

November 4, 2011

Mr. Claes Gerdin Manager,
Quality Assurance
Westinghouse Electric Sweden AB
SE-721 63 Västerås, Sweden

SUBJECT: NRC INSPECTION REPORT NO. 99901408/2011-201 AND NOTICE OF
NONCONFORMANCE

Dear Mr. Gerdin:

On September 12-16, 2011, the U.S. Nuclear Regulatory Commission (NRC) staff conducted an inspection at the Westinghouse Electric Sweden AB (Westinghouse) facility in Västerås, Sweden. The purpose of this limited scope inspection was to assess Westinghouse's compliance with the provisions in Title 10 of the *Code of Federal Regulations* (10 CFR) Part 21, "Reporting of Defects and Noncompliance," and selected portions of Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants," to 10 CFR Part 50, "Domestic Licensing of Production and Utilization Facilities." The enclosed report presents the results of this inspection. This NRC inspection report does not constitute NRC endorsement of your overall quality assurance (QA) or 10 CFR Part 21 programs.

During this inspection, NRC inspectors found that the implementation of your QA program failed to meet certain NRC requirements, which were contractually imposed on you by your customers or NRC licensees. The NRC inspectors identified examples of implementation issues that warrant your attention and consideration for impact on past and future safety-related work. Specifically, Westinghouse failed to establish acceptance criteria for computer code verification and validation tests, dedicate commercial software for use in safety-related applications, and prescribe an appropriate procedure for 10 CFR Part 21 discovery and evaluation. The specific findings and references to the pertinent requirements are identified in the enclosure to this letter.

Please provide a written explanation or statement within 30 days of this letter in accordance with the instructions specified in the enclosed Notice of Nonconformance. We will consider extending the response time if you show good cause for us to do so.

In accordance with 10 CFR 2.390, "Public Inspections, Exemptions, Requests for Withholding," of the NRC's "Rules of Practice," a copy of this letter, its 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, your response should not include any personal privacy, proprietary, or safeguards information so that it can be made available to the public without redaction. If personal privacy or proprietary information is necessary to provide an acceptable response, then please provide a bracketed copy of your response that identifies the information that should be protected and a redacted copy of your response that deletes such information. If you request that such material is withheld from public disclosure, you must specifically identify the portions of your response that you seek to have withheld and provide, in detail, the bases for your claim (e.g., explain why the disclosure of information will create an unwarranted invasion of personal privacy or provide the information

C. Gerdin

- 2 -

required by 10 CFR 2.390(b) to support a request for withholding confidential commercial or financial information). If Safeguards Information is necessary to provide an acceptable response, please provide the level of protection described in 10 CFR 73.21, "Protection of Safeguards Information: Performance Requirements."

Sincerely,

/RA/

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

Docket No. 99901408

Enclosures:

1. Notice of Nonconformance
2. Inspection Report No. 99901408/2011-201 and Attachment

C. Gerdin

- 2 -

required by 10 CFR 2.390(b) to support a request for withholding confidential commercial or financial information). If Safeguards Information is necessary to provide an acceptable response, please provide the level of protection described in 10 CFR 73.21, "Protection of Safeguards Information: Performance Requirements."

Sincerely,

/RA/

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

Docket No. 99901408

Enclosures:

- 1. Notice of Nonconformance
- 2. Inspection Report No. 99901408/2011-201 and Attachment

DISTRIBUTION:

RidsNroDcipCQVA
KKavanagh

RidsNroDcipCQVB
TSakadales

RidsNrrDeEQVB
EHuang

RidsNroDcip JDonoghue
gerdinci@westinghouse.com

ADAMS Accession No.: ML11300A148

*concurring via email

NRO-001

OFFICE	NRO/DCIP/CQVB	QTE	NRO/DRSA/SRSB	NRO/DRSA/SRSB	NRO/DCIP/CQVB	NRO/DCIP/CAEB	NRO/DCIP/CQVB
NAME	GNewman	JDougherty*	GThomas	JGilmer	RMcIntyre	TFrye	RRasmussen
DATE	11/03/2011	10/25/11	11/03/2011	11/03/2011	11/02/2011	11/03/2011	11/04/2011

OFFICIAL RECORD COPY

NOTICE OF NONCONFORMANCE

Westinghouse Electric Sweden AB
Västerås, Sweden

Docket No.: 99901408
Inspection Report No.: 99901408/2011-201

Based on the results of a U.S. Nuclear Regulatory Commission (NRC) inspection conducted at the Westinghouse Electric Sweden AB (Westinghouse) facility in Västerås, Sweden, on September 12–16, 2011, certain activities were not conducted in accordance with NRC requirements, which were contractually imposed on Westinghouse by its customers or NRC licensees:

- A. Criterion V, “Instructions, Procedures, and Drawings,” 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,” states, in part, that “activities affecting quality shall be prescribed by documented instructions, procedures, or drawings, of a type appropriate to the circumstances and shall be accomplished in accordance with these instructions, procedures, or drawings.”

10 CFR 21.3, “Definitions,” to 10 CFR Part 21, “Reporting of Defects and Failures to Comply,” states, in part, that “*Discovery* means the completion of the documentation first identifying the existence of a deviation or failure to comply potentially associated with a substantial safety hazard within the evaluation procedures discussed in § 21.21(a).”

10 CFR 21.21(a)(1) states, in part, to “evaluate deviations and failures to comply to identify defects and failures to comply associated with substantial safety hazards as soon as practicable, and, except as provided in paragraph (a)(2) of this section, in all cases within 60 days of discovery, in order to identify a reportable defect or failure to comply that could create a substantial safety hazard, were it to remain uncorrected.”

Westinghouse Engineering Services Procedure (ES) 21.1, “WEC 21.0 Level 3 Implementation Procedure,” Revision 1, dated December 6, 2010, states, in part, that “this Level 3 procedure implements the requirements of Westinghouse Policy/Procedure WEC 21, Revision 6, ‘Identification and Reporting of Conditions Adverse to Safety,’ and that once a potential condition adverse to safety arises, the condition is identified, documented, and assessed to determine if an actual condition adverse to safety exists.”

Contrary to the above, as of September 16, 2011, Westinghouse failed to prescribe an appropriate procedure to ensure the timely identification and evaluation of deviations and failures to comply that could create a substantial safety hazard. Specifically, ES 21.1 includes a 30-day discovery phase evaluation timeframe that may be extended for 2 weeks at a time, thus inappropriately delaying discovery and initiation of the evaluation required by 21.21(a)(1).

This issue has been identified as Nonconformance 99901408/2011-201-01.

- B. Criterion III, “Design Control,” of Appendix B to 10 CFR Part 50 states, in part, that “applicable regulatory requirements and the design basis...are correctly translated into specifications, drawings, procedures, and instructions.” It also states that “measures shall be established for the selection and review for suitability of application of materials,

parts, equipment, and processes that are essential to the safety-related functions of the structures, systems, and components.”

10 CFR 21.3 defines “Dedication,” in part, as “an acceptance process undertaken to provide reasonable assurance that a commercial grade item to be used as a basic component will perform its intended safety function and, in this respect, is deemed equivalent to an item designed and manufactured under a 10 CFR Part 50, appendix B, quality assurance program. This assurance is achieved by identifying the critical characteristics of the item and verifying their acceptability by inspections, tests, or analysis performed by the purchaser or third-party dedicating entity.”

Criterion V of Appendix B to 10 CFR Part 50 states, in part, that “activities affecting quality shall be prescribed by documented instructions, procedures, or drawings, of a type appropriate to the circumstances and shall be accomplished in accordance with these instructions, procedures, or drawings.”

“Westinghouse Quality Management System (QMS),” Section 4.3.9, “Commercial-Grade Items,” Revision 6, dated April 8, 2011, states that “commercial-grade items, items not originally intended for safety-related applications, are subjected to a dedication process that is defined and authorized by the engineering organization in accordance with procedures that meet the requirements of the governing regulatory agency, before the items are supplied for safety-related applications.”

Westinghouse Policy / Procedure (WEC) 7.2, “Dedication of Commercial Grade Items,” Section 6.1, Revision 1, dated August 3, 2009, states that “Engineering is responsible for determining the safety-related function of the item, identifying both the critical characteristics of design and acceptance of the item, and identifying the dedication method(s) to be used to verify the critical characteristics of acceptance.”

Contrary to the above, as of September 16, 2011, Westinghouse failed to appropriately dedicate commercially procured software in accordance with WEC 7.2. Specifically, Westinghouse did not conduct a technical evaluation to identify safety function, critical characteristics, and acceptance methods for a commercially procured version of the ANSYS finite-element analysis software.

This issue has been identified as Nonconformance 99901408/2011-201-02.

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

Criterion V of Appendix B to 10 CFR Part 50 states, in part, that “activities affecting quality shall be prescribed by documented instructions, procedures, or drawings, of a type appropriate to the circumstances and shall be accomplished in accordance with these instructions, procedures, or drawings.”

EP-310, “Computer Software Development and Maintenance,” Section 9.1.5, Revision 25, dated March 14, 2011, states that “a Test Plan shall be developed, documented and reviewed. The plan shall specify...[a] description of the Test Cases

which are to be used in the testing, including items to be tested, the Test Cases to be performed, test sequences, and acceptance criteria.”

Contrary to the above, as of September 16, 2011, Westinghouse failed to specify and document acceptance criteria. Specifically, Westinghouse failed to identify acceptance criteria in test plans for computer software verification and validation tests supporting changes to the BISON and POLCA-T evaluation models in documents SET 10-165, “WCAP-17202-P, Supplement 4 to BISON Topical Report RPA 90-90-P-A, June 2010,” and SET 09-248, “POLCA-T Qualification Against Peach Bottom 2 EOC 2 Turbine Trip Tests 1 and 2.”

This issue has been identified as Nonconformance 99901408/2011-201-03.

Please provide a written statement or explanation to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, DC 20555-0001, with a copy to the Chief, Quality and Vendor Branch 2, Division of Construction Inspection and Operational Programs, Office of New Reactors, within 30 days of the date of the letter transmitting this Notice of Nonconformance. This reply should be clearly marked as a “Reply to a Notice of Nonconformance” and should include for each noncompliance (1) the reason for the noncompliance or, if contested, the basis for disputing the noncompliance, (2) the corrective steps that have been taken and the results achieved, (3) the corrective steps that will be taken to avoid noncompliance, and (4) the date when the corrective action will be completed. Where good cause is shown, the NRC will consider extending the response time.

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

Dated this 4th day of November, 2011.

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

Docket No.: 99901408

Report No.: 99901408/2011-201

Vendor: Westinghouse Electric Sweden AB
SE-721 63 Västerås, Sweden

Vendor Contact: Mr. Claes Gerdin
Quality Assurance Manager
Telephone:
E-mail:

Nuclear Industry Activity: Westinghouse Electric Sweden (Westinghouse), located in Västerås, Sweden, designs and manufactures fuel assemblies for new and operating pressurized-water reactors and boiling-water reactors (BWRs). Westinghouse develops and maintains the GOBLIN, BISON, and POLCA-T computer evaluation models. The South Texas Project and Westinghouse have submitted topical reports supporting BWR and advanced BWR designs.

Inspection Dates: September 12–16, 2011

Inspectors: Richard McIntyre CQVB/DCIP/NRO, Team Leader
Garrett Newman CQVB/DCIP/NRO
James Gilmer SRSB/DSRA/NRO, TechSpecialist
George Thomas SRSB/DSRA/NRO, Tech Specialist
Mohsen Khatib-Rahbar Contractor

Approved by: Richard Rasmussen, Chief
Quality and Vendor Branch 2
Division of Construction Inspection
& Operational Programs
Office of New Reactors

EXECUTIVE SUMMARY

Westinghouse Electric Sweden AB
99901408/2011-201

The U.S. Nuclear Regulatory Commission (NRC) conducted this inspection to verify that Westinghouse Electric Sweden AB (Westinghouse), implemented an adequate quality assurance (QA) program that complied with the requirements in Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants," to Title 10 of the *Code of Federal Regulations* (10 CFR) Part 50, "Domestic Licensing of Production and Utilization Facilities." The inspection also verified that Westinghouse implemented a program under 10 CFR Part 21, "Reporting of Defects and Noncompliance," that meets the NRC's regulatory requirements. The inspectors conducted the inspection at the Westinghouse Lunda offices in Västerås, Sweden, on September 12–16, 2011.

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

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

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

The NRC had not previously performed any inspections at the Westinghouse facility in Västerås, Sweden.

The results of this inspection are summarized below.

10 CFR Part 21

With the exception of the issuance of Nonconformance 99901408/2011-201-01 for Westinghouse's failure to prescribe an appropriate procedure for 10 CFR Part 21 discovery and evaluation, the NRC inspectors determined that Westinghouse appropriately translated the requirements in 10 CFR Part 21 into implementing procedures and, for those activities reviewed by the inspectors, implemented them as required by Westinghouse procedures.

Computer Software Design and Testing

With the exception of the issuance of Nonconformance 99901408/2011-201-02 for Westinghouse's failure to dedicate commercial software for safety-related use, and Nonconformance 99901408/2011-201-03 for Westinghouse's failure to establish acceptance criteria for computer software verification and validation tests, the NRC inspectors determined that the implementation of the Westinghouse program for test control was consistent with the regulatory requirements in Criterion III, "Design Control," and Criterion XI, "Test Control," of Appendix B to 10 CFR Part 50. As part of corrective action for Nonconformance 99901408/2011-201-03, the NRC expects that Westinghouse would evaluate the examples and document the basis for acceptance. Additionally, Westinghouse should determine if other instances exist where acceptance criteria were not included in computer software testing documentation and take similar corrective action as appropriate.

Corrective Actions

The NRC inspectors determined that the implementation of the Westinghouse corrective action program was consistent with the regulatory requirements in Criterion XVI, "Corrective Action," of Appendix B to 10 CFR Part 50. Based on the limited sample of documents reviewed and on observation of corrective action program activities, the inspectors also determined that Westinghouse is effectively implementing its quality management system and the associated corrective action procedures. No findings of significance were identified.

Audits

The NRC inspectors determined that the implementation of the Westinghouse corrective action program was consistent with the regulatory requirements in Criterion XVIII, "Audits," of Appendix B to 10 CFR Part 50. Based on the limited sample of audit reports reviewed, the inspectors also determined that Westinghouse is effectively implementing its quality management system and the associated internal audit procedures. No findings of significance were identified.

REPORT DETAILS

1. 10 CFR Part 21 Program

a. Inspection Scope

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

b. Observations and Findings

b.1 Policies and Procedures

The NRC inspection team reviewed the Westinghouse policies and procedures for implementation of the 10 CFR Part 21 program to evaluate their conformance with the regulation. The Westinghouse QMS describes the policy for the 10 CFR Part 21 program. To implement the program, Westinghouse implements a number of procedures, which vary by organization and location. The NRC inspection team's review of applicable procedures to the Västerås, Sweden, location is described below.

The NRC inspection team reviewed the "Westinghouse Quality Management System (QMS)," Revision 6, dated April 8, 2011, and Westinghouse Policy / Procedure (WEC) 21.0, "Identification and Reporting of Conditions Adverse to Safety," Revision 6, dated August 3, 2009, to verify that Westinghouse had effectively implemented the requirements in 10 CFR 21.21(a)(1). Specifically, the NRC inspection team assessed Westinghouse's procedures for evaluating deviations and failures to comply associated with substantial safety hazards and the appropriateness of associated timelines for evaluation and reporting identified in 10 CFR Part 21. In addition, the NRC inspection team verified that Westinghouse's corrective action program provides a link to the 10 CFR Part 21 program. Westinghouse's 10 CFR Part 21 procedures also implemented the requirements in 10 CFR 21.21(d) in regard to directors or responsible officers notifying the NRC of identified defects or failures to comply associated with substantial safety hazards.

The NRC inspection team reviewed WEC 21.0, Westinghouse's corporate procedure used to implement the requirements of 10 CFR Part 21 for the evaluation and reporting of defects and failures to comply. The procedure includes definitions; organizational responsibilities; flow diagrams for identification, evaluation, and reporting of potential conditions adverse to safety; and posting provisions. WEC 21.0 defines a potential condition adverse to safety, in part, as "the potential existence of any...safety-related Deviation, Failure to Comply, Nonconformance." WEC 21.0 states that discovery occurs when a potential issue is opened after the evaluation of a potential condition adverse to safety.

The NRC inspection team reviewed Engineering Services Procedure (ES) 21.1, "WEC 21.0 Level 3 Implementation Procedure," Revision 1, dated December 6, 2010, which is the procedure Westinghouse uses to implement the 10 CFR Part 21 program. ES-21.1 describes in further detail the discovery phase mentioned above. The ES-21.1 discovery phase includes a 30-day evaluation period that may be extended for an additional 2 weeks at a time with management approval. During this discovery phase, Westinghouse determines whether or not a condition is a deviation. The formal 60-day, 10 CFR Part 21 evaluation process does not commence until this discovery phase completes. The NRC inspection team determined that the potential for extensions to the discovery phase was inadequate to ensure the timely identification and evaluation of deviations and failures to comply that could create a substantial safety hazard and was therefore not adequate to consistently implement 10 CFR Part 21. For the case of Westinghouse Electric Sweden AB, the NRC inspection team did not find any cases where this extension was utilized. The NRC inspection team identified this finding as Nonconformance 99901408/2011-201-01.

The NRC inspection team also reviewed Westinghouse Instruktion – Procedure (WSE) 14.7, "Rapportering av defekter och avvikelser i levererade produkter [Report of defects and noncompliances in delivered products] (10 CFR 21)," Revision 2, dated September 9, 2011, a Sweden-specific procedure that Westinghouse uses to implement the 10 CFR Part 21 program consistent with WEC 21.0. The procedure's scope states that "evaluation that is performed for deliveries to the U.S. shall be completed in conjunction with the Safety Committee, described in procedure WEC 21.0." WSE 14.7 describes the postings and posting locations to satisfy 10 CFR 21.6, "Posting Requirements," at the various Västerås facilities. The NRC inspection team noted that WSE 14.7 also contained a flowchart of the 10 CFR Part 21 program as well as customer and non-US regulatory requirements. The NRC inspection team observed that while the flowchart is not a requirement of Part 21, it did contain conflicting information for evaluation and reporting responsibilities for U.S. and non-U.S. customers. Westinghouse committed to revise the flowchart to clearly represent the differences for U.S. and non-U.S. customers.

The NRC inspection team reviewed WEC 16.2, "Westinghouse Corrective Action Process," Revision 3, dated August 1, 2011, relating to the corrective action program, and Fuel Engineering Procedure (EP) 116, "Issue Reporting," Revision 16, dated March 14, 2011, relating to technology error reports, to verify that there was an appropriate link between the Part 21 program and corrective action process. The NRC inspection team verified that each of these procedures provide adequate guidance for evaluating deficiencies, as appropriate, for 10 CFR Part 21 applicability. In addition, the NRC inspection team reviewed numerous corrective action reports and software and technology issue (STI) reports to verify that they were appropriately considered for evaluation.

b.2 10 CFR Part 21 Program Implementation

The NRC inspection team reviewed the Westinghouse 10 CFR Part 21 evaluation process and determined that once an item is identified as requiring an evaluation for reportability under 10 CFR Part 21, Westinghouse Cranberry Township (Westinghouse headquarters) is automatically notified of the issue. The remaining 10 CFR Part 21 evaluation and reporting activities are performed by Westinghouse Cranberry Township with technical support, as applicable, from Westinghouse Electric Sweden in Västerås.

The NRC inspection team reviewed a number of issue reports (IRs) that were identified as requiring an evaluation for 10 CFR Part 21 reportability and verified that the evaluation and determination, as documented in the applicable IRs, appeared to be reasonable and consistent with the requirements of 10 CFR Part 21.

The inspectors observed that Westinghouse maintained the postings in its facility locations noted in WSE 14.7 to satisfy the posting requirements in 10 CFR 21.6. The posting included a copy of Section 206 of the Energy Reorganization Act of 1974 and a notice describing the regulation and WSE 14.7, including the name of the individual to whom reports may be made.

To verify implementation of the 10 CFR Part 21 process outlined in WEC 21.0, the NRC inspectors requested copies of 10 CFR Part 21 records of evaluations and reports that Westinghouse had completed. Specifically, the NRC inspectors reviewed two Part 21 Evaluations conducted relative to computer code software related issues. The inspectors reviewed SEI10-092 revision 0, dated May 31, 2010, "10 CFR Evaluation of Incorrect Data for Part Length fuel rod from CM2/POLCA7 to STAV7," that was performed by Sweden and was based on CAPS report 10-1016-N001 related to a Westinghouse Software Issue Reports STI 13891 and 13897. The conclusion of the evaluation by Westinghouse was that the event was not reportable under 10 CFR 21. The inspectors identified no issues relative to the Part 21 evaluations performed by Sweden. The inspectors also reviewed several Issue Reports (IRs) to verify that Westinghouse had appropriately screened the issue for determination that the issue did not represent a condition adverse to nuclear safety pursuant to the requirements of WEC 21.0. The inspectors also interviewed the Westinghouse Sweden Manager of Quality Programs and verified through review of initial indoctrination and training and recurring annual training records that Sweden was conducting 10 CFR Part 21 training as required by their recurring training procedure B- 41-1, "Recurring training of workshop staff."

c. Conclusions

With the exception of the issuance of Nonconformance 99901408/2011-201-01 for Westinghouse's failure to prescribe an appropriate procedure for 10 CFR Part 21 discovery and evaluation, the NRC inspectors determined that Westinghouse appropriately translated the requirements in 10 CFR Part 21 into implementing procedures and, for those activities reviewed by the inspectors, implemented them as required by Westinghouse procedures. The inspectors also concluded that there are strong process requirements that link between the corrective action process and the Part 21 evaluation process when required.

2. Computer Software Design and Testing

a. Inspection Scope

The inspectors reviewed the implementation of the Westinghouse design, design change, and test processes for computer software development. Specifically, the inspectors interviewed personnel and reviewed the policies and procedures that govern the implementation of the Westinghouse process to verify compliance with Criterion III, "Design Control," and Criterion XI, "Test Control," of Appendix B to 10 CFR Part 50. The inspectors reviewed completed design and test documentation for updates to the GOLBIN, BISON, and POLCA-T software evaluation models to determine whether the

tests were performed in accordance with the Westinghouse QMS. The attachment to this inspection report lists the documents reviewed by the inspectors.

b. Observations and Findings

b.1 Policies and Procedures

The NRC inspection team reviewed the Westinghouse policies and procedures for implementation of computer software design and testing to evaluate their conformance with Criteria III and XI of Appendix B to 10 CFR Part 50. The Westinghouse QMS describes the policy for design and test control. Westinghouse implements a number of procedures to implement these processes. The NRC inspection team's review of applicable procedures is described below.

The NRC inspection team reviewed Section 4.2, "Design Control," of the Westinghouse QMS, which describes the requirements for the design process. It states that engineering organizations are responsible for developing, maintaining, and implementing procedures compliant with the QMS. The engineering organizations also establish design and document interfaces between organizations. Sections 4.2.3 through 4.2.6 describe the requirements for controlling design inputs, analyses, outputs, and verification. Section 4.2.7 requires that design changes be subject to the same review and approval as the original design. Section 4.2.9, "Computer Software," states that software developed as a safety-related product or used in the design of a safety-related structure, system, or component is controlled in accordance with American Society of Mechanical Engineers (ASME) NQA-1, "Quality Assurance Requirements for Nuclear Facility Applications"; specifically, Part I, Supplement 11S-2, "Supplementary Requirements for Computer Program Testing," and Part II, Subpart 2.7, "Quality Assurance Requirements of Computer Software for Nuclear Facility Applications."

The NRC inspection team reviewed EP-302, "Documentation and Verification of Design Analysis," Revision 33, dated March 14, 2011, which defines the procedural requirements for performing, documenting, and verifying design analyses and revisions to design analyses. The procedure requires that design information transmitted between groups or outside Westinghouse be verified and approved. EP-302 also requires that individuals or groups other than the original perform verification activities.

The NRC inspection team reviewed EP-310, "Computer Software Development and Maintenance," Revision 25, dated March 4, 2011, which defines the procedural requirements for overall computer software quality assurance. The procedure covers software design and development, verification and validation, maintenance, and control. EP-310 requires that software qualification documents define the limits of applicability of a program as well as pertinent assumptions. During the design process, functional requirements, design documentation, implementation, and testing are verified. At the completion of development, software is validated to ensure that it satisfies the functional requirements and produces correct results. A project management plan is created to capture the above requirements, establishing the design stages, design inputs, verification and validation requirements, and other requirements. For software testing, Section 9.1.5 requires a description of the test cases, including the acceptance criteria. The NRC inspection team noted that EP-310 mirrors the requirements of ASME NQA-1, Part I, Supplement IIS-2, and Part II, Subpart 2.7.

The NRC inspection team reviewed WEC 7.2, "Dedication of Commercial Grade Items," Revision 1, dated August 3, 2009, Westinghouse's procedure for commercial grade dedication. The procedure instructs Westinghouse staff to conduct a technical evaluation to identify safety function, critical characteristics, and acceptance methods as part of the dedication process.

The NRC inspection team reviewed EP-313, "External Computer Software," Revision 8, dated August 14, 2009, which describes the requirements for acceptance, dedication, and installation of external computer software. External computer software is software that Westinghouse does not develop internally; it can be procured safety-related from an approved, Appendix B supplier or commercially from a nonqualified supplier. According to EP-313, for external software procured from nonqualified suppliers, Westinghouse conducts a documentation review, documents the range of capabilities of the software, and performs validation testing. The NRC inspection team noted that these activities do not meet all of the requirements in WEC 7.2 for conducting a technical evaluation as part of the dedication process. Specifically, EP-313 does not direct the user to conduct a technical evaluation to identify safety function, critical characteristics, and acceptance methods. The NRC identified one example in which EP-313 was followed without including the technical evaluation requirements of WEC 7.2. Westinghouse conducted verification and validation activities for acceptance of a commercially procured version of ANSYS finite-element analysis software without conducting a technical evaluation. The NRC inspection team identified this issue as Nonconformance 99901408/2011-201-02.

b.2 Implementation of Computer Software Design and Testing

The NRC inspection team focused its review primarily on the software development and maintenance process described in procedure EP-310 and on the error reporting process addressed in procedure EP-116. The NRC inspection team sampled representative examples of new code version development activities for both the BISON and POLCA-T codes. In general, the NRC inspection team determined that design specifications, testing, and documentation were developed and reviewed in accordance with the requirements of EP-310 for both the BISON and POLCA-T program version changes.

For the BISON computer program, the NRC inspection team reviewed various software development, testing, verification, and operational usage documents listed in the attachment, including Supplement 4 to BISON Topical Report RPA-90-90-P-A (WCAP-17202-P). This document includes numerous benchmark test comparisons for verifying code options by comparison of code calculations to test results. As an example, the Peach Bottom Turbine Trip Tests are a standard benchmark used throughout the Nuclear Industry for thermal hydraulic computer programs. While most of the plotted variable comparisons provided a close match with the tests, there are some, such as Figure 3-8 for Normalized Power, where the test results are noticeably under- or overpredicted by BISON. The NRC inspectors noted that the results were judged to be in "good agreement" with no discussion of the reasons for the variation.

For the POLCA-T computer program, the NRC inspection team reviewed various software development, testing, verification, and operational usage documents listed in the attachment, including WCAP-16747-P, "POLCA-T: System Analysis Code with Three-Dimensional Core Model, Appendices C and D". A typically benchmark example, Figure C.5-11, shows a comparison of calculated and measured turbine inlet pressure for the same Peach Bottom Turbine Trip Tests discussed above. The NRC inspectors

noted that while the transient trends are well-predicted, the deviation between the calculated and test results is often noteworthy. Similar to the BISON example, “good agreement” was documented, without a discussion of the reasons for the variation.

In addition to the two examples documented above, the NRC inspection team discussed other examples with Westinghouse personnel during the inspection. The NRC inspection team identified this issue Nonconformance 99901408/2011-201-03. As part of corrective action for this nonconformance, the NRC expects that Westinghouse would evaluate these examples and document the basis for acceptance. Additionally, Westinghouse should determine if other instances exist where acceptance criteria were not included in computer software testing documentation and take similar corrective action as appropriate.

c. Conclusions

With the exception of the issuance of Nonconformance 99901408/2011-201-02 for Westinghouse’s failure to dedicate commercially procured software for safety-related use, and Nonconformance 99901408/2011-201-03 for Westinghouse’s failure to establish acceptance criteria for computer software verification and validation tests, the NRC inspectors determined that the implementation of the Westinghouse program for test control was consistent with the regulatory requirements in Criterion III and Criterion XI of Appendix B to 10 CFR Part 50. Based on the sample of records reviewed, the inspectors determined that personnel were using qualified equipment and processes to adequately implement the Westinghouse quality assurance program and the associated procedures.

3. Corrective Action

a. Inspection Scope

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

b. Observations and Findings

b.1 Policies and Procedures

The NRC inspection team reviewed the Westinghouse policies and procedures for implementation of the corrective action process to evaluate their conformance with Criterion XVI of Appendix B to 10 CFR Part 50. The Westinghouse QMS describes the policy for the correction action process. Procedures WEC 16.2 and EP-116 implement the corrective action process for computer software development activities. WEC 16.2 describes the overall Westinghouse corporate corrective action program, while EP-116 describes the Fuel Engineering process for correcting software and technology issues.

The NRC inspection team reviewed Section 5.5, "Corrective and Preventative Action," of the Westinghouse QMS, which defines the processes for the identification and documentation of corrective and preventive actions. It requires the identification, documentation, analysis, and correction of conditions adverse to quality. For significant conditions adverse to quality, it also requires the documentation of the cause of the condition, verification of its corrective action, and communication to management.

The NRC inspection team reviewed WEC 16.2, which assigns requirements and responsibilities for identifying, documenting, correcting, and communicating conditions adverse to quality. Conditions adverse to quality are documented in Issue reports (IRs) and processed through CAPS, the Westinghouse corrective action program. WEC 16.2 describes the circumstances that require the generation of an IR. IRs are reviewed by the issue review committee and assigned an issue owner.

The NRC inspection team also reviewed Fuel Engineering Procedure EP-116, which supplements WEC 16.2 by defining the responsibilities and requirements for identifying, documenting, and resolving nuclear fuel product management and engineering issues using the Westinghouse corrective action process. The procedure focuses on software or technology Issues (STIs) in Westinghouse's UNITS system and defines the specific requirements for evaluating problems in software and technology, and their impact on prior uses and notification of users. EP-116 contains links to WEC 16.2 and WEC 21.0 for correcting conditions adverse to quality and evaluating potentially reportable conditions.

b.2 Corrective Action Program Implementation

The NRC inspection team reviewed a sample of IRs of varying significance and noted that each IR contained a detailed description of the condition and actions taken to address it. The inspectors also reviewed the closeout documentation supporting the specific IRs. The NRC inspection team attended the weekly meeting of the Issue Review Committee for fuel analysis issues and determined that it appropriately categorized issues and assigned them for appropriate correction actions. The NRC inspection team also reviewed a sample of STIs and attended the weekly STI Categorization meeting. The inspectors observed that both of these meetings were very detailed and provide for an excellent exchange and questioning attitude between the committee members that resulted in appropriate recommendations on how to handle the various issues that were discussed.

The NRC inspection team verified that error notifications were provided to software users as required by EP-116. The team concluded that the UNITS tool is an effective means for communicating potential software issues to program users and that it meets the requirements of EP-116. The inspectors also reviewed the IRs to verify that Westinghouse had appropriately screened the issue for determination that the issue potentially did not represent a condition adverse to nuclear safety pursuant to the requirements of WEC 21.0 and did not identify IRs that warranted evaluation under Part 21.

c. Conclusions

The NRC inspectors determined that the implementation of the Westinghouse corrective action program was consistent with the regulatory requirements in Criterion XVI of Appendix B to 10 CFR Part 50. Based on the limited sample of documents reviewed and on the observation of corrective action program activities such as the IRC and the STI, the inspectors also determined that Westinghouse is effectively implementing its QMS and the associated corrective action procedures. No findings of significance were identified.

4. Internal Audits

a. Inspection Scope

The inspectors reviewed the implementation of the Westinghouse process for conducting internal audits. Specifically, the inspectors reviewed the policies and procedures that govern the implementation of the Westinghouse process to verify compliance with Criterion XVIII, "Audits," of Appendix B to 10 CFR Part 50. In addition, the inspectors reviewed the internal audits conducted over the past 2 years and discussed the program with Westinghouse personnel responsible for the implementation of the audit program. The attachment to this inspection report lists the documents reviewed by the inspectors.

b. Observations and Findings

b.1 Policies and Procedures

The NRC inspection team reviewed the Westinghouse policies and procedures for implementation of the internal audit program to evaluate their conformance with Criterion XVIII of Appendix B to 10 CFR Part 50. The Westinghouse QMS describes the policy for the internal audit program. Westinghouse uses WEC 18.1 to implement the internal audit program.

The NRC inspection team reviewed Section 5.6, "Internal Quality Audits," of the Westinghouse QMS, which provides guidance for verifying compliance with, and assessing the effectiveness of, the QMS. The QMS requires that internal audits be scheduled, planned, and performed in accordance with written procedures. The QMS also provides high-level requirements for auditor qualification, audit team composition, audit planning, audit scheduling, audit reporting, communication, and corrective actions.

The NRC inspection team reviewed WEC 18.1, "Internal Audit," Revision 1, dated August 3, 2009, which contains the requirements for coordinating, planning, performing, and reporting Westinghouse internal audits. WEC 18.1 also delineates responsibilities for accomplishing these requirements. WEC 18.1 requires that internal audits be performed annually within the company. The procedure describes requirements for entering audit issues into the corrective action program and verifying the adequacy of corrective actions taken.

b.2 Implementation of Internal Audits

The NRC inspection team reviewed the Westinghouse internal audits for 2009 and 2010 and verified that they were planned and performed using the applicable procedures, documented with objective evidence, and distributed to the appropriate management within the timeframes prescribed by WEC 18.1. The inspection team verified that knowledgeable personnel who have no direct responsibility for the areas under review perform internal audits annually. The NRC inspection team also verified that issues identified during the course of an audit were entered into the corrective action program, that audit reports were typically issued within the required timeframe, and that the results were communicated to responsible Westinghouse management. The NRC inspection team verified that a sample of the audit findings entered into the corrective action program were followed up and corrected.

c. Conclusions

The NRC inspectors determined that the implementation of the Westinghouse corrective action program was consistent with the regulatory requirements in Criterion XVIII of Appendix B to 10 CFR Part 50. Based on the limited sample of audit reports reviewed, the inspectors also determined that Westinghouse is effectively implementing its QMS and the associated internal audit procedures. No findings of significance were identified.

5. Entrance and Exit Meetings

On September 12, 2011, the inspectors discussed the scope of the inspection with Mr. Claes Gerdin, Westinghouse Quality Assurance Manager, and with the Westinghouse management and staff. On September 16, 2011, the inspectors presented the inspection results and observations during an exit meeting with Mr. Gerdin and other Westinghouse staff. The attachment to this report lists the entrance and exit meeting attendees and those interviewed by the inspectors.

ATTACHMENT

1. ENTRANCE/EXIT MEETING ATTENDEES

<u>Name</u>	<u>Affiliation</u>	<u>Entrance</u>	<u>Exit</u>	<u>Interviewed</u>
Richard McIntyre	NRC/NRO	X	X	
Garrett Newman	NRC/NRO	X	X	
James Gilmer	NRC/NRO	X	X	
George Thomas	NRC/NRO	X	X	
Mohsen Khatib-Rahbar	ERI	X	X	
P.M. Heinemann	Interpreter	X	X	
Kiyoshi Iwasawa	Toshiba	X	X	
Debby LaPay	Westinghouse	X	X	
Mattias Lodin	Westinghouse	X	X	X
Yonatan Dag	Westinghouse	X	X	X
Patricia Quaglia	Westinghouse	X	X	X
Claes Gerdin	Westinghouse	X	X	X
Johan Hallen	Westinghouse	X	X*	
Nicole Brichacek	Westinghouse	X	X	X
Tim Walker	NINA	X	X	
Björn Thörnstrom	Westinghouse	X	X	X
Ed Renaud	Westinghouse	X	X	
Jan In de Betou	SSM	X		
Riku Mattila	STUK	X		
Elisabeth Rudbäck	SSM	X		
Håkan Svensson	Westinghouse	X	X	X
Jim Tomkins	NINA	X	X	
Robert Quinn	Westinghouse	X	X	
Jenni Laine	STUK		X	
Hans Troseliks	Westinghouse		X	
Gunnar Hede	Westinghouse		X	
Ryan Lenahan	Westinghouse		X	
Kris Cummings	Westinghouse	X	X	X
Kazuki Yano	Toshiba		X	
Tom Rodack	Westinghouse		X*	
Kjell-Olof Bjork	Westinghouse			X
Ernst Thulin	Westinghouse			X
Berndt Holmqvist	Westinghouse			X
Lena Olsson	Westinghouse			X

* via telephone

2. INSPECTION PROCEDURES USED

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

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

3. LIST OF ITEMS OPENED, CLOSED, AND DISCUSSED

The following items were found during this inspection:

<u>Item Number</u>	<u>Status</u>	<u>Type</u>	<u>Description</u>
99901408/2011-201-01	Open	NON	Criterion V
99901408/2011-201-02	Open	NON	Criteria III and V
99901408/2011-201-03	Open	NON	Criteria V and XI

4. DOCUMENTS REVIEWED

"Software Engineering Methodology Manual," Revision 40, dated August 2011

"Westinghouse Quality Management System (QMS)," Revision 6, dated April 8, 2011

B 41-1, "Återkommande utbildning av verkstadspersonal [Recurring training of workshop staff]," Revision 7, dated July 1, 2011

BTD 09-0102, "BISON Version 6.7.7—Software Project Management Plan and Technical Specifications," Revision 0, dated March 31, 2009

BTD 09-0103, "BISON—Version 6.7.7, Release Notes," Revision 0, dated September 1, 2010

BTD 09-0373, "Västerås Engineering Services Software Procedures and Engineering Software," Revision 2, September 3, 2010

BTD 09-0376, "BISON—Version 6.7.7, Test Diaries and STI Test Records," Revision 1, dated February 25, 2011

BTD 09-1418, "POLCA-T Version 1.11.0—Software Project Management Plan and Technical Specifications," Revision 2, dated January 17, 2011

BTD 10-0131, "POLCA-T Version 1.11.0—Release Notes," Revision 0, dated July 8, 2010

BTD 10-0133, "POLCA-T Version 1.11.0—Test Diaries, STI Test Records, Issue Reports, Software Quality Review and Inspection Summary," Revision 0, dated July 7, 2010

BTD 10-0134, "POLCA-T Version 1.11.0—Requirements, Design, and Test Procedures," Revision 0, dated August 16, 2010

BTD 10-0135, "POLCA-T Version 1.11.0—Software Test Summary," Revision 0, dated July 8, 2010

BTD 10-1855, "Past Use Review av fel : Excel för BTD enligt CAPs #10-258-N004," dated December 13, 2010

BTD 11-0314, "BISON Version 6.7.7—Software Test Summary," Revision 0, dated February 28, 2011

CN-BWR-CODE-07-010, "BISON Version History and U.S. Licensing Basis," Revision 0, dated October 27, 2006

CN-D2-CY21-16, "Dresden 2 Cycle 21 Report", dated November 27, 2006

EP-116, "Issue Reporting," Revision 16, dated March 14, 2011

EP-125, "USNRC Licensed Methodology Compliance," Revision 16, dated March 12, 2010

EP-302, "Documentation and Verification of Design Analysis," Revision 33, dated March 14, 2011

EP-307, "Computer Software Delivery," Revision 16, dated March 12, 2010

EP-310, "Computer Software Development and Maintenance," Revision 25, dated March 4, 2011

EP-313, "External Computer Software," Revision 8, dated August 14, 2009

EP-314, "Single Application Computer Programs," Revision 8, August 14, 2009

ES-21.1, "WEC 21.0 Level 3 Implementation Procedure," Revision 1, dated December 6, 2010

Internal Audit Report WEC-09-45, "European LWR Fuel Business Västerås Sweden," dated September 14, 2009

Internal Audit Report WEC-10-07, "European LWR Fuel Business Västerås," dated October 14, 2010

IR 08-029-S003, "Fuel Enthalpy Calculated by POLCA-T Is too Conservative," dated January 29, 2008

IR 08-029-S003, "Fuel Enthalpy Calculation by POLCA-T is too conservative," dated January 29, 2008

IR 10-089-N008, "Inconsistent Results between BISON and POLCA-T, Possibly Caused by Different SAFIR Versions Utilized by the Codes," dated March 29, 2010

IR 10-102-M027, "Error Identified in Microsoft Excel 2003/ 2007—Paste Special into Merged Cells," April 12, 2010

IR 10-286-C008, "Non-compliant Laptops," dated October 13, 2010

IR 10-294-N004, "Nonconservatism in SLMCPR Calculation with McSLAP," dated October 21, 2010

IR 11-207-M011, "Errors Found in WCAP-17202-P 'Supplement 4 to BISON Topical Report RPA 90-90-P-A' during RAI Response," dated July 26, 2011

IR 11-207-M011, "Errors Found in WCAP-17292-P Supplement 4 to BISON Topical Report RPA 90-90-P-A During RAI Responses," dated July 26, 2011

IR 11-244-N002, "The Poster for 10 CFR 21 WSE 14.7_B11 Don't Meet All the Requirements," dated September 1, 2011

IR 11-245-M006, "CAPs IRs and Commitments," dated September 2, 2011

IR 11-245-M011, "ANSYS," dated September 2, 2011

IR 11-245-M012, "EP-313 on Third Party Software," dated September 2, 2011

IR 11-257-M001, "Commercial Procured Software Used for Safety Related Applications," dated September 14, 2011

IR 11-258-M006, "2011 NRC Inspection at Sweden: Improve the STI Categorization Criteria in EP-116," dated September 15, 2011

LTR-RCPL-0970, "Level 3 Procedure Replacing RLE-4A, RLE-4B and RLE-4C of the 'Administrative Manual for Regulatory Licensing Engineering,'" dated April 30, 2009

LTR-SRC-11-4, "Closeout Request for PI-10-018, 'Non-conservatism in SLMCPR Calculation with McSLAP,'" dated January 20, 2011

PQP-ES-08-0774, "South Texas Project Units 3 & 4 Project Quality Plan," Revision 2, issued April 2011

RPB 90-93-P-A, "Water Reactor Emergency Core Cooling System Evaluation Model, Code Description and Qualification," dated October 1991

SE 06-092, "10CFR21 Evaluation of SVEA-96 Optima2 CPR R-factor Model Shortcomings," dated January 11, 2007

SEI 10-092, "10CFR21 Evaluation of Incorrect Data for Part Length Fuel Rods from CM2/POLCA7 to STAV 7," Revision 0, dated May 31, 2010

SES 03-306, "ANSYS, generelt FE-program—Instruktion för installation, verifiering och dokumentation [ANSYS, general FE-program—Instruction for installation, verification, and documentation]," dated October 14, 2003

SES 05-246, "ANSYS 10.0—Verification," Revision 0

SET 09-157, "BISON Version 6.7.7—Placeholder for EP-125-1," Revision 0, dated June 17, 2009

SET 09-224, "BISON—Model for Water Level Surface Steam Condensation," Revision 1, dated June 30, 2010

SET 09-248, "POLCA-T Qualification Against Peach Bottom 2 EOC 2 Turbine Trip Tests 1 and 2"

SET 10-165, "WCAP-17202-P, Supplement 4 to BISON Topical Report RPA 90-90-P-A," dated June 2010

SET 10-257, "Validation of POLCA-T Transient Dryout and Peak Cladding Temperature Calculations against FRIGG Optima2 Measurements"

STI-10710, "BISON," dated March 4, 2009

STI-15090, "Error in Microsoft Excel 'Paste Special -> Formulas' Feature," dated August 25, 2010

STI-18712, "code2edms Should Verify the Contents of the ZIP File Attached to the Release Notes in EDMS," dated September 14, 2011

STI-8768, "Fuel Enthalpy Calculated for Determining Pellet Enthalpy Is too Conservative," dated December 18, 2007

SWN-11-58, "Release of SEMM Revision 40," dated August 25, 2011

WEC 16.2, "Westinghouse Corrective Action Process," Revision 3, dated August 1, 2011

WEC 16.3, "Corrective Action Review Board," Revision 1, dated August 1, 2011

WEC 16.4, "Root Cause Analysis," Revision 1, dated August, 2011

WEC 16.5, "Apparent Cause Analysis," Revision 0, February 29, 2008
WEC 18.1, "Internal Audit," Revision 1, dated August 3, 2009

WEC 21.0, "Identification and Reporting of Conditions Adverse to Safety," Revision 6, dated August 3, 2009

WEC 7.2, "Dedication of Commercial Grade Items," Revision 1, dated August 3, 2009

WSE 14.7, "Rapportering av defekter och avvikelser i levererade produkter [Report of defects and noncompliances in delivered products] (10 CFR 21)," Revision 2, dated September 9, 2011

WSE 2.5, "Nuclear Services Engineering/Nuclear Fuel Engineering Interface Agreement—Engineering Software," Revision 0, February 17, 2005