GENERAL ATOMICS

July 18, 2013
GAESI/NRC-4589

U.S. Regulatory Commission
ATTN: Document control Desk
Washington, DC20555-0001

Subject: Reply to Notice of Nonconformance

References: 1) Docket No. 99900265

2) Rasmussen, Richard A. (NRC) Letter to Matthew Siegel (General Atomics – ESI), NRC Inspection Report No. 99900265/2013-201 and Notice of Nonconformance

This letter and enclosure provides General Atomics - Electronic Systems, Inc.'s (GA-ESI's) reply to the Notice of Nonconformance (NON) described in Reference 2.

The enclosure to this letter addresses the reason for the noncompliance, corrective steps that have been taken and 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-ESI 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

Keith E. Asmussen, Ph.D., Director
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Enclosure: Response to Notice of Nonconformance

cc: Richard A. Rasmussen, NRC
Matthew Siegel, GA-ESI
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IE09
NRD

General Atomics-Electronic Systems, Inc.'s Reply
to
Notice of Nonconformance No: 99900265/2013-201-01

Text from the Nuclear Regulatory Commission Inspection Report No. 99900265/2013-201 and Notice of Nonconformance will appear in *italics* within the body of this response.

Noncompliance Statement

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

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

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

   1. *Tests and inspections to be performed according to CCAP*
   2. *Test methods and inspection techniques to be used*
   3. *Acceptance criteria previously derived from the technical evaluation*
   4. *Documentation requirements for inspection and test results*

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

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

   1. *GA-ESI procured commercial grade items for use in safety-related applications without verifying the functional critical characteristic of the radioiodine cartridge filter to demonstrate that it can collect particulates from an air sample.*
   2. *GA-ESI's Amphenol connector documentation did not provide technical justification for the acceptance criteria for the critical characteristics regarding material composition. "*

The reason for the noncompliance, or if contested, the basis for disputing the noncompliance

Per NQA-1, Part II, Sub-Part 2.14, Commercial Grade Dedication (CGD) 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, two of six instances reviewed had insufficient technical evaluations, which lead to incorrect or lacking basis for identification of critical characteristics and verification by documented critical characteristics acceptance plans. Specifically:

1. Hi-Q filter PN 50015405-001 did not specify flow requirement and efficiency of the filter as a critical characteristic, and

2. Amphenol Connector PN 50004269-001 had unnecessarily identified critical characteristics that did not apply to the safety related function of the component.

The insufficient technical evaluation was due to a broad interpretation of the safety related function of the entire RMS unit to determine the critical characteristics of the individual component versus a technical evaluation of how the particular component contributes to overall safety related function of the RMS unit. When the original technical evaluations performed on the items listed above were conducted, almost 20 years ago, an application of a broad technical evaluation of overall safety related function of RMS unit lead to partial or insufficient verification of critical characteristics in the acceptance plans.

The corrective steps that have been taken and the results achieved

Critical Characteristic Acceptance Plan (CCAP) 50015405-001 (Radioiodine Filter) & 50004269-001 (Connector) were re-evaluated by Engineering and Quality Assurance with the following changes made to the CCAPs:

CCAP-50015405-001 Radioiodine Filter was found to lack verification of its efficiency. All orders have been required to have a Radioiodine Penetration/Efficiency Test Report from the supplier for each lot sampled. The CCAP evaluation now incorporates verification against the test report of the now established minimum efficiency for the filter (Greater than or equal to 95% efficiency and less than or equal to 1 in. Hg Pressure Drop at 2SCFM).

A review of all past purchase orders for the Radioiodine Filter (PN 50015405-001) verified that every lot of filters met the minimum requirement of greater than or equal to 95% efficiency and less than or equal to 1 in. Hg Pressure Drop at 2SCFM. Past dedications of the filter did not stipulate the minimum efficiency since engineering performed a review of the certified test documentation provided by the supplier and performed calculations to determine acceptability of the filters using the specific efficiency on every lot of filters procured prior to use in a RMS unit provided to the customer.

CCAP-50004269-001 Connector was found to have defined unnecessary characteristics of the visual material inspection of the body and insulation. The intent of the inspection was to ensure

that the connector was being constructed in the same manner as it was originally procured when the original RMS unit underwent qualification testing. These required inspections have been removed and substituted with the certificate of conformance and the continued conduct of method 2 surveys of Amphenol Company. The CCAP has been updated to remove the visual inspection for a Teflon insulation and silver plating of the component and added the requirement of the certification of conformance along with continued periodic schedule of surveys of Amphenol in the manufacture of the component. The requirements of physical inspection, dimension checks, and continuity of the connector still remain in the CCAP.

The corrective steps that will be taken to avoid noncompliance

The CGD Engineering and Quality Assurance team conducted refresher training on performance of commercial grade dedication technical evaluations, determination of critical characteristics, and development of critical characteristic acceptance plans. Focusing on how the specific component's role in the assembly contributes to the overall safety related function of the RMS unit.

The CGD team is conducting a review of all CCAPs to verify that the critical characteristics have been properly identified for all safety related components manufactured by GA-ESI. The verification of CCAP critical characteristics is currently in progress and all safety related parts provided to GA-ESI customers since the NRC inspection has been through the verification process prior to release to the customer.

A CCAP continuation page has been added to complex CCAPs as necessary to provide information on how the CGD has been determined for future review and retention of salient information pertaining to the dedication.

The date when the corrective action will be completed

Planned completion of the review of all existing CCAPs is estimated to be complete by September 30, 2013.