September 24, 2009

Mr. Raymond S. Sterman, Chairman
Prime Technology, LLC
344 Twin Lakes Road
North Branford, CT 06471

SUBJECT: NRC INSPECTION REPORT NO. 99901382/2009-201, NOTICE OF VIOLATION AND NOTICE OF NONCONFORMANCE

Dear Mr. Sterman:

From August 11 to August 14, 2009, the U.S. Nuclear Regulatory Commission (NRC) conducted an inspection at the Prime Technology, LLC (Prime) facility in North Branford, Connecticut. The enclosed report presents the results of this inspection.

This was a limited scope inspection, which focused on assessing your compliance with the provisions of Part 21 of Title 10 of the *Code of Federal Regulations* (10 CFR Part 21) "Reporting of Defects and Noncompliance," and selected portions of Appendix B to 10 CFR Part 50, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants." This NRC inspection report does not constitute NRC endorsement of your overall quality assurance (QA) or 10 CFR Part 21 programs.

Based on the results of this inspection, the NRC has determined that one Severity Level IV violation of NRC requirements occurred. The violation is cited in the enclosed Notice of Violation (Notice) and the circumstances surrounding it are described in detail in the subject inspection report. The violation is being cited in the Notice because NRC inspectors identified that Prime failed to meet the requirements set forth in 10 CFR Part 21 for procedures to evaluate deviations.

You are required to respond to this letter and should follow the instructions specified in the enclosed Notice when preparing your response. The NRC will use your response, in part, to determine whether further enforcement action is necessary to ensure compliance with regulatory requirements.

During this inspection, NRC inspectors also found that implementation of your QA program failed to meet certain NRC requirements contractually imposed on you by your customers. The NRC inspectors noted six deficiencies for: 1) failure of the corrective action/nonconformance process to identify deviations; 2) untimely corrective actions; 3) failure to establish an adequate process to perform commercial-grade dedication activities; 4) lack of documentation and technical justification for design process changes; 5) failure to implement an employee training program; and 6) lack of controls and approval for document changes. The specific findings and references to the pertinent requirements are identified in the enclosures to this letter.

Please provide a written explanation or statement within 30 days of this letter in accordance with the instructions specified in the enclosed Notice of Nonconformance.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter, its enclosures, and your response will be made available electronically for public inspection in the NRC Public Document Room or from the NRC's document system (ADAMS), accessible from the NRC Web site 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 is 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 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.

Sincerely,

Patrick Hiland ***/RA/***
Division Director
Division of Engineering
Office of Nuclear Reactor Regulation

Docket No.: 99901382

Enclosures:
1. Notice of Violation
2. Notice of Nonconformance
3. Inspection Report 99901382/2009-201

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter, its enclosures, and your response will be made available electronically for public inspection in the NRC Public Document Room or from the NRC's document system (ADAMS), accessible from the NRC Web site 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 is 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 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.

Sincerely,

Patrick Hiland ***/RA/***
Division Director
Division of Engineering
Office of Nuclear Reactor Regulation

Docket No.: 99901382

Enclosures: 1. Notice of Violation
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3. Inspection Report 99901382/2009-201

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NOTICE OF VIOLATION

Prime Technology, LLC
344 Twin Lakes Road
North Branford, CT 06471

Docket Number 99901382
Inspection Report No. 99901382/2009-201

Based on the results of a Nuclear Regulatory Commission (NRC) inspection conducted August 11 to August 14, 2009, of activities performed at Prime Technology LLC (Prime), one violation of NRC requirements was identified. In accordance with the NRC Enforcement Policy, the violation is listed below:

> 10 CFR Part 21, Section 21.21(a)(1), "Notification of failure to comply or existence of a defect and its evaluation," states in part that, "each individual, corporation, partnership, or other entity subject to 10 CFR Part 21 shall adopt appropriate procedures to evaluate deviations and failures to comply associated with substantial safety hazards as soon as practicable."
>
> Contrary to the above, as of August 14, 2009:
>
> Prime's 10 CFR Part 21 Procedure No. 5.3, "Reporting of Defects and Noncompliance," Revision 2, was not an appropriate procedure to ensure effective identification and evaluation of deviations and failures to comply associated with a substantial safety hazard. Specifically, Prime's Procedure 5.3 did not contain appropriate guidance on how to evaluate deviations.

This issue has been identified as Violation 99901382/2009-201-01.

This is a Severity Level IV violation (Supplement VII).

Pursuant to the provisions of 10 CFR 2.201, "Notice of Violation," you are required to submit a written statement or explanation to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555-0001, with a copy to the Director, Division of Engineering, Office of Nuclear Reactor Regulation, within 30 days of the date of the letter transmitting this Notice of Violation. This reply should be clearly marked as a "Reply to a Notice of Violation" and should include: (1) the reason for the violation, or, if contested, the basis for disputing the violation; (2) the corrective steps that have been taken and the results achieved; (3) the corrective steps that will be taken to avoid further violations; and (4) the date when full compliance will be achieved. Your response may reference or include previous docketed correspondence, if the correspondence adequately addresses the required response. Where good cause is shown, consideration will be given to extending the response time.

If you contest this enforcement action, you should also provide a copy of your response, with the basis for your denial, to the Director, Office of Enforcement, United States Nuclear Regulatory Commission, Washington, DC 20555-0001.

Because your response will be made available electronically for public inspection in the NRC Public Document Room or from the NRC's Agency-wide Documents Access and Management 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 Web site 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 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 this 24nd day of September 2009

NOTICE OF NONCONFORMANCE

Prime Technology, LLC
344 Twin Lakes Road
North Branford, CT 06471

Docket Number 99901382
Inspection Report No. 99901382/2009-201

Based on the results of a Nuclear Regulatory Commission (NRC) inspection conducted August 11 to August 14, 2009, of activities performed at Prime Technology, LLC (Prime), certain activities were not conducted in accordance with NRC requirements, which were contractually imposed upon Prime by NRC licensees.

A. Criterion XVI, "Corrective Action," of Appendix B to 10 CFR Part 50, states in part that, "measures shall be established to assure that conditions adverse to quality, such as failures, malfunctions, deficiencies, deviations, defective material and equipment, and nonconformances are promptly identified and corrected."

Prime Quality Assurance Manual, Revision 4, dated October 1, 2008, Procedure No. 2.7, "Corrective Action," Revision 3, "Policy," states in part that, "It is the policy of Prime Technology, LLC to maintain a corrective action system which eliminates recurrences of non-conforming material and departures from established procedures. The purpose of this procedure is to describe the steps for initiating and completing corrective action when evidence shows that product quality or operational performance has degraded."

Contrary to the above, as of August 14, 2009:

1. Prime failed to enter the findings from the last Nuclear Procurement Issues Committee (NUPIC) audit performed in February of 2009, into their corrective action process.

2. Corrective actions for findings identified during an internal audit in 2004 and entered into Prime's corrective action process were still not completed. Specifically, the "Internal Audit Corrective Action Request," CAR07-02, dated May 30, 2006, related to training stated that, "As such, the company should set a training program to satisfy each department needs and comply with commitment made to 2004 Internal Audit in terms of *the entire company will be trained*." As of August 14, 2009, Prime still had no training program in place.

This issue has been identified as Nonconformance 99901382/2009-201-02.

B. Criterion XVI, "Corrective Action," of Appendix B to 10 CFR Part 50, states in part that, "measures shall be established to assure that conditions adverse to quality, such as failures, malfunctions, deficiencies, deviations, defective material and equipment, and nonconformances are promptly identified and corrected."

Prime Quality Assurance Manual, Revision 4, dated October 1, 2008, Procedure No. 4.5, "Disposition/Corrective Action for Non-Conforming Material," Revision 3, "Policy," states in part that, "It is the policy of Prime Technology, LLC to process nonconforming material in a systematic manner and to establish corrective action to eliminate future occurrences. The purpose of this statement is to establish a procedure for the review of nonconforming material and implementation of a corrective action system."

Contrary to the above, on August 14, 2009:

Prime Procedure No. 2.7, “Corrective Actions,” Revision 4, and Procedure No. 4.5, “Disposition/Corrective Action for Non-Conforming Material,” Revision 3, did not establish measures for the identification of deviations.

This issue has been identified as Nonconformance 99901382/2009-201-03.

C. Criterion III, “Design Control,” of Appendix B to Title 10 Part 50, states in part that, “These measures shall include provisions to assure that appropriate quality standards are specified and included in design documents and that deviations from such standards are controlled. Measures shall be established for the selection and review for suitability of application of materials, parts, equipment, and processes that are essential to the safety-related functions of the structures, systems and components.”

Contrary to the above, as of August 14, 2009:

1. Prime’s dedication process was not defined under their Quality Assurance Manual as a controlled activity under 10 CFR Appendix B.

2. Prime’s dedication program did not include measures to provide reasonable assurance that the materials, parts, equipment, and processes evaluated under the dedication program will perform their intended safety-related functions. Specific examples identified were: 1) the start and completion notes on the test data sheets were not property recorded by Prime’s staff; 2) the burn-in process was not performed in accordance with Prime’s procedures; and 3) The certificates of conformance were signed before tests were completed.

This issue has been identified as Nonconformance 99901382/2009-201-04.

D. Criterion III, “Design Control,” of Appendix B to 10 CFR Part 50, states in part that, “Measures shall be established for the selection and review for suitability of application of materials, parts, equipment, and processes that are essential to the safety-related functions of the structures, systems and components.”

Prime Quality Assurance Manual, Revision 4, dated October 1, 2008, Procedure No. 3.2, “Engineering Change Control,” Revision 3, states in part that, “There is one practice employed within Prime Technology, LLC for the evaluation, coordination, approval, or configuration identification. The change control system provides for systematic review and approval of engineering changes.”

Contrary to the above, as of August 14, 2009:

Prime failed to document technical justification for design process changes in the following examples:

1. Prime’s Test Procedure A820-262, “Test Procedure Model 9270 circuit Board Assy. # C92-9062-xxx Sigma Board Assy. #AT-1162-x,” Issue C, dated May 5, 1993, and Form 927021BVB1809, Issue B, dated April 7, 1992, required different burn-in times for Class 1E cards. There was no documented engineering justification for changing of the burn-in time.

2. Prime's Quality Assurance Procedure (QAP)-101, "Workmanship Standard Soldering Techniques and Layout of Components," Revision 3, states that, "This standard has been written in accordance with the intent of MIL-STD-454, Requirements 5 and 9, and ANSI J-STD-001." These two standards contained contradicting solder requirements. There was no documented engineering justification for the current implemented solder requirements.

3. Prime's method to re-form capacitors that exceeded their normal shelf life was in standard JIS C 5101-4. There was no documented engineering justification available for the use of this standard's capacitor re-forming method.

This issue has been identified as Nonconformance 99901382/2009-201-05.

E. Criterion II, "Quality Assurance Program," of Appendix B to 10 CFR Part 50, states in part that, "The program shall provide for indoctrination and training of personnel performing activities affecting quality as necessary to assure that suitable proficiency is achieved and maintained."

Prime Quality Assurance Manual, Revision 4, dated October 1, 2008, Procedure No. 2.4, "Critical Resource Training and Certification," states in part that, "Critical Operations require specialized training. Training/Certification Plans shall be documented." Procedure No. 2.4 further defines Critical Operation in part as, "an operation involving a knack or skill that must be learned through specific training/experience."

Contrary to the above, as of August 14, 2009:

Prime lacked a documented personnel training/certification program for skills that required specialized training/experience.

This issue has been identified as Nonconformance 99901382/2009-201-06.

F. Criterion VI, "Document Control," of Appendix B to 10 CFR Part 50, states in part that, "Measures shall be established to control the issuance of documents, such as instructions, procedures, including changes thereto, which prescribe all activities affecting quality. These measures shall assure that documents, including changes, are reviewed for adequacy and approved for release by authorized personnel and are distributed to and used at the location where the prescribed activity is performed."

Prime Quality Assurance Manual, Revision 4, dated October 1, 2008, Procedure No. 3.2, "Engineering Change Control," Revision 3, states in part that, "Drawings which have been released for production will not have their technical contents changed without an Engineering Change Notice (ECN) having been processed, reviewed for accuracy, and approved by all cognizant personnel."

Contrary to the above, as of August 14, 2009:

Prime Quality Assurance Manual, Revision 4, dated October 1, 2008, did not have controls established for the issuance and revision of instructions, procedures and documents for activities affecting quality. Specifically,

1. Prime's Procedure FIS-1000-9270, "Quality Control Final Test Procured for Model 9270 Indicated Alarm Instruments and Indicators," was last reviewed October 9, 1984. Sheet 4, revision C, dated April 17, 2009, had no corresponding review signature present. Prime failed to have the revised procedure reviewed for adequacy, and approved for release by authorized personnel.

2. Prime's Procedure FIS-1000-1151/1251, "Final Inspection Standards Model 1151/1251," was last reviewed September 5, 1990. Sheet 4, revision C, dated April 17, 2009, had no corresponding review signature present. Prime failed to have the revised procedure reviewed for adequacy, and approved for release by authorized personnel.

This issue has been identified as Nonconformance 99901382/2009-201-07.

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 Director, Division of Engineering, 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 non-compliances; 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), accessible from the NRC Web site at http://www.nrc.gov/reading-rm/adams.html, 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. 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 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 this 24th day of September 2009.

U.S. NUCLEAR REGULATORY COMMISSION
OFFICE OF NUCLEAR REACTOR REGULATION
DIVISION OF ENGINEERING
VENDOR INSPECTION REPORT

Docket No.:	99901382
Report No.:	99901382/2009-201
Vendor:	Prime Technology, LLC. 344 Twin Lakes Road North Branford, CT 06471
Vendor Contact:	Paul Grabek Quality Assurance Manager Phone: (203) 481-5721 pgrabek@primetechnology.com
Nuclear Industry:	Prime Technology, LLC is a manufacturer of precision instruments for commercial, nuclear, and military applications.
Inspection Dates:	August 11 to August 14, 2009
Inspection Team Leader:	Carla Roquecruz, DE/NRR
Inspectors:	Aaron Armstrong, DE/NRR Jonathan Ortega-Luciano, DCIP/NRO Bernard Dittman, DE/NRR Paul Prescott, DE/NRR
Approved by:	Dale Thatcher, Chief Quality & Vendor Branch Division of Engineering Office of Nuclear Reactor Regulation

ENCLOSURE 3

EXECUTIVE SUMMARY

Prime Technology, LLC.
99901382/2009-201

The purpose of this inspection was to review selected portions Prime Technology, LLC.'s (Prime's) quality assurance (QA) and 10 CFR Part 21 (Part 21) programs. The inspectors focused on Prime's products and services supplied as basic components to NRC-licensed facilities. The inspection was conducted at Prime's manufacturing facility in North Branford, Connecticut.

The NRC inspection bases were:

- Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants," to Part 50 of Title 10 of the *Code of Federal Regulations;* and
- 10 CFR Part 21, "Reporting of Defects and Noncompliance."

There were no NRC inspections of Prime's facility in North Branford, Connecticut in the previous five years. The results of this inspection are summarized below.

10 CFR Part 21 Program

The inspectors identified one violation of Part 21. Violation 99901382/2009-201-01 was cited for failure to adopt an appropriate procedure to ensure effective identification and evaluation of deviations and failures to comply associated with a substantial safety hazard. With the exception of the violation noted above, the inspectors concluded that Prime's Part 21 program was consistent with regulatory requirements.

Corrective Action

The inspectors identified two nonconformances to 10 CFR Part 50, Appendix B. Nonconformances 99901382/2009-201-02 and 99901382/2009-201-03 were cited for inadequate and untimely corrective actions and failure to establish adequate measures for the identification of deviations, respectively. With the exception of the above nonconformances, the inspectors determined that Prime's corrective action program and implementation met the requirements of Criterion XVI of Appendix B to 10 CFR Part 50.

Commercial-Grade Dedication

The inspectors identified one nonconformance to 10 CFR Part 50, Appendix B. Nonconformance 99901382/2009-201-04 was cited for failure to establish a suitable commercial-grade dedication process for safety-related components. Prime failed to establish measures to provide reasonable assurance that the materials, parts, equipment, and services evaluated under the dedication program will perform their intended safety-related functions. With the exception of this nonconformance, the inspectors concluded that Prime's commercial-grade dedication program and implementation were consistent with the regulatory requirements of Criterion III of Appendix B to 10 CFR Part 50.

Design Control

The inspectors identified one nonconformance to10 CFR Part 50, Appendix B. Nonconformance 99901382/2009-201-05 was cited for Prime's lack of documentation and engineering justification for design process changes. With the exception of this nonconformance, Prime's design control process met the requirements of Criterion III of Appendix B to 10 CFR Part 50.

Training

The inspectors identified one nonconformance to 10 CFR Part 50, Appendix B. Nonconformance 99901382/2009-201-06 was cited for Prime's failure to establish and implement a documented personnel training/certification program for skills that required specialized training. With the exception of this nonconformance, Prime's quality assurance program met the requirements of Criterion II of Appendix B to 10 CFR Part 50.

Document Control

The inspectors identified one nonconformance to 10 CFR Part 50, Appendix B. Nonconformance 99901382/2009-201-07 was cited for failure to establish adequate measures for the revision and approval of documents which prescribe activities affecting quality. With the exception of this nonconformance, Prime's document controls met the requirements of Criterion VI of Appendix B to 10 CFR Part 50.

REPORT DETAILS

1. 10 CFR Part 21 Program

   a. Inspection Scope

   The inspectors reviewed Prime's Quality Assurance Manual (QAM), Revision 4, dated October 1, 2008, and procedures that govern the Part 21 program to determine compliance with Part 21. Specifically, the inspectors focused on Procedure 5.3, Revision 2, "Reporting of Defects and Noncompliance," dated May 30, 2006; Procedure 5.1, Revision 2, "Return Authorization," dated May 30, 2006; Procedure 4.5, Revision 3, "Disposition/Corrective Action for Non-Conforming Material," dated May 30, 2006; and Procedure 2.7, Revision 3, "Corrective Action," dated May 30, 2006.

   The inspectors discussed the Part 21 process with members of Prime's management and technical staff to evaluate Prime's Part 21 program. Prime had not performed any Part 21 evaluations for the inspectors' review.

   b. Observations and Findings

   The inspectors verified that Prime's Procedure 5.3 met the requirements of Part 21. The inspectors noted that Procedure 5.3 outlined the process used by Prime for the reporting of defects and noncompliances, as well as the responsibilities of employees, managers, and the QA manager with respect to Part 21.

   The inspectors noted that the section entitled, "Reporting a Defect or Noncompliance," in Procedure 5.3, stated that, "Any employee reporting a deviation or possible nonconformance shall identify the deviation or possible nonconformance using Form 150. The employee shall forward the completed form to the Quality Assurance Manager." Additionally, in discussions with the QA manager it was noted that Return Material Authorizations (RMAs), Material Rejection Reports (MRRs) and Corrective Action Requests (CARs) are initialized by different departments within the company and not all of these reports are reviewed by trained management or quality personnel for the potential need to perform an evaluation in accordance with Part 21. Specifically, Procedure 5.1, states that, "Quality Assurance receives selected RMAs as determined by the Sales Administrator." The inspectors discussed these procedures with Prime's QA manager and confirmed that not all Prime personnel are trained to Part 21 requirements.

   The inspectors noted that Procedure 4.5 and 2.7 did not have a process to initiate an evaluation for a potential deviation. Procedure 5.1, states that, "If required by the customer, the manager, Quality Assurance, completes the Test Failure Report or Corrective Action Request." According to Prime's QA manager, a Failure Analysis Report, for a returned item, is only initiated if the customer requested it in their initial purchase order (PO) or when the item is returned. No procedure was found that prescribed the process to do a failure analysis report. Additionally, Exhibit B of Procedure 5.3, "10CFR21 Potential Reportable Determination Checklist," used to do the evaluation for potential defects was not adequate as it was missing information necessary to determine if an item is a basic component and Part 21 applicability.

Prime's failure to identify deviations as part of its evaluation of a potential deviation was identified as Violation 99901382/2009-201-01.

As a result of a recent order of circuit boards returned to Prime by PPL Susquehanna, LLC and the licensee's request, Prime performed a Failure Analysis Report to determine if a Part 21 report was necessary for solder workmanship issues in circuit boards. Failure Analysis Report for RMA # 19654, "Part 21 Determination Report," dated June 22, 2009, concluded that:

> "The basis for not reporting under Part 21 is that although the workmanship of the soldering is not up to standard on the component side of the circuit boards they function electrically and would not fail in a manner that would necessitate Part 21 reporting. The circuit boards are double sided and have plated through holes."

The failure analysis report also specified that the indicators were tested and it was revealed that failure of the indicators was due to an internal problem with the bargraphs and not the solder workmanship. The failure analysis report was sent to the licensee and Prime was waiting for the licensee's input. The inspectors discussed the conclusions of the failure analysis report with Prime's QA manager and identified that Prime's personnel did not appear to have a thorough understanding of Part 21 regulations. The inspectors noted that Prime's QA manager believed that if a failure was isolated or not generic, it was not a deviation and therefore, no evaluation was warranted. As a result of the inspection, Prime QA manager initiated a revision of Procedure 5.3, "Part 21, Reporting of Defects and Noncompliance."

c. Conclusions

The inspectors identified one violation of Part 21. Violation 99901382/2009-201-01 was cited for failure to adequately prescribe the process to perform an evaluation as specified in Part 21. With the exception of the violation noted above, the inspectors concluded that Prime's Part 21 program was consistent with regulatory requirements.

2. Corrective Action

a. Inspection Scope

The inspectors reviewed the procedures governing the implementation of Prime's corrective action program to ensure the procedures provided adequate guidance consistent with the requirements of Appendix B to 10 CFR Part 50 and Part 21. The inspectors also reviewed a sample of CARs to assess Prime's implementation of the corrective action program. Additionally, the inspectors reviewed Prime's nonconformance and return material processes and assessed implementation through a review of a sample of MRRs.

b. Observations and Findings

The inspectors noted that Prime's Procedure No. 2.7, "Corrective Actions," Revision 3, dated May 30, 2006, and Procedure No. 4.5, "Disposition/Corrective Action for Non-Conforming Material," Revision 3, dated May 30, 2006, established the process for

initiating corrective action and eliminating recurrence of nonconforming material and departures from established procedures. Prime's Procedure 2.7 and 4.5 detailed the responsibilities, definitions, implementation, and preventive actions to address identified nonconformances. The inspectors also noted that Prime's Procedure 5.1, "Return Authorization," Revision 2, dated May 30, 2006, documented a method for processing returned product for repair, replacement, modification, or upgrade and states that, "if required by customer, the Manager, Quality Assurance, completes the Test Failure Report and Corrective Action Request."

The inspectors discussed these procedures with Prime's QA manager and identified that while Procedure 2.7, "Corrective Action," states that the purpose of the procedure is to describe the steps for initiating and completing corrective action when evidence shows that product quality or operational performance has degraded, CARs are only used to address internal administrative nonconformances and audit findings. Prime initiates an MRR to documents issues with materials and components. An MRR is for shipped product and incoming items.

Prime's MRR document is used to identify issues, report measures and actions taken to evaluate and resolve an apparent condition and track required actions through completion. The MRR form is reviewed and analyzed by QA personnel to determine if corrective action is required. Procedure 2.7 states in part, "The Material Review Board (MRB) Chairman who conducts the MRB or preliminary review insures causes of non-conformances are determined, and corrective actions initiated when required. The MRB Chairman assures corrective actions are evaluated, and feedback is provided to appropriate personnel. The QA manager maintains a file of the completed copy of the MRR."

The inspectors reviewed a sample of CARs and MRRs. During the review of Prime's CARs the inspectors identified an instance of a CAR that was closed without completing the proposed corrective action. CAR07-02, Revision 4, dated May 30, 2006, was initiated as a result of a finding from the 2004 Nuclear Procurement Issues Committee (NUPIC) audit and stated in part: "As such, the company should set a training program to satisfy each department's needs and comply with the commitment made to the 2004 Internal Audit in terms of "*the entire company will be trained.*" The CAR further stated that: "This CAR shall be satisfied via CAR 2009-02." As of August 14, 2009, no training program has been implemented by Prime. The inspectors determined that Prime's CAR process did not ensure that conditions adverse to quality were promptly identified and corrected, per Criterion XVI of Appendix B to 10 CFR Part 50. This was one identified example of Nonconformance 99901382/2009-201-02.

Furthermore, the inspectors noted that a CAR document had not been initiated for this issue or for any of the issues found during the NUPIC audit in 2008. The QA manager had all the findings from the latest audit documented in "Corrective Actions for CAR 2009-01 through CAR 2009-06," and Prime was still in the process of entering these findings into Prime's CAR process. This was a second identified example of Nonconformance 99901382/2009-201-02.

During the review of Prime's Corrective Action Program and MRR process, the inspectors identified that Prime's corrective action procedures and forms would not identify deviations and nonconformances in a timely manner. This was identified as Nonconformance 99901382/2009-201-03. The inspectors noted that Prime employees

were expected to complete an MRR form when product non-conformances are identified. The Corrective Action procedure and MRR form did not discuss the identification and/or evaluation of deviations and did not prompted employees to address potential Part 21 concerns.

c. Conclusion

Nonconformances 99901382/2009-201-02 and 99901382/2009-201-03 were cited for inadequate and untimely corrective actions and failure to establish adequate measures for the identification of deviations, respectively. With the exception of the above nonconformances, the inspectors determined that Prime's corrective action program and implementation was consistent with regulatory requirements.

3. Commercial-Grade Dedication Process

a. Inspection Scope

The inspectors reviewed Prime's QAM, Revision. 7, dated October 1, 2008, and the implementation process for commercial-grade dedication activities. This assessment included a review of the procedures governing the commercial-grade dedication activities, interviews with Prime's personnel, tour and observation of ongoing activities of the facility and a review of a sample of completed commercial-grade dedication packages.

b. Observations and Findings

The inspectors noted that Prime's dedication process was not defined or documented in its QAM as a controlled activity under Appendix B to 10 CFR. Additionally, Prime did not have procedures for the implementation of dedication activities. Prime's staff performs dedication as a legacy activity mainly accomplished by using Method 1 of the EPRI guidance NP-5652, "Guideline for the Utilization of Commercial Grade Items in Nuclear Safety-Related Applications." Method 1 is acceptance of items by special test and inspections when performing dedication.

The inspectors reviewed Procedure 810-064, "Work Order Process," Revision A, dated May 1, 2006, which is used during dedication activities. The inspectors noted that the procedure did not describe the dedication process, but explained the process for generating a work order and the rules and responsibilities of different departments with regards to the work order. Procedure 810-064 states in part that the Material Control Department is responsible for gathering all the engineering drawings, technical information, supporting documents, and parts required in order to complete the kit(s) necessary to generate the part(s) required by the procurement document. The Material Department generates the Acknowledgment of Order that is attached to the work order and then is placed in a bin of completed work orders waiting to be transferred to the Assembly Department. This document lists the requirements in the procurement document and the classification of the product.

The inspectors reviewed three dedication packages for the Model 9270 Indicators and one dedication package for 9 circuit board cards to determine whether Prime was implementing an adequate dedication program. The packages reviewed were associated with three completed safety-related POs from PPL Susquehanna, Southern

California Edison Company, Georgia Power Company, and one repair PO for Nebraska Public Power.

The inspectors reviewed Dedication Package II013422-C1, "9270 Lumigraph Temperature Indicator." The inspectors verified that the content of the package was in accordance with Procedure 810-064. Once the Material Department generated the Acknowledgment of Order that is attached to the work order, the Assembly Department performed the activities following the requirements listed in the work order package. Once the Assembly Department signed off on the work order as completed, the Assembly Department Manager sends the unit to the In-Process Inspection Department. The In-Process Inspection Department is one of the three points at which Prime's personnel verify critical characteristics as part of the dedication process.

For Dedication Package II013422-C1, the unit was not inspected by the in-process inspector and no inspection record card was created as require by Prime's legacy dedication process. The inspectors noted that for Dedication Package 11013422-C1 there were no signoffs or records that indicated that the unit was inspected by the In-Process Inspection Department prior to being certified by the QA Department. The QA manger was not able to find the records indicating that the in-process inspection was performed. The inspectors confirmed that this is not an isolated occurrence. No documentation existed to indicate that Prime performed the in-process inspections in the past for completed units similar to the one procured under Order Number: II013422-C1. The inspectors identified this as an example of Nonconformance 99901382/2009-201-04.

The In-Process Inspector is responsible for verifying that the unit is put together by the Assembly Department in accordance with design drawings. As part of his function, a visual inspection is performed of all the components in the unit for workmanship. The information is documented in the inspection record cards. The inspection record cards list the critical characteristics that the inspector must verify as part of the dedication process. Once the inspector completes his visual inspection, he signs off on the work order and sends the unit to the Material Department for storage, where the unit awaits testing. The Material Department verifies the work order and generates the proper documentation that is going to be used by the Test Department. The Test Department reports to the QA manager. This is the second point at which Prime's personnel verify critical characteristics as part of the dedication process.

The inspectors also reviewed Dedication Package II013598-C1. The customer ordered 9 Class 1E (safety-related) circuit boards. The inspectors noted that the documentation of the dedication package was not in accordance with Prime's practices. The boards were tested in accordance with Procedure 820-271, "Test Requirements for Circuit Boards Part Number 92-9406-008," Revision B, dated April 17, 2009. The test results were recorded on data sheets as required by Procedure 820-271, but the incorrect date was logged on the test data sheet for the burn in process of three out of the nine circuit boards tested. Additionally, three of the circuit boards exceeded the 24-hour of the burn-in process and one had a burn-in time of less than 24 hours. The 24-hour burn-in process is one of the tests that Prime Technology performs to detect infant mortality failure.

Additionally, one of the nine test data sheets from Dedication Package II013598-C1 was missing the signature of the technician that performed the test. The dedication package

contains three Certifications of Calibration (CofCs). Each CofC was signed by the QA manager on April 28, 2009. The tests of the circuit boards were not completed until April 29, 2009. The circuit boards were certified before the certification process was completed by the technicians. This was the final QA inspection and the third point to verify the critical characteristics in the dedication process. According to Prime's dedication process, the QA inspector performs a visual inspection and tests the assembly in accordance with Final Inspection Standard (FIS)-1000-9270, "Quality Control Final Test Procedure for Model 9270 Indicating Alarm Instrument and Indicators," Revision A, dated December 9, 1975, and then compares the test results against document 927021BVB1809, Issue B, dated April 7, 1992. Document 927021BVB1809 contains the critical characteristics, test and processes necessary to classify the part as a Class 1E (safety-related) component.

For Dedication Package II013598-C1, Prime did not provide adequate documentation for the dedication process for these 9 Class 1E circuit boards. Specifically:

1. The start and completion dates on the test data sheets were not properly recorded by the technical staff;

2. The burn-in process was not performed in accordance with Prime's procedures; and

3. The CofCs were signed by the QA manager before the tests were completed.

This is another example of Nonconformance 99901382/2009-201-04.

c. Conclusion

The inspectors identified one nonconformance to 10 CFR Part 50, Appendix B. Nonconformance 99901052/2009-201-04 was cited for failure to establish suitable processes for the dedication of commercial grade items. Specifically, the failure to establish measures to provide reasonable assurance that the materials, parts, equipment, and processes evaluated under the dedication program will perform their intended safety-related functions. With the exception of the above nonconformance, the inspectors concluded that Prime's commercial grade dedication program was consistent with regulatory requirements.

4. Design control

a. Inspection Scope

The inspectors reviewed Prime's QAM, Revision 7, dated October 1, 2008, and inspection, test and work documents to evaluate conformance to 10 CFR Part 50 Criteria III. The inspectors reviewed information related to maintaining design control in the following documents: purchase orders; a design basis seismic qualification test report; Prime's Quality Assurance Procedure (QAP)-101, "Workmanship Standard Soldering Techniques and Layout of Components," (all associated revisions); an assembly drawing that references QAP-101; inspection, test and work flow sheets; acceptance test procedures; and an e-mail related to a purchase order deviation. Additionally, the following military and industry standards were reviewed: MIL-STD-454N, "Standard General Requirements for Electronic Equipment;" MIL-STD-2000A, "Standard

Requirements for Soldered Electrical and Electronic Assemblies;" MIL-S-45743E, "Soldering, Manual Type, High Reliability, Electrical and Electronic Equipment:" IPC J-STD-001D, "Requirements for Soldered Electrical and Electronic Assemblies." The inspectors interviewed the QA manager, an in-process inspector, and a solder station operator on processes, procedures and products associated with these documents.

b. Observations and Findings

The inspectors reviewed Susquehanna Steam Electric Station Unit 1&2, Pennsylvania Power and Light Company Specification 8856-J-04, "Technical Specification for Q-Listed Electronic Indicating Panel Instrumentation," Revision 2, dated November 28,1983. Specification 8856-J-04, section 7.1, identified the requirement for an equipment burn-in time of at least 100 hours, with an allowance to substitute standard component screening and equipment testing. Prime's test procedure A820-262, "Test Procedure Model 9270 circuit Board Assy. # C92-9062-xxx Sigma Board Assy. #AT-1162-x," Issue C, dated May 5, 1993, and Form 927021BVB1809, Issue B, dated April 7, 1992, required burn-in times of 48 and 24 hours, respectively. Prime's QA manager was unable to provide the any documents for engineering changes justifying the revised burn-in times. Prime failed to implement measures for the selection and review for suitability of application of safety-related materials, parts, equipment, and processes. This was one identified example of Nonconformance 99901382/2009-201-05.

The inspectors reviewed the following documentation related to soldering workmanship and inspection criteria, QAP-101, and all associated revisions. The QAP-101, Revision None, did not reference or implement a military or industry standard. QAP-101, Revision 2, referenced the following military standards related to soldering workmanship: MIL-STD-2000A, dated February 14, 1991; MIL-STD-454F, dated March 13, 1978; and MIL-S-45743, dated October 15, 1976. MIL-S-45743 states that the solder may be depressed, not to exceed 25 percent of the hole depth including pads, only on the component side of the board, with good wetting completely around the hole, equivalent to 100% or 360° coverage. MIL-STD-2000A contradicted MIL-S-45743 by allowing for a minimum of 90 percent good solder wetting to exist around the hole, equivalent to 330° circumferential coverage. The QAP-101, Revision 3, references MIL-STD-454, but replaces its reference to MIL-STD-2000A with a reference to Association Connecting Electronics Industry IPC J-STD-001, Revision D. IPC J-STD-0001D is consistent with MIL-STD-2000A's required criteria of "75% fill" equivalent to "25% depression, and its criteria of "330° circumferential fillet" 90% solder flow. The IPC J-STD-0001D is contradictory to MIL-S-45743 soldering guidelines. The inspectors questioned Prime's QA manager about the engineering changes justifying the difference in the wetting circumferences referenced in QAP-101. Prime's QA manager was unable to produce any documents for engineering changes justifying the difference in the wetting circumferences. Prime failed to implement measures for the selection and review for suitability of application of safety-related materials, parts, equipment, and processes. This issue is the second example of Nonconformance 99901382/2009-201-05.

The inspectors reviewed documentation for reforming aluminum electrolytic capacitors with date codes in excess of six years. The licensee agreed to the reforming activities via an e-mail confirmation, but no formal PO revision was made to eliminate its shelf-life clause contained in P.O. 00383390 Revision 1. Prime proposed to implement JIS C 5101-4, Clause 4.1 as an alternative approach to meeting the licensee's date code clause for the aluminum electrolytic capacitors. The version of JIS C 5101-4 Clause 4.1

was not available at the time of the inspection. Prime's QA manager indicated that the version used was obtained free from a website, and that this single licensee is the only to have the shelf-life requirement. The inspectors requested documentation of the engineering justification to support the use of JIS C 5101-4 Clause 4.1. Prime was unable to produce the supporting documentation to justify the changes for reforming the capacitors. Prime failed to implement the measures established for the selection and review for suitability of application of safety-related materials, parts, equipment, and processes. This issue is the third example of Nonconformance 99901382/2009-201-05.

c. Conclusion

The inspectors identified one nonconformance to Appendix B to 10 CFR Part 50. Nonconformance 99901382/2009-201-05 was cited for Prime's lack of documentation and engineering justification for design process changes. Specifically, Prime's changes to the solder workmanship procedure, burn-in requirements, and shelf-life requirements were unaccompanied by formal technical justifications. With the exception of the above nonconformance, the inspectors concluded that Prime's design control process was consistent with regulatory requirements.

5. Training

a. Inspection Scope

The inspectors reviewed Prime's QAM, Revision 4, dated October 1, 2008, and the QA procedures governing the implementation of the training and qualification program. The inspectors reviewed Prime's training documents and interviewed its personnel and identified the lack of a mechanism by which Prime's QA program monitors work performance and qualification of personnel. The inspectors reviewed the current Revision 3 of Prime's Quality Assurance Procedure (QAP)-101, which governs soldering workmanship and military and industry standards referenced in QAP-101 revisions. The inspectors also reviewed QAP-115 "Personnel Training," and QAP-104 "Rejection Tag Procedure."

b. Observations and Findings

The inspectors identified that Prime's soldering workmanship processes and standards have gone through several revisions from October 1973 through December 2006, and major changes to the training and qualification requirements were evident. Specifically:

1. Revision 0 of QAP-101 contained no references to training;

2. Revision 2, Section 5.4, of QAP-101 included certification and training requirements in accordance with this procedure, and referenced a "Category C instructor," training records, and periodic evaluation of trained personnel applicable work; and

3. Revision 3, Section 5.4, of QAP-101 included certification and training requirements in accordance with this procedure, and referenced only training records

In contrast with Revision 2, Revision 3 no longer referenced a "Category C instructor" or "periodic evaluation of trained personnel applicable work." The inspectors' review determined that the training scope, which is included within this procedure's revisions, was first added and then portions were subsequently removed. While Revision 1 of QAP-101 was unavailable for inspector review, Revision 2, dated August 31, 1992, remained in effect after creation of QAP-115 "Personnel Training" and QAP-104 "Rejection Tag Procedure." QAP-101 stated in part that, "periodic evaluation of trained personnel applicable work shall be implemented." However, no evidence of periodic evaluation of trained personnel could be produced by Prime at the time of the inspection.

According to Prime, QAP-101, Revision 3, created after release of QAP-115 "Personnel Training," also remains in effect at this time and this revision states that, "All certification and training should be done in accordance with this procedure. A documented record will be maintained for all trained personnel." However, evidence of certification and training in accordance with the latest revision of QAP-101 via documented records could not be produced by Prime. Interviews of Prime personnel revealed that Prime's changes to its soldering workmanship procedures and standards have not been accompanied by corresponding indoctrination and training.

Additionally, the inspectors identified that Prime has had audit findings in the area of training during the last NUPIC and Prime audits. CAR 07-02 initiated by Prime to address a NUPIC finding stated in part that, "As such, the company should set a training program to satisfy each department's needs and comply with the commitment made to 2004 Internal Audit in terms of "*the entire company will be trained*". The CAR further stated that: "This CAR shall be satisfied via CAR 2009-02." As of August 14, 2009 no training program has been implemented by Prime. This issue has been identified as Nonconformance 99901382/2009-201-06.

c. Conclusion

The inspectors identified one nonconformance of Appendix B to 10 CFR Part 50. Nonconformance 99901382/2009-201-06 was cited for failure to establish and implement a program for indoctrination and training of personnel performing activities affecting quality as necessary to assure that suitable proficiency is achieved and maintained. With the exception of the above nonconformance, the inspectors concluded that Prime's quality assurance program was consistent with regulatory requirements.

6. Document Control

a. Inspection Scope

The inspectors reviewed Prime's QAM, Revision 4, dated October 1, 2008, and QA procedures that govern the implementation of QA document control. Specifically, the inspectors reviewed Procedure 3.2, "Engineering Change Control," Revision 3, dated October 1, 2008. The inspectors also reviewed Prime's Final Inspection Standard (FIS) for the implementation of document changes and controls for issuance of instructions, procedures, and drawings that prescribe activities affecting quality. Additionally, the inspectors interviewed Prime's QA manager on the implementation of the process to control QA document changes.

b. Observations and Findings

The inspectors noted that Procedure 3.2, "Engineering Change Control," is employed within Prime for the evaluation, coordination, approval, or disapproval of changes in the configuration of an item (part, assembly, or product) after establishment of its configuration. Prime's change control process provides for systematic review and approval of engineering drawings released for production. Procedure 3.2 governs the change process for Prime's technical drawing's documentation and does not allow technical content in these drawings to be changed without processing an Engineering Change Notice (ECN), reviewing the change for accuracy, and obtaining approval by all cognizant personnel. However, the inspectors identified that Procedure 3.2 does not cover quality control documents. Through further discussion with Prime's QA manager, the inspectors learned that Prime lacked a documented process for control of QA document changes.

The inspectors reviewed Prime's FIS-1000-9270, "Quality Control Final Test Procured for Model 9270 Indicated Alarm Instruments and Indicators," Revision A, dated December 9, 1975. According to this standard, Prime personnel are directed to perform visual inspections and final testing of these meters. The FIS-1000-9270 was last reviewed on October 9, 1984. On April 17, 2009, Sheet 4, Revision C, was added to the standard but no corresponding review signature was present. The FIS-1000-9270 coversheet had review signatures for the past two revisions, but no review signature was present for the Revision C changes added to this standard. This identified issue is as an example of Nonconformance 99901382/2009-201-07.

The inspectors found another example of lack of document control on Prime's FIS-1000-1151/1251, "Final Inspection Standards Model 1151/1251," dated September 5, 1990. PO II013500-C1, dated March18, 2009, ordered instruments as Class1E safety-related items. According to this standard Prime performs Class 1E instrument visual inspection and final testing of the model 1151/1251 meters. Sheet 4, Revision C, added to the standard on April 17, 2009, had no corresponding review signature present. The FIS-1000-1151/1251 coversheet had three review signatures for Revision A and Revision B, but no review signature was present for the Revisions C sheets added to the FIS. This issue is another example of Nonconformance 99901382/2009-201-07.

c. Conclusion

The inspectors identified one nonconformance of Appendix B to 10 CFR Part 50. Nonconformance 99901382/2009-201-07 was cited for Prime's failure to establish measures to control the issuance of documents, and changes thereto, which prescribe to activities affecting quality. No measures were present to ensure that changes to QA documents are reviewed for adequacy, and approved for release by authorized personnel. With the exception of the above nonconformance, the inspectors concluded that Prime's document control process was consistent with regulatory requirements.

7. Exit Meeting

On August 14, 2009, the inspectors presented the inspection scope and findings during an exit meeting with Prime's CEO, Raymon S. Sterman, and other Prime personnel.

ENCLOSURE

1. PERSONS CONTACTED

R. Sterman, President, Prime Technology
P.Grabek, QA manager, Prime Technology

2. INSPECTION PROCEDURES USED

IP 36100, “Inspection of 10 CFR Parts 21 and 50.55(e) Programs for Reporting Defects and Noncompliance”
IP 43001, “Reactive Inspection of Nuclear Vendors”

3. LIST OF ITEMS OPENED, CLOSED, AND DISCUSSED

There were no NRC inspections of Prime’s facility in North Branford, Connecticut in the previous five years.

Item Number	Status	Type	Description
99901382/2009-201-01	Opened	NOV	21.21 Evaluations
99901382/2009-201-02	Opened	NON	Criterion XVI
99901382/2009-201-03	Opened	NON	Criterion XVI
99901382/2009-201-04	Opened	NON	Criterion III
99901382/2009-201-05	Opened	NON	Criterion III
99901382/2009-201-06	Opened	NON	Criterion II
99901382/2009-201-06	Opened	NON	Criterion VI

4. LIST OF ACRONYMS USED

NRC	Nuclear Regulatory Commission
Prime	Prime Technology, LLC
CFR	Code of Federal Regulations
QA	Quality Assurance
NUPIC	Nuclear Procurement Issues Committe
QAP	Quality Assurance Program
ECN	Engineering Change Notice
QAM	Quality Assurance Manual
MRR	Material Rejection Reports
RMA	Return Material Authorization
CAR	Corrective Action Reques
PO	Purchase Order
MRB	Material Review Board
CofC	Certifications of Calibration
FIS	Final Inspection Standard