A Westinghouse Electric Company

CS Innovations
Scottsdale Operations
7400 E Tierra Buena Ln, Suite 101
Scottsdale, AZ 85260 USA

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

Direct tel: 480-567-1036
Direct fax: 480-315-9359
e-mail: robertrs@westinghouse.com
Your ref: 99901404/2011-201
Our ref: 9200-00004
August 19, 2011

SUBJECT: REPLY TO A NOTICE OF VIOLATION
REFERENCE: REPORT NO: 99901404/2011-201

Pursuant to the provisions of 10 CFR 2.201, CS Innovations, a subsidiary of Westinghouse Electric Company LLC, herein provides a response to your Inspection Report of July 21, 2011, regarding your inspection of CS Innovations conducted April 25th through April 29th 2011. This response letter and the information provided within address the referenced notice of violation and non-conformances.

Appendix A provides a concise response to the violation of NRC requirements specified in NRC Inspection Report Number 99901404/2011-201.

Appendix B provides a concise response to the non-conformances to NRC requirements specified in NRC Inspection Report Number 99901404/2011-201.

The commitments provided by CS Innovations herein resolve the notice of violation and respond to the non-conformances identified within NRC Inspection Report 99901404/2011-201. CS Innovations has established robust and effective corrective actions that are responsive to and comprehensively address the violation and non-conformances in a timely manner, and will provide lasting and effective upgrades to the process.

CS Innovations considers quality and safety as its utmost responsibilities. CS Innovations is informing the NRC of organizational changes that have occurred since the April 2011 vendor inspection, but prior to receipt of the inspection report, which have been made to better ensure quality control and implementation and project execution. Scott Roberts has replaced Bill Hadovski, former Chief Operating Officer. Mr. Roberts' title is Director Scottsdale Operations and his responsibilities include focusing efforts on Quality Assurance and Operations. Mr. Roberts reports to Jan Dudiak, Westinghouse Vice President Operations and Production. Mesut Uzman has been appointed Director ALS Platform and Systems, focusing on engineering activities specific to Advanced Logic System (ALS) development. Mr. Uzman reports to Meena Mutyala, Westinghouse Vice President Engineering and Products. Andrew Konzel, Westinghouse Nuclear Automation Quality Assurance Manager, has been assigned to take a more active role in oversight of CS Innovations Quality Management. These organizational changes are intended to provide a more concentrated effort on quality assurance, project execution, and regulatory compliance.

The enclosed CS Innovations response is comprehensive and addresses the issues identified in NRC Inspection Report 99901404/2011-201. Should you have any questions or require additional information, please telephone Scott Roberts at CS Innovations direct line (480) 567-1036.

Sincerely,

Scott Roberts
Director, Scottsdale Operations

Mesut Uzman
Director, ALS Platform and Systems

IE09

APPENDIX A

CS Innovations Response to the Notice of Violation

The July 21, 2010, Inspection Report (99901404/2011-201) and Notice of Violation (NOV), states that during a U.S. Nuclear Regulatory Commission (NRC) inspection, a violation of NRC requirements was identified. NRC described the violation as listed below:

During a U.S. Nuclear Regulatory Commission (NRC) inspection conducted at the CS Innovations, Inc. (CSI), facility in Scottsdale, AZ, from April 25-29, 2009, a violation of NRC requirements was identified. In accordance with the NRC Enforcement Policy, the violation is listed below:

Title 10 of the Code of Federal Regulations (10 CFR) 21.21(a) requires, in part, that each individual, corporation, partnership, or other entity subject to 10 CFR Part 21, "Reporting of Defects and Noncompliance," shall adopt appropriate procedures to evaluate those deviations and failures to comply associated with substantial safety hazards as soon as practicable. Contrary to the above, as of April 29, 2011, CSI implementing procedure Quality Control Procedure (QCP) 9000-01501, "10 CFR Part 21," Revision 3, dated September 22, 2010, and associated QCPs related to the 10 CFR Part 21 program failed to provide procedural guidance for evaluating deviations and failures to comply associated with substantial safety hazards. Specifically, CSI procedures QCP 9000-01501; QCP 9000-01500, "Control of Nonconformance," Revision 6, dated December 12, 2010; and QCP 9000-01600, "Corrective Action," Revision 8, dated February 17, 2011, did not include guidance for evaluating deviations and failures to comply and misused terms, such as "defect" and "deviation," that altered their intended meaning as defined in 10 CFR 21.3, "Definitions."

This issue has been identified as Violation 99901404/2011-201-01.

This is a Severity Level IV Violation (Section 6.5.d).

A.1 ACKNOWLEDGEMENT OF THE VIOLATION

CS Innovations acknowledges the violation as identified in Inspection Report and Notice of Violation, Report Number: 99901404/2011-201.

A.2 REASON FOR THE VIOLATION

An internal audit conducted at CS Innovations in November 2010 concluded that the CS Innovations process for Part 21 evaluations was weak and CS Innovations should adopt the robust WEC 21.0 process. WEC 23.20, "Westinghouse Nuclear Automation/CS Innovations Interface Agreement," aligning CS Innovations and Westinghouse quality process was approved on January 13, 2011 which was used as the implementing approval process to facilitate the change to WEC 21.0. The implementation of WEC 21.0 was not completed at the time of the NRC inspection in April 2011 as CS Innovations had only partially implemented WEC 21.0 and did not fully obsolete the CSI Part 21 process. CS Innovations conducted a causal analysis and determined that CS Innovations did not prioritize the implementation of the WEC 21.0 process and therefore did not apply the necessary level of effort required to implement the process completely and expeditiously.

A.3 CORRECTIVE ACTIONS TAKEN AND RESULTS ACHIEVED

The following actions were completed to incorporate the WEC 21.0, Nuclear Safety (Part 21 process), into the CS Innovations Quality Assurance Manual:

- Made CS Innovations procedure QCP 9000-01501 (10 CFR Part 21) obsolete, removed it from the CS Innovations active procedure list, and added WEC 21.0 to the CS Innovations active procedure list.

- Posted WEC 21.0 around CS Innovations facility and trained all CS Innovations personnel on WEC 21.0.

- Posted blank issue report (IR) forms in a bin next to the WEC 21.0 procedures and Part 21 notification posters to ensure all personnel have the ability to report potential issues without computer aid.

- Made CS Innovations procedure QCP 9000-01600 (Corrective Action) obsolete, removed it from CS Innovations active procedure list, added WEC 16.2 (Westinghouse Corrective Actions Process) to the CS Innovations active procedure list, and trained all CS Innovations personnel on WEC 16.2.

- Installed Westinghouse Lotus Notes CAPs software on all PCs at CS Innovations.

- Revised QCP 9000-01500 Rev. 6 (Control of Non-conformance) to refer to WEC 21.0 for evaluation of "deviations" and failures to comply and ensure use of the terms "deviation" and "defect" in the procedure are consistent with the NRC definitions provided in 10 CFR Part 21.

- Revised CS Innovations Quality Manual to:

    - Remove references to QCP 9000-01501 and replace with WEC 21.0
    - Remove references to QCP 9000-01600 and replace with WEC 16.2
    - Ensure use of the terms "deviation" and "defect" in the procedure are consistent with the NRC definitions provided in 10 CFR Part 21.

- Reviewed CS Innovations procedures to validate that no additional procedural changes were needed beyond the procedural changes noted above.

- Section 1.b.2 of the Executive Summary (P 5) notes that , the team reviewed a sample of recent non-conformance reports (NCRs) and corrective action reports (CARs) and, in Section 4 of the Executive Summary, identified a departure from technical requirements (deviation) that CS Innovations did not identify as a deviation that needed an evaluation. CS Innovations completed the following with regard to extent of condition:

    - Entered new CAPs Issue Report (IR) to capture all NCRs and CARs without documented Part 21 Review; specifically reviewed CAR 9010-00035, as this was cited as an example of CAR that did not provide criteria to determine the existence of a deviation.

    - Created a spreadsheet to document a review of all NCRs and CARs noted in Section 4 of the Executive Summary to identify the deviation and if it constitutes a defect. The spreadsheet was included in the IR for Issue Review Committee (IRC) review to evaluate and document its 10 CFR Part 21 reportability.

- The Westinghouse Regulatory Compliance Group reviewed the spreadsheet in the IR to evaluate and document any 10 CFR Part 21 reportability issues.

- Revised the Interface Agreement to remove/replace 9000-01600 Corrective Actions with WEC 16.2

- CS Innovations personnel have been trained in WEC 16.2 and WEC 21.0 processes.

A.4 DATE WHEN FULL COMPLIANCE WILL BE ACHIEVED

All actions are complete

A.5 ACTIONS TO PREVENT RECURRENCE

In addition to the above actions, the following corrective steps that WILL BE TAKEN to avoid further violations:

Revised the Personnel Training Checklist to specify WEC 21.0 and WEC 16.2 for training to ensure all new employees are trained to the new procedures, and established a periodic review process of personnel training records to ensure full compliance.

APPENDIX B

CS Innovations Response to the Notice of Non Conformance

Nonconformance 99901404/2011-201-02

A. Criterion III, "Design Control," of Appendix B to Title 10 of the Code of Federal Regulations (10 CFR) Part 50 states, in part, that "measures shall be established for the selection and review for suitability of application of materials, parts, equipment, and processes that are essential to the safety-related function of the structures, systems, or components."

Criterion VII, "Control of Purchased Material, Equipment, and Services," 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," states, in part, that "the effectiveness of the control of quality by contractors and subcontractors shall be assessed by the applicant or designee at intervals consistent with the importance, complexity, and quantity of the product or services."

CS Innovations Report No. 9000-00000, "Quality Assurance Manual," (QAM) Revision 4, dated July 9, 2010, states, in part, that, "Quality performance of vendors is monitored and evaluated." It also states that "vendors are evaluated by audits, surveillance, performance, and review of certification documentation with regard to their quality and process capability."

CS Innovations' purchase order to its sub-supplier, Suntron Corporation, required the sub-supplier to perform component assembly activities in accordance with Standard IPC-A-610, "Acceptability of Electronic Assemblies," Revision E-201 0, dated February 2005. Standard IPC-A-610 provides acceptance requirements for the manufacture of electrical and electronic assemblies, and provides for the control of critical characteristics associated with such activities.

Contrary to the above, as of April 29, 2011, CS Innovations failed to conduct adequate oversight of its supplier to verify that its supplier's quality programs adequately controlled critical characteristics of commercial-grade items for use as basic components. Specifically, CS Innovations required the supplier to fabricate the modules in accordance with Standard IPC-A-61 O. However, CS Innovations failed to implement measures to verify the supplier manufactured the CIM sub-assemblies consistent with the critical processes defined in the standard.

A.1 ACKNOWLEDGEMENT OF THE NONCONFORMANCE

Westinghouse acknowledges the non-conformance as identified in Inspection Report Report Number: 99901404/2011-201.

A.2 REASON FOR THE NONCONFORMANCE

An internal audit was conducted at CS Innovations in November 2010 which concluded that the CS Innovations Commercial Grade Dedication and Supplier Oversight processes were weak and that CS Innovations should adopt Westinghouse processes. To facilitate the change, CS Innovations and Westinghouse included WEC 7.1 and 7.2 in Revision 0 of the Interface Agreement. The implementation of WEC 7.1 and 7.2 was not completed at the time of the NRC inspection in April 2011. CS Innovations did not prioritize the implementation of the Commercial Grade Dedication and Supplier Oversight

processes and therefore did not apply the necessary level of effort required to implement the process completely and expeditiously.

A.3 CORRECTIVE ACTIONS TAKEN AND RESULTS ACHIEVED

A.3.1 Actions Completed

CS Innovations determined the extent of condition, including a review of the number of suppliers impacted, what assemblies were produced, and where the assemblies are in the production process.

A.3.2 Actions Remaining

- Determine any additional products that were received from suppliers that did not receive adequate oversight, identify critical characteristics for components, and subsequently develop commercial dedication instructions (CDIs) accordingly.

- Prioritize implementation of commercial grade dedication (CGD) activities to assure completion of dedication actions on products prior to delivery to customers.

- Determine the method for verifying that supplier provided component interface module (CIM) sub-assemblies consistent with critical process requirements by developing CDIs for the CIM sub-assemblies produced by suppliers.

- Specify the use of Westinghouse Operational Support Quality Assurance organizations (Supplier Quality Assessment [SQA] and Supplier Quality Oversight [SQO]) to perform oversight of CS Innovations safety-related suppliers. Revise QCP 9000-00701 (Control of Purchased Safety Related Material, Equipment and Services) to specify use of Westinghouse procedures WEC 7.1 (Supplier Qualification & Evaluation, already in Interface agreement), WEC 7.3 (Commercial Grade Surveys), and WEC 7.10 (Quality Oversight at Supplier Facilities).

- Add WEC 7.1, 7.3, and 7.10 to the CS Innovations active procedure list.

Revise the CS Innovations Quality Manual reference to QCP 9000-00701 to specify use of WEC procedures 7.1 (Supplier Qualification & Evaluation), 7.3 (Commercial Grade Surveys), and 7.10 (Quality Oversight at Supplier Facilities) and to use only suppliers on the Westinghouse Qualified Suppliers List (QSL) for procurement of safety and safety-related items or services; and for procurement of commercial grade items or services to be dedicated for nuclear safety-related use utilizing Method 2, Commercial Grade Survey.

- Train CS Innovations QA personnel on revised quality control procedures (QCPs) and WEC 7.1, 7.3, and 7.10.

- Revise Westinghouse/CS Innovations Interface Agreement to specify that CS Innovations will control suppliers through use of Westinghouse procedures 7.1 (Supplier Qualification & Evaluation), 7.3 (Commercial Grade Surveys), and 7.10 (Quality Oversight at Suppliers facilities).

- Issue revised Westinghouse/CS Innovations Interface Agreement.

- Review CS Innovations procedures to validate that no other procedural changes are needed, and review cross-references.

- Develop item and/or service specific CDIs to support commercial grade surveys of commercial suppliers providing items and/or services to be commercially dedicated by CS Innovations utilizing Method 2, Commercial Grade Survey, as a sole or combined method for commercially dedicating customer deliverable items and/or services for nuclear safety-related use..

- Contact SQA to schedule commercial grade surveys for CS Innovations suppliers providing items and/or services subject to commercial dedication utilizing Method 2, Commercial Grade Survey.

- Complete CGS for all CS Innovations suppliers and issue survey reports.

- Add CS Innovations suppliers to the Westinghouse Approved Supplier List (ASL) and Westinghouse Quality Suppliers List (QSL) accordingly.

- Train CS Innovations QA personnel to only use suppliers on the Westinghouse QSL for safety and safety-related purchases; and for procurement of commercial grade items or services to be dedicated for nuclear safety-related use utilizing Method 2, Commercial Grade Survey.

A.4 DATE WHEN FULL COMPLIANCE WILL BE ACHIEVED

December 30, 2011

A.5 ACTIONS TO PREVENT RECURRENCE

The Westinghouse Quality Assurance organization will manage supplier audits, commercial grade surveys, and supplier oversight of CS Innovations suppliers.

B. Nonconformance 99901404/2011-201-03

Criterion XV, "Nonconforming Materials, Parts, or Components," states, in part, that "Measures shall be established to control materials, parts, or components which do not conform to requirements in order to prevent their inadvertent use or installation."

Contrary to the above, as of April 29, 2011, CS Innovations failed to establish and implement provisions to collect information on error reports related to discrete components used in safety-related applications. Specifically, the NRC inspection team determined that CS Innovations procedure QCP 9000-01500, "Control of Nonconformance," Revision 6, dated December 12, 2010, did not have provisions for the collection, evaluation, disposition, and notification to affected organizations of nonconforming conditions related to discrete components, such as field programmable gate arrays used in safety-related applications.

As a result CS Innovations did not formally collect and evaluate error reports for such safety-related components to determine if nonconforming conditions could exist.

B.1 ACKNOWLEDGEMENT OF THE NONCONFORMANCE

Westinghouse acknowledges the non-conformance as identified in Inspection Report Report Number: 99901404/2011-201.

B.2 REASON FOR THE NONCONFORMANCE

An internal audit was conducted at CS Innovations in November 2010 which concluded that the CS Innovations Commercial Grade Dedication and Supplier Oversight processes were weak and that CS Innovations should adopt Westinghouse processes. To facilitate the change, CS Innovations and Westinghouse included WEC 7.1 and 7.2 in Revision 0 of the Interface Agreement signed January 13, 2011, which authorized the change. The implementation of WEC 7.1 and 7.2 was not completed at the time of the NRC inspection in April 2011. CS Innovations did not prioritize the implementation of the Commercial Grade Dedication and Supplier Oversight processes and therefore did not apply the necessary level of effort required to implement the process completely and expeditiously.

B.3 CORRECTIVE ACTIONS TAKEN AND RESULTS ACHIEVED

B.3.1 Actions Completed

Determined adequacy of QCP 9000-01500 and entered CAP IRs as applicable.

QCP 9000-01500 (Control of Non-conformance) was reviewed to determine if it provides a methodology for the collection, evaluation, disposition, and notification to affected organizations of non-conforming conditions (error reports related to discrete components used in safety-related applications). It was determined that 9000-01500 does not provide a method to collect and evaluate error reports related for safety-related discrete components to determine if non-conforming conditions could exist.

B.3.2 Actions Remaining

- Perform extent of condition assessment to evaluate if error reports (from the user community forums) for discrete components used in the CIM design, such as field programmable gate arrays (FPGAs), are applicable to the CS Innovations product line, considered for potential Part 21 applicability, and then ensure that affected organizations are notified, as applicable.

- CS Innovations engineering and QA to create a procedure for collecting and evaluating error reports from the manufacturers of discrete components. The procedure will consist of the following as a minimum:
    1. Listing of discrete components used in safety-related applications, their manufacturer, and whether or not the manufacturer issues error reports.
    2. Develop a methodology to periodically collect the error reports from the manufacturers.
    3. Provisions for entry of the collected error reports into the Westinghouse CAPs system for evaluation by the appropriate engineering personnel applying WEC 21.0 and for potential impacts to current production activities or previously shipped components.

- Review CS Innovations procedures to validate that no other procedural changes are needed to resolve this issue.

B.4 DATE WHEN FULL COMPLIANCE WILL BE ACHIEVED

September 30, 2011

B.5 ACTIONS TO PREVENT RECURRENCE

Corrective Actions will be reviewed during Westinghouse internal audits of CS Innovations to verify effective corrective action and continued compliance to requirements.

C. Nonconformance 99901404/2011-201-04

Criterion III, "Design Control," of Appendix B to 10 CFR Part 50 states, in part, that "measures shall be established for the selection and review for suitability of application of materials, parts, equipment, and processes that are essential to the safety-related function of the structures, systems, or components." Additionally, Criterion III states, in part, that "design control measures shall provide for verifying the adequacy of design" and that "the verifying or checking process shall be performed by individuals or groups other than those who performed the original design."

CS Innovations Report No. 6105-00003, "The CIM-SRNC V&V Plan," Revision 2, and CS Innovations Report No. 6105-00013, "The CIM-SRNC IV&V Plan," Revision 0, require, in part, that CS Innovations perform verification and validation testing, and that an independent verification and validation (IV&V) team conduct requirements traceability analysis, and develop an IV&V test plan. Additionally, CS Innovations Report No. 6105-00013, requires that the IV&V team perform independent review activities, including independent testing, throughout the requirements, design, implementation, and validation portions of the CIM-SRNC development lifecycle.

Contrary to the above, as of April 29, 2011, CS Innovations failed to establish measures to assure that applicable requirements associated with specific independent verification and validation activities were implemented. Specifically:

- *CS Innovations' IV&V process failed to provide for the development of an independent testing tool during the component or module-based level of development for the CIM-SRNC subsystem, and*
- *CS Innovations' IV&V process did not include specific independent test plans for implementation by the IV&V team as required by CS Innovations Report No. 6105-00013.*

C.1 ACKNOWLEDGEMENT OF THE NONCONFORMANCE

Westinghouse acknowledges the non-conformance as identified in Inspection Report Report Number: 99901404/2011-201.

C.2 REASON FOR THE NONCONFORMANCE

Westinghouse acknowledges that CS Innovations did not meet the requirements for specific independent verification and validation. Processes were not in place to support adequate IV&V activities and to properly document IV&V oversight.

C.3 CORRECTIVE ACTIONS TAKEN AND RESULTS ACHIEVED

The documentation history of the verification and validation process leading to the independent verification and validation process is as follows:

The Component Interface Module (CIM) and the Safety Remote Node Controller (SRNC) Verification and Validation (V&V) processes were captured in CS Innovations document "CIM-SRNC V&V Plan, 6105-00003, Revision 1," which depicted the verification and validation processes executed by CS Innovations prior to the Westinghouse acquisition. Subsequent to the CS Innovations organization being acquired by Westinghouse, 6105-00003, Revision 1, was updated to Revision 2 by the IV&V organization to encompass the Independent Verification and Validation (IV&V) activities. The IV&V

organization developed the "CIM-SRNC IV&V Plan, 6105-00013, Revision 0," to supersede 6105-00003, Revision 2. The CIM-SRNC IV&V Plan describes IV&V activities for the FPGA-based software development lifecycle with better visibility as to the independent review and signature of testing activities by IV&V personnel.

Since the NRC inspection at the end of April 2011, "CIM-SRNC IV&V Plan, 6105-00013, Revision 0" was updated to Revision 1 to strengthen the visibility of IV&V's role and independence in the CIM-SRNC project. In addition to design and implementation phase IV&V activities, for the integration phase, the component level testing is recognized as a function of IV&V, whose test plan is included within the CIM-SRNC IV&V Simulation Environment Specification, 6105-00021, Rev. 0, Section 5 "Test Plan". Applicable test plans and test procedures have been reviewed, revised, revised, and re-issued under the IV&V organization's oversight and approval. In addition to the IV&V authority and accountability of FPGA testing during the design and implementation phase of CIM- SRNC, the component level testing in the integration phase of the product has been performed under the oversight and approval of the IV&V organization. The IV&V manager who has the authority and accountability for the IV&V activities now belongs to the Westinghouse Nuclear Automation Independent Verification and Validation organization and is organizationally independent from CS Innovations.

The "CIM-SRNC Test Plan, 6105-00005, Revision 5" defines the test activities at the integration phase (Hardware/Software integration at component level). These test activities are the accountability of the IV&V organization. The test plan, test design specifications, test case specifications, test procedures, and the test summary report for FPGA integration with hardware were all developed by personnel independent of the FPGA design personnel. All these documents have been reviewed by independent personnel from the IV&V organization and approved by the IV&V manager.

C.4 DATE WHEN FULL COMPLIANCE WILL BE ACHIEVED

September 30, 2011

C.5 ACTIONS TO PREVENT RECURRENCE

The integration phase tests were executed using the Automated Test Equipment (ATE) and an additional level of testing was performed on a diverse tool to mitigate any potential vulnerabilities of the ATE tool. The IV&V organization has required execution of this additional test, witnessed its execution, and plans to issue the CIM/SRNC IV&V Summary Report by September 30, 2011.

Organizational changes at CS Innovations and clarification of the accountability of the Westinghouse Nuclear Automation Independent Verification and Validation organization in overseeing CS Innovation products were implemented in June 2011. Staffing of the IV&V organization has been augmented by the addition of test engineers. It has also been clarified in the IV&V Plan that test functions performed by technically independent personnel in other organizations are under the functional oversight, review, and approval of the IV&V organization and management. Similar to corrective actions taken for the CIM/SRNC project, additional testing with a diverse tool to mitigate potential vulnerabilities of the ATE tool will be implemented for IV&V activities for other CS Innovations projects such as ALS.

D. Nonconformance 99901404/2011-201-05

Criterion I, "Organization," of Appendix B to 10 CFR Part 50 states, in part, that "the persons and organizations performing quality assurance functions shall have sufficient authority and organizational freedom to identify quality problems."

CS Innovations QAM, Section 1, "Organization," Revision 4, dated July 9, 2010, states, in part, that "the QA manager and appointed employees are vested with the authority and responsibility to ensure activities affecting quality are performed and documented to the responsibility to ensure activities affecting quality are performed and documented to the established requirements and have organizational freedom to identify quality problems. The QA manager is responsible for ensuring compliance with QA and quality control policies and procedures in all effected departments."

Contrary to the above, as of April 29, 2011, CS Innovations failed to adequately describe and implement its process to ensure that the QA function retains process independence from those design control activities for which QA functions exist. Specifically, Step 3.9.5 of CS Innovations Quality Control Procedure (QCP) 9000-00600, "Document Control," states, in part, that "the QA manager or designee may be [the] final approver if [the] functional manager deems so," has allowed the QA manager to be the final technical approver of the design documents while also having ultimate responsibility for the QA functions associated with those design activities and as a result, CS Innovations failed to adequately describe and implement the CS Innovations design control process to ensure that the QA function retains process independence from those activities for which QA functions exist.

.

D.1 ACKNOWLEDGEMENT OF THE NONCONFORMANCE

Westinghouse acknowledges the non-conformance as identified in Inspection Report Report Number: 99901404/2011-201.

D.2 REASON FOR THE NONCONFORMANCE

CS Innovations did not properly differentiate between technical and quality approval signatories on technical documentation by allowing the Quality Assurance Manager to sign as an approving technical manager.

D.3 CORRECTIVE ACTIONS TAKEN AND RESULTS ACHIEVED

D.3.1 Actions Completed

- CS Innovations QCP 9000-00600 has undergone 3 additional revisions since the NRC inspection, and is currently at Revision 12. Revisions 10; 11, and 12 were reviewed and it was confirmed that the phrase in Section 3.9.5 of Revision 9, "The CSI Quality Manager or designee may be the final document approver if the functional manager deems so." is not contained in Revisions 10, 11, and 12 of QCP 9000-00600.

Removal of this statement prohibits the QA Manager from undertaking any technical approval responsibilities, and ensures the QA function retains process independence from those design control activities for which QA functions exist. The QA Manager now reviews documents only to ensure that they meet the requirements of the CS Innovations Quality Program.

D.3.2 Actions Remaining

- Identify design documents that had technical content approved by the QA Manager, or designee responsible to the QA function, to determine if any of the documents should be re-approved without QA as a technical signatory. Revise and re-approve documents not in compliance.

- Train CS Innovations personnel to the latest revision of QCP 9000-00600 (Document Control Procedure) and provide refresher training on the requirements of Criterion I of 10 CFR Part 50 Appendix B.

D.4 DATE WHEN FULL COMPLIANCE WILL BE ACHIEVED

November 30, 2011

D.5 ACTIONS TO PREVENT RECURRENCE

Corrective Actions will be reviewed during Westinghouse internal audits of CS Innovations to verify effective corrective action and continued compliance to requirements.

E. Nonconformance 99901404/2011-201-06.

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

CSI QAM, "Corrective Action," Section 16, defines the overall policies, responsibilities, and authorities for implementing the CSI corrective action program (CAP). The QAM references CSI procedure QCP 90000-01600 for detailed implementation of the CAP.

CSI Procedure QCP 9000-01600, "Corrective Action," Revision 8, dated February 17, 2011, applies to all identified conditions adverse to quality, such as failures, malfunctions, deficiencies, deviations, defective equipment, and program nonconformance. This procedure describes the process used to identify, report, document, and disposition conditions adverse to quality, and required the identification and documentation of all conditions adverse to quality.

Contrary to the above, as of April 29, 2011, CSI failed to identify and document deviations as part of its corrective action process. Specifically, CSI failed to identify and document all deviations that described departures from technical requirements and failed to promptly enter multiple identified deficiencies into its corrective action program as required by QCP 9000-01600.

E.1 ACKNOWLEDGEMENT OF THE NONCONFORMANCE

Westinghouse acknowledges the non-conformance as identified in Inspection Report Report Number: 99901404/2011-201.

E.2 REASON FOR THE NONCONFORMANCE

An internal audit was conducted at CS Innovations in November 2010 which concluded that the CS Innovations Corrective Action Program was weak and that CS Innovation should adopt the robust WEC 16.2 process. To facilitate the change, CS Innovations and Westinghouse included WEC 16.2 in Revision 0 of the Interface Agreement. The implementation of WEC 16.2 had not been completed at the time of the NRC inspection in April 2011, as CS Innovations had only partially implemented WEC 16.2 and had not fully obsoleted the CS Innovations Corrective Action process. CS Innovations did not prioritize the implementation of the Corrective Action process and therefore did not apply the necessary level of effort required to implement the process completely and expeditiously.

E.3 CORRECTIVE ACTIONS TAKEN AND RESULTS ACHIEVED

E.3.1 Actions Completed

- QCP 9000-01600 (Corrective Action) Rev. 8 has been made obsolete.
- CS Innovations CAR Form 9010-00035 has been made obsolete.
- Updated Quality Manual Section 16.4 to reference WEC 16.2.
- Completed review of CS Innovations procedures for other references to QCP 9000-01600 and 9010-00035. References are identified and are in process of being removed.

- Verified CAR 2010-010 closure was valid.

- Reviewed CS Innovations test plan document 6101-10012 to determine how a departure from technical requirements should be addressed. CAR 2011-051 was identified in the NRC report because departures from technical requirements for Wolf Creek were not evaluated for possible Part 21 reporting. CS Innovations created a spreadsheet to document the Part 21 review of NCRs and CARs for delivered product. NCRs and CARs have been reviewed with the conclusion that there were no departures from specification.

- Reviewed IR 11-111-M010, supplier oversight deficiency identified in March 2010, for proper closure and concluded that closure was inappropriate; the issue was re-captured via IR 11-206-M050. CAPs IR 11-206-M050 documents the non-conformance in the NRC inspection report. CDIs for components are being developed as part of CAPs IR # 11-206-M050. Oversight of CS Innovations suppliers has been transitioned to Westinghouse Supplier Quality Assessment and (SQA) and Westinghouse Supplier Quality Oversight (SQO). This transition plan is also being developed as part of IR# 11-206-M050.

- CS Innovations has addressed the timing of entry and completion by providing a separate management process with weekly status reviews to ensure proper entry, direction, visibility, and oversight of issues. With the adoption of the Westinghouse CAPs process, reporting metrics and performance are monitored continuously for timeliness and completeness.

- Entered new CAPs IRs for each open CAR.

- Completed an extent of condition assessment and documented Part 21 evaluation under WEC 21.0 for all historical NCRs and CARs related to delivered product. No issues were found to be reportable.

- Verified that all personnel are trained to WEC 16.2 and WEC 21.0.

E.3.2 Actions Remaining

- IR-111-M015 (regarding CIM/SRNC human diversity) is still open and will be closed by September 30, 2011.

- Review CAR 2010-015 to ensure that IR-111-M013 was adequately closed.

E.4 DATE WHEN FULL COMPLIANCE WILL BE ACHIEVED

September 30, 2011

E.5 ACTIONS TO PREVENT RECURRENCE

Corrective Actions will be reviewed during Westinghouse internal audits of CS Innovations to verify effective corrective action and continued compliance to requirements