November 29, 2016

Dr. Keith E. Asmussen, Director
Licensing, Safety & Nuclear Compliance
General Atomics
Mail Stop A09-114
P.O Box 85608
San Diego, CA 92186-5608

SUBJECT: NUCLEAR REGULATORY COMMISSION INSPECTION REPORT
NO. 99901473/2016-201 AND NOTICE OF NONCONFORMANCE

Dear Dr. Asmussen:

From September 12 through September 16, 2016, the U.S. Nuclear Regulatory Commission (NRC) staff conducted an inspection at the General Atomics Electromagnetic Systems Group (GA-EMS), facility in San Diego, CA. A re-exit meeting was conducted on October 19, 2016, in which the NRC staff presented the inspection results and observations with members of GA-EMS management and technical staff. The purpose of this limited-scope inspection was to assess GA-EMS'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-EMS's production of radiation monitoring systems (RMSs) for the U.S. AP1000 fleet and 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. The NRC inspection team determined that GA-EMS was not fully implementing its QA program in the areas of design control, related to commercial-grade dedication; control of purchased material, equipment, and services; control of measuring and test equipment; and corrective action. Specifically, GA-EMS failed to: 1) maintain the original environmental qualification of conformal coated printed wiring assemblies installed in RMSs; 2) dedicate or verify commercial-grade calibration services used for safety-related applications; 3) establish measures for the use of measuring and test equipment and the calibration process for the RMS detectors to ensure the accuracy of the detectors is within necessary limits; and 4) implement adequate corrective action to correct conditions adverse to quality. The specific findings and references to the pertinent requirements are identified in the enclosures to this letter.

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 Notice of Nonconformance. 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 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 document system (ADAMS), accessible at http://www.nrc.gov/reading-rm/adams.html. To the extent possible, your response, (if applicable), should not include any personal privacy, proprietary, or safeguards information so that it can be made available to the Public without redaction. If personal privacy or proprietary information is necessary to provide an acceptable response, then please provide a bracketed copy of your response that identifies the information that should be protected and a redacted copy of your response that deletes such information. If you request that such material is withheld from public disclosure, you must specifically identify the portions of your response that you seek to have withheld and provide in detail the bases for your claim (e.g., explain why the disclosure of information will create an unwarranted invasion of personal privacy or provide the information 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.

Sincerely,

Kerri Kavanagh, Chief **/RA/**
Quality Assurance Vendor Inspection Branch-3
Division of Construction Inspection
and Operational Programs
Office of New Reactors

Docket No.: 99901473

Enclosures:
1. Notice of Nonconformance
2. Inspection Report 99901473/2016-201
   and Attachment

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 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 document system (ADAMS), accessible at http://www.nrc.gov/reading-rm/adams.html. To the extent possible, your response, (if applicable), should not include any personal privacy, proprietary, or safeguards information so that it can be made available to the Public without redaction. If personal privacy or proprietary information is necessary to provide an acceptable response, then please provide a bracketed copy of your response that identifies the information that should be protected and a redacted copy of your response that deletes such information. If you request that such material is withheld from public disclosure, you must specifically identify the portions of your response that you seek to have withheld and provide in detail the bases for your claim (e.g., explain why the disclosure of information will create an unwarranted invasion of personal privacy or provide the information 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.

Sincerely,

Kerri Kavanagh, Chief **/RA/**
Quality Assurance Vendor Inspection Branch-3
Division of Construction Inspection
and Operational Programs
Office of New Reactors

Docket No.: 999001473

Enclosures:
1. Notice of Nonconformance
2. Inspection Report 99901473/2016-201
   and Attachment

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DATE	10/27/16	10/28/16	10/31/16	11/22/16
OFFICE	NRO/DCIP/QVIB-3	NRO/DCIP/QVIB-1		
NAME	KKavangh	ABelen*		
DATE	11/29 /16	11 /28/16		

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NOTICE OF NONCONFORMANCE

General Atomics Electromagnetic Systems Group
10880 Thornmint Road
San Diego, CA 92127

Docket No.: 99901473

Based on the results of a U.S. Nuclear Regulatory Commission (NRC) inspection conducted at the General Atomics Electromagnetic Systems Group (GA-EMS) facility in San Diego, CA, on September 12 through September 16, 2016, certain activities were not conducted in accordance with NRC requirements, which were contractually imposed on GA-EMS by its customers or NRC licensees.

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, that, "Measures shall be established to assure that applicable regulatory requirements and design basis, as defined in § 50.2 and as specified in the license application, for those structures, systems, and components to which this appendix applies are correctly translated into specifications, drawings, procedures, and instructions. Measures shall be established for the selection and review for suitability of application of materials."

   Section 3 of S00008001, "RMS Quality Assurance Manual," Revision V, dated April 30, 2014, states in part that, "The final design shall be relatable to the design input by documentation in sufficient detail to permit design verification as applicable to the project."

   Contrary to the above, as of September 16, 2016, GA-EMS failed to assure applicable regulatory requirements and design basis were correctly translated into specifications, drawings, procedures, and instructions, and to establish measures for the review and suitability of application of materials. Specifically, GA-EMS failed to: 1) provide objective evidence that the current specifications and procedures for the thickness and chemical composition of conformal coating applied to printed wiring assemblies (PWAs) installed in safety-related radiation monitoring systems (RMSs) meet the applicable standards; and 2) establish measures for the review and suitability of application of conformal coating consistent with the original environmental qualification of the PWAs.

   This issue has been identified as Nonconformance 99901473/2016-201-01.

B. Criterion VII, "Control of Purchased Material, Equipment, and Services," 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, "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."

   Criterion XII, "Control of Measuring and Test Equipment," 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 that, "Measures shall be established to assure that tools, gages, instruments, and other measuring and testing devices used in activities affecting quality are properly controlled, calibrated, and adjusted at specified periods to maintain accuracy within necessary limits."

Section D of Quality Assurance Procedure QAP-7-02, "Design Control Assurance of Commercial Grade Items & Services in Nuclear Safety-Related Applications," Revision K, dated March 2013, states in part that, "The Quality Manager or designee shall establish measures to assure the commercial grade services, which have a classification as safety related are controlled."

Contrary to the above, as of September 16, 2016, GA-EMS failed to obtain objective evidence of quality furnished by a commercial supplier for the calibration of sources used to calibrate safety-related RMS detectors to assure that the source is properly controlled, calibrated and adjusted at specified periods to maintain accuracy within necessary limits. Specifically, GA-EMS did not perform commercial-grade dedication (CGD) of the calibration service vendor to verify the adequacy of the calibration services the vendor performed, which could adversely affect the accuracy of RMS detectors. As a result of GA-EMS not performing CGD, the following areas affecting the accuracy of the RMS detectors were not verified: 1) verification that the calibration vendor's detector was sufficiently irradiated to obtain an accurate reading; 2) verification that the calibration vendor's use of the inverse square law to obtain dose rate vs distance data for dose rates points in a highly scattered environment was acceptable; 3) verification that the calibration vendor used temperature and pressure instrumentation that were adequately calibrated and; 4) verification that the calibration vendor performed radiation measurements to ensure that the source was positioned in the middle of the exposure port.

This issue has been identified as Nonconformance 99901473/2016-201-02.

C. Criterion XII, "Control of Measuring and Test Equipment," 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 that, "Measures shall be established to assure that tools, gages, instruments, and other measuring and testing devices used in activities affecting quality are properly controlled, calibrated, and adjusted at specified periods to maintain accuracy within necessary limits."

Section 4.2 of EMS-QAP-05, "Control of Measuring and Test Equipment," Revision K, states that "M&TE is to be calibrated, utilized, transported, and stored in an environment controlled to the extent necessary to ensure continued measurements of required accuracy, giving due consideration to temperature, humidity, vibration, cleanliness, and other controllable factors."

Contrary to the above, as of September 16, 2016, GA-EMS failed to establish measures to assure that sources, detectors and calibration assemblies used in activities affecting quality were properly controlled, calibrated, and adjusted at specified periods to maintain accuracy within necessary limits. Specifically:

1. GA-EMS failed to establish sufficient controls, as illustrated in the following examples, on the configuration of a Cesium-137 (Cs-137) source assembly to assure that the characteristics of the radiation field during GA-EMS calibrations of RMS detectors are the same as when the vendor performed the Cs-137 source calibration, which assures the accuracy of the RMS detectors is within the specified limits provided to GA-EMS' customer.
   a) GA-EMS did not evaluate effects of the decay of the Cs-137 source or how

placing the detector closer to the source could result in a lower primary beam and more scattered radiation near the detector.

b) GA-EMS did not provide objective evidence that the current configuration of attenuator #1 was the same configuration as when the vendor performed calibration of the source.

c) GA-EMS did not perform periodic checks of the attenuators and had not evaluated the impact of an attenuator's deformation on expected exposure rates.

d) GA-EMS did not evaluate whether the configuration of a loose bracket on the source assembly had any impact on the location of the vendor's detector, and thus an effect on the detector reading.

e) GA-EMS did not properly control the calibration cart assembly configuration per their drawing or evaluate the effect of adding and removing lead bricks on the amount of scattered radiation.

f) GA-EMS did not properly control the position of the RMS detector during calibration.

g) GA-EMS did not ensure that the detector was adequately adjusted in the source beam or perform periodic checks to ensure the cart path is aligned and level to the source beam.

2. GA-EMS failed to adequately control or document an evaluation of the added uncertainty and its impact on the specified accuracy of the RMS detectors for the:1) effect of high scatter radiation on the calibration accuracy of the RMS detectors caused by positioning the RMS detectors closer to the source due to decay of the Cs-137 source; 2) configuration of the Cs-137 source assembly used during calibration; 3) orientation and alignment of the RMS detectors with respect to the radiation beam during calibration; and 4) effect of GA-EMS calibrations of RMS detectors on the uncertainty provided by the calibration vendor for the calibration of the Cs-137 source and its impact on the total accuracy and uncertainty values of the RMS detectors provided to their customers.

3. GA-EMS failed to implement controls for the maintenance of disk sources and did not evaluate the effects of damages to disk sources on their accuracy.

This issue has been identified as Nonconformance 99901473/2016-201-03.

D. Criterion XVI, "Corrective Action," 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, "Measures shall be established to assure that conditions adverse to quality, such as failures, malfunctions, deficiencies, deviations, defective material and equipment, and nonconformances are promptly identified and corrected."

Section 16 of S00008001, "RMS Quality Assurance Manual," Revision V, dated April 30, 2014, states in part that, "Measures shall be established and documented to assure that conditions adverse to quality, such as failures, malfunctions, defective material and equipment, and other non-conformances are promptly identified and corrected as soon as practicable. All deficiencies shall be analyzed to determine their causes and appropriate corrective actions shall be applied to prevent recurrence."

Contrary to the above, as of September 16, 2016, GA-EMS failed to assure that conditions adverse to quality were promptly identified and corrected. Specifically, GA-EMS failed to

adequately implement the corrective actions identified in Corrective Action/Prevention Action (CAPA) 2254, generated in response to NRC Notice of Nonconformance (NON) 99900265/2013-201-01, related in part to GA-EMS's failure to properly identify and verify critical characteristics for the dedication of electrical connectors. CAPA 2254 stated that GA-EMS would perform a review of all safety-related Critical Characteristics Acceptance Plans (CCAPs) and implement actions to update any CCAPs identified in the review as needing revisions, and documented that the corrective actions were completed on September 30, 2013. GA-EMS failed to adequately update CCAP 50004269-001 for an electrical connector to replace the visual inspection of Teflon insulation and silver plating with a verification of the Certificate of Conformance (CoC). In addition, GA-EMS failed to perform an adequate review of all safety-related CCAPs and implement actions to update any CCAPs identified in the review as needing revisions. Specifically, GA-EMS did not identify as requiring revision, CCAPs 5003191-001 and 03587002-059, which did not identify an adequate acceptance method that would ensure that the commercial-grade item meet the acceptance criteria specified for the material critical characteristics, and CCAP 50004261-001, which incorrectly identified the radiological requirements for environmental qualifications of safety-related electrical connectors used in containment for post-accident monitoring. Additionally, CCAP 50004261-001 did not properly identify the material critical characteristics of the electrical connectors.

This issue has been identified as Nonconformance 99901473/2016-201-04.

Please provide a written statement or explanation to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, DC 20555-0001 with a copy to the Chief, Quality Assurance Vendor Inspection Branch-3, 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 your corrective action will be completed. Where good cause is shown, consideration will be given to extending the response time.

Because your response will be made available electronically for public inspection in the NRC Public Document Room or from the NRC's document system (ADAMS), accessible from the NRC Web site at http://www.nrc.gov/reading-rm/adams.html, to the extent possible, it should not include any personal privacy, proprietary, or safeguards information so that it can be made available to the public without redaction. If personal privacy or proprietary information is necessary to provide an acceptable response, then please provide a bracketed copy of your response that identifies the information that should be protected and a redacted copy of your response that deletes such information.

If you request withholding of such material, you must specifically identify the portions of your response that you seek to have withheld and provide in detail the bases for your claim of withholding (e.g., explain why the disclosure of information will create an unwarranted invasion of personal privacy or provide the information required by 10 CFR 2.390(b) to support a request for withholding confidential commercial or financial information). If safeguards information is necessary to provide an acceptable response, please provide the level of protection described in 10 CFR 73.21.

Dated this 29th day of November 2016

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

Docket No.:	99901473
Report No.:	99901473/2016-201
Vendor:	General Atomics Electromagnetic Systems Group 10880 Thornmint Road San Diego, CA 92127
Vendor Contact:	Mr. Patrick O'Shaughnessy, Nuclear Quality Assurance Manager Telephone: 858-964-6766 E-mail: patrick.o'shaughnessy@ga.com
Background:	GA-EMS designs and manufactures custom environmentally and seismically qualified radiation monitoring systems for the AP1000 reactor design and operating nuclear power plants.
Inspection Dates:	September 12–16, 2016
Inspection Team Leader:	Thomas Kendzia, NRO/DCIP/QVIB-3
Inspectors:	Ashley Ferguson, NRO/DCIP/QVIB-3 Andrea Keim, NRO/DCIP/QVIB-3 Ronald LaVera, NRO/DSEA/RPAC
Approved by:	Kerri Kavanagh, Chief Quality Assurance Vendor Inspection Branch-3 Division of Construction Inspection and Operational Programs Office of New Reactors

EXECUTIVE SUMMARY

General Atomics Electromagnetic Systems Group.
99901473/2016-201

The U.S. Nuclear Regulatory Commission (NRC) conducted this vendor inspection to verify that General Atomics Electromagnetics Systems Group (hereafter referred to as GA-EMS) has implemented an adequate quality assurance (QA) program 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," and 10 CFR Part 21, "Reporting of Defects and Noncompliance." The NRC inspection team conducted the inspection of the GA-EMS San Diego, California facility from September 12 through September 16, 2016. This was the second NRC vendor inspection of GA-EMS. The first inspection was in 2013 at the General Atomics Electronics Systems, Inc. (GA-ESI) facility prior to the consolidation with GA-EMS.

This inspection specifically evaluated GA-EMS's implementation of QA activities related to the design, manufacturing, dedication, nonconformance, and corrective action for safety-related radiation monitoring systems (RMSs) supplied for the US AP1000 and US operating nuclear power plants. In addition, this inspection verified the implementation of GA-EMS's corrective actions in response to nonconformances identified in NRC Inspection Report 99900265/2013-201.

The NRC inspection team observed portions of the following activities:

- assembly of a Beta-scintillation detector
- assembly of a solenoid operated valve
- testing of a 5 volt power supply
- transfer calibration of an area radiation monitor
- materials review board (MRB) meeting
- weekly corrective action review board (CARB) meeting
- twice weekly management (Tiger team) meeting

The NRC inspection team observed a demonstration of the following activities:

- conformal coating of a printed wiring assembly (PWA)
- calibration of an RMS detector

The NRC inspection team also performed a facility walkdown to verify, in part, that:

- measuring and test equipment (M&TE) was properly identified, marked, calibrated and used within the calibration range
- M&TE that was out of calibration, damaged, or past it's due date was segregated to prevent use
- nonconforming items were identified and segregated to prevent use
- Part 21 information was posted as required

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

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

The NRC inspection team used Inspection Procedure (IP) 43002, "Routine Inspections of Nuclear Vendors;" IP 43004, "Inspection of Commercial-Grade Dedication Programs;" and IP 36100, "Inspection of 10 CFR Part 21 and Programs for Reporting Defects and Noncompliance."

The information below summarizes the results of this inspection.

10 CFR Part 21 Program

The NRC inspection team concluded that GA-EMS established a 10 CFR Part 21 program in accordance with the regulatory requirements. Based on the limited sample of documents reviewed, the NRC inspection team determined that GA-EMS is implementing its policies and procedures associated with 10 CFR Part 21. No findings of significance were identified.

Design Control and Commercial-Grade Dedication

The NRC inspection team issued Nonconformance 99901473/2016-201-01 in association with GA-EMS's failure to implement the requirements of Criterion III, "Design Control," of Appendix B to 10 CFR Part 50. Nonconformance 99901473/2016-201-01 cites GA-EMS for failure to assure applicable regulatory requirements and design bases were correctly translated into specifications, drawings, procedures, and instructions, and establish measures for the review and suitability of applications of materials. Specifically, GA-EMS failed to: 1) provide objective evidence that the current specifications and procedures for the thickness and chemical composition of conformal coating applied to printed wiring assemblies (PWAs) installed in safety-related RMS detectors meet applicable standards; and 2) establish measures for the review and suitability of application of conformal coating consistent with the original environmental qualification of the PWAs.

Control of Measuring & Test Equipment

The NRC inspection team issued Nonconformance 99901473/2016-201-02 in association with GA-EMS's failure to implement the requirements of Criterion VII, "Control of Purchased Material, Equipment and Services," and Criterion XII, "Control of Measuring and Test Equipment," of Appendix B to 10 CFR Part 50. Nonconformance 99901473/2016-201-02 cites GA-EMS for failure to include provisions, as appropriate, for source evaluation and selection, objective evidence of quality furnished by the contractor, inspection at the contractor, and examination of the products upon delivery to assure that the source is properly controlled, calibrated, and adjusted at specified periods to maintain accuracy within necessary limits. Specifically, GA-EMS did not perform commercial-grade dedication of the calibration services or verify the adequacy of the calibrations performed by the vendor, which could adversely affect the accuracy of RMS detectors.

The NRC inspection team issued Nonconformance 99901473/2016-201-03 in association with GA-EMS's failure to implement the requirements of Criterion XII, "Control of Measuring and

Test Equipment," of Appendix B to 10 CFR Part 50. Nonconformance 99901473/2016-201-03 cites GA-EMS for failure to establish measures to assure that tools, gages, instruments, and other measuring and testing devices used in activities affecting quality are properly controlled, calibrated, and adjusted at specified periods to maintain accuracy within necessary limits. Specifically, GA-EMS failed to: 1) establish sufficient controls on the configuration of a Cesium-137 (Cs-137) source assembly to assure a repeatable geometry and radiation field for calibrations of the Cs-137 source and RMS detectors; 2) assure the accuracy of the RMS detectors is within the specified limits provided to GA-EMS' customers; and 3) implement controls for the maintenance of disk sources and did not evaluate the effects of damages to disk sources on their accuracy.

Nonconformances and Corrective Actions

The NRC inspection team issued Nonconformance 99901473/2016-201-04 in association with GA-EMS's failure to implement the requirements of Criterion XVI, "Corrective Action," of Appendix B to 10 CFR Part 50. Nonconformance 99901473/2016-201-04 cites GA-EMS for failure to assure conditions adverse to quality are promptly identified and corrected. Specifically, GA-EMS failed to adequately implement the corrective actions as identified in CAPA 2254, generated in response to NON 99900265/2013-201-01 issued as a result of the 2013 NRC inspection of GA-EMS. The NRC inspection team identified that GA-EMS failed to update CCAP 50004269-001 for an electrical connector to replace the visual inspection of Teflon insulation and silver-plating with a survey of the vendor and verification of the certificate of conformance (CoC). In addition, GA-EMS failed to perform an adequate review of all safety-related CCAPs and implement actions to update any CCAPs identified in the review as needing revisions. Additional examples of GA-EMS's failure to assure conditions adverse to quality were promptly identified and corrected included: 1) CCAP 50003191-001 failed to include justification for the suitability of a visual inspection to verify the body of the fuse was in fact glass with metal ferrules; 2) CCAP 03587002-059 used a magnetic test to verify the critical characteristics for the material, which would not demonstrate that the casing of the gauge was in fact stainless steel and had the proper composition to function in the required environment; and 3) CCAP 50004261-001 did not identify the material of the Teflon insulation as a critical characteristic and indicate that the connector would be qualified for use in harsh environments.

Manufacturing Controls

The NRC inspection team concluded that GA-EMS has established a program that adequately controls manufacturing and special processes in accordance with the regulatory requirements of Criterion V, "Instructions, Procedures, and Drawings;" Criterion IX, "Control of Special Processes;" and Criterion X, "Inspection," of Appendix B to 10 CFR Part 50. Based on the limited sample of documents reviewed, operations observed, and personnel interviewed, the NRC inspection team determined that GA-EMS is effectively implementing its policies and procedures governing manufacturing and special processes. No findings of significance were identified.

Handling, Shipping and Storage

The NRC inspection team concluded that GA-EMS has established a program that adequately controls handling, storage, and shipping in accordance with the regulatory requirements of Criterion XIII, "Handling, Storage and Shipping," of Appendix B to 10 CFR Part 50. Based on the limited sample of documents reviewed, the NRC inspection team

determined that GA-EMS is effectively implementing its policies and procedures governing handling, storage, and shipping. No findings of significance were identified.

REPORT DETAILS

1. 10 CFR Part 21 Program

   a. Inspection Scope

   The NRC inspection team reviewed General Atomics Electromagnetics Systems Group's (hereafter referred to as GA-EMS'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 NRC inspection team interviewed the nuclear quality assurance (QA) manager and other GA-EMS staff, on the implementation of the Part 21 program and reviewed a sample of completed 10 CFR Part 21 evaluations.

   The NRC inspection team also verified that GA-EMS's nonconformance and corrective action procedures referenced the 10 CFR Part 21 program. In addition, the NRC inspection team verified that a sample of the corrective action and nonconforming materials, parts, or components were appropriately screened for 10 CFR Part 21 applicability.

   The attachment to this inspection report lists the individuals interviewed and documents reviewed by the NRC inspection team.

   b. Observations and Findings

   No findings of significance were identified.

   c. Conclusions

   The NRC inspection team concluded that GA-EMS established a 10 CFR Part 21 program in accordance with the regulatory requirements. Based on the limited sample of documents reviewed, the NRC inspection team determined that GA-EMS is implementing its policies and procedures associated with 10 CFR Part 21. No findings of significance were identified.

2. Design Control and Commercial Grade Dedication

   a. Inspection Scope

   The NRC inspection team reviewed GA-EMS's policies and implementing procedures that govern the design control and commercial-grade dedication (CGD) programs to verify compliance with the regulatory requirements of Criterion III, "Design Control," of Appendix B to10 CFR Part 50.

   General Atomics Electronic Systems Inc. (GA-ESI), the former General Atomics affiliated company responsible for the radiation monitoring system (RMS) production line, was consolidated into GA-EMS in 2013. The NRC conducted an inspection of GA-ESI in May 2013 prior to the consolidation. As a result of the consolidation, GA-EMS revised

its operating procedures that governed design documentation, engineering change notices, design reviews, and drawing changes.

The NRC inspection team reviewed the revised procedures that govern GA-EMS's design control process, EMS-EDP-03, "Project Technical Review," Revision C, dated August 5, 2015 and EMS-CMP-23, "Configuration Change Control of Commercial and IR&D Products" Revision D, dated November 12, 2015, to verify that GA-EMS was maintaining adequate control of design inputs and outputs, analyses and testing, records and reports, and design changes.

The NRC inspection team reviewed Engineering Change Request (ECR) CR057171 and Engineering Change Notice (ECN) 078013. ECR CR057171 and ECN 078013 were implemented for a change to a safety-related connector, which is a subcomponent of the high range RMS assembly to be used for the AP1000 reactor design. The NRC inspection team verified the changes were made in accordance with EMS-EDP-03 and EMS-CMP-23.

The NRC inspection team reviewed the implementation GA-EMS's CGD process associated with RMS subcomponents. The NRC inspection team reviewed nine dedication packages associated with AP1000 components or products supplied in the last two years to assess elements of GA-EMS's CGD program. The dedication packages included purchase orders (POs), technical evaluations including the critical characteristics acceptance plans, commercial-grade surveys, receipt inspection reports, certificates of conformance (CoCs), design drawings, sampling plans, and manufacturer's technical specifications. Specifically, the NRC inspection team reviewed the CGD packages to determine if GA-EMS performed technical evaluations that adequately identified all critical characteristics and developed and implemented acceptance methods suitable to verify all critical characteristics. The NRC inspection team verified that a technical evaluation was included in the dedication packages for RMS sub-assemblies, for which components have been changed. The NRC inspection team discussed the dedication process with GA-EMS management and technical staff associated with performance of the CGD process to verify their understanding of regulatory requirements and the GA-EMS procedures.

The attachment to this inspection report lists the individuals interviewed and documents reviewed by the NRC inspection team.

b. Observations and Findings

b.1 Conformal Coating

The inspectors observed GA-EMS's use of conformal coating for printed wiring assemblies (PWAs). The NRC inspection team discussed with GA-EMS staff whether the PWAs used in safety-related RMSs were originally environmentally qualified with conformal coating. GA-EMS was unable to provide the original environmental qualification. The NRC inspection team determined that without dedicating the coating material, establishing shelf life of the coating material, and having procedures for coating thickness and measurement of the coating thickness consistent with the applicable standard, GA-EMS could not ensure that the current specifications and procedures for the thickness and chemical composition of the conformal coatings are consistent with

the original environmental qualification.

GA-EMS is committed to following standard IPC-A-610, “Acceptability of Electronic Assemblies,” for the application of conformal coating. The NRC inspection team reviewed GA-EMS’s procedure, MSP00007013, “Conformal Coating of Printed Wiring Assemblies,” and QCI-212, “Inspection of Conformal Coated Printed Circuit Boards,” to verify the procedures adequately specify the acceptability criteria for conformal coating application in accordance with IPC-A-610. The NRC inspection team observed that the minimum thickness specified in MSP00007103 and QCI-212 was less conservative than the minimum thickness specified in IPC-A-610 for Type SR silicone conformal coating. MPS00007013 Section 4.5.3 and QCI-212 Section 4.5 states that the minimum thickness for Type SR coating material is 0.001 inches. IPC-A-610, Revision E specifies a minimum thickness for type SR coating of 0.00197 inches. GA-EMS did not provide a technical justification for this inconsistency, and could not assure that thickness specified in MPS0007013 was consistent with the original environmental qualification for PWAs. The NRC inspection team identified this as the first example of Nonconformance 99901473/2016-201-01 for GA-EMS’s failure to provide objective evidence that the current specifications and procedures for the thickness and chemical composition of conformal coating applied to PWAs meet applicable standards and are consistent with the original environmental qualification. GA-EMS issued Internal Corrective Action Reports (iCARs) Quality Notification (QN) Nos. 7016948 and 7017023 associated with this issue.

In addition, IPC-A-610 requires that conformal coatings uniformly cover the board and components. MPS00007013 Section 4.5 states that the coating shall be applied evenly and Section 4.6.3 states that the coating thickness should be checked at three points on the PWA to verify the coating thickness. GA-EMS uses calibrated caliper micrometers to verify the coating meets the specified thickness requirements. Due to the configuration of the measuring head, measurements are made at three points on the outside edges of the PWA. GA-EMS was unable to provide objective evidence that the interior areas, including mounted components, not reachable by the caliper micrometer were within the required minimum and maximum thickness consistent with IPC-A-610 and the original environmental qualification of the PWAs. The NRC inspection team identified this as the second example of Nonconformance 99901473/2016-201-01 for GA-EMS’s failure to provide objective evidence that the current specifications and procedures for the thickness and chemical composition of conformal coating applied to PWAs meet applicable standards and are consistent with the original environmental qualification. GA-EMS issued iCARs QN Nos. 7016948 and 7017023 associated with this issue.

The NRC inspection team examined spray cans of conformal coating material, Fine-L-Coat 2103-12S AR (an acrylic based coating spray) and 2102-12 SR (a silicon based coating spray) used by GA-EMS. The NRC inspection team observed that the expiration dates for the cans of 2102-12 SR and 2103-12S AR were labeled as N/A. The vendor recently recommended a shelf life for the 2102-12 SR and 2103-12 AR of 1 year and 2 years, respectively; however, GA-EMS was not aware of the vendor recommendations. GA-EMS did not perform periodic testing of the chemical composition of the coating material that was in use to ensure the continued efficacy of the coating material, nor did GA-EMS verify the shelf life of the coating material. As such, GA-EMS could not verify the composition of the material for each application was consistent with the original environmental qualification for the PWAs. The NRC inspection team identified this as the third example of Nonconformance 99901473/2016-201-01 for GA-EMS’s failure to

provide objective evidence that the current specifications and procedures for the thickness and chemical composition of conformal coating applied to PWAs meet applicable standards and are consistent with the original environmental qualification. GA-EMS issued iCARs QN Nos. 7016948 and 7017023 associated with this issue.

c. Conclusion

The NRC inspection team issued Nonconformance 99901473/2016-201-01 in association with GA-EMS's failure to implement the requirements of Criterion III, "Design Control," of Appendix B to 10 CFR Part 50. Nonconformance 99901473/2016-201-01 cites GA-EMS for failure to assure applicable regulatory requirements and design bases were correctly translated into specifications, drawings, procedures, and instructions, and establish measures for the review and suitability of applications of materials. Specifically, GA-EMS failed to: 1) provide objective evidence that the current specifications and procedures for the thickness and chemical composition of conformal coating applied to PWAs installed in safety-related RMS detectors meet applicable standards; and 2) establish measures for the review and suitability of application of conformal coating consistent with the original environmental qualification of the PWAs.

3. Control of Measuring and Test Equipment

a. Inspection Scope

The NRC inspection team reviewed GA-EMS's policies and implementing procedures that govern the measuring and test equipment (M&TE) program, including procurement of M&TE services, to verify compliance with Criterion XII, "Control of Measuring and Test Equipment," and Criterion VII, "Control of Purchased Material, Equipment, and Services." of Appendix B to 10 CFR Part 50. The NRC inspection team also verified that, for the six pieces of M&TE found to be out of calibration for the last 12 months, GA-EMS identified how the M&TE was used since the last valid calibration date and determined the validity of its previous uses. The NRC inspection team verified that M&TE that was broken or past calibration date, were segregated for non-use. The NRC inspection team verified that GA-EMS records use of M&TE and indentifies which M&TE is used on which jobs. The NRC inspection team verified that a sample of M&TE in the field was identified with a unique number, calibration date, and calibration due date. The NRC inspection team also verified the M&TE was within the calibration due date, and the information in the GA-EMS M&TE electronic database was the same as identified on the M&TE.

The NRC inspection team observed work being performed for Work Order No. 50021100, which was for a safety-related RD-10B radiation detector, using Procedure No. 02819030, "Detector Assembly Area Monitor RD-10B, Calibration Procedure RD-10, RD-11 & RD-12." The initial radiation exposures for the RMS detectors are performed at the General Atomics laboratory facility located in Torrey Pines, California. The RMS detectors are then brought to the main facility housing the GA-EMS RMS product line where the transfer calibration values are determined with an RT-10 source. The NRC inspection team visited the Torrey Pines facility to observe the calibration methods for process and area radiation monitoring equipment. The NRC inspection team reviewed radiation source calibration methods and traceability report to National Institute of Standards and Technology (NIST), the methods GA-EMS staff used to handle the

radiation sources, and conditions of the radiation sources.

The attachment to this inspection report lists the individuals interviewed and documents reviewed by the NRC inspection team.

b. Observations and Findings

b.1 Calibration Services for the Source Material

The NRC inspection team observed that GA-EMS uses a Cesium 137 (Cs-137) source to calibrate RMS detectors. The vendor contracted to perform calibrations (vendor designated as CalV hereafter) of the Cs-137 source no longer maintained an Appendix B to 10 CFR Part 50 program and was not included on GA-EMS's approved supplier list. GA-EMS did not perform commercial-grade dedication of the CalV's calibration service or verify the adequacy of the calibration data. The NRC inspection team identified this issue as Nonconformance 99901473/2016-201-02 for GA-EMS's failure to include provisions, as appropriate, for source evaluation and selection, objective evidence of quality furnished by the contractor, inspection at the contractor, and examination of the products upon delivery to assure that the source is properly controlled, calibrated and adjusted at specified periods to maintain accuracy within necessary limits. GA-EMS issued iCAR QN No. 7017000 on this issue and stopped use of the Cs-137 source for calibration until the potential effect of the use of an unevaluated calibration vendor for the RMS detector calibration could be determined.

The NRC inspection team identified the following four issues that GA-EMS had not evaluated due to their failure to perform CGD of the CalV calibration services:

1. The NRC inspection team observed that the data provided by CalV, did not include correction factors to ensure the dose rate points were accurate. To obtain an accurate reading at a dose rate point, the detector used during calibration must be uniformly irradiated, and charge particle equilibrium must exist at the detector (refer to item 4 of Figure-1 in the Attachment). These conditions are usually established by maintaining geometry conditions that ensure that the radius of the radiation beam sufficiently exceeds the size of the radiation detector, or by the application of correction factors by the calibration service. There was no indication in the data provided by CalV that geometry correction factors had been applied. GA-EMS staff did not verify that the size of CalV's detector was sufficiently irradiated to obtain an accurate reading. The NRC inspection team identified this as the first example of Nonconformance 99901473/2016-201-02 for GA-EMS's failure to include provisions, as appropriate, for source evaluation and selection, objective evidence of quality furnished by the contractor, inspection at the contractor, and examination of the products upon delivery to assure that the source is properly controlled, calibrated and adjusted at specified periods to maintain accuracy within necessary limits.

2. The NRC inspection team observed that the calibration certificate dated September 18, 2015, from CalV contained tables of dose rate versus distance for different attenuator combinations. The certificate stated that the dose rates versus distance values were derived by application of the inverse square law to the dose rate. The inverse square law is an approximation that is only valid in low scatter environments, however due to the configuration of the source assembly, conditions during

calibration reflect a highly scattered environment. GA-EMS staff did not verify that the calibration vendor's use of the inverse square law to obtain at dose rate versus distance data for dose rates points in a highly scattered environment was acceptable. The NRC inspection team identified this as second example of Nonconformance 99901473/2016-201-02 for GA-EMS's failure to include provisions, as appropriate, for source evaluation and selection, objective evidence of quality furnished by the contractor, inspection at the contractor, and examination of the products upon delivery to assure that the source is properly controlled, calibrated and adjusted at specified periods to maintain accuracy within necessary limits. GA-EMS issued iCAR QN No. 7017028 on this issue and stopped use of the Cs-137 source for calibration until the effect on calibration could be determined.

3. The NRC inspection team discussed the effects of temperature and pressure on calibration activities for the RMS detectors. GA-EMS stated that the calibration of the detectors is not affected by temperature or pressure. However, the calibration of the Cs-137 source assembly is temperature and pressure dependent (Refer to item 5 of Figure-1 in the Attachment). Temperature and pressure are used to correct the data from the vented ion chamber used by CalV to calibrate the source assembly. GA-EMS staff stated that CalV used a portable weather station to measure the temperature and pressure. However, GA-EMS did not ensure that CalV used temperature and pressure instrumentation that were adequately calibrated. The NRC inspection team identified this as the third example of Nonconformance 99901473/2016-201-02 for GA-EMS's failure to include provisions, as appropriate, for source evaluation and selection, objective evidence of quality furnished by the contractor, inspection at the contractor, and examination of the products upon delivery to assure that the source is properly controlled, calibrated and adjusted at specified periods to maintain accuracy within necessary limits. GA-EMS issued iCAR QN No. 7017028 on this issue and stopped use of the Cs-137 source for calibration until the effect on calibration could be determined.

4. The NRC inspection team observed that Drawing No. 5.14-SK-120-A, dated August 28, 1967, which shows the configuration of the source rod, did not contain any dimensional information. Part of the positioning system included spacer, washers and nuts that could be used to assure that the source was properly positioned in the middle of the source exposure port (refer to item 2 of Figure-1 in the Attachment). The source beam exposure pattern is dependent on the orientation of the actual radiation source material within the source port. GA-EMS staff did not verify if CalV had performed radiation measurements to ensure that the source was positioned in the middle of the exposure port. This could affect the calibration of the Cs-137 source by CalV. The NRC inspection team identified this as the fourth example of Nonconformance 99901473/2016-201-02 for GA-EMS's failure to include provisions, as appropriate, for source evaluation and selection, objective evidence of quality furnished by the contractor, inspection at the contractor, and examination of the products upon delivery to assure that the source is properly controlled, calibrated and adjusted at specified periods to maintain accuracy within necessary limits. GA-EMS issued iCAR QN No. 7017028 on this issue and stopped use of the Cs-137 source for calibration until the effect on the RMS detector calibration could be determined.

b.2 Calibration of Radiation Monitoring Systems

The NRC inspection team observed GA-EMS's process for calibrating RMS detectors. The following seven issues regarding the configuration of the Cs-137 source assembly used during calibration were identified:

1. The NRC inspection team observed that GA-EMS' Cs-137 source was nominally 40 curies in June 1968 and has since decayed to approximately 13 curies. This decrease in activity affects the distance from the shield assembly at which a given exposure rate can be obtained (refer to item 1 of Figure-1 in the Attachment). The closer the detector is to the source, the more narrow the primary beam of the radiation source and the more scattered (lower energy) radiation may be present at the detector location, which could result in an inaccurate calibration reading. GA-EMS did not evaluate the more scattered (lower energy) radiation that may be present at the detector location and how it can affect the accuracy of the readings. The NRC inspection team identified this as the first example of Nonconformance 99901473/2016-201-03 for GA-EMS's failure to establish sufficient controls on the configuration of a Cs-137 source assembly to assure a repeatable geometry and radiation field for calibrations of the Cs-137 source and RMS detectors. GA-EMS issued iCAR QN No. 7017028 on this issue and stopped use of the Cs-137 source for calibration until the effect on calibration could be determined.

2. The NRC inspection team reviewed drawings describing the Cs-137 source assembly, which included the source, attenuators, and the cart which holds the detectors. The NRC inspection team observed that the drawings did not have descriptions of attenuator #1, used by GA-EMS during calibrations. GA-EMS staff stated that the attenuator was built in-house, and consisted of lead and aluminum plates wrapped in duct tape. GA-EMS staff did not know the dimensions of the aluminum plates and tape thickness used to build the attenuator. The calibration certificate, dated September 18, 2015, from CalV, indicated that calibration exposures were performed using attenuator #1. GA-EMS staff could not provide objective evidence that the current configuration of attenuator #1 was the same configuration as when CalV performed calibration of the source (refer to item 8 of Figure-1 in the Attachment). The NRC inspection team determined that GA-EMS had not established adequate measures to control the configuration of the source assembly to ensure that conditions during source calibration were representative of conditions used to calibrate RMS detectors, thus adding to the uncertainty of the calibration of RMS detectors. The NRC inspection team identified this as the second example of Nonconformance 99901473/2016-201-03 for GA-EMS's failure to establish sufficient controls on the configuration of a CS-137 source assembly to assure a repeatable geometry and radiation field for calibrations of the Cs-137 source and RMS detectors. GA-EMS issued iCAR QN No. 7017028 on this issue and stopped use of the Cs-137 source for calibration until the effect on calibration could be determined.

3. The NRC inspection team examined two filled (x10 and x1000) attenuators and two hollow collimated (6 inch and 8 inch) attenuators used by GA-EMS. The NRC inspection team observed that the hole on the 6-inch hollow collimated attenuator was deformed. GA-EMS staff could not verify whether the deformation occurred prior to or after the last calibration of the source assembly. GA-EMS did not perform periodic checks of the attenuators and had not evaluated the impact of the attenuator's deformation on expected exposure rates. The NRC inspection team determined that the deformation could constrict the opening of the attenuator, which

could result in a lower than expected delivered dose rate and add to the uncertainty of the calibration process (refer to item 9 of Figure-1 in the Attachment). The NRC inspection team identified this as the third example of Nonconformance 99901473/2016-201-03 for GA-EMS's failure to establish sufficient controls on the configuration of a Cs-137 source assembly to assure a repeatable geometry and radiation field for calibrations of the Cs-137 source and RMS detectors. GA-EMS issued iCAR QN No. 7017028 on this issue and stopped use of the Cs-137 source for calibration until the effect on calibration could be determined.

4. The NRC inspection team examined the cart used with the Cs-137 source assembly. The NRC inspection team observed that the drawing for the cart, Drawing No. 5.14-SK-123-A, dated January 4, 1968, did not indicate a large metal bracket that was used by GA-EMS to position the CalV detector (refer to item 3 of Figure-1 in the Attachment). While GA-EMS stated that this metal bracket was in place at the time CalV performed the last calibration, the cart assembly was not in the documented configuration. The NRC inspection team observed that one of the bolts holding the bracket to the back of the radiation stop, had ¼ inch of slack. GA-EMS had not evaluated whether the configuration of the bracket had any impact on the location of CalV's detector, and thus an effect on the detector reading. The NRC inspection team determined that GA-EMS failed to properly control the bracket position which could potentially add to the uncertainty of the calibration of Cs-137 source. The NRC inspection team identified this as the fourth example of Nonconformance 99901473/2016-201-03 for GA-EMS's failure to establish sufficient controls on the configuration of a Cs-137 source assembly to assure a repeatable geometry and radiation field for calibrations of the Cs-137 source and RMS detectors. GA-EMS issued iCAR QN No. 7017028 on this issue and stopped use of the Cs-137 source for calibration until the effect on calibration could be determined.

5. The NRC inspection team also determined that Drawing No. 5.14-SK-123-A of the cart assembly did not include the lead bricks, which GA-EMS staff had stacked below the platform as counter weight for the cart. The NRC inspection team observed GA-EMS staff adding and removing lead shields from the stack of lead bricks below the platform without documenting the change in configuration. GA-EMS staff were unaware of the amount of scattered radiation in the area, and the effect of adding and removing lead from the cart on the amount of scattered radiation (refer to item 10 of Figure-1 in the Attachment). GA-EMS failed to properly control the calibration cart assembly configuration per their drawing and to evaluate the effect of adding and removing lead bricks on the amount of scattered radiation. The NRC inspection team identified this as the fifth example of Nonconformance 99901473/2016-201-03 for GA-EMS's failure to establish measures to assure that tools, gages, instruments, and other measuring and establish sufficient controls on the configuration of a Cs-137 source assembly to assure a repeatable geometry and radiation field for calibrations of the Cs-137 source and RMS detectors. GA-EMS issued iCAR QN No. 7017028 on this issue and stopped use of the Cs-137 source for calibration until the effect on calibration could be determined.

6. GA-EMS staff stated that a stand and clamp with tape is used to fix the position of RMS detectors being calibrated. The NRC inspection team noticed that there were a number of pencil marks on the equipment platform. GA-EMS staff stated that these marks are used to position the detectors (refer to item 6 of Figure-1 in the Attachment). Changing the position of the detector being calibrated, can affect the

delivered dose rate, introducing errors that are dependent on the proximity of the detector to the source and the orientation of the detector to the primary radiation beam. The fixture used to position the detectors during calibration were located near or in the primary radiation beam. These fixtures, which were not present during CalV's calibration of the source assembly, may cause additional scattered radiation that changes the energy spectrum near the RMS detector. GA-EMS failed to properly control the position of the detector which affects the calibration of the equipment. The NRC inspection team identified this as the sixth example of Nonconformance 99901473/2016-201-03 for GA-EMS's failure to establish sufficient controls on the configuration of a Cs-137 source assembly to assure a repeatable geometry and radiation field for calibrations of the Cs-137 source and RMS detectors. GA-EMS issued iCAR QN No. 7017028 on this issue and stopped use of the Cs-137 source for calibration until the effect on calibration could be determined.

7. GA-EMS performs calibrations at different points (distances) than those specifically calibrated by CalV, which is allowable with the correct adjustment. GA-EMS had noted problematic (repeatability issues) dose rate points and implemented a change to their RMS detector calibration procedure to substitute other positions. The discrepancy in the dose rate points was not assessed by GA-EMS to determine if this was an indication of the effects of the difference in the amount of scattered radiation present and/or a problem with aligning the RMS detector with the source beam. GA-EMS staff did not ensure that the detector was adequately adjusted in the source beam or perform periodic checks to ensure the cart path is aligned and level to the source beam, thus potentially adding to the uncertainty of calibration of the RMS detectors (refer to items 6 and 7 of Figure-1 in the Attachment). The NRC inspection team identified this as the seventh example of Nonconformance 99901473/2016-201-03 for GA-EMS's failure to establish sufficient controls on the configuration of a Cs-137 source assembly to assure a repeatable geometry and radiation field for calibrations of the Cs-137 source and RMS detectors. GA-EMS issued iCAR QN No. 7017028 on this issue and stopped use of the Cs-137 source for calibration until the effect on calibration could be determined.

Additionally, the calibration certificate dated September 18, 2015, provided by CalV stated that the overall uncertainty of the calibration performed for the Cs-137 source, was 5% at the 95% confidence level. CalV did not provide a description of what factors were considered in determining these values (refer to item 11 of Figure-1 in the Attachment). GA-EMS did not perform measurement uncertainty calculations for the calibrations of the RMS detectors to verify that the RMS detectors meet the design requirement for accuracy. The NRC inspection team determined that GA-EMS was unable to verify, if the total measurement uncertainty for the GA-EMS calibration provided to their customers was adequately calculated or if the RMS detectors meet the design requirement for accuracy. The NRC inspection team identified this as an example of Nonconformance 99901473/2016-201-03 for GA-EMS's failure to assure the accuracy of the RMS detectors is within the specified limits provided to GA-EMS customers. GA-EMS issued iCAR QN No. 7017028 on this issue and stopped use of the Cs-137 source for calibration until the effect on calibration could be determined.

b.3 Maintenance of National Institute of Standards and Technology Traceable Disk Sources

The NRC inspection team observed the NIST traceable disk sources used by GA-EMS staff to perform primary calibrations of GA-EMS process radiations monitors, such as

particulate, noble gas and iodine airborne activity monitoring systems, and liquid activity monitoring systems. The NRC inspection team noticed that Chlorine-36 (Cl-36) source 03600731-001-A, serial number 113, dated June 19, 2007, had scratch marks, scuff marks and finger prints on the active area of the source. Cl-36 source number 85-103, dated May 22 1985, also had scuffs and scratches on the active area of the source. Disk source Cobalt-60 (Co-60) model S-565 serial number 92-145, which was used for energy adjustments, had tears in the film covering the active source area. GA-EMS staff stated that they did not perform any periodic emission checks of the calibration sources. Scratch and scuff mark are indicators of potential damage or displacement to the underlying source material (the source material is deposited on the disks and covered by the film to maintain its integrity). Displacement of the source material can impact the distribution of the emitted radiation from the source and thus the radiation monitor reading. Finger prints indicate the presence of contaminants on the source emission surface which may impact the energy spectrum of the emitted radiation. Since GA-EMS does not perform periodic emission tests of these sources, it is not possible to assess their performance over time. The NRC inspection team also noted that several sources were past their expiration date and some had no expiration date. GA-EMS stated that they had a letter from the source provider saying it was acceptable to use the sources past their expiration date, but GA-EMS had not assessed the effect of using sources past their expiration date on using the sources in calibration. The NRC inspection team determined that GA-EMS failed to properly control their disk sources and to evaluate the effects of damages to disk sources on their accuracy. The NRC inspection team identified this as an example of Nonconformance 99901473/2016-201-03 for GA-EMS's failure to implement controls for the maintenance of disk sources and to evaluate the effects of damages to disk sources on their accuracy. GA-EMS issued iCAR QN Nos. 7017027 and 7017029 on these issues and stopped use of the sources for calibration until the effect on calibration could be determined.

c. Conclusion

The NRC inspection team issued Nonconformance 99901473/2016-201-02 in association with GA-EMS's failure to implement the requirements of Criterion VII, "Control of Purchased Material, Equipment and Services," of Appendix B to 10 CFR Part 50. Nonconformance 99901473/2016-201-02 cites GA-EMS for failure to include provisions, as appropriate, for source evaluation and selection, objective evidence of quality furnished by the contractor, inspection at the contractor, and examination of the products upon delivery to assure that the source is properly controlled, calibrated and adjusted at specified periods to maintain accuracy within necessary limits. Specifically, GA-EMS did not perform commercial-grade dedication of the calibration services or verify the adequacy of the calibrations performed by the vendor, which could adversely affect the accuracy of RMS detectors.

The NRC inspection team issued Nonconformance 99901473/2016-201-03 in association with GA-EMS's failure to implement the requirements of Criterion XII, "Control of Measuring and Test Equipment," of Appendix B to 10 CFR Part 50. Nonconformance 99901473/2016-201-03 cites GA-EMS for failure to establish measures to assure that tools, gages, instruments, and other measuring and testing devices used in activities affecting quality are properly controlled, calibrated, and adjusted at specified periods to maintain accuracy within necessary limits. Specifically, GA-EMS failed to: 1) establish sufficient controls on the configuration of a Cs-137 source assembly to assure a repeatable geometry and radiation field for calibrations of the Cs-

137 source and RMS detectors; 2) assure the accuracy of the RMS detectors is within the specified limits provided to GA-EMS customers; and 3) implement controls for the maintenance of disk sources and did not evaluate the effects of damages to disk sources on their accuracy.

4. Nonconformances and Corrective Action

a. Inspection Scope

The NRC inspection team reviewed GA-EMS's policies and implementing procedures that govern the Nonconformance and Corrective Action programs to verify compliance with the requirements of Criterion XV, "Nonconforming Materials, Parts, or Components," and Criterion XVI, "Corrective Action," of Appendix B to 10 CFR Part 50. GA-EMS identifies nonconforming materials, parts or components in nonconformance reports and processes them as QNs. For conditions adverse to quality and significant conditions adverse to quality, GA-EMS uses corrective actions/preventative actions (CAPAs) designated as iCARs for internal issues and supplier corrective action requests (sCARs) for supply issues. The NRC inspection team verified the GA-EMS procedures for QNs and CAPAs provide a link to the 10 CFR Part 21 program. The NRC inspection team reviewed other processes at GA-EMS that could identify a condition adverse to quality (such as internal and external audits, review of QNs, and review of trends) to ensure that GA-EMS used the corrective action process to identify conditions adverse to quality.

The NRC inspection team reviewed the list of 2016 QNs and selected 45 for a detailed review. For the QNs reviewed, the NRC inspection team verified that GA-EMS identified, documented, evaluated, segregated, and provided a technical justification for accept-as-is dispositions of nonconforming items. The NRC inspection team also performed a detailed review of the 8 iCARs issued over the last 12 months, and the iCAR for the NRC Notice of Nonconformance (NON) issued in 2013. Specifically, the NRC verified for the iCARs reviewed, that conditions adverse to quality were promptly identified and corrected, screened for Part 21 reporting, disposition appeared appropriate, and that none were significant conditions adverse to quality.

The NRC inspection team observed a materials review board (which reviews QNs) meeting, and a corrective action review board (which reviews CAPAs) meeting to determine if GA-EMS is processing nonconforming items and conditions adverse to quality in accordance with the regulations and their procedures. The NRC inspection team discussed the corrective action and nonconformance process with GA-EMS's management and technical staff.

The attachment to this inspection report lists the individuals interviewed and documents reviewed by the NRC inspection team.

b. Observations and Findings

The NRC inspection team reviewed GA-EMS's implementation of corrective actions, identified in CAPA 2254, to address the 2013 NRC inspection findings documented in Inspection Report 99900265/2013-201. The NRC issued NON 99900265/2013-201-01 for GA-EMS's failure to properly identify and verify critical characteristics of a radioiodine filter cartridge and electrical connector to demonstrate that the components would be

able to perform their safety function. Specifically, for the radioiodine filter cartridge, GA-EMS failed to identify the critical characteristics of flow and efficiency, which were relative to the radioiodine filter's safety function of filtering and collecting particulates from sampled air. For the electrical connector, GA-EMS identified critical characteristics for the material of the connector to be silver plated and its insulation to be Teflon; however, GA-EMS performed a visual inspection, which was inadequate to physically verify the material.

In response to the NRC, GA-EMS's corrective actions for the dedication of the radioiodine filter were to update Critical Characteristic Acceptance Plan (CCAP) 50015405-001 to include verification of the Radioiodine Penetration/Efficiency Test Report from the supplier for each lot sampled. The NRC inspection team verified that CCAP 50015405-001 included verification of Radioiodine Penetration/Efficiency Test Report from the supplier as the acceptance method for verifying the critical characteristic of efficiency.

GA-EMS's corrective actions for the dedication of the electrical connector were to revise CCAP 50004269-001 to replace the visual inspection of Teflon insulation and silver plating of the connector with a verification of the CoC upon performing a commercial-grade survey of the supplier. In reviewing CCAP 50004269-001, the NRC inspection team identified that the CCAP had not been adequately updated. CCAP 50004269-001 had been updated to delete the visual exam; however, it did not include verification of the Teflon insulation and silver-plating of the connector via a CoC from the supplier. In addition, the NRC inspection team reviewed GA-EMS's commercial-grade survey of the supplier, and determined that the survey did not adequately evaluate the supplier's quality controls related to ensuring that the critical characteristics of the material for the connectors being dedicated. As a result, in April 2015 under Work Order No. 96920109, an incomplete dedication was performed using CCAP 50004269-001, in which the critical characteristics of the material for the electrical connector were not verified. The NRC inspection team identified this as the first example of Nonconformance 99901473/2016-201-04 for GA-EMS's failure to assure conditions adverse to quality are promptly identified and corrected.

In addition, GA-EMS's corrective actions identified in CAPA 2254 included conducting a review of all CCAPs to verify that the critical characteristics have been properly identified for all safety-related components manufactured by GA-EMS. The NRC inspection team assessed the documentation for the review completed by GA-EMS and performed a review of a seven additional CGD packages that included CCAPs that were reviewed by GA-EMS as part of the corrective actions. The NRC inspection team identified the following additional three examples of improper selection and verification of critical characteristics:

1) For the review of the dedication of a fuse (Part No. 50003191-001), the Commercial Grade Item Engineering Evaluation identified the material of the body of the fuse as a critical characteristic, which was specified as glass with metal ferrules. CCAP 50003191-001 required the performance of a visual inspection to verify the material of the fuse. The CCAP did not include justification for the suitability of a visual inspection to verify the body of the fuse was in fact glass with metal ferrules. As a result, in June 2015, an inadequate dedication was performed using CCAP 50003191-001, in which the critical characteristics for the material of the fuse were improperly verified. The NRC

inspection team identified this as the second example of Nonconformance 99901473/2016-201-04 for GA-EMS's failure to assure conditions adverse to quality are promptly identified and corrected.

2) For the review of the dedication of a gauge (Part No. 03587002-059), the Commercial Grade Item Engineering Evaluation identified the material of the casing of the gauge as a critical characteristic, which was specified as stainless steel. The technical evaluation of the critical characteristics, performed by GA-EMS, stated that although 316 Stainless Steel is specified in the source control drawing, Engineering determined that stainless steel is required to survive the environment; but, the specific alloy of stainless steel is not important to the safety-related function. CCAP 03587002-059 required a magnetic test to be performed to determine if the casing of the gauge is stainless steel. The NRC inspection team determined that using a magnetic test to verify the critical characteristics for the material, GA-EMS was unable to demonstrate that casing of the gauge was in fact stainless steel and had the proper composition to function in the required environment. The NRC inspection team identified this as the third example of Nonconformance 99901473/2016-201-04 for GA-EMS's failure to assure conditions adverse to quality are promptly identified and corrected.

3) For the review of the dedication package for an electrical connector (Part No. 50004261-001) CCAP 50004261-001, indicated the use of a visual examination of the color of Teflon insulation on the connector as the acceptance method for the material critical characteristic. However, the Commercial Grade Worksheet, did not identify the material of the Teflon insulation as a critical characteristic. Also, the engineering evaluation completed as part of the dedication package, did not indicate that the connector would be qualified for use in harsh environments. Contrary to the engineering evaluation, this connector is used as the mating connector for a safety-related process radiation monitor used during post-accident conditions. The engineering evaluation did not identify Teflon insulation as a critical characteristic for the material properties of the connector. As a result, verification of the material critical characteristics specified for the connector to be used in safety-related applications was not performed and the connector was not adequately dedicated for operation in harsh environments. The NRC inspection team identified this as the fourth example of Nonconformance 99901473/2016-201-04 for GA-EMS's failure to assure conditions adverse to quality are promptly identified and corrected.

c. Conclusion

The NRC inspection team issued Nonconformance 99901473/2016-201-04 in association with GA-EMS's failure to implement the requirements of Criterion XVI, "Corrective Action," of Appendix B to 10 CFR Part 50. Nonconformance 99901473/2016-201-04 cites GA-EMS for failure to assure conditions adverse to quality are promptly identified and corrected. Specifically, GA-EMS failed to adequately implement the corrective actions as identified in CAPA 2254, generated in response to NON 99900265/2013-201-01 issued as a result of the 2013 NRC inspection of GA-EMS. The NRC inspection team identified that GA-EMS failed to update CCAP 50004269-001 for an electrical connector to replace the visual inspection of Teflon insulation and silver plating with a survey of the vendor and verification of the CoC. In addition, GA-EMS

failed to perform an adequate review of all safety-related CCAPs and implement actions to update any CCAPs identified in the review as needing revisions. Additional examples of GA-EMS's failure to assure conditions adverse to quality were promptly identified and corrected included: 1) CCAP 50003191-001 failed to include justification for the suitability of a visual inspection to verify the body of the fuse was in fact glass with metal ferrules; 2) CCAP 03587002-059 used a magnetic test to verify the critical characteristics for the material, which would not demonstrate that casing of the gauge was in fact stainless steel and had the proper composition to function in the required environment; and 3) CCAP 50004261-001 did not identify the material of the Teflon insulation as a critical characteristic and indicate that the connector would be qualified for use in harsh environments.

5. Manufacturing Controls

a. Inspection Scope

The NRC inspection team reviewed GA-EMS's policies and implementing procedures that govern manufacturing and special processes to verify their compliance with the regulatory requirements of Criterion V, "Instructions, Procedures, and Drawings," Criterion IX, "Control of Special Processes," and Criterion X, "Inspection," of Appendix B to 10 CFR Part 50.

The NRC inspection team observed the inspection and testing of PWAs installed in an RMS. The NRC inspection team reviewed the procedures implemented for the control of PWA soldering and conformal coating processes for compliance with IPC- A-610, "Acceptability of Electronic Assemblies," and IPC-7111/7721, "Rework, Modification, and Repair of Electronic Assemblies." The NRC inspection team reviewed a sample of documents for inspection and soldering of PWAs to ensure that personnel performing soldering were qualified in accordance J-STD-001, "Requirements for Soldered Electrical Assemblies." In addition, the NRC inspection team observed the process for applying conformal coating to PWAs, which is discussed in more detail in section 2 "Design Control and Commercial Grade Dedication" of this report.

The NRC inspection team discussed the control of the manufacturing and special processes program with GA-EMS's management, technical staff, craft supervision and craft personnel.

The attachment to this inspection report lists the individuals interviewed and documents reviewed by the NRC inspection team.

b. Observations and Findings

No findings of significance were identified.

c. Conclusion

The NRC inspection team concluded that GA-EMS has established a program that adequately controls manufacturing and special processes in accordance with the regulatory requirements of Criterion V, "Instructions, Procedures, and Drawings," Criterion IX, "Control of Special Processes," and Criterion X, "Inspection," of Appendix B

to 10 CFR Part 50. Based on the limited sample of documents reviewed and operations observed, the NRC inspection team determined that GA-EMS is effectively implementing its policies and procedures governing manufacturing and special processes. No findings of significance were identified.

6. Handling, Shipping and Storage

   a. Inspection Scope

      The NRC inspection team reviewed GA-EMS's policies and implementing procedures that govern handling, storage, and shipping to verify their compliance with the requirements of Criterion XIII, "Handling, Storage, and Shipping," of Appendix B to 10 CFR Part 50. The NRC inspection team verified that safety-related structures, systems and components are handled, stored, and shipped in accordance with procedures and contract requirements. The NRC inspection team verified a sample of documentation sent to purchasers contained the appropriate information regarding check sources installed inside RMSs and calibration sources to be used by purchasers. In addition, the NRC inspection team verified that a sample of shipping documentation met the regulatory requirements for shipping radioactive material.

      The attachment to this inspection report lists the individuals interviewed and documents reviewed by the NRC inspection team.

   b. Observations and Findings

      No findings of significance were identified.

   c. Conclusion

      The NRC inspection team concluded that GA-EMS has established a program that adequately controls handling, storage, and shipping in accordance with the regulatory requirements of Criterion XIII, "Handling, Storage and Shipping," of Appendix B to 10 CFR Part 50. Based on the limited sample of documents reviewed, the NRC inspection team determined that GA-EMS is effectively implementing its policies and procedures governing handling, storage, and shipping. No findings of significance were identified.

7. Entrance and Exit Meeting

   On Monday, September 12, 2016, the NRC inspection team discussed the inspection scope during an entrance meeting with Mr. Scott Forney, President, and other members of GA-EMS's management and technical staff. On Friday, September 16, 2016, the NRC inspection team presented the inspection results during an exit meeting with Mr. Scott Forney, President, and other members of GA-EMS's management and technical staff. On October 19, 2016, the NRC inspection team conducted a re-exit to present inspection results and observations to Mr. Patrick O'Shaughnessy, GA-EMS Nuclear Quality Assurance Manager, and other members of GA-EMS's management and technical staff. The attachment to this report lists the attendees of the entrance and exit meetings, as well as those individuals whom the NRC inspection team interviewed.

ATTACHMENT

1. ENTRANCE/EXIT MEETING ATTENDEES

Name	Title	Affiliation	Entrance	Exit	Interviewed
Keith Asmussen	Director, LSNC	GA-EMS	X	X	X
Doug Brown	Director, Eng. ACG	GA-EMS		X*	
Ilja Breslica	RMS Systems Engineer	GA-EMS		X	X
Tony Casey	Supervisor, Material Control	GA-EMS			X
Dianna Correa	QA	GA-EMS			X
Mike Cuarenta	QMS CAPA	GA-EMS	X		
Tarek Dagher	RMS Engineering Manager	GA-EMS	X	X*	X
Sarah DeHart	Director, Material Management	GA-EMS			X
Cesar Davila	Material Control	GA-EMS			X
James Duffy	RMS Customer Service Manager	GA-EMS	X	X*	
Art Evans	RMS Engineer	GA-EMS	X	X*	X
Travis Evans	Systems Engineer	GA-EMS			X
Ben Gibbens	Operations Manager	GA-EMS	X	X	X
Scott Forney	President	GA-EMS	X	X	
Josh Forte	Quality Engineer	GA-EMS			X
Robert Khan	COO	GA-EMS	X	X	
Joe Kunz	Lead Maintenance Technician	GA-EMS			X
John Ladrillano	QA	GA-EMS		X	X
Huy Le	Detector Test Technician	GA-EMS			X
Jamie Lehto	Project Manager	GA-EMS	X		
Cesar Martinez	Stock Employee	GA-EMS			X
Laura Meza	Production Specialist Lead	GA-EMS			X
Ted Nance	Quality Engineer	GA-EMS	X	X*	X
Phillip Newman	Senior Engineer	GA-EMS			X
Anh Nguyen	General Technician	GA-EMS			X
Phuong Nguyen	QA Engineer	GA-EMS			X
Thomas Nguyen	Quality Assurance	GA-EMS			X
Patrick O'Shaughnessy	Nuclear QA Manager	GA-EMS	X	X*	X
Daryle Owen,	Production Planer, Production Control	GA-EMS			X
Katherine Partain	Lead Nuclear Auditor	GA-EMS			X
Paul Pater	Health Physicist	GA-EMS	X	X*	X
Maribel Perez	Manufacturing Engineer	GA-EMS			X
Sanjay Phatah	PMO	GA-EMS		X	
Gregory Priddie	Engineer	GA-EMS		X	
Michael Quadrini	Head Of EMS Product Lines	GA-EMS		*	
Patricia Reed	Production Planer, Production	GA-EMS			X

	Control				
Frank Sadlowski	Quality Engineer	GA-EMS			X
Michelle Saumur	Product Lines	GA-EMS			X
John Sigmuno	Technician	GA-EMS			X
Kim Soukkhyphiangkeo	QA Inspector	GA-EMS			X
Timothy Snoke	Quality Assurance Director	GA-EMS	X	X	
Karen Strand	QMS Compliance Manager	GA-EMS	x		
Joe Sullivan	Range Laboratory Manager	GA-EMS			X
David Sumego	Nuclear Engineer	GA-EMS		*	X
Jack Templeton	QA Inspector	GA-EMS			X
Daniel Todd	QMS Audit	GA-EMS	X	X	X
Rick Toms	Director, RMS	GA-EMS	X	X	
Michael Tran	Inventory Control Technician	GA-EMS			X
Marcelino Villalon	Technician	GA-EMS			X
Brian Vellante	Inventory Control Technician	GA-EMS			X
Mathew Waiden	Mfg. Eng. Manager	GA-EMS		X	
Patricia Wise	Production Planning & Material Planning Group	GA-EMS	X	X	X
James Yockey	QA Inspector	GA-EMS			X
Jay Zhang	SW Manager	GA-EMS	X		
Ashley Ferguson	Inspector	NRC	X	X	
Kerri Kavanagh	QVIB-3 Branch Chief	NRC		X	
Andrea Keim	Inspector	NRC	X	X	
Thomas Kendzia	Team Lead	NRC	X	X	
Ronald Lavera	Inspector	NRC	X	X	

* Teleconference participant for October 19, 2016 re-exit.

2. INSPECTION PROCEDURES USED

IP 43002 “Routine Inspections of Nuclear Vendors,” dated July 15, 2013 (Agencywide Documents Access and Management System (ADAMS) Accession No. ML13148A361)

IP 43004, “Inspection of Commercial-Grade Dedication Programs,” dated November 29, 2013 (ADAMS Accession No. ML13280A478)

IP 36100, Inspection of 10 CFR Part 21 and Programs for Reporting Defects and Noncompliance,” dated February 13, 2012 (ADAMS Accession No. ML113190538)

3. LIST OF ITEMS OPENED, CLOSED, AND DISCUSSED

Item Number	Status	Type	Description	Applicable ITAAC
99900265/2013-201-01	Discussed	NON	Criterion III	N/A
99901473/2016-201-01	Opened	NON	Criterion III	N/A
99901473/2016-201-02	Opened	NON	Criterion IIV	N/A
99901473/2016-201-03	Opened	NON	Criterion XII	N/A
99901473/2016-201-04	Opened	NON	Criterion XVI	N/A

4. DOCUMENTS REVIEWED

Procedures

- Assembly of Valve, Sol, 1/ ¼ NPT NC Assembly, 10016-10018, 50021511
- EMS-ADP-16, “Corrective Action, Preventive Action, and Continual Improvement,” Revision G, dated November 12, 2015
- EMS-EDP-03, “Project Technical Review,” Revision C, dated August 5, 2015
- EMS-CMP-23, “Configuration Change Control of Commercial and IR&D Products,” Revision D, dated November 12, 2015
- EMS-QAP-01, “Control of Nonconforming Items,” Revision F, dated April 25, 2011
- EMS-QAP-05, “Control of Measuring and Test Equipment,” Revision K, dated August 20, 2015
- EMS-QAP-13, “EMS Approved Supplier List,” Revision L, dated March 21, 2016
- GA 0360-1199, “Test Procedure 5 VDC Logic Power Supply”
- MP-005, “MRO Process,” Revision L, dated August 29, 2012
- MSP00007013, “Conformal Coating of Printed Wiring Assemblies,” Revision T, dated October 30, 2012
- MPS-00007078, “Installation of BNC and MHV Connectors for Industrial Projects,” July 30, 1987
- MPS-00007160, “Testing of Soldering Iron Tip Temperatures,” Revision A, dated March 21, 2013
- MPS00007091, “The Cleaning of Printed Wiring Assemblies (PWA),” Revision J

- OP-1.4-180, “Compliance with 10CFR21,” Revision J, dated April 16, 2013
- OP-7.3- 110, “Safety Related Equipment Qualification,” Revision D, dated April 16, 2013
- OP-7.3- 240, “Safety-Related Commercial Grade Item Parts Accepted,” Revision M, dated May 10, 2013
- OP-8.2-130, “Customer Calls for Support or Compliant,” Revision L, dated July 7, 2014
- QAP 22-01, “Verification of 10 CFR 21 Compliance,” Revision H, dated March 31, 2016
- QAP 7-02, “Design Control Assurance of Commercial Grade Items & Services in Nuclear Safety Related Applications,” Revision K, dated March 7, 2013
- S00008001, “RMS Quality Assurance Manual,” Revision V, dated April 30, 2014
- QAP 3-01, “Design Control Assurance,” Revision G, dated March 29, 2013
- QAP 13-01, “Verification of Handling, Storage, and Shipping Controls,” Revision E, dated June 27, 2013
- QCI-100, “Receiving Instructions (General),” Revision W, dated July 14, 2014
- QCI-139, “Inspection of Action PAK Isolation Transmitters Model AP3000/AP4310 and AP1080,” Revision G, dated October 4, 2013
- QCI-200, “In-Process Inspection,” Revision G, dated September 6, 2013
- QCI-212, “Inspection of Conformal Coated Printed Circuit Boards,” Revision C, dated September 11, 2009
- QDI 3-2,”Commercial Grade Dedication,” Revision A, dated April 14, 2016
- 02819010, “Packing, Shipping and Storage Procedure for Radiation Monitoring Equipment,” Revision D, dated June 6, 1978

Corrective and Preventive Action Requests (CAPAs)

2254, 7005794, 709418, 7010947, 7011573, 7013313, 7013804, 7014315, 7010650

CAPAs Generated During the Inspection

- 7016948, “Conformal coating thickness,” dated September 14, 2016
- 7016949, “Completed test procedure 281-9046 missing test data,” dated September 14, 2016
- 7016963, “Soldering Qualification and Record Package (Form SE-0165E) for Steve Puhn was incomplete,” dated September 14, 2016
- 7017019, “Temperature and Humidity monitoring system that notifies individuals of abnormal conditions is not calibrated,” dated September 16, 2016
- 7017023, “Conformal coat process is not treated as safety related,” dated September 15, 2016
- 7017000, “The Vendor who calibrates the Cs-137 source is not procured as safety related and is not dedicated,” dated September 15, 2016
- 7017026, “General Atomics uses sources in testing and calibration that may require periodic calibration,” dated September 15, 2016

- 7017027, “General Atomics uses sources in testing and calibration that have some physical degradation that may have an adverse effect,” dated September 15, 2016
- 7017028, “General Atomics uses a test range that the configuration control and usage may lead to decreased accuracy of calibrations,” dated September 15, 2016
- 7017029, “General Atomics uses sources in testing and calibration that are past their expiration date, although they have a letter from the vendor stating the sources can still be used, General Atomics needs to verify the acceptability in the application they are being used,” dated September 15, 2016
- 7017030, “An equivalency evaluation for a heat exchanger did not include a dimensional analysis for field installed equipment,” dated September 15, 2015
- 7017031, “Minimal trending performed on QN’s written in the last year,” September 15, 2016
- 7017042, “Engineering Dedication of Amphenol Connectors (Part # 50004269) Qualification document changes were incomplete,” dated September 15, 2016
- 7017043, “EQ Amphenol Connector Part # 50004261 Qualification document incorrectly checked non-harsh environment and material characteristics were not checked,” dated September 15, 2016
- 7017046, “For soldering iron temperature checks, there is no guidance on whether an engineering evaluation is required,” dated September 16, 2016

Nonconformance Reports

QN 7009239, 7009421, 7009507, 7009607, 7009710, 7009749, 7009750, 7009795, 7009815, 7009864, 7009954, 7010378, 7010386, 7010395, 7010426, 7010670, 7010676, 7010963, 7010989, 7011009, 7011064, 7011396, 7011530, 7011665, 7011681, 7011870, 7012159, 7012160, 7012171, 7012304, 7012322, 7012361, 7012429, 7012834, 7012883, 7013262, 7013608, 7013980, 7014272, 7014385, 7014495, 7014704, 7015154, 7015944, 7015965,7016012, 7016205, 701665, 7016886, 7016829

Commercial Grade Dedication Documents

- Dedication Package for CONN, MHV, SKT, NON-CONST, CLAMP Part No. 50004269-001
- Dedication Package for CONN, MHV, SKT, NON-CONST, CLAMP Part No. 50004261-001
- Dedication Package for XMTR, ISOL, DC, 0-1 VDC, 4-20 MA, Part No. 03600673-005
- Dedication Package for Heat XCHR, 1100 BTU/HR, 4”Tall, Part No. 306330
- Dedication Package for IC regulator UA7232TH, Part No. 50002135-001
- Dedication Package for 1A, 250V, slow-blow fuse Part No. 5003191-001
- Dedication Package for Radio Iodine Filter Part No. 50015405-001
- Dedication Package for Charcoal Filter Part No. 50009091-001
- Dedication package for GAUGE, VAC, 30-0 HG, PNL, MNT, Part No. 035587002-059

Purchase Orders (POs)

- PO 4700015331 for Heat Exchanger, 1100 BTU/HR, 4" Tall
- PO 68562061608 for Power Supply Assembly
- PO 4500045977 for onsite calibration services
- PO 4500056687 for calibration services
- PO 50021217 for Power Supply Assembly

Training and Qualification Records

Soldering Qualification Record Form SE-0165E for Laura Meza, Thay Vo, Anh Nguyen, Hue Irwin, Tuyet Le, Marcelino Villalon, Cipriana Bayalan, Yee Yang, and Steven Puhn, all dated August 22, 2013

Shipping Packages

- Packing No. 80163530 for Sales Order 10052501, shipped September 12, 2016
- Packing No. 80163222 for Sales Order 10056218, shipped September 7, 2016
- Packing No. 80164074 for Sales Order 10052808, shipped September, 12, 2016

Drawings

- GA Drawing 5.14-SK- 120A "Calibration Unit Assembly"
- GA Drawing 5.14-SK- 126A "Calibration Unit Assembly," dated August 25, 1967
- GA Drawing 5.14-SK-123A-B "Calibration Unit Instrument Cart Assembly," dated January 4, 1968
- Drawing No. 02819030 "Detector Assembly Area Monitor RD-10B, Calibration Procedure RD-10, RD-11 & RD-12," Revision J
- Drawing No. 03573101, "Test Procedure HV Power Supply, 500-1250 Volt," Revision M, dated November 18, 1988
- Drawing No. 281-9046, "RP-23 Test Procedure," Revision A, dated August 10, 1981

Calibration Records

- Certificate of Calibration No. 91423290 – Anmar Metrology, dated December 17, 2015
- Certificate of Calibration No. 91422762 – Anmar Technology, dated December 14, 2015
- Certificate of Calibration No. 91393997 – Anmar Technology, dated December 17, 2015
- Certificate of Calibration No. 91379354 – Anmar Technology, dated September 19, 2015
- Certificate of Calibration No. 91427990 – Anmar Technology, dated September 19, 2015
- Certificate of Calibration No. 91430756 – Anmar Technology, dated March 9, 2016
- Certificate of Calibration No. 91446511 – CalV, dated September 18, 2015

Other

- Audit No. 13-305561, conducted November 25-26, 2013

- IA 12-2015, “QMS Internal Audit Report, Control of Monitoring and Measuring Equipment,” dated January 6, 2016
- FLUKE “77 Series III Multimeter, Service Manual” Revision 1, dated November 1999
- FLUKE “77/75/23/21 Series III Multimeter, Instruction Sheet,” Revision 2, dated July 1998
- DeFelsko Corporation “6000 SERIES Coating Thickness Gage Instruction Manual version 3.0”
- DeFelsko Corporation “PosiTector 6000 Instruction Manual V. 6.2/M for Memory (3) models, Coating Thickness Gages”
- Techspray “Technical Data Sheet, Fine-L-Kote AR Acrylic Conformal Coating 2103” Product 2103-12S
- Techspray email, “Subject: Shelf life of Techspray products”, dated October 29, 2013.
- GA ECR No. CR057171 ECN-078013 “Change Description WIP 20023353, 20023354,” initiated September 17, 2015, signed March 18, 2016.
- GA E-254-960 “Test Report Class 1E Design Qualification Testing of Analog High Range Radiation Monitor (RD-23, RP-2C, RP-23 and RP-20-01),” dated May 1, 1981
- GA Ref: 492:2016: KP: 004 “QA Audit Report N. 15003 Ludlum Measurements Inc. (Final Report),” dated February 8, 2016.
- GA “Audit 15003 – Check List Questions”
- ECN-080297 “CSCAL Verification Report,” Revision J, dated April 4, 2016
- IPC-A-610F, “Acceptability of Electronic Assemblies,” Revision F, dated July 2014
- QAP 22-01, “Verification of 10 CFR 21 Compliance,” Appendix A 10 CFR 21 Checklist, completed on May 11, 2016 for sensor in thermowell not fully seated reported by Calvert Cliffs on March 28, 2016, dated May 11, 2016

5. ACRONYMS USED

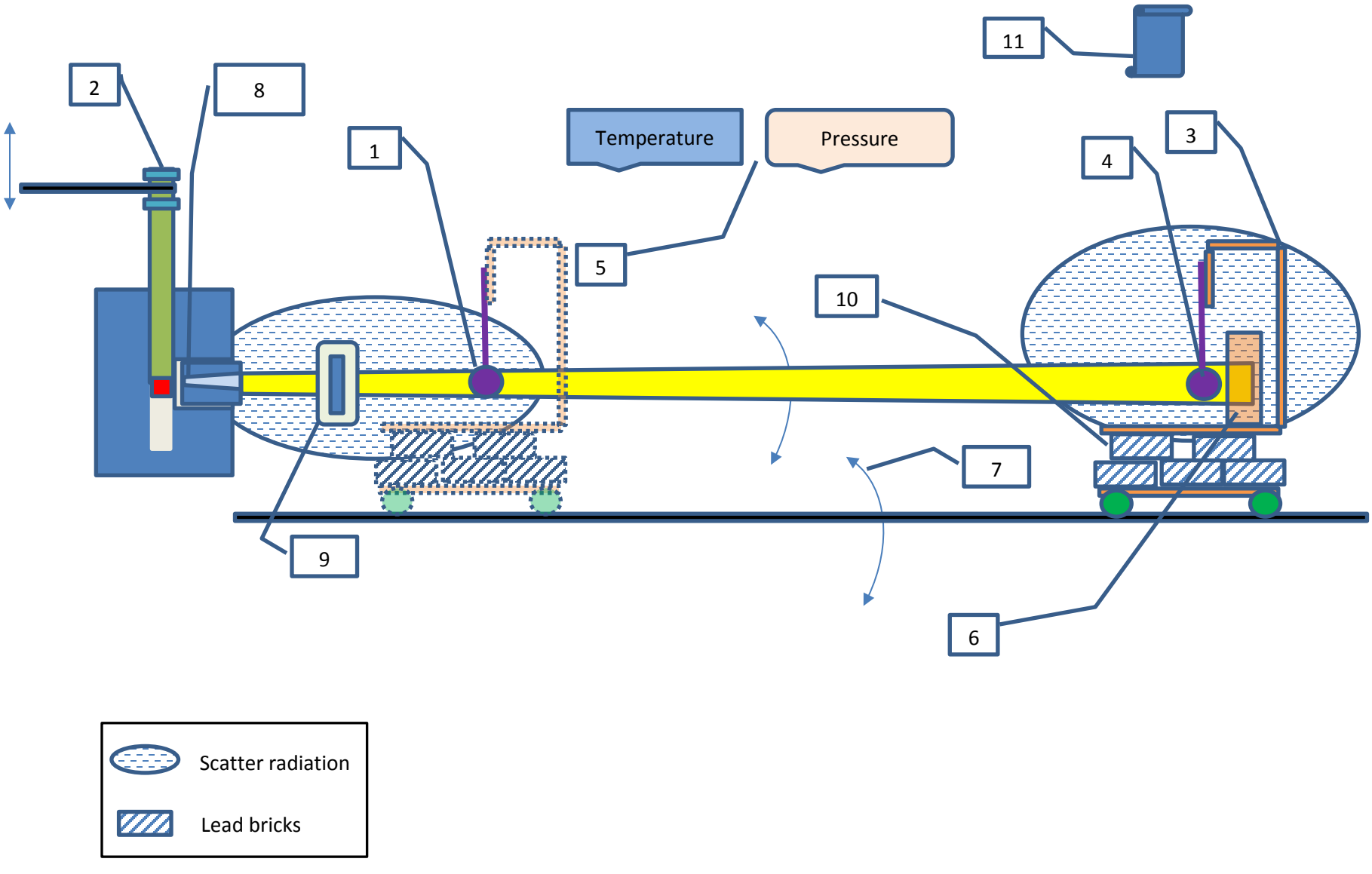
CAPA	corrective action/preventative action
CCAP	critical characteristics acceptance plan
CFR	*Code of Federal Regulations*
COC	certificate of conformance
EQ	environmental qualification
iCAR	internal corrective action request
IP	inspection procedure
M&TE	measuring and test equipment
NON	notice of nonconformance
NIST	Nation Institute of Standards and Technology
NRC	U.S. Nuclear Regulatory Commission
NRO	Office of New Reactors
PO	purchase order
PWA	printed wiring assembly
QA	quality assurance
QN	quality notification
RMS	radiation monitoring system

sCAR	supplier corrective action request
URI	unresolved item

6. Potential Inaccuracies in Source Assembly (refer to Figure-1 below)

(1) Decay of the Cs-137 source requires the detector to be placed closer to the source and results in a lower primary beam and more scattered radiation near the detector. This could result in an inaccurate calibration reading of the source.
(2) GA-EMS drawings did not specify the position of Cs-137 source in the source exposure port or verify that the source was centered. If the source is off center, the orientation of the radiation beam may not be horizontal, thus adding to the uncertainty of the calibration of the RMS detectors.
(3) GA-EMS did not have measures to prevent movement of the bracket used to hold the CalV detector, which could potentially add to the uncertainty of calibration of the Cs-137 source.
(4) GA-EMS did not to ensure that the radius of the radiation beam sufficiently exceeded the size of the CalV detector and did not appropriately apply correction factors to ensure accurate dose rate points were obtained.
(5) GA-EMS did not ensure that M&TE used by CalV to measure pressure and temperature, which is used by CalV to correct the output of the vented ion chamber used for the calibration of the Cs-137 source, was properly calibrated. This could reduce the accuracy and increase the uncertainty of the calibration of the Cs-137 source.
(6) GA-EMS did not adequately control the orientation or alignment of the RMS detectors in respect to the source beam during calibration.
(7) GA-EMS did not ensure the alignment of the track with the beam, which could result in off center exposers of the CalV or RMS detectors.
(8) GA-EMS did not adequately control the configuration of the attenuators used for the Cs-137 source assembly. The configuration of the attenuators affects the amount of scatter radiation from the source shield and the attenuators which can change the energy spectrum near the source. This may invalidate the use of inverse-square as a method of estimating the exposure rate.
(9) A deformation of the attenuating collimator was observed. The deformation could restrict the opening of the collimator which could result in a lower than expected delivered dose rate, and thus adding to the uncertainty of the calibration of the RMS detectors.
(10) GA-EMS changed the configuration of lead material without documenting or evaluating the effects of the change on the amount of scatter radiation in the area. Changing the material in the vicinity of the detector can cause scatter that effects the radiation readings.
(11) GA-EMS did not account for the uncertainty provided by CalV to the total accuracy and uncertainty stated by GA-EMS to their customers for the RMS detectors.

Figure -1 Typical Source Range



Reference Documents

- ANSI/IEEE N323C-2009, “Radiation Protection Instrumentation Test and Calibration—
- Air Monitoring Instruments,” dated November 6, 2009
- IEEE-N42.12-1994 “American National Standard Calibration and Usage of Thallium
- Activated Sodium Iodide Detector Systems for Assay of Radionuclides,” dated December 8, 1994
- IEEE N323D-2002, “Installed Radiation Protection Instrumentation,” dated January 27, 2003
- Electric Power Research Institute (EPRI) Technical Report (TR) 1011965 “Calibration of Radiation Monitors at Nuclear Power Plants,” dated December 22, 2005
- EPRI TR-102644 “Calibration of Radiation Monitors at Nuclear Power Plants,” dated March 1994
- EPRI TR-1007909 “Area and Process Radiation Monitoring System Guide, Revision 2 of TR-104682” dated August 13, 2003