability.

Contrary to the above, as of March 4, 2011, Limatorque failed to adopt appropriate procedures to evaluate deviations and failures to comply. Specifically, Limatorque failed to document the basis for determining a nonconforming condition associated with safety related LCAR to be “Not Reportable” or “Not Applicable” and to adequately document the basis for determining nonconforming conditions associated with multiple ADNs to be “Not Reportable” or “Not Applicable.” In addition, Limatorque failed to include procedural guidance to evaluate Customer Reported Problems and Field Service Reports for defects and failures to comply associated with substantial safety hazards in QAP 14.2, “Customer Complaint Procedure,” and QAP 19.3, “Servicing,” respectively.

These issues have been identified as Violation 99900100/2011-201-02.

This is a Severity Level IV Violation (Section 6.5).

Reasons for the Violation

The LCAR, ADN , and CC database had been revised in the past year to require Part 21 evaluation and ATEX evaluation to all entries of this database. When this was done this feature automatically populated the existing entries with this requirement even if they had previously been closed. Flowserve failed to realize that we needed to go back through previously closed entries and document for Part 21 evaluation. Also, Flowserve did not have documented procedural guidance in QAP 14.2 “ Customer Complaint Procedure” and QAP 19.3 “Service Procedure” for Part 21 evaluation.

Corrective Actions Taken

Flowserve has gone back through (3) years of safety related LCAR's, ADN's and CC's to document the evaluations for Part 21 reportability. Flowserve will revised QAP 14.2 "Customer Complaint Procedure" and QAP 19.3 "Service Procedure" appropriately to require nonconforming conditions and deviations that could create a substantial safety hazard to be evaluation appropriately for reportability.

Actions to Avoid Future Violations

Follow all established procedures relating to the evaluation of nonconforming conditions or deviations that could create a substantial safety hazard for Part 21 reportability.

Date of Full Compliance

Corrective actions will be completed by 5/31/11.

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Violation VIO 99900100/2011-201-03

The Violation as stated in the referenced Notice of Violation (NOV) is as follows:

10 CFR 21.31 states, in part, that “[e]ach individual, corporation, partnership, dedicating entity, or other entity subject to the regulations in this part shall ensure that each procurement document for a facility, or a basic component issued . . . specifies, when applicable, that the provisions of 10 CFR Part 21 apply.”

QAP 6.1, “Purchasing Procedure,” states that the procurement documents are to impose the requirements of 10 CFR Part 21 on its qualified suppliers in purchase orders for nuclear safety related materials, items, and services.

Contrary to the above, 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 services were procured from an approved vendor without imposing 10 CFR Part 21 reporting requirements.

This issue has been identified as Violation 99900100/2011-201-03.

This is a Severity Level IV Violation (Section 6.5).

Reasons for the Violation

Safety related testing services were procured using a blanket purchase requisition form without imposing the requirement of 10CFR Part 21. Exova Testing Services Quality System meets the requirements of 10 CFR50 Appendix B and 10 CFR Part 21.

Corrective Actions Taken

The blanket Purchase Requisition form has been revised as follows: “ TESTING SHALL BE DONE IN ACCORDANCE WITH EXOVA QUALITY ASSURANCE MANUAL REV. 2 DATED 2/1/10, 10CFR50 APPENDIX B, 10CFR PART 21, AND NQA-1 “. Also, Revised QAP 6.1 appropriately to state requirements of safety related testing services.

Actions to Avoid Future Violations

Adhere to requirements of QAP 6.1

Date of Full Compliance

Corrective actions completed as of 5/18/11.

Reply to Notice of Nonconformance
NRC Inspection Report 99900100/2011-201; Flowserve

Nonconformance NON 99900100/2011-201-04

The Nonconformance as stated in the referenced Notice of Notice of Nonconformance (NON) is as follows:

Criterion III, "Design Control," of Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants," to Title 10 of the *Code of Federal Regulations* (10 CFR) Part 50, "Domestic Licensing of Production and Utilization Facilities," states, in part, that "[m]easures shall be established to assure that applicable regulatory requirements and the design basis . . . are correctly translated into specifications, drawings, procedures, and instructions The design control measures shall provide for verifying or checking the adequacy of design The verifying or checking process shall be performed by individuals or groups other than those who performed the original design."

Flowserve's "Quality Management System Manual" (QMSM), states, in part, that "design and development changes shall be identified and records maintained," and that "changes shall be reviewed, verified, and validated, as appropriate, and approved before implementation."

Contrary to the above, as of March 4, 2011, Limatorque 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, Limatorque 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 Limatorque actuators.

This issue has been identified as Nonconformance 99900100/2011-201-04.

Reasons for the Nonconformance

The product configurator is not used for the design of the SMB and HBC nuclear product. The configurator is solely used for the selection of the appropriate B/M's to construct the final assembly. When changes are made to the controlling EPS documents an ECN is generated. Subsequently the configurator will also be updated. Only the configurator administrator can make changes to the EPS document and the product configurator itself. Once the product configurator and EPS is updated the configurator administrator will run a sample check configurator to verify that the product configurator output is correct. At this point we were not performing an independent review of the software configurator changes.

Corrective Actions Taken

Flowserve will add an additional step to the product configurator output for SMB and HBC nuclear product that will require the ECN originator and another Engineer for verification. A signed scanned copy of this configuration output will be attached to the ECN. QAP 5.1 has been revised accordingly.

Actions to Avoid Future Nonconformance

Flowserve will verify this process by way of internal audits of the procedure QAP 5.1 and the process.

Date of Full Compliance

Corrective actions completed as of 5/20/11.

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Nonconformance NON 99900100/2011-201-05

The Nonconformance as stated in the referenced Notice of Nonconformance (NON) is as follows:

Criterion IV, "Procurement Document Control," of Appendix B to 10 CFR Part 50 states, in part, that "[m]easures shall be established to assure that applicable regulatory requirements, design basis and other requirements which are necessary to assure adequate quality are suitably included or referenced in the documents for procurement of material, equipment, and services."

Quality Assurance Procedure (QAP), QAP 6.1, "Purchasing Procedure," states that the procurement documents are to impose the requirements of Appendix B to 10 CFR Part 50 on its qualified suppliers in purchase orders (POs) for nuclear safety related materials, items, and services.

Contrary to the above, as of March 4, 2011, Limatorque failed to impose the requirements of Appendix B to 10 CFR Part 50 in documents for the procurement of safety related equipment and services. Specifically, Limatorque issued POs 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, Limatorque 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.

These issues have been identified as Nonconformance 99900100/2011-201-05

Reasons for the Nonconformance

Purchase notes for electric motors did impose 10CFR Part 21 but did not specifically state 10CFR50 Appendix B. Also, "Open" PO's for services did not specifically state the requirement for 10CFR50 Appendix B.

Corrective Actions Taken

Purchase note (POL 17) for procurement of safety related motors has been revised to state both 10CFR50 Appendix B and 10CFR Part 21 are required. The "open" PO blankets for services have been revised to state the requirement of 10CFR50 Appendix B.

Actions to Avoid Future Nonconformance

Above notes are automatically generated when the buyer procures any of the above nuclear safety related material, equipment, or services.

Date of Full Compliance

Corrective actions completed 4/28/11.

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Nonconformance NON 99900100/2011-201-06

The Nonconformance as stated in the referenced Notice of Nonconformance (NON) is as follows:

Criterion V, "Instructions, Procedures, and Drawings," of Appendix B to 10 CFR Part 50, states, in part, that "[a]ctivities affecting quality shall be prescribed by documented instructions, procedures, or drawing."

Flowserve's QMSM states, in part, that "[p]rocedures are established and shall be maintained that ensure the standard SMB, SMC, SB, SBD, and HBC qualified product design is maintained and that changes are reviewed for impact on Equipment Qualification."

Contrary to the above, as of March 4, 2011, Limitorque failed to provide instructions and procedures for certain activities affecting quality. Specifically, Limitorque used uncontrolled information (Additional QC Checks for SMB-000 Torque Switches) not documented in a quality related procedure to identify quality checks that need to be evaluated for SMB-000 torque switches used in safety related actuators. In addition, Limitorque failed to assure that activities affecting quality are correctly documented in quality procedures (e.g., QAP 3.1 and QAP 4.1) and assembly procedures (e.g., Assembly Procedure (AP) AP 9.2 and AP 9.3) used to design and assemble safety related actuators.

These issues have been identified as Nonconformance 99900100/2011-201-06.

Reasons for the Nonconformance

QC Inspector was using a document generated by Engineering that contained additional checks for SMB-000 torque switches that was not controlled in a procedure. Flowserve also had several procedures that needed to be revised to meet current assembly practices.

Corrective Actions Taken

IP 10.39 (Inspection Plan for Torque Switches) was revised to incorporate the additional checks established by engineering. QAP 3.1 "Order Entry Procedure", QAP 4.1 "Design & Development Procedure", AP 9.2 "Wiring Procedure", AP 9.3 "Mechanical Assembly Procedure" have been revised appropriately.

Actions to Avoid Future Nonconformance

Flowserve will review all procedures by the appropriate department for accuracy once every two years.

Date of Full Compliance

Corrective actions completed as of 5/19/11.

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Nonconformance NON 99900100/2011-201-07

The Nonconformance as stated in the referenced Notice of Nonconformance (NON) is as follows:

Criterion VII, "Control of Purchased Material, Equipment, and Services," of Appendix B to 10 CFR Part 50 states, in part, that "measures shall be established to assure that purchased material, equipment, and services whether purchased from a contractor or subcontractor conform to the procurement documents. . . . The effectiveness of the control of quality by contractors and subcontractors shall be assessed by the applicant or designee"

Contrary to the above, as of March 4, 2011, Limatorque failed to establish measures to assure that the purchase of material, equipment, or services conformed to procurement documents. Specifically, Limatorque accepted material test reports for components and materials used in safety related actuators provided by a non Appendix B subcontractor. In addition, Limatorque failed to identify or reference acceptance criteria for receipt inspection to verify that purchased equipment conform to procurement documents.

These issues have been identified as Nonconformance 99900100/2011-201-07.

Reasons for the Nonconformance

Inspection procedure QCP 10.5 "Inspection of Safety related Nuclear Service Units Parts Orders" did not give clear reference to the acceptance criteria or where to find the acceptance criteria. Also, Flowserve was performing a spectral analysis on all incoming bar stock steel and was comparing this to the certified material test reports received with the material, but Flowserve failed to realize that the mechanical properties (tensile, yield, elongation, ect..) on the certifications needed to be verified by way of a "commercial grade survey" of the testing lab.

Corrective Actions Taken

The laboratory performing the mechanical testing for Earle M. Jorgenson will be added to the 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, QCP 10.5 has been revised to incorporate the acceptance criteria of the engineering drawings.

Actions to Avoid Future Nonconformance

See corrective actions

Date of Full Compliance

Corrective action will be completed by 6/30/11

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Nonconformance NON 99900100/2011-201-08

The Nonconformance as stated in the referenced Notice of Notice of Nonconformance (NON) is as follows:

Criterion VII of Appendix B to 10 CFR Part 50, states, in part, that "measures shall be established to assure that purchased material, equipment, and services conform to the procurement documents. These measures shall include provisions, as appropriate, for source evaluation and selection, objective evidence of quality furnished by a contractor or subcontract, inspection at a contractor or subcontract source, and examination of product upon delivery."

Contrary to the above, as of March 4, 2011, Limatorque 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, Limatorque 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 (ISO) 9001:2000 and International Standardization Organization/International Electrotechnical Commission (ISO/IEC) 1725 for calibration services but did not include an evaluation of the applicable requirements for Appendix B to 10 CFR Part 50.

This issue has been identified as Nonconformance 99900100/2011-201-08

Reasons for the Nonconformance

Flowserve maintains Instrument Calibration & Technical Services on our Approved Vendors listing for the purpose of providing commercial grade calibration services. ICTS is audited by Flowserve and meets all requirements of ISO 9001:2000, ISO/IEC 17025:2005 & ANSI/NCSL Z540-1-1994. Flowserve uses the ANSI/NCSL Z540-1-1994 Evaluation checklist to document all audit activities. Flowserve maintains an "open" blanket PO that contains a purchasing note that requires all calibration services to accompany a certificate of calibration that contains any "out of tolerance" conditions found. Flowserve would then take this information and evaluate its effect by way of our 10 CFR50 Appendix B Quality System. Flowserve does not feel that this is a valid nonconformance.

Corrective Actions Taken

Develop a "Commercial Grade Survey" checklist and re-audit to this new criteria.

Actions to Avoid Future Nonconformance

See above comments

Date of Full Compliance

Flowserve feels we are in compliance but will also develop the new checklist as stated above and re-audit ICTS by 6/30/11.

Reply to Notice of Nonconformance
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Nonconformance NON 99900100/2011-201-09

The Nonconformance as stated in the referenced Notice of Nonconformance (NON) is as follows:

Criterion XI, "Test Controls," of Appendix B to 10 CFR Part 50 states, in part, that a "Test Program shall be established to assure that all testing required to demonstrate that structures, systems, and components will perform satisfactory in service is identified and performed in accordance with written procedures which incorporate the requirements and acceptance limits contained in applicable design documents."

Engineering Instruction Procedure (EIP) EIP 373, "Production Test Procedure for SMB/SB Series Units Built for Westinghouse Project AP1000 Per Specification APP-PV95-Z-001," provides the detailed instructions for setting torque switches for SMB and SB series actuators. EIP 373 prescribes initial testing with the torque switch set at 1.0. Testing continues by progressively increasing the torque switch setting by half increment until the maximum torque switch setting is reached. The maximum torque switch setting for an SB-00 actuator is estimated to be approximately 2.5 as determined by Limitorque.

Contrary to the above, as of March 4, 2011, Limitorque failed to perform test activities consistent with the instructions in EIP 373 that was established to assure that actuator torque switches will perform satisfactory in service. Specifically, Limitorque technicians used an initial test setting of 2.75, and subsequently decreased the torque switch setting by half increments until reaching a torque switch setting of 1.0 during a full performance test of a safety related SB-00 actuator.

This issue has been identified as Nonconformance 99900100/2011-201-09.

Reasons for the Nonconformance

Testing instructions EIP 373 did not accurately reflect the proper sequence of steps in balancing the torque switch and verifying it's performance at each ½ increment setting.

Corrective Actions Taken

Flowserve revised EIP 373 appropriately to have the procedure reflect the proper test sequence for the actuator test process. Test lab associates were trained to the revised procedure and documented.

Actions to Avoid Future Nonconformance

Test lab associates should immediately notify engineering if a test procedure does not accurately reflect all steps in a test process.

Date of Full Compliance

Corrective actions completed as of 5/20/11.