July 29, 2011

Ms. Barbara Agans, Quality Assurance Manager
Continuum Dynamics, Inc.
34 Lexington Avenue
Ewing, NJ 08618

SUBJECT: NRC INSPECTION REPORT NO. 99901265/2011-201 AND NOTICE OF NONCONFORMANCE

Dear Ms. Agans:

On June 13–17, 2011, the U.S. Nuclear Regulatory Commission (NRC) staff conducted an inspection at the Continuum Dynamics, Inc. (CDI), facility in Ewing, NJ. The purpose of this limited scope inspection was to assess CDI's compliance with the provisions in Title 10 of the *Code of Federal Regulations* (10 CFR) Part 21, "Reporting of Defects and Noncompliance," and selected portions of Appendix B, "Quality Assurance Program Criteria for Nuclear Power Plants and Fuel Reprocessing Plants," to 10 CFR Part 50, "Domestic Licensing of Production and Utilization Facilities." The enclosed report presents the results of this inspection. This NRC inspection report does not constitute NRC endorsement of your overall quality assurance (QA) or 10 CFR Part 21 programs.

During this inspection, NRC inspectors found that your QA program generally met the NRC requirements imposed on you by your customers or NRC licensees. However, the inspectors did find multiple examples of implementation issues that warrant your attention and consideration for impact on previous safety related work. Specifically, CDI failed to dedicate commercial calibration services for use in safety-related applications; failed to perform a supplier qualification audit before procuring safety-related services; failed to translate technical requirements into specifications, drawings, procedures, and instructions; failed to establish adequate written test procedures; and failed to ensure that audits were performed by personnel not having direct responsibilities in the areas being audited. The specific findings and references to the pertinent requirements are identified in the enclosure 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. We will consider extending the response time if you show good cause for us to do so.

In accordance with 10 CFR 2.390, "Public Inspections, Exemptions, Requests for Withholding," of the NRC's "Rules of Practice," a copy of this letter, its enclosure, 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 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 "Protection of Safeguards Information: Performance Requirements."

Sincerely,

/RA/

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

Docket No. 99901265

Enclosures:
1. Notice of Nonconformance
2. Inspection Report No. 99901265/2011-201 and Attachment

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 "Protection of Safeguards Information: Performance Requirements."

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NOTICE OF NONCONFORMANCE

Continuum Dynamics, Inc.
Ewing, NJ

Docket No.: 99901265
Inspection Report No.: 99901265/2011-201

Based on the results of a Nuclear Regulatory Commission (NRC) inspection conducted at the Continuum Dynamics, Inc. (CDI) facility in Ewing, NJ, on June 13 - 17, 2011, certain activities were not conducted in accordance with NRC requirements which were contractually imposed on CDI:

A. Criterion III, "Design Control," of Appendix B, "Quality Assurance Program Criteria for Nuclear Power Plants and Fuel Reprocessing Plants," to Title 10 of the *Code of Federal Regulations* (10 CFR) Part 50, "Domestic Licensing of Production and Utilization Facilities," states, in part, that "measures shall also 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."

Criterion V, "Instructions, Procedures, and Drawings," of Appendix B to 10 CFR Part 50 states that "activities affecting quality shall be prescribed by documented instructions, procedures, or drawings, of a type appropriate to the circumstances and shall be accomplished in accordance with these instructions, procedures, or drawings. Instructions, procedures, or drawings shall include appropriate quantitative or qualitative acceptance criteria for determining that important activities have been satisfactorily accomplished."

Contrary to the above, as of June 17, 2011, CDI failed to review the suitability of the application of commercially calibrated measuring and test equipment for use in safety-related applications and failed to adequately prescribe its commercial-grade dedication process by appropriate procedures. Specifically, CDI procured commercial calibration services for measuring and test equipment for use in safety-related applications and did not perform a commercial-grade item dedication. In addition, CDI did not develop instructions or procedures that provide guidance for controlling commercial-grade item dedication activities.

This issue has been identified as Nonconformance 99901265/2011-201-01.

B. Criterion VII, "Control of Purchased Material, Equipment, and Services," of Appendix B to 10 CFR Part 50 states, in part, that "measures shall be established to assure that purchased material, equipment, and services, whether purchased directly or through contractors and subcontractors, conform to the procurement documents. These measures shall include provisions, as appropriate, for source evaluation and selection, objective evidence of quality furnished by the contractor or subcontractor, inspection at the contractor or subcontractor source, and examination of products upon delivery."

Contrary to the above, as of June 17, 2011, CDI failed to provide for source evaluation and selection of contractors or subcontractors that had a third-party certification, such as the American Society of Mechanical Engineers certificate of authorization, accreditation through the National Voluntary Laboratory Accreditation Program or the American Association for Laboratory Accreditation, or an International Standardization Organization 9000 registration.

This issue has been identified as Nonconformance 99901265/2011-201-02.

C. Criterion III of Appendix B to 10 CFR Part 50 states, in part, that "measures shall be established to assure that applicable regulatory requirements and the design basis, as defined in § 50.2 and as specified in the license application, for those structures, systems, and components to which this appendix applies are correctly translated into specifications, drawings, procedures, and instructions" and that "measures shall also 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 June 17, 2011, CDI failed to translate technical requirements into specifications, drawing, procedures and instructions. Specifically, CDI failed to incorporate acceptance criteria related to the test chamber dimensions into the test plan and design drawing. As a result, CDI failed to identify and evaluate the out-of-tolerance condition of the test chamber before using the test chamber for safety-related tests and certifying the test results.

This issue has been identified as Nonconformance 99901265/2011-201-03.

D. Criterion XI, "Test Control," of Appendix B to 10 CFR Part 50 states, in part, that "a test program shall be established to assure that all testing required to demonstrate that structures, systems, and components will perform satisfactorily in service is identified and performed in accordance with written test procedures, which incorporate the requirements and acceptance limits contained in applicable design documents."

CDI Test Plan 11-02, "AREVA EPR Fuel Assembly Downstream Effects Test Plan," Revision 6, dated June 13, 2011 describes the testing that demonstrates that the AREVA EPR Fuel Assembly will perform satisfactorily in service.

Contrary to the above, as of June 17, 2011, CDI's test program, as described in CDI Test Plan 11-02, failed to identify a test required to demonstrate that U.S. Evolutionary Power Reactor fuel assemblies will perform satisfactorily inservice. Specifically, the test facility included flow control valves whose seat leakage could have adversely affected test validity, but CDI failed to include provisions in the test plan to monitor and account for seat leakage.

This issue has been identified as Nonconformance 99901265/2011-201-04.

E. Criterion XVIII, "Audits," of Appendix B to 10 CFR Part 50 states, in part, that "audits shall be performed in accordance with the written procedures or checklists by appropriately trained personnel not having direct responsibilities in the areas being audited."

Section 5.8 of CDI Quality Procedure (QP)-18.1, "Audits," Revision 1, dated June 14, 2007, states, in part, that "audit[s] shall be conducted by personnel having no direct responsibility in the areas being audited."

Contrary to the above, as of June 17, 2011, a CDI employee who has direct responsibility for the technical areas within the quality assurance program performed all areas of a CDI quality assurance internal audit on June 1, 2009. Specifically, the

employee was the principle investigator for commercial nuclear safety-related testing projects during 2008 and 2009, with responsibility in the areas of design control, test control, and control of measuring and test equipment.

This issue has been identified as Nonconformance 99901265/2011-201-05.

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, 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 noncompliance, and (4) the date when the corrective action will be completed. Where good cause is shown, the NRC will consider 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 Agencywide Documents Access and Management System, which is 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 that such material be withheld, 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, "Protection of Safeguards Information: Performance Requirements."

Dated this 1st day of August, 2011.

U.S. NUCLEAR REGULATORY COMMISSION
OFFICE OF NEW REACTORS
DIVISION OF CONSTRUCTION INSPECTION AND OPERATIONAL PROGRAMS
VENDOR INSPECTION REPORT

Docket No.:	99901265
Report No.:	99901265/2011-201
Vendor:	Continuum Dynamics, Inc. 34 Lexington Ave. Ewing, NJ 08618
Vendor Contact:	Ms. Barbara Agans Quality Assurance Manager Telephone: (609) 538-0444, extension 106 E-mail: barbara@continuum-dynamics.com
Nuclear Industry Activity:	Continuum Dynamics, Inc. (CDI), located in Ewing, NJ, provides modeling and analysis services, including reactor flow analysis, valve dynamic modeling, acoustic circuit analysis, piping system modeling, thermal cycling modeling, jet pump vibration load prediction, and accident analysis. CDI also tests steam lines and steam dryers, safety valves, strainers, and jet-pump-flow-induced vibration. A large fraction of CDI's nuclear safety-related work is containment strainer testing and design. CDI conducted passive strainer testing for boiling-water reactors, strainer testing for pressurized-water reactors, and fuel filter testing. CDI is currently under contract to perform Generic Safety Issue 191, "Assessment of Debris Accumulation on PWR Sump Performance," downstream effects testing in support of the AREVA U.S. Evolutionary Power Reactor design certification.
Inspection Dates:	June 13–17, 2011
Inspectors:	Samantha Crane — CQVB/DCIP/NRO, Team Leader Timothy Steadham — CIB3/DCI/R-II Douglas Bollock — CQVB/DCIP/NRO Shanlai, Lu, — SRSB/DSRA/NRO, Technical Specialist
Approved by:	Richard Rasmussen, Chief Quality and Vendor Branch 2 Division of Construction Inspection & Operational Programs Office of New Reactors

EXECUTIVE SUMMARY

Continuum Dynamics, Inc.
99901265/2011-201

The U.S. Nuclear Regulatory Commission (NRC) conducted this inspection to verify that Continuum Dynamics, Inc. (CDI), implemented an adequate quality assurance (QA) program that complied with the requirements in Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants," to Title 10 of the *Code of Federal Regulations* (10 CFR) Part 50, "Domestic Licensing of Production and Utilization Facilities." The inspection also verified that CDI implemented a program under 10 CFR Part 21, "Reporting of Defects and Noncompliance," that meets the NRC's regulatory requirements. The Inspectors conducted the inspection at the CDI facility in Ewing, NJ, on June 13–17, 2011.

The following regulations served as the bases for the NRC inspection:

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

The inspectors implemented Inspection Procedure (IP) 35034, "Design Certification Testing Inspection," dated January 27, 2010; IP 43002, "Routine Inspections of Nuclear Vendors," dated April 25, 2011; and IP 36100, "Inspection of 10 CFR Part 21 and 10 CFR 50.55(e) Programs for Reporting Defects and Noncompliance," dated April 25, 2011, during the conduct of this inspection.

The NRC had not previously performed any inspections at the CDI facility in Ewing, NJ.

The results of this inspection are summarized below.

10 CFR Part 21

CDI appropriately translated the requirements in 10 CFR Part 21 into implementing procedures and, for those activities reviewed by the inspectors, implemented them as required by CDI procedures. No findings of significance were identified.

Training and Qualification of Personnel

The inspectors determined that the training and qualification of CDI personnel conforms to the regulatory requirements in Criterion II, "Quality Assurance Program," of Appendix B to 10 CFR Part 50. In addition, the inspectors determined that, for the limited sample reviewed, the CDI staff has been effectively implementing the CDI, "Quality Assurance Program Description," Revision 14, dated February 28, 2006 (QAPD) and implementing procedures for the training and qualification of its personnel. No findings of significance were identified.

Procurement Document Control

With the exception the issuance of Nonconformance 99901265/2011-201-01 for CDI's failure to review the suitability of the application of commercially calibrated measuring and test equipment in safety-related testing and for its failure to dedicate the commercial calibration services, the inspectors determined that the implementation of the CDI procurement document control

program was consistent with the regulatory requirements in Criterion IV, “Document Control,” of Appendix B to 10 CFR Part 50.

Control of Purchased Material, Equipment, and Services and Audits

With the exception the issuance of Nonconformance 99901265/2011-201-02 for CDI’s placement of a safety-related purchase order with Exelon PowerLabs without having performed a supplier qualification audit, the inspectors determined that the implementation of the CDI control of purchased material, equipment, and services is consistent with the regulatory requirements in Criteria VII, “Control of Purchased Material, Equipment, and Services,” of Appendix B to 10 CFR Part 50.

Test Control and Configuration Management

With the exception of the issuance of Nonconformance 99901265/2011-201-04 for CDI’s failure to account for and establish written test procedures to test for valve leakage and Nonconformance 99901265/2011-201-03 for CDI’s failure to translate the test chamber tolerance requirements into the test plan and design drawings, the inspectors determined that the implementation of the CDI program for test control was consistent with the regulatory requirements in Criterion III, “Design Control,” and Criterion XI, “Test Control,” of Appendix B to 10 CFR Part 50. Based on the sample of records reviewed, the inspectors determined that qualified personnel were using qualified equipment and processes to adequately implement the CDI quality assurance program description and the associated special test control procedures.

Control of Measuring and Test Equipment

The inspectors determined that the implementation of the CDI program for test control was consistent with the regulatory requirements in Criterion XII, “Control of Measuring and Test Equipment,” of Appendix B to 10 CFR Part 50. Based on the sample of records reviewed, the inspectors determined that measuring and test equipment was properly controlled, calibrated, and adjusted at specified periods to maintain accuracy within necessary limits as required by the CDI QAPD and the associated special test control procedures. No findings of significance were identified.

Nonconforming Materials, Parts, or Components

The inspectors determined that the implementation of the CDI program for control of nonconforming material, parts, or components was consistent with the regulatory requirements in Criterion XV, “Nonconforming Materials, Parts, or Components,” of Appendix B to 10 CFR Part 50. Based on the limited sample of documents reviewed and its observation of ongoing testing activities at the CDI facilities, the inspectors also determined that CDI is effectively implementing its QAPD and the associated nonconformance procedures. No findings of significance were identified.

Corrective Actions

The inspectors determined that the implementation of the CDI corrective action program was consistent with the regulatory requirements in Criterion XVI, “Corrective Action,” of Appendix B to 10 CFR Part 50. Based on the limited sample of documents reviewed and on observation of ongoing testing activities at the CDI facilities, the inspectors also determined that CDI is

effectively implementing its QAPD and the associated corrective action procedures. No findings of significance were identified.

Quality Assurance Records

The inspectors determined that the implementation of the CDI QA records program was consistent with the regulatory requirements in Criterion XVII, "Quality Assurance Records," of Appendix B to 10 CFR Part 50. Based on the limited sample of documents reviewed, the inspectors also determined that CDI is effectively implementing its QAPD and the associated procedures. No findings of significance were identified.

Audits

With the exception of the issuance of Nonconformance 99901265/2011-201-05 for CDI's failure to ensure that auditors were not responsible for the areas audited, the inspectors determined that, based on the limited sample of audits reviewed, the implementation of the CDI internal audit program was consistent with the regulatory requirements in Criterion XVIII, "Audits," of Appendix B to 10 CFR Part 50.

REPORT DETAILS

1. 10 CFR Part 21 Program

   a. Inspection Scope

   The inspectors reviewed the policies and implementing procedures that govern the Continuum Dynamics, Inc. (CDI), program under Title 10 of the *Code of Federal Regulations* (10 CFR) Part 21, "Reporting of Defects and Noncompliance," to verify its compliance with the U.S. Nuclear Regulatory Commission's (NRC) regulatory requirements. The inspectors also reviewed the CDI procedures that govern corrective action and the control and correction of nonconforming items to verify an adequate link to the 10 CFR Part 21 process. The attachment to this inspection report lists the documents reviewed by the inspectors.

   b. Observations and Findings

   Quality Procedure (QP)-15.2, "Evaluations of Nonconformances for Reportability," Revision 3, dated June 3, 2011, establishes the requirements for CDI's compliance with the requirements in 10 CFR Part 21 and appropriately describes the requirements for including 10 CFR Part 21 applicability in CDI-issued purchase orders (POs), the posting requirements in 10 CFR Part 21, and record retention.

   The inspectors verified that QP-15.2; QP-16.1, "Corrective Action," Revision 2, dated May 27, 2011; and Section 16 of CDI's Quality Assurance Program Description (QAPD) provided a connection to the 10 CFR Part 21 program.

   The inspectors verified that CDI had not performed any evaluations on deviations or failures to comply in accordance with 10 CFR 21.21(a). All deviations identified in nonconformance reports (NCRs) and in corrective action reports (CARs) were identified during testing before the final test report results were delivered to the purchaser. The inspectors interviewed a principle investigator (PI) who would perform such evaluations and found that the PI was appropriately trained and capable of properly evaluating and reporting an issue in accordance with QP-15.2 and 10 CFR Part 21.

   The inspectors observed that CDI maintained one posting in its facility to satisfy the posting requirements in 10 CFR 21.6, "Posting Requirements." The posting included a copy of Section 206 of the Energy Reorganization Act of 1974 (as amended), a copy of 10 CFR Part 21, a copy of 10 CFR 50.55(e), and copies of QP-15.1, "Control of Nonconforming Items and Materials," Revision 4, dated November 1, 2010, and QP-15.2.

   The inspectors verified that, for a sample of CDI POs, CDI had implemented a program consistent with the requirements in 10 CFR 21.31, "Procurement Documents," for specifying the applicability of 10 CFR Part 21 in its POs for basic components.

   c. Conclusions

   The inspectors concluded that CDI appropriately translated the requirements in 10 CFR Part 21 into implementing procedures and, for those activities reviewed by the team, implemented them as required. No findings of significance were identified.

2. Training and Qualification of Personnel

a. Inspection Scope

The inspectors reviewed CDI's policies and procedures to verify that CDI was implementing training activities in a manner consistent with regulatory requirements and industry standards. The inspectors reviewed the personnel training and qualification process and the training and qualification records of four test personnel and three lead auditors to verify conformance with the requirements in Criterion II, "Quality Assurance Program," of Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants," to 10 CFR Part 50, "Domestic Licensing of Production and Utilization Facilities." In addition, the NRC inspection team discussed the personnel training and qualification process with CDI management and technical staff. The attachment to this inspection report lists the documents reviewed by the inspectors.

b. Observations and Findings

The inspectors verified that CDI had established and implemented training programs for the indoctrination and training of personnel who perform activities that affect quality, including testing personnel, engineers, and QA personnel, to ensure that proficiency was achieved and maintained. QP-2.2, "Indoctrination and Training," Revision 3, dated May 23, 2001, describes how CDI trains personnel who perform work that affects quality so that employees have sufficient training and skills for consistent job and task performance. The inspectors verified that qualification records appropriately documented certifications required by industry and contract requirements and that they have been periodically evaluated, reviewed, and approved in accordance with QA program requirements.

b.1 Testing Personnel

QP-2.3, "Qualification and Certification of Testers," Revision 3, dated June 17, 2009, describes how CDI trains and certifies test personnel. Test personnel are certified as Level I, II, or III test personnel based on the PI's evaluation of their education and experience. Nonmandatory Appendix 2A-1, "Nonmandatory Guidance on the Qualifications of Inspection and Test Personnel," to American Society of Mechanical Engineers (ASME) Nuclear Quality Assurance (NQA)-1-1994, "Quality Assurance Requirements for Nuclear Facility Applications," issued 1994, informs this evaluation. For each test personnel, the PI identifies the activities that the test personnel is certified to perform. For each test program, the PI selects test personnel based on education and previous experience, and each test personnel receives additional training and indoctrination on the specific technical objectives and quality requirements for each project. This training includes prejob briefings, training on the test plans and procedures, and an evaluation of the test personnel's demonstration of his or her ability to perform specific testing. The final certification of test personnel for each test program is reviewed and approved by the PI and the QA manager and documented in the associated design record file (DRF). For a sample of four test personnel, the inspectors verified that the personnel were trained and qualified in accordance with the CDI QAPD, applicable procedures, and the technical and quality requirements in the AREVA fuel testing program. The inspectors verified that the training of test facility personnel was

conducted and documented to familiarize them with facility hardware and software, equipment operation, test plans and procedures, and test specifications.

b.2 Audit Personnel

The inspectors verified that CDI's training and qualification program for lead auditors describes the authority, responsibility, and qualification requirements for lead auditors. QP-2.4, "Qualification and Certification of Audit Personnel," Revision 3, dated May 25, 2011, describes the process used to qualify and certify lead auditors to perform internal program audits, project audits, external supplier audits, and self-assessments. The inspectors determined that the qualification requirements are consistent with Supplement 2S-3, "Supplementary Requirements for the Qualification of Quality Assurance Program Audit Personnel," to ASME NQA-1-1994; Nonmandatory Appendix 2A-3, "Nonmandatory Guidance on the Education and Experience of Lead Auditors," to ASME NQA-1-1994; and Criterion II of Appendix B to 10 CFR Part 50.

The NRC inspection team verified that the training and qualification records for three lead auditors include training, experience, qualification credits, audit participation, examination scores, and annual evaluations approved by the QA manager or the president of CDI. The NRC inspection team verified that CDI had documented training on the appropriate training record forms in accordance with CDI procedures.

c. Conclusions

The inspectors concluded that CDI's program requirements for training and qualification of personnel are consistent with the requirements in Criterion II of Appendix B to 10 CFR Part 50. The inspectors also concluded that CDI's QAPD and associated training and qualification procedures were adequate and effectively implemented. No findings of significance were identified.

3. Procurement Document Control

a. Inspection Scope

The inspectors reviewed the CDI policies and procedures for procurement document control to verify compliance with Criterion IV, "Document Control," of Appendix B to 10 CFR Part 50. In addition, the inspectors reviewed the approved suppliers list (ASL) and a sample of POs to verify proper implementation of the CDI procurement program. The attachment to this inspection report lists the documents reviewed by the inspectors.

b. Observations and Findings

b.1 Procedural Controls for the Release of Procurement Documents

The inspectors noted that the QAPD and QP-4.1, "Procurement Document Control," Revision 2, dated May 25, 2011, provided sufficient guidance for the release of procurement documents. QP-4.1 describes how CDI controls the generation and content of procurement documents and subsequent changes. QP-4.1 identifies the information that must appear in the PO, including the description of the item or service supplied technical requirements, applicable QA requirements, and any documentation requirements.

b.2 Implementation of CDI Purchase Orders

For a sample of seven POs, the inspectors verified that the POs specify quality requirements, including technical, administrative, regulatory, and reporting requirements, and that they specify, where appropriate, that the supplier uses a documented QA program that is implemented and meets the applicable regulatory requirements. For the two safety-related POs issued to Westinghouse Electric Company and Structural Integrity Associates, the inspectors found that CDI appropriately implemented its program in accordance with its QA program and applicable regulations.

However, CDI issued five POs to Exelon PowerLabs and one to the Utah State University for commercial calibration services for measuring and test equipment (M&TE) that will be used in safety-related applications. The inspectors identified that CDI neither included the requirements to conform with 10 CFR Part 21 and Appendix B to 10 CFR Part 50 in the POs, nor did CDI dedicate the calibration services.

The inspectors also noted that CDI did not describe a commercial-grade dedication process in its QAPD. Furthermore, CDI did not develop instructions or procedures that provided guidance for controlling commercial grade item dedication activities such as (a) performing a technical evaluation and identifying critical characteristics, (b) determining the appropriate verification methods for each critical characteristic, (c) identifying the acceptance criteria for the verification method, and (d) documenting the dedication process in a dedication plan.

While the measuring and testing equipment calibrated by the Utah State University will be used for safety related testing, CDI had not used it at the time of the inspection. CDI took immediate corrective action and issued NCR 251 that committed to developing a commercial grade dedication procedure and performing a commercial grade dedication prior to using the instruments calibrated by the Utah State University.

CDI did use the M&TE calibrated by Exelon PowerLabs in safety related testing and did not perform a review to determine if the use of commercially calibrated measuring and testing equipment was suitable for safety related testing. The inspectors identified the failure to perform a review of the suitability of the application of the commercially calibrated measuring and testing equipment in safety related testing and without performing a commercial-grade dedication of the commercial calibration services as Nonconformance 99901265/2011-201-01.

c. Conclusions

The inspectors identified Nonconformance 99901265/2011-201-01 for CDI's failure to review the suitability of the application of commercially calibrated M&TE in safety-related testing and for its failure to dedicate the commercial calibration services. The inspectors concluded that the implementation of the CDI procurement document control program was inconsistent with the regulatory requirements in Criterion IV of Appendix B to 10 CFR Part 50.

4. Control of Purchased Material, Equipment, and Services

a. Inspection Scope

The inspectors reviewed the policies and procedures that govern the implementation of the CDI processes to verify compliance with Criterion VII, "Control of Purchased Material, Equipment, and Services," and Criterion XVIII, "Audits," of Appendix B to 10 CFR Part 50. The inspectors reviewed a sample of POs, the associated internal and external audit reports, and the supplier evaluations to evaluate compliance with program requirements and adequate implementation of those requirements. In addition, the inspectors reviewed the qualifications of auditors and corrective actions that address deficiencies identified by the audit findings for adequacy and timeliness. The attachment to this inspection report lists the documents reviewed by the inspectors.

b. Observations and Findings

b.1 Maintenance of the Approved Suppliers List

QP-4.2, "Evaluation of Suppliers," Revision 4, dated May 25, 2011," establishes the method for evaluating, auditing, qualifying, and approving suppliers that furnish quality-related items and services to CDI. QP-4.2 also establishes the method for the control and distribution of the ASL. The ASL identifies each approved supplier and its address, the scope of supply and any limits or restrictions, the initial supplier qualification date, the date of the most recent audit, and the date of the two interim annual evaluations.

QP-4.2 requires maintenance of the following documentation for each approved supplier:

- an ASL
- suppliers' evaluation forms
- supplier audit reports
- annual supplier evaluations

The inspectors verified that the ASL documents (1) the vendor name and address, (2) the scope of the vendor's qualification, (3) the required limitations and restrictions, if necessary, (4) the date of the last survey or audit, as applicable, and (5) the vendor's quality program and any CDI-established controls, if applicable. In addition, the inspectors verified the listings from the ASL and cross-referenced the information with applicable audit reports.

However, the inspectors identified one example of a supplier that was inappropriately placed on the ASL based on an inappropriate use of third-party accreditations. Criterion VII of Appendix B to 10 CFR Part 50 states, in part, that "measures shall be established to assure that purchased material, equipment, and services, whether purchased directly or through contractors and subcontractors, conform to the procurement documents. These measures shall include provisions, as appropriate, for source evaluation and selection, objective evidence of quality furnished by the contractor or subcontractor, inspection at the contractor or subcontractor source, and examination of products upon delivery."

Contrary to the above, CDI procedures QP-4.2 and QP-7.1, "Control of Purchased Materials, Equipment, and Services," Revision 3, dated May 23, 2011 improperly allow vendors to be placed on its ASL based on third party accreditation instead of source

evaluation and selection. Specifically, Step 5.3 in QP-4.2 states, "Suppliers who have a third party certification such as ASME certificate of authorization, a NAVLAP certification, an A2LA certification, or an ISO 9000 registration shall be evaluated by review of the scope and current status of accreditation. A CDI qualification audit is not required unless there is some reason to believe that there are limitations or restrictions that need further evaluation by qualification audit." In addition, Bullet 4 of Step 6.2 in QP-7.1 allows CDI to use a supplier's certification from a nationally recognized source, such as ASME, National Institute of Standards and Technology, American National Standards Institute, National Voluntary Laboratory Accreditation Program (NVLAP), or American Association for Laboratory Accreditation (A2LA), in lieu of an onsite evaluation if CDI obtains a copy of the certificate and verifies the supplier's capabilities based on the certificate and if the certificate not expired. CDI used QP-4.2 and QP-7.1 and improperly placed Exelon PowerLabs on its ASL based on third-party accreditation instead of source evaluation and selection

The use of third-party certification in lieu of source evaluation and selection of safety-related suppliers is inappropriate. As described in Information Notice 86-21, "Recognition of American Society of Mechanical Engineers Accreditation Program for N Stamp Holders," dated April 16, 1991, and its supplements, the NRC's recognition of ASME accreditation as evidence that a supplier has an acceptable documented QA program applies only to the programmatic aspects of the ASME accreditation program. Licensees, construction permit holders, and their subcontractors are still responsible for ensuring that the supplier is effectively implementing the approved QA program. The NRC does not recognize International Standardization Organization (ISO) 9000 as an acceptable method for meeting the requirements in Appendix B to 10 CFR Part 50 and does not consider ISO 9000 registration an acceptable basis for qualifying a supplier of basic components. Lastly, NVLAP or A2LA accreditation may only be used as the basis for qualifying a commercial calibration laboratory as part of the commercial-grade dedication process when all of the requirements described in the Arizona Public Service Company safety evaluation report (Agencywide Documents Access and Management System Accession No. ML052710224) are met. NVLAP and A2LA accreditation may not be used as the basis for qualifying safety-related calibration services.

The inspectors verified that Exelon PowerLabs was the only supplier that CDI placed on its current ASL based on third-party certification. The inspectors reviewed the basis for CDI's qualification of Exelon PowerLabs. This qualification included a review of Exelon PowerLabs' A2LA accreditation to verify that its accreditation included the scope of supply that CDI wanted to procure. CDI reviewed Exelon PowerLabs' capabilities described in its A2LA certificate and identified that Exelon PowerLabs' A2LA certification did not cover the complete scope of supply that CDI wanted to procure. CDI performed an audit of Exelon PowerLabs' Appendix B to 10 CFR Part 50 program and qualified Exelon PowerLabs as a safety-related supplier for the scope of supply outside of its A2LA certification.

CDI took immediate corrective action and opened NCR 252 to correct QP-4.2 and QP-7.1. The inspectors identified CDI's issuance of a safety-related PO to Exelon PowerLabs without the performance of a supplier qualification audit as Nonconformance 99901265/2011-201-02.

b.2 External Audits

The inspectors verified the CDI approval process for an external audit of Westinghouse Electric Company for the procurement of safety-related engineering and testing services, an external audit of Structural Integrity Associates for the procurement of safety-related engineering and testing services, an external audit of Exelon PowerLabs for the procurement of safety-related calibration services, and a surveillance of Utah State University for the procurement of safety-related calibration services.

The inspectors identified two examples of CDI's failure to appropriately qualify vendors, as identified in Nonconformance 99901265/2011-201-01 for failing to perform a review of the suitability of the application of the commercially calibrated M&TE from the Utah State University and Exelon PowerLabs in safety-related testing and Nonconformance 99901265/2011-201-02 for inappropriately qualifying Exelon PowerLabs based on third-party accreditation. However, the inspectors observed that for other safety-related procurements, the audits reviewed were adequately documented and provided evidence of the vendor's compliance with QA requirements. In addition, the inspectors verified that the checklists were prepared and completed for the audit and contained sufficient objective evidence to support the conclusions made by CDI. Furthermore, the inspectors also verified that CDI had approved the vendor's corrective actions for the issuance of any findings and that the approval was properly documented. The inspectors did not identify any additional issues in this area.

c. Conclusions

With the exception of the issuance of Nonconformance 99901265/2011-201-02 for CDI's issuance of a safety-related PO to Exelon PowerLabs without the performance of a supplier qualification audit, the inspectors concluded that CDI's implementation of control of purchased material, equipment, and services is not consistent with the regulatory requirements in Criteria VII of Appendix B to 10 CFR Part 50.

5. Test Control and Configuration Management

a. Inspection Scope

The inspectors reviewed the implementation of the CDI test control and configuration management process. Specifically, the inspectors interviewed personnel and reviewed the policies and procedures that govern the implementation of the CDI process to verify compliance with Criterion III and Criterion XI, "Test Control," of Appendix B to 10 CFR Part 50. The inspectors observed one Generic Safety Issue (GSI)-191, "Assessment of Debris Accumulation on PWR Sump Performance," downstream effects test for AREVA Evolutionary Power Reactor (EPR) fuel and reviewed documentation related to the test. The inspectors also observed the preparation of chemical surrogate material and the measurement of testing chamber dimensions. The inspectors observed these activities to determine whether the tests were conducted in accordance with written procedures and to determine whether the test procedures and test plan were consistent with the requirements in the customer specifications. The inspectors reviewed completed test documentation on six similar EPR GSI-191 downstream effects tests for the same contract to determine whether the tests were performed in accordance with the project specifications and the CDI QAPD. The attachment to this inspection report lists the documents reviewed by the inspectors.

b. Observations and Findings

b.1 Test Program

The inspectors verified that the CDI testing program clearly and comprehensively describes the processes necessary to accomplish the stated test program objectives. The test plan, test procedures, and CDI QP-11.1, "Test Control," Revision 3, dated June 17, 2009, provide the controls necessary for the successful performance of the tests and for the functionality of test equipment.

QP-11.1 describes the roles and responsibilities of the CDI test facility staff and support personnel. CDI assigns a PI to each test. The PI is responsible for developing and conducting the test program and for maintaining overall responsibility for the test program and data reduction. The PI is also responsible for ensuring that properly qualified and trained individuals perform the tests. The PI creates a DRF for each test that will include the supporting documentation for each test, such as the test plan, test procedures, data analysis, test personnel qualifications, and M&TE records assigned to the test.

DRF-AR-308, "EPR Fuel Assembly Head Loss Tests," documents the overall test plan for performing downstream effects testing on AREVA EPR fuel and comprises four hot-leg and three cold-leg injection tests. The inspectors observed hot-leg injection Test No. 6-FG-HLI-FPC and verified that the test plan clearly described the purpose and objectives of the test, test prerequisites, instrumentation, test sequence, and data acquisition hardware and software. The test plan clearly described the responsibilities of test personnel and the data to be collected. The inspectors observed the performance of portions of the test facility prerequisites, including the preparation of the chemicals, particulates, and fiber, and determined that they were adequately performed. Test personnel followed written procedures and signed each step before proceeding to the next.

The inspectors verified that completed test records and documentation for the previous six tests that CDI performed under DRF-AR-308 were in compliance with the CDI QAPD and project specifications. Specifically, the data collection and equipment used met the requirements established by the testing plan, the tests data were properly documented with completed data sheets, and all procedure steps were appropriately signed off.

Technical and quality information that crossed organizational interfaces was appropriately controlled. The CDI business unit received POs and provided complete copies of the POs to the PI. For the observed test, the PO was based on a CDI bid proposal, and the DRF included both the completed bid proposal and PO. Additional written communications between CDI and the customer that imposed changes to the technical requirements were also included in the DRF and were incorporated into the test plan.

However, the inspectors did identify one example where CDI failed to translate the technical requirements of the AREVA PO into the test plan and design drawings. Criterion III of Appendix B to 10 CFR Part 50 states, in part, that "measures shall be established to assure that applicable regulatory requirements and the design basis, as defined in § 50.2 and as specified in the license application, for those structures, systems, and components to which this appendix applies are correctly translated into specifications, drawings, procedures, and instructions" and that "measures shall also 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."

The AREVA PO specifies the required dimensions for the rectangular test chamber that encased the mockup fuel assembly during the test. These dimensions were specified with a tolerance of +/-0.005 inch. Achieving the specified width and depth of the rectangular test chamber was essential for ensuring that the gaps between each edge of the fuel assembly and the test chamber wall were representative of the half-gap width between EPR fuel assemblies and for ensuring that the test would measure prototypical pressure drops.

The inspectors learned that CDI did not identify the test chamber as a basic component and did not control the test chamber dimensions as attributes essential to demonstrate the safety-related functions of the fuel assemblies. CDI created an uncontrolled design drawing of the chamber that included dimensions but did not include tolerances. In addition, the test plan did not include acceptance criteria for the gaps between each edge of the fuel assembly and the test chamber wall, which are derived from the test chamber tolerances.

Upon completion of hot-leg injection Test No. 6-FG-HLI-FPC, CDI disassembled the test chamber and measured that the gaps between each edge of the fuel assembly and the test chamber wall. However, because of a lack of acceptance criteria in the test plan, CDI did not identify that the gap measurements were in a low out-of-tolerance condition in the left to right direction. The inspectors reviewed all seven tests performed under DRF-AR-308 and the tests performed under the initial DRF that used the chamber (DRF-AR-289, "Fuel Filter/Bottom Nozzle Testing") and identified that the test chamber dimensions for each test was outside of the lower bounds of the tolerance range. Although the actual chamber dimensions were not within the tolerance specifications, the inspectors noted that the smaller gaps would have conservatively affected the measured pressure differential

Because CDI failed to incorporate acceptance criteria related to the test chamber dimensions into the test plan and design drawing, CDI failed to identify and evaluate the out-of-tolerance condition of the test chamber used for DRF-AR-308 and, therefore, failed to receive approval from the customer before certifying the test results. CDI took immediate corrective action and opened NCR 254. The inspectors identified this example of a failure to translate technical requirements into specifications, drawings, procedures, and instructions as Nonconformance 99901265/2011-201-03.

b.2 Test Plan and Procedures

The test plan and test procedures appropriately contained test objectives, QA requirements, facility description and control, data acquisition and analysis, initial conditions, prerequisites, instructions, acceptance criteria, and post test activities. Revisions to the test plan were appropriately documented and controlled.

The inspectors witnessed one design certification test and reviewed documentation on six completed tests. The inspectors noted that for each of the six tests, CDI appropriately documented the following information:

- test parameters, initial conditions, and prerequisites
- test acceptance criteria

- test facility environmental conditions
- test anomalies and their disposition

Additionally, the inspectors verified that test instrumentation range, accuracy, and uncertainty were appropriate for the test, test instrumentation calibration was current, test procedure sequence was followed, and deviations from this test procedure sequence were adequately evaluated and documented.

However, the inspectors did identify one example in which CDI failed to provide an appropriate test procedure. Criterion XI of Appendix B of 10 CFR Part 50 states, in part, that "a test program shall be established to assure that all testing required to demonstrate that structures, systems, and components will perform satisfactorily in service is identified and performed in accordance with written test procedures, which incorporate the requirements and acceptance limits contained in applicable design documents."

The test facility used four flow control valves to direct flow through the fuel assembly. Depending on the test, two valves would be fully opened and the other two fully closed to simulate either hot- or cold-leg injection. The inspectors noted that any seat leakage past the closed valves, if present, would bypass the fuel assembly and would be recorded by the downstream flow meter. Because all of the measured flow was assumed to have passed through the fuel assembly the failure to measure the seat leakage past the closed valves represented a potential nonconservative error and could have adversely affected test validity. CDI had not considered testing the seat leakage past the closed valves as part of the test program and had failed to include provisions in the test plan to monitor and account for seat leakage.

However, as a result of the inspectors' questions, CDI took immediate corrective action, opened NCR 253, and tested the leaktightness of the valves. CDI determined that all four remained essentially leaktight and, therefore, did not invalidate previous test results. The inspectors identified this example of a failure to establish adequate written test procedures before the test as Nonconformance 99901265/2011-201-04.

b.3 Configuration Management

CDI QP-11.1 required that all changes to the test plan or procedure be reviewed and approved in the same manner as the original. CDI revised the test plan for DRF-AR-308 six times. The DRF contained all test plan revisions, and all previous revisions were clearly marked as being superseded. The DRF identified all facility instrumentation and components approved for the test and included the latest calibration certificates for each instrument.

However, the inspectors identified that CDI did not control the test chamber drawing as a quality document. Consequently, CDI modified the chamber by adding provisions to inject and vent nitrogen for the observed test. Although those modifications were reviewed by the PI and included in the test plan, the drawing revisions were not specifically verified and approved because CDI did not consider them to be quality

related. This issue is part of Nonconformance 99901265/2011-201-03, and the NRC is not dispositioning it as a separate nonconformance.

CDI QP-15.2 and QP-16.1 contain controls and instructions for documenting test failures or deviations that occurred during the conduct of design certification tests. No rework, modification, or repair activities were performed during this inspection.

b.4 Test Results and Data Reduction

In accordance with the project specifications, CDI recorded test data both manually using a paper data sheet and automatically using data acquisition software. CDI documented the verification and validation for the software used for DRF-AR-308 using Procedure No. TP-029 on December 2, 2008. The inspectors reviewed the completed procedure and determined that CDI effectively validated the software.

The software recorded pressure, flow, and temperature approximately every 2 seconds. The CDI data acquisition software converted the measured voltage from each monitored test instrument into engineering units for each data point. CDI calculated each instrument response using equations from the latest calibration certificate and documented the calculations appropriately. The inspectors' independent response curve calculations for each instrument correlated well to the CDI calculations. The inspectors reviewed the data output and the configuration of the installed instruments to confirm that the correct instruments were connected to the correct data point and that CDI correctly input the response curve coefficients into the software.

c. Conclusions

With the exception of Nonconformance 99901265/2011-201-04 for failure to account for and establish written test procedures to test for valve leakage and Nonconformance 99901265/2011-201-03 for failure to translate the test chamber tolerance requirements into the test plan and design drawings, the inspectors concluded that the implementation of the CDI program for test control was consistent with the regulatory requirements in Criterion III and Criterion XI of Appendix B to 10 CFR Part 50. Based on the sample of records reviewed, the inspectors concluded that qualified personnel were using qualified equipment and processes to adequately implement the CDI QAPD and the associated special test control procedures.

6. Control of Measuring and Test Equipment

a. Inspection Scope

The inspectors reviewed the implementation of the CDI process for control of M&TE. Specifically, the inspectors reviewed the policies and procedures governing the implementation of the CDI process to verify compliance with Criterion XII, "Control of Measuring and Test Equipment," of Appendix B to 10 CFR Part 50. The inspectors walked down the test laboratory and M&TE storage locations to verify that M&TE was properly labeled with the M&TE number and calibration period. The inspectors interviewed personnel responsible for the storage, control, and calibration of M&TE and reviewed the calibration history and certificates for a sample of M&TE. The inspectors reviewed records related to 10 instruments that were used for the observed test, such as pressure transmitters, thermocouples, a flow meter, pH probe, scale, and digital

displays, to determine whether the instruments were properly calibrated. The inspectors selected five instruments for a more detailed review to determine the historical performance of each instrument and to determine whether CDI was appropriately evaluating the effects on previous tests that used instruments found out of calibration. The attachment to this inspection report lists the documents reviewed by the inspectors.

b. Observations and Findings

All M&TE used during the test was adequately labeled with clear identification numbers, calibration dates, and calibration due dates. All M&TE was within the calibration interval, and CDI had current calibration certificates for each instrument used with DRF-AR-308. Additionally, CDI maintained an individual file for all M&TE that contained usage and calibration history. The inspectors noted several previous instances in which M&TE was found out of calibration and verified that CDI performed an adequate review of the usage history in each instance to ensure that the results of previous tests that used those instruments remained valid.

All calibration certificates document the National Institute of Standards and Technology calibration standards used to support the calibration as required by CDI QP-12.1, "Control of Calibrated Measuring and Test Equipment," Revision 4, dated June 1, 2011. QP-12.1 also contains adequate requirements for the control, calibration, storage, and handling of M&TE. For the observed test, the inspectors verified that the M&TE ranges, accuracies, and uncertainties were in compliance with the project specifications.

c. Conclusions

The inspectors concluded that the implementation of the CDI program for control of M&TE was consistent with the regulatory requirements in Criterion XII of Appendix B to 10 CFR Part 50. Based on the sample of records reviewed, the inspectors concluded that M&TE was properly controlled, calibrated, and adjusted at specified periods to maintain accuracy within necessary limits as required by the CDI QAPD and the associated special test control procedures. No findings of significance were identified.

7. Nonconforming Materials, Parts, or Components

a. Inspection Scope

The inspectors reviewed the CDI policies and procedures for control of nonconforming materials, parts, or components to verify compliance with Criterion XV, "Nonconforming Materials, Parts, or Components," of Appendix B to 10 CFR Part 50. The inspectors reviewed a sample of vendor NCRs to verify that CDI's implementation and control over nonconforming quality materials, parts, or components was adequate. The attachment to this inspection report lists the documents reviewed by the inspectors.

b. Observations and Findings

Section 15 of the CDI QAPD establishes measures to control nonconforming items or activities. In addition, QP-15.1, "Control of Nonconforming Items and Materials," Revision 4, dated November 1, 2010, describes the detailed actions necessary to implement the program, such as defining the roles and responsibilities of CDI personnel and establishing the requirements for the identification, documentation, control,

disposition, review, and approval of nonconforming materials and services. QP-15.1 also establishes documentation requirements, such as NCRs. Furthermore, QP-15.1 includes steps that direct CDI employees to follow QP-15.2 when an evaluation is necessary to identify a potential substantial safety hazard.

The inspectors verified that the nonconformance reporting methods adequately identified the equipment, description of the physical item(s), description of the nonconformance (where applicable), and cause of the deficiency. In addition, the inspectors identified the QA management reviewer, the justification for the disposition, the final quality review, the closure date and signature, and the corrective actions completed and verified by the QA and quality control staff. The inspectors reviewed every NCR written since 2006 and verified that the aforementioned controls were appropriately implemented.

The inspectors walked down the CDI shop floor and verified that nonconforming materials were properly identified, marked, and segregated when practical to ensure that they were not reintroduced into the production processes. The inspectors verified that CDI had adequate controls for the segregation of in-process, nonconforming materials.

c. Conclusions

The inspectors concluded that the implementation of the CDI program for control of nonconforming material, parts, and components is consistent with the regulatory requirements in Criterion XV of Appendix B to 10 CFR Part 50. Based on the limited sample of documents reviewed and on the observation of ongoing testing activities at the CDI facility, the inspectors also determined that CDI is effectively implementing its QAPD and the associated nonconformance procedures. No findings of significance were identified.

8. Corrective Actions

a. Inspection Scope

The inspectors reviewed the implementation of the CDI process for corrective actions. Specifically, the inspectors reviewed the policies and procedures governing the implementation of the CDI process to verify compliance with Criterion XVI, “Corrective Action,” of Appendix B to 10 CFR Part 50. In addition, the inspectors reviewed a sample of NCRs and CARs associated with materials that depart from technical requirements and discussed the program with CDI personnel responsible for the implementation of the corrective action program. The attachment to this inspection report lists the documents reviewed by the inspectors.

b. Observations and Findings

Section 16 of the CDI QAPD defines the processes for the identification and documentation of corrective and preventive actions. It describes the detailed actions necessary to implement the corrective action program, such as defining the roles and responsibilities of CDI personnel, establishing documentation requirements (e.g., CAR forms), identifying a periodic review process for NCRs for the initiation of a CAR form, and establishing actions to correct the condition and preventive its reoccurrence.

QP-16.1 assigns responsibilities for identifying and reviewing NCRs and CARs, documentation, and the disposition of deviations or failures to comply. The procedure describes the process for identifying, evaluating, reporting, and correcting nonconformances. In addition, the inspectors discussed the nonconformance and corrective action process with the vendor, including the establishment and roles of the QA manager in the periodic review process.

The NRC inspection team noted that each NCR contained a detailed description of the nonconformance and a justification for dispositioning the condition that led to the nonconformance, which usually included undertaking corrective action to prevent its recurrence, when applicable. The inspectors noted that CDI's corrective action procedures lead them to evaluate conditions for 10 CFR Part 21 reportability, when required.

The inspectors discussed the corrective action section of the QAPD with the vendor, as defined in Section 16 of the QAPD. The inspectors noted that although the CARs written since 2006 were all developed to correct actions from external and internal audits only, CDI's corrective action program, together with its nonconformance program, effectively captured deficiencies.

c. Conclusions

The inspectors concluded that, based on the limited sample of CARs reviewed, the implementation of the CDI program for corrective actions was consistent with the regulatory requirements in Criterion XVI of Appendix B to 10 CFR Part 50.

9. Quality Assurance Records

a. Inspection Scope

The inspectors reviewed the CDI policies and procedures that govern the control of QA records and interviewed CDI personnel to verify compliance with the requirements in Criterion XVII, "Quality Assurance Records," of Appendix B to 10 CFR Part 50. In addition, the inspectors reviewed a sample of POs, DRFs, training and qualification records, test records, and calibration reports to verify the implementation of the CDI QA records program. The attachment to this inspection report lists the documents reviewed by the inspectors.

b. Observations and Findings

QP-17.1, "Quality Records," Revision 1, dated March 28, 2008, establishes the methods for the identification, review, storage, retention, and turnover of QA records generated by CDI. QP-6.1, "Document Control," Revision 1, dated March 28, 2008, describes how CDI controls the release and subsequent revision to documents that specify quality requirements, prescribe activities affecting quality, or record results of quality activities.

The inspectors verified that CDI had implemented a document records system that provided measures for the identification, classification, validation, and distribution controls of records. Procedures are in place to verify the process for receipt control, processing, corrections, and safekeeping for all documented records.

The inspectors verified that the QA program provided for the administration, identification, receipt, storage, preservation, safekeeping, and disposition of all records and that CDI had developed procedures and policies to adequately implement the requirements for record retention. The CDI staff indicated that while QP-17.1 describes a retention scheme, CDI has not destroyed any quality record that exceeded its specified retention period. The records and retention times complied with Regulatory Position C.2 and Table 1 in Regulatory Guide 1.28, "Quality Assurance Program Criteria (Design and Construction)," Revision 3, issued August 1985, for design, construction, and initial startup.

For a sample of training records, DRFs, calibration records, POs, and audits, the inspectors verified that the records were legible, adequate, retrievable, adequately protected, and traceable.

c. Conclusions

The inspectors concluded that the requirements of the CDI QA records program were consistent with the regulatory requirements in Criterion XVII of Appendix B to 10 CFR Part 50. Based on the QA records reviewed, the NRC inspection team also determined that CDI adequately implemented the QAPD and implementing procedures. No findings of significance were identified.

10. Internal Audits

a. Inspection Scope

The inspectors reviewed the implementation of the CDI process for conducting internal audits. Specifically, the inspectors reviewed the policies and procedures that govern the implementation of the CDI process to verify compliance with Criterion XVIII of Appendix B to 10 CFR Part 50. In addition, the inspectors reviewed the internal audits conducted over the past 5 years and discussed the program with CDI personnel responsible for the implementation of the audit program. The attachment to this inspection report lists the documents reviewed by the inspectors.

b. Observations and Findings

Section 18 of the QAPD defines the CDI processes for conducting audits. It describes the detailed actions required to implement the audit program, such as defining the roles and responsibilities of CDI personnel and establishing actions to correct the audit findings.

QP-18.1, "Audits," Revision 1, dated June 14, 2007, assigns responsibilities for conducting and reviewing audits and describes how CDI can take credit for the conduct of external audits at its facility. CDI's auditors review and verify the external audit plan and checklist used meets CDI's requirements; and that the auditors are qualified in accordance with CDI's requirements. The inspectors noted that CDI did not have all the training records of the external auditors on site; however, CDI assured the inspectors that the auditors were qualified and quickly obtained copies of the auditors' qualification records for verification.

The inspectors noted that CDI's QA program is broken down into two sections to conduct audits: (1) administrative and (2) technical. While conducting internal audits, the auditors use Internal Audit Checklist, Revision 3, Part 1, "Administrative," and Part 2, "Technical." The only two employees currently qualified as lead auditors at CDI are the QA manager and one senior associate, who is also the PI for all safety-related testing. Because of their responsibilities in other areas, the QA manager conducts the technical part, and the senior associate conducts the administrative part. The inspectors identified that during the June 1, 2009, internal audit, the senior associate conducted both sections of the audit. The senior associate was designated as the PI for all safety-related work in 2008 and 2009; this period covered the June 1, 2009, audit.

The QAPD defines the PI's responsibilities, which include designating and supervising investigators on quality-related projects, determining which contracts require the preparation of a DRF, ensuring that all analyses and engineering calculations are reviewed and checked, and approving DRFs.

Criterion XVIII of Appendix B to 10 CFR Part 50 states, in part, that "the audits shall be performed in accordance with the written procedures or check lists by appropriately trained personnel not having direct responsibilities in the areas being audited."

Section 5.8 of CDI QP-18.1 states, in part, that "the audit shall be conducted by personnel having no direct responsibility in the areas being audited."

Contrary to the above, a CDI employee who has direct responsibility for the technical areas within the QA program conducted the entire CDI QA internal audit on June 1, 2009. Specifically, the employee was the PI for commercial nuclear safety-related testing projects during 2008 and 2009 with responsibility in the areas of design control, test control, and control of M&TE. The inspectors reviewed the internal audits from 2010 and 2011 and verified that no issues of significance were identified in the areas in which the PI had direct responsibility. In addition, CDI took immediate corrective action and opened NCR 255. This issue has been identified as Nonconformance 99901265/2011-201-05.

c. Conclusions

With the exception of Nonconformance 99901265/2011-201-05 issued for CDI's failure to ensure that auditors are not responsible for the areas audited, the inspectors concluded that, based on the limited sample of audits reviewed, the implementation of the CDI internal audit program was consistent with the regulatory requirements in Criterion XVIII of Appendix B to 10 CFR Part 50.

11. Entrance and Exit Meetings

On June 13, 2011, the inspectors discussed the scope of the inspection with Ms. Barbara Agans, CDI Quality Assurance Manager, and with the CDI management and staff. On June 17, 2011, the inspectors presented the inspection results and observations during an exit meeting with Ms. Agans and other CDI staff. The attachment to this report lists the entrance and exit meeting attendees and those interviewed by the inspectors.

ATTACHMENT

1. ENTRANCE/EXIT MEETING ATTENDEES

Name	Title	Affiliation	Entrance	Exit	Interviewed
Samantha Crane	Inspection Team Lead	NRC/NRO	X	X	
Douglas Bollock	Inspector	NRC/NRO	X	X	
Timothy Steadham	Inspector	NRC/R-II	X	X	
Shanlai Lu	Technical Specialist	NRC/NRO	X	X	
Jason Carneal	Project Manager	NRC/NRO	X		
Barbara Agans	Quality Assurance Manager	CDI	X	X	X
Andrew Kaufman	Senior Associate	CDI	X		X
Thomas Curbishley	Associate	CDI		X	X
David Perez	Senior Technician	CDI			X

2. INSPECTION PROCEDURES USED

Inspection Procedure (IP) 43002, "Routine Inspections of Nuclear Vendors," dated April 25, 2011

IP 35034, "Design Certification Testing Inspection," dated January 27, 2010

IP 36100, "Inspection of 10 CFR Parts 21 and 50.55(e) Programs for Reporting Defects and Noncompliance," dated April 25, 2011

3. LIST OF ITEMS OPENED, CLOSED, AND DISCUSSED

The following items were found during this inspection:

Item Number	Status	Type	Description
99901265/2011-201-01	Open	NON	Criteria III and V
99901265/2011-201-02	Open	NON	Criterion VII
99901265/2011-201-03	Open	NON	Criterion III
99901265/2011-201-04	Open	NON	Criterion XI
99901265/2011-201-05	Open	NON	Criterion XVIII

4. DOCUMENTS REVIEWED

AREVA Purchase Order (PO) 1011030203, "Perform EPR Fuel Assembly Downstream Effects Testing," dated May 3, 2011

Audit of Westinghouse Electric Company, March 2009

Audit of Exelon PowerLabs for calibration services, May 2011

Audit of Structural Integrity Associates for engineering and testing services

Calibration Certificate No. 4801911 for Instrument No. 0643, dated July 8, 2010

Calibration Certificate No. 10642363 for Instrument No. 0734, dated April 29, 2011

Calibration Certificate No. 10642364 for Instrument No. 0733, dated April 21, 2011

Calibration Certificate No. 10642753 for Instrument No. 0633, dated May 3, 2011

Calibration Certificate No. 10645138 for Instrument No. 0280, dated May 16, 2011

Calibration Certificate No. 10645140 for Instrument No. 0660, dated May 26, 2011

Calibration Certificate No. 10645142 for Instrument No. 0377, dated May 9, 2011

Calibration Certificate No. 10645144 for Instrument No. 0663, dated May 26, 2011

Calibration Certificate No. 10648937 for Instrument No. 0836, dated May 26, 2011

Calibration Certificate No. 10646805 for Instrument No. 0595, dated May 17, 2011

Corrective Action Report (CAR) 012, "TVA/NUPIC Deviation Report 2007V-14-02 Procedures Do Not Reflect Actual Practices," dated November 8, 2007

CAR 013, "TVA/NUPIC Deviation Report 2007V-14-03 Implementation of CARs," dated November 8, 2007

CAR 014, "GENE CAR 44121 Quality Assurance Manager Not Independent of Cost and Scheduling," dated November 28, 2007

CAR 015, "GENE CAR 44140 NCR Form/Corrective Action Information," dated November 29, 2007

CAR 016, "GENE CAR 44141 No Internal Audit for 2005," dated November 29, 2007

CAR 017, "GENE CAR 44142 Deviation from CDI/GE Interface Agreement," dated November 29, 2007

CAR 018, "GENE CAR 44143 Wrong Version of QA Manual Referred to in QA Procedures," dated November 29, 2007

CAR 019, "Internal Audits," dated October 15, 2008

CAR 020, "Missing Closeout of NCRs and CARs by QA Manager," dated June 1, 2009

CAR 021, "Missing DRF Closeout by QA Manager," dated June 1, 2009

CAR 022, "Forms QA24 and QA37 Not Changed," dated June 1, 2009

CAR 023, "Various Inconsistencies in QA Program Administration," dated June 8, 2009

CAR 024, "Quality Records Not Filed Properly," dated June 9, 2010

CAR 025, "Deficiencies in Quality Assurance Internal Audits," dated June 9, 2010

CAR 026, “Inadequacy of External Audits,” dated June 9, 2010

CAR 027, “Inadequacy of Annual Evaluation of Supplier,” dated June 9, 2010

CAR 028, “CDI POs Do Not Specify QA Requirements Properly,” dated July 16, 2010

CAR 029, “QA Program Needs Improvement,” dated July 16, 2010

CAR 030, “Rework/Reexamination Procedure Required (NIAC CAR M017),” dated September 7, 2010

CAR 031, “CARs Not Closed Out Timely (NIAC CAR M018),” dated September 7, 2010

CAR 032, “Procedure for Validation and Verification of Software (NIAC CAR M019),” dated September 7, 2010

CAR 033, “Failure to Provide Semi-Annual Distribution Report to EPRI,” dated November 30, 2010

Continuum Dynamics, Inc., “Quality Assurance Program Description,” Revision 14, dated February 28, 2006

CDI Approved Suppliers List (ASL)

CDI Design Record File (DRF)-AR-289, “Fuel Filter/Bottom Nozzle Testing”

CDI DRF-AR-308, “EPR Fuel Assembly Head Loss Tests”

CDI Measuring and Test Equipment (MT&E) Log File, current as of June 15, 2011

CDI Procedure TP-027, “Bypass Fiber Generation,” Revision 0, dated September 30, 2009

CDI Procedure TP-029, “Data Acquisition Software Verification of LSP60.exe,” Revision 0, dated December 2, 2008

CDI Procedure TP-034, “Fuel Assembly Hot-Leg Injection Test,” Revision 0, dated May 31, 2011

CDI Proposal No. P11-34, “Proposal for EPR Fuel Assembly Head Loss Tests,” dated April 26, 2011

CDI Test Plan 11-02, “AREVA EPR Fuel Assembly Downstream Effects Test Plan,” Revision 6, dated June 13, 2011

CDI Procedure TP-010, “Generate Chemical Surrogates,” Revision 1, dated May 23, 2011

CDI Procedure TP-010, “Generate Chemical Surrogates, Revision 1, dated May 25, 2011

CDI Procedure TP-010, “Generate Chemical Surrogates,” Revision 1, dated May 31, 2011

CDI Procedure TP-010, “Generate Chemical Surrogates,” Revision 1, dated June 3, 2011

CDI Procedure TP-010, “Generate Chemical Surrogates,” Revision 1, dated June 6, 2011

CDI Procedure TP-010, “Generate Chemical Surrogates,” Revision 1, dated June 8, 2011

CDI Procedure TP-010, “Generate Chemical Surrogates,” Revision 1, dated June 13, 2011

Engineering Calculation for Differential Pressure Cell and Display 0287/0292, 0377/0280, and 0614/0611, dated May 19, 2011

Engineering Calculation for Differential Pressure Cell and Display 0633/0292, dated May 20, 2011

Engineering Calculation for Flow Meter 0643, dated July 12, 2010

Engineering Calculation for Thermocouple 0734, dated May 19, 2011

Fuel Assembly Cold-Leg Injection Test No. 1-FG-CLI-FPC, dated May 23, 2011

Fuel Assembly Cold-Leg Injection Test No. 1-FG-CLI-FPC-2, dated May 25, 2011

Fuel Assembly Hot-Leg Injection Test No. 2-FG-HLI-FPC, dated June 2, 2011

Fuel Assembly Hot-Leg Injection Test No. 3-FG-HLI-FPC, dated June 3, 2011

Fuel Assembly Cold-Leg Injection Test No. 4-FG-CLI-FPC, dated June 7, 2011

Fuel Assembly Hot-Leg Injection Test No. 5-FG-HLI-FPC, dated June 9, 2011

Fuel Assembly Hot-Leg Injection Test No. 6-FG-HLI-FPC, dated June 14, 2011

Instrumentation Log for Contract No. T222, dated June 2, 2011

Instrument Calibration Record for Krohne Flow Meter, Log No. 0643

Instrument Calibration Record for Omega pH/mV/Temperature Meter, Log No. 0660

Instrument Calibration Record for Rosemount Differential Pressure Cell, Log No. 0377

Instrument Calibration Record for Rosemount Differential Pressure Cell, Log No. 0633

Instrument Calibration Record for Sensotec Display, Log No. 0280

Internal Audit Checklist, Rev 3 Part 1 “Administrative”

Internal Audit Checklist, Rev 3 Part 2 “Technical”

Leak Check for Flow Control Valves, dated June 14, 2011

Nonconformance Report (NCR) 211A, “Anomaly in Flow,” dated June 2, 2008

NCR 212, “Loose Wire on Temperature Meter,” dated June 9, 2008

NCR 213, “Indeterminate Temperature Measurement,” dated June 10, 2008

NCR 214, “Temperature Display Was out of Cal[ibration] during Testing,” dated June 24, 2008

NCR 215, “Incorrect Dimension Used in Calculations,” dated August 22, 2008

NCR 216, “4 Power Supplies and 1 Pressure Transducer Were out of Cal[ibration] during Testing,” dated September 26, 2008

NCR 217, “NCR 0216 Was Not Written When the Nonconformance Was Recognized,” dated September 26, 2008

NCR 218, “MT&E Calibrated without Purchase Order and Instructions,” dated October 2, 2008

NCR 219, “Differential Pressure cell ‘P2’ Exceeded Calibrated Rant of 150” H_2O: Test FG-FPC-W-2,” dated December 8, 2008

NCR 220, “Test pH Level Exceeded Upper Limit: Test FG-FPCSC-W-5,” dated December 18, 2008

NCR 221, “AlOOH Settling Test Conducted at 9.7 g/ml Rather Than 2.2 g/ml Specified by Westinghouse,” dated December 18, 2008

NCR 222, “Pipe Fitting Cracked during Test: Test FG-FPCSC-W-5,” dated December 18, 2008

NCR 223, “Test pH Level Exceeded Upper Limit: Test FG-FPCSC-W-3,” dated December 18, 2008

NCR 224, “A/D System Momentarily Displayed (and Recorded) Incorrect Data during Test FG-FPC-CE-7,” dated December 23, 2008

NCR 225, “Anomaly in A/D Readings,” dated December 29, 2008

NCR 226, “Erroneously Reported Fiber Addition,” dated December 29, 2008

NCR 227, “Test LV-528T-205 Data Overwritten,” dated January 29, 2009

NCR 228, “Thermocouple Contacts Became Wet,” dated February 18, 2009

NCR 229, “Range of Applicability Not Explicitly Stated,” dated August 25, 2009

NCR 230, “Loose Wire on Pressure Display 0634,” dated October 1, 2009

NCR 231, “Temp[erature] Probe Arrived out of Spec[ification],” dated October 1, 2009

NCR 232, “Differential Pressure Display 0281 Used out of Calibration,” dated May 11, 2010

NCR 233, “0633 Differential Pressure Cell Was Found out of Calibration,” dated May 10, 2011

NCR 234, “0390 12” Dial Caliper Found out of Tolerance,” dated May 13, 2011

NCR 235, “0669 Thermocouple out of Tolerance at High Temp[erature] (400 Degrees),” dated May 13, 2011

NCR 236, “0745 Thermocouple out of Tolerance,” dated May 13, 2011

NCR 237, “0292 Display Found out of Tolerance,” dated May 18, 2011

NCR 238, “Rosemount Differential Pressure 0287 Would Not Zero Properly at Pretest Check,” dated May 20, 2011

NCR 239, “Instrument Folder for 0371 Is Missing,” dated May 20, 2011

NCR 240, “0611 Display Found out of Tolerance,” dated May 23, 2011

NCR 241, “0371 Dataq A/D Found out of Tolerance,” dated May 23, 2011

NCR 242, “Inst[rument] 0643 Has 2 Calibration Stickers,” dated May 25, 2011

NCR 243, “Display 0611/0614 Began Reading Negative Pressures,” dated May 26, 2011

NCR 244, “Flow Rate for Test 2-FG-HLI-EPC Fell below Setpoint,” dated June 2, 2011

NCR 245, “Test 5-FG-HLI-FPC: Pressure Lines to Differential Pressure Cell 0377 Reversed,” dated June 9, 2011

NCR 246, “Recording Error: Test 5-FG-HLI-FPC Recorded Fiber Addition on Wrong Line of Data Sheet,” dated June 9, 2011

NCR 247, “Posttest Calibration-Inoperative Probe,” dated June 10, 2011

NCR 248, “Rotameter Inoperative,” dated June 10, 2011

NCR 249, “Procedure Does Not Reference Reducing Flow Rate per Test Plan,” dated June 11, 2011

NCR 250, “Auditor Certifications Incomplete,” dated June 15, 2011

NCR 251, “USU on ASL without Commercial-Grade Dedication,” dated June 16, 2011

NCR 252, “Calibrations Procured from A2LA or NVLAP Vendor Requirements Procedures Incorrect,” dated June 16, 2011

NCR 253, “Potential Leak Path Through Valves Was Note Checked by Written Procedures,” dated June 16, 2011

NCR 254, “Fuel Guard Gaps Exceed Tolerance,” dated June 16, 2010

NCR 255, “Internal Audit for 2009 Was Done by AEK Who Did Not Have Complete Independence of The Areas Being Audited,” dated June 16, 2011

PO 08-509 to Structural Integrity Associates for engineering services

PO 09-0389 to Westinghouse Electric Company for engineering services

PO 11-117 to Utah State University for calibration services

PO 11-161, Calibration Services to Exelon PowerLabs, dated April 7, 2011

PO 11-200, Calibration Services to Exelon PowerLabs, dated April 28, 2011

PO 11-200A to Exelon PowerLabs, LLC, for calibration services

PO 11-222 to Exelon PowerLabs, LLC, for calibration services

PO 11-268 to Exelon PowerLabs, LLC, for calibration services

Quality Assurance (QA) Internal Audit performed July 28, 2006

QA Internal Audit performed July 27, 2007, followed external Nuclear Industry Assessment Committee (NIAC) Audit using NIAC

Audit Checklist, Revision 4, dated June 9, 2004

QA Internal Audit performed October 22–23, 2008

QA Internal Audit performed June 1, 2009

QA Internal Audit performed July 27, 2010, followed external NIAC Audit using NIAC

Audit Checklist, Revision 8, dated September 16, 2009

Quality Procedure (QP)-2.2, “Indoctrination and Training,” Revision 3, dated May 23, 2001

QP-2.3, “Qualification and Certification of Testers,” Revision 3, dated June 17, 2009

QP-2.4, “Qualification and Certification of Audit Personnel,” Revision 3, dated May 25, 2011

QP-3.1, “Design Control,” Revision 5, dated May 31, 2011

QP-3.2, “Control of Computer Software and Error Control,” Revision 3, dated October 29, 2010

QP-4.1, “Procurement Document Control,” Revision 2, dated May 25, 2011

QP-4.2, “Evaluation of Suppliers,” Revision 4, dated May 25, 2011

QP-6.1, “Document Control,” Revision 1, dated March 28, 2008

QP-7.1, “Control of Purchased Materials, Equipment, and Services,” Revision 3, dated May 23, 2011

QP-10.2, “Inspection,” Revision 1, dated March 28, 2008

QP-11.1, “Test Control,” Revision 3, dated June 17, 2009

QP-12.1, “Control of Calibrated Measuring and Test Equipment,” Revision 4, dated June 1, 2011

QP-15.1, “Control of Nonconforming Items and Materials,” Revision 4, dated November 1, 2010

QP-15.2, “Evaluations of Nonconformances for Reportability,” Revision 3, dated June 3, 2011

QP-16.1, “Corrective Action,” Revision 2, dated May 27, 2011

QP-17.1, “Quality Records,” Revision 1, dated March 28, 2008

QP-18.1, “Audits” Revision 1, dated June 14, 2007

QP-18.1, “Audits,” Revision 2, dated June 17, 2009

Raw Data from Test 6-FG-HLI-FPC, dated June 14, 2011

Surveillance of Utah State University, April 2011

Training and qualification records for four test personnel and three lead auditors