GENERAL ATOMICS

January 26, 2017
NRC/QA-4767

U. S. Nuclear Regulatory Commission
ATTN: Document Control Desk
Washington, DC 20555-0001

Subject: Reply to Notice of Non-conformance

References: 1) Docket No. 99901473

2) Kerri Kavanagh (NRC) Letter to Dr. Keith E. Asmussen (GA), *Nuclear Regulatory Commission Inspection Report No. 99901473/2016-201 and Notice of Nonconformance*, November 29, 2016

3) Kerri Kavanagh (NRC) Letter to Dr. Keith E. Asmussen (GA), *Request for Extension of Time to Respond - Nuclear Regulatory Commission Inspection of General Atomics, Inspection Report No. 99901473/2016-201 and Notice of Nonconformance*, December 16, 2016

This letter and enclosure provides General Atomics Electromagnetic Systems (GA-EMS) Group's reply to the Reference 2 Notice of Nonconformance.

General Atomics (GA) believes its participation in the NRC vendor inspection program was, and will be going forward, beneficial in strengthening its quality program and culture. Also, GA would like to thank you for granting the additional time required to prepare this reply (Reference 3).

GA is pleased that you found a sound quality culture in place, but we realize, as a result of the NRC audit team observations, we need to implement appropriate corrective actions (please see enclosure) to be fully compliant with NRC requirements. The enclosure to this letter addresses the reason for each noncompliance, corrective steps that have been taken, the results achieved to date, corrective steps that will be taken to avoid future non-compliances, and the date when all corrective actions will be complete. GA takes any noncompliance very seriously and also sees it as an opportunity to improve our quality and safety. Our commitment to quality and safety is the foundation of our business. Each radiation monitoring system we produce goes through substantial operational testing and each design is environmentally qualified to prove suitability for use in a nuclear power plant. These corrective actions will further improve our processes and build on our safety culture.

GA trusts its response and corrective actions will be found appropriate and satisfactory. If you have any questions related to this response, please contact me at 858-455-2823 or by email at Keith.Asmussen@ga.com.

Very truly yours,

Keith E. Asmussen

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Enclosure: Response to Notice of Nonconformance 99901473

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ENCLOSURE: RESPONSE TO NOTICE OF NONCONFORMANCE 99901473

NONCONFORMANCE 99901473/2016-201-01

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.

Response:

1) Reason for the noncompliance, or if contested, the basis for disputing the noncompliance:

GA-EMS acknowledges the notice of nonconformance, and internal corrective action request (iCAR) 7016948 and iCAR 7017023 were initiated. GA-EMS is a continuous improvement company where safety is unequivocally the foundation of our culture. We are conducting a detailed analysis and testing of our safety related PWA designs. It is significant to note that GA-EMS has an extensive operational history with safety related PWAs going back decades. Our ongoing analysis has found no defects in fielded components that would result in a safety related failure. Additionally, based on anecdotal evidence from both the nuclear power plants we serve and GA personnel with several decades of experience, we have found no record of concerns or requests to investigate either our PWA design or quality. GA-EMS is committed to a course of action that will complete the PWA investigation and testing by 14 April, 2017. Upon completion of this investigation, GA-EMS will provide a thorough update to our customers.

A key part of the investigation is the development of process improvements to further enhance our existing processes related to the conformal coating of PWAs. The GA-EMS corrective action processes in part include reviewing the nonconformance for 10 CFR Part 21 applicability, and the use of any nonconforming material.

GA complies with 10 CFR 50 Appendix B by adopting NQA-1, the American Society of Mechanical Engineers (ASME) standard. The sections in italics below refer to the NQA-1 verbiage corresponding to the 10 CFR 50 Appendix B paragraph specified by the NRC, for clarification purposes.

a) *Per NQA-1, Part 1, Requirement 3, Design Control, in part requires the final design shall (1) be relatable to the design input by documentation in sufficient detail to permit design verification.*

(2) Specify required inspections and tests and include or reference appropriate acceptance criteria. (3) Identify assemblies and/ or components that are part of the item being designed. When such an assembly or component part is a commercial grade item, the critical characteristics of the item to be verified for acceptance and the acceptance criteria for those characteristics shall meet the requirements of Part II, Subpart 2.14, Quality Assurance Requirements for Commercial Grade Items and Services.

The required conformal coating thickness was not consistent among the Manufacturing Process Specification (MPS), Quality Control Instruction (QCI), and the IPC-A-610 "Acceptability of Electronic Assemblies" standard. The originally qualified coating material GA was using was Urethane Resin (Type UR). GA-EMS believes, and is presently evaluating, that the addition of an alternate coating material, Silicone Resin (Type SR), was the catalyst for the introduction of the 0.001 inch thickness discrepancy between the MPS and QCI documentation and the IPC-A-610 standard. GA-EMS believes the Type UR thickness was appropriately identified, but the higher thickness requirement for Type SR was not correctly indicated upon update. Without exception all GA-EMS employees must follow strict verbatim procedural compliance. When the conformal coat thickness for Type SR was not updated properly the technicians followed the procedure verbatim thus resulting in the nonconformance.

In accordance with IPC-A-610, GA-EMS has continuously utilized a measurement process for ensuring uniformity of the coating thickness on the surface of RMS PWAs. As an organization committed to continuous improvement GA-EMS, per NRC guidance, has further reviewed the MPS and QCI procedures. Accordingly, while not in conflict with the IPC-A-610 standard, GA-EMS enhanced the MPS00007013 procedure to increase the number of measurement points and locations on the board to better determine board conformal coat uniformity and modified QCI-212 to verify that documented measurements are within specification.

b) *Per NQA-1, Part II, Sub-Part 2.14, Commercial Grade Dedication (CGD), in part requires technical evaluations and identification of Critical Characteristics important to design, material, and performance characteristics of a commercial grade item or service that, once verified, will provide reasonable assurance that the item or service will perform its intended safety function.*

The basis of qualification for PWAs is determined during system qualification testing. GA-EMS Design Engineering took the position that since the conformal coating is challenged and sufficiently tested during PWA operational testing and infant mortality burn-in, additional testing of the conformal coating would not be necessary. During the audit the NRC found that this position did not provide sufficient technical evaluation to assure that the PWAs were consistent with the original design basis.

Since the original design qualification had not identified the need for CGD of the conformal coating, the apparent cause analysis results are:

a) A determination had been made by GA-EMS that additional testing of the conformal coating would not be necessary as described above.

b) Because GA-EMS engineers had assessed that additional testing of the conformal coating would not be necessary, CGD was not initiated, leading to the material being purchased as bulk consumable manufacturing floor stock. This prevented the material from going through the normal processes of establishing a GA-EMS part number, specification requirements, shelf-life, engineering review and CGD documentation.

c) Some of GA-EMS' equipment design configurations date back over 40 years. The qualification report for the specific PWA that the auditor was reviewing was not able to be located from archives and made available during the audit period; however, the qualification requirements

have subsequently been retrieved and will be used as the basis for the new CGD documentation.

d) Inconsistencies in the documentation indicating required thickness of the conformal coating were introduced during the transition from conformal coating material Type UR to material Type SR.

e) While not in conflict with the IPC-A-610 uniform coating distribution requirement, the number of points sampled in the MPS and QCI documents did not provide the requested objective evidence at the surface points requested during the audit.

2) Corrective steps that have been taken and the results achieved:

a) To immediately address the use of conformal coating in safety-related systems, GA-EMS assigned a part number to the conformal coating material, dedicated the conformal coating, and approved and released a Critical Characteristics Acceptance Package (CCAP). The CCAP identifies the critical characteristics and the acceptance criteria for use on safety-related RMS assemblies. The material is inspected and commercially dedicated as it is procured to verify for the critical characteristics. The Quality Assurance Guide (QAG) EMS-QAG-037 challenges the characteristics for dielectric withstand and material master requirements, to verify at least 50% of conformal coat material shelf-life remains at time of receipt.

b) GA-EMS contacted the manufacturer of the conformal coat product during the audit to verify the existence of an expiration date/shelf-life. At that time, the manufacturer stated that conformal coat 2102-12S (SR) did not have an expiration date. GA-EMS contacted the manufacturer's parent company. The parent company advised of the existence of a similar conformal coat product, which they stated had a one-year shelf-life for their "SR" coating. Subsequently, GA-EMS instituted a shelf-life of one year for the "SR" conformal coat product. On 17 January 2017, GA-EMS received a letter from the manufacturer stating that effective 9 January 2017 all Certificate of Compliance (C of C) documents received from the manufacturer will contain the shelf-life for that particular product. Additional discussion with the parent company's customer service department on 23 January 2017 indicated that the shelf-life that will be utilized on the C of C will be one year for 2102-12S (SR). GA-EMS has verified that the shelf-life listed in the applicable Material Masters is correct. Additionally, GA-EMS MPS00007013 Revision U reflects the updates to ensure the technician applying the conformal coat verifies shelf-life before use.

   To address the change in shelf-life identified by the manufacturer, each can of conformal coating material is inspected for date of manufacture, and then a label showing the expiration date is applied based on the manufacturer's recommended shelf-life. Applicable inspection and manufacturing personnel have been trained on proper identification of material shelf-life in general, and this product has been added to those they should identify.

c) To immediately address the conformal coating thickness discrepancy between GA-EMS MPS00007013 Revision T, QCI-212 Revision C, and IPC-A-610 Revision F, an internal corrective action request was issued as iCAR 7016948. Under iCAR 7016948, the MPS00007013 was revised to Revision U via change activity (CA) CA083055 and QCI-212 Revision C was revised to Revision D via CA083103 to reflect the 0.002 inch to 0.008 inch acceptable thickness range per IPC-A-610 for Type SR silicone conformal coating.

d) IPC-A-610 for Acceptability of Electronic Assemblies, states conformal coating should "uniformly cover" the printed circuit board and components. There is no further requirement for thickness uniformity or quantity of measurement locations. As a continuous improvement-focused

company and to embrace the NRC recommendation, MPS00007013 now requires that conformal coating thickness measurements be taken at five locations, to include four corners of the board plus a location in the center. Prior to the audit, MPS00007013 required three points of the coated assemblies to be measured for thickness. Statistical Process Control (SPC) data collected since increasing from three measurement points to five points provides a statistically insignificant improvement in thickness accuracy.

Further, GA-EMS conducted training for conformal coating receipt inspection (EMS-QAG-037 Rev. A) application process (MPS00007013 Rev. U) and inspection of conformal coated printed circuit boards (QCI-212 Rev. D) to ensure procedural compliance.

In parallel to these actions, GA-EMS conducted a review of all returned goods records associated with conformal coated printed circuit boards. This review included 114 repair records over a five-year period covering all returned conformal coated assemblies. The results of the review revealed that no failures were attributed to conformal coat issues.

3) Corrective steps that will be taken to avoid noncompliance:

In addition to the corrective actions already taken under iCAR 7016948 GA-EMS initiated an investigative review of all conformal coated circuit boards installed in GA radiation monitoring systems under iCAR 7017023. The characteristics of the conformal coating material were reviewed for the specific installed application of each printed circuit assembly. It was determined in each case that the environmental protection provided by the conformal coating was an enhancement and not required.

For some printed circuit board assemblies with close conductor spacing, the dielectric withstand property of the conformal coating was important. GA-EMS is performing an ongoing evaluation of fielded PWAs to assess for any potential impact. Those printed circuit board assemblies are being analyzed to assure that the minimum thickness of conformal coating will provide the required electrical dielectric withstand.

Initial assessments indicate that the conformal coating in fielded systems is performing as intended in the application and no safety or operational issues exist. The investigation is ongoing, upon completion GA-EMS will provide an update to the user community.

4) Date when corrective action will be completed:

The iCARs, which will include a root-cause analysis associated with Non-conformance 99901473/2016-201-01, will be completed no later than 14 April 2017.

NONCONFORMANCE 99901473/2016-201-02

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.

Response:

1) Reason for the noncompliance, or if contested, the basis for disputing the noncompliance:

GA-EMS acknowledges the notice of nonconformance, and iCAR 7017000 was initiated to investigate and develop process improvements to enhance existing GA-EMS processes. The GA-EMS corrective action processes in part include reviewing the nonconformance for 10 CFR Part 21 applicability, and containment of nonconforming material.

a) *Per NQA-1, Part 1, Requirement 12, Control of Measuring and Test Equipment, in part requires tools, gages, instruments, and other measuring and test equipment used for activities affecting quality shall be controlled, calibrated at specific periods, adjusted, and maintained to required accuracy limits.* Contrary to this requirement, CGD of the calibration service vendor was not performed.

b) *Per NQA-1, Part II, Sub-Part 2.14, Commercial Grade Dedication (CGD), in part requires technical evaluations and identification of Critical Characteristics important to design, material, and performance characteristics of a commercial grade item or service that, once verified, will*

provide reasonable assurance that the item or service will perform its intended safety function. Contrary to this requirement, the vendor providing the calibration services was not dedicated.

GA-EMS has a lengthy history of maintaining compliance with regulatory requirements and providing high-quality products, and has long-established procedures and processes to promote continuous improvement and ensure its quality program and culture are sustained. The apparent cause analysis results are that GA-EMS did not extend to the Health Physics team the requirement of CGD for the calibration service.

Although a CGD of the calibration service vendor was not conducted prior to the subject NRC inspection, GA remains confident that previously calibrated detectors were calibrated within the required range of accuracy, based on consistency among biennial calibrations of GA's range by a nationally recognized and respected service provider (previously 10 CFR 50 Appendix B approved) with National Institute of Standards and Technology (NIST) traceability. This confidence was validated by measurements and actions taken subsequent to the inspection, which demonstrated that previously calibrated detectors were properly calibrated.

2) Corrective steps that have been taken and the results achieved

When GA-EMS became aware that the calibration service vendor was not commercially dedicated, GA-EMS performed a Commercial Grade Survey of the vendor and dedicated the calibration service based on this vendor survey. Subsequently, the calibration service vendor was added to the GA Approved Supplier List (ASL).

Through the audit and dedication process GA-EMS verified the accuracy and traceability of the calibration vendor's measurement systems. In December 2016 the calibration service vendor returned to GA-EMS to verify the prior calibration. The measured exposure rates were found to be within accuracy requirements providing verification that previously calibrated detectors were acceptable for use.

In addition, the following corrective steps have been taken to address the NRC RMS detector accuracy concerns:

1) GA-EMS verified that the calibration vendor's detector was sufficiently irradiated to obtain an accurate reading. An independent, commercially dedicated supplier's calibrated detector was used to record radiation source beam diameter measurements to verify that the detector used by the calibration service vendor was sufficiently irradiated during the calibration measurements and would obtain an accurate reading of the exposure rate at that location.
2) GA-EMS verified that the calibration vendor's use of the inverse square law to obtain dose rate versus distance data for dose rates points in a highly scattered environment was acceptable. The vendor's use of the inverse square law to obtain exposure rate versus distance data was verified during the re-calibration process following CGD of the calibration vendor. Measurements were taken at a specific distance, and then predictions were calculated using the inverse square law for locations both closer to the source and further from the source. New measurements at these data points accurately matched the inverse square law predictions, verifying that use of the inverse square law was appropriate.
3) GA-EMS verified that the vendor used temperature and pressure instrumentation that were adequately calibrated. During the re-calibration process, GA-EMS obtained temperature and pressure calibration certificates. Further, Health Physics Procedure NCP NO.1105 was created to provide improved process control of the required inspections and calibrations, including requiring

traceable calibration documentation of the vendor's temperature and pressure instrumentation used during all future calibrations.

4) GA-EMS verified the source was consistently positioned in the exposure port. Source location sensitivity measurements were performed to calculate the impact of the source being axially displaced. Markings were placed on the source fixture to confirm that the source is consistently raised to the same location for each measurement. This ensures the calibration data is obtained at the same source location as all subsequent detector measurements, allowing for a valid use of the calibration data and inverse square law.

3) Corrective steps that will be taken to avoid noncompliance:

GA-EMS will add a final report from the calibration vendor to GA-EMS quality records, documenting their measurement results and the traceability of their calibration process and equipment

4) Date when the corrective action will be complete:

The iCAR will include a root-cause analysis associated with Non-conformance 99901473/2016-201-02 and will be completed no later than 3 March 2017.

NONCONFORMANCE 99901473/2016-201-03

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.*

Response:

1) Reason for the noncompliance, or if contested, the basis for disputing the noncompliance:

GA-EMS acknowledges the notice of nonconformance, and iCARs 7017026, 7017027, 7017028, and 7017029 were initiated. The GA-EMS corrective action processes in part include reviewing the nonconformance for 10 CFR Part 21 applicability, and containment of nonconforming material.

a) *Per NQA-1, Part 1, Requirement 12, Control of Measuring and Test Equipment, in part requires tools, gages, instruments, and other measuring and test equipment used for activities affecting quality shall be controlled, calibrated at specific periods, adjusted, and maintained to required accuracy limits.* Contrary to this requirement, GA-EMS could not provide objective evidence that sources, detectors and calibration assemblies are maintained within their necessary accuracy limits.

The Health Physics department maintains the source used to calibrate designated RMS area monitors. GA-EMS personnel have been using the same source location for many years, and have extensive experience with the operation, configuration, and what might significantly affect the detector readings. Both Health Physics and GA-EMS personnel are always present during vendor calibration activities. The apparent cause analysis results are that the Health Physics department was not made aware that strict configuration control documentation of the source was required to demonstrate that possible uncertainty had been minimized.

2) Corrective steps that have been taken and the results achieved:

In an effort to add additional data points during calibration of the GA range, GA-EMS audited and dedicated the manufacturer of the ion chamber, as a provider of calibration services. After the manufacturer was added to the GA-EMS ASL, the manufacturer calibrated the ion chamber.

This ion chamber was subsequently used at the GA range during the calibration performed by the calibration services provider to independently measure exposure rates and to confirm the calibration services provider data.

The resulting calibration added additional data points for accuracy considerations. GA-EMS obtained a side-by-side comparison of results for select exposure rates by an independent third-party detector to provide confirmation of the calibration vendor's measurements. This ion chamber is also used by GA-EMS to perform additional scattering and beam sensitivity studies.

In addition, GA-EMS has taken the following measures to ensure 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 uses a source assembly in a controlled configuration to perform calibration measurements on safety-related detectors. GA-EMS has improved the calibration process, configuration control, and uncertainty analysis by performing the following corrective steps:
   a) GA-EMS evaluated the effects of the decay of the CS-137 source. GA-EMS uses decay correction calculations to accurately determine the source distance during each calibration measurement.

      GA-EMS evaluated the impact of moving the detector closer to the source and the effects of scattered radiation. GA-EMS has used the inverse square law to predict exposure points closer to the beam opening and found by measurement that these locations agreed with the inverse square law predictions. This demonstrates that at locations closer to the beam used

by GA-EMS to produce required exposures rates, the measured exposure rate is consistent with the calibration results.

b) GA-EMS performed a sensitivity study to demonstrate that the rotation of the #1 attenuator has no significant impact on the resulting readings, and has purchased and documented new attenuators for use at the range. These new attenuators are solid lead squares with no modifiable geometry and were used during the range calibration performed in December 2016.

c) GA-EMS performed a sensitivity study to measure the effect of small changes in the attenuator geometry on expected exposure rates and found any change to be not statistically significant. In addition, the new attenuators were used in the December 2016 detector range calibration. During the periodic calibration process, the attenuators were confirmed to be producing the expected response.

d) Alignment of the detector with the source centerline remains independent of the source assembly. Accordingly, the loose bracket identified on the source assembly had no impact on the vendor's detector alignment, and thus no effect on the detector reading. GA-EMS tightened all bolts and connections on the calibration cart assembly with adhesive to ensure the configuration remains consistent between vendor calibrations.

e) GA-EMS performed a sensitivity study that consisted of altering the lead brick counterweights below the detector platform, removing all detector equipment under the track and found the change in results to be insignificant. The configuration drawing package is being updated as required.

f) GA-EMS verified control of the position of the detector during calibration, as the December 2016 re-calibration confirmed the "as-found" measured exposure rates are within accuracy requirements.

As an enhancement to increase the repeatability of the detector position GA-EMS has designed and manufactured a vendor calibration detector holder. Additionally, a precision laser level is used as an aid in verifying alignment with the beam centerline.

GA-EMS also performed repeatability studies to document the uncertainty of detector alignment. Resulting measurements confirmed that repeatability uncertainty is low, and can be accounted for within measurement of total uncertainty. This verifies that the setup, alignment, and movement of each detector by GA-EMS qualified technicians are repeatable.

g) GA-EMS performed beam width measurements to verify that the detector is adequately placed in the source beam, and verified the cart path is aligned and level to the source beam prior to each measurement. Additionally, GA-EMS placed markings on the source fixture to serve as a visual aid to confirm that the source is consistently raised to the same location for each measurement.

2) GA-EMS is creating a source configuration and uncertainty report that will explicitly document the known uncertainties and their effect on the reported uncertainty of the detector.

1) GA-EMS performed measurements at the closest locations used by GA-EMS and found the effects of scatter did not impact the expected exposure rates.

2) GA-EMS established a controlled configuration for the range, including the cart, track, and test fixture. Calibration was re-performed in this new configuration with results consistent with the previous calibration performed in September 2015.

3) GA-EMS performed beam diameter measurements to verify that the active sections of detectors calibrated by the source are fully within the beam at all locations. GA-EMS also performed an analysis of the repeatability for consistent setup and placement of the detectors to quantify the uncertainty with the detector placement and its effect on the uncertainty of the measurement.

4) GA-EMS is performing an uncertainty analysis to quantify and document all measurement process uncertainties; however, these uncertainties are small and do not impact the overall RMS detector uncertainty reported to customers.

3) Using the GA-EMS disk sources for calibration measurements requires comparing results to previous calibration data using the same traceable sources. Meeting the criteria of acceptable count rate deviation also demonstrates that no change in source strength other than expected radioactive decay has occurred due to possible scratching or losing seal integrity. The sources are periodically leak-checked by the Health Physics department to verify there is no loss of source material.

3) Corrective steps that will be taken to avoid noncompliance:

To confirm that the GA-EMS detector calibration process is controlled, a source configuration and uncertainty report will be created to document:

a) The effects of scatter caused by the detector's distance to the source and associated uncertainty
b) Mapping of the source beam diameter under open beam and collimator configurations
c) The impact scatter has on the measurements due to potential changes in lead brick configuration near the detector
d) Total measurement process uncertainty from all factors listed above on the total uncertainty of all RMS detectors calibrated at the GA facility.

In support of current procedures that compare source count rates to expected count rates, GA-EMS is creating a procedure to periodically assay the GA-EMS disk sources and re-verify that no changes in activity have occurred due to potential damage of the source. The procedure will include the frequency of the assay, inspections required, and results documented.

4) Date when corrective action will be completed:

The iCARs, which will include a root-cause analysis associated with Non-conformance 99901473/2016-201-03, will be completed no later than 7 April 2017.

NONCONFORMANCE 99901473/2016-201-04

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.

Response:

1) Reason for the noncompliance, or if contested, the basis for disputing the noncompliance:

GA-EMS acknowledges the notice of nonconformance, and iCARs 7017042, 7017043, and 7017057 were initiated. The GA-EMS corrective action processes in part include reviewing the nonconformance for 10 CFR Part 21 applicability, and containment of nonconforming material.

a) *Per NQA-1, Part 1, Requirement 16, Corrective Action, requires conditions adverse to quality shall be identified promptly and corrected as soon as practicable. In the case of a significant condition adverse to quality, the cause of the condition shall be determined and corrective action taken to preclude recurrence. The identification, cause, and corrective action for significant conditions adverse to quality shall be documented and reported to appropriate levels of management. Completion of corrective actions shall be verified.* Contrary to this requirement, GA-EMS failed to adequately implement the corrective actions identified in Corrective Action/Prevention Action (CAPA) 2254.

The apparent cause analysis results are that the Critical Characteristic Acceptance Plan (CCAP) review process was determined to be ineffective, as shown by the absence of a formalized process

documenting what was reviewed and what changes had actually been made to each individual CCAP. This lack of formalization resulted in some older CCAPs not being updated as stated in this report.

2) Corrective steps that have been taken and the results achieved:

GA-EMS implemented a tracking system for each CCAP that is utilized and ensures that each CCAP is reviewed, and updated as required, prior to the item shipping. The tracker lists the applicable CCAP, the part number, the utility requesting it, what updates were made to the CCAP (if any), and who performed the review. The review process and tracking system in use was incorporated into GA-EMS Procedure OP-8.1-110, Processing and Handling RMS Spare Parts.

GA-EMS conducted training on the purpose and use of this tracking/review system.

GA-EMS has reviewed, and updated as required, all CCAPs for safety-related parts that have shipped since the NRC inspection. These reviews have been documented in the tracking system.

CCAP 50004269-001 (Connector), 50004261-001 (Connector), 50003191-001 (Fuse), and 03587002-059 (Gauge) were re-evaluated by Engineering, with the following changes made to the CCAPs:

a) 50004269-001, Connector, identified material for the insulation and silver plating of the contact by visual means. The characteristics were re-evaluated and a verification of the insulator, PTFE, and center conductor plating, silver, was added via a C of C. Material is verified via C of C to verify the original equipment manufacturer (OEM) specification of the part that was ordered. A commercial-grade survey of the manufacturer was also completed in October 2016 and is listed on the GA ASL. The identification of the plating of the body was deemed not critical, as it did not impact the safety-related function of the Connector, and was removed from the CCAP. The Connector is challenged by performing QCI-110, Inspection of Connectors. The QCI consists of a fit test, insulation resistance test, conductor resistance test, testing for shorts between the shell and conductor, and a continuity test across the Connector and its mate.

b) 50004261-001, Connector, erroneously identified its use in a mild environment and generically identified the silver plating of parts. GA updated the CCAP to indicate that the Connector was used in a harsh environment, and removed the visual identification of silver plating and added functional testing to QCI-110, Inspection of Connectors. The Connector was qualified for use in a harsh environment, but an administrative error on the CCAP identified the part as used in a mild environment. Upon engineering re-evaluation, GA determined the visual identification of the silver plating of the body was not critical as it does not contribute to the safety-related function of the Connector. The material of the insulation and center contact will be verified via a C of C. A Commercial Grade Survey was also completed of the manufacturer in October 2016 and is listed on the GA ASL.

   Complete, full challenge of the qualified part can be demonstrated by similarity to the connector documented in Qualification Test Report E-255-1047. GA created a supplement to the original Qualification Report, E-254-960, referencing E-255-1047 and other supporting documents to provide reasonable assurance that the connector and insulator were sufficiently challenged for use in a harsh environment. The manufacturer also confirmed that their part number is and always was co-polymer of styrene, as an insulator.

c) 50003191-001, Fuse, failed to include justification for the suitability of a visual inspection to verify the body of the fuse as glass. Upon engineering review of the existing characteristics, this attribute was deemed unnecessary. The glass body does not serve a safety-related function in the end use subassembly. Identification of the glass body as a critical characteristic was

removed from the CCAP. The part is fully challenged by performing a current carrying test, then a destructive test to open the fuse (in the time recommended by the manufacturer), on a representative sample of the lot.

d) 03587002-059, Gauge, used a magnetic test to verify the critical characteristics for the material, to demonstrate 300 series stainless steel. The CCAP was re-evaluated by Engineering and it was determined that an X-Ray Fluorescence (XRF) material analysis would be implemented to identify the 300 series stainless steel. Identification of a specific grade stainless steel was not critical to the safety-related function of the gauge. The manufacturer's data sheet states 316 stainless steel for housing.

3) Corrective steps that will be taken to avoid noncompliance:

GA-EMS will continue to review, and update as necessary, CCAPs for safety-related parts as the parts are ordered and shipped out the door. The tracking system that was developed will be utilized to document these reviews and updates.

4) Date when corrective action will be completed:

The iCARs associated with Nonconformance 99901473/2016-201-04 have been completed.