

Sulzer Pumps (US) Inc.

U.S. Nuclear Regulatory Commission
ATTN: Document Control Desk,
Washington, D.C. 20555-0001

Sulzer Nuclear Service Center
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6/2/2010

Subject: **"Reply to a Notice of Violation"**

The purpose of this memorandum is to document actions taken by Sulzer Pumps (US) pursuant to the Nuclear Regulatory Commission (NRC) violation 99901361/2010-201-01.

NRC Notice of Violation:

Sulzer Pumps (US) Inc. procedure CHQ-001, "Compliance with 10 CFR Part 21," Revision 1, dated July 10, 2007, did not provide adequate guidance to meet the requirements of 10 CFR Part 21. Specifically:

1. CHQ-001 did not provide guidance to inform the purchasers or affected licensees when Sulzer makes the determination that they do not have the capability to perform the evaluation to determine if a defect exists.
2. CHQ-001 did not reflect the time frames of 10 CFR 21.51 for maintenance and retention of Part 21 records.

Sulzer Response:

Reason for the violation:

Lack of periodic reviewing NRC database for updates to 10 CFR Part 21 prior to implementation.

Corrective Steps that have been taken and the results achieved:

The procedure was reviewed and revised to revision (2) dated 3/24/2010 and implemented. Copy attached.

Corrective Steps that will be taken to avoid further violations:

Quarterly reviews of 10 CFR Part 21 for updates to CHQ-001.

Date when full compliance will be achieved:

Implementation date was 4/13/2010 when training was conducted (session # 2010-025) for Sulzer personnel.

JEO9
NRR

Sulzer Pumps (US) would like to thank the NRC investigators for their professionalism and thoroughness during their inspection which was conducted on March 23-26, 2010. We appreciated the input enabling us to make programmatic improvements.

Should you have questions please don't hesitate to contact us as necessary.

Respectfully,

Tommy Craig

Quality Assurance Manager

Sulzer Pumps (US)

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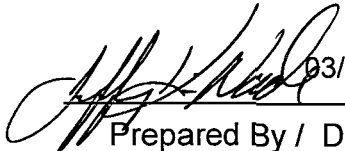
Attachment:
CHQ-001 (R2)


SULZER

SULZER PUMPS (US) INC.
SULZER NUCLEAR SERVICE CENTER
CHATTANOOGA, TENNESSEE

Procedure: CHQ-001
Revision No: 2
Date: March 24, 2010
Page: 1 of 5

COMPLIANCE WITH 10CFR PART 21


03/24/10
Prepared By / Date


03/24/10
QA Approval / Date

1.0 PURPOSE AND SCOPE

- 1.1 This procedure describes actions taken at Sulzer Pumps (US) Inc Sulzer Nuclear Service Center (SNSC) to fully comply with the requirements of the Code of Federal Regulation, 10 CFR Part 21.
- 1.2 This procedure is applicable to operations of Sulzer Pumps Sulzer Nuclear Service Center where the requirements of 10 CFR Part 21 have been invoked by *Customer Purchase Orders*.

2.0 RESPONSIBILITY

- 2.1 Any coworker who obtains information indicating that a nuclear safety related component or assembly provided by or repaired Sulzer Pumps could contain a condition (condition may be a defect (*as defined in the regulation 10 CFR Part 21*), non-compliance or failure to comply) which would cause the component or assembly to fail to perform its intended function will promptly report the condition to the *Sulzer Nuclear Service Center Quality Assurance Manager*.
- 2.2 Each individual and department responsible for the handling of basic components (as defined in the regulation 10 CFR Part 21) will comply with the requirements defined in this procedure and so document the means for compliance.
- 2.3 The *Sulzer Nuclear Service Center Manager* has delegated the responsibility for handling 10 CFR Part 21 reports, evaluations and notifications to the Quality Assurance Manager *but retains overall responsibility*.
- 2.4 The Quality Assurance Manager is responsible to ensure all conditions are reported in accordance with this procedure and to ensure the following is accomplished:
 - 2.4.1 Ensure the applicable 10 CFR Part 21 regulation is posted and accessible to SNSC coworkers.
 - 2.4.1.1 *Current copies of the 10 CFR Part 21 regulations, Section 206 of the Energy Reorganization Act of 1974 and a copy of this procedure shall be posted in the SNSC lunchroom at a minimum.*
 - 2.4.2 *If Sulzer determines inadequate capabilities exist to perform the evaluation to determine if a defect exists, the Quality Assurance Manager shall notify the purchaser or affected licensee within five working days after discovery.*
 - 2.4.3 *If it is determined to be a defect creating a substantial safety hazard (as defined in the regulation 10CFR21) shall promptly inform the NRC after discovery in accordance with this procedure.*

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2.4.3 To notify the Sulzer Pumps (US) Inc. General Manager Nuclear Services of the potential for a 10CFR Part 21 violation as soon as practical but within five working days at a minimum *after completion of the evaluation*.

2.4.3.1 The General Manager Nuclear Services is a member of the Sulzer Pumps (US) Inc Nuclear 10CFR Part 21 review committee.

3.0 COMMUNICATION**3.1 Internal:**

3.1.1 Internal communication and reports concerning compliance with 10 CFR Part 21 will be directed to the Quality Assurance Manager.

3.2 External:

3.2.1 *Except as required otherwise written communications and reports shall be addressed to the NRC's Document Control Desk by mail to the U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001.*

4.0 PROCUREMENT DOCUMENT CONTROL

4.1 Each procurement document for a basic component (procurement document means a contract that defines the requirements which basic components must meet in order to be considered acceptable by the purchaser) will specify 10 CFR Part 21 applicability as defined by the Customer purchase order.

5.0 EVALUATION

5.1 Upon receipt of information (*CAR/NCR, etc.*) which indicates a nuclear safety related component or assembly may have a condition which could cause it to fail to perform its intended function, the Quality Assurance Manager shall perform an immediate preliminary evaluation and convene a meeting of the 10 CFR Part 21 committee as defined in 6.0, but in all cases be done within 60 days of discovery.

5.2 The Quality Assurance Manager shall prepare and submit to the NRC an interim report should an evaluation be unable to be completed within 60 days from discovery. The interim report shall describe the deviation or failure to comply and state when the evaluation will be completed. This interim report shall be submitted in writing within 60 days of discovery of the deviation or failure to comply.

5.3 The Quality Assurance Manager shall be notified as soon as practicable and in all cases within 5 working days after completion of evaluations. Alternatively, an authorized designee shall be notified.

5.4 The committee shall evaluate and document its findings that shall include but not be limited to:

5.4.1 Identification of the assembly or component to be evaluated.

5.4.2 Nature of the reported defect or failure and the potential impact on the safety related function that could be created by the condition.

5.4.3 The date on which information of such condition was obtained.

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- 5.4.4 The number and location of all such components in use at, supplied for, or being supplied to facilities subject to the regulation of 10 CFR Part 21.
- 5.4.5 The corrective actions which has been, is being, or will be taken, along with the name of the individual, organization, or department responsible for this action; and the length of time that has been or will be taken to complete the action.
- 5.4.6 Any advice related to the condition about the plant or component that has been, is being, or will be given to purchasers or licensees.

6.0 COMMITTEE

- 6.1 The following details the people that comprise the committee:
 - 6.1.1 Permanent members of the Material Review Board (MRB): Chairperson: SNSC Quality Assurance Manager and the Engineer Manager (or their assigned representative during absence). Additional assistance may be required of other coworkers as deemed necessary by the committee.
- 6.2 At the request of the Quality Assurance Manager, the committee will be assembled and conduct an evaluation in accordance with 5.0 and the requirements of 10 CFR Part 21.
- 6.3 Upon completion of the evaluation, the determination will be made regarding reporting and, if deemed necessary, will comply 7.0.

7.0 REPORTING PROCEDURE

- 7.1 Notifications *of a defect* to the NRC shall be in accordance with the following guidelines:
 - 7.1.1 Initial notification by facsimile, which is the preferred method of notification, to the NRC Operations Center at (301) 816-5151 or by telephone at (301) 816-5100 within two days *after notification to the General Manager Nuclear Services*. Verification that the facsimile has been received should be made by calling the NRC Operations Center.
 - 7.1.2 Written notification *of a defect* shall be made *in accordance with this procedure* within 30 days *after notification to the General Manager Nuclear Services*. to the following address:
 - 7.1.3 Document Control Desk
U.S. Nuclear Regulatory *Commission*
Washington, DC 20555
 - 7.1.4 The written report shall include, but need not be limited to, the following information, to the extent know:
 - 7.1.4.1 Name and address of the individual or individuals informing the commission.

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- 7.1.4.2 Identification of the facility, the activity, or the basic component supplied for such facility or such activity within the United States which fails to comply or contains a defect.
 - 7.1.4.3 Identification of the firm constructing the facility or supplying the basic component which fails to comply or contains a defect.
 - 7.1.4.4 Nature of the defect or failure to comply and the safety hazard which is created or could be created by such defect or failure to comply.
 - 7.1.4.5 The date on which the information of such defect or failure to comply was obtained.
 - 7.1.4.6 In the case of a basic component which contains a defect or fails to comply, the number and location of all such components in use at supplied for, or being supplied for one or more facilities or activities subject to the regulations in this part.
 - 7.1.4.7 The corrective action, which has been, is being, or will be taken; the name of the individual or organization responsible for the action; and the length of time that has been or will be taken to complete the action.
 - 7.1.4.8 Any advice related to the defect or failure to comply about the facility, activity, or basic component that has been, is being, or will be given to purchasers or licensees.
 - 7.1.4.9 The Quality Assurance Manager or responsible officer may authorize an individual to provide the notification required by this paragraph provided that this shall not relieve his or her responsibility.
- 7.2 *After discovery and if* during the evaluation process it is determined that the condition may be reportable under the provisions of 10 CFR Part 21, THEN the Quality Assurance Manager shall do the following as a minimum:
- 7.2.1 The evaluation will be reported to the SNSC Manager and Sulzer Pumps (US) Inc. General Manager Nuclear Services within one (1) day following the evaluation.
- 7.2 IF it is determined that the condition is reportable under the provisions of 10 CFR Part 21, THEN notification to the NRC shall be made by the General Manager Nuclear Services.

COMPLIANCE WITH 10CFR PART 21**8.0 RECORD MAINTENANCE**

- 8.1 Any condition as defined in this procedure will require records to be prepared in connection with the reported condition regarding design, manufacture, fabrication, placement, erection, installation, modification, inspection or testing.
- 8.2 *Records of evaluations of all deviations and failures to comply for a minimum of five years after the date of the evaluation.*
- 8.2 *Records of notifications sent to purchasers and affected licensees shall be retained for five years after the date of the notification.*
- 8.3 Records associated with 10CFR21 violations shall be maintained for 10 years, including a record of the purchasers of basic components.

9.0 ACCESS

- 9.1 Access to the *Sulzer Nuclear Service Center* by a representative of the Commission will be allowed for the purpose of inspection of the records, premises and basic components as necessary to ensure compliance with the regulation.