

September 22, 2009

Steve DiMauro, Quality Assurance Manager
Tioga Pipe Supply Company Inc.
Forks Distribution Center
100 Mort Drive
Easton, Pennsylvania 18040

SUBJECT: NRC INSPECTION REPORT NO. 99900879/2009-201 AND NOTICE OF
NONCONFORMANCE TO TIOGA PIPE SUPPLY COMPANY INC.

Dear Mr. DiMauro,

On August 11-12, 2009, the Nuclear Regulatory Commission (NRC) staff conducted a follow-up inspection at the Tioga Pipe Supply Company Inc. (Tioga) facility in Easton, Pennsylvania (PA). The purpose of the inspection was to review the implementation of corrective actions described in your June 6, 2008, and August 12, 2008, response letters to the NRC's Notice of Violation (NOV) and Notices of Nonconformance (NON) issued May 8, 2008.

Based on your replies and the results of this inspection, the NRC inspectors confirmed that the issues identified in NOV 99900879/2008-201-01 and NONs 99900879/2008-201-01, 99900879/2008-201-02, 99900879/2008-201-03, 99900879/2008-201-04, and 99900879/2008-201-05 have been adequately addressed in your completed corrective actions.

Based on the results of this inspection, the NRC inspectors identified one new nonconformance. Specifically, the NRC inspectors found that Tioga's quality system procedure (QSP)-16, "Record Maintenance Procedure," failed to document controls for quality assurance (QA) record retention requirements (i.e., duration, location and assigned responsibility) including the types of QA records that shall be stored in 2-hour fire rated cabinets at Tioga. In response to this nonconformance, you issued Condition Report (CR) 2009-21 dated August 11, 2009, and committed to address corrective actions to update QSP-16 to include QA record retention requirements including the types of QA records that shall be stored in 2-hour fire rated cabinets at Tioga. This nonconformance to 10 CFR Part 50, Appendix B, Criterion XVII, "QA Records," is cited in the enclosed NON and the circumstances surrounding it is described in detail in the subject inspection report. Please provide a written explanation or statement within 30 days of this letter in accordance with the instructions specified in the enclosed NON.

In accordance with 10 CFR 2.390, "Public Exemptions, Requests for Withholding," the agency will make a copy of this letter and its enclosures available electronically for public inspection in the NRC Public Document Room or from the NRC's Agencywide Documents Access and Management System (ADAMS), accessible 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. 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 that such material be withheld from public disclosure, you must specifically identify the portions of your response that you seek to have withheld and provide in detail the bases for your

S. DiMauro

claim (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, "Requirements for the Protection of Safeguards Information."

Sincerely,

/RA/

John A. Nakoski, Chief
Quality and Vendor Branch 2
Division of Construction Inspection
& Operational Programs
Office of New Reactors

Docket No: 99900879

Enclosure: Notice of Nonconformance
Inspection Report 99900879/2009-201

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DATE	9/15/09	9/15/09	9/15/09
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NAME	FTalbot	R. Pascarelli	John Nakoski
DATE	9/15/09	9/21/09	9/22/09

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NOTICE OF NONCONFORMANCE

Tioga Pipe Supply, Inc
Forks Distribution Center
100 Mort Drive
Easton, Pennsylvania 18040

Docket No: 99900879
Inspection Report Number: 2009-201

Based on the results of a Nuclear Regulatory Commission (NRC) inspection conducted August 11-12, 2009, at Tioga Pipe Supply, Incorporated (Tioga), the NRC inspectors found that certain activities were not conducted in accordance with NRC requirements that were contractually imposed upon Tioga by NRC licensees.

Criterion XVII, "Quality Assurance Records," of Appendix B to Title 10 Part 50, "Domestic Licensing of Production and Utilization facilities," of the *Code of Federal Regulations* (10 CFR Part 50), states, in part, that, "Sufficient records shall be maintained to furnish evidence of activities affecting quality. The records shall include at least the following: inspections, tests, audits, monitoring of work performance and material analyses. The records shall include closely-related data such as qualifications of personnel, procedures and equipment. Inspection of test records shall as a minimum identify the inspector or data recorder, the type of observation, the results, the acceptability of action taken in connection with any deficiencies noted. Records shall be identifiable and retrievable. Requirements shall be established concerning records retention, such as duration, location and assigned responsibility."

Contrary to the above, on August 12, 2009, Tioga's Quality System Procedure (QSP) 16, "Records Maintenance Procedure," failed to document controls for quality assurance (QA) record retention requirements (i.e., duration, location and assigned responsibility) including the types of QA records that shall be stored in 2-hour fire rated cabinets at Tioga.

This issue has been identified as Nonconformance 99900879/2009-201-01.

Please provide a written statement or explanation to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, DC 20555-0001 with a copy to the Chief, John A. Nakoski, Chief, Quality and Vendor Branch 2, Division of Construction Inspection and Operational Programs, Office of New Reactors, within 30 days of the date of the letter transmitting this Notice of Nonconformance. This reply should be clearly marked as a "Reply to a Notice of Nonconformance" and should include for each noncompliance: (1) the reason for the noncompliance, or if contested, the basis for disputing the noncompliance; (2) the corrective steps that have been taken and the results achieved; (3) the corrective steps that will be taken to avoid noncompliances; and (4) the date when your corrective action 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 document 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 Website 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

ENCLOSURE 1

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 at Rockville, Maryland, this 22nd day of September 2009.

EXECUTIVE SUMMARY

Tioga Pipe Supply Incorporated
99900879/2009-201

The purpose of this inspection was to review the Tioga Pipe Supply Incorporated (Tioga) corrective action activities described in Tioga's response letters dated June 6, 2008, and August 12, 2008. The inspection was conducted at the Tioga facility in Easton, PA.

The NRC inspection bases were the following:

- 10 CFR Part 21
- 10 CFR Part 50, Appendix B

The NRC staff implemented Inspection Procedure 43002, "Routine Inspections of Nuclear Vendors" and Inspection Procedure 36100, "Inspection of 10 CFR Part 21 and 50.55(e) Programs for Reporting Defects and Nonconformance," during the conduct of this inspection.

The last NRC inspection conducted at Tioga's facility in Easton, PA occurred in March 2008. During that inspection, the NRC inspectors identified one violation and five nonconformances. A summary of each is included below:

- Violation 99900879/2008-201-01 was issued because Tioga failed to establish appropriate controls or procedures to assure that records were prepared and maintained as required by 10 CFR 21.51.
- Nonconformance 99900879/2008-201-01 was issued because Tioga failed to implement distribution and revision controls to procedures in accordance with 10 CFR Part 50, Appendix B, Criterion VI, "Document Control," the Quality System Manual (QSM) and Quality System Procedure (QSP)-14, "Quality System & Quality Inspection Manual Control Procedure." Tioga failed to implement formal document controls to assure uniformity between guidance in the QSM and QSPs. Tioga did not have formal procedure measures for control and maintenance of controlled copies of Tioga Test Instructions (TI), revisions to TIs, or assurance that the latest TIs were used at Tioga work and test sites. Tioga TI-3, "Tension Testing," did not contain the required Form TI-3-1 to complete implementation activities for TI-3. In accordance with the Tioga QSM and QSP-14, Tioga staff also failed to complete acknowledge receipts within 15 days from when new procedure revisions were issued.
- Nonconformance 9900879/2008-201-02 was issued because Tioga personnel failed to perform tension testing in accordance with procedure steps in Tioga TI-3, "Tension Testing," Revision 1. Tioga performed hydrostatic testing activities on safety-related pipes using an unanalyzed "dirty water" supply. Tioga did not establish acceptance criteria in TI-1 "Hydrostatic Testing," Revision 1 for minimum and maximum hold times, document maximum allowable test pressure, and use of a timing device to record start and stop times for hydrostatic tests. Tioga QSP-36, "Ultrasonic Thickness Gauging," Revision 2, did not require post-test calibration checks of the ultrasonic thickness instrument to verify that the instrument does not drift outside its calibration range during testing.

- Nonconformance 99900879/2008-201-03 was issued because Tioga failed to control the preservation of austenitic stainless steel coming in direct contact with non-stainless steel metal pins and unapproved and unqualified taping material at Tioga's Easton, PA facility. Tioga also did not follow QSP-10 when a purchaser order item was shipped to a customer with the wrong document package.
- Nonconformance 99900879/2008-201-04 was issued because Tioga failed to follow QSP-17, "Nonconformance Procedure," Step 4.5, in that, when notified of a nonconforming condition by a customer, the Tioga's quality assurance (QA) department did not initiate a notice of nonconformance report (NCR) and an associated corrective action report (CAR). Tioga did not follow QSP-17, Steps 4.5 and 4.6 requiring issuance an NCR and CAR when a customer rejected a butt weld elbow fitting sent back to Tioga. In accordance with Tioga QSP-26, "Corrective Action Procedure," Tioga did not issue a CAR when numerous and repetitive non conformances occurred over a three year period from two different suppliers.
- Nonconformance 99900879/2008-201-05 was issued because Tioga failed to specify requirements in QSM, Section 17.0, "Quality Assurance Records," and QSP-16, "Records Maintenance Procedure," for the storage and preservation of records. Additionally, single copy QA records were stored in one-hour fire rated cabinets while others were only stored in standard, non-fire rated metal file cabinets at Tioga's facilities in Easton, PA and Philadelphia, PA.

During the August 2009 inspection, the NRC inspectors concluded that Tioga's completed corrective actions were responsive to the Notice of Violation (NOV) 99900879/2008-201-01, and Notices of Nonconformance (NON) 99900879/2008-201-01, 99900879/2008-201-02, 99900879/2008-201-03, and 99900879/2008-201-04. These issues were adequately resolved and in compliance with the applicable requirements of 10 CFR Part 21 and 10 CFR Part 50, Appendix B. The corrective actions in response to NON 99900879/2008-201-05 were not effective in assuring compliance with 10 CFR Part 50, Appendix B. As described later in this inspection report, NON 99900879/2008-201-05 has been closed with a new NON being issued to address the staff's concern with records retention at Tioga.

Nonconformance 99900879/2009-201-01

During this inspection, the NRC inspectors identified Nonconformance 99900879/2009-201-01 as a result of Tioga's failure to meet an NRC requirement imposed through procurement documents from its customers. Specifically, the NRC inspectors found that Tioga's Quality System Procedure (QSP)-16, "Record Maintenance Procedure," failed to document controls for quality assurance (QA) record retention requirements (i.e., duration, location and assigned responsibility) including the types of QA records that shall be stored in 2-hour fire rated cabinets at Tioga.

When the inspectors identified this finding during the inspection, Tioga prepared Condition Report (CR) 2009-21, dated August 11, 2009, to initiate corrective action to update QSP-16 to include QA record retention requirements including the types of QA records that shall be stored in 2-hour fire rated cabinets at Tioga. Tioga anticipates completing this corrective action by April 30, 2010.

The NRC inspectors found that Tioga failed to complete corrective action to address a previously identified deficiency in QSP-16 to document controls for QA record retention requirements including the types of QA records that shall be stored in 2-hour fire rated cabinets at Tioga. As such, QSP-16 does not meet the requirements in 10 CFR Part 50, Appendix B, Criterion XVII, "Quality Assurance Records." Therefore, this issue has been identified as Nonconformance 99900879/2009-201-01.

REPORT DETAILS

1. REVIEW OF CORRECTIVE ACTIONS - VIOLATION 99900879/2008-201-1

During the March 2008 NRC inspection of Tioga, the NRC inspectors found that Tioga failed to establish appropriate controls or procedures to assure that records were prepared and maintained as required by 10 CFR 21.51, "Maintenance and Inspection of Records."

This issue was identified as Violation 99900879/2008-201-01.

a. Inspection Scope

To verify that Tioga took corrective action to resolve this NOV, the NRC inspectors reviewed the following Tioga documents:

- Tioga Response Letter to the NRC, dated June 6, 2008, Corrective Action Report (CAR) 286, dated May 2, 2008
- Quality System Procedure (QSP)-16, Records Maintenance Procedure, Revision 11, dated June 4, 2008

b. Observations and Findings

The NRC inspectors reviewed CAR 286 and Tioga QSP-16, Revision 11 and found the following new information in QSP-16, Step 2.11:

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:

- Evaluation of deviations and failures to comply for a minimum of 5 years after the date of the evaluation;
- Notification sent to purchasers and affected licensees for a minimum of 5 years after the notification; and
- Records of purchasers of basic components for 10 years after delivery of the basic component or service associated with a basic component.

The NRC inspectors found these changes acceptable since they meet the requirements in 10 CFR 21.51.

c. Conclusions

The NRC inspectors concluded that the corrective actions Tioga implemented in response to NOV 99900879/2008-201-01 were consistent with the regulatory requirements of 10 CFR Part 21.51. Therefore, Violation 99900879/2008-201-01 is closed.

2. REVIEW OF CORRECTIVE ACTIONS - NONCONFORMANCE 99900879/2008-201-01

During the March 2008 NRC Vendor Inspection, the NRC inspectors found the following examples where document control requirements were not met contrary to the requirements in 10 CFR Part 50, Appendix B, Criterion VI, "Document Control," and QSM Section 6.0, "Document Control:"

- On March 5, 2008, the NRC inspectors found instances where processes that Tioga had implemented for QSM distribution and revision control were not performed in accordance with QSP-14.
- On March 6, 2008, the NRC inspectors found an inconsistency between Tioga's QSM and an associated QSP. Although QSP-21, "Auditor Training and Qualification Procedure," Revision 4, stated that the QA Manager will annually review Lead Auditor qualifications, Tioga's QSM stated that Lead Auditor certificates of qualification will be assessed annually by either the QA Manager, the Executive Vice President, or another qualified Lead Auditor. Tioga failed to implement formal document control measures to assure uniformity between guidance provided in the QSM and guidance presented in their QSPs.
- On March 7, 2008, the NRC inspectors found that although two copies of the Testing Instructions (TIs) were verbally identified as "controlled copies" by Tioga's QA manager, the TI Distribution Log did not specify that any of these copies were controlled. Also, the inspectors noted that the physical copies carried no formal identifiers, such as a control number or controlled copy stamping. Therefore, the NRC inspectors were unable to identify any formal procedural measures for; 1) the control and maintenance of controlled copies of the TIs, 2) revision of TIs, or 3) assurance that the TIs used at the various Tioga work and test sites were the latest revisions.
- On March 7, 2008, the NRC inspectors reviewed TI-3, "Tension Testing," Revision 1, and noted that each tension test performed shall be documented on Form TI-3.1. Although "Form TI-3.1" was listed as an attachment to TI-3, the form was not attached to the controlled copy of the TI found in Tioga's Philadelphia office.
- In accordance with Tioga's QSM and QSP-14, "Quality System & Quality Inspection Manual Control Procedure," Revision 7, when a revision is made to Tioga's QSM, "controlled QSM" manual holders are to receive a notification of the revision. The manual holders are then required to acknowledge receipt of the revision within a 15 work-day time period. However, on March 5, 2008, the NRC inspectors found that two receipt responses from employees at Tioga's Tennessee facility, regarding a December 2006 QSM revision, were recorded after the 15 work-day time period allowed by the QSP. Tioga personnel failed to take the required corrective actions that were called for in the QSP.
- On March 4, 2008, the NRC inspectors found that Tioga QA department personnel retained acknowledgments of the receipt of revised Tioga procedures instead of destroying them as required by QSP-15, "Quality System Procedure Control Instruction," Revision 9.

Inspection Scope

To verify that the above examples of inadequate document control were resolved, the NRC inspectors reviewed the following documents:

- Tioga Quality System Manual (QSM), "Quality Systems Program," Revision 10, dated November 27, 2006
- Tioga Response Letter to the NRC dated June 6, 2008, CAR 282 dated March 7, 2008
- Tioga QSP-14, "Quality System & Quality Inspection Manual Control Procedure," Revision 7, dated October 10, 2003
- Tioga QSP-15, "Quality System Procedure Control," Revision 10, dated August 6, 2008
- Tioga Form QSP 15.2, "Quality System Procedure Revision Distribution Log"
- Tioga QSP-21, "Auditor Training and Qualification Procedure," Revision 5, dated June 4, 2008.
- Tioga Testing Instruction (TI)-1, "Hydrostatic Test Procedure," Revision 2, dated July 15, 2008
- Tioga TI-2, Spectrometric Analysis, Revision 2, dated June 23, 2008
- Tioga TI-3, Tension Testing, Revision 2, dated September 23, 2008

b. Observations and Findings

Tioga's June 6, 2008, response letter stated:

The date signed (approval date) in several cases is later than the revision date. It is appropriate for the approval date to be later than the prepared date to allow time for reviews.

Tioga did not consider this an issue requiring corrective action nor was any revision made to the QSM and QSP-14. The NRC inspectors found this Tioga response is acceptable; therefore, this issue is closed.

Tioga's June 6, 2008, response letter stated:

Often the QSPs are intentionally more restrictive than the QSM. Tioga considers this a prudent practice to enable us to consistently meet our commitments. However, QSP-21 has been revised to include a provision for approval of a Lead Auditor when it is the QA Manager and to correct conflicts between the QSM and QSP-21.

The NRC inspectors reviewed QSP-21, Revision 5. Tioga revised QSP-21, Section 8.0, "Certification Records," to add Step 8.1 relative to certifying lead auditors:

Lead Auditors and Auditors may only be certified by the QA Manager or a Qualified Lead Auditor. Training, indoctrination/instruction and examination may be performed either by the QA Manager, or his designee.

The NRC inspectors found this acceptable to resolve inconsistencies between the QSM and QSP-21, therefore, this issue is closed.

Tioga's June 6, 2008, response letter stated:

Previously test instructions had very limited distribution and did not change. Accordingly, Tioga Pipe Supply Co., Inc. did not realize the need for controlled copy numbers. In addition, test instructions were not within the scope of QSP-15 and as a result were never assigned controlled copy numbers.

QSP-15 will be revised by September 30, 2008, to include the methodology for preparation, review, changes, approval, periodic review, on the spot changes, and distribution for the QSPs, test instructions, and supporting procedures.

The NRC inspectors reviewed QSP-15, Revision 10, dated August 6, 2008, and found the following changes in QSP-15, Step 3.1:

The QA Manager:

- Approves all procedures in support of the Nuclear Production department activities.
- Distributes and assures implementation of procedures which support the Quality Program.

In QSP-15, Revision 10, Tioga added Steps 5.1.1, 5.1.2, 5.12 and 5.13 that state:

- The QA manager will assign appropriate personnel to review new or revised procedures.
- Procedure review form will be used to document comments by reviewers. After comments have been satisfactorily resolved, concurrence of assigned reviewers will be indicated by signature on the cover page of documents within the scope of the procedure.
- All QSPs shall not be removed from the facility without prior written approval from management personnel addressed within the Quality Program.
- The Tioga initiator can perform spot changes to procedures. Both the initiator and the QA manager will initial and date the change indicating approval.

Additionally, Tioga uses QSP-15, Form QSP-15.2, "Quality System Procedure Revision Distribution Log," to submit a transmittal letter with letter date noting procedures revised and revision date. The form contains the control number, transmittal date, response date and recording person.

Based on these changes to QSP-15, the NRC inspectors found Tioga's response is acceptable; therefore, this issue is closed.

Tioga's June 6, 2008, response letter stated:

Tioga Pipe Supply revised the procedure but the attachment was not revised. Inadvertently, the attachment was discarded without assuring its inclusion in the revised procedure.

An audit of all controlled copies of TI-3 has been conducted and Form TI-3.1 has been attached to the procedure.

The NRC inspectors reviewed TI-3, Revision 2, and found Form TI-3.1 attached to the procedure; therefore, this issue is closed.

Tioga's June 6, 2008, response letter stated:

The date in the log was the actual entered date. In reality, notification of receipt was received within the 15 day time period as required but not entered into the log until approximately two weeks later due to other work priorities.

The individual involved was counseled on the need to record the receipt date of the Acknowledgment versus the actual date the information is entered. No further action is required.

The NRC inspectors found Tioga's response is acceptable; therefore, this issue is closed.

Tioga's June 6, 2008, response letter stated:

Although the practice is not in compliance with QSP-15, QA department personnel considered the information contained on the forms to have value and thus retained them. QSP-15 will be revised by September 9, 2008, to delete the requirement for destruction of the receipt acknowledgement forms.

The NRC inspectors found that there is no requirement in Appendix B, Criterion VI, for destruction of receipt acknowledgement forms. Tioga stated that they plan to keep the receipt acknowledgement forms since it documents the latest controlled copies of procedures sent to Tioga management and staff. The NRC inspectors found Tioga's response is acceptable; therefore, this issue is closed.

The NRC inspectors found Tioga responses and procedure changes to the examples noted above are acceptable; therefore, Nonconformance 99900879/2008-201-01 is closed.

c. Conclusions

The NRC inspectors concluded that the corrective actions Tioga implemented in response to Nonconformance 99900879/2008-201-01 were consistent with the regulatory requirements in 10 CFR Part 50, Appendix B, Criterion VI, "Document Control." Therefore, Nonconformance 99900879/2008-201-01 is closed.

3. REVIEW OF CORRECTIVE ACTIONS - NONCONFORMANCE 99900879/2008-201-02

Contrary to the requirements in 10 CFR Part 50, Appendix B, Criterion XI, "Test Control" the NRC inspectors found the following examples where test control requirements were not met during the March 2008 NRC vendor inspection:

- On March 6, 2008, NRC inspectors found that Tioga personnel performing tension testing in accordance with Tioga Testing Instruction 3 (TI-3), "Tension Testing," Revision 1, did not perform step 6.6.2, performed steps 7.1 through 7.3 out of sequence, and performed step 7.4 incorrectly.
- On March 5, 2008, the NRC inspectors found an unanalyzed, "dirty water" supply was used for conducting hydrostatic test activities at Tioga's Easton, PA facility. Exposing test piping to this environment could be detrimental to austenitic stainless steel material.
- On March 5, 2008, the NRC inspectors found the acceptance criteria of TI-1, "Hydrostatic Testing," Revision 1, required holding hydrostatic pressure for a specified "hold time." However, TI-1 does not require testing personnel to document maximum allowable test pressure or use an appropriate time measuring device to record the start and stop times of the "hold time."
- On March 5, 2008, the NRC inspectors found that QSP-36, "Ultrasonic Thickness Gauging," Revision 2, did not require a post-test calibration check of the thickness instrument to verify that the instrument does not drift outside its calibration range during testing. This calibration check is specified in the test equipment manufacture's operating instructions.

a. Inspection Scope

To verify that the above examples of inadequate test control were resolved, the NRC inspectors reviewed the following:

- Tioga's Response Letter to the NRC, CAR 279, Revision 1, dated August 28, 2008
- TI-1, "Hydrostatic Pressure Testing," Revision 2, dated July 15, 2008
- TI-3, "Tension Testing," Revision 2, dated September 23, 2008
- QSP-36, "Ultrasonic Thickness Gauging," Revision 3, dated June 4, 2008

b. Observations and Findings

In Tioga's response letter to the NRC staff, Tioga initiated CAR-279, Revision 1, to address the nonconformance. Based on CAR 279, Revision 1, the NRC inspectors verified effective implementation of corrective actions.

In CAR 279, Revision 1, Item 1, Tioga personnel determined that although the steps taken by the test personnel deviated slightly from the sequence in TI-1, Revision 1, they are still within the judgment of the "skill of the craft" and were conducted by a qualified test engineer. Tioga committed to revise TI-3 to allow test personnel more flexibility when applicable.

The NRC inspectors reviewed TI-3, Revision 2 and found the following wording was added:

Steps in this procedure may be conducted out of sequence at the discretion of the qualified tester as long as all steps are completed.

The NRC inspectors found this acceptable based on the skill and experience of the personnel performing the testing at Tioga.

In response to item 2 identified in Nonconformance 99900879/2008-201-02, Tioga had the water analyzed in the two tanks used for hydrostatic testing and discontinued the practice of using tank water for stainless steel piping. In addition, TI-1, "Hydrostatic Pressure Testing," Revision 2, July 15, 2008, added "NOTE - Only potable water shall be used for testing stainless steel pipe and tubing." ASTM standard specifications do not address the water quality to be used for hydrostatic testing. Discussions with Tioga personnel stated that purchase orders have not required hydrostatic testing using high quality water. Final cleaning is performed using Quality System Procedure, QSP-7, "Final Cleaning and Preservation Procedure," Revision 6, dated October 11, 2000. Only final cleaning for certain materials requires water purity requirements which are addressed in QSP-7. QSP-7 meets water purity requirement in NQA-1. The requirements for water quality when performing the hydrostatic test is determined by the customer and is included as part of the purchase order.

The NRC inspectors find that the use of potable water for hydrostatic testing stainless steel pipe and tank water for hydrostatic testing carbon steel pipe is acceptable consistent with the customer requirements in purchase orders and procurement documents.

The NRC inspectors reviewed the revisions to TI-1, "Hydrostatic Pressure Testing," Revision 2, dated July 15, 2008. The test instruction was revised to require documentation of maximum allowable test pressure and the use of an uncalibrated timepiece using the conservative hold time of 15 seconds. The test instruction and test record was also revised to require recording the test pressure hold time duration.

The NRC inspectors reviewed QSP - 36, "Ultrasonic Thickness Gauging," Revision 3 dated June 4, 2008, which added Step.9.4 "A post inspection calibration check must be performed after the inspection is complete; verify the reading at the calibration location has not drifted. If necessary, recalibrate and re-perform all inspections." The NRC staff observed the Tioga personnel perform testing using the revised procedure and finds the changes to be satisfactory.

The NRC inspectors found Tioga's responses and procedure changes to the four items identified in Nonconformance 99900879/2008-201-02 were acceptable; therefore, Nonconformance 99900879/2008-201-02 is closed.

c. Conclusions

The NRC inspectors concluded that the corrective actions implemented in Tioga' response to the four items in Nonconformance 99900879/2008-201-02 were consistent with the requirements in 10 CFR Part 50, Appendix B, Criterion XI, "Test Control;" Therefore, Nonconformance 99900879/2008-201-02 is closed.

4. REVIEW OF CORRECTIVE ACTIONS - NONCONFORMANCE 99900879/2008-201-03

Contrary to the requirements in 10 CFR Part 50, Appendix B, Criterion XIII, "Handling, Storage, and Shipping" the NRC inspectors found the following two examples where handling, storage, and shipping requirements were not met during the March 2008 NRC vendor inspection:

- On March 5, 2008, NRC inspectors identified four examples of austenitic stainless steel coming into direct contact with non-stainless steel metal pins and unapproved and "unqualified" taping material at Tioga's Easton, PA facility.
- QSP-10, "Final Material Inspection Procedure," Revision 10, describes Tioga's process for the shipping of materials. On March 6, 2008, the NRC inspectors found that Tioga staff did not follow QSP-10 when a purchase order item was shipped to a customer with the wrong document package.

a. Inspection Scope

To verify that these examples of inadequate handling, storage, and shipping were resolved, the NRC inspectors reviewed the following:

- Tioga Response Letter to the NRC, dated June 6, 2008, CAR 283, dated March 6, 2008
- QSP-6, "Handling and Storage Procedure," Revision 6, dated June 5, 2008
- QSP-10, "Final Material Inspection Procedure," Revision 10, dated October 11, 2000
- Standard Operating Procedure 202, "Nuclear Order Processing," Revision 3, dated April 2, 2009

b. Observations and Findings

In Tioga's response letter dated June 6, 2008, to the NRC staff, Tioga initiated CAR-283 to address the nonconformance. Based on CAR 283, the NRC inspectors verified effective implementation of the following corrective actions:

- QSP-6, "Handling and Storage Procedure," Revision 6, dated June 5, 2008, addressed the use of using carbon steel spring clips on carbon steel piping and stainless steel clips on stainless steel piping. This revision of QSP-6 also addresses potential sources of contamination and the use of approved tapes by warehouse personnel and monitored by the Quality Assurance Department. The NRC inspectors noted that the CAR-283 states that "Controls on the use of approved tapes and other potential sources of contamination have been included in a recent revision of QSP-6." QSP-6 did not specifically address the controls for the use of approved tapes and adhesives. The NRC inspectors asked Tioga what controls they have in place. Tioga stated that only one type of tape is used at the Tioga Easton, PA warehouse. Tioga supplied the NRC inspectors with Covalence Adhesives Nuclear Certification for Lot Number 7151 dated August 27, 2007. The certification states that the tape meets the requirements of Nuclear Specifications: ANSI N45.2.2 and NRC RG 1.38, Regulatory Position 2C Division A.3.5.2 (1)(A) and ASME NQA-1. The NRC inspectors found that this response was acceptable.

- In CAR-283, Tioga states that “A process change has recently been implemented to enhance the guidance in QSP-10. This requires a sign-off by Nuclear Production personnel after ensuring inclusion of appropriate documentation with the order. Personnel have been trained on the process change as well as the importance of ensuring that documentation is enclosed for all line items. After the effectiveness of these changes has been demonstrated, Tioga will incorporate the practice into an appropriate procedure.”

Tioga incorporated these process changes into Standard Operating Procedure 202, “Nuclear Order Processing,” Revision 3, dated April 2, 2009. The NRC inspectors found this Tioga response was acceptable.

The NRC inspectors found Tioga’s responses and procedure changes to the two items identified in Nonconformance 99900879/2008-201-03 were acceptable; therefore, Nonconformance 99900879/2008-201-03 is closed.

c. Conclusions

The NRC inspectors concluded that the corrective actions implemented in Tioga’s response to the two items in Nonconformance 99900879/2008-201-03 were consistent with the requirements in 10 CFR Part 50, Appendix B, Criterion XIII, “Handling, Storage, and Shipping;” Therefore, Nonconformance 99900879/2008-201-03 is closed.

5. REVIEW OF CORRECTIVE ACTIONS - NONCONFORMANCE 99900879/2008-201-04

During the March 2008 inspection, the NRC inspectors identified Nonconformance 99900879/2008-201-04 documenting Tioga’s failure to adhere to the requirements in QSP-17, “Nonconformance Procedure,” Revision 7, Steps 4.5 and 4.6. These QSP-17 steps required Tioga to initiate a notice of nonconformance report (NCR) and a CAR. QSP-26, “Corrective Action Procedure,” Revision 8, also required Tioga to initiate a CAR form after repetitive non-conformances have occurred.

a. Inspection Scope

The inspectors reviewed Tioga’s corrective actions associated with Nonconformance 99900879/2008-201-04. The NRC inspectors reviewed the following procedures, records, and other documents:

- QSP-26, “Condition Reporting Procedure,” Revision 9, dated March 26, 2009
- Tioga Response Letter to the NRC CAR 281, Revision 1, dated August 28, 2009
- Corrective Action Reports issued from March 2008 thru March 2009
- Condition Reports issued from April 2009
- Condition Reports Log
- Condition Review Group meeting minutes

b. Observations and Findings

In Tioga's response letter to the NRC, Tioga initiated CAR 281, Revision 1 to address the nonconformance and to identify corrective actions to prevent recurrence. Based on CAR 281, Revision 1, the inspectors verified that Tioga completed commitments to implement NRC requirements to resolve NON 999000879/2008-201-04. The completion date stipulated in CAR 281, Revision 1 was October 30, 2008, but it was not until March 2009 that the corrective actions were completed.

The NRC inspectors asked Tioga if Part 21 evaluations of past issues were conducted in order to assess the extent of condition of any issues related to possible Part 21 notifications to customers. Tioga stated that further review of Tioga's NCRs and CARs, when determining Part 21 applicability, indicated that Part 21 evaluations were not issued since no defects or deviations from technical requirements were found.

The NRC inspectors reviewed NCRs and CARs issued from October 2008 thru March 2009. The NRC inspectors found that the quantity of NCRs and CARs significantly increased since NRC's March 2008 inspection. However, it was not until March 2009, that Tioga revised QSP-26 to address NRC issues related to completion of evaluations for Part 21 applicability in Tioga Condition Reports (CRs). In QSP-26, the CR process replaced the CAR process.

The CR process identified the following information, as applicable:

- The code, procedure, or specification requirement violated
- The details of the actual condition(s)
- The entity responsible for correction action (vendor or individual)
- Requested reply date for corrective action
- Probable cause and corrective action
- Date for completion of corrective action
- Individual issuing corrective action
- Verification of corrective action

In Tioga's August 28, 2008, response letter to the NRC, Tioga stated that the following enhancements will be included in the proposed revision to QSP-26:

- The program will change to a Condition Reporting System for the identification of any issue by any Tioga employee.
- A Management Review Group (MRG) will be used to determine significance levels, and Part 21 applicability.

- The MRG will determine if NCRs should be generated as a result of the identified condition. The Tioga procedure will continue to drive issuance of a CR with appropriate significance level when the applicable determination is made.

The NRC inspectors found that Tioga changed its CAR Procedure to a CR Procedure in that “All Tioga employees who are involved in activities covered under our Quality Systems Manual are encouraged to identify and report conditions adverse to quality, safety, or material condition. The condition reporting system may also be used to identify potential areas for improvement.”

The NRC inspectors found that QSP-26 describes use of a Condition Review Group (CRG) instead of the use of a MRG. The Tioga staff completed CRs that are evaluated and reported to the CRG. The QA manager chairs the CRG group and has the authority to initiate immediate corrective actions for new issues.

The NRC inspectors also found some editorial errors in CRG meeting minute documents. Although the CR process complies with the corrective actions in 10 CFR Part 50, Appendix B, Criterion XVI, “Corrective Action,” Tioga staff stated that improvements could be made to CRG meeting minute documents to accurately reflect corrective actions taken in CRs. The CRG meeting minute documents by itself raises confusion as to who made the decision on closed CRs. The examples included:

- CR 2009-03, 2009-04, 2009-09, 2009-10 have close out dates before their respective CRG meeting dates.
- CR 2009-08, although still open, is categorized as a significance level A in the CR, but the meeting minute had a significance level B, again allowing for confusion between document meeting minutes and the condition report.

Tioga stated that CRG meeting minutes are planning tools to resolve corrective action in CRs and are not QA records; thus, the NRC inspectors should focus on the accuracy of QA records such as NCRs and CRs.

In Tioga August 28, 2008, response letter, Tioga made the following commitment:

- The MRG will determine if NCRs should be generated as a result of the identified condition.

The NRC inspectors found that this commitment did not result in any change to QSP-26. The Tioga QA manager stated that it was never its intent to make the CRG responsible for generating NCRs. All Tioga staff, not the Tioga CRG, generate NCRs when issues are identified justifying issuance of an NCR. The Tioga CRG only needs to review NCRs for trends related to needed corrective action. The NRC inspectors found this response acceptable since Tioga’s process for generating NCRs in QSP-17, “Nonconformance Procedure,” meets the requirements in 10 CFR Part 50, Appendix B, Criterion XV, “Nonconforming Material, Parts, or Components.”

The NRC inspectors found Tioga’s changes to QSP-26, Revision 9, acceptable since they meet the requirements in 10 CFR Part 50, Appendix B, Criterion XVI, “Corrective Action,” for generating CRs or CARs. When assessing the training and implementation of the changes made to QSP-26, the NRC inspectors reviewed training logs and emails related to Tioga staff

training. The inspectors verified Tioga administrative and technical staff received and understood training related to changes made in QSP-26, Revision 9.

Based on the information provided above, the NRC inspectors found that changes made to QSP-26, including training provided to Tioga staff, closed Nonconformance 99900879/2008-201-04.

c. Conclusions

The NRC inspectors concluded that the corrective actions implemented in Tioga's response to the items in NON 99900879/2008-201-04 were consistent with the requirements in 10 CFR Part 50, Appendix B, Criterion XVI, "Corrective Action;" Therefore, Nonconformance 99900879/2008-201-04 is closed.

6. REVIEW OF CORRECTIVE ACTIONS - NONCONFORMANCE 99900879/2008-201-05

During the March 2008 inspection, the NRC inspectors identified Nonconformance 99900879/2008-201-05 because Tioga's QSM Section 17.0, "Quality Assurance Records," and QSP-16, "Records Maintenance Procedure," Revision 10, dated October 10, 2003, failed to specify the requirements for the storage and preservation of QA records. Additionally, some single copy QA records were stored in one-hour fire rated cabinets while others were stored in standard, non-fire rated metal file cabinets at Tioga's facilities in Easton, PA and Philadelphia, PA.

a. Inspection Scope

The inspectors reviewed Tioga's corrective actions associated with Nonconformance 99900879/2008-201-05 identified during the March 2008 NRC inspection. Within the scope of this area of the inspection, the NRC inspectors reviewed the following procedures, records, and other documents:

- Tioga Response Letter to the NRC, CAR 280, Revision 1, dated August 28, 2009
- QSM Section 17, "Quality Assurance Records," Revision 8
- QSP-16, "Record Maintenance Procedure," Revision 11, dated June 4, 2008
- Tioga Response Letter to the NRC, dated August 12, 2008, CAR 280, Revision 1
- NUPIC Deviation Report 2009V-09-05, dated June 25, 2009

b. Observations and Findings

During this inspection, the NRC inspectors found that a new 2-hour fire rated cabinet was installed at Tioga facility in Easton, PA for the storage of QA records. Tioga also informed the NRC inspectors that a new 2-hour fire cabinet for the storage of QA records was installed at the Tioga Philadelphia, PA facility. The NRC inspectors found that the 2-hour fire cabinets were acceptable.

However, during this inspection, the NRC inspectors found that QSP-16, Revision 11 failed to define storage location and retention (duration) requirements for QA records including the types of QA records that shall be stored in 2-hour fire rated cabinets at Tioga facilities.

The Tioga QA manager recalled that a NUPIC audit conducted in June 2009 identified an issue with the protection of QA records. Therefore, the QA manager provided the NRC inspectors with a copy of NUPIC Deviation Report No. 2009V-09-05. The NUPIC Deviation Report stated: Contrary to the above requirements, based on review of QSM-17, Rev 8, dated 10/17/05, "QA Records" and QSP-16, Rev 11, dated 6/04/08, "Record Maintenance Procedure," the following deficiencies were identified:

- The QSM and QSP need to clearly define what documents Tioga considers to be QA records i.e., the following conflicting information regarding what is considered to be a QA Record requires corrective/clarification; QSM Section 17.1.4 identified 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."
- QA Record storage location(s) and responsibilities need to be clearly defined/clarified. At the time, several quality records are being maintained at the Easton, PA location. It was also found that some quality records were being maintained at the Philadelphia office. The QSM and QSP require revision to define storage location requirements for the various types of records (including archiving) and responsibilities for maintaining the records.
- QSP needs to identify storage requirements. QSP-16 currently identifies storage of records within metal filing cabinets. In response to NRC NON 999000879/2008-201-05, Tioga Pipe issued CAR 280, Rev 1, (dated 9/08/08) which resulted in the procurement of 2-hour fire rated 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 different locations.

Tioga failed to take any corrective action to address these issues when it was reported. Based on this NRC inspection finding, Tioga initiated CR 2009-21, dated August 11, 2009, to address corrective actions to update QSP-16 to include QA record retention requirements including the types of QA records that shall be stored in 2-hour fire rated cabinets at Tioga. Tioga committed to complete this corrective action by April 30, 2010.

The NRC inspectors found that QSP-16 failed to document the QA controls for record retention (i.e., duration, location and assigned responsibility) requirements including the types of QA records that shall be stored in 2-hour fire rated cabinets at Tioga. This issue is not consistent with the requirements in 10 CFR Part 50, Appendix B, Criterion XVII, "Quality Assurance Records." This issue has been identified as Nonconformance 99900879/2009-201-01.

c. Conclusions

The NRC inspectors concluded that Tioga implemented corrective action by installing 2-hour fire rated cabinets at Tioga facilities for storing QA records. This was sufficient to conclude that Nonconformance 99900879/2008-01-05 could be closed.

However, the NRC inspectors concluded that QSP-16 failed to document the QA controls for record retention (i.e., duration, location and assigned responsibility) requirements including the types of QA records that shall be stored in 2-hour fire rated cabinets at Tioga. This issue is not consistent with the requirements in 10 CFR Part 50, Appendix B, Criterion XVII, "Quality Assurance Records." This issue has been identified as Nonconformance 99900879/2009-201-01.

ATTACHMENT

1. ENTRANCE/EXIT MEETING ATTENDEES AND KEY PERSONS CONTACTED

NAME	ORGANIZATION	TITLE	ENTRANCE	EXIT	INTERVIEWED
Robert Cahill	TIOGA	Vice President of Operations	√	√	
Steve DiMauro	TIOGA	Quality Assurance Manager	√	√	√
Nick Tambakis	TIOGA	Quality Control Supervisor	√	√	
Rich Crowley	TIOGA	Operations Manager	√	√	√
Gerald Gruver	TIOGA	Test Engineer			√
Lisa Smith	TIOGA	Quality Assurance Technician			√
Jill Allen	TIOGA	Quality Assurance Technician			√
Kory Sandt	TIOGA	Nuclear Warehouse Technician			√
Tony Cox	TIOGA	Nuclear Warehouse Technician			√
Cathy Hamilton	TIOGA	Inventory Control Administrator			√
Frank Talbot	USNRC	Lead Inspector	√	√	
Andrea Keim	USNRC	Inspector	√	√	
Carolyn Faria	USNRC	Inspector	√	√	
Kevin Nietmann	USNRC	OIG Technical Advisor	√	√	
Michael Zeitler	USNRC	OIG Senior Management Analyst	√	√	

2. INSPECTION PROCEDURES USED

Inspection Procedure 36100, "Inspection of 10 CFR Part 21 and 10 CFR 40.55(e) Programs for Reporting Defects and Noncompliance"

Inspection Procedure 43002, "Routine Inspections of Nuclear Vendors."

3. LIST OF ITEMS OPEN, CLOSED AND DISCUSSED

<u>Item Number</u>	<u>Status</u>	<u>Type</u>	<u>Description</u>
99900879/2008-201-1	Closed	NOV	Violation of 10 CFR 21.51
99900879/2008-201-1	Closed	NON	10 CFR 50, Appendix B, Criterion VI
99900879/2008-201-2	Closed	NON	10 CFR 50, Appendix B, Criterion XI
99900879/2008-201-3	Closed	NON	10 CFR 50, Appendix B, Criterion XII
99900879/2008-201-4	Closed	NON	10 CFR 50, Appendix B, Criterion XVI
99900879/2008-201-5	Closed	NON	10 CFR 50, Appendix B, Criterion XVII
99900879/2009-201-1	Open	NON	10 CFR 50, Appendix B, Criterion XVII