February 8, 2006

Mr. Rafiq Bandukwala, Manager
Quality Assurance
Flowserve, Flow Control Division
1900 S. Saunders Street
Raleigh, North Carolina 27603

SUBJECT: NRC INSPECTION REPORT 99901356/2006-201 AND NOTICE OF NONCONFORMANCE

Dear Mr. Bandukwala:

On January 10-13, 2006, the U.S. Nuclear Regulatory Commission (NRC) conducted an inspection at the Flowserve facility in Raleigh, North Carolina. The purpose of the inspection was (1) to verify if Flowserve's corrective actions from the August 2004 Nuclear Procurement Issues Committee (NUPIC) audit have been adequately implemented, and (2) to verify that Flowserve has an adequate Title 10 of the *Code of Federal Regulations*, Part 21 (10 CFR Part 21) program and commercial grade item dedication process that meets NRC requirements. The enclosed report presents the details of that inspection.

During this inspection it was found that the implementation of your quality assurance program failed to meet certain NRC requirements. Flowserve did not adequately implement the corrective action process as required by the Flowserve quality assurance manual. Flowserve did not document the review of 3,000 dedication packages as part of their corrective actions in response to an utility surveillance finding. Additionally, Flowserve did not have procedures in place requiring a 10 CFR Part 21 evaluation for nonconformances described in Quality Problem Corrective Action Plans, that are determined to be significant conditions adverse to quality. Finally, Flowserve failed to implement appropriate procedural guidance required by the Flowserve quality assurance manual. The specific findings and reference to the pertinent requirements are identified in the enclosure of this letter.

Four nonconformances are cited in the enclosed Notice of Nonconformance (NON) and described in detail in the enclosed report. You are requested to respond to the NON, and should follow the instructions specified in the enclosed NON when preparing your response.

In accordance with §2.390, "Public inspections, exemptions, requests for withholding," of 10 CFR 2, "Rules of Practice for Domestic Licensing Proceedings and Issuance of Orders," a copy of this letter, its enclosures, and your response will be made available electronically for public inspection in the NRC Public Document Room (PDR) or from the NRC's

document system (ADAMS), accessible from the NRC Web site at http://www.nrc.gov/reading-rm/adams.html. To the extent possible, your response should not include any personal privacy, proprietary, or safeguards information so that it can be made available to the Public without redaction.

Sincerely,

/RA/

Michael E. Mayfield, Director
Division of Engineering
Office of Nuclear Reactor Regulation

Enclosures:
1. Notice of Nonconformance
2. Inspection Report 99901356/2006-201

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.

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NOTICE OF NONCONFORMANCE

Flowserve
Raleigh, North Carolina

Docket Number 99901356
Inspection Report Number 2006-201

Based on the results of a Nuclear Regulatory Commission (NRC) inspection conducted January 10-13, 2006, of activities performed at Flowserve Raleigh facility, it appears that certain activities were not conducted in accordance with NRC requirements.

1. Criterion XVI, “Corrective Action," of Appendix B to 10 CFR Part 50, states, in part, that measures shall be established to assure that conditions adverse to quality, such as failures, malfunctions, deficiencies, deviations, defective material and equipment, and nonconformances are promptly identified and corrected. The identification of the significant condition adverse to quality, the cause of the condition, and the corrective action taken shall be documented and reported to appropriate levels of management.

   The Flowserve Quality Assurance Manual (QAM), “Quality Assurance Manual ASME Section III, Division 1, Classes 1, 2, and 3,” Revision 32, dated January 15, 2005, describes, in part, the general requirements for the implementation of a corrective action system. Section 16.2.2 of the QAM states, in part, that identification of conditions adverse to quality, the cause of the conditions, the corrective action taken, and the date required to complete corrective action shall be documented on a Quality Problem Corrective Action Plan (QPCAP) form. Section 16.2.2 also requires that the Quality Assurance (QA) manager, or his designee, verifies the completed corrective actions taken within 15 days of the date specified for completion.

   Plant Internal Operating Procedure (PIOP) 36-40-09-17, “Material Review Board Disposition for Defective Material, Including Corrective Action Control,” dated April 6, 2005, requires that nonconformances caused by internal actions shall be documented on a QPCAP, including an evaluation of the root cause of the nonconformance and the proposed corrective action to preclude repetition, and the QPCAP returned to QA within 15 days. Section 3.2.2 requires that the proposed corrective action shall include a schedule for completion. Additionally, Section 3.2.4 requires that completion of the proposed corrective action be verified within 15 days of the proposed completion date.

   Contrary to the above, Flowserve did not implement the corrective action process as required by the Flowserve quality assurance manual. For corrective action associated with a nonconformance caused by internal actions, Flowserve did not identify a date for completion of the proposed corrective action on any of the QPCAPs. As a result, there was no objective evidence that the QA manager or his designee completed their verification of the corrective action within 15 days of proposed completion date of the corrective action since the proposed completion date was not provided on the QPCAP. This issue has been identified as Nonconformance 99901356/2006-201-01.

2. Criterion XVI, “Corrective Action," of Appendix B to 10 CFR Part 50, states, in part, that measures shall be established to assure that conditions adverse to quality, such as failures, malfunctions, deficiencies, deviations, defective material and equipment, and

nonconformances are promptly identified and corrected. The identification of the significant condition adverse to quality, the cause of the condition, and the corrective action taken shall be documented and reported to appropriate levels of management.

Flowserve QAM, Section 16.1.2, states, in part, that the identification of conditions adverse to quality, the cause of the condition, and the corrective action taken shall be documented.

PIOP 36-40-09-17, Section 3.2.2, requires that nonconformances caused by internal actions shall be documented on a QPCAP, including an evaluation of the root cause of the nonconformance and the proposed corrective action to preclude repetition.

Contrary to the above, Flowserve was not able to produce any documented objective evidence that over 3,000 dedication packages were reviewed for completeness and were verified for signatures on the dedication forms for completeness of dedication activities as part of their corrective actions in response to an utility surveillance finding. This issue has been identified as Nonconformance 99901356/2006-201-02.

3. 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.

   Flowserve QAM, Section 16.2.2, states, in part, that the identification of conditions adverse to quality, the cause of the conditions, the corrective action taken, and the date required to complete corrective action shall be documented in a QPCAP by the individual assigned responsibility.

   PIOP 36-40-03-06, "Methods for Reporting to NRC Defects Creating Substantial Safety Hazards," dated August 25, 2004, describes the methods for reporting to the NRC potential problems that could create substantial safety hazards in delivered valves, actuator control systems, and/or parts.

   Contrary to the above, Flowserve corrective action process procedures did not identify when a 10 CFR Part 21.21 evaluation for reportability of significant conditions adverse to quality is required. This issue has been identified as Nonconformance 99901356/2006-201-03.

4. 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.

   Flowserve QAM, Section 1.3.3, states, in part, that the Manufacturing Manager provide and implement indoctrination and training programs and maintain training records for those personnel under his supervision whose activities affect quality. Section 1.5.6 states that the Inside Sales and Applications Manager provide indoctrination and training programs and maintain training records for those personnel under his supervision

whose activities affect quality. Section 7.2.9.1, states, in part, that the QA manager, or his designee, shall review for acceptance the procedures for conducting audits or surveys.

PIOP 36-41-01-18, "Procedures for Performance of Vendor Audits and Assessments," dated September 15, 2004, provides a high level discussion of the purpose of the audits, planning and coordination guidance, frequency of supplier audits, and the correction of any non-compliance identified in an audit report.

Contrary to the above, Flowserve failed to implement appropriate procedural guidance required by the Flowserve quality assurance manual. This is evidenced by the following examples:

1. Flowserve's Manufacturing Operations and Inside Sales and Applications personnel did not have a documented procedure to describe training requirements for those personnel performing activities affecting quality.

2. No procedural guidance existed for the conduct of commercial grade surveys.

These issues have been identified as Nonconformance 99901356/2006-201-04.

Please provide a written statement or explanation to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555, 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 Notice of Nonconformance" and should include for each nonconformance: (1) the reason for the nonconformance, or if contested, the basis for disputing the nonconformance, (2) the corrective steps that have been taken and the results achieved, (3) the corrective steps that will be taken to avoid further noncompliances, and (4) the date when your corrective actions 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 Agency-wide Documents Access and Management 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. 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 8th day of February 2006.

U.S. NUCLEAR REGULATORY COMMISSION
OFFICE OF NUCLEAR REACTOR REGULATION

Report No:	99901356/2006-201
Organization:	Flowserve, Flow Control Division 1900 S. Saunders Street Raleigh, NC 27603
Vendor Contact:	Mr. Rafiq Bandukwala Quality Assurance Manager (919) 831-3304
Nuclear Industry:	The Flowserve Raleigh facility is a major supplier of safety related valves and flow control devices to the nuclear industry. In addition, Flowserve Raleigh facility has a basic component and commercial grade dedication program in operation since the early 1970s for the nuclear industry.
Inspection Dates:	January 10 - 13, 2006
Inspectors:	Paul F. Prescott, Lead Inspector, EQVA/DE/NRR Richard P. McIntyre, EQVA/DE/NRR Kerri A. Kavanagh, EQVA/DE/NRR Milton Concepcion, EQVA/DE/NRR
Approved by:	Dale F. Thatcher, Chief Quality and Vendor Branch A Division of Engineering Office of Nuclear Reactor Regulation

ENCLOSURE 2

1.0 INSPECTION SUMMARY

The purpose of this inspection at Flowserve Raleigh was to verify if Flowserve's proposed corrective actions from the August 2004 Nuclear Procurement Issues Committee (NUPIC) joint utility quality assurance audit have been adequately implemented. Representatives of the U.S. Nuclear Regulatory Commission (NRC) staff observed the August 2004 NUPIC audit which identified 21 findings. Therefore, the NRC inspectors only reviewed documentation that was generated after the August 2004 NUPIC audit. The inspection also assessed whether Flowserve has an adequate 10 CFR Part 21 program and commercial grade dedication process that meets NRC requirements.

The inspection was conducted at Flowserve's facility in Raleigh, North Carolina. The inspection bases were:

- Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants," to 10 CFR Part 50, and

- 10 CFR Part 21, "Reporting of Defects and Noncompliance."

1.1 NONCONFORMANCES

- Nonconformance 99901356/2006-201-01 was identified and is discussed in Section 3.1 of this report.

- Nonconformance 99901356/2006-201-02 was identified and is discussed in Section 3.2 of this report.

- Nonconformance 99901356/2006-201-03 was identified and is discussed in Section 3.3 of this report.

- Nonconformance 99901356/2006-201-04 was identified and is discussed in Sections 3.4 and 3.5 of this report.

1.2 OBSERVATIONS

- Observation 99901356/2006-201-01 was identified and is discussed in Section 3.1 of this report.

- Observation 99901356/2006-201-02 was identified and is discussed in Section 3.1 of this report.

- Observation 99901356/2006-201-03 was identified and is discussed in Section 3.1 of this report.

- Observation 99901356/2006-201-04 was identified and is discussed in Section 3.2 of this report.

- Observation 99901356/2006-201-05 was identified and is discussed in Section 3.4 of this report.

2.0 STATUS OF PREVIOUS INSPECTION FINDINGS

No previous NRC inspections findings were reviewed during this inspection.

3.0 INSPECTION FINDINGS AND OTHER COMMENTS

3.1 CORRECTIVE ACTION PROCESS

a. Inspection Scope

The NRC inspectors reviewed the implementation of the Flowserve corrective action process. Specifically, the NRC inspectors reviewed the procedures governing the implementation of the Flowserve corrective action process, and reviewed the current status of corrective actions associated with the August 2004 NUPIC audit and the corrective actions identified since the August 2004 NUPIC audit.

b. Observations and Findings

b.1 Corrective Action System

The NRC inspectors reviewed the Flowserve procedures governing the corrective action process to assure those guidelines provided an adequate description of the process and implementation requirements consistent with the requirements of Appendix B to 10 CFR Part 50, Criterion XVI, "Corrective Actions."

The Flowserve Quality Assurance Manual (QAM), "Quality Assurance Manual ASME Section III, Division 1, Classes 1, 2, and 3," Revision 32, dated January 15, 2005, describes, in part, the general requirements for the implementation of a corrective action system. Procedures and practices are established which provide assurance that conditions adverse to quality are promptly identified, documented, and corrected or otherwise handled in accordance with established procedures. Section 16.1.2 of the QAM requires that reject tickets be analyzed quarterly to detect recurring types of quality problems and that customer complaints be reviewed for significant trends.

Flowserve has three Plant Internal Operating Procedures (PIOPs) which govern the corrective action system. These three PIOPs, discussed below, document the corrective action process for (1) nonconformances of material and quality record errors, (2) customer complaints, and (3) internal audits. The NRC inspectors discussed these PIOPs with the responsible Quality Assurance (QA) supervisor who confirmed that the three PIOPs and the associated corrective actions are currently independent of each other and closure of the associated corrective actions are tracked separately. A trend analysis report is generated quarterly to analyze reject tickets, bill of material errors, complaint reports, and internal audit findings for adverse trends. The NRC inspectors reviewed the trend analysis report dated December 1, 2005, and did not identify any issues. However, the NRC inspectors concluded that Flowserve's corrective action process would be more efficient and effective if the corrective action plans were tracked under one process instead of three. This is identified as observation 99901356/2006-201-01.

The August 2004 NUPIC audit identified that Flowserve was not documenting or completing adequate corrective action to prevent recurrence. In response to the NUPIC finding, Flowserve revised their corrective action program to clarify the process of identifying the root cause and corrective action to prevent recurrence. The revised process also includes a review by QA to

assure that the corrective action has been adequately completed. Flowserve also implemented a new system to track Quality Problem-Corrective Action Plan (QPCAP) forms. The Quality Program Corrective Action Log, with a first entry dated October 22, 2004, had 139 QPCAPs documented at the time of the NRC inspection. The NRC inspectors reviewed 25 of the 139 QPCAPs and verified that QPCAPs were consistent with the corrective actions implemented in response to the August 2004 NUPIC audit. The NRC inspectors discussed Flowserve's corrective actions associated with the August 2004 NUPIC audit with the responsible QA supervisor who stated that only 7 of the 21 NUPIC findings were captured into the existing QPCAP log prior to October 2004. The responsible QA supervisor also confirmed that the current practice was to track findings identified by customer surveillances, NUPIC audits, NRC inspections, and customer inspections in the QPCAP. This practice is not documented in procedures. The NRC inspectors concluded that this practice was appropriate but it should be documented in the appropriate procedures. This is identified as observation 99901356/2006-201-02.

b.2. Material Review Board Disposition and Corrective Action

The Flowserve QAM requires corrective action followup and closeout to assure that corrective action commitments are implemented. Section 16.2.2 of the QAM states, in part, that identification of conditions adverse to quality, the cause of the conditions, the corrective action taken, and the date required to complete corrective action shall be documented on a QPCAP form. Section 16.2.2 also requires that the QA manager, or his designee, verifies completed corrective actions taken within 15 days of the date specified for completion.

PIOP 36-40-09-17, "Material Review Board Disposition for Defective Material, Including Corrective Action Control," dated April 6, 2005, states, in part, that the purpose of the corrective action program is to analyze possible causes for the occurrence of defective material or quality record errors and issue directives to department heads to determine root causes and implement actions to prevent recurrence. Specifically, Section 3.2.2 requires that nonconformances caused by internal actions shall be documented on a QPCAP, including an evaluation of the root cause of the nonconformance and the proposed corrective action to preclude repetition, and the QPCAP returned to QA within 15 days. Section 3.2.2 also requires that the proposed corrective action shall include a schedule for completion. Additionally, Section 3.2.4 requires that completion of the proposed corrective action be verified within 15 days of the proposed completion date.

The NRC inspectors reviewed all of the QPCAPs generated since October 2004. Based on the documentation, the NRC inspectors determined that some of the QPCAPs were not returned to QA within the 15-day procedural requirement. In addition, the NRC inspectors were not able to identify a date for completion of the proposed corrective action on any of the QPCAPs. The NRC inspectors verified that the closed QPCAPs were reviewed by the QA manager or his designee. However, the NRC inspectors were unable to conclude that the QA manager or his designee completed their verification of the corrective action within 15 days of the proposed completion date of the corrective action since the proposed completion date was not provided on the QPCAP. This issue has been identified as Nonconformance 99901356/2006-201-01.

b.3 Customer Complaints

PIOP 36-40-26-07, "Complaint Report Procedure," dated January 15, 1991, defines areas of responsibility and describes specific actions to be taken when a Complaint Report is received at Edward Valves, Inc. (Flowserve). Section 3.0 requires that the assigned reviewer be

responsible for investigating the problem and developing a response addressing all aspects of the problem, probable cause, and conclusion. Section 6.0 also requires that a Complaint Engineering Report (CER) be used to respond to all complaint reports.

The NRC inspectors reviewed 14 complaint report files for complaints received during 2005 from both nuclear and non nuclear customers. Approximately 150 complaint reports were received in 2005. The NRC inspectors verified that each complaint report file had a complete CER. Of the 14 complaint files that were reviewed, representatives from QA engineering identified 4 complaint reports in which a QPCAP was generated to address the probable cause of the customer complaint. Of the remaining 10 complaint report files reviewed, the NRC inspectors determined that QPCAPs should have been generated for 7 complaint files since the CERs concluded that the probable causes for the complaints were attention to detail and failure to follow procedures. The NRC inspectors noted that PIOP 36-40-26-07 does not have a requirement to generate QPCAPs to address probable causes of customer complaints. The NRC inspectors concluded that the practice of generating a QPCAP to address probable causes of customer complaints was appropriate but should be documented in the appropriate procedures. This is identified as observation 99901356/2006-201-03.

b.4 Internal Audits

PIOP 36-40-23-13, "Quality Assurance Internal Audit and Corrective Action," dated December 2, 2004 requires that an internal auditor document deficiencies on a Quality Audit Report (QAR) and that the deficiencies be brought to the attention of the responsible Staff Head. The Staff Head is responsible for investigating any deficiencies, formulating measures to prevent recurrence, and developing and implementing all required corrective actions.

The NRC inspectors reviewed the internal quality audit reports from the three internal audits: (1) procurement process, (2) final documentation process/ shipping process, and design control process, and (3) manufacturing, record storage, and nonconforming material / corrective action processes, that were performed by Flowserve in 2005. The three internal audits identified 28 findings. All corrective actions associated with the findings had been closed as denoted on the associated QARs. The NRC inspectors did not identify any issues with the internal audit reports and associated QARs.

c. Conclusions

The NRC inspectors determined that the Flowserve corrective action system requirements were described in the Flowserve procedures, and were consistent with the requirements of Appendix B to 10 CFR Part 50, Criterion XVI. However, the NRC inspectors identified multiple examples where QPCAPs for corrective actions associated with a nonconformance caused by internal actions were not implemented in accordance with the Flowserve procedures. This issue has been identified as Nonconformance 99901356/2006-201-01.

The NRC inspectors concluded that Flowserve's corrective action process would be more efficient and effective if the corrective action plans were tracked under one process instead of three. This is identified as observation 99901356/2006-201-01. In addition, the NRC inspectors identified two observations related to current practices that are not documented in procedures. These are identified as observations 99901356/2006-201-02 and 99901356/2006-201-03.

3.2 COMMERCIAL DEDICATION PROCESS

a. Inspection Scope

The NRC inspectors reviewed the Flowserve quality assurance manual commitments and the implementation process for commercial grade dedication activities. Specifically, the NRC inspectors reviewed the procedures and Standard Operating Instructions (SOIs) which govern the implementation of commercial grade dedication inspection and testing activities. The NRC inspectors also reviewed the Flowserve documented corrective actions for three audit findings related to commercial grade dedication identified during the August 2004 NUPIC audit. Finally, the NRC inspectors reviewed several Flowserve dedications of commercial grade items.

b. Observations and Findings

b.1 Commercial Dedication Process

Flowserve QAM, Section 7.6, generally outlines and describes the process for the use of commercial grade items in the design of valves and further states, in part, that the detailed requirements of the commercial grade item dedication subsystem are contained in a Plant Internal Operating Procedure.

PIOP 36-41-09-06," Dedication of Commercial Grade Items," dated July 20, 2005, describes the program where commercial grade items, as defined in 10 CFR Part 21, are "dedicated" as basic components and become suitable for use under the provisions of Appendix B to 10 CFR Part 50. It further states, in part, that the program is patterned after EPRI-NP-5652 guidelines as outlined in the Final report of March 1988.

SOI 70-39-07, "Dedication of Commercial Grade Components to 10 CFR Part 21," dated July 28, 2005, states that the purpose of the procedure is to provide guidelines for determining critical attributes that must be verified when dedicating commercial parts as basic components under 10 CFR Part 21. SOI 70-39-07 stipulates that the Manager of Engineering or his designee has the responsibility to specify the critical attributes and method(s) of verification for a specific part that is to be dedicated under this procedure. It also states that the dedication process is intended to verify that the critical attributes of the part conforms with the applicable engineering specifications. The process generally involves verification of the part dimensions and verification of material composition and is considered part of the design control process.

During the August 2004 NUPIC audit, three findings were identified for failure to perform effective dedications of commercial grade items. This included varying examples of inadequate safety classification of parts, incomplete identification of critical attributes, and incomplete verification of critical attributes. The NRC inspectors reviewed the Flowserve corrective actions and verified closure of the three findings by both Flowserve and the follow-up NUPIC audits and/or surveillances conducted between October 2004 and February 2005.

In response to the NUPIC audit findings and surveillances, Flowserve implemented upgrades and enhancements to the dedication process, including procedure revisions to clarify certain dedication verification activities, revisions to the existing 10 CFR Part 21 Dedication Form, and documenting and implementing the RAL-7487, "Raleigh Material Code Index For 10 CFR Part 21 Commercial Grade Dedication." This document specifies the critical attributes and verification methods for the material specifications that are regularly referenced and used on the 10 CFR Part 21 Dedication Form.

b.2 Corrective Actions Associated With Commercial Grade Dedication

Flowserve QAM, Section 16.1.2, states, in part, that the identification of conditions adverse to quality, the cause of the condition, and the corrective action taken shall be documented.

PIOP 36-40-09-17, Section 3.2.2, requires that nonconformances caused by internal actions shall be documented on a QPCAP, including an evaluation of the root cause of the nonconformance and the proposed corrective action to preclude repetition.

As part the review of the August 2004 NUPIC audit findings on commercial grade dedication, the NRC inspectors reviewed a sample of the QPCAP documents. The NRC inspectors identified QPCAP-56 and QPCAP-57, dated May 18 and 25, 2005, respectively, as being corrective actions associated with commercial grade dedication. QPCAPs-56 and -57 were written to address a Nuclear Management Company (NMC) surveillance finding as documented in their Supplier Finding Report 2005-0133-01, dated May 19, 2005. The two part finding related to an incomplete verification of the critical characteristics identified on the Technical Evaluation Worksheet for Safety Related Items (commonly referred to as a PDF by Flowserve) for the dedication of an air check valve. The 10 CFR Part 21 Dedication of Commercial Grade Items form identified the appropriate PDF00062 form, however, the Technical Evaluation Worksheet did not reference the appropriate PDF00062 number on the Technical Evaluation Worksheet. In addition, all the selected critical characteristics identified on the Technical Evaluation Worksheet for verification did not include objective evidence that the required testing (hydrostatic shell and seat tightness) had been performed. The testing was ultimately performed with successful results. Flowserve addressed the failure to include the PDF number on the Technical Evaluation Worksheet form under QPCAP-56. QPCAP-57 was written to address the second part of the NMC finding related to the generic aspect as to whether other examples existed where the dedication was signed off by the inspector indicating that the testing (verification) operations were completed, but, the testing activity had not been performed.

The NRC inspectors inquired as to how this issue in QPCAP-57 was addressed and noted that in a November 22, 2005, letter to NMC that over 3,000 dedication packages were reviewed for completeness and were verified for signatures on the dedications form for completeness of dedication activities. However, when requested by the NRC inspectors, Flowserve was not able to produce any documented objective evidence that this quality activity to support corrective actions associated with QPCAP-57 was actually performed. This issue has been identified as Nonconformance 99901356/2006-201-02.

To follow up this issue the NRC inspector interviewed the Flowserve inspector who had lead responsibility for the review of 3,000 dedication packages. The Flowserve inspector stated that he looked at the dedication forms to verify the following:

- material verification section was complete
- dimensional verification section was complete
- appropriate sampling lot was entered
- inspector signature was entered on bottom
- PDF number was entered on the 10 CFR Part 21 Dedication of Commercial Grade Items Dedication form
- PDF number was entered Technical Evaluation Worksheet form

The Flowserve inspector also stated that he reviewed the attached PDF documents to verify that all required tests per the PDF had been completed through verification of the inspector initials/signature and date on the PDF. The Flowserve inspector further stated that he did find examples where the above types of information was missing on the documents. He further described some specific issues that he recalled were identified during the review concerning missing or incorrect information on the dedication sheet and/or PDF:

- dimensional inspection as found conditions were not documented for each piece of a the sample lot that was inspected
- incorrect part number
- missing engineer initials and date
- missing Raleigh Material Code (RMC) number
- PDF tests not initialed but tests were completed per method specification
- PDFs without engineering signatures
- missing PDF numbers
- accumulator kit dedication issues
  - incorrect part numbers on PDF
  - incorrect drawing numbers on PDF

Based on the type of issues identified during the Flowserve review of the 3,000 dedications packages, the NRC inspectors determined that these items should have been entered into the Flowserve corrective action program and would have been extremely useful in trending and ultimately improving the overall commercial grade item dedication process through the lessons learned, the identification of additional corrective actions and the determination of what additional training was needed to correct the problems and adequately implement the dedication process requirements. This is identified as observation 99901356/2006-201-04.

b.3 Dedication of Commercial Grade Items

The NRC inspectors reviewed a recent sample of dedicated items/components selected from different lists within the Flowserve system to identify a varied sample of dedicated components/items. The NRC inspectors selected from a list based on item part numbers for different components, from a Index of PDF files (items with accompanying Technical Evaluation Worksheets) and from the RAL-7487, “Raleigh Material Code Index for 10 CFR Part 21 Commercial Grade Dedication” document.

The NRC inspectors reviewed the following documentation, as applicable, associated with the dedicated items: the licensee purchase order; the Engineering Quality Assurance Plan (QAP) Input form; Material Substitutions; the Technical Evaluation Worksheet (identified with PDF numbers); the Method Specification for testing requirements, the 10 CFR Part 21 Dedication of Commercial Grade Items form, various certification documents received from the vendors (Certificate of Compliance, CMTR - Certified Material Test Report, various Test Certificate) and the commercial grade survey report for Method 2 dedications.

The NRC inspectors reviewed dedication packages for the following items:

- swing check valve disc nut and hinge pin
- air check valve
- 3" Valtek Maxflo plug valve
- 316 SS hex jam nut
- valve shaft
- bearing race
- teflon valve seat
- ¼" hydraulic relief valve

- Boston gear
- check valve assembly
- ½" pneumatic air check valve
- solenoid valve

c. Conclusions

The NRC inspectors determined through review of dedication packages for various items that Flowserve is generally implementing a commercial grade dedication process in compliance with regulatory and industry guidance and Flowserve quality program requirements documented in their QAM and implemented through various PIOPs, SOIs, and other implementing documents. However, a Nonconformance 99901356/2006-201-02 as described above was identified during this part of the inspection for failure to provide documented objective evidence for review and corrective actions taken as part of QPCAP-57.

Additionally, the type of issues identified during the Flowserve review of the 3,000 dedications packages should have been entered into the Flowserve corrective action program and would have been extremely useful in trending and ultimately improving the overall commercial grade item dedication process through the lessons learned, the identification of additional corrective actions and the determination of what additional training was needed to correct the problems and adequately implement the dedication process requirements. This is identified as observation 99901356/2006-201-04.

3.3 10 CFR PART 21 PROGRAM

a. Inspection Scope

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

b. Observations and Findings

Flowserve QAM, Section 2.1.6, states, in part, that the Flowserve - Raleigh quality assurance program incorporates the requirements of 10 CFR Part 21, as it affects the products Flowserve manufactures. Section 2.1.6 further states, in part, that particulars relative to this document are posted in the facility and are included in plant documents when applicable.

Flowserve QAM, Section 16.2.2, states, in part, that the identification of conditions adverse to quality, the cause of the conditions, the corrective action taken, and the date required to complete corrective action shall be documented in a QPCAP by the individual assigned responsibility.

PIOP 36-40-03-06, “Methods for Reporting to NRC Defects Creating Substantial Safety Hazards,” dated August 25, 2004, describes the methods for reporting to the NRC potential problems that could create substantial safety hazards in delivered valves, actuator control systems, and/or parts. Specifically, PIOP 36-40-03-06 outlines responsibilities of each department to identify customer orders and purchase orders for critical components where Part 21 is invoked; including posting, notification, and record retention requirements.

PIOP 36-40-09-17, Section 3.2.2, requires that nonconformances caused by internal actions shall be documented on a QPCAP.

The NRC inspectors reviewed the quality assurance program, implementing procedures, and policy guidelines governing Flowserve's Part 21 program to verify that the guidance was consistent with the requirements described in 10 CFR Part 21. The NRC inspectors verified that the Flowserve process adequately outlined the requirements for identification, evaluation, and reporting of significant conditions adverse to quality. The NRC inspectors verified postings of the Part 21 regulations, sampled safety deviation reports, 10 CFR Part 21 Evaluation Committee Summary Sheets, and procurement documents. The NRC inspectors found them to be in accordance with the provisions of the regulation.

The NRC inspectors discussed Flowserve's Part 21 program with the QA manager and inquired as to how a nonconformance identified as a condition adverse to quality on a QPCAP would be evaluated under the Part 21 program. The NRC inspectors determined that the Flowserve corrective action process procedures did not identify when a 10 CFR Part 21.21 evaluation for reportability of significant conditions adverse to quality is required. This issue has been identified as Nonconformance 99901356/2006-201-03.

At the time of the exit meeting, the Flowserve QA manager had taken steps to revise the QPCAP procedure to require a review as to whether a Part 21 evaluation was required.

c. Conclusions

The NRC inspectors determined that Flowserve's Part 21 program was consistent with the requirements of 10 CFR Part 21. However, the NRC inspectors concluded that Flowserve did not have a mechanism in place to determine if a significant condition adverse to quality captured in the QPCAP warranted a Part 21 evaluation. Specifically, the inspectors determined that PIOP 36-40-03-06 and PIOP 36-40.09.17 did not explicitly provide guidance to determine if a significant condition adverse to quality identified in the QPCAP warranted a Part 21 evaluation. This issue has been identified as Nonconformance 99901356/2006-201-03.

3.4 TRAINING AND QUALIFICATION OF PERSONNEL

a. Inspection Scope

The NRC inspectors reviewed the implementation of the Flowserve personnel training and qualification process. Specifically, the NRC inspectors verified that the Flowserve personnel training and qualification process was consistent with the requirements of 10 CFR Part 50, Appendix B, Criterion II, "Quality Assurance Program."

b. Observations and Findings

b.1 Qualification and Training of Auditors Performing QA Internal Audits

Flowserve QAM, Section 2.1.4, states, in part, that personnel performing activities affecting quality shall receive adequate indoctrination and training to assure that suitable proficiency in their area of activity is achieved and maintained. Section 2.4.5 provides the requirements for training and indoctrination of auditors and lead auditors. Specifically, Section 2.4.5, states that audit personnel shall be trained and certified in accordance with a PIOP. Personnel selected for quality assurance auditing assignments shall have experience or training (formal and on-the-job) commensurate with the scope, complexity, or special nature of the activities to be

audited. Auditors shall have, or be given, appropriate training or orientation to develop their competence for performing required audits.

SOI 40-26-08, "Qualification and Training of Auditors Performing QA Internal Audits," dated December 10, 2004, provides guidance for indoctrination and training of auditors and lead auditors. SOI 40-26-08 specifies the minimum experience and/or technical training requirements for auditors and lead auditors. Each individual shall be indoctrinated or instructed in the applicable quality assurance procedures, and maintain its proficiency through regular participation in the audit process, procedure reading, or by participation in training programs.

The NRC inspectors performed a sample review of training records of auditors and lead auditors, including qualification certificates and requalification activities to verify that they were current in qualification to perform their respective activities. For the training records and certifications reviewed, documentation was available to show that personnel had received training and there was documented evidence of recent auditor and lead auditor certifications. The NRC inspectors did not find any discrepancies.

b.2 Engineering, Manufacturing Operations and Inside Sales and Applications Indoctrination and Training Activities

Flowserve QAM, Section 1.3.3 states that the Manufacturing Manager provide and implement indoctrination and training programs and maintain training records for those personnel under his supervision whose activities affect quality. Section 1.5.6 states that the Inside Sales and Applications Manager provides indoctrination and training programs and maintains training records for those personnel under his supervision whose activities affect quality.

SOI 70-18-06, "Product Engineering Training Program," dated August 11, 1997, provides guidance for indoctrination and training of new personnel in the Engineering Department. SOI 70-18-06 establishes the minimum requirements on personnel proficiency for engineers, non-engineers, and clerical support staff.

The NRC inspectors reviewed the training procedure for employees in the engineering department. The NRC inspectors noted that Exhibit I of SOI 70-18-06 is utilized as the training record for each individual during and after completion of the training program. This form outlined the training requirements for each individual commensurate with their job responsibilities. The NRC inspectors verified that training activities were properly documented using the training documentation form in Exhibit I. For the training records reviewed, documentation was available to show that personnel had received training. The NRC inspectors did not find any discrepancies related to personnel training and indoctrination.

However, during the review the NRC inspectors identified that, for some individuals, the training form shown in Exhibit I of the procedure was not part of the training record; instead, a new matrix was used. The Flowserve QA Manager and the QA Supervisor informed the NRC inspectors that this new training matrix was the training record used by the Williamsport personnel who was transferred to the Raleigh facility. After the consolidation of the Williamsport and Raleigh plants, this new training matrix has been used to record training activities. The NRC inspectors determined that the use of the new training matrix was inconsistent with SOI 70-18-06. This is identified as observation 99901356/2006-201-05.

The NRC inspectors verified training records for Manufacturing Operations and Inside Sales and Applications personnel. The NRC inspectors requested the procedure associated with the training activities of the Manufacturing Operations and Inside Sales and Applications personnel whose activities affect quality. The NRC inspectors were informed by Flowserve representatives that there was no training procedure in place for these personnel and that training for these individuals was conducted using the engineering training procedure, SOI 70-18-06. The NRC inspectors determined that the lack of a documented procedure which describes the training requirements for personnel performing activities affecting quality is inconsistent with the Flowserve QAM and is an example of Nonconformance 99901356/2006-201-04.

Although no training procedure was in place for these personnel, the NRC inspectors were able to verify that training was completed by each employee in both Manufacturing Operations and Inside Sales and Applications departments. In addition, the NRC inspectors verified that the training activities were documented using either Exhibit I of SOI 70-18-06 or the new training matrix.

c. Conclusions

The NRC inspectors determined that the Flowserve personnel training and qualification process requirements were described in the Flowserve procedures, and were consistent with the requirements of 10 CFR Part 50, Appendix B, Criterion II. However, the NRC inspectors identified several examples where the training record documentation was inconsistent with the Flowserve procedure. This is identified as observation 99901356/2006-201-05. In addition, the NRC inspectors identified that a specific training procedure for the Manufacturing Operations and Inside Sales and Application departments did not exist. This issue has been identified as Nonconformance 99901356/2006-201-04.

3.5 EXTERNAL AUDITS

a. Inspection Scope

The NRC inspectors reviewed the implementation of the Flowserve external audit program. Specifically, the NRC inspectors verified that the Flowserve external audit program was consistent with the requirements of 10 CFR Part 50, Appendix B, Criterion XVIII, “Audits.”

b. Observations and Findings

Flowserve QAM, Section 1.2.12, states, in part, that the QA manager shall plan and coordinate vendor quality surveys and audits; evaluate the results of such surveys and audits; make recommendations for and provide follow-up on corrective actions; inform Operations (Purchasing) and Supply Chain Manager of Quality Assurance approved vendors. Section 7.2.9.1, states, in part, that the QA manager, or his designee, shall review for acceptance the procedures for conducting audits or surveys, the procedures for auditor qualification and certification, and the lead auditor’s qualification and certification records.

PIOP 36-41-01-18, “Procedures for Performance of Vendor Audits and Assessments,” dated September 15, 2004, provides a high level discussion of the purpose of the audits, planning and coordination guidance, frequency of supplier audits, and the correction of any non-compliance

identified in an audit report. The procedure also included the appropriate documentation to support the audits.

The NRC inspectors performed a review of selected commercial grade surveys performed by the Nuclear Industry Assessment Committee (NIAC) and Flowserve personnel to verify that the audits were performed in accordance with the requirements specified in the implementing procedures and policy guidelines. The NRC inspectors requested the procedure utilized by Flowserve in the performance of commercial grade surveys. The NRC inspectors were informed by Flowserve representatives that the auditors have performed commercial grade surveys using the same procedure used for vendor audits. After a detailed review of the aforementioned procedure the NRC inspectors concluded that it did not provide specific guidance for the performance of a commercial grade survey. The NRC inspectors determined that the lack of a documented procedure for the performance of commercial grade surveys is inconsistent with the Flowserve QAM and is another example of Nonconformance 99901356/2006-201-04.

c. Conclusions

The NRC inspectors determined that the Flowserve activities related to external audits was consistent with the requirements of Appendix B to 10 CFR Part 50, Criterion XVIII. However, the NRC inspectors did not identify any procedural guidance for the performance of commercial grade surveys. This issue has been identified as another example of Nonconformance 99901356/2006-201-04.

4.0 ENTRANCE AND EXIT MEETINGS

In the entrance meeting on January 10, 2006, the NRC Inspectors discussed the scope of the inspection, outlined the areas to be inspected, and established interfaces with Flowserve staff and management. In the exit meeting on January 13, 2006, the NRC Inspectors discussed their concerns and findings with Flowserve management and staff.

5.0 PARTIAL LIST OF PERSONS CONTACTED

Rafiq Banukwala	Manager, Quality Assurance	Flowserve ***
Jim Tucker	Manager, Engineering	Flowserve ***
Mike Dunkelberger	Supervisor, QA Engineering	Flowserve ***
John Chappell	General Manager	Flowserve ***
Mark Alsip	Sales	Flowserve ***
Bernie Carothers	Supervisor, Mat. Process Control	Flowserve ***
Dave Osborne	Team Leader, West	Flowserve ***
W. Glenn Rains	Supervisor, QA Engineering	Flowserve ***
Gary Shaw	Team Leader, South	Flowserve ***
James Cobb	Gage/Dedication Lab	Flowserve
Joseph Gallagher	Sr. Principal Product Engineer	Flowserve
Gene Graham	Manager, Product Design	Flowserve
Eric Fletcher	Supervisor, Quality Control	Flowserve**
Audrey Garrett	Marketing	Flowserve**
Daniel Hall	Supervisor, Marketing	Flowserve**
Kenny Stewart	Manager, Operations	Flowserve**

* Attended Entrance Meeting
** Attended Exit Meeting
*** Attended Entrance & Exit Meeting