



P.O. Box 185
Twin Lakes Road
North Branford, CT 06471

November 30, 2009

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

Attention: Document Control Desk

Cc: Director, Division of Engineering
Raymon Serman, CEO, Prime Technology LLC

Subject: Response to Inspection Report No. 99901382/2009-201-01.

Reply to Notice of Violation 99901382/2009-01.

The violation is for procedural guidance not appropriate for evaluating Part 21 deviations. Prime Technology LLC (Prime) Procedure 5.3 (Reporting of Defects and Non-Conformances) was derived from legacy documentation dating back to the 1970's. International Instruments (II) developed the original procedure prior to acquisition by Prime. Licensees had previously reviewed procedure 5.3 and the previous II procedure for content without comment in any previous audits.

Corrective actions:

- A) A procedure on the generation and issuing of a Failure Report shall be written and released.
- B) Corrective Action Requests (CAR), Material Review Reports (MRR), and Returned Material Authorization (RMA) forms shall be revised to incorporate Part 21 Defect Reporting.
- C) Quality Manual (QM) Procedures 2.7 (Corrective Action), and 4.5 (Disposition / Corrective Action for Non-Conforming Material) shall be revised to include a process to initiate evaluations for Part 21 compliance.
- D) Procedure 5.3 was reviewed and edited by NRC personnel for compliance.
- E) Training for personnel associated with Part 21 requirements shall be conducted. The training shall be for Administration, Quality, Sales, and Test departments. Training shall consist of a review of requirements and procedural instruction. The training shall include the definition of what constitutes a Part 21 Deviation. An abbreviated training session shall be held for remaining personnel to provide an understanding of Part 21 and how to report a possible deviation to management. New personnel shall be trained within a reasonable time frame, but before performing any function related to Part 21.
- F) Prime shall conduct a semiannual review for revisions / updates to requirements by monitoring the NRC and NUPIC websites.

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Corrective action shall be in place by March 31, 2010.

Reply to Notice of Non-Conformance 99901382/2009-201-02.

The Non-Conformance is for corrective actions not closed in a timely manner.

Business conditions required personnel reductions starting in the year 2005. The reductions included the staff engineer from the Quality department. CARs are the responsibility of the Quality Engineer. The process of documenting and timely closing of such corrective action has been delinquent due to loss of staff and workload in the Quality department.

The Quality Department has been reorganized as of October 2009. Test Technicians report to the Production Manager and a Test Engineer reports to the Chief Technology Officer. A Quality Staff Engineer has been hired and is presently receiving training in the operations of the Quality Department.

CAR forms shall now document all corrective actions from internal or outside auditors. QM Procedures 2.7, 4.5, and 5.1 (Return Authorization) shall be updated for compliance to Criterion XVI of Appendix 'B'.

Corrective action shall be in place by March 31, 2010.

Reply to Notice of Non-Conformance 99901382/2009-201-03.

The Non-Conformance is for Prime Procedures 2.7 and 4.5. The procedures do not establish measures to identify deviations.

Reference paragraph one of 'Reply to Notice of Violation 99901382/2009-01'. This paragraph states the reason for non-compliance.

QM Procedures 2.7 and 4.5 and associated forms shall be revised for compliance to Part 21.

Corrective action shall be in place by March 31, 2010.



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Reply to Notice of Non-Conformance 99901382/2009-201-04.

The Non-Conformance in Prime's QM does not contain a procedure for dedication of Safety Related products and materials as a controlled activity under 10 CFR Appendix B.

As of August 13, 2009 all safety related products receive a documented in-process inspection prior to testing. The Quality department reorganization eliminates the confusion of sending material directly to test since the Test department no longer reports to the Quality Manager.

A procedure delineating 'Dedication' shall be written and added to the QM. The procedure shall outline the responsibilities by department for dedication of Safety Related products and materials

Corrective action shall be in place by March 31, 2010.

Reply to Notice of Non-Conformance 99901382/2009-201-05.

The Non-Conformance is Prime's failure to document justification for design process change.

No legacy documentation exists from II on reduction in burn-in times, or early revisions to QAP 101 (Workmanship Standard Soldering Techniques and Layout of Components).

The latest revision of QAP 101 was to update the document to present industry standards.

An industry standard was used and approved by the licensee to reform capacitors that were not readily available.

Engineering shall review and document justification for the changes described above. The documented justification shall be filed in the Quality department files along with a digital copy stored on the company intranet.

Corrective action shall be in place by March 31, 2010.

Reply to Notice of Non-Conformance 99901382/2009-201-06.

The Non-Conformance is Prime's failure to establish and implement a program for indoctrination and training of personnel performing activities affecting quality as necessary to assure proficiency is achieved and maintained.



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QAP 101, 104 (Rejection Tag), and 115 (Personnel Training) shall be revised to reflect training procedures initiated by department for processes that are specified as requiring special skills such as soldering, wire bonding, painting, etc.

Training shall be documented and performed by the responsible department manager or his designee. The Quality department shall schedule and monitor training. The documented training shall be filed in the Quality department files along with a digital copy stored on the company intranet.

A training schedule shall be in place by January 29, 2010. A training procedure starting with soldering shall be completed by February 28, 2010. Training for soldering shall be complete by March 31, 2010. Training in other departments shall run in parallel such as painting. Training for the balance of identified special skill training shall be complete by December 15, 2010.

Reply to Notice of Non-Conformance 99901382/2009-201-07.

The Non-Conformance is Prime's failure to establish adequate measures for the revision and approval of documents that prescribe activities affecting quality.

Final Inspection Procedures FIS1000 -1151 / 1251 and - 9270 shall be reviewed and the cover sheets initialed by the Quality Manager to comply with previous quality document reviews.

Procedure 810-033 Engineering Documentation and Release Process, revision 'C' is presently under going rewrite and shall include the statement 'for all documents that prescribe activities affecting quality shall be controlled by this procedure'.

This shall place quality documentation under the same ECN (Engineering Change Notification) procedure for engineering and production documentation.

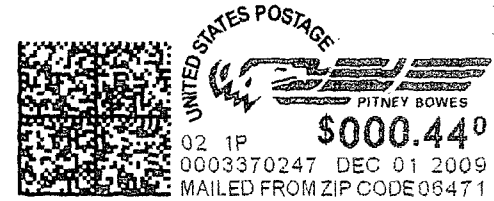
Corrective action shall be in place by January 31, 2010.

Sincerely,

Paul Grabek
Quality Manager
Prime Technology LLC



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