July 20, 2011

Mr. William Hadovski, Chief Operating Officer
CS Innovations, Inc.
7400 East Tierra Buena Lane, Suite 101
Scottsdale, AZ 85260

SUBJECT: NRC INSPECTION REPORT NO. 99901404/2011-201 AND NOTICE OF VIOLATION AND NOTICE OF NONCONFORMANCE

Dear Mr. Hadovski:

From April 25–29, 2011, the U.S. Nuclear Regulatory Commission (NRC) staff conducted an inspection at the CS Innovations, Inc. (CSI), facility in Scottsdale, AZ. The purpose of this limited scope inspection was to assess CSI's compliance with the provisions of 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.

Based on the results of this inspection, the NRC has determined that a Severity Level IV violation of NRC requirements occurred. The NRC evaluated the violations in accordance with the agency's Enforcement Policy, which is available on the NRC's Web site at http://www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html.

The violation is cited in the enclosed Notice of Violation (Notice) and the circumstances surrounding it are described in detail in the subject inspection report. The violation is being cited in the Notice because CSI did not provide adequate procedural guidance to evaluate deviations and failures to comply associated with substantial safety hazards consistent with the requirements of 10 CFR Part 21.

You are required to respond to this letter and should follow the instructions specified in the enclosed Notice when preparing your response. If you have additional information that you believe the NRC should consider, you may provide it in your response to the Notice. The NRC review of your response to the Notice will also determine whether further enforcement action is necessary to ensure compliance with regulatory requirements.

In addition, during the inspection, the NRC inspection team found that the implementation of your QA program failed to meet certain NRC requirements imposed on you by your customers. Specifically, the NRC inspection team determined that CSI was not implementing aspects of its corrective action program, design control program, document control program, and commercial-grade dedication program consistent with regulatory requirements or with CSI Report No. 9000-00000, "Quality Assurance Manual (QAM)," Revision 4. The enclosures to this letter identify the specific findings and references to the pertinent requirements.

Please provide a written statement or explanation within 30 days from the date 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 enclosures, and 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, accessible at http://www.nrc.gov/reading-rm/adams.html. To the extent possible (and if applicable), your response should not include any personal privacy, proprietary, or safeguards information so that the response 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 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/

Juan D. Peralta, Chief
Quality and Vendor Branch 1
Division of Construction Inspection
and Operational Programs
Office of New Reactors

Docket No.: 99901404

Enclosures:
1. Notice of Violation
2. Notice of Nonconformance
3. Inspection Report No. 99901404/2011-201

Please provide a written statement or explanation within 30 days from the date 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 enclosures, and 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, accessible at http://www.nrc.gov/reading-rm/adams.html. To the extent possible (and if applicable), your response should not include any personal privacy, proprietary, or safeguards information so that the response 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 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/

Juan D. Peralta, Chief
Quality and Vendor Branch 1
Division of Construction Inspection
and Operational Programs
Office of New Reactors

Docket No.: 99901404

Enclosures:
1. Notice of Violation
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GGalletti	SSmith	MConcepcion	MWaterman
Hadovswl@westinghouse.com	Seelmarj@westinghouse.com		

ADAMS Accession No.: ML 1118900005 NRO-002

OFFICE	NRO/DE/IDE1	NRO/DCIP/ICE1	RES/DE/DICB	RES/DE/DICB	NRO//DCIP/CQVB
NAME	JZhao	WRoggenbrodt	MWaterman	MConcepcion	SSmith
DATE	07/ 20 /2011	07/20/2011	07/20/2011	07/20/2011	07/20/2011
OFFICE	NRO//DCIP/CQVA	NRO/DCIP/CAEB	NRO/DCIP/CQVA		
NAME	GGalletti	TFrye	JPeralta		
DATE	07/20/2011	07/21/2011	07/20/2011		

OFFICIAL RECORD COPY

NOTICE OF VIOLATION

CS Innovations, Inc.
7400 East Tierra Buena Lane
Scottsdale, AZ 85260

Docket No. 99901404
Inspection Report No. 99901404/2011-201

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).

Pursuant to the provisions of 10 CFR 2.201, "Notice of Violation," CSI is hereby required to submit a written statement or explanation to the U.S. Nuclear Regulatory Commission (NRC), ATTN: Document Control Desk, Washington, DC 20555-0001 with a copy to the Chief, Quality and Vendor Branch 1, Division of Construction Inspection and Operational Programs, Office of New Reactors, within 30 days of the date of the letter transmitting this Notice of Violation (Notice). This reply should be clearly marked as a "Reply to a Notice of Violation" and should include for each violation: (1) the reason for the violation, or, if contested, the basis for disputing the violation or severity level, (2) the corrective steps that have been taken and the results achieved, (3) the corrective steps that will be taken to avoid further violations, and (4) the date when full compliance will be achieved. Your response may reference or include previous docketed correspondence if the correspondence adequately addresses the required response. Where good cause is shown, the NRC will consider extending the response time.

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

Because your response will be made available electronically for public inspection in the NRC Public Document Room or from the NRC's Agencywide Documents Access and Management

System, accessible from the NRC Web site http://www.nrc.gov/reading-rm/adams.html, to the extent possible, it should not include any personal privacy, proprietary, or safeguards information so that it can be made available to the public without redaction. If personal privacy or proprietary information is necessary to provide an acceptable response, then please provide a bracketed copy of your response that identifies the information that should be protected and a redacted copy of your response that deletes such information. If you request withholding of such material, you must specifically identify the portions of your response that you seek to have withheld and provide in detail the bases for your claim of withholding (e.g., explain why the disclosure of information will create an unwarranted invasion of personal privacy or provide the information required by 10 CFR 2.390(b) to support a request for withholding confidential commercial or financial information). If Safeguards Information is necessary to provide an acceptable response, please provide the level of protection described in 10 CFR 73.21, "Requirements for the Protection of Safeguards Information."

Dated this 20th day of July 2011.

NOTICE OF NONCONFORMANCE

CS Innovations, Inc.
7400 East Tierra Buena Lane
Scottsdale, AZ 85260

Docket No. 99901404
Inspection Report No. 99901404/2011-201

Based on the results of a U.S. Nuclear Regulatory Commission (NRC) inspection conducted from April 25–29, 2011, of activities performed at the CS Innovations, Inc. (CSI), facility in Scottsdale, AZ, CSI did not conduct certain activities in accordance with NRC requirements, which were contractually imposed upon CSI by NRC applicants or licensees.

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."

CSI 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."

CSI's 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-2010, 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, CSI 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, CSI required the supplier to fabricate the modules in accordance with Standard IPC-A-610. However, CSI failed to implement measures to verify the supplier manufactured the CIM sub-assemblies consistent with the critical processes defined in the standard.

This issue has been identified as Nonconformance 99901404/2011-201-02.

B. 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, CSI 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 CSI 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 CSI did not formally collect and evaluate error reports for such safety-related components to determine if nonconforming conditions could exist.

This issue has been identified as Nonconformance 99901404/2011-201-03.

C. 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."

CSI Report No. 6105-00003, "The CIM-SRNC V&V Plan," Revision 2, and CSI Report No. 6105-00013, "The CIM-SRNC IV&V Plan," Revision 0, require, in part, that CSI 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, CSI 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, CSI failed to establish measures to assure that applicable requirements associated with specific independent verification and validation activities were implemented. Specifically:

- CSI's 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
- CSI's IV&V process did not include specific independent test plans for implementation by the IV&V team as required by CSI Report No. 6105-00013.

These issues have been identified as examples of Nonconformance 99901404/2011-201-04.

D. 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."

CSI 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

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, CSI 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 CSI 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, CSI failed to adequately describe and implement the CSI design control process to ensure that the QA function retains process independence from those activities for which QA functions exist

This issue has been identified as Nonconformance 99901404/2011-201-05.

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

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.

This issue has been identified as Nonconformance 99901404/2011-201-06.

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 1, 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 the following 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 your 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 20th day of July 2011.

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

Docket No.:	99901404
Report No.:	99901404/2011-201
Vendor:	CS Innovations, Inc. 7400 East Tierra Buena Lane Scottsdale, AZ 85260
Vendor Contact:	Mr. William Hadovski, Chief Operating Officer Hadovswl@westinghouse.com
Nuclear Industry Activities:	CS Innovations, Inc. is a wholly-owned subsidiary of Westinghouse that specializes in providing digital instrumentation and control systems and components for the AP1000 reactor design. CS Innovations, Inc., has also provided digital instrumentation and control solutions to the U.S. commercial nuclear power industry.
Inspection Dates:	April 25–29, 2011
Inspectors:	Greg Galletti, Team Leader, NRO/DCIP/CQVA Stacy Smith, NRO/DCIP/CQVB William Roggenbrodt, NRO/DE/ICE1 Jack Zhao, NRO/DE/ICE1 Milton Concepcion, RES/DE/DICB Michael Waterman, RES/DE/DICB
Approved by:	Juan Peralta, Chief Quality and Vendor Branch 1 Division of Construction Inspection and Operational Programs Office of New Reactors

EXECUTIVE SUMMARY

CS Innovations, Inc.
99901404/2011-201

The purpose of this inspection by the U.S. Nuclear Regulatory Commission (NRC) was to verify that CS Innovations, Inc. (CSI), had implemented an adequate quality assurance (QA) program that complies with the requirements of 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 CSI implemented a program under 10 CFR Part 21, "Reporting of Defects and Noncompliance," that meets the NRC's regulatory requirements. The inspection took place at the CSI facility in Scottsdale, AZ, during the period April 25–29, 2011.

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

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

The NRC inspection team implemented Inspection Procedure (IP) 43002, "Routine Inspections of Nuclear Vendors," dated April 25, 2011; IP 36100, "Inspection of 10 CFR Part 21 and 50.55(e) Programs for Reporting Defects and Noncompliance," dated April 25, 2011; and IP 43004, "Inspection of Commercial-Grade Dedication Programs," dated April 25, 2011, during the conduct of this inspection.

The NRC had not previously performed an inspection at the CSI facility in Scottsdale, AZ.

The results of the current inspection are summarized below.

10 CFR Part 21

The NRC inspection team issued Violation 99901404/2011-201-01 for CSI's failure to adopt appropriate procedures under 10 CFR 21.21, "Notification of Failure To Comply or Existence of a Defect and Its Evaluation." Specifically, the NRC inspection team determined that CSI Quality Control Procedure (QCP) 9000-01501, "10 CFR Part 21," Revision 3, dated September 22, 2010; QCP 9000-01500, "Control of Nonconformance," Revision 6, dated December 12, 2010; and QCP 9000-01600, QCP 9000-01600, "Corrective Action," Revision 8, dated February 17, 2011, were not appropriate procedures for evaluating deviations and failures to comply because of the lack of guidance necessary to perform these evaluations and because of the misuse of terms, such as "defect" and "deviation," that altered their intended meaning as defined in 10 CFR 21.3, "Definitions."

Commercial-Grade Dedication Program

The NRC inspection team issued Nonconformances 99901404/2011-201-02 and 99901404/2011-201-03 for CSI's failure to provide reasonable assurance that all commercial items received from its suppliers would conform to the applicable specification requirements. Specifically, the NRC inspection team determined that CSI failed to conduct commercial-grade surveys to verify the supplier's quality program for the control of critical characteristics provided reasonable assurance that commercial-grade items for use as basic components would perform

their intended safety function and that it failed to establish and implement provisions to collect information on error reports related to discrete components used in safety-related applications.

Design Control

The NRC inspection team issued Nonconformance 99901404/2011-201-04 and Nonconformance 99901404/2011-201-05 for CSI's failure to implement an independent verification and validation process consistent with NRC requirements and for the failure to implement a design control process that ensured adequate organizational independence of the design and quality assurance functions.

The NRC inspection team also identified a non-cited issue on CSI's failure to properly document completed inspection and test personnel qualification activities. This failure constitutes a violation of minor significance and is not subject to formal enforcement action.

Corrective Actions

The NRC inspection team issued Nonconformance 99901404/2011-201-06 for CSI's failure to identify deviations as part of its corrective action program and to promptly identify and correct conditions adverse to quality. Specifically, the NRC inspection team determined that CSI failed to identify deviations that described departures from technical requirements and to promptly enter multiple identified deficiencies into its corrective action program.

REPORT DETAILS

1. 10 CFR Part 21 Program

a. Inspection Scope

The U.S. Nuclear Regulatory Commission (NRC) inspection team reviewed the policies and implementing procedures that govern the CS Innovations, Inc. (CSI), process under Title 10 of the *Code of Federal Regulations* (10 CFR) Part 21, "Reporting of Defects and Noncompliance," to verify its compliance with the NRC's regulatory requirements. Specifically, the NRC inspection team focused on Quality Control Procedure (QCP) 9000-01501, "10 CFR Part 21," Revision 3, dated September 22, 2010; QCP 9000-01500, "Control of Nonconformance," Revision 6, dated December 12, 2010; and QCP 9000-01600, "Corrective Action," Revision 8, dated February 17, 2011.

The NRC inspection team also reviewed procurement documents and the following CSI procedures to verify the requirements in 10 CFR Part 21:

- CSI Report No. 9000-00000, "Quality Assurance Manual (QAM)," Revision 4, dated July 9, 2010
- QCP 9000-01501
- QCP 9010-00009, "Nonconformance Report" form, Revision 2
- QCP 9000-01500
- QCP 9000-01600
- QCP 9010-00035, "Corrective Action Request" form
- Work Instruction 9006-00008, "Return Material Authorization," Revision 1, dated
- Returned Material Authorization (RMA) 110119-1
- RMA 110119-2
- Wolf Creek Purchase Order (PO) 746194/0
- Wolf Creek PO 754097/0
- Work Creek PO 751264/3
- Corrective Action Report (CAR) 2011-056, dated April 27, 2011
- Nonconformance Report (NCR) 101-0042, dated April 4, 2011
- CAR 2010-005, dated September 15, 2010
- CAR 2011-051, dated April 15, 2011

b. Observations and Findings

b.1 Postings

The NRC inspection team observed that CSI had posted notices in conspicuous locations within the facility. The notice included a summary of Section 206 of the Energy

Reorganization Act of 1974, as amended; a copy of 10 CFR Part 21; and a copy of QCP 9000-01501.

b.2 10 CFR Part 21 Procedure

QCP 9000-01501 describes and establishes necessary requirements for the identification and reporting of deviations and defects as described in 10 CFR Part 21. It also describes the responsibility of the supervisor or manger to determine whether a condition is a departure from the technical requirements imposed in the procurement documents and the required timelines for the evaluation and notification of deviations and defects. Section 4.4 of QCP 9000-01501, states, in part, that if the supervisor or manager determines that a defect may exist, he or she shall generate an NCR on NCR Form 9010-00009 to document the condition. The NCR form contains a reportability box that states, "Evaluate NCR for 10 CFR 21 Reportability."

QCP 9000-01500 describes and establishes the necessary requirements for the control of identified nonconforming material, parts, and components. Section 6.11 states, in part, that "if nonconforming conditions affect items that have been provided to the customer, the nonconformance shall be evaluated under the requirements of 10 CFR 21." In addition, QCP 9000-01600 describes and establishes the necessary requirements for the identification, control, and documentation of conditions adverse to quality. Step 5.7 states, in part, that "all significant conditions adverse to quality shall be evaluated for possible reporting under the requirements of 10 CFR 21."

The NRC inspection team reviewed QCP 9000-01501, QCP 9000-01500, QCP 9000-01600 and their associated forms and discussed them with the quality assurance (QA) manager and with the CSI senior level personnel responsible for the development and maintenance of the 10 CFR Part 21 program. The NRC inspection team noted that QCPs had not used terms "defect" and "deviation" in accordance with their definitions. For example, Step 4.5 of QCP 9000-01501 states, in part, that "the nonconforming report detailing the defect is routed to the CS Innovation's COO [chief operating officer] for review," and Step 4.6 states, in part, that "if the technical and quality reviews and evaluations provide evidence that a deviation or failure to comply exists, the COO shall send notification to the NRC in accordance with paragraph 21.21." The misuse of these terms has the potential to incorrectly screen or report 10 CFR Part 21 issues.

In addition, the NRC inspection team determined that QCP 9000-01501, QCP 9000-01500, and QCP 9000-01600 and their associated forms lack guidance for the evaluation of deviations or failures to comply consistent with the requirements in 10 CFR 21.21, "Notification of Failure To Comply or Existence of a Defect and Its Evaluation." Specifically, the NRC inspection team determined that the QCPs for 10 CFR Part 21 were not appropriate procedures for evaluating deviations and failures to comply because of the lack of any guidance necessary to perform these evaluations. The NRC inspection team identified the lack of procedural guidance to evaluate deviations and failures to comply as Violation 99901404/2011-201-01.

The NRC inspection team noted that CSI had not performed any 10 CFR Part 21 evaluations in the past several years. The team reviewed a sample of recent NCRs and CARs and, in Section 4 of this report, identified a departure from technical requirements that CSI did not identify as a deviation that needed an evaluation.

CSI had initiated Issue Report (IR) 11-102-M042 on April 12, 2011, to discuss the transition from its current corrective action and 10 CFR Part 21 programs to the Westinghouse Electric Corporation (WEC) implementing procedures WEC 16.2, "Westinghouse Corrective Actions Process," Revision 2, dated February 8, 2010, and WEC 21.0, "Identification and Reporting of Conditions Adverse to Quality," Revision 6, dated August 3, 2009. Although the transition was originally scheduled for a date after the NRC inspection, CSI decided to implement the transition and training of the WEC implementing procedures, effective April 28, 2011, to address deficiencies with its 10 CFR Part 21 and corrective action programs.

c. Conclusions

The NRC inspection team issued Violation 99901404/2011201-01 for CSI's QCP 9000-01501 and the associated QCPs related to the 10 CFR Part 21 program for failure to provide procedural guidance for evaluating deviations and failures to comply associated with substantial safety hazards. Specifically, the NRC inspection team determined that QCP 9000-01501, QCP 9000-01500, and QCP 9000-01600 were not appropriate procedures for evaluating deviations and failures to comply because of the lack of guidance necessary to perform these evaluations and because of the misuse of terms such as "defect" and "deviation" that altered their intended meaning as defined in 10 CFR 21.3.

2. Commercial-Grade Dedication Program

a. Inspection Scope

The NRC inspection team reviewed CSI's implementing policies and procedures that govern the commercial-grade dedication process to ensure that those guidelines adequately described the process as required by 10 CFR Part 21. The NRC inspection team also evaluated a limited sample of available dedication-related documentation for safety-related components to verify compliance with program requirements and adequate implementation of those requirements.

Specifically, the NRC inspection team reviewed the following policies and procedures:

- CSI Commercial-Grade Dedication Procedure 9000-00301, "Commercial-Grade Dedication," Revision 5, dated September 20, 2010
- CSI Report No. 6105-00000, "CIM-SRNC Management Plan," Revision 3, dated August 12, 2010
- CSI Report No. 6105-20041, "CIM Module Traveler," Revision 0, dated February 4, 2011
- CSI Report No. 6105-00005, "CIM-SNRC Test Plan," Revision 4, dated February 4, 2011
- CSI Report No. 6105-20003, "CIM Hardware Specification," Revision 1, dated August 14, 2010
- CSI Report No. 6105-20004, "CIM FPGA Specification," Revision 5, dated March 7, 2011

- Several POs and shop travelers related to components and services used in the development process of component interface modules (CIMs)

b. Observations and Findings

b.1 Policies and Procedures for the Dedication of Commercial Items

CSI Procedure 9000-00301 describes the process that CSI uses to dedicate commercial-grade items used in safety-related applications. CSI implements this procedure to evaluate and verify the acceptability of commercial-grade components used in the development and testing of CIMs. CSI Procedure 9000-00301 includes a reference to Electric Power Research Institute (EPRI) NP-5652, "Guidelines for Utilization of Commercial-Grade Items in Nuclear Safety-Related Application (NCIG-07)," issued June 1988, for dedication activities. EPRI NP-5652 provides four methods for accepting commercial-grade items: Method 1, "Special Tests and Inspections"; Method 2, "Commercial-Grade Survey of Supplier"; Method 3, "Source Verification"; and Method 4, "Acceptable Supplier/Item Performance Record."

During the review of the procedure, the NRC inspection team noted that all of the dedication activities focused on special tests and inspections of commercial-grade components procured and received by CSI. The NRC inspection team also noted that the dedication procedure does not document any addition provisions for commercial-grade surveys, source verifications, or analysis of historical records for acceptable performance. The procedure did state that the industry guidance in EPRI NP-5652 constituted a part of the procedure activities, but it did not include requirements for periodic supplier assessments. The NRC inspection team asked why the procedure did not include provisions for the other acceptance methods described above because all components used to manufacture CIMs are commercial-grade components. CSI personnel stated that, based on the scope of supply and the components used to assemble the CIMs, they thought that the implementation of additional activities was not necessary to verify the acceptability of such components.

During the review of selected POs that CSI issued to commercial suppliers, the NRC inspection team noted that the vendor had imposed industry standards and specific CSI technical and quality requirements on commercial suppliers. For example, CSI imposed Standard IPC-A-610, "Acceptability of Electronic Assemblies," Revision E-2010, issued February 2005, which provides acceptance requirements for the manufacture of electrical and electronic assemblies, on POs that the vendor issued to a commercial supplier that performed assembly activities for it. In addition, the NRC inspection team noted that CSI developed Work Order No. 59 that was classified as Class 1E and imposed the work order on a commercial supplier PO as a quality requirement for the final assembly of CIMs. However, CSI had not conducted surveys of this supplier to confirm that it was adequately implementing these requirements.

Although the NRC inspection team confirmed that CSI monitored activities conducted by suppliers through informal e-mail correspondence and site visits, the vendor had not formally documented onsite review activities to verify that adequate controls were implemented by manufacturers, as well as, distributors when required. This inadequate oversight impeded CSI from adequately verifying the acceptability of electronic components assembled by suppliers, any potential changes in the manufacturing processes implemented by suppliers, and changes in materials used by suppliers that

could affect the component's ability to perform its safety function. In summary, CSI failed to document provisions in its dedication procedure for supplier evaluation and performance and, as a result, was unable to provide objective evidence of oversight activities in support of the assembly of CIMs. This issue is identified as Nonconformance 99901404/2011-201-02.

The NRC inspection team also inquired about the evaluation, selection, and testing of field programmable gate arrays (FPGAs) used in CIMs. FPGAs are a class of programmable logic devices that can be programmed in the field after the manufacture of these devices to implement specific design functions. CSI developed the CIM control logic that is programmed in the FPGAs. This control logic arbitrates between component command signals to provide high integrity component control and allows the nonsafety system to control the component if a command from the safety system is not present. Subsection b.2, below, documents additional information related to the selection and programming of FPGAs.

The NRC inspection team confirmed that the FPGAs used in the CIMs are commercial components that are purchased through catalog specifications and that are not subject to nuclear specifications. In interviews with CSI engineering and manufacturing personnel, the NRC inspection team asked about the FPGA design features and specifications. Specifically, the NRC inspection team asked about CSI's process for ensuring the suitability of the selected FPGAs for their intended applications, consideration of potential design changes in the FPGA design by manufacturers, and evaluation of error reports related to design deficiencies that could jeopardize FPGA behavior in its operating environment. The interviewees informed the NRC inspection team that CSI personnel participate in user community forums and that they receive informal notifications of error reports associated with the FPGAs used in the CIM design. The collection and evaluation of error reports provides valuable information that system engineers can use to ensure that identified design flaws are not affecting FPGA operations. However, during the review of QCP 9000-01500, the NRC inspection team found that no formal provisions were in place to ensure that CSI collected error reports associated with discrete components used in the CIM design, such as FPGAs, evaluated them for applicability in its product line, dispositioned them, and notified affected organizations, when applicable. This lack of procedural control to collect and evaluate error reports is identified as Nonconformance 99901404/2011-201-03.

b.2 Review of Design Documentation

The NRC inspection team focused their review on the D105 project, which covers the design and development of CIMs and safety remote node controller (SRNC) modules for AP1000 units built in China. The NRC inspection team learned that CSI has developed several prototypes that are considered "Hardware Build 4" and that are in the process of being qualified for seismic and environmental applications. The NRC inspection team were also informed that CSI has not officially delivered CIMs or SRNCs to Westinghouse. Although CSI is not formally dedicating the modules developed for the D105 project, the vendor informed the NRC inspection team that it will implement its dedication process on all the modules that will be used in AP1000 plants.

During the review of CSI's dedication process, the vendor informed the NRC inspection team that it has dedicated two CIM components: (1) the bare printed circuit boards and (2) the printed circuit board assemblies. These components are verified during receipt

inspection activities and are tested at CSI. A receipt inspector examines the boards in accordance with Procedure 9000-00702. As part of this process, the inspector verifies whether the boards conform to PO requirements, examines the board's technical drawings, and takes high-resolution pictures. Upon acceptance, CSI stores the boards in the Class 1E room for future use and testing. The NRC inspection team asked CSI how it handles other components, such as resistors, transistors, and connectors, and learned that the vendor accepts and tests these components after assembling them in the CIM circuit boards. The NRC inspection team reviewed Procedure 6105-20042 and the CIM Traveler No. 20041, which are associated with the final assembly of the CIMs. CSI initiates and completes a traveler through the assembly, test, and packaging phases. Activities that the traveler records include kitting, module assembly, FPGA programming, voltage tests, final acceptance tests, and final QA inspections.

The NRC inspection team asked CSI personnel to provide objective evidence that they followed the engineering process (technical evaluation) to make critical characteristic (CC) determinations and to describe the methods used to verify those characteristics that they selected as critical for the CIMs. The CSI personnel informed the NRC inspection team that the vendor had not developed technical evaluations to identify CCs and acceptance methods. Instead, the NRC inspection team was given life-cycle documentation that contained the design basis for the CIMs and the engineering methodology that CSI uses to test the CIMs.

The NRC inspection team reviewed a sample of CIM design and life-cycle documents that CSI developed for the D105 project. Specifically, the NRC inspection team reviewed the following documentation that describes the design and testing of CIMs:

- Report No. 6105-00000
- Report No. 6105-00005
- Report No. 6105-20003
- Report No. 6105-20004

The NRC inspection team noted that these documents identified the CIMs' safety functions, application requirements, CCs, acceptance criteria, and testing activities. The NRC inspection team confirmed that adequate information was available to demonstrate the suitability of the CIMs' design for their intended application. No findings of significance were identified.

c. Conclusions

The NRC inspection team issued Nonconformances 99901404/2011-201-02 and 99901404/2011-201-03 for CSI's failure to provide reasonable assurance that all commercial items received from its suppliers would conform to the applicable specification requirements. Specifically, the NRC inspection team determined that CSI failed to conduct adequate oversight (e.g., commercial-grade surveys) to verify the supplier's quality program for the control of CCs and failed to establish and implement provisions to collect information on error reports related to potential nonconformances of discrete components used in safety-related applications.

3. Design Control

a. Inspection Scope

The NRC inspection team reviewed the implementation of CSI's process for design control. Specifically, the NRC inspection team reviewed the policies and procedures that govern the implementation of CSI's process used to verify compliance with Criterion III "Design Control," 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 team reviewed specific design documentation related to design diversity between the CIS and diverse actuation system (DAS), evaluated the translation of technical requirements into design and fabrication documentation, and evaluated verification and validation (V&V) processes used for the CIS system development to verify that the implementation of the program was consistent with CSI's documented controls.

The NRC inspection team reviewed the following documents for this inspection area:

- APP-DAS-J4-004, "AP1000 DAS System Design," Revision A, issued July 2010
- APP-DAS-J4-003, AP1000 DAS Sub-System Requirements Specification," Revision 0, issued November 2009
- CSI Report No. 6105-00030, "CIM-SRNC Design Tools," Revision 2, dated August 18, 2010
- CSI Report No. 6106-00104, "DAS ALS Sub-System Requirements Specifications," Revision A, dated March 7, 2011
- CSI Report No. 6106-00105, "DAS ALS Sub-System Design Specifications," Revision B, dated December 21, 2010
- CSI Report No. 6002-00031, "ALS Diversity Analysis," Revision 1
- CSI Report No. 6105-10002, "SRNC Architecture Specification," Revision 2
- CSI Report No. 6105-10004, "SRNC FPGA Specification, Revision 0
- CSI Report No. 6105-10004, "SRNC FPGA Specification, Revision 0
- CSI Report No. 6105-20002, "CIM Architecture Specification," Revision 3
- CSI Report No. 105-20003, "CIM Hardware Specification," Revision 1
- CSI Report No. 6105-20004, "CIM FPGA Specification," Revision 5
- WEC APP-DAS-J1-001, "AP1000 Diverse Actuation System Functional Requirements," Revision 0
- WEC APP-DAS-J1-103, "AP1000 Functional Diagram Diverse Actuation System," Revision 3
- WEC APP-DAS-J4-001, "AP1000 Diverse Actuation System Design Specification," Revision C
- WEC APP-PMS-J0-001, "AP1000 PMS Architecture Division A," Revision E

- WEC APP-PMS-J1-001, “AP1000 Protection and Monitoring System Functional Requirements,” Revision 2
- WEC APP-PMS-J4-020, “System AP1000 System Design Specification for the Protection and Safety Monitoring System,” Revision A
- WEC APP-RCS-M3C-101, “RCS Instrumentation and Packaged Mechanical System Interface Requirements,” Revision 5, dated December 20, 2010
- WEC APP-RXS-M3C-101, “RXS (Including IIS) Instrumentation and Packaged Mechanical System Interface Requirements,” Revision 3, dated December 27, 2010
- WEC APP-SGS-M3C-101, “SGS Instrumentation and Packaged Mechanical System Interface Requirements,” Revision 3, dated April 22, 2010
- WEC APP-RCS-M3C-101, “VCS Instrumentation Requirements,” Revision 2, dated January 28, 2011
- WEC WCAP-15775, “AP1000 Instrumentation and Control Defense in Depth and Diversity Report,” Revision 4, dated May 28, 2010
- WEC WCAP-16675-P, “PMS Architecture Report, ” Revision 3, issued December 2009
- WEC WCAP-17179P, “AP1000 Component Interface Module Technical Report,” Revision 1, dated May 28, 2010
- CSI Report No. 6105-0013, “CIM-SRNC IV&V Plan,” Revision 0, issued January 2011
- WNA-DS-01271-GEN, “Component Interface Module,” Revision 8, issued August 2010
- WNA-DS-01272-GEN “SRNC,” Revision 6, issued August 2010
- WNA-DS-0231-GEN, “Component Interface Module Logic,” Revision 0
- CSI Report No. 6105-00003, “The CIM-SRNC V&V Plan,” Revision 1
- CSI Report No. 6105-00013, “The CIM-SRNC IV&V Plan,” Revision 0
- CSI Report No. 6105-00030, “The CIM-SRNC Design Tools,” Revision 0
- WNA-DS-01271, “Component Interface Module,” Revision 7
- CAR 10-310-M006, dated November 6, 2010
- CSI QCP 9000-00600, “Document Control,” Revision 3
- CSI Report No. 9000-01001, “Qualification and Certification of Inspection and Test Personnel,” Revision 3
- CSI Form 9010-00031, “Certificate of Qualification,” Revision 3
- CAP 11-119-M044, dated April 29, 2011

b. Observations and Findings

b.1 Translation of Westinghouse's Component Interface Module/Diverse Actuation System Technical Requirements into Design and Fabrication Processes

The NRC inspection team reviewed CSI's processes for analyzing and translating technical specification requirements (i.e., WEC's AP1000 design certification amendment application requirements) from Westinghouse to assess CSI's ability to integrate requirements for both CIMs and the DAS into production. In addition, the NRC inspection team held numerous discussions with the CSI and WEC project team on the development of CSI design and fabrication documents and procedures based on technical requirements input from Westinghouse's AP1000-related procurement documents, topical reports, and technical reports to better understand the implementation of the CSI design and procurement processes. Based on these activities, the NRC inspection team verified that CSI had an adequate design control process to identify, track, and integrate the technical requirements in procurement and technical documentation into CSI-specific design and fabrication documentation.

As part of the inspection, the NRC inspection team noted that CSI had not updated some of its design documents to incorporate the most recent changes to system functional requirements in the latest revisions of WEC's technical documents. After discussions with the CSI and WEC staff, the NRC inspection team noted that CSI was in the process of incorporating these new changes to the system functional requirements in accordance with its engineering design procedures. The NRC inspection team confirmed that CSI had processes in place and had implemented them to help maintain configuration control. No findings of significance were identified.

b.2 Diversity Evaluation

The NRC inspection team performed a review to verify that diversity requirements, consistent with the WEC AP-1000 DCA, were adequately implemented on the protection and safety monitoring system (PMS) and DAS designs to verify that sufficient diversity exists between the two systems. The NRC inspection team used the staff guidance in NUREG/CR-6303, "Method for Performing Diversity and Defense-in-Depth Analyses of Reactor Protection Systems," dated December 31, 1994 (Agencywide Documents Access and Management System (ADAMS) Accession No. ML071790509), as augmented by the staff guidance in NUREG/CR-7007, "Diversity Strategies for Nuclear Power Plant Instrumentation and Control Systems," dated February 23, 2010 (ADAMS Accession No. ML100541256) to support the inspection.

The NRC inspection team compared the Westinghouse Common Qualified Platform (Common-Q)-and CIM/SRNC based PMS and the CSI advanced logic system (ALS)-based DAS designs using the diversity attributes and associated diversity attribute criteria described in NUREG/CR-6303, as supplemented by NUREG/CR-7007. The NRC inspection team compared the two systems from two different perspectives: (1) the safety function perspective and (2) the similar hardware component perspective. The system function diversity perspective addressed diversity between the safety function processing features of the PMS and DAS. This perspective addressed differences between the PMS and DAS on the processing of input signals into safety actuation signals. The hardware component diversity perspective addressed the diversity

between the FPGA-based SRNC and CIM components in the PMS and the FPGA-based components in the DAS.

At both levels of comparison, the NRC inspection team used 25 diversity-related characteristics addressing the seven diversity attributes described in NUREG/CR-7007 (i.e., design, equipment manufacturer, logic processing equipment, function, life cycle, signal, and logic) to categorize system and hardware component diversity features between the PMS and DAS.

Based on its comparisons using the diversity characteristics and attributes, the NRC inspection team determined that CSI had adequately implemented the diversity requirements, consistent with the WEC AP-1000 DCA, and verified that sufficient diversity exists between the PMS and DAS systems. No findings of significance were identified.

b.3 Independent Verification and Validation

The inspection team reviewed the V&V and the independent verification and validation (IV&V) testing of the CIM subsystem with the WEC AP1000 instrumentation and control safety system and the PMS. The PMS comprises two subsystems: (1) the Common-Q-based portion of the PMS, which provides the sensor input, logic, and logic output distribution signal functions, and (2) the CIM subsystem, which performs the safety-related component control functions. The CIM subsystem also serves as a priority module that receives component control input signals for safety-related components from both the safety-related PMS and the nonsafety-related plant control system (PLS) and determines which input takes priority over the other based on plant conditions.

The CIM subsystem contains two major components: the CIM and the SRNC. The SRNC serves as an input translation device that converts the inputs from the PMS that uses the Common-Q Advant Controller 160 microprocessor-based controllers, using the Asea Brown Boveri Master Programming Language. A second input node controller, known as the remote node controller, translates the inputs received from the Ovation-based PLS. Both the SRNC and remote node controller inputs are applied to the CIM to determine which system, the PMS or the PLS, provides safety-related component control to the final output device.

The NRC inspection team reviewed the CSI and WEC design documents (CSI Report No. 6105-00003, CSI Report No. 6105-00013, WNA-DS-01271-GEN, and WNA-DS-01272-GEN) related to V&V and IV&V activities associated with the CIM-SRNC project and held numerous discussions with CSI and WEC project personnel. The NRC inspection team noted that the documents describe V&V and IV&V methodologies used for the CIM-SRNC project for several phases of the development life cycle.

The NRC inspection team noted that the CIM-SRNC IV&V plan (CSI Report No. 6105-00013) describes IV&V activities, including the use of a separate and diverse V&V team from WEC that is responsible for the conduct of CIM-SRNC project IV&V activities. The CIM-SRNC IV&V plan also describes how the WEC IV&V team will conduct its own independent review activities during the requirements, design, implementation, and validation portions of the CIM-SRNC development. The CIM-SRNC IV&V plan also

refers to the IV&V team's use of CIM-SRNC design tools (CIS Report No. 6105-00030). This document describes how the WEC IV&V team will develop and use design tools and simulations with a different set of software design tools than those used by the CSI design and V&V team. The NRC inspection team determined that the description provided in CIS Report No. 6105-00030, as supplemented by additional IV&V activities during that phase of development, such as requirements traceability analysis (RTA), was adequate for CIM-SRNC project software development during the design phase.

However, based on its review, the NRC inspection team identified several concerns about the IV&V processes implemented for this project based on its review. Specifically, the NRC inspection team identified the following issues:

- The development of the CIM-SRNC module and the coding and testing of the module components during the design and implementation phases of development relies primarily on the oversight of activities through RTA and other on-site evaluations of the CSI staff by the WEC IV&V team. The NRC inspection team did not identify any independent and separate test plans that govern the WEC IV&V team activities separate from those instituted by the CSI design and test team.

- The NRC inspection team determined that the component or module-based level of development for the CIM-SRNC subsystem uses a singular automated test environment test tool developed by the CSI design and test team to test the inputs and outputs of the CIM and SRNC. The NRC inspection team noted that should a flaw exist in the automated test environment test tool, the currently proposed IV&V process would not necessarily detect this potential error because the current IV&V process does not require the WEC IV&V team to develop or acquire a second independent testing tool. The lack of a second independent testing tool cannot ensure the mitigation of this potential testing vulnerability.

These issues are identified as examples of Nonconformance 99901404/2011-201-04 for failure to implement an adequate IV&V process.

b.4 Design Document Control

The NRC inspection team reviewed the implementation of the CSI process for controlling documents and quality records as part of the evaluation of the CSI design control process. During the inspection, the NRC inspection team reviewed sample design documents, CSI document control procedures and policies, and selected CARs and discussed the document control program with CSI personnel responsible for the implementation of the program.

The NRC inspection team verified that CSI has written procedures and has policies in place to control the development, revision, distribution, retention, and storage of design documentation associated with the CIM-SRNC system. The NRC inspection team determined that CSI was implementing a program to control CIM-SRNC system design documentation that was consistent with CSI Report No. 9000-00000, "Quality Assurance Manual (QAM)," Revision 4, dated July 9, 2010, and the associated QAM implementing procedures. However, as a result of the review, the NRC inspection team determined that the CSI design control process failed to meet NRC requirements with respect to ensuring adequate independent review and approval of design documents consistent

with those requirements. Specifically, the NRC inspection team identified that CSI had not adequately addressed a previously identified concern (CAR 10-310-M006) about the use of the QA manager as the final technical approver of design documentation. In response to the concern, CSI revised the document control process to establish functional and administrative process owners and revised Step 3.8 of QCP 9000-00600 to state, in part, that "the approver is [a] technically competent functional manager or lead individual. [The] QA manager may be added as [an] approver. If requested, [the] QA [manager] shall verify [that the] document meets the CSI QA program requirements." Additionally, CSI revised Step 3.9.2 to state, in part, that "the process owner may delegate approval signature to others within [a] functional area," and revised Step 3.9.5 of QCP 9000-00600 to state, in part, that "the QA manager or designee may be [the] final approver if [the] functional manager deems so."

As a result of these changes to the CSI procedures, the design control process continued to allow for the QA manager to act as the final technical approver of the design documents. The NRC inspection team reviewed a sample of current design documents and verified that CSI had, in fact, designated the QA manager as the approval authority as evidenced by his signature as approving official. The NRC inspection team determined that the revisions made to the CSI document control program were insufficient to prevent recurrence of the initial concerns identified in CAR 10-310-M006 and that the use of the QA manager to act as final approver is inconsistent with the requirements of Criterion I of Appendix B to 10 CFR Part 50, which the NRC established to ensure the QA function retains process independence from those activities for which QA functions exist. The NRC inspection team identified CSI's failure to adequately describe and implement the CSI design control process to ensure that the QA function retains process independence from those activities for which QA functions exist as Nonconformance 99901404/2011-201-05.

b.5 Training and Qualification of CSI Inspection and Test Personnel

The NRC inspection team reviewed the implementation of the CSI process for controlling and documenting the training and qualification of inspection and test personnel involved in the CIM-SRNC program. The NRC inspection team reviewed a sample of qualification and training records and CSI training and qualification procedures and policies and discussed the inspection and testing training and qualification program with CSI personnel responsible for the implementation of the program.

CSI Procedure 9000-01001 describes the use of CSI Form 9010-00031 to document that an individual has successfully completed his or her qualification program and to serve as certification that the individual is capable of performing those activities required by the certification. CSI Procedure 9000-01001 further requires CSI to keep a written record of qualification for all affected personnel as a quality record.

Based on the review of a sample of qualification records for CSI inspection and test personnel, the NRC inspection team identified two examples of training records that did not contain the required certification form as required by CSI Procedure 9000-01001. The examples identified were for CSI QA personnel responsible for verifying the proper assembly of safety-related materials and the performance of verification activities during module assembly. Based on discussions with the CSI personnel responsible for the implementation of the training and qualification process, the NRC inspection team confirmed that the individuals did complete the required training; however, CSI had not

completed the required CSI Form 9010-00031 for either individual. CSI did acknowledge the discrepancy and initiated corrective actions (CAP 11-119-M044) to properly document the status of the individual's qualifications and to evaluate the extent of the condition. Based on the low safety significance of the finding and the immediate corrective actions initiated by the vendor, this nonconformance is not being cited. This failure constitutes a violation of minor significance and is not subject to formal enforcement action.

c. Conclusions

The NRC inspection team issued Nonconformance 99901404/2011-201-04 for failure to implement an IV&V process consistent with NRC requirements, and Nonconformance 99901404/2011-201-05 for failure to implement an adequate design control process to ensure that the QA function retains process independence from those activities for which QA functions exist. The NRC inspection team also documented a non-cited nonconformance on training and qualification records management.

4. Corrective Action Program

a. Inspection Scope

The NRC inspection team reviewed the implementation of the CSI process for corrective actions. Specifically, the NRC inspection team reviewed the policies and procedures that govern the implementation of the CSI process to verify compliance with Criterion XVI, "Corrective Actions," of Appendix B to 10 CFR Part 50. In addition, the NRC inspection team reviewed a sample of NCRs, CARs, and RMAs associated with materials that depart from technical requirements and discussed the program with CSI personnel responsible for the implementation of the corrective action program.

The NRC inspection team reviewed the following documents for this inspection area:

- CSI Report No. 9000-00000
- QCP 9000-01600
- QCP 9000-01501
- QCP 9000-01500
- RMA 110119-1
- RMA 110119-2
- Wolf Creek PO 746194/0
- Wolf Creek PO 754097/0
- Work Creek PO 751264/3
- CSI Report No. 6101-10012, "MSFIS ALS Test Plan," Revision 1.01, dated March 31, 2011
- CAR 2011-051
- CAR 2010-014, dated March 29, 2010

- CAR 2010-015, dated March 31, 2010
- IR 11-111-M010, dated April 21, 2011
- IR 11-111-M011, dated April 21, 2011
- IR 11-111-M013, dated April 21, 2011
- IR 11-111-M015, dated April 21, 2011
- commercial-grade dedication plan for ALS-101 for the main steam feedwater isolation system (MSFIS)/main feedwater isolation valve system

b. Observations and Findings

Section 16 the CSI QAM defines the general policy, responsibility, and policies for the corrective action program. It describes the policy for conditions adverse to quality, corrective action, preventative action, and the evaluation and potential reporting associated with the 10 CFR Part 21 program. Step 16.3.5 states, in part, that "all corrective actions shall be evaluated for potential reporting under the requirements of 10 CFR Part 21."

QCP 9000-01600 applies to all identified conditions adverse to quality, such as failures, malfunctions, deficiencies, deviations, defective equipment, and program nonconformance. QCP 9000-01600 assigns responsibilities to the quality manager or designee for the quality program, including the monitoring, measurement, analysis, and improvement application. The procedure describes the process used to identify, report, document, and disposition of conditions adverse to quality, such as a deviation or failure to comply. Step 6.7 states, in part, that "all significant conditions adverse to quality shall be evaluated for possible reporting under the requirements on 10 CFR 21." In addition, Step 6.3 states, in part, that a CAR may be voided only if a CAR is a duplicate of another open CAR, if a CAR describes a problem that is inappropriate for a CAR, or if a CAR is submitted in error.

The NRC inspection team noted that each corrective action captured on CAR 9010-00035 described the discrepant condition, cause, and corrective action that CSI had taken or had planned to take to prevent recurrence. The NRC inspection team discussed the corrective action section of the QAM with CSI as defined in Section 16 of the CSI QAM and in QCP 9000-01600.

While reviewing a sample of corrective actions, the NRC inspection team noted that, although CAR 9010-00035 included a check box to evaluate for reportability in accordance with 10 CFR Part 21, it did not provide criteria to determine the existence of a deviation. For example, CAR 2011-051 discusses a departure from technical requirements in the test plan (CSI Report No. 6101-10012) for the core logic board in the MSFIS. The MSFIS core logic board had been delivered as safety related to Wolf Creek. The CAR failed to identify this as a deviation that needed to be evaluated for possible reporting under 10 CFR Part 21. This corrective action had been closed despite CSI's failure to complete its discrepant condition and causes on the CAR. The closed CAR documented that 10 CFR Part 21 was not applicable. The NRC inspection team discussed this corrective action with the QA manager and immediate corrective action was taken to reopen the corrective action and perform an evaluation. CSI completed a prompt evaluation in accordance with 10 CFR Part 21 and documented that

the deviation did not cause a substantial safety hazard. CSI completed the evaluation within 60 days of CSI first documenting the condition in CAR 2011-051, as required by 21.21(a)(1). As described in Section 1 of this report, the NRC inspection team identified that CSI does not have an adequate procedure for evaluating deviations to determine the existence of a defect associated with a substantial safety hazard.

CAR 2010-010 is an additional example of the inadequate implementation of the corrective action process. CAR 2010-010 discusses the consideration for additional V&V of software to ensure that it is performing all intended functions, including a periodic review of all error reports for evaluation of potential impacts. CAR 2010-010 had a due date of September 15, 2010, and then was voided. The NRC inspection team noted that this CARwas not voided in accordance with cases that QCP 9000-01600 stated as allowable reasons to void a corrective action. The NRC identified a nonconformance in Section 2 of this report that addresses the inadequate review of error reports.

In addition, the NRC inspection team noted that there were multiple examples of identified conditions adverse to quality that CSI had not entered into the corrective action process in a timely manner. For example, IR 11-111-M010 documented the lack of documentation associated with subcontractor oversight. An NRC audit identified this issue in March 2010 (ADAMS Accession No. ML101410395), and CSI's corrective action program had not added it until April 21, 2011.

As described above and in Section 2 of this report, CSI delivered safety-related core logic boards for MSFIS under Wolf Creek POs 754097/0 and 751264/3. These POs specify that all work must be performed in accordance with Appendix B to 10 CFR Part 50 and that CSI must ensure that all suppliers and manufacturers of safety-related items or services are on its approved vendor list (AVL). The POs further state that all suppliers and manufactures that were on CSI's AVL must be added to the AVL based on an acceptable implementation audit. CSI did not have documentation to show subcontractor oversight associated with the Wolf Creek POs despite the identified deficiency of subcontractor oversight in March 2010.

Additional examples of untimely corrective actions that the NRC inspection team identified include the following:

- IR 11-111-M015 discusses a lack of supporting documentation for human diversity. The IR was initiated on April 21, 2011, and was identified in March 2010.
- IR 11-111-M011 discusses an inconsistency about how a test simulation environmental specification was being applied to the ALS platform. The IR was initiated on April 21, 2011, and was identified in March 2010.
- IR 11-111-M013 discusses text reference errors in several documents. The IR was initiated on April 21, 2011, and was identified in March 2010.

The NRC inspection team identified CSI's failure to identify deviations as part of its corrective action process and to promptly identify and correct conditions adverse to quality as Nonconformance 99901404/2011-201-06.

c. Conclusions

The NRC inspection team issued Nonconformance 99901404/2011-201-06 for CSI's failure to identify deviations as part of its corrective action program and to promptly

identify and correct conditions adverse to quality. Specifically, the NRC inspection team determined that CSI failed to identify deviations that described departures from technical requirements and to promptly enter multiple identified deficiencies into its corrective action program.

5. Entrance and Exit Meetings

On April 25, 2011, the NRC inspection team discussed the scope of the inspection with Mr. William Hadovski, Chief Operating Officer, and with the CSI management, engineering, and production staff. On April 29, 2011, the NRC inspection team presented its inspection results and observations during an exit meeting with Mr. Hadovski and other CSI management and engineering staff. The attachment to this report lists the entrance and exit meeting attendees and those personnel who were interviewed by the NRC inspection team.

ATTACHMENT

1. ENTRANCE/EXIT MEETING ATTENDEES

Name	Affiliation	Entrance	Exit
William Hadovski	CSI	X	X
Murat Uzman	WEC	X	X
Marci Mahel	WEC	X	X
Kyra Durinsky	WEC	X	X
John Dudiak	WEC	X	X
Tom Tweedle	WEC	X	X
Jen Drylie	WEC	X	X
David Dunsavage	CSI	X	X
Robert Seelman	WEC	X	X
Mesut Uzman	WEC	X	X
Bil Irmen	CSI	X	X
Joe Lorson	CSI	X	X
Steen Sorensen	CSI	X	X
Ken Kloes	WEC	X	X
Mark Stofko	WEC	X	X
Brian Studaker	CSI	X	X
Dar Dragoon	CSI	X	
Ed Gee	CSI	X	X
Steve Seaman	WEC/CSI	X	X
Thom Ray	WEC		X
Dale Harmon	WEC		X
Larry Erin	WEC		X
Andrew Konzel	WEC		X
Charlie Bobbitt	CSI	X	X
Warren Odess-Gillett	WEC		X
Greg Galletti	NRC	X	X
Stacy Smith	NRC	X	X
Milton Concepcion	NRC	X	
Michael Waterman	NRC	X	X

William Roggenbrodt	NRC	X	X
Jack Zhao	NRC	X	X
Juan Peralta	NRC		X

2. INSPECTION PROCEDURES USED

IP 43002, “Routine Inspections of Nuclear Vendors”

IP 43004, “Inspection of Commercial-Grade Dedication Programs”

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

3. LIST OF ITEMS OPENED, CLOSED, AND DISCUSSED

The following items were found during this inspection:

Item Number	Status	Type	Description
99901404/2011-201-01	Open	NOV	10 CFR Part 21
99901404/2011-201-02	Open	NON	Criterion III and VII
99901404/2011-201-03	Open	NON	Criterion XV
99901404/2011-201-04	Open	NON	Criterion III
99901404/2011-201-05	Open	NON	Criterion I
99901404/2011-201-06	Open	NON	Criterion XVI