June 28, 2013

Mr. Matthew Siegel, President
General Atomics Electronics Systems, Inc.
4990 Greencraig Lane
San Diego, CA 92123

SUBJECT: NUCLEAR REGULATORY COMMISSION INSPECTION REPORT
NO. 99900265/2013-201 AND NOTICE OF NONCONFORMANCE

Dear Mr. Siegel:

From May 13 to May 16, 2013, the U.S. Nuclear Regulatory Commission (NRC) staff conducted an inspection at the General Atomics Electronics Systems, Inc. (GA-ESI), facility in San Diego, CA. The purpose of the limited-scope inspection was to assess GA-ESI's compliance with the provisions of selected portions 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," and 10 CFR Part 21, "Reporting of Defects and Noncompliance."

This inspection specifically evaluated GA-ESI's production of radiation monitoring systems (RMS) for the U.S. AP1000 fleet, and for other operating reactor plants. The enclosed report presents the results of the inspection. This NRC inspection report does not constitute NRC endorsement of your overall quality assurance (QA) or 10 CFR Part 21 programs.

Based on the results of this inspection, the NRC inspection team found that the implementation of your QA program did not meet certain NRC requirements imposed on you by your customers or NRC licensees. Specifically, GA-ESI failed to identify critical characteristics for a radioiodine filter used in its RMS systems and failed to verify critical material characteristics of an Amphenol connection. The enclosed notice of nonconformance (NON) cites these nonconformances, and the circumstances surrounding them are described in detail in the enclosed inspection report.

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

In accordance with 10 CFR 2.390, "Public Inspections, Exemptions, Requests for Withholding," of the NRC's "Rules of Practice," the NRC will make a copy of this letter, its enclosures, and your response available electronically for public inspection in the NRC's Public Document Room or through the NRC's document system, Agencywide Documents Access and Management System (ADAMS), which is 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 the inclusion of Safeguards Information is necessary to provide an acceptable response, please provide the level of protection described in 10 CFR 73.21, "Protection of Safeguards Information: Performance Requirements."

Sincerely,

/RA/

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

Docket No.: 99900265

Enclosures:
1. Notice of Nonconformance
2. Inspection Report 99900265/2013-201

If personal privacy or proprietary information is necessary to provide an acceptable response, then please provide a bracketed copy of your response that identifies the information that should be protected and a redacted copy of your response that deletes such information. If you request that such material is withheld from public disclosure, you must specifically identify the portions of your response that you seek to have withheld and provide in detail the bases for your claim (e.g., explain why the disclosure of information will create an unwarranted invasion of personal privacy or provide the information required by 10 CFR 2.390(b) to support a request for withholding confidential commercial or financial information). If safeguards information is necessary to provide an acceptable response, please provide the level of protection described in 10 CFR 73.21, "Protection of Safeguards Information: Performance Requirements."

Sincerely,

/RA/

Richard A. Rasmussen, Chief
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Division of Construction Inspection
and Operational Programs
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Docket No.: 99900265

Enclosures:
1. Notice of Nonconformance
2. Inspection Report 99900265/2013-201

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OFFICE	NRO/DCIP/CEVB	NRO/DCIP/CEVB	NRO/DCIP/CQAB	NRO/DCIP/CQAB
NAME	DBollock	GGalletti	PPrescott	ABelen
DATE	6/13/2013	6/13/2013	6/18/2013	6/13/2013
OFFICE	NRO/DCIP/CAEB	NRO/DCIP/CEVB		
NAME	TFrye	RRasmussen		
DATE	6/20/2013	6/28/2013		

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NOTICE OF NONCONFORMANCE

General Atomics Electronic Systems, Inc. Docket No.: 99900265
San Diego, CA Inspection Report No.: 99900265/2013-201

Based on the results of a U.S. Nuclear Regulatory Commission (NRC) inspection conducted at the General Atomics Electronic Systems, Inc. (GA-ESI) facility in San Diego, CA, on May 13–16, 2013, certain activities were not conducted in accordance with NRC requirements that NRC licensees contractually imposed on GA-ESI:

A. Criterion III, "Design Control," of Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants," to Title 10 of the *Code of Federal Regulations* (10 CFR) Part 50, "Domestic Licensing of Production and Utilization Facilities," states, in part, "measures shall also be established for the selection and review for suitability of application of materials, parts, equipment, and processes that are essential to the safety-related functions of the structures, systems, and components."

   General Atomics procedure OP-7.3-240, "Safety-Related Commercial Grade Item Parts Acceptance," Rev L, dated January 3, 2013, Section 4.a, states, in part, that the critical characteristics shall be verified by a documented critical characteristics acceptance plan (CCAP) or checklist. It shall include:

   1. tests and inspections to be performed according to CCAP
   2. test methods and inspection techniques to be used
   3. acceptance criteria previously derived from the technical evaluation
   4. documentation requirements for inspection and test results

   The documentation as a result of the tests and inspections shall become part of the documentation package that is stored with the purchase order.

   Contrary to the above, as of May 16, 2013, NRC staff identified two examples where GA-ESI failed to establish adequate measures for the selection and review for suitability of application of materials, parts, equipment, and processes that are essential to the safety-related functions of the structures, systems, and components. Specifically:

   1. GA-ESI procured commercial grade items for use in safety-related applications without verifying the functional critical characteristic of the radioiodine cartridge filter to demonstrate that it can collect particulates from an air sample.

   2. GA-ESI's Amphenol connector documentation did not provide technical justification for the acceptance criteria for the critical characteristics regarding material composition.

   This issue has been identified as Nonconformance 99900265/2013-201-01.

Please provide a written statement or explanation to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, DC 20555-0001, with a copy to the Chief, Construction Electrical Vendor Branch, Division of Construction Inspection and Operational Programs, Office of New Reactors, within 30 days of the date of the letter transmitting this notice of nonconformance. This reply should be clearly marked as a "Reply to a Notice of Nonconformance" and should include for each noncompliance: (1) the reason for the

noncompliance, or if contested, the basis for disputing the noncompliance, (2) the corrective steps that have been taken and the results achieved, (3) the corrective steps that will be taken to avoid noncompliance, and (4) the date when the corrective action will be completed. Where good cause is shown, the NRC will consider extending the response time.

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

Dated this the 28th day of June 2013.

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

Docket No.:	99900265
Report No.:	99900265/2013-201
Vendor:	General Atomics Electronics Systems Inc. 4990 Greencraig Lane San Diego, CA 92123
Vendor Contact:	John Morris, Director, RMS Programs Telephone: 858-522-8425 E-mail: john.morris@ga-esi.com
Background:	General Atomics Electronics Systems, Inc., is a provider of radiation monitoring systems and replacement parts of those systems for the U.S. commercial nuclear fleet. They are also producing the radiation monitoring systems for the U.S. AP1000 new reactors.
Inspection Dates:	May 13–16, 2013
Inspection Team Leader:	Douglas Bollock, NRO/DCIP/CEVB
Inspectors:	Paul Prescott, NRO/DCIP/CQAB Greg Galletti, NRO/DCIP/CEVB Aixa Belen, NRO/DCIP/CQAB
Approved by:	Richard A. Rasmussen, Chief Electrical Vendor Branch Division of Construction Inspection and Operational Programs Office of New Reactors

EXECUTIVE SUMMARY

General Atomics Electronics Systems Inc.
99900265/2013-201

The U.S. Nuclear Regulatory Commission (NRC) conducted this vendor inspection to verify aspects of the implementation by General Atomics Electronics Systems Inc. (GA-ESI), of its quality assurance (QA) program as required by 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," and 10 CFR Part 21, "Reporting of Defects and Noncompliance."

This inspection specifically evaluated GA-ESI's design, production, and dedication of safety-related radiation monitoring systems (RMS) for the U.S. AP1000 new reactors. GA-ESI also produces other RMSs for operating commercial nuclear plants in the United States and provides repair and replacement of those systems. The NRC inspection team reviewed the procurement, design, production, commercial grade dedication, and testing of the GA-ESI RMS systems, along with reviewing GA-ESI's 10 CFR Part 21 program. The NRC conducted this inspection at GA-ESI's facility in San Diego, CA.

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

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

The inspectors used Inspection Procedure (IP) 43002, "Routine Inspections of Nuclear Vendors," dated April 25, 2011, IP 43004, "Inspection of Commercial-Grade Dedication Programs," dated April 25, 2011, and IP 36100, "Inspection of 10 CFR Part 21 and Programs for Reporting Defects and Noncompliance," dated February 13, 2012.

The information below summarizes the results of this inspection.

10 CFR Part 21

The inspectors determined that GA-ESI appropriately translated the requirements of 10 CFR Part 21 into implementing procedures and, for those activities that the inspectors reviewed, implemented them as required by GA-ESI procedures. No findings of significance were identified.

Commercial Grade Dedication

The inspectors reviewed GA-ESI's implementing procedures governing the commercial-grade dedication program to verify compliance with the requirements of Criterion III, "Design Control," and Criterion VII, "Control of Purchased Material, Equipment, and Services," of Appendix B to 10 CFR Part 50.

Based on this review, the inspectors issued Nonconformance 99900265/2013-201-01 for GA-ESI's failure to implement the regulatory requirements of Criterion III, "Design Control," of Appendix B to 10 CFR Part 50. Specifically, GA-ESI failed to verify critical characteristics related to flow and efficiency of a radioiodine filter cartridge and electrical connector material to demonstrate that the components would be able to perform their safety function.

Design Control

The inspectors determined, based on the samples reviewed, that the vendor design control process met the requirements of Criterion III, “Design Control,” of Appendix B to 10 CFR Part 50. With the exception of Nonconformance 99900265/2013-201-01, in section 2 Commercial Grade Dedication of this report, no findings of significance were identified.

Procurement

The inspectors determined that GA-ESI’s procurement processes conformed to the requirements of Criteria IV, “Procurement Document Control,” and VII, “Control of Purchased Material, Equipment, and Services,” of Appendix B to 10 CFR Part 50 and that GA-ESI’s QA policy and procedures were being effectively implemented for the AP1000 RMS work. No findings of significance were identified.

Testing

The inspectors determined that GA-ESI’s testing quality controls conformed to the requirements of Criteria XI, “Test Control” of Appendix B to 10 CFR Part 50 and that GA-ESI’s QA policy and procedures were being effectively implemented for the AP1000 RMS work. No findings of significance were identified.

Measuring and Test Equipment

The inspectors determined that GA-ESI has established a program that adequately controls calibration and use of measuring and test equipment (M&TE) in accordance with the regulatory requirements of Criterion XII, “Control of Measuring and Test Equipment,” of Appendix B to 10 CFR Part 50. No findings of significance were identified.

Nonconformances and Corrective Actions

The inspectors determined that the implementation of GA-ESI’s programs for control of nonconforming material, parts, or components and corrective action were consistent with the regulatory requirements in Criterion XV, “Nonconforming Materials, Parts, or Components,” and Criterion XVI, “Corrective Action,” of Appendix B to 10 CFR Part 50. No findings of significance were identified.

REPORT DETAILS

1. 10 CFR Part 21 Program

a. Inspection Scope

The inspectors reviewed General Atomics Electronics Systems, Inc.'s (GA-ESI's) policies and implementing procedures that govern its Title 10 of the *Code of Federal Regulations* (10 CFR) Part 21 program to verify compliance with the requirements of 10 CFR Part 21, "Reporting of Defects and Noncompliance." The inspectors interviewed the quality assurance (QA) director and staff members of GA-ESI, on the implementation of the Part 21 program and reviewed a sample of completed 10 CFR Part 21 evaluations.

The inspectors also reviewed GA-ESI's procedures that govern corrective action and the control and correction of nonconforming items to verify an adequate link to the 10 CFR Part 21 process.

b. Observations and Findings

OP-1.4-180, "Compliance with 10 CFR 21," Revision J, April 16, 2013, establishes the requirements for GA-ESI's compliance with the requirements in 10 CFR Part 21. QAP 22-01, "Verification of 10 CFR 21 Compliance," Revision G, April 5, 2013, provides the guidance for conducting 10 CFR Part 21 evaluations and meeting the requirements. Also, the inspectors verified that QAP 15-01, "Administration of Nonconforming Items," and QP-017, "Corrective and Preventative Action," provide a connection to the 10 CFR Part 21 program. To confirm adequate implementation of the process, two 10 CFR Part 21 evaluations were reviewed. The inspectors concluded that GA-ESI's 10 CFR Part 21 evaluations were adequate.

The inspectors observed that GA-ESI satisfied the posting requirements in 10 CFR 21.6, "Posting Requirements." The postings included a copy of Section 206 of the Energy Reorganization Act of 1974, as amended, a copy of 10 CFR Part 21, and a notice containing the information of OP-1.4-180.

The inspectors verified a sample of GA-ESI's purchase orders (PO), and determined that GA-ESI had implemented a program consistent with the requirements in 10 CFR 21.31, "Procurement Documents," for specifying the applicability of 10 CFR Part 21 in its POs for basic components.

c. Conclusions

The inspectors determined that GA-ESI appropriately translated the requirements of 10 CFR Part 21 into implementing procedures and, for those activities that the inspectors reviewed, implemented them as GA-ESI procedures required. No findings of significance were identified.

2. Commercial Grade Dedication

a. Inspection Scope

The inspectors' review of GA-ESI's commercial grade dedication process focused on activities associated with U.S. AP1000 RMS system components. The inspectors reviewed a sample of CGD packages to determine if the process identified in GA-ESI's procedure OP-7.3-240, "Safety-Related Commercial Grade Item Parts and Acceptance," Revision L, dated January 3, 2013, for dedicating its components related to the U.S. AP1000 RMS system was being adequately implemented. OP-7.3-240 provided instructions for evaluating commercial grade items that have safety-related applications in RMS equipment supplied by GA-ESI. A commercial grade item may be furnished as an integral part of RMS equipment at original assembly by GA-ESI or as a spare or replacement part for equipment previously assembled and delivered to the customer. The inspectors observed the dedication testing of RMS replacement system components by GA-ESI staff. The inspectors discussed the dedication process with GA-ESI management and technical staff associated with performance of the CGD process.

b. Observations and Findings

During review of Dedication Package Number 50015405-001, "Cartridge, Radioiodine Sampler," the inspectors identified two critical characteristics related to flow and efficiency of the filter that were not identified or verified in the associated dedication package. The inspectors determined that, without verifying the critical characteristics of flow and efficiency, GA-ESI was unable to demonstrate that the radioiodine filter cartridge was capable of performing its safety function as documented in the technical evaluation. The technical evaluation documented the filter cartridge as a passive mechanical part whose normal function is to filter and collect particulates of a predetermined size from sampled air. This issue is identified as the first example of Nonconformance 99900265/2013-201-01.

During review of Dedication Package Number 50042695-001, "Conn, MHV, SKT, NON-CONST, Clamp" (Amphenol electrical connectors), the inspectors noted that GA-ESI identified material critical characteristics related to insulation, which was specified to be Teflon and the connector, which was specified to be silver-plated. The "determination of critical characteristics" sheet required that the material be visually inspected. The inspectors' review of the dedication package did not find any justification for suitability of a visual inspection. This was based, in part, that a survey was not conducted of the vendor to determine its controls of material used in the connectors. The inspectors determined that without physically verifying the critical characteristics for material, GA-ESI was unable to demonstrate that the Amphenol electrical connectors were suitable for performing their safety function as documented in the technical evaluation. Specifically, that the silver-plated connector was in fact silver and had the required conductive properties and the Teflon was actually Teflon and had the proper insulation properties. The technical evaluation documented the Amphenol electrical connectors as a passive mechanical part whose normal function is to allow an electrical connection by mechanical means. This issue is identified as the second example of Nonconformance 99900265/2013-201-01. GA-ESI initiated CAPA Number 2254 to address the two issues.

c. Conclusions

The inspectors reviewed GA-ESI's policies and implementing procedures that govern the commercial-grade dedication program to verify compliance with the requirements of

Criterion III, “Design Control,” and Criterion VII, “Control of Purchased Material, Equipment, and Services,” of Appendix B to 10 CFR Part 50.

Based on this review, the inspectors issued Nonconformance 99900265/2013-201-01 for GA-ESI’s failure to adequately verify critical characteristics related to flow and efficiency of a radioiodine filter cartridge and electrical connector material to demonstrate that the components would be able to perform their safety function.

3. Design Control

a. Inspection Scope

The inspectors reviewed GA-ESI’s policies and implementing procedures that govern the design control program to verify compliance with the regulatory requirements in Criterion III, “Design 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.”

The inspectors also reviewed a sample of procurement and system design specification documents, assembly drawings, bills of materials, engineering change notices (ECNs) and in-process nonconformance reports, and associated GA ESI POs. In addition, the team reviewed GA-ESI’s test reports to verify that the vendor was maintaining adequate design control with respect to the results from the qualification testing related to the first article (qualification unit) of the Radiation High Range Monitor module of the RMS.

The inspectors evaluated a sample of design requirements related to both environmental (CE102 conducted emissions, high-frequency, 10 kilohertz to 2 megahertz) and seismic testing requirements for both operating-basis earthquake and safe-shutdown earthquake qualifications. In addition, the inspectors reviewed samples of recent ECN’s and in-process nonconformance reports associated with the Containment High Range Monitor design and ongoing qualification testing implementation.

The inspectors also discussed the design control program with GA-ESI’s management and technical staff. The attachment to this inspection report lists the documents reviewed by the inspectors.

b. Observations and Findings

Section 3-01, “Design Control Assurance,” of GA-ESI’s Quality Assurance Procedure (QAP) describes GA-ESI’s design control process in accordance with the applicable regulatory requirements and relevant industry standards such as Military Standards (Mil-Spec) and Institute of Electrical and Electronics Engineers guidelines. The inspectors confirmed that GA-ESI’s design control process provides controls for design inputs and outputs, analyses and testing, records and reports, and interface controls between Westinghouse Electric Corporation (WEC) and GA-ESI.

The inspectors verified that the sample of WEC AP1000 procurement specification and system specification documents reviewed were adequately translated into GA-ESI’s qualification plans and testing procedures.

Examples of both, internally generated changes, based on recent electromagnetic interference and radio-frequency interference testing results, and external change requests from WEC to account for plant configuration changes, were adequately identified, and design changes incorporated into pertinent design documents and drawings.

The inspectors confirmed that (1) design documents specified and included the appropriate technical and quality requirements, (2) WEC and GA-ESI coordinated sufficiently on the Containment High Range Monitor design for the ongoing AP1000 components, (3) GA-ESI integrated independent design reviews and verification activities consistent with the design control program requirements into the design and testing documentation and performed activities in accordance with those procedures, and (4) GA-ESI effectively controlled and implemented design changes.

c. Conclusions

The inspectors determined, based on the samples reviewed, that the vendor design control process met the requirements of Criterion III, "Design Control," of Appendix B to 10 CFR Part 50. With the exception of Nonconformance 99900265/2013-201-01, in Section 2, Commercial Grade Dedication, of this report no findings of significance were identified.

4. Procurement

a. Inspection Scope

The inspectors reviewed GA-ESI's policies and procedures for procurement processes to verify compliance with Criterion IV and Criterion VII of Appendix B to 10 CFR Part 50. Specifically, the inspection evaluated GA-ESI's procurement controls to ensure they included the regulatory requirements, design basis, and other applicable requirements in procurement documents for the U.S. AP1000 new reactor RMS systems. In addition, the inspectors reviewed GA-ESI's applicable implementing procedures, along with samples of POs that contained work scopes, contract services requirements, supplier quality assurance program descriptions, and methods GA-ESI used to dedicate suppliers of commercial items and services.

The inspectors reviewed GA-ESI's PO number 45032546, dated November 24, 2009, from Westinghouse associated with the AP1000 radiation monitoring systems for Vogtle Units 3 and 4. The PO identified the items that were safety-related: APP-PXS-JS-161, 162, 163 Containment High Range Monitors, and APP-VBS-JS-01A, 01B for the Main Control Room Supply Air Duct Monitors for both units. Additionally, the PO specified that the associated seismic and environmental qualification testing was to be performed as a safety-related service.

The inspectors reviewed Westinghouse's document, APP-RMS-GP-001, "AP-1000 Radiation Monitoring System Procurement Specification document," Revision 0, dated November 2009, that provided the technical specifications for the containment high range monitors and main control room supply air duct monitors. Additionally, the inspectors reviewed Drawing Number 04641501-CRS, "Configuration Requirements Specification, Heat Traced Fixed Filter PIG [Particulate, Iodine, and Gas] Monitor," Revision B, dated October 16, 2012. The document translated the technical

specifications into the software requirements for the Main Control Room Supply Air Duct Radiation Monitor.

The inspectors reviewed GA-ESI's Quality Assurance Manual which details the controls established to ensure procurement documents and purchased items and services meet applicable technical and quality requirements. The inspectors also reviewed QAP 7-01, "Purchased Material, Equipment and Services Acceptability Controls," Revision G, dated December 31, 2012, which describes GA-ESI's process for verifying and documenting the acceptability of purchased material, equipment, or services and QAP 04-01, "Procurement Document Review," Revision P, dated April 5, 2013, describes the process of inclusion of the applicable quality and customer requirements in the POs.

The inspectors reviewed GA-ESI's approved suppliers' list (ASL) entries and noted that the majority are commercial-grade suppliers. Also, the inspectors reviewed QAP-4-04, "Authorized Suppliers," Revision F, dated April 5, 2013, which explains the method for the qualification of selected suppliers and the steps for the administration of the quality assurance controlled ASL. The ASL includes general information of the vendor, the service or items they supplied, standards applied, dates of the last survey or audit performed, and the dates of the next audit and surveys.

b. Observations and Findings

The inspectors' review determined that the technical and quality requirements from these documents accurately reflect PO documentation for the safety-related U.S. AP1000 RMS systems and are contractually passed down to GA-ESI suppliers through POs. The inspectors also determined that GA-ESI's documentation associated with the translation of PO requirements into technical specifications was complete and accurate.

The inspectors reviewed a sample of POs to verify that specific procurement requirements were met and documented correctly. Also, the inspectors verified that the POs included, as applicable, scope of work, right of access to facilities and records for source inspections and audits, reporting and approving disposition of nonconformances, references to specific drawings, codes, and specifications.

c. Conclusions

The inspectors determined that GA-ESI's procurement processes conformed to the requirements of Criteria IV, "Procurement Document Control," and VII, "Control of Purchased Material, Equipment, and Services," of Appendix B to 10 CFR Part 50 and that GA-ESI's QA policy and procedures were being effectively implemented for the AP1000 RMS work. No findings of significance were identified.

5. Testing

a. Inspection Scope

The inspectors reviewed GA-ESI's policies and procedures governing the implementation of its testing program to verify compliance with Appendix B to 10 CFR Part 50. Specifically, the inspectors evaluated samples of equipment testing related to the U.S. AP1000 RMS systems. In addition, the inspectors sampled GA-ESI's Measuring and Test Equipment (M&TE) calibration records for test equipment to ensure

that all requirements of instrument and testing devices used in activities affecting quality were properly controlled. The inspectors reviewed QC 108B, "Inspection of Pump/Motor Assembly," Revision C, dated January 18, 2012, which describes the testing procedure for the metal bellows pump and includes the acceptance criteria. The inspectors reviewed A58307, "Acceptance Test Procedure, PWA, Temperature Controller Backplane," Revision B, dated April 19, 2012, which describes the testing procedure and includes the acceptance criteria.

b. Observations and Findings

The inspectors observed and evaluated the testing for metal bellows pumps that are used to provide a sample air flow for volumetric sample calculations for the AP1000 RMS 2200. The testing was performed as part of the dedication process for the pumps. The inspectors verified that testing was performed according to the procedure; the parameters measured were inside the acceptance criteria; and the measuring and test equipment used were calibrated.

In addition, the inspectors observed the functional test on the printed circuit boards associated with the temperature controller backplane assembly. The inspectors verified that testing was performed according to the procedure; the parameters measured were inside the acceptance criteria; and the measuring and test equipment used were calibrated.

c. Conclusions

Based on the sample of documentation reviewed, the inspectors determined that GA-ESI's testing controls satisfy the regulatory requirements set forth in Criterion XI, "Test Control," Appendix B to 10 CFR Part 50. No findings of significance were identified.

6. Measuring and Test Equipment

a. Inspection Scope

The inspectors reviewed M&TE policies and procedures to determine if GA-ESI's controls were in 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 inspectors verified the implementation of M&TE control through direct observation of inspection activities of GA-ESI personnel and review of certificates of calibration for a sample of M&TE. The inspectors reviewed evaluations performed by GA-ESI of commercial calibration services supplier, Anmar Metrology, and confirmed that the surveys evaluated Anmar's QA program documentation and processes against acceptance criteria of ISO IEC 17025 and ISO 9001:2008 to assure control of critical M&TE calibration processes. Process included detailed audit plans, checklist, summary report, letter to commercial calibration supplier and calibration laboratory accreditation documentation.

b. Observations and Findings

The inspectors evaluated a sample of M&TE associated with the testing and production of the Containment High Range Monitor module. Specifically, the NRC High Range

Monitor, Revision A, dated August 13, 2012, and Production Order Package, Order 300005763, "Containment High Range Monitor Assembly," dated July 5, 2012, and confirmed that the vendor used calibrated equipment for testing and production in accordance with GA-ESI's testing procedures. The inspectors confirmed that the instruments were calibrated and appropriate for the range of operation for each described activity.

The inspectors evaluated GA-ESI's calibration frequency for common items and discussed the basis for the calibration frequency with GA-ESI personnel. The inspectors confirmed that the calibration frequency was based on standards recommended by the original equipment manufacturer, operational experience, and frequency of use.

Additionally, GA-ESI's supplier calibration services oversight process was evaluated. The inspectors confirmed that the accreditation covered the ranges of parametric values for which these devices were used during testing. The inspectors confirmed traceability to National Institute of Standards and Technology calibration standards and that all test and inspection equipment used for the observed inspection and test activities were controlled, documented, and current for calibration requirements.

c. Conclusions

The inspectors determined that GA-ESI has established a program that adequately controls calibration and use of M&TE in accordance with the regulatory requirements of Criterion XII, "Control of Measuring and Test Equipment," of Appendix B to 10 CFR Part 50. No findings of significance were identified.

7. Nonconformances and Corrective Actions

a. Inspection Scope

The inspectors reviewed GA-ESI's policies and procedures governing the implementation of nonconforming components and corrective actions to verify compliance with Criterion XV, "Nonconforming Materials, Parts, or Components," and Criterion XVI, "Corrective Action," of Appendix B to 10 CFR Part 50. In addition, the inspectors conducted several interviews of GA-ESI's management and technical staff about the evaluation process of nonconforming components and corrective actions. The inspectors also reviewed QAP 15-01, "Administration of Nonconforming Items," Revision N, April 4, 2013, that describes the requirements for identification, documentation, evaluation, segregation, disposition, and control of nonconforming items.

The inspectors reviewed QAP 16-01, "Corrective and Preventative Action," Revision M, January 14, 2013, that describes the processes and procedures for addressing conditions adverse to quality.

b. Observations and Findings

While conducting a review of GA-ESI's nonconformance reports called Quality Notifications (QN) and Corrective Action/Preventative Action reports (CAPA), the inspectors noted that GA-ESI takes extra steps in evaluating its CAPAs to identify root causes, if available, and actions to prevent recurrence. Inspectors also verified that all GA-ESI CAPAs are reviewed for 10 CFR Part 21 reportability. In addition, the inspectors

noted that GA-ESI QNs are reviewed by Quality Assurance engineers to determine if there is a potential 10 CFR Part 21 reportability, in which case a CAPA is created for the evaluation. QNs are also reviewed during a frequent Material Review Board meeting, which occurs between two to five times a week, in which any QN that has potential 10 CFR Part 21 reportability is addressed in the group review, including engineering, and quality assurance personnel.

The inspectors verified that, for the sample of nonconformances reviewed, GA-ESI had: (1) dispositioned the nonconformances it identified in accordance with GA-ESI approved procedures, (2) presented an appropriate technical justification for various dispositions, (3) taken adequate action with regard to the nonconforming material or item, and (4) subjected all identified nonconformances, as appropriate, to a 10 CFR Part 21 assessment or evaluation. The inspectors also reviewed a sample of corrective action documents to ensure that conditions adverse to quality: (1) were properly identified and correctly dispositioned in the appropriate processes, (2) contained proper management review approval, and (3) were evaluated for their effect on the item's safety function or qualification, when applicable.

c. Conclusions

The inspectors determined that the implementation of GA-ESI's programs for control of nonconforming material, parts, or components and corrective action were consistent with the regulatory requirements in Criterion XV and Criterion XVI of Appendix B to 10 CFR Part 50. No findings of significance were identified.

7. Entrance and Exit Meetings

On May 13, 2013, the inspectors presented the inspection scope during an entrance meeting with Mr. Matthew Siegel, President of GA-ESI, and other GA-ESI personnel. On May 16, 2013, the inspectors presented the inspection results during an exit meeting with Mr. Siegel and other GA-ESI personnel.

ATTACHMENT

1. PERSONS CONTACTED AND NRC STAFF INVOLVED

Name	Title	Affiliation	Entrance	Exit	Interviewed
Matthew Siegel	President	GA-ESI	X	X	
John Morris	Director of Quality Assurance	GA-ESI	X	X	X
Steven Karsten	RMS	GA-ESI	X	X	X
Steven Babb	Quality Assurance	GA-ESI	X		
Ben Gibbens	Production	GA-ESI	X		
Keith Asmussen	Licensing	GA-ESI	X	X	
Junaid Razvi	Nuclear Compliance	GA-ESI	X	X	X
Jimmy Duffy	RMS	GA-ESI	X	X	X
Paul Starenas	Manufacturing/Ops	GA-ESI	X	X	
Douglas Brown	Engineering	GA-ESI	X	X	
Art Evans	Engineering	GA-ESI	X	X	
John Ladrillano	Quality Assurance	GA-ESI	X	X	X
Kevin Bonser	Quality Assurance	GA-ESI	X	X	X
Steven Jaramillo	Lead Manufacturing Specialist	GA-ESI			X
Phuong Nguyen	QC Inspector	GA-ESI			X
Laura Meza	Production Specialist	GA-ESI			X
Nathan White	RMS Electronics Technician	GA-ESI			X
Phil Newman	RMS Customer Service	GA-ESI		X	
Art Butt	QA Engineer	GA-ESI		X	
Ted Nance	Quality Control	GA-ESI		X	
Neil Puri	Quality Assurance	GA-ESI		X	X
P. Mamode	System Engineer	GA-ESI			X
I. Brslica	System Engineer	GA-ESI			X

Name	Title	Affiliation	Entrance	Exit	Interviewed
T. Dagher	SE Manager	GA-ESI			X
B. Soukkyphiangkeo	QC Equipment Calibration	GA-ESI			X
Douglas Bollock	Inspection Team Leader	NRC	X	X	
Paul Prescott	Inspection Team Member	NRC	X	X	
Greg Galletti	Inspection Team Member	NRC	X	X	
Aixa Belen	Inspection Team Member	NRC	X	X	

2. INSPECTION PROCEDURES USED:

IP 43002, "Routine Inspections of Nuclear Vendors"

IP 43004, "Inspection of Commercial-Grade Dedication Programs"

IP 36100, "Inspection of 10 CFR Part 21 and Programs for Reporting Defects and Noncompliance"

3. ITEMS OPENED, CLOSED, AND DISCUSSED:

Item Number	Status	Type	Description
99900265/2013-201-01	OPEN	NON	Criterion III

4. DOCUMENTS REVIEWED:

GA-ESI Procedures

- QAP 16-01, "Corrective and Preventative Action," Revision M, January 14, 2013
- QP-017, "Corrective and Preventative Action," Revision K, January 4, 2013
- QAP 22-01, "Verification of 10 CFR 21 Compliance," Revision G, April 5, 2013
- OP-1.4-180, "Compliance with 10 CFR 21," Revision J, April 16, 2013
- QCI-608, "Corrective and Preventative Action Sharepoint Instruction," Revision A, December 10, 2012
- QAP 15-01, "Administration of Nonconforming Items," Revision N, April 4, 2013
- QAP 19-02, "Control of Customer Returns," Revision D, December 17, 2004
- 0357-8031, "Test Procedure CPU-I/O Board Bus, RM-80," Revision B, January 9, 1979
- 03579007, "Test Procedure, PC Assembly Burn-In RM-80," Revision F, January 15, 1982
- 03572019, "Supplemental Procedure for PWR, ISO, Motherboard, CPU, & I/O PCB Assemblies," Revision N, December 10, 1982
- 03572031, "Test Procedure-PC Assembly Input/Output," Revision U, November 9, 1978

- 03572030-018, “Manufacturing Work Instructions. PCA-I/O, RM-80,” Revision B, June 7, 2011
- OP 4.0-120, “Design Documentation,” Revision H, December 17, 2004
- OP 4.0-130, “Engineering Change Notice,” Revision AC, May 8, 2013
- OP 4.0-140, “Design Control,” Revision R, July 11, 2011
- OP 4.0-150, “Design Reviews,” Revision N, December 17, 2004
- OP 4.0-190, “Maintenance of RMS Database,” Revision Y, May 7, 2013
- OP 6.6-145, “Direct Drawing Change,” Revision C, December 17, 2004
- OP 6.6-160, “RMS Change Control Board,” Revision C, December 17, 2004
- OP 6.6-180, “RMS Release and Control Systems,” Revision N, May 9, 2013
- OP 7.3-110, “Safety-Related Equipment Qualification,” Revision D, April 16, 2013
- QAP 3-01, “Design Control Assurance.”
- QAP 7-02, “Design Control Assurance of Commercial Grade Items on Nuclear Safety-Related Applications,” Revision K, March 7, 2013
- QAP12-01, “Calibration and Control of Measuring Equipment,” Revision R, May 6, 2013

<u>GA-ESI Nonconformance Reports and Corrective Actions</u>

- CAPA Number 2052, June 11, 2012
- CAPA Number 2092, July 3, 2012
- CAPA Number 2174, November 29, 2012
- CAPA Number 2180, November 26, 2012
- CAPA Number 2171, November 19, 2012
- CAPA Number 2198, December 26, 2012
- CAPA Number 2200, December 26, 2012
- CAPA Number 2201, December 26, 2012
- CAPA Number 2083, March, 22, 2012
- CAPA Number 2179, November 26, 2012
- CAPA Number 2084, April, 23, 2012
- CAPA Number 200000160, May 17, 2011
- CAPA Number 200000151, May 17, 2011
- CAPA Number 200000152, May 17, 2011
- CAPA Number 200000153, May 18, 2011
- CAPA Number 200000162, May 19, 2011
- CAPA Number 200000161, May 19, 2011
- CAPA Number 2247, February 11, 2013
- CAPA Number 2253, May 16, 2013
- CAPA Number 2254, May 16, 2013
- CAPA Number 2255, May 16, 2013
- QN 12753, February 5, 2013
- QN 10731, August, 16, 2011
- QN 10730, August 16, 2011
- QN 12714, February 1, 2013
- QN 12715, February 1, 2013
- QN 12716, February 1, 2013
- QN 12570, January 2, 2013

- QN 12573, January 4, 2013
- QN 12604, January 8, 2013
- QN 12606, January 8, 2013
- QN 12679, January 23, 2013
- QN 12910, March 11, 2013
- QN 13233, May 7, 2013
- QN 12902, March 5, 2013
- QN 13104, April 18, 2013
- QN 13266, May 13, 2013
- QN 12990, March 25, 2013
- QN 12753, February 5, 2013

In-Process Nonconformance Report

- INR3092-EUT Assembly, dated May 13, 2013
- INR3089, PC ASSY-ADC/DAC, RM-80, dated May 10, 2013

Drawings

- PL04700930-002, "Detector Assembly, RD-60-HT, PIG," Revision B, December 2, 2011
- 04700930, "Detector Assembly RD-60," Revision C, December 2, 2011, sheets 1–4
- 04700933, "Wiring Diagram, Detector, RD-60," Revision B, December 2, 2011
- PL0357-2030-18, "PCA-I/O, RM-80," Revision B, April 30, 1981
- 0357-2030, "PC ASSY-Input/Output, RM-80," July 17, 1978
- 0357-2032, "Schematic-Input/Output, RM-80," June 25, 1978
- 04644910, Block Diagram, Containment High Range Monitor, Revision B, dated May 7, 2012
- 04644920. Customer Connection Diagram, Containment High Range Monitor, Revision D, dated May 15, 2012
- 04644900, Outline, Containment High Range Monitor, Revision A, dated February 28, 2011
- 04644901, Containment High Range Monitor Assembly, Revision B, dated October 5, 2012

Miscellaneous Documents

- "10 CFR Part 21 Evaluation Summary for part # 04622005-001, conductive EMI gasket reported to be insulative," dated March 27, 2013
- "10 CFR Part 21 Evaluation Summary for zinc plated Carbon Steel Bolt used in place of Stainless Steel Bolt," dated September 16, 2011
- Document No. S00008008, Issue # 1, RMS, TRIGA, GULF, LYNX, CAPS AND TAP PRODUCTS APPROVED SUPPLIER LIST, dated March 8, 2013
- 04648900, AP1000 Important to Safety Radiation Monitoring System Qualification Plan, Revision B, November 30, 2011
- APP-GW-G1-002, AP1000 Plant Equipment Qualification Methodology, Revision 2
- Institute of Electrical and Electronics Engineers (IEEE) Std 323-1974, "IEEE Standard for Qualifying Class IE Equipment for Nuclear Power Generating Stations," dated February 28, 1974

- IEEE Standard (Std.) 344-2004, "IEEE Recommended Practice for Seismic Qualification of Class 1E Equipment for Nuclear Power Generating Stations," issued January 2004
- Regulatory Guide (RG) 1.89, "Environmental Qualification of Certain Electric Equipment Important to Safety for Nuclear Power Plants," Revision 1, June 1984
- RG 1.180, "Guidelines for Evaluating Electromagnetic and Radio-Frequency Interference," Revision 1, October 2003
- RG 1.100, "Seismic Qualification of Electrical and Active Mechanical Equipment and Functional Qualification of Active Mechanical Equipment for Nuclear Power Plants," Revision 3, October 2009
- MIL-STD-461E, "Requirements for the Control of Electromagnetic Interference Characteristics of Subsystems and Equipment," U.S. Department of Defense, August 20, 1999

Production Order Packages

- Order # 30009409, Material # 04700930-002, Detector Assembly RD-60-HT PIG, RMS System, dated April 26, 2013
- Order # 30009222, Material # 03572030-018, PCA-I/O, RM-80, RMS System, April 5, 2013

Certificates of Calibration

- Report No. 9132798, Hygro-thermometer clock, Revision 0, dated April 9, 2013
- Report No. 91329470, Thermal Profiler, Revision 0, dated May 2, 2013

Engineering Change Notice (ECN)

- ECN 400003601, AP1000 RMS, dated March 27, 2013
- ECN 400003577, AP1000 RMS, dated January 21, 2013
- ECN 400003147, AP1000 RMS, dated October 8, 2012

Manufacturing Instructions

- 04644990, "Equipment Under Test (EUT) Assembly, Containment High Range Monitor," Revision A, dated October 16, 2012
- 04644901-001, "Containment High Range Monitor Assembly," Revision B, dated August 11, 2011

Procurement and System Specifications

- APP-RMS-GP-001, AP1000 Radiation Monitoring System Procurement Specification, Revision 0, November 2009
- APP-RMS-J7-001, AP1000 Radiation Monitoring System Specification Document, Revision 3, November 2010
- 04644901-CRS, Configuration Requirement Specification, Containment High Range Monitor, Revision A, dated February 17, 2012

Supplier Surveys (M&TE)

- Anmar Metrology, Audit No. 09:5011, dated April 7, 2009
- Commercial Grade Survey Plan, Anmar Metrology, Inc., dated February 15, 2013
- Quality Assurance Audit Checklist, Audit No. 13-102746, Anmar Metrology, dated February 19, 2013

Test Procedure

- 04644901-1EC, Engineering Checkout Procedure (ECP) Containment High Range Monitor, Revision B, dated February 16, 2012
- 04718902, Containment High Range Monitor Electromagnetic Compatibility Test Procedure, Revision B, dated December 4, 2012
- 04718904, Containment High Range Monitor Seismic Test Procedure, Revision X3, dated March 29, 2013

Purchase Orders

- PO 300005763, Containment High Range Monitor Assembly, dated on July 5, 2012
- PO 4200007382 from GA-ESI to Senior Operations for metal bellows pumps dated on October 4, 2012
- PO 4200006348 from GA-ESI to GE-Reuter Strokes for gamma ion chamber dated on September 21, 2012
- PO 4200006860 from GA-ESI to GE-Reuter Strokes for gamma ion chamber dated on September 21, 2012
- PO 4200005943 from GA-ESI to Feeger Lucas Wolfe, Inc., for 30–0 Hg Vac gauge dated on May 22, 2012
- PO 4200005943 from GA-ESI to Feeger Lucas Wolfe, Inc., for 0–30 psi gauge dated on May 22, 2012
- PO 4200008211 from GA-ESI to Fastenal Company for washer dated on April 4, 2013
- PO 4200007569 from GA-ESI to Eckert & Ziegler Isotope Products for Beta S+D 35mm D Active Area dated on October 22, 2012

Commercial Grade Dedication Packages

- Metal bellows pumps, PO 4200007382, material number 04643101-001, supplied by Senior Operations
- Gamma ion chamber, PO 4200006348/0010, material number 50010432-001, supplied by GE-Reuter Strokes
- Gamma ion chamber, PO 4200006860/0010, material number 50010432-001, supplied by GE-Reuter Strokes
- Pressure gauge (30–0 Hg Vac), PO 4200005943/0030, material number 03587002-059, supplied by Feeger Lucas Wolfe
- Pressure gauge (0–30 psi), PO 4200006128/0010 material number 03587002-058, supplied by Feeger Lucas Wolfe, Inc.
- Washer, PO 4200008211, material number 50005197-001, supplied by Fastenal Company

- Beta S+D 35mm D Active Area, PO 4200007569, material number 03600721-013, supplied by Eckert & Ziegler Isotope Products
- Conn, MHV, SKT, Clamp, PO 4200005953/00060, material number 50004269-001, supplied by GA Electronic Systems
- Radioiodine sampler cartridge (filter), PO 4200007098/0010, material number 50015405-001, supplied by Hi-Q Environmental Products

Measuring and Test Equipment

- Test Gauge Pressure 09783-6 calibrated by NBS Calibrations, Inc. on March 13, 2013, ID 19-3-97
- Test Gauge Pressure 09665-6 calibrated by NBS Calibrations, Inc. on October 25, 2012, ID 14-3-54
- Fluke multimeter current calibrated by Calibrated Anmar Metrology, on May 2, 2013, ID 204-00213
- Fluke multimeter voltage calibrated by Calibrated Anmar Metrology, on September 18, 2012, ID 07-1-1L
- Control inch caliper calibrated by Calibrated Anmar Metrology, on June 8, 2012, ID 16-5-AH

5. ACRONYMS USED:

CAPA	corrective action/preventative action
CEVB	Construction Electrical Vendor Branch
CFR	*Code of Federal Regulations*
DCIP	Division of Construction Inspection and Operational Programs
EMI	electromagnetic interference
EQ	environmental qualification
IEEE	Institute of Electrical and Electronics Engineers
IP	inspection procedure
M&TE	measuring and test equipment
GA-ESI	General Atomics Electronic Systems, Inc.
NON	notice of nonconformance
NRC	U.S. Nuclear Regulatory Commission
NRO	Office of New Reactors
PO	purchase order
QA	quality assurance
QAM	quality assurance manual
QC	quality control
QN	quality notification
QP	qualification plan
RMS	radiation monitoring system
WEC	Westinghouse Electric Corporation