

September 1, 2011

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

SUBJECT: NRC INSPECTION REPORT NO. 05200021/2011-202 AND NOTICE OF VIOLATION

Dear Mr. Ogata:

On July 25–29, 2011, the U.S. Nuclear Regulatory Commission (NRC) staff conducted an inspection at Mitsubishi Heavy Industries (MHI) Takasago Research and Development Center (Takasago) in Takasago, Japan. The purpose of the limited scope inspection was to assess MHI's compliance with the provisions of Title 10 of the *Code of Federal Regulations* (10 CFR) Part 21, "Reporting of Defects and Noncompliance," and selected portions of Appendix B, "Quality Assurance Program Criteria for Nuclear Power Plants and Fuel Reprocessing Plants," to 10 CFR Part 50, "Domestic Licensing of Production and Utilization Facilities." The inspection focused on downstream effects testing activities conducted regarding the U.S. Advanced Pressurized-Water Reactor (US-APWR) design certification (DC) application. 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 six 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 the circumstances surrounding the violations are described in detail in the subject inspection report. The violations are being cited in the Notice because MHI 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, and because MHI failed to implement aspects of its personnel training and qualification program, supplier oversight program, procurement document control program, inspection program, and storage, shipping, and handling program consistent with regulatory requirements.

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 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. 05200021

Enclosures:
As stated

DC Mitsubishi - US APWR Mailing List
cc:

(Revised 05/18/2011)

Ms. Michele Boyd
Legislative Director
Energy Program
Public Citizens Critical Mass Energy
and Environmental Program
215 Pennsylvania Avenue, SE
Washington, DC 20003

Atsushi Kumaki
Mitsubishi Heavy Industries, Ltd.
APWR Promoting Department
Wadasaki-cho- 1-1-1, Hyogo-ku
Kobe 652-8585 JAPAN

Dr. Masanori Onozuka
Mitsubishi Nuclear Energy Systems, Inc.
1001 19th Street North, Suite 710
Arlington, VA 22201-5426

Dr. C. Keith Paulson
Mitsubishi Nuclear Energy Systems, Inc.
300 Oxford Drive, Suite 301
Monroeville, PA 15146

Mr. Tom Sliva
7207 IBM Drive
Charlotte, NC 28262

Mr. Robert E. Sweeney
IBEX ESI
4641 Montgomery Avenue
Suite 350
Bethesda, MD 20814

Mr. Gary Wright, Director
Division of Nuclear Facility Safety
Illinois Emergency Management Agency
1035 Outer Park Drive
Springfield, IL 62704

DC Mitsubishi - US APWR Mailing List

Email

APH@NEI.org (Adrian Heymer)
atsushi_kumaki@mhi.co.jp (Atsushi Kumaki)
awc@nei.org (Anne W. Cottingham)
bgattoni@roe.com (William (Bill) Gattoni)
BrinkmCB@westinghouse.com (Charles Brinkman)
ck_paulson@mnes-us.com (C Keith Paulson)
ckpaulson@aol.com (C.K. Paulson)
CumminWE@Westinghouse.com (Edward W. Cummins)
cwaltman@roe.com (C. Waltman)
david.hinds@ge.com (David Hinds)
david.lewis@pillsburylaw.com (David Lewis)
DeLaBarreR@state.gov (R. DeLaBarre)
Derlinda.Bailey@chguernsey.com (Derinda Bailey)
donald.woodlan@luminant.com (Donald Woodlan)
eliza.seedcoalition@gmail.com (Elza Brown)
erg-xl@cox.net (Eddie R. Grant)
ewallace@nuscalepower.com (Ed Wallace)
f.tanaka@mnes-us.com
gcesare@enercon.com (Guy Cesare)
james.beard@gene.ge.com (James Beard)
jerald.head@ge.com (Jerald G. Head)
jim.riccio@wdc.greenpeace.org (James Riccio)
Joseph_Hegner@dom.com (Joseph Hegner)
jrund@morganlewis.com (Jonathan Rund)
KSutton@morganlewis.com (Kathryn M. Sutton)
kwaugh@impact-net.org (Kenneth O. Waugh)
lchandler@morganlewis.com (Lawrence J. Chandler)
lon.burnam@house.state.tx.us (Lon Burnam)
m.goto@mnes_us.com
Marc.Brooks@dhs.gov (Marc Brooks)
maria.webb@pillsburylaw.com (Maria Webb)
mark.beaumont@wsms.com (Mark Beaumont)
Mark.Crisp@chguernsey.com (Mark Crisp)
mark.g.giles@dom.com (Mark Giles)
mark.vannoy@mnes-us.com
masahiko_kaneda@mhi.co.jp (Masahiko Kaneda)
masanori_onozuka@mnes-us.com (Masanori Onozuka)
masato.oba@mnes-us.com
masayuki_kambara@mhi.co.jp (Masayuki Kambara)
matias.travieso-diaz@pillsburylaw.com (Matias Travieso-Diaz)
mayorsouthern@granbury.org (Mayor David Southern)
media@nei.org (Scott Peterson)
mike_moran@fpl.com (Mike Moran)
MSF@nei.org (Marvin Fertel)

DC Mitsubishi - US APWR Mailing List

mutsumi_ishida@mnes-us.com (Mutsumi Ishida)
mwetterhahn@winston.com (M. Wetterhahn)
nan_sirirat@mnes-us.com (Sirirat Mongkolkam)
nirsnet@nirs.org (Michael Mariotte)
Nuclaw@mindspring.com (Robert Temple)
patriciaL.campbell@ge.com (Patricia L. Campbell)
paul.gaukler@pillsburylaw.com (Paul Gaukler)
Paul@beyondnuclear.org (Paul Gunter)
pbessette@morganlewis.com (Paul Bessette)
plarimore@talisman-intl.com (Patty Larimore)
pshastings@duke-energy.com (Peter Hastings)
RJB@NEI.org (Russell Bell)
ryan_sprengel@mnes-us.com (Ryan Sprengel)
sabinski@suddenlink.net (Steve A. Bennett)
sandra.sloan@areva.com (Sandra Sloan)
satoshi_hanada@mnes-us.com (Satoshi Hanada)
satoshi_watanabe@mnes-us.com (Satoshi Watanabe)
sfrantz@morganlewis.com (Stephen P. Frantz)
shinji_kawanago@mnes-us.com (Shinji Kawanago)
stephan.moen@ge.com (Stephan Moen)
steven.hucik@ge.com (Steven Hucik)
strambgb@westinghouse.com (George Stramback)
Tansel.Selekler@nuclear.energy.gov (Tansel Seleklek)
tgilder1@luminant.com (Tim Gilder)
tmatthews@morganlewis.com (T. Matthews)
tom.miller@hq.doe.gov (Tom Miller)
trsmith@winston.com (Tyson Smith)
Vanessa.quinn@dhs.gov (Vanessa Quinn)
vijukrp@westinghouse.com (Ronald P. Vijuk)
Wanda.K.Marshall@dom.com (Wanda K. Marshall)
whorin@winston.com (W. Horin)
yoshiki_ogata@mhi.co.jp (Yoshiki Ogata)

NOTICE OF VIOLATION

MHI Takasago
Takasago, Japan

Docket Number 05200021
Inspection Report Number 2011-202

During a U.S. Nuclear Regulatory Commission (NRC) inspection conducted at Mitsubishi Heavy Industries (MHI) Takasago Research and Development Center (Takasago) facility in Takasago, Japan, on July 25-29, 2011, violations of NRC requirements were identified. In accordance with the NRC Enforcement Policy, the violations are listed below:

- A. 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.

Contrary to the above, as of July 25, 2011, MHI Takasago's implementing procedure TA QMS91-N05, "Report Procedure for Defects and Nonconformities for Nuclear R&D," Revision 2, dated September 10, 2007, had not adopted an appropriate procedure for evaluating deviations and failures to comply. Specifically, TA QMS91-N05 did not contain adequate guidance for evaluating deviations and failures to comply as required by 10 CFR 21.21(a)(1).

This issue has been identified as Violation 05200021/2011-202-01.

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

- B. Criterion II, "Quality Assurance Program," of Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants," to 10 CFR Part 50, "Domestic Licensing of Production and Utilization Facilities," states, in part, that, a program must be established "to provide for indoctrination and training of personnel performing activities affecting quality as necessary to assure that suitable proficiency is achieved and maintained. The applicant shall regularly review the status and adequacy of the quality assurance program."

MHI Takasago's Quality Assurance Manual (QAM) TA QMS91-N01, "Takasago R&D Center Nuclear Energy R&D Quality Assurance Manual," Revision 12, dated June 30, 2011, Section 2.2, "Skill Evaluation and Certification of Personnel," Step 2 states, in part, that "Testers shall be certified after passing the test by applying Center Standard TA QMS91-N02 'Nuclear Energy R&D Tester Certification Procedure.' The certifier shall prepare the Nuclear Energy R&D Individual Tester Certification Record, and the head of the relevant unit shall retain that record together with the test answer sheet for record."

MHI Report TA QMS91-N02, "Nuclear Energy R&D Tester Certification Procedure," Steps 4.7.2, 4.7.3 and 4.8 further state that MHI shall document results of visual acuity evaluations, perform and document periodic reevaluation of testers, and document written test results on the Nuclear Energy R&D Individual Tester Certification Record.

Contrary to the above, as of July 25, 2011, MHI failed to establish measures to ensure the implementation of applicable requirements associated with test personnel training and qualification activities. Specifically, MHI failed to adequately document the results of the following:

- visual acuity examinations of test personnel on Nuclear Energy R&D Individual Tester Certification Records
- periodic reevaluations of test personnel on Nuclear Energy R&D Individual Tester Certification Records
- written examinations of test personnel on Nuclear Energy R&D Individual Tester Certification Records

These issues have been identified as examples of Violation 05200021/2011-202-02.

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

- C. Criterion IV, "Procurement Document Control," of Appendix B to 10 CFR Part 50 states, in part, "Measures shall be established to assure that applicable regulatory requirements, design bases, and other requirements which are necessary to assure adequate quality are suitably included or referenced in the documents for procurement of material, equipment, and services, whether purchased by the applicant or by its contractors or subcontractors. To the extent necessary, procurement documents shall require contractors or subcontractors to provide a quality assurance program consistent with the pertinent provisions of this appendix."

MHI Takasago's QAM TA QMS91-N01, Revision 12, Section 4, "Procurement Document Control," Step 1 states, in part, that "The procurement document (Ordering Specification) shall be submitted to the supplier at the time of placement of order."

TA QMS91-N01, Section 7, "Control of Purchase Material, Equipment, and Services," Step 7.1, "Procurement Plan," states, in part, that "The assigned person in charge of the relevant unit shall prepare a procurement document (Ordering Specification) to correctly convey the requirements to the supplier."

MHI Procurement Specification 5BE-UAP-20110010-R2, "USAPWR Sump Strainer Downstream Effect Core Inlet Blockage Test (Part 2) Procurement Specification," Revision 2, dated July 6, 2011, requires that MHI Takasago perform testing activities in accordance with Appendix B to 10 CFR Part 50 and with 10 CFR Part 21, "Reporting of Defects and Noncompliance."

Contrary to the above, as of July 25, 2011, MHI failed to establish measures to ensure the implementation of applicable requirements associated with procurement document control. Specifically, MHI failed to do the following:

- implement requirements specified in MHI report TA QMS91-N01 for the preparation and submittal of an ordering specification (Purchase Specification Form QMS91-N01-10) to MHI's subsuppliers of measurement and test equipment (M&TE)

- require its subsuppliers to provide M&TE and calibration services as a safety-related activity as required by MHI Procurement Specification 5BE-UAP-20110010-R2.

These issues have been identified as examples of Violation 05200021/2011-202-03.

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

- D. Criterion VII, "Control of Purchased Material, Equipment, and Services," of Appendix B to 10 CFR Part 50 states, in part, that "measures shall be established to assure that purchased material, equipment, and services...conform to the procurement documents. These measures shall include provisions, as appropriate, for source evaluation and selection, objective evidence of quality furnished by the contractor or subcontractor, inspection at the contractor or subcontractor source, and examination of products upon delivery."

MHI Takasago's QAM TA QMS91-N01, Revision 12, Section 7, Subpart 7.2, "Selection of Supplier," describes the methods for evaluating suppliers of safety-related material, equipment, or services. Step 7.2.2.b.1 of TA QMS91-N01 requires, in part, that the evaluation of the supplier be based on "the results of checking of the supplier's present quality record, which has been documented to enable objective evaluation."

Contrary to the above, as of July 25, 2011, MHI failed to conduct adequate oversight of its suppliers to verify that its suppliers' quality programs adequately met established procurement requirements. Specifically, MHI failed to document adequate objective evidence to support multiple audit conclusions and to verify all relevant quality assurance criteria within the scope of its suppliers' quality assurance program.

This issue has been identified as Violation 05200021/2011-202-04.

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

- E. Criterion X, "Inspection," of Appendix B to 10 CFR Part 50 states, in part, that "A program for inspection of activities affecting quality shall be established and executed by or for the organization performing the activity to verify conformance with the documented instructions, procedures, and drawings for accomplishing the activity."

MHI Procurement Specification 5BE-UAP-20110010-R2, Revision 2, requires that MHI Takasago perform testing activities in accordance with Appendix B to 10 CFR Part 50 and 10 CFR Part 21 requirements. In addition, 5BE-UAP-20110010-R2 invoked the requirement that testing activities be conducted in accordance with American Society of Mechanical Engineers Nuclear Quality Assurance (NQA)-1-1994, "Quality Assurance Requirements for Nuclear Facility Applications."

NQA-1-1994, Section 10, "Inspection," Subsection 6.1, "In-process inspection," states, in part, that "inspection of items in-process or under construction shall be performed for work activities where necessary to verify quality." In addition, Subsection 6.2, "Combined Inspection and Monitoring," Step 6.2.1 states, in part, that "a combination of inspection and process monitoring methods, when used, shall be performed in a

systematic manner to assure that the specified requirements for control of the process and quality of the item are being achieved throughout the duration of the process.”

Contrary to the above, as of July 25, 2011, MHI failed to conduct adequate oversight of testing activities to verify that its quality programs adequately met established procurement requirements. Specifically, MHI failed to perform in-process inspections of ongoing core inlet blockage test activities and had not developed formal plans to implement monitoring of core inlet blockage test activities as required in support of the design certification application for the U.S. Advanced Pressurized-Water Reactor.

This issue has been identified as Violation 05200021/2011-202-05.

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

- F. Criterion XIII, “Handling, Storage and Shipping,” of Appendix B to 10 CFR Part 50 states, in part, that “Measures shall be established to control the handling, storage, shipping, cleaning and preservation of material and equipment in accordance with work and inspection instructions to prevent damage or deterioration.”

Contrary to the above, as of July 25, 2011, MHI Takasago’s QAM, TA QMS91-N01, Revision 12, Section 13, “Handling, Storage, and Shipping,” failed to establish measures to control handling and storage of M&TE. Specifically, MHI failed to establish controls for M&TE associated with downstream testing for the design certification application for the US-APWR.

This issue has been identified as Violation 05200021/2011-202-06.

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

Pursuant to 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 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."

Dated at Rockville, MD, this 01 day of September 2011.

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

Docket No.: 05200021

Report No.: 05200021/2011-202

Applicant: Mitsubishi Heavy Industries
Wadasaki-cho-1-1-1, Hyogo-ku
Kobe 652-8285 Japan

Applicant Contact: Mr. Ryan Sprengel, Lead Licensing Engineer

Background: Mitsubishi Heavy Industries (MHI) submitted an application for a standard design certification for the U.S. Advanced Pressurized-Water Reactor (US-APWR) on December 31, 2007. Takasago Research and Development Center is a subsidiary of MHI that provides research and development activities aimed at the development and application of advanced technologies for MHI products. MHI Takasago will be performing plant-specific US-APWR downstream effects testing associated with containment spray/residual heat removal and safety injection pumps.

Inspection Dates: July 25–29, 2011

Inspection Team: Greg S. Galletti NRO/DCIP/CQVA Team Leader
Stacy Smith NRO/DCIP/CQVB
Juan D. Peralta NRO/DCIP/CQVA
Christopher Van Wert NRO/DSRA/SRSB

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

EXECUTIVE SUMMARY

MHI Takasago
05200021/2011-202

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 (MHI) Takasago Research and Development Center (Takasago) had implemented an adequate QA program in support of US-APWR sump strainer downstream effects 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 Takasago 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 MHI Takasago facility in Takasago, Japan, during July 25–29, 2011.

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

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

During the conduct of this inspection, the NRC inspection team implemented Inspection Procedure (IP) 35034, "Design Certification and Testing," 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."

Concurrent with this inspection, the NRC performed an audit that reviewed and evaluated testing methods and implementation for the MHI Design Certification, Section 6.3, "Emergency Core Cooling Systems (ECCS)," as well as related Technical Report MUAP-08013-P, "US-APWR Sump Strainer Downstream Effects," Revision 1.

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

10 CFR Part 21 Program

The NRC inspection team identified Violation 05200021/2011-201-01 associated with MHI'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 TA QMS910N05, "Report Procedure for Defects and Nonconformities for Nuclear R&D," Revision 2, dated September 10, 2007, did not contain guidance for evaluating deviations and failures defects and failures to comply associated with substantial safety hazards, as required by 10 CFR 21.21(a)(1).

Quality Assurance Program

The NRC inspection team identified Violation 05200021/2011-201-02 associated with MHI's failure to implement the requirements of Criterion II, "Quality Assurance Program," of Appendix B to 10 CFR Part 50. Specifically, MHI failed to adequately document the results of (1) visual acuity examinations of test personnel on Nuclear Energy R&D Individual Tester Certification Records, (2) periodic reevaluations of test personnel on Nuclear Energy R&D Individual Tester Certification Records, and (3) written examinations of test personnel on Nuclear Energy R&D Individual Tester Certification Records.

Procurement Document Control

The NRC inspection team identified Violation 05200021/2011-201-03 associated with MHI's failure to implement the requirements of Criterion IV, "Procurement Document Control," of Appendix B to 10 CFR Part 50. Specifically, MHI failed to (1) implement requirements specified in MHI report TA QMS91-N01, "Takasago R&D Center Nuclear Energy R&D Quality Assurance Manual," for the preparation and submittal of an ordering specification (Purchase Specification Form QMS91-N01-10) to MHI's subsuppliers of measurement and test equipment (M&TE), and (2) require subsuppliers to provide M&TE and calibration services as a safety-related procurement as required by MHI Procurement Specification 5BE-UAP-20110010-R2, "USAPWR Sump Strainer Downstream Effect Core Inlet Blockage Test (Part 2) Procurement Specification," Revision 2, dated July 6, 2011.

Control of Purchased Material, Equipment and Services

The NRC inspection team identified Violation 05200021/2011-201-04 associated with MHI's failure to implement the requirements of Criterion VII, "Control of Purchased Material, Equipment, and Services," of Appendix B to 10 CFR Part 50. Specifically, MHI failed to document adequate objective evidence to support multiple audit conclusions and failed to verify all relevant QA criteria within the scope of supply of its suppliers' QA programs.

Test Control

The NRC inspection team concluded that MHI's test control process and procedures were consistent with the regulatory requirements of Criterion XI of Appendix B to 10 CFR Part 50. However, based on its review, the NRC inspection team identified that MHI failed to meet the requirements of 10 CFR Part 50, Appendix B, Criterion X, "Inspection," as it related to the CIB test activities. Specifically, MHI failed to perform in-process inspections of ongoing core inlet blockage test activities and had not developed formal plans to implement monitoring of core inlet blockage test activity as required in support of the DC application for the US-APWR. The NRC inspection team identified this issue as Violation 05200021/2011-201-05.

Control of Measuring and Test Equipment

The NRC inspection team identified Violation 05200021/2011-201-06 associated with MHI Takasago's failure to implement the requirements of Criterion XIII, "Handling, Storage and Shipping," of Appendix B to 10 CFR Part 50. Specifically, MHI failed to establish controls for M&TE used during downstream testing associated with the DC application for the US-APWR.

Nonconforming Materials, Parts, or Components

The NRC inspection team concluded that MHI Takasago's nonconformance process and procedures to assess and control nonconforming items were consistent with the regulatory requirements of Criterion XV, "Nonconforming Materials, Parts, or Components," of Appendix B to 10 CFR Part 50. Based on its review, the NRC inspection team determined that MHI is effectively implementing its policies and procedures in support of testing activities associated with the US-APWR DC. No findings of significance were identified.

Corrective Action

The NRC inspection team concluded that MHI Takasago's corrective action process and procedures adequately identify and correct conditions adverse to quality and preclude repetition of significant conditions adverse to quality consistent with the regulatory requirements of Criterion XVI, "Corrective Actions," of Appendix B to 10 CFR Part 50. Based on its review, the NRC inspection team determined that MHI is effectively implementing its corrective action policies and procedures in support of testing activities associated with the US-APWR DC. 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 Mitsubishi Heavy Industries (MHI) Takasago'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. In addition, the NRC inspection team observed Part 21 postings and reviewed a sample of MHI's purchase orders (POs) for compliance with the requirements of 10 CFR 21.6, "Posting Requirements," 10 CFR 21.31, "Procurement Documents," and 10 CFR 21.21, "Notification of Failure To Comply or Existence of a Defect and Its Evaluation," respectively. To verify an adequate link to the Part 21 process, the NRC inspection team also reviewed the MHI procedures that govern nonconformance and corrective action and the control and correction of nonconforming items.

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

- TA QMS91-N05, "Takasago R&D Report Procedure for Defects and Nonconformities for Nuclear R&D," Revision 2, dated September 10, 2007
- PO THCIES-110279-R0, "US-APWR Core Inlet Blockage Test," Revision 0, dated June 29, 2011
- Purchase Specification 5BE-UAP-20110010-R2, "USAPWR Sump Strainer Downstream Effect Core Inlet Blockage Test (Part 2) Procurement Specification," Revision 2, dated July 6, 2011
- TA QMS91-06, "Nonconformance Report and Corrective/Preventative Nuclear Procedure," Revision 4, dated March 26, 2007
- QMS-91-06-01, "Nonconforming and Disposition/Corrective Action Request Report," Revision 10, dated June 30, 2011

b. Observations and Findings

b.1 Postings

The NRC inspection team observed that MHI had posted a notice at the location where the downstream testing was being performed in support of the U.S. Advanced Pressurized-Water Reactor (US-APWR) design certification (DC). It included a copy of Section 206 of the Energy Reorganization Act of 1974, a current copy of 10 CFR Part 21, a description of the reporting procedure, and the name of the person responsible for maintaining this procedure. The Part 21 reporting procedure and posting contained guidance in both English and Japanese.

b.2 10 CFR Part 21 Procedure

Procedure TA QMS91-06 contains detailed instructions to identify and disposition nonconformances. The form to document nonconforming conditions, QMS91-06-01, contains a box to document the need to perform a Part 21 evaluation. The NRC inspection team discussed the sections of the form pertaining to Part 21 with the Quality Manager and MHI personnel.

The reporting procedure for defects and nonconformities, TA QMS91-N05, identifies reporting criteria for conditions adverse to quality. It includes the responsibilities of employees and managers and all applicable timelines for reporting and evaluation in accordance with 10 CFR Part 21. However, TA QMS91-N05 failed to provide procedural guidance for evaluating deviations and failures to comply. Specifically, TA QMS910-N05 did not contain guidance for evaluating deviations and failures to comply in order to identify defects and failures to comply associated with substantial safety hazards as required by 10 CFR 21.21(a)(1).

b.3 10 CFR Part 21 Implementation

At the time of the inspection, MHI Takasago had not performed any Part 21 evaluations. The NRC inspection team reviewed a sample of nonconformances and corresponding documentation supporting Part 21 evaluation necessities to determine if an evaluation should have been performed. For the sample reviewed, the NRC inspection team did not identify any instances in which MHI should have performed an evaluation.

c. Conclusions

The NRC inspection team concluded that MHI failed to adopt appropriate procedures to evaluate deviations and failures to comply. Specifically, the NRC inspection team determined that TA QMS910N05 did not contain guidance for evaluating deviations and failures to comply in order to identify defects and failures to comply associated with substantial safety hazards as required by 10 CFR 21.21(a)(1).

2. Quality Assurance Program

a. Inspection Scope

The NRC inspection team reviewed the MHI quality assurance manual (QAM) and implementing procedures that govern MHI's training and qualification process to verify compliance with the requirements of Criterion II, "Quality Assurance Program," 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 NRC inspection team reviewed MHI's personnel training and qualification records and discussed personnel training and qualification activities with MHI management and technical staff.

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

- MHI Report TA QMS91-N01, "Takasago R&D Center Nuclear Energy R&D Quality Assurance Manual," Revision 12, dated June 30, 2011

- TA QMS91-N02 , “Nuclear Energy R&D Tester Certification Procedure,” Revision 3, dated May 31, 2010
- Sample of Test Personnel Certification Records, TA QMS91-N02-01. “Nuclear Energy R&D Individual Tester Certification Record,” Revision 1, dated June 27, 2008, September 12, 2008, and May 31, 2010
- Corrective Action Report (CAR) 15-2011, dated July 28, 2011

b. Observations and Findings

b.1 Policies and Procedures

Section 2, “Quality Assurance Program,” of TA QMS91-N01 establishes measures for the control of the quality assurance program (QAP). Section 2.2, “Skill Evaluation and Certification of Test Personnel,” of TA QMS91-N01 describes the process for the indoctrination and training of personnel including engineers, testers, and auditors; requires such activities to be 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.

TA QMS91-N02 describes the training requirements for MHI employees, including MHI Solutions Technology personnel, contracted by MHI to perform the core inlet blockage (CIB) testing, as well as the requirements for planning, scheduling, executing, and documenting personnel training. The procedure also requires training for MHI employees to the extent necessary for the employee to achieve a level of proficiency that complies with the QAP requirements. In addition, TA QMS91-N02 clarifies the certification requirements for personnel who conduct testing related to nuclear energy products for the R&D Center. The procedure describes the acceptance standards for the tests and checklists for Level I, II, and III testers, provides for recertification of all testers on a triannual basis, and requires annual evaluation of testers’ visual acuity.

b.2 Implementation of the Training and Qualification Program

The NRC inspection team reviewed training records for MHI test personnel who performed CIB testing activities in support of MHI’s DC for the US-APWR. The NRC inspection team noted that MHI Solutions Technology personnel performing CIB testing activities were working under MHI’s QAP and thus must be trained and qualified under MHI’s QAP implementing procedures.

The NRC inspection team examined training and qualification records for a sample of CIB testing personnel. Specifically, the NRC inspection team reviewed a sample of qualification records for Level I, II, III testers involved in the CIB test program and determined that the qualification records were deficient in several respects, including (1) failure to adequately document visual acuity evaluations for all personnel records, (2) failure to document periodic evaluation of testers in accordance with Steps 4.7.2, 4.7.3, and 4.8 of QMS91-N01, and (3) lack of written test results on qualification records. Based on these observations, the NRC inspection team could not initially confirm that those individuals designated for CIB testing activities were qualified to the levels of proficiency necessary to perform those activities, in part because the qualification

records were not consistent with record requirements defined in the quality assurance program description (QAPD). This issue has been identified as Violation 05200021/2011-201-02.

In response to the NRC inspection team's finding, MHI initiated CAR 15-2011, dated July 28, 2011, to document the issue. As part of the corrective actions, MHI determined the extent of condition and updated the current tester qualification cards to document the proper information. Based on these actions, MHI did confirm that those test personnel involved in the CIB testing were in fact qualified to perform the work. The root cause determination for why the qualification records were deficient was ongoing at the time of the inspection exit; however, the NRC inspection team's review of the extent of condition and immediate actions taken by MHI confirmed that the lack of adequate training documentation did not affect the CIB testing.

c. Conclusions

The NRC inspection team identified Violation 05200021/2011-201-02 associated with MHI's failure to implement the requirements of Criterion II of Appendix B to 10 CFR Part 50. Specifically, MHI failed to adequately document the results of (1) visual acuity examinations of test personnel on Nuclear Energy R&D Individual Tester Certification Records, (2) periodic reevaluations of test personnel on Nuclear Energy R&D Individual Tester Certification Records, and (3) written examinations of test personnel on Nuclear Energy R&D Individual Tester Certification Records.

3. Procurement Document Control

a. Inspection Scope

The NRC inspection team reviewed the MHI Takasago QAM and implementing procedures that govern MHI Takasago's process for controlling documents used to procure material, equipment, and services to verify compliance with 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 MHI management and technical staff.

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

- Section 4, "Procurement Document Control," of TA QMS91-N01, "Takasago R&D Center Nuclear Energy R&D Quality Assurance Manual—QA Program Description (QAPD)," Revision 12, dated June 30, 2011
- QMS91-N01-10-R7, "Ordering Specification (Purchasing Specification)," dated July 15, 2011
- QMS91-N06-07-01-2011, "List of Suppliers," dated July 8, 2011
- QMS91-N09, "Requirement Specification," Revision 0, dated July 20, 2011

- TA QMS91-N01-11, "Confirmation Record of Receiving Inspection Conditions," dated 2010

b. Observations and Findings

b.1 Policies and Procedures

Section 4, "Procurement Document Control," of TA QMS91-N01 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. These controls apply to the procurement of test equipment and test services, as well as calibration and examination services, in support of the MHI Takasago R&D Center activities in support of the US-APWR DC.

Specifically, with respect to the processing of MHI procurement documents, TA QMS91-N01, Section 4, Step 1, of the MHI QAPD states, in part, "The procurement document (ordering Specification) shall be submitted to the supplier at the time of placement of order." Furthermore, TA QMS91-N01, Section 7, "Control of Purchase Material, Equipment, and Services, Step 7.1, "Procurement Plan," states, in part, "The assigned person in charge of the relevant unit shall prepare a procurement document (Ordering specification) to correctly convey the requirements to the supplier."

MHI procedures QMS91-N01-10-R7 and QMS91-N09 supplement the requirements described in Section 4 of the QAPD 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 applied 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.

b.2 Implementation of MHI Takasago Purchase Orders

The NRC inspection team reviewed the following MHI Takasago procurement documents:

- 5BE-UAP-20110010-R2, "USAPWR Sump Strainer Downstream Effect Core Inlet Blockage Test (Part 2) Procurement Specification," Revision 2, dated July 6, 2011
- ORIX Rentec, PO 2764, "Equipment Rental and Calibration Services," dated June 21, 2010
- Daio Denke, PO 8654, "Electronic Flowmeter Calibration Services," dated January, 1, 2010
- Okazaki, PO 6362, "Thermocouples," dated May 30, 2010

- Certificate of Conformance 2011727, Daio Denki, dated July 27, 2011
- Certificate of Conformance QA11-012, ORIX Rentec, dated July 27, 2011
- Certificate of Conformance AD-0581, Okazaki, dated July 28, 2011

The NRC inspection team reviewed a sample of POs and associated documents between MHI Kobe, MHI Takasago, and three material and testing equipment (M&TE) subsuppliers to MHI that are supporting the CIB testing activities to verify proper implementation of the MHI procurement document control programs.

The NRC inspection team confirmed that the MHI PO 5BE-UAP-20110010-R2, between MHI Kobe and MHI Takasago, prescribed that the testing activities performed by MHI Takasago were, in fact, safety related and required that they be conducted in accordance with an approved 10 CFR Part 50, Appendix B, QAP and a 10 CFR Part 21 program. In addition, the PO invoked the requirement that the testing activities be conducted in accordance with American Society of Mechanical Engineers (ASME) Nuclear Quality Assurance (NQA)-1-1994, "Quality Assurance Requirements for Nuclear Facility Applications." This PO also required MHI Takasago to "pass down" those requirements to its subsuppliers performing safety-related activities.

The NRC inspection team reviewed a sample of POs between MHI Takasago and its subsuppliers providing M&TE and calibration service to confirm that the quality assurance (QA) and technical requirements were adequately imposed on those subsuppliers through the procurement process. Based on that review, the NRC inspection team determined that for the three subsupplier POs reviewed, MHI had not prepared and conveyed a purchase specification to each subsupplier in accordance with the requirements of Sections 4 and 7 of TA QMS91-N01 and had not passed down the requirements to perform all work in accordance with 10 CFR Part 50, Appendix B, requirements as specified in Section 4 of PO 5BE-UAP-20110010-R2. As a result, the test equipment and services were procured as commercial products. The NRC inspection team noted that MHI Kobe performed an audit of the CIB testing activities performed at MHI Takasago in 2011 and found that MHI Takasago had not adequately passed down 10 CFR Part 21 requirements to its subsuppliers. CAR-04-2011 documented this finding. However, the MHI Kobe audit failed to identify that MHI Takasago did not adequately pass down 10 CFR Part 50, Appendix B, requirements and ordering specifications to subsuppliers as required by TA QMS91-N01. These issues are identified as examples of Violation 05200021/2011 201-03.

During the NRC inspection, MHI revised CAR 04-2011 to include additional description of the failure to require POs to include the Appendix B requirements and initiated CAR-09-2011 to document the failure to implement the ordering specification. In addition, MHI requested and received from each affected subsupplier a certificate of conformance that explicitly stated that the services and equipment provided to MHI were in conformance with the subsupplier's programs under Appendix B to 10 CFR Part 50 and under 10 CFR Part 21.

c. Conclusions

The NRC inspection team identified Violation 05200021/2011-201-03 associated with MHI's failure to implement the requirements of Criterion IV of Appendix B to 10 CFR Part 50. Specifically, MHI failed to (1) implement requirements specified in MHI report TA QMS91-N01 for the preparation and submittal of an ordering specification (purchase specification form QMS91-N01-10) to MHI's subsuppliers of M&TE, and (2) require its subsuppliers to provide M&TE and calibration services as a safety-related procurement as required by MHI Procurement Specification 5BE-UAP-20110010-R2.

4. Control of Purchased Material, Equipment, and Services

a. Inspection Scope

The NRC inspection team reviewed the MHI Takasago QAM and implementing procedures that govern MHI Takasago's process for controlling purchased material, equipment, and services to verify compliance with Criterion VII, "Control of Purchased Material, Equipment and Services," of Appendix B to 10 CFR Part 50. In addition, the NRC inspection team discussed the programs for the control of purchased equipment, material, and services with the management and technical staff of MHI.

Specifically, the NRC inspection team reviewed the following policies, procedures, and supporting documentation 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
- 5BE-UAP-20110010-R2, "USAPWR Sump Strainer Downstream Effect Core Inlet Blockage Test (Part 2) Procurement Specification," Revision 2, dated July 6, 2011
- Section 7, "Control of Purchased Material, Equipment, and Services," of TA QMS91-N01, "Takasago R&D Center Nuclear Energy R&D Quality Assurance Manual—QA Program Description (QAPD)," Revision 12, dated June 30, 2011
- TA QMS91-N06, "Nuclear Energy R&D Audit Procedure," Revision 4, dated April 1, 2009
- TA QMS91-N07, "Nuclear Energy R&D Auditor Certification Procedure," Revision 2, dated April 20, 2009
- TA QMS91-N06-01, "Audit Plan"
- TA QMS91-N06-02, "Audit Form"
- TA QMS91-N06-05, "Nuclear Energy R&D Supplier Evaluation Report"
- TA QMS91-N01-02, "Nuclear Energy R&D Audit Leader Certification Record"

- TA QMS91-N06-07-01-2011, “List of Suppliers,” dated July 8, 2011
- TA QMS91-N06-03, “ASME Audit Checklist”
- QMS91-N06-01-03-2011, ORIX Rentec, Supplier of Measurement Equipment and Calibration Services for Pressure Devices, dated February 15, 2011

b. Observations and Findings

b.1 Policies and Procedures for Vendor Qualification

Section 7 of TA QMS91-N01 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, “Selection of Supplier,” describes the method of selecting and evaluating suppliers to meet the requirements of Appendix B to 10 CFR Part 50, and NQA-1 for safety-related materials, items, or services. Specifically, it states that 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, the results of audits performed by other parties, or a combination of these. Section 4 of TA QMS91-N01, states, in part, that the Nuclear Energy Quality Control Manager is responsible for maintaining and distributing the List of Suppliers (QMS91-N06-07-01-2011) to the Research Support Section responsible for material purchasing.

TA QMS91-N06 provides general guidance for conducting both internal audits and vendor audits. The standard establishes the minimum requirements for audit plans, reports, and conduct; it also requires that audit plans be prepared before each audit and includes an audit checklist and references templates for each activity. The procedure also describes the process for performing annual audits of vendors for safety-related items and services. It requires that qualified lead auditors perform annual audits and results of the audits be documented in accordance with established MHI procedures.

TA QMS91-N07 defines the process for qualifying auditors and lead auditors for MHI, including the process for maintaining the auditor qualification and the education, training, and experience required to perform the audit function

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

The NRC inspection team reviewed TA QMS91-N06-07-01-2011 to ensure that qualified and approved suppliers were listed; that authorized personnel periodically maintained, distributed, and updated the lists; and that any revisions to the lists were made according to the applicable procedures. The NRC inspection team confirmed that the suppliers performing work for MHI with respect to the DC testing of the CIB strainers were appropriately listed on TA QMS91-N06-07-01-2011. In addition, the NRC inspection team confirmed that the scope of supply was documented and consistent with the activities contracted with MHI.

b.3 External Audits

The NRC inspection team reviewed a sample of external audits to verify the implementation of the MHI supplier audit program. 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.

The NRC inspection team determined that the external audit reports reviewed did not contain a review of all relevant QA criteria in Appendix B to 10 CFR Part 50 for the activities performed by the individual suppliers. Specifically, the NRC inspection team found that the audits failed to evaluate any of the subsuppliers' programs for the storage, shipping, and handling of equipment within the subsuppliers' scope of supply. In addition, the NRC inspection team identified that in several audit review areas, the documentation lacked any objective evidence to support the audit conclusions. In many cases, the only evidence was a simple citation of a procedure for a particular activity. No further evidence supporting proper implementation of the program requirements was documented. These issues are identified as examples of Violation 05200021/2011-201-04.

b.4 Auditor Training and Qualification

The NRC inspection team reviewed a sample of the training and qualification records for some of MHI's lead auditors and auditors. This review confirmed that auditing personnel had completed all required training and maintained qualification and certification in accordance with MHI policies and procedures. The NRC inspection team also verified that audit teams selected by MHI were sufficiently qualified to evaluate areas within the scope of the audit. Auditor and lead auditor qualification records were documented in detail and confirmed that the requisite training and experience had been achieved before the performance of auditing activities. The inspection team confirmed that these qualification records were adequately controlled in accordance with the requirements of TA QMS91-N01 and TA QMS91-N07.

c. Conclusions

The NRC inspection team identified Violation 05200021/2011-201-04 associated with MHI's failure to implement the requirements of Criterion VII of Appendix B to 10 CFR Part 50. Specifically, MHI failed to document adequate objective evidence to support multiple audit conclusions and verify all relevant QA criteria within the scope of supply of its suppliers' QAPs.

5. Test Control

a. Inspection Scope

The NRC inspection team reviewed the MHI Takasago QAM and applicable implementing procedures that govern the MHI Takasago test control process to verify compliance with the requirements of Criterion XI, "Test Control," of Appendix B to 10 CFR Part 50. In addition, the inspection team interviewed MHI personnel and reviewed source documentation to verify implementation of the test control program associated with testing for the DC application for the US-APWR.

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

- Section 10, "Inspection," of TA QMS91-N01, "Takasago R&D Center Nuclear Energy R&D Quality Assurance Manual—QA Program Description (QAPD)," Revision 12, dated June 30, 2011
- ASME NQA-1-1994, "Quality Assurance Requirements for Nuclear Facility Applications," issued 1994
- 5BE-UAP-20110010, "US-APWR—Sump Strainer Downstream Effect Core Inlet Blockage Test (Part 2) Procurement Specification," Revision 2, dated July 6, 2011
- 5BS-UAP-20100242, "US-APWR—Core Inlet Blockage Test—Test Plan Document," Revision 1
- 5BS-UAP-20110041, "US-APWR Test Conditions for Core Inlet Blockage Test," Revision 3
- Takasago R&D Center, WGS 04967, "US-APWR Sump Downstream Impact Fuel Inlet Blockage Test (Part 2) #30–#37 Tests—Test Plan," Revision 0
- Takasago R&D Center, Test Procedure WGE00394, "Disassembling and Assembling Work," Revision 6
- Takasago R&D Center, Test Procedure WGE00465, "Operation and Measurement," Revision 1
- Takasago R&D Center, Test Procedure WHS08508, "Gap Measuring," Revision 1
- Takasago R&D Center, Technical Document WHS08622, "US-APWR Sumpstrainer Downstream Effects Core Inlet Blockage Test #37—The Report of Gap Measurement Results by UT Method," Revision 2

b. Observations and Findings

b.1 Policies and Procedures

The procurement specification from MHI Kobe to MHI Takasago, 5BE-UAP-20110010, describes MHI's objectives for conducting the CIB test at the Takasago R&D Center. In addition, it specifies the technical and quality requirements to be met by the Takasago R&D Center in conducting these tests. The procurement specification invokes explicit QA program requirements for design and test activities. These QA program requirements include Appendix B to 10 CFR Part 50; ASME NQA-1-1994; NRC Regulatory Guide 1.28, "Quality Assurance Program Criteria (Design and Construction)"; and 10 CFR Part 21.

The CIB tests simulate the flow of debris-laden fluid through a US-APWR fuel assembly during post-lost-of-coolant accident (post-LOCA) recirculation mode to evaluate the effect of the debris that bypasses the sump strainer and clogs the core inlet. During the test, the pressure drop increase caused by debris accumulation at the fuel assembly is measured to establish the adequacy of post-LOCA long-term cooling of the US-APWR design. The CIB tests conducted at Takasago simulate the following LOCA scenarios: hot-leg break, cold-leg break, and cold-leg break after hot-leg switchover.

The test conditions document, 5BS-UAP-20110041, describes the scope of tests to be performed in accordance with the summary of detailed test conditions in the procurement specification. The test conditions include the formal tests, as well as various trial tests, conducted to verify key assumptions or parameters. The trial tests were not part of this inspection effort. The test conditions also define the debris input parameters to be used for the different tests and identify applicable source documents.

The test plan described in 5BE-UAP-20100242 describes the CIB test objectives and scope consistent with the provisions in the Procurement Specification 5BE-UAP-20110010. To satisfy the requirements in the test plan document, test conditions, and the procurement specification, the Takasago R&D Center developed WGS 04967, Revision 0. WGS 04967 establishes the critical parameters, test loop configuration, test conditions, acceptance criteria, and overall personnel assignments for conducting the CIB tests at the Takasago R&D Center. Section 5.5, "Test Procedures," of WGS 04967 outlines the test procedures and the sequence of their implementation in conducting the CIB tests.

b.2 Downstream Effect Testing

The inspection team observed the conduct of CIB test No. 31, "Hot Leg Break Pressure Loss Verification Test," by Takasago R&D Center test personnel and verified that the test was conducted in accordance with the guidance in WGS 04967. Specifically, the inspection team observed that Takasago R&D Center test personnel added debris (fiber, chemicals, and particles) into the test loop reservoir and verified that the test loop instrumentation was recording the differential pressure at the specified locations of the fuel assembly specimen. The inspection team also verified that Takasago R&D Center personnel adhered to the test sequence and schedule specified in WGE00465, the operation and measurement test procedure. Following the completion of the test sequence specified in WGE00465, the inspection team witnessed the disassembly of the test apparatus by Takasago R&D Center test personnel in accordance with WGE00394, the disassembling and assembling work test procedure. The inspection team also observed the accumulation of debris in the fuel assembly specimen and noted that the heaviest accumulation had occurred around the bottom grid and first intermediate grid. These grids contained a debris bed that appeared to be relatively uniform. The second intermediate grid demonstrated the beginnings of a fiber bed that was developing from the perimeter towards the interior. The top grid showed only small amounts of debris deposition. This overall result showed that debris was being distributed among the grids and the resulting pressure drop was below the specified criterion.

The NRC inspection team verified that the dimensions of the new acrylic fuel assembly container gap measurement results documented in WHS08622, the technical document describing gap measurement results, were collected in accordance with WHS08508, the gap measuring test procedure. The results of the gap measurements indicate that the

acrylic fuel assembly container gap is correctly sized at 0.5 millimeters and within the specified tolerance.

The NRC inspection team witnessed the extraction of the mock fuel rods from the test assembly and verified that MHI Takasago personnel followed the process outlined in the disassembling and assembling test procedure. The NRC inspection team noted that the fiber bed appeared to remain mostly intact during the extraction process, but some small pieces of the bed did become dislodged. This outcome is consistent with previous observations of the fiber bed during testing in 2010.

b.3 Inspection of Test Activities

The NRC inspection team reviewed the methods used by the MHI QA organization to monitor the CIB testing activities and observed test activities. The NRC inspection team reviewed the detailed CIB test procedure and noted that there were no specific QA evaluation hold points or in-process witness points designated for the test evolution. During the test observations, the NRC inspection team noted that there was no formal documented oversight of the test activities by the MHI QA organization. The NRC inspection team discussed these observations with the MHI staff and confirmed that although the MHI program has requirements for the conduct of monitoring of activities affecting quality, the MHI QA staff had not currently performed any formal monitoring of the on-going testing and had not developed a formal schedule for conducting such activities throughout the period of the testing. The NRC inspection team identified this issue as Violation 05200021/2011-201-05.

c. Conclusions

The NRC inspection team concluded that MHI's test control process and procedures were consistent with the regulatory requirements of Criterion XI of Appendix B to 10 CFR Part 50. However, based on its review, The NRC inspection team identified that MHI failed to meet the requirements of 10 CFR Part 50, Appendix B, Criterion X, "Inspection," and identified this as Violation 05200021/2011-201-05.

6. Control of Measuring and Test Equipment

a. Inspection Scope

The NRC inspection team reviewed the MHI Takasago QAM and applicable implementing procedures that govern the MHI Takasago Measuring and Test Equipment Program to verify compliance with the requirements of Criterion XII, "Control of Measuring and Test Equipment," 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:

- Section 12, "Control of Measuring and Test Equipment," of TA QMS91-N01, "Takasago R&D Center Nuclear Energy R&D Quality Assurance Manual—QA Program Description (QAPD)," Revision 12, dated June 30, 2011
- Section 7, "Control of Purchased Material, Equipment, and Services," in TA QMS91-N01, "Takasago R&D Center Nuclear Energy R&D Quality

Assurance Manual—QA Program Description (QAPD),” Revision 12, dated June 30, 2011

- TA QMS91-08, “Validity Control Procedure for Test Equipment and Measuring Equipment,” Revision 3, dated September 10, 2007
- WGS04947, “US-APWR Sump Downstream Impact Fuel Entry Closure Test M&TE Calibration Record,” Revision 1, dated April 1, 2011
- US-APWR, “Sump Downstream Effect Fuel Core Inlet Blockage Test Electronic Balance Acceptance Test Record,” Revision 0, dated March 18, 2011
- US-APWR, “Sump Downstream Effect Fuel Core Inlet Blockage Data Logger Acceptance Test Record,” Revision 0, dated June 20, 2011

b. Observations and Findings

b.1 Policies and Procedures

The NRC inspection team reviewed MHI Takasago’s implementing procedure TA QMS91-08; QAM Section 12, “Control of Measuring and Test Equipment”; and QAM Section 7, “Control of Purchased Material, Equipment, and Services.” Section 7 of the QAM describes the acceptance inspection process for M&TE and references the form used to record the receiving inspections, QMS91-N01-11, “Confirmation Record of Receiving Inspection Conditions.” Section 12 of the QAM describes the control of M&TE, including selection, calibration, and control measures. TA QMS91-08 establishes the process for controlling the validity of test equipment and instrumentation and discusses criteria for judging acceptance or rejection of inspection results, based on inspection method and calibration and validation of the M&TE.

b.2 Implementation of Control of Measuring and Test Equipment

For the M&TE observed, the NRC inspection team verified that the equipment was labeled in a manner to ensure traceability to the calibration records. For the following sample of M&TE, the NRC inspection team reviewed calibration records and verified that the dates calibrated, the due dates, the calibration frequency, and the nationally recognized standards for calibration were consistent with procedural requirements:

- S09-11123—Electronic Flow Meter
- 27E523884—Digital Manometer
- AB13912—Type Thermocouple
- AB13913 0 Type K Thermocouple
- 91H256534—Data Logger
- 1126353450—Scale

b.3 Storage, Shipping, and Handling of Measuring and Test Equipment

The NRC inspection team reviewed the methods used by the MHI test team to store and maintain M&TE used for the CIB testing and observed the actual handling of M&TE during the test observations. The M&TE was staged at the testing location adjacent to

the test fixture within the open-atmosphere test laboratory. Equipment was suitably labeled and, to the extent possible, enclosed within protective fixtures such as boxes and plastic containers, which were covered by protective tarps. The NRC inspectors did not observe any formal barriers to the removal of or uncontrolled manipulation of equipment and did not observe any formal location designated for the potential control and segregation of nonconforming M&TE. Temperature readings were recorded at the fixture location as part of the experimental test setup, but ambient humidity measurements were not recorded. The NRC inspection team discussed these observations with the MHI staff and reviewed the QAP documentation associated with this activity and, as a result, determined that the MHI QAP did not include formally documented provisions for the conduct of storage, shipping, and handling of M&TE and other equipment (e.g., fuel bundles). Specifically, the NRC inspection team reviewed TA QMS91-01, Section 13, "Storage, Shipping, and Handling," and noted that it did not describe any programmatic process or controls over this area. Additionally, the NRC reviewed the audit reports performed by MHI Kobe of the MHI Takasago R&D Center and those performed by MHI Takasago of its M&TE subsuppliers, in preparation for the conduct of the CIB testing, and noted that the audit reports did not contain any review of the storage, shipping, or handling process associated with the CIB test M&TE or other equipment. Additional discussions between the NRC inspection team and the MHI staff confirmed that MHI had not implemented any formal process for the storage, shipping, or handling of M&TE associated with this project. The NRC inspection team identified these issues as examples of Violation 05200021/2011-201-06.

c. Conclusions

The NRC inspection team identified Violation 05200021/2011-201-06 associated with MHI Takasago's failure to implement the requirements of Criterion XIII, "Handling, Storage and Shipping," of Appendix B to 10 CFR Part 50. Specifically, MHI failed to establish controls for M&TE associated with testing for the DC application for the US-APWR.

7. Nonconforming Materials, Parts, or Components

a. Inspection Scope

The NRC inspection team reviewed the MHI Takasago QAM and implementing procedures that govern MHI Takasago's process for the control of nonconforming items to verify compliance with Criterion XV, "Nonconforming Materials, Parts, or Components," of Appendix B to 10 CFR Part 50. The NRC inspection team reviewed MHI Takasago nonconformance documentation and records and discussed the nonconformance process with responsible MHI management and staff.

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

- Section 12, "Control of Measuring and Test Equipment," of TA QMS91-N01, "Takasago R&D Center Nuclear Energy R&D Quality Assurance Manual—QA Program Description (QAPD)," Revision 12, dated June 30, 2011

- Section 15, “Control of Nonconforming Items,” of TA QMS91-N01, “Takasago R&D Center Nuclear Energy R&D Quality Assurance Manual—QA Program Description (QAPD),” Revision 12, dated June 30, 2011
- TA QMS91-08, “Validity Control Procedure for Test Equipment and Measuring Equipment,” Revision 3, dated September 10, 2007
- QMS-91-06-01, “Nonconforming and Disposition/Corrective Action Request Report,” Revision 10, dated June 30, 2011
- TA QMS91-06, “Nonconformance Report and Corrective/Preventative Nuclear Procedure,” Revision 4, dated March 26, 2007
- TA QMS91-N08, “Nuclear Energy Research and Development CGD Procedure,” Revision 1, dated December 28, 2010
- Nonconformance Report 02-2011, Fuel Assembly, dated April 4, 2011
- Nonconformance Report 03-2011, RG 1.28, dated July 4, 2011
- Nonconformance Report 05-2011, Internal Audit, dated July 4, 2011
- Nonconformance Report 06-2011, 2010 Audit Checklist, dated July 4, 2011
- Nonconformance Report 07-2011, CIB Test, dated July 4, 2011
- Nonconformance Report 10-2011, QA Procedure and Part 21 Evaluation, Revision 1, dated July 26, 2011,
- Nonconformance Report 11-2011, QA Manual, Part 21, and Appendix B, dated July 26, 2011
- Nonconformance Report 13-2011, Nonconforming Items, dated July 26, 2011
- TA QMS91-N04, “Nuclear R&D Software Control Procedure,” Revision 4, dated November 9, 2007

b. Observations and Findings

Section 15, “Control of Nonconforming Items,” of the QAM discusses detection and action for nonconforming items and the required documentation on the nonconformance report form, “Nonconformance Report and Modification/Corrective Action Form.” Step 15.1 states, in part, that nonconforming items include design analysis or testing not meeting technical requirements; QA activity not meeting any quality requirement; and failure, faulty maintenance, defects, or missing parts of equipment.

MHI Takasago chose to establish specific measures required in Criterion XV of Appendix B to 10 CFR Part 50, such as segregation and documented procedures for acceptance/rejection of nonconformances, for M&TE despite the broader description of nonconformances given in Step 15.1. Section 12, “Control of Measuring and Test

Equipment,” of the QAM and an associated implementing procedure for test and measuring equipment, TA QMS91-08, currently contain the established measures to control inadvertent use of or installation of nonconforming items and review of nonconformances for accepted, rejected, repaired, or reworded in accordance with documented procedures.

At the time of the inspection, there were no segregated nonconforming items; therefore, the NRC inspection team could not verify that nonconforming materials, parts, and components were appropriately identified and tagged. The NRC inspection team reviewed a sample of nonconformance reports. Although MHI Takasago’s segregation measures and implementing procedures for disposition are established only for M&TE, the NRC inspection team observed that MHI Takasago, in practice, appropriately dispositioned and segregated identified nonconforming conditions. Specifically, in Nonconformance Report 02-2011, MHI Takasago personnel identified damage to a fuel assembly used in the downstream testing. According to the nonconformance report, the fuel assembly was appropriately segregated, and a technical justification was provided for final disposition.

MHI took prompt action and generated a nonconformance report on July 26, 2011, to address the failure to have a process or procedures to prevent use of nonconforming items, specifically equipment that is not M&TE. However, the NRC inspection team verified that all items procured under 10 CFR Part 50, Appendix B, for the CIB testing in support of the DC application for the US-APWR were in accordance with Criterion XV of Appendix B to 10 CFR Part 50.

c. Conclusions

The NRC inspection team concluded that MHI’s nonconformance process and procedures to assess and control nonconforming items were consistent with the regulatory requirements of Criterion XV of Appendix B to 10 CFR Part 50. Based on its review, the NRC inspection team determined that MHI Takasago is effectively implementing its policies and procedures to support the DC application for the US-APWR. No findings of significance were identified.

8. Corrective Action

a. Inspection Scope

The NRC inspection team reviewed MHI Takasago’s policies and procedures that govern the corrective action process to ensure that they adequately describe the process and implement the requirements of Criterion XVI, “Corrective Action,” of Appendix B to 10 CFR Part 50. The NRC inspection team reviewed MHI Takasago’s corrective action program and activities, including documentation and records, and discussed the corrective action process with responsible MHI Takasago management and staff.

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

- QMS-91-06-01, “Nonconforming and Disposition/Corrective Action Request Report,” Revision 10, dated June 30, 2011

- TA QMS91-06, “Nonconformance Report and Corrective/Preventative Nuclear Procedure,” Revision 4, dated March 26, 2007
- QMS-91-06-01, “Nonconforming and Disposition/Corrective Action Request Report,” Revision 10, dated June 30, 2011
- Section 15, “Control of Nonconforming Items,” of TA QMS91-N01, “Takasago R&D Center Nuclear Energy R&D Quality Assurance Manual—QA Program Description (QAPD),” Revision 12, dated June 30, 2011
- Section 16, “Corrective Action,” of TA QMS91-N01, “Takasago R&D Center Nuclear Energy R&D Quality Assurance Manual—QA Program Description (QAPD),” Revision 12, dated June 30, 2011
- TA QMS91-N05, “Takasago R&D Report Procedure for Defects and Nonconformities for Nuclear R&D,” Revision 2, dated September 10, 2007
- Nonconformance Report 02-2011, Fuel Assembly, dated April 4, 2011
- Nonconformance Report 03-2011, RG 1.28, dated July 4, 2011
- Nonconformance Report 05-2011, Internal Audit, dated July 4, 2011
- Nonconformance Report 06-2011, 2010 Audit Checklist, dated July 4, 2011
- Nonconformance Report 07-2011, CIB Test, dated July 4, 2011
- Nonconformance Report 10-2011, QA Procedure and Part 21 Evaluation, Revision 1, dated July 26, 2011,
- Nonconformance Report 11-2011, QA Manual, Part 21, and Appendix B, dated July 26, 2011
- Nonconformance Report 13-2011, Nonconforming Items, dated July 26, 2011

b. Observations and Findings

The NRC inspection team reviewed MHI Takasago’s implementing procedure TA QMS91-06 and QAM Sections 15 and 16, which describe the general requirements for implementing the MHI Takasago Corrective Action Program, including identification, documentation, tracking, evaluation, and closeout of nonconforming conditions. Figure 1, “Steps of the Preparation of NCR-CAR,” of QMS91-06 provides a flowchart detailing how to appropriately complete the nonconformance report form, QMS-91-06-01. The NRC inspection team also reviewed a sample of nonconformance reports to determine whether they were properly documented and adequately described conditions adverse to quality, significant conditions adverse to quality, the cause of these conditions, and the corrective actions taken, and when applicable, the actions to prevent reoccurrence.

The NRC inspection team discussed the corrective action process with MHI Takasago. The inspection team verified that the QA manager examines the nonconformance reports for trends and that appropriate levels of management reviewed the extent of condition and measures to prevent reoccurrence.

The NRC inspection team reviewed a sample of nonconformance reports associated with the US-APWR testing and verified that corrective actions were being completed in accordance with the QAM and implementing procedures.

c. Conclusions

The NRC inspection team concluded that MHI's corrective action process and procedures adequately identify and correct conditions adverse to quality and preclude repetition of significant conditions adverse to quality consistent with the regulatory requirements of Criterion XVI of Appendix B to 10 CFR Part 50. No findings of significance were identified.

9. Translation of Documents

The NRC inspection team learned that MHI Takasago primarily uses the Japanese version of implementing procedures and POs, and the English version is mainly for use during audits by external parties. Through the course of the review, the NRC contract translators identified only minor differences that did not affect the application of the requirements.

10. Entrance and Exit Meetings

On July 25, 2011, the NRC inspection team discussed the scope of the inspection with Mr. Matsuda, and with the MHI Takasago management and staff. On July 29, 2010, the inspection team presented the inspection results and observations during an exit meeting with Mr. Matsuda and other MHI 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

<u>Name</u>	<u>Title</u>	<u>Affiliation</u>	<u>Entrance</u>	<u>Exit</u>	<u>Interviewed</u>
Greg S. Galletti	Senior Operations Engineer	NRC	X	X	
Stacy Smith	Reactor Operations Engineer	NRC	X	X	
Christopher Van Wert	Senior Reactor Systems Engineer	NRC	X	X	
Juan D. Peralta	Chief of QA & Vendor Inspection Branch 1	NRC	X	X	
Diego Saenz	Reactor Systems Engineer	NRC	X	X	
Chandu Patel	Senior Project Manager	NRC	X	X	
Michiko Yobe	Interpreter	NHK Global Media Service	X	X	
Atsuko Fujimoto	Interpreter	NHK Global Media Service	X	X	
Masaharu Andy Tabinaki	Interpreter	Independent	X	X	
Chieko Okada	Interpreter	Independent	X	X	
Ikuo Otake	QA Department Manager	MNES		X	X
Takeshi Matsuda	QA Manager	MHI	X	X	X
Masayoshi Suzuki	Engineering Manager QA	MHI	X	X	X
Akifumi Takahashi	Engineering Manager QA	MNES	X	X	X
Ryan Sprengel	Lead Licensing Engineer	MNES	X	X	X
M. Vann Mitchell	GMQA	MNES	X	X	X
Yuji Momose	Layout Engineer	MHI	X		
Shuhei Miyake	Manager	MNES	X	X	X
Yutaka Tanaka	Manager Research and Development	MHI	X	X	X
Chikara Karimara	Manager	MHI	X	X	X
Kayoko Kawata	Research Manager	MHI	X	X	X
Shimji Otami	Engineering Manager	MHI	X	X	X
Nobuo Ishihara	Engineering Manager	MHI	X	X	X

<u>Name</u>	<u>Title</u>	<u>Affiliation</u>	<u>Entrance</u>	<u>Exit</u>	<u>Interviewed</u>
Hiroshi Matsuoka	Engineering Manager	MHI	X		
Takanori Yasuda	Manager	MHI	X		
Hirokazu Miyata	Chemical Engineer	MHI	X	X	X
Takashi Fukuda	Manager	MNES			
Taiki Asahara	Engineer	MHI	X	X	X
Takayuki Nakano	Engineering Manager	MHI THCIES	X	X	X
Tadakatsu Yodo	Engineer	MHI THCIES	X	X	X
Kurt R. Walter	Engineer	MSES	X	X	
Hideo Fukuda	Engineering Manager	MHI	X		
Hideyuki Sakata	Heat Transfer Laboratory			X	X

2. INSPECTION PROCEDURES USED

IP 35034, "Design Certification Testing Inspection"

IP 35017, "Quality Assurance Implementation Inspection"

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:

<u>Item Number</u>	<u>Status</u>	<u>Type</u>	<u>Description</u>
05200021/2011-202-01	Open	NOV	10 CFR 21.21(a)
05200021/2011-202-02	Open	NOV	10 CFR Part 50, App. B, Criterion II
05200021/2011-202-03	Open	NOV	10 CFR Part 50, App. B, Criterion IV
05200021/2011-202-04	Open	NOV	10 CFR Part 50, App. B, Criterion VII
05200021/2011-202-05	Open	NOV	10 CFR Part 50, App. B, Criterion X
05200021/2011-202-06	Open	NOV	10 CFR Part 50, App. B, Criterion XIII