August 9, 2011

Mr. Yoshiki Ogata, General Manager
APWR Promoting Department
Mitsubishi Heavy Industries, Ltd.
16-5, Konan 2-Chome, Minato-Ku
Tokyo 108-8215 Japan

SUBJECT: NRC INSPECTION REPORT NO. 05200021/2011-201 AND
NOTICE OF VIOLATION

Dear Mr. Ogata:

From June 13, 2011 through June 17, 2011, the U.S. Nuclear Regulatory Commission (NRC) conducted an inspection at the Alden Research Laboratory facilities in Holden, MA. The purpose of the NRC inspection was to verify that Mitsubishi Heavy Industries, Ltd (MHI) effectively implemented quality assurance (QA) processes and procedures for testing activities performed in support of the U.S. Advanced Pressurized-Water Reactor design certification application. The inspection focused on assessing compliance with the provisions of Title 10 of the *Code of Federal Regulations* (10 CFR) Part 21, "Reporting of Defects and Noncompliance," and selected portions of Appendix B, "Quality Assurance Program Criteria for Nuclear Power Plants and Fuel Reprocessing Plants," to 10 CFR Part 50, "Domestic Licensing of Production and Utilization Facilities." The enclosed report presents the results of this inspection.

Based on the results of this inspection, the NRC determined that two Severity Level IV violations 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.

These violations are cited in the enclosed Notice of Violation (Notice) and circumstances surrounding them are described in detail in the subject inspection report. The violations are being cited in the Notice because the NRC inspection team identified an example in which MHI failed to adequately oversee the implementation of AREVA's document, test control, and training programs in accordance with Appendix B to 10 CFR Part 50.

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 accordance with 10 CFR 2.390, "Public Inspections, Exemptions, Requests for Withholding," of 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 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.: 05200021

Enclosures:
1. Notice of Violation
2. Inspection Report No. 05200021/2011-201 and Attachment

made available to the public without redaction. If personal privacy or proprietary information is necessary to provide an acceptable response, then please provide a bracketed copy of your response that identifies the information that should be protected and a redacted copy of your response that deletes such information. If you request that such material be withheld from public disclosure, you must specifically identify the portions of your response that you seek to have withheld and provide, in detail, the bases for your claim (e.g., explain why the disclosure of information will create an unwarranted invasion of personal privacy or provide the information required by 10 CFR 2.390(b) to support a request for withholding confidential commercial or financial information). If Safeguards Information is necessary to provide an acceptable response, please provide the level of protection described in 10 CFR 73.21, "Protection of Safeguards Information: Performance Requirements."

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OFFICE	NRO/DCIP/CQVA	NRO/DCIP/CQVB	NRO/DCIP/CQVA
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DATE	08/08/2011	08/05/2011	08/05/2011
OFFICE	NRO/DCIP/CQVA	NRO/DSRA/SPCV	NRO/DSRA/SBCV
NAME	*RNolan	*CAshley	SHaider
DATE	08/08/2011	08/05/2011	08/05/2011
OFFICE	*RLanksbury	NRO/DCIP/CAEB	NRO/DCIP/CQVA
NAME	R-II/DCP/CPB2	TFrye	JPeralta
DATE	08/04/2011	08/08/2011	08/09/2011

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NOTICE OF VIOLATION

Mitsubishi Heavy Industries, Ltd.
Wadasaki-cho-1-1-1, Hyogo-ku
Kobe 652-8285 Japan

Docket No.: 05200021
Report No. 2011-201

During a U.S. Nuclear Regulatory Commission (NRC) inspection of Mitsubishi Heavy Industries, Ltd. (MHI) conducted at the Alden Research Laboratory facilities in Holden, MA, on June 13, 2011 through June 17, 2011, violations of NRC requirements were identified. In accordance with the NRC Enforcement Policy, the violations are described below:

A. Criterion II, "Quality Assurance Program," of Appendix B to Title 10 of the *Code of Federal Regulations* (10 CFR) Part 50, states, in part that, "the program shall provide for indoctrination and training of personnel performing activities affecting quality as necessary to assure that suitable proficiency is achieved and maintained."

   AREVA Document No. 56-9141754-000, "Quality Assurance Program," Revision 0, dated August 15, 2010, Section 2.6, "QAP Indoctrination and Training," states that, "Personnel performing or managing activities affecting quality shall receive indoctrination in their job responsibilities and authority that includes general criteria, technical objectives, requirements of applicable codes and standards, regulatory commitments, company procedures, and quality assurance program requirements."

   Contrary to the above, as of June 17, 2011, MHI, which has the overall responsibility for design certification testing activities, failed to verify that Alden Research Laboratory (ARL) personnel performing test activities in support of the U.S. Advanced Pressurized-Water Reactor (US-APWR) Emergency Core Cooling System (ECCS) strainer performance testing for AREVA received all of the required training in accordance with AREVA Document No. 56-9141754-000. Specifically, three ARL employees were not trained to procedures AP 1302-01, "Document Control of Printed Hard Copies from the Electronic Document Control," and AP 1703-01, "Restraint Order," as required by AREVA AP
   1702-22, "Employee Training," Revision 30, dated October 29, 2010.

This issue has been identified as Violation 05200021/2011-201-01.

This is a Severity Level IV violation (Section 6.5.d of the NRC Enforcement Policy).

B. Criterion XI, "Test Control," of Appendix B, "Quality Assurance Program Criteria for Nuclear Power Plants and Fuel Reprocessing Plants," to 10 CFR Part 50, "Domestic Licensing of Production and Utilization Facilities," 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 VI, "Document Control," of Appendix B to 10 CFR Part 50, states, in part, that "Measures shall be established to control the issuance of documents, such as instructions, procedures, and drawings, including changes thereto, which prescribe all activities affecting quality. Changes to documents shall be reviewed and approved by

the same organizations that performed the original review and approval unless the applicant designates another responsible organization."

Criterion V, "Instructions, Procedures, and Drawings," 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."

Section 5.1, "General," of AREVA Document 56-9141754, "Quality Assurance Program," Revision 0, dated August 15, 2010, states, in part, that "measures are established and documented to assure that activities affecting the quality of items are established in instructions, procedures, or drawings, and accomplished in accordance with these documents. Instructions, procedures, and drawings shall be prepared, reviewed, approved, and distributed before beginning the activity."

Section 6.2.2, "Document Change Control," of AREVA Document 56-9141754 states, in part, that "Changes and revisions to the documents listed in Section 6.1 shall have at least the same review and approval as the original document."

Section 6.1, "General," of AREVA Document 56-9141754 states, in part, that "Company procedures and instruction detail the methods for preparation, review, approval, revision, distribution, and use of documents. The following types of documents are controlled within the document control system: Technical Documents includes inspection, field, test, and special process procedures and documents…"

Contrary to the above, as of June 17, 2011, MHI, which has the overall responsibility for design certification testing activities, failed to verify that an activity affecting quality (i.e., testing) was accomplished using an approved procedure. Specifically, testing was performed in accordance with unapproved changes to Technical Document 63-9160802-000, "US-APWR Test Plan for ECCS Strainer Performance Testing 2011," Revision 0, dated June 3, 2011. These unapproved changes were made in the field by the AREVA test engineer and did not have the same review and approval as the original document as required by AREVA Document 56-9141754.

This issue has been identified as Violation 05200021/2011-201-02.

This is a Severity Level IV violation (Section 6.5.d of the NRC Enforcement Policy).

In accordance with the provisions of 10 CFR 2.201, "Notice of Violation," MHI 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 from 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."

Dated at Rockville, MD, this 9th day of August 2011.

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

Docket No.:	05200021
Report No.:	05200021/2011-201
Applicant:	Mitsubishi Heavy Industries, Ltd. Wadasaki-cho-1-1-1, Hyogo-ku Kobe 652-8285 Japan
Applicant Contact:	Mr. Ryan Sprengel Lead Licensing Engineer
Background:	Mitsubishi Heavy Industries, Ltd. submitted an application for a standard design certification for the U.S. Advanced Pressurized-Water Reactor on December 31, 2007.
Inspection Dates:	June 13-17, 2011

Inspectors:			
	Yamir Diaz-Castillo	NRO/DCIP/CQVA	Team Leader
	Garrett Newman	NRO/DCIP/CQVB	
	Raju Patel	NRO/DCIP/CQVA	
	Ryan Nolan	NRO/DCIP/CQVA	
	Clinton Ashley	NRO/DSRA/SPCV	
	Syed Haider	NRO/DSRA/SBCV	
	Roger Lanksbury	R-II/DCP/CPB2	

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

Enclosure 2

EXECUTIVE SUMMARY

Mitsubishi Heavy Industries, Ltd.
05200021/2011-201

The U.S. Nuclear Regulatory Commission (NRC) inspection focused on quality assurance (QA) policies and procedures implemented to support the design certification (DC) application for the U.S. Advanced Pressurized-Water Reactor (US-APWR), as described in NRC Inspection Manual Chapter 2508, "Construction Inspection Program: Design Certification." The purpose of this inspection was to verify that Mitsubishi Heavy Industries, Ltd. (MHI) had implemented an adequate QA program in support of US-APWR DC emergency core cooling system (ECCS) strainer performance testing activities that complies with the requirements of Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants," to Title 10 of the *Code of Federal Regulations* (10 CFR) Part 50, "Domestic Licensing of Production and Utilization Facilities." The inspection also verified that MHI had implemented a program under 10 CFR Part 21, "Reporting of Defects and Noncompliance," that meets NRC regulatory requirements.

MHI performed plant specific US-APWR containment sump strainer head loss testing associated with containment spray/residual heat removal and safety injection pumps to qualify its strainer design. MHI contracted with Performance Contracting Inc. (PCI) to both supply the strainer and perform the strainer head loss testing. PCI subcontracted the development of the head loss testing procedure for the strainer to AREVA NP Inc. AREVA then subcontracted test performance to Alden Research Laboratory (ARL). For several years, ARL has conducted head loss testing of PCI strainers with technical assistance from AREVA and PCI. Although ARL does not have a QA program (QAP) that meets the requirements of Appendix B to 10 CFR Part 50, ARL performs this DC testing under AREVA's QA program (QAP), therefore all testing activities are being procured as safety-related. ARL performed two tests during the inspection: the Fiber Only Bypass (FOB) Test and the Debris Laden Test Strainer Head Loss (DTSHL) Test.

The NRC based its inspection on the following:

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

During this inspection, the NRC inspection team implemented Inspection Procedure (IP) 35034, "Design Certification Testing Inspection," as supplemented by IP 35017, "Quality Assurance Implementation Inspection," and IP 36100, "Inspection of 10 CFR Part 21 and 10 CFR 50.55(e) "Programs for Reporting Defects and Noncompliance."

Before this inspection, the NRC performed two audits in June 2010 and June 2011, as part of a US-APWR DC testing review. Both audits were performed at ARL's facility in Holden, MA.

With the exception of the two violations described below, the NRC inspection team concluded that AREVA is effectively implementing its QA and 10 CFR Part 21 programs in support of MHI's US-APWR DC testing activities.

10 CFR Part 21 Program

The NRC inspection team concluded that the implementation of MHI, PCI, and AREVA's 10 CFR Part 21 programs in support of MHI's DC testing for the US-APWR ECCS strainers is

consistent with the regulatory requirements of 10 CFR Part 21. Based on its review, the NRC inspection team also determined that MHI, PCI and AREVA are effectively implementing its policies and associated procedures in support of MHI's US-APWR DC testing activities. No findings of significance were identified.

Training and Qualification

The NRC inspection team identified one violation associated with MHI's failure to implement the requirements of Criterion II, "Quality Assurance Program," of Appendix B to 10 CFR Part 50. Violation 05200021/2011-201-01 involved MHI's failure to ensure testing personnel received all of the required training in accordance with AREVA's Document No. 56-9141754-000.

Procurement Document Control

The NRC inspection team concluded that the implementation of the MHI, PCI, and AREVA procurement document control programs is consistent with the regulatory requirements of Criterion IV, "Procurement Document Control," of Appendix B to 10 CFR Part 50. Based on its review, the NRC inspection team determined that MHI, PCI, and AREVA are effectively implementing their policies and procedures in support of MHI's US-APWR DC testing activities. No findings of significance were identified.

Control of Purchased Equipment, Materials, and Services

The NRC inspection team concluded that the implementation of the MHI, PCI and AREVA programs for control of purchased equipment, materials and services is consistent with the regulatory requirements of Criterion VII, "Control of Purchased Material, Equipment, and Services" of Appendix B to 10 CFR Part 50. Based on its review, the NRC inspection team determined that MHI, PCI, and AREVA are effectively implementing their policies and procedures in support of MHI's US-APWR DC testing activities. No findings of significance were identified.

Test Control

The NRC inspection team identified one violation associated with MHI's failure to implement the requirements of Criterion V, "Instruction, Procedures, and Drawings;" Criterion VI, "Document Control;" and Criterion XI, "Test Control," of Appendix B to 10 CFR Part 50. Violation 05200021/2011-201-02 involved MHI's failure to ensure that testing was accomplished using a properly issued procedure. Testing was performed in accordance with unapproved changes to Technical Document 63-9160802-000, "US-APWR Test Plan for ECCS Strainer Performance Testing 2011," Revision 0, dated June 3, 2011.

Control of Measuring and Test Equipment

The NRC inspection team concluded that the implementation of AREVA's control of measuring and test equipment program in support of MHI's DC testing for the US-APWR's ECCS strainers is consistent with the regulatory requirements of Criterion XII, "Control of Measuring and Test Equipment," of Appendix B to 10 CFR Part 50. Based on its review, the NRC inspection team determined that AREVA is effectively implementing its policies and procedures in support of MHI's US-APWR DC testing activities. No findings of significance were identified.

Nonconforming Materials, Parts or Components and Corrective Actions

The NRC inspection team concluded that the implementation of the AREVA's corrective action program in support of MHI's DC testing for the US-APWR's ECCS strainers is consistent with the regulatory requirements of Criterion XVI, "Corrective Action," of Appendix B to 10 CFR Part 50. Based on its review, the NRC inspection team determined that AREVA is effectively implementing its policies and procedures in support of the US-APWR DC testing activities. No findings of significance were identified.

Quality Assurance Records

The NRC inspection team concluded that the implementation of AREVA's QA records program in support of MHI's DC testing for the US-APWR's ECCS strainers is consistent with the regulatory requirements of Criterion XVII, "Quality Assurance Records;" of Appendix B to 10 CFR Part 50. Based on its review, the NRC inspection team determined that AREVA is effectively implementing its policies and procedures in support of MHI's US-APWR DC testing activities. No findings of significance were identified.

REPORT DETAILS

1. 10 CFR Part 21 Program

a. Inspection Scope

The U.S. Nuclear Regulatory Commission (NRC) inspection team reviewed the implementation of portions of the Mitsubishi Heavy Industries, Ltd., (MHI), Performance Contracting Incorporated (PCI), and AREVA programs under Title 10 of the *Code of Federal Regulations* (10 CFR) Part 21, "Reporting of Defects and Noncompliance," in support of MHI's design certification (DC) testing for the U.S. Advanced Pressurized-Water Reactor (US-APWR) Emergency Core Cooling System (ECCS) strainers. Specifically, the NRC inspection team reviewed the policies and procedures governing the implementation of the MHI, PCI and AREVA programs to verify compliance with the regulatory requirements of 10 CFR Part 21. In addition, the NRC inspection team discussed the 10 CFR Part 21 program with the management and technical staff of MHI, PCI and AREVA.

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

- MHI Purchase Order (PO) No. MNP-0458, "US-APWR Design Certification for Design and Evaluation of Sump Strainer]," to PCI, dated September 12, 2008
- PCI PO No. 9627, "MHI-US APWR Tank Test," to AREVA, dated April 14, 2011
- AREVA PO No. 1030046914 to Davis INOTEK Instruments, LLC for calibration of digital multimeter ALDEN S/N 788, AREVA Control # VH-11575, dated September 24, 2010
- PCI Quality Control (QC) Procedure 1010, "10 CFR 21 Reporting and Posting," Revision 4, dated May 13, 2009
- PCI QC Procedure 1510, "Non-Conformances," Revision 6, dated May 13, 2009
- AREVA Policy No. 0401, "Evaluation and Reporting per 10 CFR 21," Revision, dated January 15, 2011
- AREVA Administrative Procedure (AP) 1707-01, "Evaluation and Reporting per 10 CFR 21," Revision 38, dated December 18, 2008
- AREVA AP 1717-06, "Corrective Action Program - WebCAP," Revision 5, dated June 16, 2010
- AREVA WebCAP 2011-4032-CR, "Paint Chips in APWR ECCS Strainer Test Flume at Alden," dated June 6, 2011
- AREVA WebCAP 2011-4164-CR, "Chemical Mixing," dated June 9, 2011

b. Observations and Findings

b.1 Postings

The NRC inspection team verified that AREVA had posted notices that included: (1) a copy of Section 206 of the Energy Reorganization Act of 1974; (2) a description of 10 CFR Part 21 and the AREVA procedure that implements the regulation; and (3) the name of the individual to whom reports could be made.

b.2 Purchase Orders

The NRC inspection team reviewed a sample of MHI, PCI, and AREVA POs to verify the implementation of a program consistent with the requirements described in 10 CFR 21.31, "Procurement Documents," about specifying the applicability of 10 CFR Part 21 in POs for safety-related services. The NRC inspection team verified that MHI, PCI, and AREVA imposed the requirements of 10 CFR Part 21 on qualified suppliers having programs meeting the requirements of Appendix B to 10 CFR Part 50.

b.3 10 CFR Part 21 Procedures and Implementation

The NRC reviewed MHI's 10 CFR Part 21 program during a December 2010 inspection performed at its offices in Kobe, Japan (Agencywide Documents Access Management System (ADAMS) Accession Number (No.) ML110210624).

PCI's QC Procedure 1010 defines the process to report defects in accordance with 10 CFR Part 21 and the posting requirements. This procedure also outlines the responsibilities, timelines, and actions for identifying and evaluating deviations and failures to comply and for reporting defects.

AREVA's Policy 0401 ensures that procedures are established to effectively implement a 10 CFR Part 21 program. This policy also requires that all POs and change orders for components, materials, or safety-related services shall include a clause stating that the requirements of 10 CFR Part 21 are applicable.

AREVA's AP 1707-01 establishes the process and responsibilities for compliance with 10 CFR Part 21 requirements as well as the reporting timelines and requirements for identified deviations. AP 1717-06 defines AREVA's Corrective Action Program (WebCAP), where potential deviations are identified and documented in condition reports (CRs). Section 7 of this report discusses AP 1717-06 in further detail. AP 1707-01 also requires that potential deviations be evaluated and documented in the Deviation Determination (DD) field in WebCAP. AP 1707-01 describes how DDs are documented in WebCAP which starts the 10 CFR Part 21 evaluation process.

The NRC inspection team verified that AREVA's procedural guidance was adequate to initiate the 10 CFR Part 21 process when a CR was written that could have an impact on the US-APWR DC application. The NRC inspection team also verified that AREVA's staff is knowledgeable about the conditions that would warrant a 10 CFR Part 21 evaluation.

The NRC inspection team noted that PCI and AREVA had performed no 10 CFR Part 21 evaluations to date as part of the US-APWR ECCS DC strainer performance testing. The NRC

inspection team reviewed a sample of AREVA WebCAP reports and identified no issues that would have warranted reporting under AREVA's 10 CFR Part 21 program.

Conclusions

The NRC inspection team concluded that the implementation of the MHI, PCI, and AREVA 10 CFR Part 21 programs is consistent with the regulatory requirements of 10 CFR Part 21. Based on the sample of documents reviewed, the NRC inspection team also concluded that MHI, PCI, and AREVA are effectively implementing their policies and procedures in support of MHI's DC testing for the US-APWR ECCS strainers. No findings of significance were identified.

2. Training and Qualification of Personnel

a. Inspection Scope

The NRC inspection team reviewed the implementation of AREVA's training and qualification program in support of MHI's DC testing for the US-APWR ECCS strainers. Specifically, the NRC inspection team reviewed the policies and procedures governing the implementation of AREVA's training and qualification program to verify compliance with Criterion II, "Quality Assurance Program," of Appendix B to 10 CFR Part 50. In addition, the NRC inspection team discussed the training and qualification program with AREVA's management and technical staff.

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

- AREVA 56-9141754, "Quality Assurance Program," Revision 0, dated August 15, 2010
- AREVA AP 1702-22, "Employee Training," Revision 30, dated October 29, 2010

b. Observations and Findings

b.1 Policies and Procedures

Section 2.6 of AREVA's QAP states, in part, that the indoctrination and training of personnel is conducted in accordance with written procedures and includes instructions as to the purpose, scope, and implementation of the quality related documents, policies, procedures, and instructions.

AREVA's AP 1702-22 provides the training requirements for AREVA employees and contractors as well as the requirements for planning, scheduling, executing, and documenting personnel training. The procedure also requires training for AREVA employees to the extent necessary for the employee to achieve a level of proficiency that complies with the QAP requirements.

b.2 Implementation of the Training and Qualification Program

The NRC inspection team reviewed training records for AREVA and ARL personnel who performed ECCS strainer testing activities in support of MHI's DC for the US-APWR. The NRC inspection team noted that ARL personnel performing ECCS testing activities were working under AREVA's QAP and, as such, must be trained and qualified under AREVA's QAP implementing procedures. AREVA uses the Learning Management System (LMS), which is the official system to track personnel training and history. For contractor personnel who do not

have access to LMS, which is the case for ARL personnel, an AREVA LMS Administrator manually inputs completed training information into LMS. Consistent with AREVA procedures, for personnel working on site, training may be performed by a prejob briefing. All training received during the prejob briefing is documented in a Personnel Training Record (PTR) and subsequently, the LMS Administrator will enter the information into LMS and credit the individual's training history profile under the project specific training.

The NRC inspection team examined training and qualification records for a sample of senior management, QA, and testing personnel. The NRC inspection team verified that all personnel performing activities affecting quality had completed the required training and met all the specified requirements in accordance with the applicable procedures. During the review of training records for ARL employees, the NRC inspection team noted that certain ARL employees working under AREVA's QAP were not trained as required by AP 1702-22. Specifically, three ARL employees were not trained to procedures AP 1302-01, "Document Control of Printed Hard Copies from the Electronic Document Control," and AP 1703-01, "Restraint Order," Revision 29, dated February 17, 2011. The NRC inspection team concluded that this issue was a failure to meet the requirements of 10 CFR Part 50, Appendix B, Criterion II, "Quality Assurance Program," and identified this issue as Violation 05200021/2011-201-01. Although ARL personnel were not trained in the above two procedures, through discussions with the AREVA and ARL QA staff, and given that an AREVA test engineer is always on site while the testing activities are taking place, the NRC inspection team was able to confirm that the lack of training did not affect the strainer testing. AREVA initiated CR 2011-4301 to address this issue.

c. Conclusions

The NRC inspection team concluded that AREVA did not implement its training program consistent with the requirements of Criterion II, "Quality Assurance Program," of Appendix B to 10 CFR Part 50. The NRC inspection team issued Violation 05200021/2011-201-01 for MHI's failure to ensure testing personnel received all of the required training in accordance with AREVA's Document No. 56-9141754-000.

3. Procurement Document Control

a. Inspection Scope

The NRC inspection team reviewed the implementation of the MHI, PCI, and AREVA QA procurement document control programs in support of MHI's DC testing for the US-APWR ECCS strainers. Specifically, the NRC inspection team reviewed policies and implementing procedures governing the control of procurement documents to verify compliance with the requirements of Criterion IV, "Procurement Document Control," of Appendix B to 10 CFR Part 50. In addition, the NRC inspection team discussed the procurement document control program with the management and technical staff of MHI, PCI, and AREVA.

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

- MHI UES-20080022, "Quality Assurance Manual (QAM) Nuclear Safety Related for Non ASME Code Job," Revision 2, dated April 15, 2011

- MHI QAP Appendix A-9 (5HE9-092-050E), "Procurement Control Procedure," Revision 2, dated April 15, 2011

- PCI "Quality Assurance Program," Revision 3, dated October 1, 2010

- PCI Quality Control Procedure (QCP) No. 140, "Review of Customer Purchase Orders," Revision 4, dated August 27, 1996

- PCI Engineering System Procedure (ESP) 2010, "Customer Order Review," Revision 9, dated July 22, 2010

- AREVA 56-9141754-000, "Quality Assurance Program," Revision 0, dated August, 15, 2010

- AREVA AP 1708-08, "Quality Control Surveillance," Revision 24, dated August 8, 2008

- AREVA AP 1212-12, "Purchasing Documents," Revision 33, dated September 30, 2009

- AREVA AP 0412-67, "Processing Technical Documents from Suppliers and Customers," Revision 30, dated December 17, 2009

In addition, the NRC inspectors reviewed the following sample of POs to verify proper implementation of MHI's procurement document control program:

- MHI PO No. MNP-0458, "US-APWR Design Certification for Design and Evaluation of Sump Strainer [Part A]," to Performance Contracting Inc., dated September 12, 2008

- MHI PO No. MNP-0136, "US-APWR Design Certification/Purchase Order for Design and Evaluation of Sump Strainer [Part C]," to PCI, Revision 1, dated April 22, 2011.

- MHI Document No. 4CE-UAP-20080009, "US-APWR Standard Design Purchasing Specification Design and Evaluation of Sump Strainer," Revision 1, dated August 25, 2008,and Revision 11, dated May 16, 2011

- 4CS-UAP-20080045, "Technical Information and Requirements for ECCS/CS Sump Strainer," Revision 9, dated May 13, 2011

- PCI Customer Order Review (COR) Issue No. 5, dated May 31, 2011

- PCI PO No. 9627, "MHI-US APWR Tank Test," dated April 14, 2011 to AREVA

- PCI Technical Document No. TDI-6032-01, "SFS Surface Area, Flow and Volume MHI US-APWR," Revision 3 dated June 3, 2011

- PCI COR of MHI PO No. MN-0458, PCI Job No. 90-6032, dated November 25, 2008.

- PCI Document No. SFS-TI-01, "Material Handling and Storage Instructions for Debris Testing Sure-Flow Strainers, Revision 1, dated June 2, 2011

- AREVA PO No. 01011036857, Change Order No. 001, to ARL, dated June 6, 2011

- AREVA PO No. 1030046914 to Davis INOTEK Instruments, LLC for calibration of Digital Multimeter ALDEN S/N 788, AREVA Control # VH-11575, dated September 24, 2010

b. Observations and Findings

b.1 Policies and Procedures

Section 4 of MHI's QAM describes the process for developing POs, including a description of the procedure for the development and distribution of purchasing specifications, procurement planning, organizational roles and responsibilities, verification of purchased product, selection of vendors and services, methods for source and receipt inspection, and vendor evaluation. This QAM applies to the procurement of nuclear safety related jobs and those not related to the American Society of Mechanical Engineers (ASME) Boiler and Pressure Vessel Code jobs for the US-APWR DC project.

Appendix A-9 of MHI's QAP supplements the requirements of the QAM by providing specific guidance for the preparation, review, and approval of procurement documents. All procurement document changes shall be subject to the same degree of control as in the preparation of the original documents. Applicable technical, regulatory, administrative, quality, and reporting requirements (such as specifications, codes, standards, tests, inspections, special processes, and 10 CFR Part 21 requirements) are invoked for the procurement of items and services.

Section 400 of PCI's QAP describes procedures established to verify that design inputs and quality requirements are included in procurement documents. All procurement document changes are subject to the same degree of control as utilized in the preparation of the original documents.

PCI QCP 140 supplements the requirements of PCI's QAP by providing specific guidance for the preparation, review, and approval of customer procurement documents and transfer of requirements into the design and fabrication of ECCS strainers.

PCI ESP No. 2010 describes the customer order review process and the authority and responsibilities for the review, approval, and documentation of each COR on the COR form. Changes or revisions to customer POs receive the same level of review as the original PO.

Section 4.0 of AREVA's QAP defines the procurement document controls for safety-related services, and describes the process for developing POs including a description of the procedure for purchasing materials and equipment, organizational roles and responsibilities, scope of purchase documentation, verification of purchased product, supplier surveillance, and control of production and service processes.

AREVA's AP 1212-12 defines the purchasing method, responsibilities, quality requirements, and actions necessary to prepare and process purchasing documents.

b.2 Implementation of Procurement Document Process

The NRC inspection team reviewed the following POs and associated documents to verify proper implementation of the MHI, PCI, and AREVA procurement document control programs.

MHI PO No. MNP-0136 [PART C] Revision 2, to PCI

MHI contracted PCI to provide a qualified Sure-Flow Suction Strainer (SFS) specifically designed for the US-APWR to be used in the ECCS in accordance with the requirements of MHI's PO Specification No. 4CE-UAP-20080009.

Section 2 of 4CE-UAP-20080009 specifies that PCI shall perform sump strainer design and evaluation work. The scope of work required PCI to: (1) perform additional testing for the debris laden condition(s) of the SFS system; (2) provide an additional test report of the prototype testing; (3) provide the total strainer head loss calculation using the results of additional testing and the calculated clean strainer head loss; (4) provide licensing support and documentation necessary to obtain NRC approval for the SFS design and; (5) evaluate the strainer bypass ratio of fiber debris and provide a report of the evaluation.

The NRC inspection team reviewed elements of the work authorization agreement, with particular attention to the provisions of Section 4, "Quality Assurance," Section 7, "Non Conformance," and Section 8, "Right of Access." These sections required the activities to be conducted in accordance with a 10 CFR Part 50 Appendix B program and with ASME NQA-1-1994, "Quality Assurance Requirements for Nuclear Facility Applications." Nonconformance reporting, right of access to suppliers, and 10 CFR Part 21 were also invoked.

The NRC inspection team confirmed that MHI's purchase specification adequately transferred the requirements to each lower tier of procurement such as right of access to the contractor's facilities and records for inspection or audit, reporting of nonconformances, storage of documents and records, QA requirements, design control and changes, and acceptance inspection conditions and delivery.

In addition, the NRC inspection team verified that PCI reviewed an MHI revision to the PO and incorporated changes into PCI's work order in accordance with PCI's QAP. PCI documented this PO review in PCI COR Issue No. 5.

PCI PO No. 9627 to AREVA

PCI subcontracted with AREVA to develop the testing procedures and to perform testing activities under AREVA's 10 CFR Part 50 Appendix B QAP. The PO scope included testing services for SFS qualification testing for MHI which included debris testing at ARL. Any nonconformances or deviations from the protocols of the test plan developed by AREVA were required to be identified for disposition and concurrence with PCI and MHI before implementation.

The NRC inspection team reviewed elements of the work authorization agreement, with particular attention to the provisions of PCI VQ-1, "Vendor Quality Requirements Safety Related," attached to the contract. PCI VQ-1 requires suppliers to implement a QAP that meets the applicable regulatory, code(s) and standard(s) including compliance with the requirements of Appendix B to 10 CFR Part 50, basic and supplementary requirements of NQA-1-1994, QA requirements for certificate of conformance, certificate of material test report requirements, maintenance of identification and traceability of all materials, and extension of technical and quality requirements to subsuppliers with regard to the right of access to facilities and subtier suppliers, 10 CFR Part 21 reporting requirements, reporting of nonconforming conditions to PCI and the right to inspect and test materials before acceptance.

The NRC inspection team verified that PCI design inputs were adequately transmitted to AREVA for test plan preparation and confirmed that all technical and quality requirements imposed by PCI were adequately incorporated into PO No. 9627.

The NRC inspection team also verified that AREVA documented its contract review of PCI PO No. 9627 on Project Work Authorization Form 0303-F01in accordance with the requirements of AREVA's QAP.

AREVA PO No. 1011036857 - Change Order No. 001 to Alden Research Laboratories

AREVA contracted with ARL to use of its test facility, measuring and test equipment (M&TE), and test support personnel during the SFS testing in support of MHI's US-APWR DC application. This contract was an augmented quality PO that required ARL to provide test support under the control of AREVA's QAP. The contract required ARL to provide procedures, QA data packages, certificates of conformance, drawings, and the right to access its vendor facility. Change Order No. 001 was initiated to revise the PO and invoke PCI document No. SFS-TI-01. The contract included provisions for surveillance and verification activities by AREVA and for the use of M&TE.

AREVA's PO No. 1030046914 dated September 24, 2010 to Davis INOTEK Instruments, LLC for calibration of Digital Multimeter ALDEN S/N 788, AREVA Control# VH-11575

AREVA subcontracted with Davis INOTEK Instruments for the supply of safety-related calibration services for ARL's M&TE to be used in MHI's DC testing of the ECCS strainers. The NRC inspection team reviewed this PO to determine whether the requirements identified in the procedures were imposed on the purchasing document. The NRC inspection team verified that the AREVA PO adequately documented the procurement requirements in accordance with AREVA's QAP. Documentation included task definitions and responsibilities, imposition of appropriate quality, technical, and regulatory requirements, and identification of applicable codes and standards. In addition, the NRC inspection team found that the PO adequately defined contract deliverables, disposition of nonconformances, access rights, and extension of contractual requirements to subcontractors.

c. Conclusions

The NRC inspection team concluded that the implementation of MHI, PCI and AREVA's procurement document program is consistent with the regulatory requirements of Criterion IV, "Procurement Document Control," of Appendix B to 10 CFR Part 50. Based on the sample of documents reviewed, the NRC inspection team determined that MHI, PCI and AREVA are effectively implementing their policies and procedures in support of MHI's DC testing for the US-APWR ECCS strainers. No findings of significance were identified.

4. Control of Purchased, Material, Equipment and Services

a. Inspection Scope

The NRC inspection team reviewed the implementation of the MHI, PCI, and AREVA QA programs for control of purchased material, equipment, and services in support of MHI's DC testing for the US-APWR ECCS strainer. Specifically, the NRC inspection team reviewed the policies and implementing procedures governing the implementation of the MHI, PCI, and AREVA programs for the control of purchased material, equipment, and services to verify

compliance with the regulatory requirements of Criterion VII, “Control of Purchased Material, Equipment, and Services,” of Appendix B to 10 CFR Part 50. In addition, the NRC inspection team also discussed the programs for the control of purchased equipment, material, and services with management and technical staff of MHI, PCI and AREVA.

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

- MHI UES-20080022, “Quality Assurance Manual (QAM) Nuclear Safety Related for Non ASME Code Job,” Revision 2, dated April 15, 2011
- MHI QAP Appendix A-9 (5HE9-092-050E), “Procurement Control Procedure,” Revision 2, dated April 15, 2011
- MHI 5ZD91-56, “Audit Procedure,” Revision 0, dated April 28, 2011
- MHI 5ZD91-55, “QA Monitoring Procedure for Vendor,” Revision 0, dated April 28, 2011
- MHI 5ZD91-57, “Procedure for Annual Evaluation of Vendors,” Revision 0, dated April 28, 2011
- MHI 5ZD91-51, “Qualification and Certification Procedure of Lead Auditor,” Revision 0, dated May 25, 2011
- MHI UES-20112036, “Qualified Auditor and Lead Auditor List,” Revision 2, dated January 9, 2011
- MHI 5HE9-092-052E, “Supplier Quality Assurance Program Requirements for Design and Test Activities,” Revision 1, dated November 30, 2010
- PCI QCP 4050, “Material Procurement,” Revision 5, dated March 1, 1999
- PCI QCP 0710, “Vendor Evaluation and Classification,” Revision 11, dated March 21, 2009
- PCI QCP 0715, “Vendor Evaluation for Nuclear Safety Related Suppliers,” Revision 0, dated March 31, 2009
- PCI QCP 1820, “Lead Auditor Certification,” Revision 6, dated July 22, 2010
- PCI SFS-TI-01, “Material Handling and Storage Instructions for Debris Testing Sure-Flow Strainers, Revision 1, dated June 2, 2011
- AREVA 56-9141754-000, “Quality Assurance Program,” Revision 0, dated August, 15, 2010
- AREVA AP 1212-12, “Purchasing Documents,” Revision 33, dated September 30, 2009
- AREVA AP 1708-08, “Quality Control Surveillance,” Revision 25, dated September 23, 2010

- AREVA AP 1710-02, "Appointment of Level III Quality Control Inspection and Surveillance Examiner," Revision 013, dated October 13, 2010

- AREVA Technical Document No. 63-9160802, "US-APWR Test Plan for ECCS Strainer Performance," Revision 0, dated June 3, 2011

b. Observations and Findings

b.1 Policies and Procedures for Vendor Qualification

Section 4 of MHI's QAM establishes the measures and governing procedures to control the procurement of items and services to ensure conformance with specified requirements. It also describes the process for source evaluation, selection, and annual evaluation of vendors. Vendors are audited triennially and evaluated annually. Annual evaluations may be completed through audits or by a review of vendor-furnished documents, results of previous source and receiving inspections, and/or the results of audits performed by other parties. Section 4 states that the Nuclear Plant Quality Assurance Section (NPQAS) is responsible for preparing, approving, and distributing the qualified vendor list, (QVL) and any revisions thereto.

Appendix A-9 of MHI's QAP provides further details on MHI's policies for evaluating the quality control capability of vendors supplying material and equipment. The appendix includes templates for the "Checklist for Vendor's Quality Assurance Program" used to identify the audit and survey criteria and the "Questionnaire for Performance Assessment" used as a tool for gathering information from vendors for annual evaluations.

Section 6 of MHI 5ZD91-56 provides general guidance for conducting both internal audits and vendor audits. The standard sets forth the minimum requirements for audit plans, reports, and conduct; it also requires that audit plans be prepared before each audit and include an audit checklist. Reports must be written within 30 days of audit completion.

MHI 5ZD91-57 describes the process for performing annual audits of vendors for safety-related items and services. Annual audits shall be performed by qualified lead auditors and results of the audits shall be documented in accordance with established MHI procedures.

MHI 5ZD91-51 defines the process for qualifying auditors and leads auditors for MHI, including the process for maintaining the auditor qualification and the education, training, and experience required to perform the audit function.

QCP 0710 defines the methodology and criteria for vendor selection, vendor qualification, source surveillance, vendor audits, and commercial-grade surveys performed to support procurement activities for nuclear or augmented quality customer orders. Vendors are classified based on the scope of supply: Class I for nuclear safety-related material and services, and Class II for suppliers of commercial grade materials and services that may be dedicated for nuclear safety related applications.

QCP 0715 establishes the requirements and methods for implementing the program for evaluating and classifying suppliers as nuclear safety-related or Class I. The procedure describes the method of accepting audits performed by the Nuclear Industry Assessment Committee (NIAC). NIAC consists of companies that supply goods and services to the nuclear industry based on a quality program that meets the requirements of Appendix B to 10 CFR Part 50 or ASME NQA-1 (1989), and accept 10 CFR Part 21 requirements. NIAC develops and

maintains procedures and processes necessary to plan, guide, and share supplier evaluations (audits) with its members. PCI uses NIAC audits to support the qualification and maintenance of its suppliers.

QCP 1820 describes specific controls for qualifying lead auditors for PCI, including the process for maintaining auditor qualification and the requisite education, training, and experience required to perform the audit function.

Section 7 of AREVA's QAP establishes measures for the control of purchased safety related materials, items, and services including source evaluation and selection of suppliers, source inspection, and receiving inspection in accordance with regulatory and contract requirements. Section 7.2, "Supplier Evaluation, and Selection," describes the method of selecting, evaluating suppliers to meet the requirements of Appendix B to 10 CFR Part 50, and NQA-1 for safety related materials, items, or services. Section 7.2.2 describes the process for qualifying and placing procurements on commercial calibration suppliers for safety related applications. Section 7.3, "Approved Suppliers List (ASL)," describes the authority and responsibility for maintaining, and updating the ASL based on suppliers meeting AREVA's qualification criteria for safety related items and services.

b.2 Maintenance of the Qualified Vendor List/Approved Vendor List/Approved Supplier List

The NRC inspection team reviewed the QVL for MHI and the AVL for PCI and ASL for AREVA to ensure that qualified and approved suppliers were listed, that the lists were maintained, distributed, and periodically updated by authorized personnel, and that any revisions to the lists were implemented following the applicable procedures. The NRC inspection team confirmed that the suppliers performing work for MHI, PCI, and AREVA with respect to the DC testing of the ECCS strainers were appropriately listed on the MHI, PCI, and AREVA lists. In addition, the NRC inspection team confirmed that their scope of supply was documented and consistent with the activities contracted with MHI, PCI, and AREVA.

b.3 External Audits

The NRC inspection team reviewed a sample of external audits and annual vendor evaluations to verify the implementation of the MHI, PCI and AREVA audit programs. The NRC inspection team verified that plans identifying the audit scope, focus, and applicable checklist criteria had been prepared and approved before the initiation of the audit activity. In addition, the NRC inspection team verified that qualified lead auditors and auditors performed the external audits.

The NRC inspection team confirmed that the audit, annual evaluation, and commercial grade survey reports contained a review of the relevant QA criteria in Appendix B to 10 CFR Part 50 for the activities performed by the individual suppliers as well as documentation of pertinent supplier guidance associated with each criterion. For audits and surveys resulting in findings, the NRC inspection team verified that the supplier had established a plan for corrective action and that MHI had reviewed and approved the corrective action and verified its satisfactory completion and proper documentation.

b.4 Source Surveillance and Receiving Inspections

Sections 4.3.10.1 and 4.3.10.2 of MHI's QAM describe the requirements for performing source and receiving inspections, respectively. Source inspections are performed at the vendor site, as

required by the purchase specification and are performed by qualified QA or QC personnel. QC personnel also perform receipt inspections using a checklist.

PCI SFS-TI-01 provides the receiving, handling, and storage instructions for PCI's strainer testing vendor. The procedure describes the requirements for debris related to material receiving, storage, handling, inventory, and use. This procedure states that upon receipt of the test units, the vendor will examine the packaging to ensure that no significant damage has occurred. If any damage is found, PCI shall be contacted for further instructions.

Section 7.6 ,"Receiving Inspection," of AREVA's QAP describes the process of performing receipt inspection to verify objective evidence such as proper configuration, identification, dimensional, physical, and other characteristics, freedom from shipping, damage, and cleanliness. Incoming items at the site or at AREVA for use in safety related component applications will undergo receiving inspection by inspection personnel before release of such items for further processing. Receipt inspections will be performed to ensure compliance with procurement documents. AREVA QA personnel will verify that all supplier documentation required by procurement documents has been reviewed for completeness and meets compliance requirements.

The NRC inspection team reviewed the receipt inspection performed on the following:

- MHI acceptance check sheet of deliverables dated June 7, 2011, documenting review and approval of PCI's documents ensuring that deliverables meet MHI procurement documents.

- PCI receiving inspection report for MRR No. LN-620 from OCC, on PO No. 8569, performed and accepted on December 11, 2007, receiving NUKON Base Wool product code 53-020 lot No. 10/09/7ND5.

- AREVA as-built dimensional receipt inspection dated June 6, 2011, documenting, " as-built satisfactory," of US-APWR Test Tank, Piping Schematic and Test Flume Configuration.

- AREVA draft Quality Control Surveillance Report No. 9162972-00 for PO No. 1011023857, documenting ongoing QA oversight of ARL testing activities performed in accordance with AREVA QAP.

- AREVA receipt inspection report dated December 3, 2010, for Scale 30 kg, AREVA Control No. VH-11585, ARL S/N 2925189, calibrated by Tektronix Service Solutions (Davis INOTEK Instruments).

- AREVA receipt inspection report dated May 16, 2011 for PO No. 1011020419 documenting calibration of Flowmeter, AREVA Control No. VH-11691, ARL954 calibrated by ARL

- AREVA receipt inspection report dated October 27, 2010 for PO No. 59228, documenting calibration services performed by Textronix Services Solutions (Davis INOTEK Instruments) on Pressure Cell AREVA Control No. VH-11578, S/N 0279408, ARL S/N ARL0938,

- PCI Calculation Cover Sheet for Calculation No. EC-MHIUSA-6032-1010, Revision 0, "AREVA Document 63-9160802-000, "US-APWR Test Plan for ECCS Strainer Performance Testing 2011," verified and approved by PCI on June 6, 2011.

The NRC inspection team reviewed a sample of source surveillances and receipt inspection reports and verified that the inspection checklists were adequately completed and that there was enough objective evidence to verify that the items conformed to the purchase specifications.

b.5 Auditor Training and Qualification

The NRC inspection team reviewed a sample of the training and qualification records for a sample of lead auditors and auditors for MHI, PCI, and AREVA and confirmed that auditing personnel had completed all required training and maintained qualification and certification in accordance with the MHI, PCI, and AREVA policies and procedures. The NRC inspection team also verified that audit teams selected by MHI, PCI, and AREVA were sufficiently qualified to evaluate areas within the scope of the audit and that the auditors were not auditing their own work.

c. Conclusions

The NRC inspection team concluded that the implementation of the MHI, PCI, and AREVA programs for the control of purchased material, equipment, and services is consistent with the regulatory requirements of Criterion VII of Appendix B to 10 CFR Part 50. Based on the sample of documents reviewed, the NRC inspection team concluded that MHI, PCI and AREVA are effectively implementing their policies and procedures in support of MHI's DC testing for the US-APWR ECCS strainers. No findings of significance were identified.

5. Test Control

a. Inspection Scope

The NRC inspection team reviewed the implementation of the AREVA'S test control program in support of MHI's DC testing for the US-APWR ECCS strainers. Specifically, the NRC inspection team reviewed the policies and procedures governing the implementation of AREVA's test control to verify compliance with the regulatory requirements of Criterion XI, "Test Control," of Appendix B to 10 CFR Part 50. In addition, the NRC inspection team also discussed the test control program with the management and technical staff of MHI, PCI and AREVA.

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

- AREVA 56-9141754, "Quality Assurance Program," Revision 0, dated August 15, 2010

- 0504-14, "Framatome ANP, Inc. (FANP) Prepared Site Support Documents," Revision 20, dated June 20, 2005

- 4CS-UAP-20080045, "US APWR Standard Design Technical Information and Requirements for ECCS/CS Sump Strainer," Revision 9, dated May 13, 2011

- 63-9160802-000, AREVA NP Inc. Technical Document, "US-APWR Test Plan for ECCS Strainer Performance Testing 2011," Revision 0, dated June 3, 2011

- AP 0412-67, "Processing Technical Documents from Suppliers and Customers," Revision 30, dated December 17, 2009

- AP 0504-14, "Framatome ANP, Inc. (FANP) Prepared Site Support Documents," Revision 20, dated June 20, 2005

- AP 0902-30, "Management and Use of Engineering Applications Software," Revision 03, dated April 8, 2011

- Technical Document SFSS-TD-2007-004, "Sure-Flow Suction Strainer – Testing Debris Preparation & Surrogates," Revision 4, dated January 16, 2009

- MHI PO MNP-0458 issued to PCI, dated September 2, 2008

- PCI PO 9627 issued to AREVA, dated April 14, 2011

- AREVA PO 1011036857 issued to ARL, dated June 6, 2011

- PCI PO 9637 issued to Chips Unlimited, Inc, dated April 28, 2011

b. Observations and Findings

b.1 Policies and Procedures

Section 7 of AREVA's QAM identifies the test control activities for testing safety-related items that are required to demonstrate compliance with regulatory and contract requirements.

AP 0504-14 identifies the guidance for preparing test procedures that included review and approval responsibilities, test objectives, system configuration, environmental conditions, acceptance criteria, data collection, a method for conducting the test, and a reference section.

AP 0902-30 describes the guidance for the management and use of engineering application software and provides procedures for using scripts, macros, small easily understood software, and program add-ins within engineering applications.

Test procedure 63-9160802-000 outlines the plan and procedures for testing ECCS strainer modules for the US-APWR in a test tank. This document also includes the test objectives and scope, acceptance criteria, configuration, special precautions, equipment, data measurement and analysis, and evaluation of results.

The NRC inspection team determined that AP 0504-14, AP 0902-30, and 63-9160802-000 provided adequate guidance for the testing associated with the US-APWR ECCS strainers in support of the MHI's US-APWR DC.

b.2 In-Process Test Control

The NRC inspection team reviewed and evaluated test procedures and observed the performance of testing activities associated with the US-APWR ECCS strainer performance testing. Specifically, the NRC inspection team observed the FOB and the DTSHL tests. The purpose of the FOB test is to establish the maximum absolute fiber amount to possibly bypass the strainer while the purpose of the DTSHL test is to measure the maximum head loss across the strainer with the design basis debris loading.

The NRC inspection team verified that the test procedures identified the objectives, requirements, prerequisites, and acceptance criteria in accordance with the MHI purchase specification. The NRC inspection team also verified that qualified individuals test results documented and evaluated the test results to ensure that the performance requirements were satisfied.

The NRC inspection team witnessed portions of the FOB and DTSHL tests to verify effective test implementation in accordance with AREVA's test plan and procedures. Specifically, the NRC inspection team observed that members of the AREVA and ARL staff adequately reviewed and documented the following: 1) completion of activities that must be performed before testing, such as test loop cleanliness, equipment installation, and test conditions (fluid temperature, flow rate); 2) calibration of equipment and recording of test equipment calibration information; 3) verification that the test apparatus configuration matches the test plan configuration; and 4) preparation and addition of debris. The NRC inspection team noted that the required data collection was recorded in a testing log book or computerized data sheets within the test procedure.

During the conduct of the FOB and DTSHL tests, the NRC inspection team observed that the AREVA test engineer made changes to the test procedures included in Technical Document 63-9160802-000 whenever he determined that the test could not be conducted as written. After writing in the change, which in some cases involved completely removing an existing step and replacing it with a different step; he would initial and date the change and continue with the test. No additional review or approval was documented contrary to Section 6.2.2 of AREVA's 56-9141754, "Document Change Control," which states, in part, that "Changes and revisions to the documents listed in Section 6.1 shall have at least the same review and approval as the original document." Section 6.1, "General," of AREVA's 56-9141754 identifies test procedures as the type of document that shall be controlled in accordance with Section 6.2.2. Additionally, Section 5.1, "General," of AREVA's 56-9141754, states that "Instructions, procedures, and drawings shall be prepared, reviewed, approved, and distributed before beginning the activity."

The observed changes ranged from minor changes to the inclusion of a complete new section to the test procedure. In one instance, the NRC inspection team observed a change made to an acceptance criterion in the nonconservative direction. The NRC inspection team reviewed the changes that were made and did not find any that would necessarily invalidate the testing results. While the one change to an acceptance criterion in the non-conservative direction was made, based on the testing process used there was considerable margin for reducing it without affecting the validity of the results. The NRC inspection team noted that none of AREVA's QA procedures reviewed allowed the test engineer to make changes to the test procedures and proceed with the test without having the changes reviewed with the same level of review and approval as the original test procedures.

Based on the above, the NRC inspection team concluded that AREVA failed to meet the requirements of 10 CFR Part 50, Appendix B, Criteria V, VI, and XI, in that a test procedure was implemented with unapproved changes. The NRC inspection team identified this issue as Violation 05200021/2011-201-02. The NRC inspection team noted that AREVA had not issued a CAR to address this issue at the time of the inspection.

c. Conclusions

The NRC inspection team concluded that AREVA did not implement its document and test control programs consistent with the requirements of Criterion XI, "Test Control;" Criterion VI, "Document Control;" and Criterion V, "Instruction, Procedures, and Drawings;" of Appendix B to 10 CFR Part 50. The NRC inspection team issued Violation 05200021/2011-201-02 for MHI's failure to verify that changes to Technical Document 63-9160802-000, Revision 0, made in the field by the AREVA test engineer, had the same review and approval as the original document.

6. Control of Measuring and Test Equipment

a. Inspection Scope

The NRC inspection team reviewed the implementation of the AREVA program for the control of M&TE equipment in support of MHI's DC testing for the US-APWR ECCS strainers. Specifically, the NRC inspection team reviewed the policies and procedures governing the implementation of AREVA's control of the M&TE program to verify compliance with the regulatory requirements of Criterion XII, "Control of Measuring and test Equipment," of Appendix B to 10 CFR Part 50. In addition, the NRC inspection team also discussed the control of the M&TE program with management and technical staff of MHI, PCI and AREVA.

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

- AREVA 56-9141754, "Quality Assurance Program," Revision 0, dated August 15, 2010
- AP 0509-11, "Measuring and Test Equipment Calibration," Revision 1, dated March 1, 2011
- AP 0902-30, "Management and Use of Engineering Applications Software," Revision 03, dated April 8, 2011
- 63-9160802-000, AREVA Technical Document, "US-APWR Test Plan for ECCS Strainer Performance Testing 2011," Revision 0, dated June 3, 2011

b. Observations and Findings

b.1 Policies and Procedures

Section 12 of AREVA's QAP establishes the elements of M&TE control as required by regulations, while AP 0509-11 contains the methods used to calibrate, identify and control M&TE.

b.2 Implementation of Control of Measuring and Test Equipment

The NRC inspection team observed the flow measurement and strainer differential pressure (DP) calibration checks. All the data acquisition intelligence and instrument calibration information was coded in a data reduction interface that was developed in-house at ARL using LabVIEW. The NRC inspection team observed the Pre-Test Instrumentation & Data Acquisition Check (Appendix I to AREVA's Document No. 63-9160802-000) as AREVA and ARL personnel performed it for the strainer testing using a micro-manometer. AREVA's 30-step Appendix I pretest procedure is essential to validating the overall M&TE calibration before the actual head loss test data could be acquired. Visual inspection of the overall measurement train of wiring, tubing, and valve setting was also a part of the Appendix I procedure. The NRC inspection team independently confirmed the data acquisition system's output by calculating the output parameters by hand, using their original calibration equations. In the Appendix I procedure, the acceptance criteria for the data acquisition system's outputs were based on the maximum discrepancy allowed between the measured and hand calculated values. For example, DP cell readings were acceptable if the discrepancy between measured and hand calculated values was less than 0.25 percent of the total range. Based on a review of the computer program and hand calculations, the NRC inspection team verified that AREVA's application of the computer program adhered to the procedural requirements. The NRC inspection team did not observe any major issues while reviewing the pretest procedure but did note that there was no acceptance criterion identified for the flow rate measurements in AREVA's pretest instrumentation and data acquisition system check. AREVA generated CR 2011-4368 to include the missing acceptance criterion for the flow rate.

At the end of the pretest check, the NRC inspection team obtained a hard copy of ARL's comparison of the data acquisition output and the hand calculations performed using the calibration equations and the independent voltmeter reading. The NRC inspection team was also able to independently verify the pretest calibration results by doing hand calculations. ARL used LabVIEW to convert test sensor outputs into standard engineering units such as flow (gpm) or DP (inches of water). The NRC inspection team concluded that the M&TE calibration was within the specified tolerance limits at the beginning of the test.

The NRC inspection team also verified that the voltmeter, DP cell, and resistance temperature detector (RTD) probe readings were within the temperature and pressure measurement acceptance criteria identified in AREVA's test procedure 63-9160802-000, as well as in Appendix I.

The NRC inspection team verified that the M&TE sampled had appropriate calibration stickers and current calibration dates, including the calibration due date, and that records were available for review. The NRC inspection team verified that the M&TE used in the laboratory was calibrated using procedures traceable to known industry standards and calibration results were recorded, reviewed, and verified by test personnel. Calibration records indicated the calibration procedure to be used, the as found and as left conditions, the accuracy required, the date of calibration and due date for recalibration, and the applicable National Institute of Standards and Technology traceable reference equipment used in the calibration.

Conclusions

The NRC inspection team concluded that the implementation of AREVA's program for the control of M&TE is consistent with the regulatory requirements of Criterion XII of Appendix B to 10 CFR Part 50. Based on the sample of documents reviewed, the NRC inspection team

concluded that AREVA is effectively implementing its policies and procedures in support of MHI's DC testing for the US-APWR ECCS strainer. No findings of significance were identified.

7. Nonconforming Materials, Parts or Components and Corrective Actions

a. Inspection Scope

The NRC inspection team reviewed the implementation of the AREVA program for the control of nonconformances and its corrective action program in support of MHI's DC testing for the US-APWR ECCS strainers. Specifically, the NRC inspection team reviewed the policies and procedures governing the implementation of AREVA's program for control of nonconformances and its corrective action program to verify compliance with the regulatory requirements of Criterion XV, " Nonconforming Material, Parts, or Components," and Criterion XVI, "Corrective Action," of Appendix B to 10 CFR Part 50. In addition, the NRC inspection team also discussed the control of nonconformances and corrective action programs with AREVA's management and technical staff.

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

- PCI "Quality Assurance Program," Revision 3, dated October 1, 2010
- PCI QA Procedure 1610, "Corrective Action," Revision 6, dated March 31, 2010
- AREVA 56-9141754, "Quality Assurance Program," Revision 0, dated August 15, 2010
- AREVA AP 1717-06, "Corrective Action Program - WebCAP," Revision 5, dated June 16, 2010
- AREVA AP 1703-01, "Restraint Order," Revision 29, dated February 17, 2011
- AREVA WebCAP 2011-4032-CR, "Paint Chips in APWR ECCS Strainer Test Flume at Alden," dated June 6, 2011
- AREVA WebCAP 2011-4164-CR, "Chemical Mixing," dated June 9, 2011

b. Observations and Findings

b.1 Policies and Procedures

Section 1600 of PCI's QAP, "Corrective and Preventative Action," describes the procedures established to identify, document, and correct conditions adverse to quality. This section also states that the procedures shall require documentation of cause and management involvement for significant conditions adverse to quality.

QA 1610 describes PCI's process for identifying and responding to activities adverse to the quality of materials and services. This procedure contains provisions for reporting conditions adverse to quality to management and documenting them in a corrective action report (CAR). The procedure also provides a link to QC Procedure 1510, and QC Procedure 1010, for evaluating 10 CFR Part 21 deviations.

Section 16 of the AREVA's QAP, "Corrective Action," describes the procedures for identifying and correcting conditions adverse to quality. The procedures ensure that nonconformances and failures are evaluated for corrective actions, that causes of nonconformances and failures are determined, that management is informed of significant conditions adverse to quality, and that follow-up actions are taken to ensure implementation of corrective actions. In accordance with Section 15 of the AREVA's QAP, "Nonconforming Items," CRs also document nonconforming items.

AREVA AP 1717-06 describes the process for identifying of conditions adverse to quality and the generation of a CR in WebCAP to document the issue. AP 1717-06 also describes controls for nonconforming items including identification, documentation in a WebCAP CR, segregation and disposition. Any anomalies, errors, or deviations identified during testing are evaluated for the generation of a CR against the thresholds in AP 1717-06. In accordance with AP 1717-06, CRs are screened for significance and potential reportability under 10 CFR Part 21 and are evaluated for corrective action. Depending on the significance of the conditions, a root or apparent cause analysis may be performed to identify additional needed preventive or corrective actions. AREVA generates and approves corrective actions in WebCAP and assigns an action owner. Once an action has been taken, objective evidence must be documented before approval and closure.

b.2 Implementation of Control of Nonconformances and Corrective Action and Programs

The NRC inspection team noted that testing activities had begun the week before the inspection and that AREVA had generated two CRs. The NRC inspection team verified that issues had been accurately documented in the CRs and screened in accordance with AP 1707-06. The NRC inspection team also verified by interviewing ARL personnel working under AREVA's QAP, as well as by attending prejob briefings, that ARL personnel had the means to identify conditions adverse to quality.

In addition, the NRC inspection team interviewed responsible AREVA staff and management as part of its evaluation of AREVA's corrective action program. The NRC inspection team noted that AREVA's policies and implementing procedures provided the necessary guidance to adequately document, evaluate, correct, report, and verify the resolution of conditions adverse to quality.

During the preparation of chemical debris, the NRC inspection team noted that the settling rate of the chemical precipitate did not achieve the acceptance criteria of the test plan. AREVA verbally informed PCI and MHI of the issue and made a note in the test plan used to conduct and document the test. Subsequently, PCI informed the NRC inspection team that it had generated CR No. 11-003 to document the failure to achieve the settling rate required by the test plan in accordance with PCI QA 1610. The NRC inspection team reviewed the CR and noted that one of the corrective actions was to change the acceptance criteria consistent with NRC's Safety Evaluation Report, "Final Safety Evaluation by the Office of Nuclear Reactor Regulation, Topical Report WCAP-16530-NP-A 'Evaluation of Post-Accident Chemical Effects in Containment Sump Fluids to Support GSI-191," dated December 21, 2007 (ADAMS Accession No. ML073520891). Another corrective action was to document and submit a deviation form to MHI as required by the PO.

Because of the short timeframe of MHI's testing activities, the NRC inspection team was unable to evaluate the timeliness or effectiveness of corrective actions for conditions adverse to quality related to the DC testing.

c. Conclusions

The NRC inspection team concluded that the implementation of AREVA's program for control of nonconformances and its corrective action program is consistent with the regulatory requirements of Criterion XV, "Nonconforming Materials, Parts or Components," and Criterion XVI, " Corrective Action," of Appendix B to 10 CFR Part 50. Based on the sample of documents reviewed, the NRC inspection team determined that AREVA is effectively implementing its policies and procedures in support of MHI's DC testing for the US-APWR ECCS strainers. No findings of significance were identified.

8. Quality Assurance Records

a. Inspection Scope

The NRC inspection team reviewed the implementation of AREVA's QA records program in support of MHI's DC testing for the US-APWR ECCS strainers. Specifically, the NRC inspection team reviewed the policies and procedures governing the implementation of AREVA's QA records process to verify compliance with Criterion XVII, "Quality Assurance Records," of Appendix B to 10 CFR Part 50. In addition, the NRC inspection team discussed the QA records program with AREVA's management and technical staff.

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

- AREVA 56-9141754, "Quality Assurance Program," Revision 0, dated August 15, 2010
- AREVA Procedure 1E1, "Records Management Program Manual," Revision 23, dated February 9, 2011
- AREVA AP 1302-01, "Records Retention," Revision 0, dated April, 28 2008
- AREVA AP 1301-01, "Documentum Contract Technical Record Processing," Revision 3, dated October 22, 2010

b. Observations and Findings

b.1 Policies and Procedures

Section 17 of AREVA's QAP describes the measures and governing procedures that have been established to ensure that records of items and activities affecting quality are collected, retained and retrievable. The provisions of such procedures establish the scope of the records retention program and include requirements for records administration, receipt, preservation, retention, storage, safekeeping, retrieval, access controls, user privileges and final disposition.

Procedure 1E1 establishes guidance for the creation, authentication, storage, maintenance, and retention of all record types generated by AREVA.

AP 1302-01 implements the requirements of AREVA's retention policy and the requirements of Program Manual 1E1. Specifically, it defines the responsibilities and processes to retain, store, and destroy official records for their entire lifecycle.

AP 1301-01 implements the requirements of 1E1, and gives specific guidance on the use of AREVA's enterprise document management system, "Documentum." AREVA uses "Documentum" for all records created during DC testing, such as logs and calculations; all documents generated become part of the official record and are incorporated into "Documentum."

b.2 Implementation of Quality Assurance Records Process

The NRC inspection team reviewed a sample of several records, including forms, tables, and logs used for identification, receipt control, processing, retention, and safekeeping for all documented records generated as part of the ECCS strainer DC testing. During this review, the NRC inspection team verified that AREVA had implemented a QA records program that provided adequate measures for the identification, classification, validation, and distribution controls of records. In addition, the NRC inspection team interviewed responsible AREVA staff and management as part of its evaluation of the AREVA QA records program. The NRC inspection team noted that AREVA's policies and implementing procedures provided the necessary guidance for the administration, identification, receipt, storage, preservation, safekeeping, and disposition of all records.

c. Conclusions

The NRC inspection team concluded that the implementation of AREVA's QA records program is consistent with the regulatory requirements of Criterion XVII, "Quality Assurance Records," of Appendix B to 10 CFR Part 50. Based on the sample of documents reviewed, the NRC inspection team determined that AREVA is effectively implementing its policies and procedures in support of MHI's DC testing for the US-APWR ECCS strainers. No findings of significance were identified.

Entrance and Exit Meetings

On June 13, 2011, the NRC inspection team presented the inspection scope during an entrance meeting with Mr. Joseph Tapia, Senior Director for Licensing, Mitsubishi Nuclear Energy Systems (MNES), and other MHI, PCI, AREVA and ARL personnel. On June 17, 2011, the NRC inspection team presented the inspection results during an exit meeting with Mr. Tapia, MNES, and other MHI, PCI, AREVA and ARL personnel.

ATTACHMENT 1

1. PERSONS CONTACTED

NAME	COMPANY	ENTRANCE MEETING	EXIT MEETING	INTERVIEWED
Takashi Fukuda	MHI	√	√	√
Kiyoaki Tokunou	MHI	√	√	√
Yuji Momose	MHI	√		√
Joseph Tapia	MNES	√	√	√
Ryan Sprengel	MNES	√		√
Erin Wisler	MNES	√		√
Hiroshi Matsuoka	MNES	√		√
Chris Kudla	PCI	√		√
Eric Cox	PCI	√	√	√
Kevin Koelsch	PCI	√	√	√
Jim Bleigh	PCI	√	√	√
Fariba Gartland	AREVA	√		√
Larry Peterson	AREVA	√	√	√
Donald LeFrancois	AREVA	√	√	√
Ludwig Haber	ARL	√	√	√
Annie Humphrey	ARL	√	√	√
Yamir Diaz-Castillo	NRC	√	√	
Garrett Newman	NRC	√	√	
Raju Patel	NRC	√	√	
Ryan Nolan	NRC	√	√	
Clinton Ashley	NRC	√	√	
Syed Haider	NRC	√	√	
Roger Lanksbury	NRC	√	√	

2. INSPECTION PROCEDURES USED

Inspection Procedure 35017, “Quality Assurance Implementation Inspection,” dated July 29, 2008.

Inspection Procedure 36100, “Inspection of 10 CFR Part 21 and 50.55(e) Programs for Reporting Defects and Noncompliance,” dated October 3, 2007.

3. LIST OF ITEMS OPENED, CLOSED, AND DISCUSSED

Item Number	Status	Type	Description
05200021/2011-201-01	Opened	NOV	Criterion II
05200021/2011-201-02	Opened	NOV	Criteria XI, VI, and V