

March 3, 2006

U.S. Nuclear Regulatory Commission Washington, D.C. 20555

Attention:

Document Control Desk

Subject:

Reply to Notice of Nonconformance

Reference:

NRC Inspection Report 99901356/2006-201 dated Feb 8, 2006

NRC Inspection of Flowserve-Raleigh of Jan 10-13, 2006

The following is provided in response to the Notice of Nonconformance issued as a result of the NRC Inspection. As requested, each response includes (1) Reason for nonconformance, (2) Corrective steps taken and results achieved, (3) Corrective steps that will be taken to avoid further noncompliance and (4) Date corrective action will be completed.

At this time, Flowserve is evaluating the observations and recommendations included within enclosure 2 of the report. A follow-up response to address these issues will be provided by April 7, 2006.

Nonconformance 99901356/2006-201-01

1. The QPCAP form did not clearly identify the requirements of the procedure.

Personnel implementing the procedure misunderstood the requirements. As stated within the report, the procedure requires 15 days to determine the root cause and propose corrective action along with a schedule for completion. Many believed that the root cause evaluation and completion of the corrective action was required within 15 days. As a result, they held on to the QPCAP until all actions were completed and never provided a schedule.

Open QPCAP's were discussed in monthly staff meetings but did not have visibility throughout the facility.

A 15 day requirement for completion of the root cause evaluation did not allow enough time to accommodate vacation schedules, holidays, and other events causing delay.

2. The QPCAP form was revised to identify the requirements of the procedure. The revised form clearly indicates the number of days and due date for providing the root cause and proposed corrective action. It also includes a space to enter the proposed date for completion of the corrective action. The revised form will drive procedure compliance.

An accountability meeting is held daily. The meeting is led by Flowserve's General Manager and involves all managers and supervisors. Open QPCAP's were added to the meeting agenda to provide visibility and stress the importance of the corrective action program.

The number of days required to complete the root cause evaluation and propose a corrective action schedule was increased to 30 days. This will allow managers to involve the appropriate personnel and complete the evaluation on-time regardless of vacation schedules, holidays, or other events.



- 3. Training on the corrective action procedure and process will be performed to ensure that all involved understand the requirements and objectives.
- 4. The training will be completed by April 7, 2006.

Nonconformance 99901356/2006-201-02

This nonconformance requires some background discussion to understand the steps taken by Flowserve.

The initial finding that led to the dedication package review involved an incomplete verification of critical characteristics. Most dedication activities take place in the Flowserve Gage Lab. The dedication plan for this particular part required special testing performed by the assembly department. The dedication plan that specified the test requirements had 2 signatures, which represented approval of the plan. The Gage Lab Inspector signed-off that the dedication was completed, because he thought the 2 signatures represented completion of the testing.

As corrective action, Flowserve revised the form to require a 'QA' signature instead of an 'Inspector' signature. The QA representative has the responsibility of verifying that all dedication steps were completed prior to signing the form. The dedication package review was performed to determine whether there were any other instances where dedication plans were signed-off prior to completion of all testing.

Over 3,000 packages were reviewed, and there was no evidence of missed dedication operations. However, the review was not documented, and there were other problems identified that were not recorded. These are the types of problems discussed with the NRC Inspector and listed in enclosure 2 of the NRC report.

- Personnel involved in the dedication package review did not recognize or understand the importance of objective evidence.
- 2. Flowserve spoke with the Inspector that performed the dedication package review. He confirmed that the review involved at least 3,000 packages and did not identify any missed dedication operations.

Flowserve conducted a new review to provide further confirmation that dedication operations were not missed. The review focused on parts that required testing similar to that missed in the initial finding. This focused scope resulted in a list of 93 dedication packages. In each case, all dedication operations were completed as required by the plan. This review reconfirmed the conclusion of the original evaluation. The missed operation was an isolated case.

Flowserve performed a review of the problems listed in enclosure 2 of the NRC report, which were identified in the original dedication package review, and determined that the problems listed would not affect the hardware or result in the shipment of defective product.

3. Training on the corrective action procedure and process will be performed to ensure that all involved understand the importance of objective evidence and the need to document steps taken during root cause evaluations and corrective action implementation.

Flowserve will review the problems listed in enclosure 2 of the NRC report, which were identified in the original dedication package evaluation, to determine whether additional corrective action is necessary.

4. The training and review will be completed by April 7, 2006.

Nonconformance 99901356/2006-201-03

- 1. Personnel involved in the issuance of Quality Program Corrective Action Plans (QPCAP's) recognized the need to consider whether a 10CFR Part 21 evaluation was necessary. Training on 10CFR Part 21 was conducted. The Manager, Quality Assurance reviewed each QPCAP that was issued. Part of that review was to determine whether a 10CFR Part 21 evaluation was necessary. However, the procedure did not specifically indicate that an evaluation should be considered.
- 2. The procedure was revised to specifically require 10CFR Part 21 consideration. The QPCAP form was revised to add a statement asking whether a Part 21 evaluation is required. Personnel completing the form must check either 'Yes' or 'No'. The revised corrective action procedure requires evaluation per the Flowserve Part 21 evaluation and notification procedure, if the 'Yes' box is checked on the form. These revisions clearly define the requirement by procedure and provide objective evidence of completion.
- 3. Training on the corrective action procedure and process will be performed to ensure that all involved understand the responsibilities associated with 10CFR Part 21 and how those responsibilities are addressed by the Flowserve corrective action process.
- 4. The training and review will be completed by April 7, 2006.

Nonconformance 99901356/2006-201-04

 Flowserve personnel did not recognize the importance of clearly defining these processes by procedure. In both cases, the activities were performed in a manner consistent with Flowserve manual and regulation requirements.

The Flowserve QA Manual requires managers to implement training programs and maintain training records. Training matrices and records were maintained, but the scope and frequency of training was not clearly defined by procedure.

Commercial grade surveys were performed in a manner consistent with regulation requirements, but the procedure did not specifically state the added considerations when performing a commercial grade survey as compared to an NCA-3800 or 10CFR50 Appendix B audit.

2. The Manufacturing Operations and Inside Sales and Applications departments generated training procedures to define their training programs.

The vendor audit procedure was revised to address commercial grade surveys specifically and clearly list the added considerations associated with this activity.

- 3. Flowserve internal audits are geared towards verifying that processes are performed in accordance with the manual and procedures. The internal audit checklists will be revised to require consideration on whether adequate procedural guidance is given for the activities being audited. This revision will allow Flowserve to identify areas other than those identified during the NRC audit.
- 4. The internal audit checklists will be revised by April 7, 2006.

If I can provide more information, please call me at (919) 831-3304.

Rafiq A. Bandukwala, Manager Quality Assurance Flowserve – Raleigh Operations 1900 S. Saunders St. Raleigh, North Carolina 27603 Tel: (919) 831-3304 e-mail: rbandukwala@flowserve.com

Cc: Director, Division of Engineering, Office of Nuclear Reactor Regulation, Washington, D.C. 20555

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