November 3, 2011

Mr. Akira Shimizu, General Manager
Obayashi Corporation
Nuclear Department, Nuclear Facilities Division
2-15-5, Konan, Minato-Ku
Tokyo 108-85 Japan

SUBJECT: NUCLEAR REGULATORY COMMISSION INSPECTION REPORT NO. 99901409/2011-201 AND NOTICE OF VIOLATION AND NOTICE OF NONCONFORMANCE

Dear Mr. Shimizu:

On September 12–16, 2011, the U.S. Nuclear Regulatory Commission (NRC) staff conducted an inspection at Obayashi Corporation (hereafter referred to as Obayashi) in Tokyo, Japan. The purpose of the limited scope inspection was to assess Obayashi'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 Criteria for Nuclear Power Plants and Fuel Reprocessing Plants," to 10 CFR Part 50, "Domestic Licensing of Production and Utilization Facilities." The inspection focused on quality activities affecting current and future design analyses, calculations, and drawings that Obayashi supplies to Westinghouse in support of the AP1000 design. The enclosed report presents the results of this inspection. This NRC inspection report does not constitute NRC endorsement of your overall quality assurance or 10 CFR Part 21 programs.

Based on the results of this inspection, the NRC has determined that one 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 the violation are described in detail in the subject inspection report. The violation is being cited in the Notice because Obayashi failed to 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 this inspection, the NRC inspection team found that the implementation of your quality assurance (QA) program failed to meet certain NRC requirements imposed on you by your customers or NRC licensees. Specifically, the NRC inspection team determined that Obayashi was not fully implementing certain aspects of its QA program (i.e., design control, control of nonconformance/corrective action, control of quality records, and audits) consistent with contractual requirements. These nonconformances are cited in the enclosed Notice of Nonconformance (NON) and the circumstances surrounding them are described in detail in the enclosed inspection report.

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

It is important to note that the NRC inspection team performed a limited scope inspection. The deficiencies identified may affect other portions of Obayashi's QA program that the NRC inspection team did not review. Therefore, Obayashi must extend its review, where applicable, beyond the specific examples identified by the NRC inspection team and apply corrective actions, as appropriate. In your response to the Notice and the identified NON, Obayashi should document the areas for which it extended its review beyond the specific examples of the deficiencies identified by the NRC inspection team, the extent of its review, any additional deficiencies, and the corrective actions implemented.

One additional area of concern identified during the NRC inspection is Obayashi's reliance on the International Standardization Organization (ISO) 9001:2000 "Quality Management System (QMS) – Requirements," provisions as the basis for the Obayashi Quality Management System. As documented in SECY-03-0117, "Approaches for Adopting More Widely Accepted International Quality Standards," ISO 9001-2000 on its own does not meet the regulatory requirements of Appendix B to 10 CFR Part 50. The NRC inspection team noted that Westinghouse Electric Company purchase orders imposed the regulatory requirements of Appendix B to 10 CFR Part 50 and the American Society of Mechanical Engineers NQA-1-1994, "Quality Assurance Requirements for Nuclear Facility Applications." Therefore, supplemental quality requirements would need to be applied to the QMS program in order to meet applicable regulatory requirements.

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 from the NRC Web site 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 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 the 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. 99901409

Enclosures:
As stated

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. 99901409

Enclosures:
As stated

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NAME	RPrato*	KKavanagh	BTegeler*	MShams*	TFrye	JPeralta
DATE	10/17/11	11/03/11	10/13/11	10/13/11	10/25/11	11/03/11

OFFICIAL RECORD COPY

NOTICE OF VIOLATION

Obayashi Corporation
Tokyo, Japan

Docket Number 99901409
Inspection Report Number 2011-201

During a U.S. Nuclear Regulatory Commission (NRC) inspection conducted at the Obayashi Corporation (hereafter referred to as Obayashi) in Tokyo, Japan, on September 12-16, 2011, 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), Section 21.21, "Notification of Failure To Comply or Existence of a Defect and Its Evaluation," paragraph 21.21(a), requires, in part, that each individual, corporation, partnership, or other entity subject to 10 CFR Part 21 shall adopt appropriate procedures to evaluate deviations and failures to comply associated with substantial safety hazards as soon as practicable.
>
> 10CFR Section 21.51, "Maintenance and Inspection of Records," requires, in part, that each individual, corporation, partnership, dedicating entity, or other entity subject to 10 CFR Part 21 shall prepare and maintain records necessary to accomplish the purpose of 10 CFR Part 21, specifically (1) retain evaluations of all deviations and failures to comply for a minimum of five years after the date of the evaluation; (2) retain any notifications sent to purchasers and affected licensees for a minimum of five years after the date of the notification; and (3) retain a record of the purchasers of basic components for 10 years after delivery of the basic component or service associated with a basic component.
>
> Contrary to the above, as of September 16, 2011, Obayashi had not adopted an appropriate procedure for evaluating deviations and failures to comply. Specifically, Obayashi procedure, AP1000-P-001, AP1000 Project Working Procedures, "Reporting of Defects/Non-Compliance and Adverse to Safety in Accordance to 10 CFR Part 21 for AP1000 Contracts," Revision 0, dated August 31, 2011, was established approximately six years after the placement of a safety-related purchase order that imposed 10 CFR Part 21 requirements on Obayashi. Additionally, Obayashi failed to evaluate at least four nonconformances/corrective actions for reportability under 10 CFR Part 21 and failed to establish the record-keeping requirements of Section 21.51 of 10 CFR Part 21.
>
> This issue has been identified as Violation 99901409/2011-201-01.
>
> This is a Severity Level IV Violation (Section 6.5).

Pursuant to the provisions of 10 CFR 2.201, "Notice of Violation," Obayashi is hereby required to submit 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 Violation. 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, consideration will be given to 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, U.S. 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 in the NRC Agencywide Documents Access and Management System, 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 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, "Protection of Safeguards Information: Performance Requirements."

In accordance with 10 CFR 19.11, you may be required to post this Notice within two working days of receipt.

Dated at Rockville, MD, this 3rd day of November 2011.

NOTICE OF NONCONFORMANCE

Obayashi Corporation
Tokyo, Japan

Docket No. 99901409
Report No. 2011-201

Based on the results of a U.S. Nuclear Regulatory Commission (NRC) inspection conducted at the Obayashi Corporation (hereafter referred to as Obayashi) in Tokyo, Japan, on September 12, 2011 through September 16, 2011, it appears that certain activities were not conducted in accordance with NRC requirements that were contractually imposed on Obayashi by NRC applicants:

A. Criterion II, "Quality Assurance Program," of Appendix B, "Quality Assurance Program Criteria for Nuclear Power Plants and Fuel Reprocessing Plants," to Title 10 of the *Code of Federal Regulations* (10 CFR) Part 50, "Domestic Licensing of Production and Utilization Facilities," states, in part, that a quality assurance program which complies with the requirements of this appendix shall be established consistent with the schedule for accomplishing the activities. This program shall be documented by written policies, procedures, or instructions and shall be carried out in accordance with those policies, procedures, or instructions.

   Westinghouse Electric Company (WEC) purchase order (PO) 4500176463, Change Notice 2, required that Obayashi design services shall be performed in accordance to Appendix B to 10 CFR Part 50, Regulatory Guide 1.28, "Quality Assurance Program Requirements (Design and Construction)", Revision 3, August 1985; and American Society of Mechanical Engineers (ASME) NQA-1-1994, "Quality Assurance Requirements for Nuclear Facility Applications."

   Contrary to the above, as of September 16, 2011, Obayashi failed to establish a quality assurance program consistent with the applicable provisions of Appendix B to 10 CFR Part 50 and the industry quality standards specified in PO 4500176463 for AP1000 safety-related engineering services.

This issue has been identified as Nonconformance 99901409/2011-201-02.

B. Criterion III, "Design Control," of Appendix B states, in part, that measures shall be established to assure that applicable regulatory requirements and the design basis for those structures, systems, and components to which Appendix B applies are correctly translated into specifications, drawings, procedures, and instructions. Measures shall be established for the identification and control of design interfaces and for coordination among participating design organizations. These measures shall include the establishment of procedures among participating design organizations for the review, approval, release, distribution, and revision of documents involving design interfaces. In addition, design changes shall be subject to design control measures commensurate with those applied to the original design and be approved by the organization that performed the original design.

   Contrary to the above, as of September 16, 2011, Obayashi failed to: 1) assure that applicable design basis are correctly translated into calculations; 2) establish procedures for the identification and control of design control interfaces and for coordination among

participating design organizations; and 3) subject design changes to the commensurate design control measures applied to the original design. Specifically, Obayashi failed to: (1) correctly implement the provisions of the American Concrete Institute (ACI) 349, "Code Requirements for Nuclear Safety-Related Concrete Structures & Commentary;" (2) implement measures to identify and implement organizational interfaces between Obayashi and Westinghouse Electric Company for design control, design changes and technical direction; and (3) ensure that design changes were reviewed and verified with the same rigor as the original design.

This issue has been identified as Nonconformance 99901409/2011-201-03.

C. Criterion XV, "Nonconforming Materials, Parts, or Components," of Appendix B to 10 CFR Part 50 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. These measures shall include, as appropriate, procedures for identification, documentation, segregation, disposition, and notification to affected organizations.

   Criterion XVI, "Corrective Action," of Appendix B to 10 CFR Part 50 states 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. In the case of significant conditions adverse to quality, the measures shall assure that the cause of the condition is determined and corrective action taken to preclude repetition. The identification of the significant condition adverse to quality, the cause of the condition, and the corrective action taken shall be documented and reported to appropriate levels of management."

   Contrary to the above, as of September 16, 2011, Obayashi failed to establish measures to adequately address nonconformances and corrective actions. Specifically, Obayashi failed to establish measures for: (1) the segregation of nonconforming calculations and drawings; (2) performing prompt corrective actions; (3) differentiating between conditions adverse to quality and significant conditions adverse to quality; (4) providing a link between the Obayashi nonconformance control and corrective action procedure and the Obayashi Part 21 procedure; and (5) implementing corrective actions on two WEC supplier corrective action reports (SCARs).

This issue has been identified as Nonconformance 99901409/2011-201-04.

D. Criterion XVII, "Quality Assurance Records," of Appendix B to 10 CFR Part 50 states, in part, that records shall include the results of reviews, inspections, tests, audits, monitoring of work performance, and materials analyses. The records shall also include closely-related data such as qualifications of personnel, procedures, and equipment. Consistent with applicable regulatory requirements, requirements shall be established concerning record retention, such as duration, location, and assigned responsibility.

   Contrary to the above, as of September 16, 2011, Obayashi failed to establish requirements for the retention of records. Specifically, Obayashi failed to: (1) provide instructions for the maintenance of records for the qualification of personnel; and (2) document the record-keeping process used by Obayashi.

This issue has been identified as Nonconformance 99901409/2011-201-05.

E. Criterion II of Appendix B to 10 CFR Part 50 states, in part, that the quality assurance program shall provide for indoctrination and training of personnel performing activities affecting quality as necessary to assure that suitable proficiency is achieved and maintained.

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

   Contrary to the above, as of September 16, 2011, Obayashi failed to adequately qualify lead auditors for internal audits of Obayashi quality-related activities consistent with the requirements of Appendix B to 10 CFR Part 50 and the provisions of ASME NQA-1-1994, as required in the Westinghouse purchase orders.

This issue has been identified as Nonconformance 99901409/2011-201-06.

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 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, 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 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, "Protection of Safeguards Information: Performance Requirements."

Dated at Rockville, MD, this 3rd day of November 2011.

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

Docket No.:	99901409
Report No.:	99901409/2011-201
Vendor:	Obayashi Corporation 2-15-2, Konan, Minato-ku Tokyo 108-8502 Japan
Vendor Contact:	Mr. Yuji Itabashi, Deputy General Manager, Design Department, Nuclear Facilities Department
Background:	Obayashi Corporation is a Westinghouse Electric Company (WEC) design partner supplying design services in support of the AP1000 design finalization project. The Obayashi scope of work includes basic structural design, settlement analyses, structural steel framing, air inlet concrete behavior study, air inlet modular behavior study, construction studies, and aircraft crash analysis. Obayashi has been working on the AP1000 design finalization project since 2002 and has participated in 23 nuclear power plant construction projects in Japan.
Inspection Dates:	September 12 - 16, 2011

Inspection Team:	Kerri Kavanagh	NRO/DCIP/CQVA	Team Leader
	Robert Prato	NRO/DCIP/CQVA	
	Bret Tegeler	NRO/DE/SEB1	
	Mohamed Shams	NRO/DE/SEB1	

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

EXECUTIVE SUMMARY

Obayashi Corporation
99901409/2011-201

The U.S. Nuclear Regulatory Commission (NRC) inspection focused on quality assurance (QA) policies and procedures implemented by Obayashi Corporation (hereafter referred to as Obayashi) in support of the AP1000 design, as described in NRC Inspection Manual Chapter 2507, "Construction Inspection Program: Vendor Inspections." The purpose of this inspection was to verify that the calculation notes and drawings prepared by Obayashi in support of the AP1000 design were developed in accordance 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 Obayashi implemented a program under 10 CFR Part 21, "Reporting of Defects and Noncompliance," that meets the regulatory requirements of the NRC. The NRC conducted the inspection at the Obayashi facility in Tokyo, Japan, during 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

During the conduct of this inspection, the NRC inspection team implemented Inspection Procedure (IP) 43002, "Routine Inspections of Nuclear Vendors," and IP 36100, "Inspection of 10 CFR Part 21 and 10 CFR 50.55(e) Programs for Reporting Defects and Noncompliance."

Although the NRC inspection team concluded that the design products it reviewed at Obayashi were technically adequate, the NRC inspection team also identified several deficiencies in Obayashi's design change control processes and in the design interface between Obayashi and Westinghouse. Additionally, since the Obayashi quality management system (QMS) is based solely on ISO 9001, the NRC inspection team could not establish its compliance with the applicable requirements of Appendix B to 10 CFR Part 50. As a result, the NRC inspection team identified several nonconformances against Obayashi's implementation of its QMS as well as one violation against 10 CFR Part 21 requirements. The details of the inspection are summarized below.

10 CFR Part 21 Program

The NRC inspection team identified Violation 99901409/2011-201-01 associated with Obayashi's failure to implement the requirements of 10 CFR 21.21, "Notification of Failure to Comply or Existence of a Defect and Its Evaluation." Specifically, the NRC inspection team determined that Obayashi procedure, AP1000-P-001, AP1000 Project Working Procedures, "Reporting of Defects/Non-Compliance and Adverse to Safety in Accordance to 10 CFR Part 21 for AP1000 Contracts," Revision 0, dated August 31, 2011, was established approximately six years after the placement of a safety-related purchase order which imposed Part 21 on Obayashi. Additionally, Obayashi failed to evaluate at least four nonconformances/corrective actions for reportability under 10 CFR Part 21 and failed to establish the record-keeping requirements of Section 21.51 of 10 CFR Part 21.

Quality Assurance Program

The NRC inspection team identified Nonconformances 99901409/2011-201-02 and 99901409/2011-202-06 associated with Obayashi's failure to implement the requirements of Criterion II, "Quality Assurance Program," of Appendix B to 10 CFR Part 50. Specifically, Nonconformance 99901409/2011-201-02 cited Obayashi for failing to establish a quality assurance program consistent with the applicable provisions of Appendix to 10 CFR Part 50 and the industry quality standards specified in purchase order (PO) 4500176463 for AP1000 safety-related engineering services. Nonconformance 99901409/2011-201-06 cited Obayashi for failing to adequately qualify lead auditors for internal audits of Obayashi quality-related activities.

Design Control

The NRC inspection team identified Nonconformance 99901409/2011-201-03 associated with Obayashi's failure to implement the requirements of Criterion III, "Design Control," of Appendix B to 10 CFR Part 50. Specifically, Obayashi failed to (1) correctly implement the code provisions of ACI-349; (2) implement measures to identify and implement an organizational interface between Obayashi and WEC for design control, design changes and technical direction; and (3) implement measures to provide adequate guidance for design change activities and to ensure that design changes were reviewed and verified with the same rigor as the original design.

Control of Nonconformances and Corrective Action

The NRC inspection team identified Nonconformance 99901409/2011-201-04 for Obayashi's failure to meet the requirements of Criterion XV, "Nonconforming Materials, Parts, or Components," and Criterion XVI, "Corrective Action," of Appendix B to 10 CFR Part 50. Specifically, Obayashi failed to establish measures for: (1) the segregation of nonconforming calculations and drawings; (2) performing prompt corrective actions; (3) differentiating between conditions adverse to quality and significant conditions adverse to quality; (4) providing a link between the Obayashi nonconformance control and corrective action procedure and the Obayashi Part 21 procedure; and (5) implement corrective actions on two WEC supplier corrective action reports (SCARs).

Quality Assurance Records

The NRC inspection team identified Nonconformance 99901409/2011-201-05 for Obayashi's failure to meet the requirements of Criterion XVII, "Quality Assurance Records," of Appendix B to 10 CFR Part 50. Specifically, Obayashi failed to (1) provide instructions for the maintenance of records for the qualification of personnel; and (2) document the record-keeping process used by Obayashi.

Audits

The NRC inspection team identified Nonconformance 99901409/2011-201-06 for Obayashi's failure to meet the requirements of Criterion XVIII, "Audits," of Appendix B to 10 CFR Part 50. Specifically, Obayashi failed to qualify lead auditors consistent with the requirements of the Appendix B to 10 CFR Part 50 and the provisions of the American Society of Mechanical Engineers (ASME) NQA-1-1994, "Quality Assurance Requirements for Nuclear Facility Applications," as required in the WEC POs.

REPORT DETAILS

1. 10 CFR Part 21 Program

a. Inspection Scope

The U.S. Nuclear Regulatory Commission (NRC) inspection team reviewed Obayashi's policies and implementing procedures that govern its program under Title 10 of the *Code of Federal Regulations* (10 CFR) Part 21, "Reporting of Defects and Noncompliance" (Part 21), to verify compliance with the requirements of Part 21.

Specifically, the NRC inspection team reviewed the following policies, procedures, and supporting documentation for this inspection area:

- AP1000-P-001, "Reporting of Defects/Noncompliance and Adverse to Safety in Accordance to 10 CFR Part 21 for AP1000 Contracts," Revision 0, August 31, 2011

- Implementing Procedure P-35, "Procedure for Work Activities of Nuclear Facilities Division," Revision 6, April 7, 2010

b. Observations and Findings

b.1 Postings

The NRC inspection team observed that Obayashi had posted a notice at the location where the design analysis was being performed. It included a copy of Section 206 of the Energy Reorganization Act of 1974, a current copy of 10 CFR Part 21, and a description of the WEC reporting procedure. However, the posting was provided by WEC, included WEC names and contact numbers, and was not consistent with Section 5.3 of AP1000-P-001.

b.2 10 CFR Part 21 Procedure

AP1000-P-001 applies to all activities or services performed by Obayashi in the design of basic components for auxiliary and shield buildings. The procedure also applies to all employees involved in safety-related services. Section 6.5, "Records," requires that evaluation reports on defects and noncompliance, noncompliance reports, and corrective action requests shall be permanently retained as described in Procedure P-35, "Procedure for Work Activities of Nuclear Facilities Division," Revision 6. In addition, section 8, "Process," requires that noncompliances and corrective action documents be processed in accordance with P-35, Revision. 6. During the disposition process for AP1000, the noncompliance is evaluated to determine if the noncompliance represents a defect and requires notification per paragraph 6.3 of AP1000-P-001 to the US NRC or WEC.

b.3 10 CFR Part 21 Implementation

At the time of the inspection, Obayashi had not performed any Part 21 evaluations. The NRC inspection team noted that Obayashi did not have a procedure in place to evaluate

deviations or failures to comply until August 31, 2011. The first safety-related purchase order (PO), PO 4500176463, was placed with Obayashi on September 16, 2005. As such, Obayashi did not have a Part 21 procedure in place to meet the requirements of Part 21 for approximately six years. In addition, applicable Obayashi staff has not been trained on the AP1000-P-001. However, the NRC inspection team noted that prior to August 31, 2011, Obayashi had training material that was in the form of a procedure for Part 21. This training material did not have a procedure number nor was it referenced in the P-35 procedure to be followed for Part 21 determinations. The NRC inspection team noted that the last training on Part 21 based on the training material was performed on February 26, 2010. Failure to have a procedure in place to evaluate deviations and failures to comply is identified as an example of Violation 99901409/2011-201-01.

The NRC inspection team reviewed a sample of nonconformances/corrective actions and corresponding documentation to determine if an evaluation should have been performed. The NRC inspection team noted that the nonconformance log stated that Part 21 was not applicable to the 51 nonconformances listed. However, for the sample reviewed, the NRC inspection team identified at least four nonconformances that should have been evaluated for Part 21 applicability. Failure to evaluate nonconformances/corrective actions for reportability under Part 21 is identified as another example of Violation 99901402/2011-201-01.

In addition, the NRC inspection team observed that Procedure P35, Section 8, did not establish measures for maintenance of records as required by Section 21.51 of 10 CFR Part 21. Specifically, Obayashi failed to establish measures to: (1) retain evaluations of all deviations and failures to comply for a minimum of five years after the date of the evaluation; (2) retain any notifications sent to purchasers and affected licensees for a minimum of five years after the date of the notification; and (3) retain a record of the purchasers of basic components for 10 years after delivery of the basic component or service associated with a basic component. This is identified as another example of Violation 99901402/2011-201-01.

c. Conclusions

The NRC inspection team concluded that Obayashi failed to adopt appropriate procedures to evaluate deviations and failures to comply at the time of receiving a safety-related PO. Specifically, the NRC inspection team determined that AP1000-P-001 was not proceduralized for approximately six years following receipt of the first safety-related PO from Westinghouse. In addition, the NRC inspection team identified at least four Obayashi nonconformances that should have been evaluated for applicability of 10 CFR Part 21 and that Obayashi failed to establish the record-keeping requirements of Section 21.51 of 10 CFR Part 21.

2. Quality Assurance Program

a. Inspection Scope

The NRC inspection team reviewed the Obayashi quality management system (QMS) and implementing procedures that govern Obayashi's quality program and training activities to verify compliance with the applicable requirements of Criterion II, "Quality Assurance Program," of Appendix B (Appendix B) to 10 CFR Part 50. In addition, the NRC

inspection team reviewed Obayashi's personnel training and qualification records and discussed personnel training and qualification activities with Obayashi management and technical staff.

Specifically, the NRC inspection team reviewed the following policies, procedures, and supporting documentation for this inspection area:

- Quality Management System (QMS) – Quality Manual, 14th Edition, September 1, 2003
- QMS – Quality Manual, Revision 3, April 1, 2010
- Implementing Procedure T-35, "Procedure for Work Activities of Nuclear Facilities Division," Revision 14, September 1, 2003
- Implementing Procedure P-35, "Procedure for Work Activities of Nuclear Facilities Division," Revision 6, April 7, 2010
- Obayashi binder, entitled "Quality Assurance Action Records for AP1000"

b. Observations and Findings

b.1 Policies and Procedures

The NRC inspection team reviewed a number of WEC POs issued to Obayashi and concluded that most of the quality requirements were not being implemented by Obayashi. Specifically, in PO 4500176463, change notice 2, WEC specified that work shall be performed in accordance with Appendix B; Regulatory Guide 1.28, "Quality Assurance Program Requirements (Design and Construction)," Revision 3, August 1985; and ASME NQA-1-1994. Obayashi performed an independent evaluation of the applicable elements of NQA-1-1994 and concluded that their quality program generally met the applicable requirements of NQA-1-1994. However, Obayashi never evaluated RG 1.28 against their quality program. In addition, in change notice 2, WEC required compliance with WEC APP-GW-GEP-001, "AP1000 Quality Assurance Program Plan," which included "service specification details" that prescribed "Mandatory Verbatim Compliance Required" for 16 WEC procedures, none of which have been used by Obayashi. PO 4500176463, as well as other POs reviewed, required the use of these mandatory procedures, as well as other WEC quality procedures that were not implemented by Obayashi.

The NRC inspection team reviewed the Obayashi QMS and noted that it was written to ISO 9001:2008, "Quality Management Systems – Requirements," and JIS Q 9001:2008, "Quality Management System Standards." JIS Q 9001:2008 contains the Japanese industrial quality requirements that are very similar to ISO 9001:2008 with a few minor additions. In addition, the NRC inspection team reviewed P-35, Obayashi's Nuclear Department implementing procedure for nuclear quality requirements applicable to AP1000-related work.

The NRC inspection team discussed the Obayashi QMS with Obayashi management and was informed that in 2004, just prior to the first WEC audit of Obayashi's quality program,

Obayashi performed an evaluation of its QMS in relation to Appendix B requirements. Obayashi documented the individual criteria of Appendix B along side of the Japanese translation including the location within the QMS and the applicable implementing procedures where each Appendix B criteria is addressed.

In 2004, WEC audited the Obayashi QA program and determined that its QA program met all applicable Appendix B requirements for safety-related engineering services with 3 recommended improvements. The results of this audit qualified Obayashi as an Appendix B supplier of engineering services for the WEC AP1000 project. WEC performed follow-up audits in 2007 and 2010, both with positive results.

The NRC inspection team obtained an English translation of the Obayashi QMS, 14th Edition, dated September 1, 2003, the version used by WEC during its 2004 audit of the Obayashi quality program. In addition, NRC inspection team translators reviewed the latest version of the QMS and identified the difference in the two documents. The NRC inspection team reviewed the translated version of the Obayashi QMS and determined that the current Obayashi QMS failed to adequately document the policies, procedures, and instructions of a quality assurance program which complies with the appropriate provisions of Appendix B. For example, the QMS failed to prescribe or provide guidance for the following: controls of safety-related services commensurate with the item's importance to safety; program for training and qualification of auditors, process for organizational interfaces; and process for controlling design changes and independent design reviews. Details of deficiencies in the QMS and implementing procedures are provided throughout this inspection report.

Obayashi accepted WEC contracts and performed safety-related work associated with the AP1000 design without meeting all the applicable requirements of Appendix B and the industry quality standards specified in each of the POs. This issue has been identified as Nonconformance 99901409/2011-201-02.

b.2 Implementation of the Training and Qualification Program

The NRC inspection team reviewed the Obayashi QMS and implementing procedures that govern Obayashi's training and qualification process to verify compliance with the training requirements of Criterion II of Appendix B to 10 CFR Part 50. The NRC inspection team reviewed Obayashi's personnel training and qualification records and discussed personnel training and qualification activities with Obayashi management and technical staff. The NRC inspection team also conducted interviews with Obayashi personnel to ensure that they have an understanding of the activities they are performing commensurate with their responsibilities.

The QMS states that each department head determines competencies (ability, knowledge, experience, skill) necessary for personnel to be engaged in the assigned work activities, and the following education/training is planned and implemented for personnel to acquire the necessary competencies:

- company-wide assembly in-house education;
- head office assembly education;
- education inside department and
- on the job training

Procedure P-35, Section 12.4, “Education in Divisions,” states, in part, that a Division Education Planning Committee develops an annual Division Education Plan, implements that plan and keeps applicable records. The Division Head checks and evaluates education results and provides input into the next term education plan.

The NRC inspection team observed that records of education/training are maintained by the department head and the training department that managed the education needs for Obayashi. The NRC inspection team reviewed training, qualification, experiences and skills records found in an Obayashi document, “Quality Assurance Action Records for AP1000,” and verified that relevant records are being maintained by the department in charge of personnel allocation and fitness.

Indoctrination training for AP1000-related project activities included required reading of Part 21, Appendix B, nonconformance and corrective actions process and policies, and quality control activities relating to software. In addition, Obayashi employees are encouraged to read NQA-1 but it is not required. Obayashi QA and engineering staff working on the AP1000 project are required to complete the indoctrination training. The NRC inspection team reviewed the records of training performed and verified that the applicable training was being documented. The NRC inspection team interviewed Obayashi quality and engineering staff and determined that they had a good understanding of the activities they were performing commensurate with their level of responsibility relative to design and engineering but weaknesses in their implementation of quality requirements were noted and have been identified within this inspection report.

In addition, the NRC inspection team noted that Obayashi had performed three internal audits of the AP1000 project. These audits were performed by two experienced general managers from the Nuclear Facilities Department, Nuclear Facilities Division that oversee safety-related activities. The NRC inspection team determined that their training included a certification from the Japan Management Association (JMA) qualifying them to ISO 9001 requirements. The NRC inspection team observed that there was no direct correlation of the JMA certification to NQA-1 auditor qualification requirements. Discussion with responsible managers indicated that a JMA certification is common practice for Japanese industries to qualify auditors to ISO 9001. However, ISO 9001 has no specific training requirements for auditors. Although the actual curriculum used for JMA certification was not available for the NRC inspection team to review, this certification was specifically developed to train auditors to ISO 9001 quality requirements, which are not consistent with the detailed provisions specified in ASME NQA-1 and Appendix B requirements as prescribed in the WEC POs. Obayashi’s failure to adequately qualify its lead auditors consistent with applicable requirements of Appendix B and NQA-1-1994 has been identified as an example of Nonconformance 99901409/2011-201-06.

c. Conclusions

The NRC inspection team identified Nonconformances 99901409/2011-201-02 and 99901409/2011-201-06 associated with Obayashi’s failure to implement the requirements of Criterion II, “Quality Assurance Program,” of Appendix B to 10 CFR Part 50. Specifically, Nonconformance 99901409/2011-201-02 cites Obayashi for failing to adequately document the policies, procedures, and instructions of its quality assurance program in the QMS consistent with Appendix B to 10 CFR Part 50 requirements and for not implementing quality requirements specified in PO 4500176463 for AP1000

safety-related engineering services. Nonconformance 99901409/2011-201-06 cites Obayashi for failing to adequately qualify auditors for internal audits of Obayashi safety-related activities.

3. Design Control

a. Inspection Scope

The NRC inspection team reviewed the Obayashi QMS and implementing procedures that govern Obayashi's design control activities to verify compliance with the requirements of Criterion III, "Design Control," of Appendix B to 10 CFR Part 50. In addition, the inspection team reviewed a number of WEC POs for Obayashi engineering services and the resulting calculations and discussed the associated activities with Obayashi management and technical staff.

Specifically, the NRC inspection team reviewed the following POs, calculations, and related supporting documentation for this inspection area:

- Quality Management System (QMS) – Quality Manual, 14th Edition, September 1, 2003
- QMS – Quality Manual, Revision 3, April 1, 2010
- Implementing Procedure T-35, "Procedure for Work Activities of Nuclear Facilities Division," Revision 14, September 1, 2003
- Implementing Procedure P-35, "Procedure for Work Activities of Nuclear Facilities Division," Revision 6, April 7, 2010.
- PO 4500176463, "Purchase of Engineering services from Obayashi Corporation," (Initial PO between WEC and Obayashi Corporation, Nuclear Division) September 16, 2005
- PO 4500176463, Change Notice 1: "Purchase of Engineering services from Obayashi Corporation," (added Line Item 4) March 30, 2006
- PO 4500176463, Change Notice 2: "Purchase of Engineering services from Obayashi Corporation," (added Line Item 4) May 31, 2006
- PO 4500176463, Change Notice 3: "Purchase of Engineering services from Obayashi Corporation," (added Line Item 5) October 27, 2006
- PO 4500176463, Change Notice 4: "Purchase of Engineering services from Obayashi Corporation," (added Line Item 6) November 22, 2006
- PO 4500176463, Change Notice 5: "Purchase of Engineering services from Obayashi Corporation," (added Line Items 7-10) December 20, 2006
- PO 4500176463, Change Notice 6: "Purchase of Engineering services from Obayashi Corporation," (added Line Item 11 & 12) May 16, 2007
- PO 4500234432, "Purchase of Engineering services from Obayashi Corporation," June 21, 2007
- PO 4500213322, "Purchase of Engineering services from Obayashi Corporation," January 31, 2007
- Calculation Report APP-1000-S2C-030,"Response Spectrum Analysis of AP1000 Auxiliary and Shield Building," Revision 3, issued June 2011.
- Calculation Report APP-1208-CCC-001,"Auxilliary Building Slab Joint Rebar to Connect with Shield Building Wall," Revision 0, issued November 2009.
- Calculation Report APP-1200-S2C-002, "ASB Thermal and Earth Pressure Analyses," Revision 3, issued July 2011

- Calculation Report APP-1230-SSC-002, “Auxiliary Building Steel Framing Design EL. 100’, Areas 3&4,” Revision 2, issued July 2008.
- Calculation Report APP-CA20-S3C-002,”CA20 Connection Design Calculation-Module Wall-to-Basemat,” Revision 4, issued February 2011
- Calculation Report APP-1200-CCC-102,”Auxiliary Building Wall 7.3 Reinforcement Design,” Revision 5, issued December 2007
- Calculation Report APP-1200-CCC-106,”Auxiliary Building Wall I Reinforcement Design,” Revision 6, issued December 2009
- Calculation Report APP-1010-CCC-005, “Basemat Design, Below Auxiliary Building,” Revision 2, issued March 2011
- Calculation Report APP-1260-SSC-002,”Auxilliary Building Steel Framing Design EL. 160’-6” Areas 3&4,” Revision 1, issued August 2010
- Drawing APP-1200-C3-911, “Auxiliary Building Key Concrete Reinforcement Wall I Elevation between Column Lines 5 and 11,” Revision 1, April, 2010.
- Drawing APP-1260-C3-346,”Auxilliary Building Key Concrete Reinforcement Roof El 160’-6” Areas 3&4,” Revision 1, March, 2011.

b. Observations and Findings

b.1 Policies and Procedures

The NRC inspection team reviewed Obayashi QMS, Section 7.0, “Realization of Structure,” which contains design control guidance and activities, as well as the applicable portions of P-35, Obayashi’s Nuclear Department implementing procedure for safety-related activities applicable to the AP1000 design.

The NRC inspection team reviewed P-35, Section 5, “Drawing Up Quality Plan Documents,” and verified that this procedure provides guidance for developing “quality plans” that organizes customer requirements; applicable laws, regulations, and construction restrictions; schedules; fundamental policy; and a check sheet for confirmation of the content of the contract. P-35 also references management and control procedures to include controls of external standards and analytical programs and provides guidance for implementing “Quality Planning Document.”

The NRC inspection team reviewed P-35, Section 6.1, “Guide for Documentation,” that provides the guidance for implementing reviews to confirm that the requirements of the customer are being addressed, and to confirm the role sharing and method for mutual arrangement and communication of information for implementing work activities or identifying problems. P-35, Section 6.1 provides for the verification of design by confirming design inputs, appropriate information for construction, the criteria of applicable standards, and a description of distinctive features of the product (such as permissible loads and requirements for handling and maintenance) that are indispensable for the product’s safe and appropriate use. The NRC inspection team verified that guidance was provided to confirm the appropriateness of the design by the procedure in the “Quality Plan Document” through confirmation of a model, simulation, or comparative evaluation; confirmation of performance during construction activities; comparative evaluation with similar certified designs or records of construction activities; or licensing requirements such as verification of building construction, and approval of the construction work plan.

b.2 Design Analyses

The NRC inspection team performed a technical review of multiple calculation reports and design drawings pertaining to reinforced concrete and steel design of the AP1000 nuclear island. Specifically, the NRC inspection team focused its efforts on reviewing the calculations and drawings relating to wall, roof, and floor sections that were either defined as critical sections in the AP1000 DCD or were representative of the application of structural codes American Concrete Institute (ACI) 349, "Code Requirements for Nuclear Safety-Related Concrete Structures and Commentary," and American Institute for Steel Construction (AISC) N690, "Specification for Safety-Related Steel Structures for Nuclear Facilities."

b.2.1 Response Spectrum Analysis of AP1000 Auxiliary and Shield Building

The NRC inspection team reviewed Obayashi calculation report APP-1000-S2C-030, "Response Spectrum Analysis of AP1000 Auxiliary and Shield Building," Revision 3, and noted references to various revisions of this calculation. WEC calculation report APP-1000-S2C-030 provides updated seismic analysis results from the AP1000 NI-05 standard design model. Results from this model are used in combination with the results of other calculations, performed by Obayashi, such as dead, live, thermal, and soil pressure loads. The NRC inspection team determined that APP-1000-S2C-030, Revision 3, dated June 6, 2011, was the most-recent revision at the time of this inspection and that calculated seismic demands had increased in certain portions of the model.

The NRC inspection team asked Obayashi to describe the process used to reconcile any Obayashi calculation that references calculation report APP-1000-S2C-030 to the latest revision of this calculation and to ensure the use of the latest revision in future calculations. After extensive discussions with Obayashi, the inspection team determined that Obayashi did not have a procedure to ensure that new AP1000 design information would be accounted for in past, present, and future Obayashi calculations. The absence of documented measures to ensure the control of changes to design information is a design change control issue and is further discussed in Section 3.b.4, "Design Change Control," of this report.

b.2.2 Auxiliary Building Slab Joint Rebar to Connect with the Shield Building Wall

The NRC inspection team reviewed Obayashi calculation report APP-1208-CCC-001, "Auxiliary Building Slab Joint Rebar to Connect with Shield Building Wall," which describes the design of the Auxiliary Building composite steel floor slabs connections to the AP1000 shield building wall. Based on review of this calculation, the NRC inspection team indentified that there were some floor slab locations with demands in excess of design capacity. Obayashi justified the exceedances on the basis that the average values of required reinforcement were less than allowed by code.

Calculation report APP-1208-CCC-001 did not describe the methodology for calculating the average values of reinforcement. Therefore, the NRC inspection team asked Obayashi to provide the necessary justification. In response, Obayashi provided finite element plots showing locations were the exceedances occur. The inspection team reviewed the finite element plots and verified that the areas of

exceedances were both small and localized. The NRC inspection team found the technical basis for addressing the exceedances to be acceptable.

b.2.3 Auxiliary Building Thermal and Earth Pressure Analysis

The NRC inspection team reviewed Obayashi calculation report APP-1200-S2C-002, "Auxiliary Building Thermal and Earth Pressure Analysis," which contains the calculations for the design member forces on walls and floors below grade due to combined thermal and seismic demands. The NRC inspection team noted that the calculation report references APP-1000-S2C-030, Revision 3, and therefore is based on the most-recent seismic analysis results (refer to Section 3.b.2.1, above). The calculation also references thermal inputs (from WEC calculations) for accident and normal load cases. The NRC inspection team noted that the calculation method used to develop dynamic soil pressure was consistent with the provisions of American Society of Civil Engineers (ASCE) 4-98, "Seismic Analysis of Safety-Related Nuclear Structures and Commentary," and AP1000 DCD Section 3.8.4.1.1, "Seismic Category I Structures."

b.2.4 Auxiliary Building Steel Framing Design EL.100"-0" Areas 3&4

The NRC inspection team reviewed Obayashi calculation report APP-1230-SSC-002, "Auxiliary Building Steel Framing Design EL.100"-0" Areas 3&4," which contains design requirements for the composite steel floor slabs at the 100-ft elevation. The NRC inspection team noted that seismic demands were based on an earlier revision of APP-1000-S2C-030 and, therefore, may need to be updated (Refer to 3.b.2.1, above). The NRC inspection team reviewed the report and determined that the approach applied for calculating the composite steel floor slabs was consistent with the provisions of ACI-349 and AISC N690. Although the NRC inspection team did not identified any technical issues specific to this calculation report, Obayashi needs to reconcile the seismic demands with the most-recent revision to APP-1000-S2C-030. This is a design change control issue, and is discussed further in Section 3.b.4 of this report.

b.2.5 CA-20 Connection Design Calculation: Module Wall-to-Basemat

The NRC inspection team reviewed Obayashi calculation report APP-CA20-S3C-002, "CA-20 Connection Design Calculation: Module Wall-to-Basemat," which contains the design requirements for the connection of the CA-20 module (a containment internal structural module) to the AP1000 nuclear island basemat. The NRC inspection team determined that the calculation references an older version of the response spectrum analysis (see 3.b.2.1, above). This is a design change control issue, and is discussed further in Section 3.b.4 of this report.

The NRC inspection team reviewed Section 5.1.2.1 of APP-CA20-S3C-002 and determined that the center of the dowel reinforcement is 10-inches from the skin reinforcement (i.e. steel face plates). In accordance with Section 12.14.2.3 of ACI-349, the lap splice distance between reinforcements is to be limited to 6-inches. In response to NRC inspection team inquiries relating to the lap splice distances, Obayashi determined that WEC had revised the calculation and modified the design of the connection. Obayashi learned of the changes implemented by WEC during

this inspection as part of its research to respond to inquiries from the NRC inspection team. This is a design interface issue, and is discussed further in Section 3.b.3, "Design Interfaces," of this report.

The NRC inspection team reviewed Section 4.5.4.4 of APP-CA20-S3C-002, and determined that accident thermal loads were excluded from the calculation, which is inconsistent with the provisions of ACI-349 that require the combination of accident thermal and seismic loads. The NRC inspection team is aware of a WEC AP1000 design commitment to combine seismic and thermal demands, as applicable, but Obayashi had not yet been informed of this commitment and the need to revise this calculation. This is a design interface issue, and is discussed further in Section 3.b.3 of this report.

b.2.6 Auxiliary Building Wall 7.3 Reinforcement Design

The NRC inspection team reviewed Obayashi calculation report APP-1200-CCC-102, "Auxiliary Building Wall 7.3 Reinforcement Design," which provided the design of an AP1000 nuclear island shear wall. The NRC inspection team noted that Section 5.1.2.2 of the report stated that the in-plane shear stress demands exceed ACI-349 Section 11.10.3 provisions pertaining to shear walls. Obayashi dealt with the exceedance by designing the wall as a corbel. Provisions for the design of corbels are described in Section 11.9 of ACI-349. In designing this share wall as a corbel, Obayashi averaged the in-plane shear stresses over the entire 60-foot wall height, thus reducing the calculated maximum shear stress applied to the wall to a lower average value.

The NRC inspection team reviewed the Obayashi justification and found the justification unacceptable. The NRC inspection team determined that the complex state of in-plane shear stresses due to penetrations and intercepting walls and floors (as demonstrated by detailed calculation results) cannot be averaged over the 60-foot wall height as was the case when Obayashi represented the shear wall as a simple corbel element. Obayashi's failure to correctly implement the provisions of ACI-349 consistent with the requirements of Criterion III of Appendix B to 10 CFR Part 50 has been identified as an example of Nonconformance 99901409/2011201-03.

The NRC inspection team evaluated this misapplication of ACI-349 and determined that it was not of high safety significance due to the high degree of redundancy. In addition, the NRC inspection team verified that cracking of the particular shear wall will not lead to a reduction in lateral resistance of the auxiliary building or shield building.

b.2.7 Auxiliary Building Wall 1 Reinforcement Design

The NRC inspection team reviewed Obayashi calculation report APP-1200-CCC-106, "Auxiliary Building Wall 1 Reinforcement Design," which provides the design of an exterior shear wall for the AP1000 nuclear island. The NRC inspection team determined that the report did not reference the most-recent AP1000 response spectrum model which indicated a 30 to 40 percent increase in seismic moment and an 80-percent increase in axial load for this particular wall (refer 3.b.1, above). In addition, the NRC inspection team determined that Section 4.5.3 of

APP-1200-CCC-106 did not include ACI-349 load combinations for thermal and seismic demands. As discussed Section 3.b.2.5 of this report, Obayashi had not yet been informed of the WEC AP1000 design commitment to combine seismic and thermal demands, as applicable, and the need to revise this calculation. This is a design interface issue, and is discussed further in Section 3.b.3 of this report.

b.2.8 Basemat Design, Below Auxiliary Building

The NRC inspection team reviewed Obayashi calculation report APP-1010-CCC-005, “Basemat Design, Below Auxiliary Building," dated March 2011. This calculation report described the design of the reinforced concrete basemat below the auxiliary building. The NRC inspection team reviewed this calculation report and determined that it references APP-1200-S2C-002, Revision 1 (September 2005). The NRC inspection team determined that APP-1200-S2C-002 was revised (to Revision 2) in October 2007, but was not referenced in the most-recent revision to APP-1010-CCC-005. Accordingly, APP-1010-CCC-005 does not reflect the most-recent information available at the time of issuance. This failure to update the calculation report is a design change control issue, and is discussed further in Section 3.b.4 of this report.

b.2.9 Auxiliary Building Steel Framing Design

The NRC inspection team reviewed Obayashi calculation report APP-1260-SSC-002, “Auxiliary Building Steel Framing Design.” This calculation report described the design for the composite steel framing used in the auxiliary building at the 160-foot elevation. The NRC inspection team performed a review of the calculation report and found the approach consistent with ACI-349 and AISC/N690 code provisions.

b.2.10 Review of ANSYS model

The NRC inspection team reviewed Obayashi’s implementation of the ANSYS finite element (FE) analysis code. The ANSYS code is a general purpose FE code used by both WEC and Obayashi to perform detailed structural calculations for design basis demands. The NRC inspection team reviewed the general implementation process and the process for receiving code errors and notices from ANSYS and implementing corrections. The NRC inspection team also reviewed the implementation of the ANSYS code as it applied to the WEC AP1000 NI-05 model, including the boundary conditions and material properties at selected locations, and verified that they were consistent with the AP1000 seismic analysis model. In addition, the inspection team verified that the total model mass is consistent with the WEC AP1000 NI-05 model.

b.2.11 Auxiliary Building Structural Drawings

The NRC inspection team reviewed Obayashi structural drawings APP-1200-C3-911, Revision 1, “Auxiliary Building Key Concrete Reinforcement Wall 1 Elevation Between Column Lines 5 & 11” and APP-1260-C3-346, Revision 2, “Auxiliary Building Areas 3&4 Key Concrete Reinforcement Floor El. 160’-6” Plan” to verify that drawing details were consistent with the supporting design calculations. The inspection team determined that Obayashi is only responsible for concrete layout reinforcement drawings and that WEC had subsequently modified the remainder of

the Obayashi drawings. The NRC inspection team determined that Obayashi did not have a formal process in place to track drawing revisions that describe and detail the AP1000 design. This is a design change control issue, and is discussed further in Section 3.b.4 of this report.

b.3 Design Interfaces

The NRC inspection team reviewed Obayashi QMS, Section 7.0, "Realization of Structure," which contains design control guidance and activities, as well as the applicable portions of P-35, Obayashi's Nuclear Department implementing procedure for safety-related activities applicable to the AP1000 design. The NRC inspection team also interviewed Obayashi management and staff and determined that measures were not in place for a process to identify and implement an organizational interface between Obayashi and WEC for design control, design changes and in some applications, technical direction.

The NRC inspection team's review of Obayashi calculation report APP-CA20-S3C-002 revealed that WEC had revised this calculation and modified the design of the module wall-to-basemat connection without Obayashi's knowledge prior to this inspection demonstrating a lack of organizational interface between Obayashi and WEC in the area of design change control and potentially affecting overall control of the AP1000 design elements contracted to Obayashi.

The NRC inspection team's review of Obayashi calculation report APP-CA20-S3C-002 determined that accident thermal loads were not applied in this calculation, which is inconsistent with the provisions of ACI-349 that require the combination of accident thermal and seismic loads. WEC has a design commitment in the AP1000 Design Control Document to combine seismic and thermal demands, as applicable, but Obayashi had not yet been given the technical direction relative to this commitment and the need to revise this and potentially other design calculations.

The NRC inspection team's review of Obayashi calculation report APP-1200-CCC-106, determined that the report did not reference the most recent AP1000 response spectrum model which indicated a 30 to 40 percent increase in seismic moment and an 80-percent increase in axial load for the applicable wall (refer 3.b.2.1, above). In addition, the NRC inspection team determined that Section 4.5.3 of APP-1200-CCC-106 did not include ACI-349 load combinations for thermal and seismic demands. Obayashi's failure to use the most recent AP1000 response spectrum model is another example of a lack of organizational interface in the area of design change control. Obayashi failure to consider both thermal and seismic loading in this calculation is another example of ineffective organizational interface between Obayashi and WEC in the area of technical direction and design control.

Obayashi's failure to implement measures to identify and implement an effective organizational interface between Obayashi and WEC for design control, design changes and technical direction consistent with the requirements of Criterion III of Appendix B to 10 CFR Part 50 has been identified as another example of Nonconformance 99901409/2011201-03.

b.4 Design Change Controls

The NRC inspection team reviewed Obayashi QMS and implementing procedure for design change control activities applicable to the AP1000 design. Obayashi's QMS and implementing procedure did not provide adequate guidance for design change activities and did not ensure that design changes were reviewed and verified with the same rigor as the original design.

The only guidance provided in Obayashi's QMS and implementing procedure for design change control was in P-35, Section 6.1.7, "Guide for Documentation," which prescribes that changes to contract specification will be reviewed to verify the related change(s) and will be implemented only after obtaining approval from the customer. In addition, the guidance prescribes notification of interested departments and preparation of records to document the change(s).

The NRC inspection team reviewed Obayashi calculation reports APP-1230-SSC-002, "Auxiliary Building Steel Framing Design EL.100"-0" Areas 3&4;" APP-CA20-S3C-002, "CA-20 Connection Design Calculation: Module Wall-to-Basemat;" APP-1200-CCC-106, "Auxiliary Building Wall 1 Reinforcement Design;" and APP-1010-CCC-005, "Basemat Design, Below Auxiliary Building," as discussed in Section 3.b.2 of this report. These calculations provide examples where design changes were not effectively controlled and implemented.

Obayashi's failure to implement measures for design change activities and to ensure that design changes were reviewed and verified with the same rigor as the original design consistent with the requirements of Criterion III of Appendix B to 10 CFR Part 50 has been identified as another example of Nonconformance 99901409/2011201-03.

c. Conclusions

The NRC inspection team identified Nonconformance 99901409/2011-201-03 associated with Obayashi's failure to implement the requirements of Criterion III, "Design Control," of Appendix B to 10 CFR Part 50. Specifically, Nonconformance 99901409/2011-201-03 cited Obayashi for failing to: (1) correctly implement the applicable provisions of ACI-349, (2) implement measures to identify and implement an effective organizational interface between Obayashi and WEC for design control, design changes and technical direction, and (3) ensure that design changes were reviewed and verified with the same rigor as the original design.

4. Control of Nonconformance and Corrective Action

a. Inspection Scope

The NRC inspection team reviewed the Obayashi QMS and implementing procedure that govern Obayashi's process for the control of nonconforming items and corrective actions to verify compliance with Criterion XV, "Nonconforming Materials, Parts, or Components," and Criterion XVI, "Corrective Action, of Appendix B to 10 CFR Part 50. The NRC inspection team reviewed Obayashi nonconformance documentation and records and discussed the nonconformance and corrective action process with responsible Obayashi management and staff.

Specifically, the NRC inspection team reviewed the following policies, procedures, and supporting documentation for this inspection area:

- QMS – Quality Manual, Revision 3, April 1, 2010
- P-35, Nuclear Business Procedures, Revision 6, April 7, 2010
- Nonconformance reports: 2, 3, 7, 8, 10, 12, 14, 15, 17, 18, 19, 23, 27, 29, 36, 38, 39, 40, 41, 42, 43, 44, 45, 46, 47, 48, 49, 50, 51

b. Observations and Findings

QMS Sections 8.3, 8.5.2, and 8.5.3 provided a high-level description of the control of nonconformances, corrective actions, and prevention of recurrence, respectively. The NRC inspection team noted that Obayashi had only one procedure, P35 Section 11, which addressed the area of control of nonconformances and corrective action. Obayashi did not have separate nonconformance and corrective action programs. At the time of the inspection, Obayashi had documented 51 nonconformance/corrective action reports between 2003 and 2011. The NRC inspection team reviewed a sample of the nonconformance/corrective action reports and observed that P35, Section 11, does not meet all the requirements in Criteria XV and XVI as evidenced by the following:

1. Obayashi's procedure P35, Section 11, did not provide instructions for the segregation of nonconforming calculations or drawings as required by Criterion XV of Appendix B. The objective of P35, Section 11, stated, in part, that measures shall be implemented to ensure that the nonconformance does not affect other activities; however, there is no description of how to do this in the procedure. The NRC inspection team discussed the issue of segregation of nonconforming calculations or drawings to prevent inadvertent use with Obayashi management and staff. Obayashi stated that once a nonconforming condition is identified in a calculation or drawing, all work on calculations or drawings that rely on the nonconforming calculation or drawing is suspended until the nonconforming condition is corrected. However, the process of suspending work on reliant calculations or drawings was not described in Section 11 of P35.

2. Procedure P35, Section 11, did not establish measures for performing prompt corrective actions as required by Criterion XVI of Appendix B. The NRC inspection team noted that most nonconformances were corrected and closed within a few weeks; however, there is no timetable in the procedure to ensure that corrective actions are prompt.

3. Procedure P35, Section 11, did not differentiate between conditions adverse to quality and significant conditions adverse to quality as specified in Criterion XVI of Appendix B. In August 2010, Obayashi implemented the use of form T-35-11-1 to document nonconforming conditions and corrective actions. The NRC inspection team observed that prior to using the T-35-11-1 form Obayashi would document the significance of the nonconformance as minor, medium or significant. With the start of using the T-35-11-1 form, Obayashi no longer documented the significance of the issue. The NRC inspection team observed that Obayashi nonconformance reports 1 through 39 were characterized based on their significance. Of the 39 nonconformance identified, 11 nonconformances were characterized as significant, 5 as medium, and the

remainder as minor. However, the NRC inspection team was not able to identify any objective evidence that Obayashi handled nonconforming conditions differently based on the significance of the nonconforming condition. In addition, the remaining 11 nonconforming conditions documented on the T-35-11-1 forms did not characterize the significance of the conditions.

4. The NRC inspection team observed that there was no connection between P35, Section 11, and the Part 21 procedure. Specifically, P35 section 11 did not provide instructions to make a determination as to whether a Part 21 evaluation should be conducted and the applicable procedure followed. In addition, as stated in section 1.b.2 of this report, NRC inspection team noted that the nonconformance log stated that Part 21 was not applicable to the 51 nonconformances listed. However, there was no objective evidence as to when and how this determination was made.

5. NRC inspection team observed that the WEC Supplier Corrective Action Reports (SCAR) from the 2010 WEC audit of Obayashi were not documented in the Obayashi nonconformance log as required by Criterion XVI to Appendix B. Since Obayashi did not open a nonconformance/corrective action for the WEC SCARs, there was no objective evidence that corrective action was taken to address the WEC SCARs. In addition, P35, Section 11 did provide instructions for initiating a nonconformance/corrective action for audit findings from purchasers or other oversight entities.

Based on the examples presented in items 1 through 5 above, the NRC inspection team has identified the failure of P35, Section 11, to meet the requirements of Criteria XV and XVI as Nonconformance 99901409/2011-201-04.

c. Conclusions

The NRC inspection team identified Nonconformance 99901409/2011-201-04 associated with Obayashi's failure to implement the requirements of Criteria XV and XVI of Appendix B to 10 CFR Part 50. Specifically, Obayashi failed to establish measures for: (1) the segregation of nonconforming calculations and drawings,(2) performing prompt corrective actions, (3) differentiating between conditions adverse to quality and significant conditions adverse to quality, (4) providing instructions to make a determination as to whether a Part 21 evaluation should be conducted and the applicable procedure followed, and (5) implementing corrective actions on two WEC SCARs.

5. Quality Assurance Records

a. Inspection Scope

The NRC inspection team reviewed the Obayashi QMS and applicable implementing procedure that govern the Obayashi process for controlling quality records to verify compliance with the requirements of Criterion XVII, "Quality Assurance Records," of Appendix B to 10 CFR Part 50. In addition, the NRC inspection team interviewed Obayashi personnel to gain an understanding of the Obayashi process for controlling quality records.

Specifically, the NRC inspection team reviewed the following policies, procedures, and supporting documentation for this inspection area:

- QMS – Quality Manual, Revision 3, April 1, 2010
- P-35, Nuclear Business Procedures, Revision 6, April 7, 2010

b. Observations and Findings

The NRC inspection team reviewed QMS, Section 4.2.3, Record Control, referred to procedure, P02, and not to P35. However, Obayashi stated that for nuclear safety-related work, it is assumed that P35 replaces P02 listed in the QMS.

The NRC inspection team noted that P35, Section 8, provided instructions for receipt and issuance of documents, and a requirement for storing quality records developed for each project. P35, Section 8, also provided descriptions of different types of records, e.g., operations report, quality plan, and nonconformance and corrective action records.

The NRC inspection team discussed the Obayashi control of quality records with the appropriate Obayashi personnel and management. The NRC inspection team learned that Obayashi manually maintained an Excel spreadsheet to keep track of the latest versions of calculation notes, drawings, etc., that have been developed by Obayashi in support of the AP1000 design. The Excel spreadsheet contained a list of calculations and drawings submitted to WEC and the associated letter for that submittal. The spreadsheet listed approximately 108 calculation notes and 76 drawings.

Obayashi stated that design documents are designated as lifetime records. Obayashi used Compass as its electronic record keeping program for documents that need to be stored for a lifetime. All Obayashi personnel in the nuclear facilities division had access to Compass. However, no one had the ability to delete or change documents in Compass. In addition, Compass was backed up on two servers, one in Tokyo and one in Osaka.

The NRC inspection team noted the P35, Section 8, delineated between quality records used while project was on-going and when project was complete. Based on discussions with Obayashi staff, the NRC inspection team learned current revisions of calculations and drawings listed on the Excel spreadsheet are maintained on the AP1000 server which was also backed up by the Osaka server. At the end of the business year, these documents are transferred to Compass. However, the NRC inspection team noted that this record keeping process, e.g., the use of the AP1000 server, Compass, etc., was not described in P35, Section 8. Specifically, P35 did not document the classification of records, validation of records, control of distribution, handling, maintenance, and storage of records as required by Criterion XVII of Appendix B and requirement 17S-1 of NQA-1-1994. The NRC inspection team has identified the failure of P35, Section 8, to provide instructions to implement the Obayashi control of quality record process as an example of Nonconformance 99901409/2011-201-05.

In addition, the NRC inspection team observed that P35, Section 8, did not establish measures to maintain the records of the qualifications of personnel as required by Criterion XVII of Appendix B. The NRC inspection team has identified Obayashi's failure to define the record keeping requirements of Criterion XVII as another example of Nonconformance 99901409/2011-201-05.

c. Conclusions

The NRC inspection team identified Nonconformance 99901409/2011201-05 for Obayashi's failure to meet the requirements of Criterion XVII, "Quality Records," of Appendix B to 10 CFR Part 50. Specifically, Obayashi failed to (1) establish instructions for the maintenance of records for the qualification of personnel and (2) document the record keeping process used by Obayashi.

6. Audits

a. Inspection Scope

The NRC inspection team reviewed the Obayashi QMS and the implementing procedure that govern the Obayashi audit program to verify compliance with the requirements of Criterion XVIII, "Audits," of Appendix B to 10 CFR Part 50.

Specifically, the NRC inspection team reviewed the following policies, procedures, and supporting documentation for this inspection area:

- QMS – Quality Manual, Revision 3, April 1, 2010
- P-35, Nuclear Business Procedures, Revision 6, April 7, 2010
- 2011 Internal Overall Audit Plan, April 1, 2011
- Audit Schedule, Revision 1, July 11, 2011
- AP1000 Project Audit Plan, July 27, 2011
- AP1000 Project Audit Report August 8, 2011

b. Observations and Findings

b.1 Policies and Procedures

The NRC inspection team reviewed QMS, Section 8.2.2 (2), Nuclear Facilities Division Quality Audit, which states that the QMS manager shall plan and implement an internal quality audit targeting sections under his purview and report the audit result to the head of Nuclear Division. The QMS manager shall also analyze the results and corrective action measures taken and report the results to the management

P35, Section 13, described internal quality audits. P35 required the QMS manager to develop the QA internal audit plan for each business year. The target of the audit was to be determined by the frequency of the audit, the importance of the activities being audited, and the results of the audits for departments subject to the QMS. The internal overall plan shall contain the audit policy and items to be audited; departments to be audited and scheduled auditors; and audit schedule.

b.2 Implementation of Audit Process

The NRC inspection team reviewed the 2011 Internal Overall Audit Plan and the associated Audit Schedule. The NRC inspection team observed that the AP1000 Project audit was planned and completed consistent with the QMS Section 8.2.2 requirements. The NRC inspection team observed that the AP1000 project audit report documented the items audited which included the verification of the status of the AP1000 project, verification that the daily operation was consistent with P35, and verification that nonconformance and improvement information was shared and utilized.

The NRC inspection team reviewed the audit checklist developed for the AP1000 project audit and noted that the checklist included special items that addressed conformance to Appendix B, NQA-1, and Part 21. The NRC inspection team discussed the special items added to the checklist with Obayashi management and personnel. In particular, the NRC inspection team observed that there were no nonconformances identified during the AP1000 project audit and that the special items added to the checklists were verified as being acceptable. Based on the discussions with Obayashi management and personnel, the NRC inspection team concluded that the Obayashi auditors had insufficient understanding of the requirements of Appendix B, NQA-1, and Part 21 to verify compliance with the requirements imposed by the WEC POs. Failure to adequately qualify lead auditors for internal audits of Obayashi quality activities is identified as another example of Nonconformance 9991409/2011-201-06.

c. Conclusions

The NRC inspection team identified Nonconformance 99901409/2011-201-06 associated with Obayashi's failure to implement the requirements of Criterion XVIII, "Audits," of Appendix B to 10 CFR Part 50. Specifically, Obayashi failed to adequately qualify lead auditors for internal audits of Obayashi safety-related activities related to the AP1000 project and did not verify compliance with the requirements imposed by the WEC POs.

10. Entrance and Exit Meetings

On September 12, 2011, the NRC inspection team discussed the scope of the inspection with Mr. Sakamoto, Senior General Director, Nuclear Facilities Division, and with the Obayashi management and staff. On September 16, 2011, the NRC inspection team presented the inspection results and observations during an exit meeting with Mr. Sakamoto and other Obayashi management and staff members. The attachment to this report lists the entrance and exit meeting attendees, as well as those interviewed by the NRC inspection team.

ATTACHMENT

1. ENTRANCE AND EXIT MEETING ATTENDEES

Name	Title	Affiliation	Entrance	Exit	Interviewed
Kerri Kavanagh	Team Lead, Sr. Reactor Engineer	NRC	X	X	
Robert Prato	Sr. Reactor Operations Engineer	NRC	X	X	
Bret Tegeler	Sr. Structural Engineer	NRC	X	X	
Mohamed Shams	Chief, Structural Engineering Branch	NRC	X	X	
Masao Nagai	Senior Officer	JNES (observer)	X	X	
Takashi Otomo	Deputy Manager, Eng Dept.	Obayashi	X	X	X
Narendra Prasad	Fellow Engineer	Westinghouse	X	X	X
Yoshitaka Takeuchi	Deputy General Manager, Eng Dept.	Obayashi	X	X	
Yoshikatsu Imazuka	General Manager, Eng Dept.	Obayashi	X	X	
Kazunori Akiyama	General Manager, Design Dept.	Obayashi	X	X	
Yuji Itabashi	Deputy General Manager, Design Dept.	Obayashi	X	X	X
Yasutaka Sakamoto	Senior General Manager, Nuclear Facilities Division	Obayashi	X	X	
Akira Ogaki	General Manager, Nuclear Facilities Dept.	Obayashi	X	X	X
Masaki Kawashima	Manager, Design Section, Design Dept.	Obayashi	X	X	
Naoki Yoshimura	Senior Inspector	JNES (observer)	X	X	
Keiko Tominaga	Interpreter	Simul	X	X	
Masashi Aizawa	Contractor	Obayashi Facilities	X		
Keiko Kobayashi	Contractor	Syspro	X		
Jun Kuwahara	Manager, Planning Section, Nuclear Facilities Dept.	Obayashi	X	X	
Akira Shimizu	General Manager, Nuclear Dept.	Obayashi	X	X	

Name	Title	Affiliation	Entrance	Exit	Interviewed
Masayuki Shirakawa	General Manager, Nuclear Facilities Division	Obayashi	X	X	
Tomohiro Iwasaki	Manager	Obayashi		X	
Ivan Bulatao	Contractor	Earth Design Co.	X	X	
Bernabe Bonifacio	Contractor	Earth Design Co.	X	X	
John Kurtik	QA Engineer	Westinghouse	X	X	X
Hiroto Inoue	Chief Researcher	JNES (observer)	X		
Hiromi Adachi	Interpreter	Simul	X	X	
Shoichi Goto	Manager, Planning Section, Nuclear Facilities Dept.	Obayashi	X		
Ted Alexovich	Manager, AP1000 International Projects Quality	Westinghouse		X*	
Mike Corletti	Director, AP1000 Plant Engineering	Westinghouse		X*	
Jamie Vasquez	Manager, Global Supplier Quality Oversight	Westinghouse		X*	

*Participated by phone

2. INSPECTION PROCEDURES USED

IP 43002, “Routine Inspections of Nuclear Vendors”

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
99901409/2011-201-01	Open	NOV	10 CFR 21.21(a)
99901409/2011-201-02	Open	NON	10 CFR Part 50, App. B, Criterion II
99901409/2011-201-03	Open	NON	10 CFR Part 50, App. B, Criterion III
99901409/2011-201-04	Open	NON	10 CFR Part 50, App. B, Criterion XV and Criterion XVI

99901409/2011-201-05	Open	NON	10 CFR Part 50, App. B, Criterion XVII
99901409/2011-201-06	Open	NON	10 CFR Part 50, App. B, Criterion II and Criterion XVIII