



U. S. Nuclear Regulatory Commission
Washington, DC 20555-0001

ATTN: Document Control Desk

Subject: Reply to Notice of Nonconformance 99900879/2009-201-01

Reference: NRC Inspection Report No. 99900879/2009-201 and Notice of
Nonconformance to Tioga Pipe Supply Co., Inc.

Date: October 8, 2009

Pursuant to the provisions of 10 CFR 2.201, attached is our response to your letter dated 9/22/09 regarding your request for reply to the subject Notice of Nonconformance.

As stated by the NRC in the referenced report, this issue had been previously identified and documented in Condition Report (CR) 2009-21. The corrective action to CR 2009-21 is now complete and a copy of the CR is attached.

If you have any additional comments or questions, please contact me at 610-252-7473, ext. 31 or call my cell phone at 215-837-7220.

Sincerely,

A handwritten signature in black ink that reads 'Steven T. DiMauro'.

Steven T. DiMauro
Quality Assurance Manager
Tioga Pipe Supply Co., Inc.

CC: Richard Rasmussen, Branch Chief
Quality and Vendor Branch B

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NRD

☐ Vendor
☒ InternalTIOGA PIPE SUPPLY CO INC.
CONDITION REPORTVendor Name: Tioga Pipe Supply Co., Inc.CR # 2009-21Location: Easton, PADate: 8/11/09**Requirement:**

10CFR50, App. B, Section XVII, Quality Assurance Records states in part, "Sufficient records shall be maintained to furnish evidence of activities affecting quality. Requirements shall be established concerning record retention (duration), location and assigned responsibility."

Finding:

See Supplementary Sheet

Reported by: NUPIC Steve DiMauro Dept.: QA Date: 8/11/09Corrective Action Responsibility Steve DiMauro Requested Reply Date NA☐ 10 CFR 21 Reportable Justification: Record storage issue only. Not a reportable condition.Category ☐ A ☒ B ☐ C**Probable Cause and Corrective Action:**

See Supplemenatry Sheet

Date Corrective Action

To Be Completed 4/30/10Signature Steven T. DiMauro**Verification of Corrective Action**

Comments:

QSP-16, Record Maintenance Procedure (copy attached) was revised on 9/24/09 to address the concerns identified herein. No additonal action is required.

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By Steven T. DiMauro Dept. QA Date 10/7/09

**Supplementary Sheet
CR 2009-21**

Finding:

Contrary to the stated requirements, based on review of QSM section 17, QA Records, Rev. 8, dated 10/17/05 and QSP-16, Record Maintenance Procedure, Rev. 8 the following deficiencies were identified:

1. The QSM & QSP need to clearly define what documents Tioga Pipe considers to be QA Records i.e. the following conflicting information regarding what is considered to be a QA Record requires correction/clarification; QSM section 17.1.4, identifies QA Records that are to be controlled per QSP-16. The wording of this section implies that the "customer order file" is not considered to be a quality record after the required documentation is forwarded to the customer. QSP-16, section 2.2.2 states in part that "after the order is complete, the customer order file is returned to the QA Department for record retention and control per QSP-16 requirements."
2. QA Record storage location(s) and responsibilities need to be clearly defined/clarified: At this time several quality records are being maintained at the Easton, PA location. It was also found that some quality records were being stored at the Philadelphia office. The QSM and QSP require revision to clearly define storage location requirements for the various types of records (including archives) and responsibility for maintaining the records.
3. QSP needs to clearly identify storage requirements:
QSP-16 currently identifies storage of records within metal filing cabinets. In response to NRC NON 99900879/2008-201-05, Tioga Pipe issued CAR #280, Rev. 1 (dated 9/08/08) which resulted in the procurement of 2-hour fire rated file cabinets (one for the Easton location and one for Philadelphia). QSP-16 is silent on the use of these 2-hour fire rated cabinets and what specific QA Records are to be stored in these cabinets at the different locations.

Probable Cause and Corrective Action:

Cause:

Tioga stores quality records appropriately but those documents considered to be quality records were inadvertently not included in QSP-16.

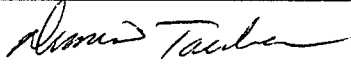



Corrective Action:

QSP-16 will be revised to clearly identify documents considered to be QA Records, clearly identify which records are to be stored in which locations, clearly identify storage requirements for quality records, and responsibility for maintaining these records at each location. In addition, the revision to QSP-16 will ensure that it is in compliance with the QSM.

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QUALITY SYSTEM PROCEDURE QSP-16
Record Maintenance Procedure

Revision 12		Signature
Date: 9/24/09		
Prepared	Dennis Tauber	
Title	Director of QA	
Concurred	Dennis Tauber	
Title	Director of QA	
Approved	Nick Tambakis	
Title	QA Supervisor	
Approved	Steve DiMauro	
Title	QA Manager	

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1.0 Purpose

- 1.1 It is the intent of this procedure to describe a program for the legibility, identification, retrievability and orderly maintenance of Quality Assurance records.

2.0 References

- 2.1 ASME Section III Subarticle NCA/WA-3800
- 2.2 10CFR50 Appendix B, Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants
- 2.3 NQA-1, Quality Assurance Requirements for Nuclear Facility Applications
- 2.4 10CFR 21, Reporting of Defects and Noncompliances
- 2.5 USNRC RegGuide 1.28

3.0 Responsibilities

- 3.1 *The Quality Assurance Manager has the responsibility to provide and maintain storage facilities for the Quality Assurance Records identified in this Procedure.*
- 3.2 *All personnel that generate or copy Quality Assurance Records have the responsibility to ensure the applicable record is complete and legible. Copies of records that are forwarded to the Customer or maintained as Objective Evidence are to be verified prior to issuance or retention for attributes such as, but not limited to:*
- a) Cut off information*
 - b) Copy marks that obliterate information*
 - c) All corrections are properly annotated.*
 - d) Copy clarity*
- 3.3 *All personnel that access or retrieve Quality Assurance Records shall be trained on the proper return of such file and trained on the equipment to ensure records are not damaged, deteriorated or lost while in their possession. Any conditions that subject Quality Assurance Records to potential damage, loss, or deterioration shall be reported to the QA Manager for action.*

4.0 Definitions

- 4.1 *Lifetime Records – are those that meet one of the following criteria:*
- 4.1.1 *Those that would be of significant value in demonstrating capability for safe operation*
 - 4.1.2 *Those that would be of significant value in maintaining, reworking, repairing, replacing, or modifying an item*

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4.1.3 *Those that would be of significant value in determining the cause of an accident or malfunction of an item*

4.1.4 *Those that provide required baseline data for inservice inspections.*

4.2 *Nonpermanent Records – those records required to show evidence that an activity was performed in accordance with the applicable requirements but need not be retained for the life of the item because they do not meet the criteria for lifetime records. Nonpermanent records shall be maintained for the identified retention period.*

5.0 Details

5.1 *Lifetime Records – Tioga Pipe Supply does not maintain any Lifetime Records. In accordance with the definitions of NQA-1 and the guidance provided in USNRC Reg. Guide 1.28 the only document which may qualify as a lifetime record is the Certified Material Test Report; which is transmitted to the customer with shipment at the time it is generated. Lifetime storage of this record is the responsibility of the Owner or their authorized agent.*

5.2 *Nonpermanent Records – Tioga Pipe Supply generates and maintains several types of nonpermanent records. These are programmatic records and not specific to a customer order. Included are:*

5.2.1 *Certified Material Test Reports for inventory*

5.2.2 *Purchase Orders and Receiving Reports for inventory*

5.2.3 *Personnel Training, Qualification and Certification Records*

5.2.4 *Vendor Audit Reports*

5.2.5 *Approved Vendor Manuals*

5.2.6 *Internal Audit Reports*

5.2.7 *Corrective Action/Condition Reports*

5.2.8 *Nonconformance Reports*

5.2.9 *Calibration certificates*

5.2.10 *Manufacturing Records*

5.2.11 *Quality Assurance Manual and Procedure distribution logs*

5.2.12 *10CFR Part 21 Records*

5.3 *Customer Order Documentation*

5.3.1 *Customer order documentation files will consist of the following as applicable:*

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- 5.3.1.1 Tioga Pipe's Certificate of Conformance and/or Certified Material Test Reports showing Quality System Certificate (Materials), Number and expiration date, and Quality System Manual revision date and category for category A through E orders.
- 5.3.1.2 Customer Purchase Order
- 5.3.1.3 Quality Assurance Checklist and reports.
- 5.3.1.4 Lab Memos, Service Orders, Test Results, and Final Inspection Reports.
- 5.3.1.5 Copies of the applicable material organization Certified Material Test Reports and/or Certificates of Compliance and supplier's certification.
- 5.3.1.6 Copies of certifications for all tests, heat treatments, and examinations performed for or by Tioga Pipe Supply Co., Inc.
- 5.3.1.7 Any nonconformances accepted by the customer.
- 5.3.1.8 *Copies of purchase orders for direct shipments to a customer are maintained as part of the customer order documentation file.*
- 5.3.2 The *Quality Assurance Department* has the responsibility of submitting to the customer the required number of copies of quality documentation as required by the Code and/or Customer order. After the Sales Order is complete it is returned to the Quality Assurance Department for record retention and controlled as outlined herein.
- 5.3.3 When not in use, Customer Order folders and files will be filed by calendar year, customer name, customer order number, and sales order number and placed in a metal file cabinet.
- 5.3.4 Customer Specifications are maintained by the QA Department.
- 5.3.5 Active documents - All active quality-related documents which are used in the daily function of the company will be maintained in the department which has use for them.
- 5.3.6 Document Changes
 - 5.3.6.1 Major changes which are other than typographical errors or editorial corrections on the Sales Orders will be reviewed by the Quality Assurance Department as part of the Sales Order review. Minor Sales Order changes such as editorial corrections or changes that do not affect quality such as price and delivery do not require Quality Assurance review. Minor changes shall only be performed by the originator of the Sales Order or supervisory personnel.

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- 5.3.6.2 Changes on the Quality Assurance Checklist will only be performed by the Quality Assurance Department and those changes will be *single-lined-out*, initialed, and dated.
- 5.6.3.3 Non-quality related changes to the customer's confirming order may be performed by Technical Sales without Quality Assurance review. No information on the customer's confirming order shall be obliterated without written consent of the customer.
- 5.6.3.4 Any changes which cannot be clearly determined as minor by the originator or supervisor will require Quality Assurance review.

5.4 Records

5.4.1 *All records described herein are nonpermanent records and will be stored by Quality Assurance in cabinets with a 2-hour fire rating. All records described below will be retained for three (3) years unless stated otherwise:*

5.4.1.1 Certified Material Test Reports

- For inventory purchased material that is purchased with Certified Material Test Reports (CMTR), the CMTR'S are forwarded to the Quality Assurance Department upon receipt. After review and acceptance the CMTR'S are filed by specification, size, and grade where applicable by the Quality Assurance Department.

5.4.1.2 Vendor Records - Quality Assurance will maintain the following vendor records for each qualified vendor:

- Vendor Qualification surveys and audits (if applicable).
- Approved Vendors Log

5.4.1.3 Purchase orders and receiving records

- Copies of Q3800 and Q50 purchase orders, with the applicable receiving reports for inventory are maintained by the Quality Assurance Department.

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5.4.1.4 Training, *Qualification*, and Certification *Records*

- Records of training, qualification, and certification for all personnel included in this program will be maintained by the Quality Assurance Department.

5.4.1.5 Calibration Certificates

- Calibration records for all measuring and test equipment included in this program will be maintained on file by the Quality Assurance Department.

5.4.1.6 Internal Audits, Nonconformance Reports and *Condition Reports*

- Internal Audit Reports, Nonconformance Reports and Corrective Action Requests/*Condition Reports* are maintained by the Quality Assurance Department.

5.4.1.7 10 CFR Part 21 Records

- As required by 10 CFR Part 21, the following records will be maintained on file by the QA Department for the time period specified:
- Evaluations of deviations and failures to comply for a minimum of 5 years after the date of the evaluation.
- Notifications sent to purchasers and affected licensees for a minimum of 5 years after the notification.
- Records of purchasers of basic components for 10 years after delivery of the basic component or service associated with a basic component.
- Definitions of these terms are in 10 CFR Part 21.

5.4.2 Quality Manuals, Procedures, and Test Instructions

5.4.2.1 The latest revision of the Quality System Manual, Quality Inspection Manual, Quality System Procedures, and Test Instructions will be controlled as outlined by the applicable procedure.

5.4.2.2 Single copies of previous revisions of these documents will be maintained by the Quality Assurance Department for record purposes.

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5.4.3 Disposition of Records

- 5.4.3.1 At the end of the above stated retention period, records may be removed from the nonpermanent storage cabinets and processed in a manner determined by the QA Manager.

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