Continuum Dynamics, Inc.

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September 9, 2011

U.S. Nuclear Regulatory Commission
Attn: Document Control Desk
Washington, DC 20555-0001

Subject: Reply to Notice of Nonconformance

Reference: NRC Inspection Report No. 99901265/2011-201

In response to US NRC Letter dated July 28, 2011, this letter contains our reply to the above referenced Inspection Report. Continuum Dynamics, Inc. has taken action to correct nonconforming items as identified by the NRC Inspection performed by Inspectors Samantha Crane, Timothy Steadham, Douglas Bullock and Shanlai Liu on June 13-17, 2011.

Our reply to Nonconformance Nos. 99901265/2011-201-01, 99901265/2011-201-02, 99901265/2011-201-03, 99901265/2011-201-04 and 99901265/2011-201-05 are enclosed with this letter.

Continuum Dynamics, Inc. appreciates the time expended by the Inspectors and their comments and suggestions to continue improvement of our nuclear quality assurance program.

Should you have any questions with regard to the enclosed responses, please do not hesitate to contact me at 609-538-0444 x106.

Very truly yours,

Barbara A. Agans
Quality Assurance Manager

c: Chief, Quality and Vendor Branch 2
Division of Construction Inspection and Operational Programs
Office of New Reactors

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NRC Nonconformance 99901265/2011-201-01

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.

Continuum Dynamics, Inc.'s Reply to Nonconformance

In response to Nonconformance **99901265/2011-201-01**, Continuum Dynamics, Inc. submits the following corrective action:

1) Reason for noncompliance

CDI performed a source verification of Utah State University (USU) by witnessing the calibration of CDI's instruments at the USU facility in accordance with Article 6.5 of CDI Quality Procedure QP-7.1 R3. CDI's program allowed source verification for procurement of complex goods or services when a supplier did not have a 10CFR Part 21 or 10 CFR Part 50 Appendix B program. CDI had misunderstood the regulatory requirements for use of a surveillance to qualify and review the suitability of a supplier. Since CDI became aware of the requirement for a commercial grade dedication of USU prior to the NRC Inspection, CDI was in the process of preparing a new Quality Procedure to be completed prior to using the calibration service provided by USU for a safety-related activity.

In addition, CDI used Exelon PowerLabs for calibration services by review of their A2LA and NVLAP certifications in accordance with Article 6.2 of CDI QP-7.1 R3.

CDI's program allowed for the use of a NVLAP or A2LA certified laboratory for calibration services in accordance with Article 5.3 of QP-4.2 and Article 6.2 of QP 7.1 by review of the laboratory's qualifications and certifications. CDI misunderstood the regulatory requirements for use of a third party vendor. Note that none of the instruments calibrated by USU or Exelon PowerLabs had been used for a safety-related activity.

2) Corrective steps that have been taken and the results achieved

CDI issued a Nonconformance Report No. 0251 committing to development of a commercial grade dedication procedure. CDI has prepared and issued a procedure for commercial grade dedication of calibration services entitled "Acceptance of Commercial Grade Calibration Services from Non-Accredited Calibration Laboratories by the Source Verification Method," CDI Quality Procedure No. QP-7.2 R0 dated August 29, 2011. CDI's surveillance of USU has been utilized to perform a commercial grade dedication following a dedication plan as documented on a newly generated form - QA Form No. 63. The dedication plan, which includes a review of the critical characteristics to assure that the services will be adequate for the intended application, has been approved by the CDI Principal Investigator and the CDI Quality Assurance Manager. It has been determined by CDI management and QA that the instruments calibrated by USU can now be used for safety-related testing.

In addition, CDI issued a Nonconformance Report No. 0252 committing to modify the Quality Procedures QP-4.2 and QP-7.1 to include guidance for controlling commercial grade dedication of NVLAP and A2LA certified calibration suppliers (described in detail in NRC Nonconformance 99901265/2011-201-02).

3) Corrective steps that will be taken to avoid noncompliance

CDI has issued a new Quality Procedure (QP-7.2), and has revised two existing Quality Procedures (QP-4.2 and QP-7.1). Issuance of these procedures required retraining of personnel to assure that new procedures are properly followed. A retraining meeting of Lead Auditors, Principal Investigators and Management was held to assure that procurements of safety-related calibration services from commercial vendors follow the new commercial grade dedication procedure (CDI QP-7.2). Requirements of QP-7.2 will be added to the Internal Audit Checklist to assure acceptable implementation of the new requirements. Also covered in the retraining meeting was a review of the requirements which must be met before a NVLAP or A2LA certified laboratory can be used for quality-related calibration services.

4) **Date when the corrective action will be completed**

Continuum Dynamics, Inc. has issued Nonconformance Report (NCR) No. 0251 and No. 0252; corrective actions have been completed.

NRC Nonconformance 99901265/2011-201-02

Criterion IV, "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 or authorization, accreditation through the National Voluntary Laboratory Accreditation Program or the American Association for Laboratory Accreditation, or an International Standardization Organization 9000 registration.

Continuum Dynamics, Inc.'s Reply to Nonconformance

In response to Nonconformance **99901265/2011-201-02**, Continuum Dynamics, Inc. submits the following corrective action:

1) Reason for noncompliance

CDI utilized a laboratory which did not have a 10 CFR Part 21 or Appendix B program to perform calibration services for a safety-related activity. However, CDI's Quality Assurance program allowed for use of a NVLAP or A2LA certified laboratory for calibration services in accordance with Article 5.3 of QP-4.2 R4 and Article 6.2 of QP 7.1 R3 by review of the laboratory's qualifications and certifications. CDI misunderstood the regulatory requirements for source evaluation and selection of contractors that were NVLAP or A2LA certified. None of the calibrations had been used for a safety-related activity.

2) Corrective steps that have been taken and the results achieved

Two of CDI's Quality Procedures have been revised. Use of third party ASME and ISO 9000 certifications has been deleted from CDI Quality Procedure 4.2. QP-4.2 has also been revised to include commercial grade dedication process for NVLAP or A2LA certified laboratories before use in safety-related activities. The commercial grade dedication includes the following: a review of NVLAP or A2LA laboratory to assure that it is a domestic calibration service provider, its NVLAP or A2LA accreditation is to ANSI/ISO/IEC 17025, and its scope of accreditation covers the contracted services to be provided. In addition, CDI's procurement documents must include reporting of as-found calibration data when calibrated items are found out-of-tolerance, identification of the laboratory equipment/standards used, and the necessity for any subsuppliers to comply to all of the requirements of CDI's procurement document. CDI's Quality Procedure 7.1

has been revised to delete acceptable third party certifications from ASME and ISO 9000 and to require commercial grade dedication of A2LA/NVLAP certified laboratories prior to adding supplier to CDI's ASL (in accordance with revised QP-4.2).

3) Corrective steps that will be taken to avoid noncompliance

CDI has revised two existing Quality Procedures (QP-4.2 and QP-7.1) which required retraining of personnel to assure that new procedures are properly followed. A retraining meeting of Lead Auditors, Principal Investigators and Management was held to assure that requirements of QP-4.2 and 7.1 are followed when a NVLAP or A2LA certified laboratory is used for safety-related calibration services. Requirements of QP-4.2 for review of NVLAP and A2LA calibration suppliers will be added to the Internal Audit Checklist to assure acceptable implementation of the new requirements.

4) Date when the corrective action will be completed

Continuum Dynamics, Inc. has issued Nonconformance Report (NCR) No. 0251 and No. 0252; corrective actions have been completed.

NRC Nonconformance 99901265/2011-201-03

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 Section 50.2 and as specified in the license application, for those structures, systems, and components to which this appendix applies are correctly translated into specification, 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.

Continuum Dynamics, Inc.'s Reply to Nonconformance

In response to Nonconformance **99901265/2011-201-03**, Continuum Dynamics, Inc. submits the following corrective action:

1) Reason for noncompliance

The test chamber dimensions were reviewed by AREVA prior to commencing testing. The cognizant engineer (from AREVA) concurred that the dimensions were satisfactory for testing, however this concurrence was never formally incorporated into the test plan, a modification of the requirements, or acceptance criteria of the test chamber dimensions. Even though the measured gaps are included in the reports documenting the tests, the out-of-tolerance condition should have been formally documented prior to using the chamber for safety-related testing and certifying the results.

2) Corrective steps that have been taken and the results achieved

Additional tests have been conducted with this chamber and the as-built dimensions have been included in the test plan which requires customer approval prior to conducting the tests. This step ensures that all tests conducted after this change will document the correct facility dimensions. The list of tests that have used the out-of-tolerance dimensions is being compiled to have the customer confirm that in all cases the out-of-tolerance dimensions are suitable.

3) Corrective steps that will be taken to avoid noncompliance

The list of tests that have used the test chamber with the out-of tolerance will be completed with the measured dimensions for each test. These data will be sent to AREVA to confirm that the as-built dimensions are suitable for their purposes and to determine if any other actions are required.

Retraining of personnel will be undertaken by the Quality Assurance Manager to ensure that out-of-tolerance conditions are formally documented and resolved prior to initiating safety-related testing and sending out certified results.

4) Date when the corrective action will be completed

Continuum Dynamics, Inc. has issued Nonconformance Report (NCR) No. 0249. The corrective action will be completed by 30 September 2011.

NRC Nonconformance 99901265/2011-201-04

Criterion III, "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 Tests Plan 11-02, failed to identify a test required to demonstrate that U.S. Evolutionary Power Reactor fuel assemblies will perform satisfactorily in service. 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.

Continuum Dynamics, Inc.'s Reply to Nonconformance

In response to Nonconformance **99901265/2011-201-04**, Continuum Dynamics, Inc. submits the following corrective action:

1) Reason for noncompliance

The valves were used only for these specific tests for two primary reasons: (1) testing required the capability to reverse flow for some tests and (2) hot leg and cold leg injection tests were going to be conducted in the same series of tests and the use of the valves provided the ability to switch flow direction when changing tests with minimum disruption to the test setup. The valves selected for these tests had been used in previous tests and had proven to be very reliable.

2) Corrective steps that have been taken and the results achieved

Since the finding the valves have been tested and it was confirmed that no leakage occurred in any direction so that there was no impact on test results, as was noted in Section b.2. This valve configuration is not being used for any future testing.

3) Corrective steps that will be taken to avoid noncompliance

None required

4) Date when the corrective action will be completed.

Continuum Dynamics, Inc. has issued Nonconformance Report (NCR) No. 0253; corrective action has been completed.

NRC Nonconformance 99901265/2011-201-05

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 area within the quality assurance program performed all areas of a CDI quality assurance internal audit on June 1, 2009. Specifically, the employee was the principal 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.

Continuum Dynamics, Inc.'s Reply to Nonconformance

In response to Nonconformance **99901265/2011-201-05**, Continuum Dynamics, Inc. submits the following corrective action:

1) **Reason for noncompliance.**

Internal audit was performed because of QA Manager change; During May 2009 Monthly Management Meeting, it was decided that QA program should be reviewed by additional internal audit to verify that program was in accordance with procedures due to dismissal of former QA Manager.

2) **Corrective steps that have been taken and the results achieved**

Internal audit performed June 1, 2009 was reviewed by QA Manager and President to assure that audit covered all areas including commercial nuclear safety-related testing projects, design control, test control and control of M&TE.

3) **Corrective steps that will be taken to avoid noncompliance**

Future Internal Audits will be performed by one *quality* representative to assure that design control and test control are covered and a second *technical* representative to assure that administrative functions of the quality program are covered. QA Form No. 61 QA Monthly Effectiveness Checklist has been revised to include this requirement. QA Procedure 1.1 has also been revised to include the revised form. A retraining meeting

was held with Management and Lead Auditors to assure that the requirement and necessity for the individuals performing audits to have no responsibility in the areas being audited.

4) Date when the corrective action will be completed

Continuum Dynamics, Inc. has issued Nonconformance Report (NCR) No. 0255; corrective action has been completed.