GENERAL ATOMICS

January 30, 2018
GEN/QA-4918

Patricia Silva, Chief
Inspections and Operations Branch
Division of Spent Fuel Management
Office of Nuclear Material Safety and Safeguards

Reference: NRC Letter (Patricia Silva) to General Atomics, "Part 71 Quality Assurance Program Approval Biennial Change Report," dated December 22, 2017

Dear Ms. Silva,

In response to your letter (Ref.) and pursuant to 10 CFR 71.106, General Atomics (GA) hereby submits its first biennial report listing the changes made to the General Atomics Nuclear Quality Assurance Program between 15 August 2015 and 15 August 2017 (Please see enclosure).

None of the changes to GA's nuclear QA program during the stated time period reduce commitments to the NRC. Of the sixty five (65) changes made to GA's nuclear QA program, thirty (30) are clarifications that do not reduce commitments; nineteen (19) are enhancements that strengthen commitments; twelve (12) are changes that continue to meet the existing commitments; two (2) are editorial in nature; one (1) is administrative; and one (1) increases a commitment.

The enclosed report is in the format of a table listing each of the changes made to GA's QA Program. Among other information, it lists the revision numbers, effective dates, titles, changed sections, the changes made (shown in red font), the reasons for the changes, and the basis for concluding that the changes did not reduce the commitments to the NRC.

If you have questions regarding this report of the changes to GA's nuclear program, please feel free to contact me at 858-455-2823, keith.asmussen@ga.com, or the mailing address below.

Sincerely,

Keith E. Asmussen

Keith E. Asmussen, Ph.D., Director
Licensing, Safety, and Nuclear Compliance

Enclosure: Table as described in text of letter

cc: P. O'Shaughnessy (GA)
K. Partain (GA)

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Summary of Changes to GA's Quality Assurance Program

QP No.	Rev. No.	Effective Date	Title	Previous	Changed Section	Change	Reason for the change	Basis for Concluding that the Revised Program Incorporating the Change Continues to Satisfy the Applicable Requirements of Subpart H of 10CFR71
Introduction	B	6/27/2016	Introduction	ASME NQA-1-2008/-1a-2011	Introduction & Statement of Authority	Changed to ASME NQA-1-2008/-1a-2009	NRC has not sanctioned NQA-1 2011. GA's QA program complies with the most recent NRC-sanctioned version of NQA-1, so had to change the number back to the sanctioned version of NQA-1.	§71.101(f) the GA QA program continues to comply with 10 CFR 50 Appendix B. Does not reduce commitments to the previously approved QA program.
Introduction	B	6/27/2016	Introduction	Inadvertently left out of previous version.	Introduction & Statement of Authority	Added: 10CFR21, "Reporting of Defects and Noncompliance"	Reinstated wording.	Does not reduce commitments to the previously approved QA program.
Introduction	B	6/27/2016	Introduction	Not in previous version	Definitions	Added Definition: Significant Deficiency – A deficiency found in design and/or construction, which if remained uncorrected, could adversely affect a structure, system or component to prevent it from performing its intended safety function. (from 10CFR50.55(e))	Added as part of the updating of the Corrective Action Program	Meets §71.133
Introduction	B	6/27/2016	Introduction	Not in previous version	Definitions	Added Definition: Substantial Safety Hazard -- Means a loss of safety function to the extent that there is a major a major reduction in the degree of protection provided to public health and safety for any facility or activity licensed or otherwise approved or regulated by the NRC, other than for export, under parts 30, 40, 50, 52, 60, 61, 63, 70, 71, or 72 of this chapter. (Quoted from 10CFR21, and CP 207)	Added as part of the updating of the Corrective Action Program	Does not reduce commitments to the previously approved QA program. Enhances commitment to safety performance.
QP-1	B	5/27/2016	Organization	3.6.2.1 Fission Energy. Fission Energy, which includes the Gas-Cooled Reactors programs, TRIGA Systems, TRIGA International, and EM ^{2}, etc., programs, reports to the Senior Vice President, Energy and Advanced Concepts Group, is responsible for engineering design of reactor systems, including design verification and interface control.	3.6.2.1 Changed name of Division from Fission to Nuclear Technology and Materials, Updated names of programs in the division	3.6.2.1 Nuclear Technology and Materials Nuclear Technology and Materials (NTM), which includes the Gas-Cooled Reactors programs (e.g. EM^2) Advanced Nuclear Fuels, Nuclear Mechanical Engineering, Radiochemical Engineering, TRIGA Systems, etc., reports to the Senior Vice President, Energy Group, and is responsible for engineering design of reactor systems, including design verification and interface control.	Changed to bring the name of the fission division and the names of the parts of the division up to date.	These are the organzations that need to comply with the QA program requirements.
QP-1	B	5/27/2016	Organization	Figure 1-1 outdated	Changed org. chart	Figure 1-1 Replaced the old org chart with an updated Org. Chart	Need to keep the org chart updated	Meets § 71.103
QP-1	B	5/27/2016	Organization	Figure 1-2 outdated	Changed org. chart	Figure 1-2 Replaced the old org chart with an updated Org. Chart	Need to keep the org chart updated	Meets § 71.103
QP-1	B	5/27/2016	Organization	3.6.6.4 Fission organization	3.6.6.4 Change of Department Name from Fission to Nuclear Technology and Materials Division (updated name)	3.6.6.4 Nuclear Technology and Materials Division	Changed to bring the name of the fission division and the names of the parts of the division up to date.	These are the organzations that need to comply with the QA program requirements.
QP-2	B	5/27/2016	Quality Assurance Program	Not in previous version	Added New Section : Applicable QP's and QDI's and adjusted numbering sequence	Added a list of the applicable Quality procedures and the Quality Division instructions that apply to the QP	Needed to show which QPs and QDI's applied to this procedure.	Clarification that does not reduce commitments.

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QP-2	B	5/27/2016	Quality Assurance Program	3.2.2.1 R&D activities include exploratory, experimental, and basic research which provides indirect support for design of systems and components.	3.2.2.1 Updated the definition of R&D levels to comply with NQA 1 definitions	4.2.2.1 R&D activities include exploratory, experimental, basic research, applied and developmental, which provides indirect support for design of systems and components. . The minimum requirements at the basic and applied levels includes identification and control of materials and M&TE is calibrated. Released procedures or fabrication travelers may be used. At the development level of R&D all 18 criteria in Part 1 of NQA-1 apply to development work activities (Table 600 in NQA-1 2008/-1a-2009 Addenda, Part IV, Subpart 4.2, "Applicability to Research and Development Activities).	Needed to enhance the definition of R&D to include development work as projects work on developing products to bring up to commercial use.	Meets §71.105. Provides a more inclusive level of quality history and degree of standardization to the work scope.
QP-2	B	5/27/2016	Quality Assurance Program	Updated section 3.3 Chief Operating Officer (COO)	Updated title from COO to Senior Vice President(s)	Section 4.3 Senior Vice President(s);	Need to keep the org chart updated	Meets § 71.103
QP-2	B	5/27/2016	Quality Assurance Program	Section 3.4.1 Indoctrination Personnel performing or managing activities affecting quality shall initially receive indoctrination in their job responsibilities and authority that includes general criteria, technical objectives, requirements of applicable codes and standards, regulatory commitments, company procedures, and quality assurance program requirements. Additional indoctrination shall be provided when changes in position, responsibility, and codes and standards occur.	Added referenced QDI 2-9	4.4.1 Indoctrination Personnel performing or managing activities affecting quality shall initially receive indoctrination in their job responsibilities and authority that includes general criteria, technical objectives, requirements of applicable codes and standards, regulatory commitments, company procedures, and quality assurance program requirements per QDI 2-9 . Additional indoctrination shall be provided when changes in position, responsibility, and codes and standards occur.	Needed to reference a specific Quality Division Instruction requiring training.	Meets §71.105. Better documents the training requirement.
QP-2	B	5/27/2016	Quality Assurance Program	Section 3.5.4.2 Training	Sect. 3.5.4.2	Section 4.5.4.2 **Training** Added : • Lead Nuclear Auditors from outside of the General Atomics Torrey Pines Quality Assurance Program (GA TP QAP) to perform internal audits of the GA TP QAP, shall be trained in the QA Procedures (QAM, QDI's, etc.) and such training documented on a Record of Training Form. (See QDI 18-2)	Change requested by external auditors. They wanted written proof that Internal Auditors from within GA were trained in the QA procedures prior to starting the internal audits.	Meets §71.105. Better documents training.
QP-2	B	5/27/2016	Quality Assurance Program	Section 3.6.1 3.6.1 The qualification of Auditor or Lead Auditor personnel shall be certified by the Quality Systems Manager. Qualification of inspection and test personnel shall be certified by the cognizant QA Manager. Personnel certifications shall be in writing and shall include the following information:	Sec. 3.6.1	4.6.1 The qualification of Auditor or Lead Nuclear Auditor personnel shall be certified by the Quality Systems Manager, or designee. This applies to both Lead Nuclear Auditors under the GA TP QA Program and Lead Nuclear Auditors who are internal to GA but external to the GA TP QA Program (e.g., from the Radiation monitoring systems program, etc.) Qualification requirements are in QDI 18-2.	Change requested by external auditors. They wanted written proof that Internal Auditors from within GA were qualified lead nuclear auditors prior to starting the internal audits.	Meets §71.105. Better documents training.
QP-2	B	5/27/2016	Quality Assurance Program	Section 3.7 Records	Section 4.7	Section 4.7, Section 4.7.1 and Section 4.7.2 Records include project training records and QA training records.	Expanded Explanation of records to include project training records and QA training records	Meets §71.135
QP-3	B	5/27/2016	Design Control	None	Added New Section : Applicable QP's and QDI's and adjusted numbering sequence	Added a list of the applicable Quality procedures and the Quality Division instructions that apply to the QP	Needed to show which QPs and QDI's applied to this procedure.	Clarification that does not reduce commitments.

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QP-3	B	5/27/2016	Design Control	Section 3.6.1.2 Review Process 3. QA review is not required for research and development (R&D) design documents that are R&D released per the P/RPM, EP-4060. However, if an R&D document describes work or results that will be used directly in the final design of safety-related components or systems, it shall be designated QAL I, reviewed by QA, and production released per the P/RPM, EP-4040.		3. QA review is not required for research and development (R&D) design documents that are for Basic or Applied level R&D that are R&D released per P/RPM EP-4060. However, if a development level R&D document describes development work activities or results that will be used directly in the final design of safety-related components or systems, it shall be designated QAL I, reviewed by QA, and production released per P/RPM EP-4040. (See Table 600 in NQA-1 2008/-1a-2009 Addenda Part IV, Subpart 4.2, "Applicability to Research and Development Activities").	Needed to enhance the definition of R&D to include development work as projects work on developing products to bring up to commercial use.	Meets §71.105. Provides a more inclusive level of quality history and degree of standardization to the work scope.
QP-3	B	5/27/2016	Design Control	3.15.5 Design information transmitted across internal interfaces shall be documented on the Document Distribution List (Form No. GA 114). Design information transmitted from suppliers to GA shall be documented on the Supplier Data Transmittal (Form No. GA 2514) when invoked in the purchase order. Design information transmitted across external interfaces shall be in accordance with contractual requirements. The designated publishing authority shall control transmitted information as well as the record(s) of review. Transmittals shall identify the status of the design information or document provided and, where necessary, identify incomplete items	3.15.5	4.15.5 Design information transmitted across internal interfaces shall be documented on the Document Distribution List (GA Form No. GA 114). Design information transmitted from suppliers to GA shall be documented on the Supplier Data Transmittal (GA Form No. GA 2514, see QDI 7-7) when invoked in the purchase order. Design information transmitted across external interfaces shall be in accordance with contractual requirements.	Added Form #s and QDI #'s. Needed to identify which forms and instruction applied to this procedure.	Clarification that does not reduce commitments.
QP-4	B	6/27/2016	Procurement Document Control	None	Added New Section: Applicable QP's and QDI's and adjusted numbering sequence	Added a list of the applicable Quality procedures and the Quality Division instructions that apply to the QP	Needed to show which QPs and QDI's applied to this procedure.	Clarification that does not reduce commitments.
QP-4	B	6/272016	Procurement Document Control	3.2.3 PR Review. Using the PR Workflow process for Network charge numbers, the SAP system automatically routes the PR to obtain a review by the cognizant quality engineer to assure consideration and/or inclusion of appropriate quality requirements. Quality engineer review and approval is electronically documented on the PR. The buyer or performing department is then responsible to insure that required quality engineer reviews and approvals are obtained at all subsequent steps in the procurement cycle. Detailed instructions for procurement document review and approval are provided in QDI-4-2, "Procurement Document Review." For PRs using internal work order numbers, Receiver Cost Center (Rec. CCtr) and Receiver Order (Rec. Order) charge numbers, QA review is not automatic, but occurs only if the PR initiator directly notifies the QA engineer of the existence of the PR.	3.2.3 became 4.2.3	4.2.3 PR Review. Using the PR Workflow process for Network charge numbers, the SAP system automatically routes the PR to obtain a review by the cognizant quality engineer to assure consideration and/or inclusion of appropriate quality requirements. Quality engineer review input of all applicable QA requirements including quality clauses, and approval is electronically documented on the PR. Detailed instructions for procurement document review and approval are provided in QDI 4-2, "Procurement Document Review." For PRs using internal work order numbers, Receiver Cost Center (Rec. CCtr) and Receiver Order (Rec. Order) charge numbers, the Quality Systems Manager, or designee, or the Nuclear Quality Manager or designee, has to make a request to Finance to be placed on work flow for those charge numbers.	Updated the section on reviewing PRS to being up to date with SAP practices.	Meets §71.109
QP-5	B	6/272016	Instructions, Procedures, and Drawings	None	Added New Section : Applicable QP's and QDI's and adjusted numbering sequence	Added a list of the applicable Quality procedures and the Quality Division instructions that apply to the QP	Needed to show which QPs and QDI's applied to this procedure.	Clarification that does not reduce commitments.

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QP-5	B	6/272016	Instructions, Procedures, and Drawings	3.2.2 QPs contained in the QAM require approval signature of the Director, Quality Assurance, and the Chief Operating Officer. Approval signatures and date are indicated on the first page of each procedure.	3.2.2 Updated COO to Senior Vice President	**4.2.2** QPs contained in the QAM require approval signature of the Director, Quality Assurance, and the Senior Vice President, **EMS.** Approval signatures and date are indicated on the first page of each procedure.	Need to keep the org titles updated	Meets §71.103
QP-5	B	6/272016	Instructions, Procedures, and Drawings	Sec. 3.3.3 The QAPD and revisions shall be approved by the Director, Quality Assurance, the responsible project manager, and the customer when contractually required. Customer approval may be achieved by mail or electronic mail.	Sec. 3.3.3 became Sec. 4.3.3	4.3.3 The initial QAPD and revisions shall at a minimum be approved by the author, the responsible project manager, the Manager Nuclear Quality Assurance, the Director, Quality Assurance and the customer when contractually required. Customer approval may be achieved by mail or electronic mail. Additional project specific signatures are added as required.	Management wanted to add the Manager of Nuclear Quality Assurance to the approvals of QAPDs.	Enhances the commitments to §71.113
QP-5	B	6/272016	Instructions, Procedures, and Drawings	3.3.4 Each QAPD shall be reviewed annually by the cognizant quality engineer, and revised if necessary, to assure that it is current, correct, and in compliance with the latest contractual and regulatory requirements.	3.3.4 Added Memo from QE to Quality Systems Manager	4.3.4 Each QAPD shall be reviewed annually by the cognizant quality engineer, and revised if necessary, to assure that it is current, correct, and in compliance with the latest contractual and regulatory requirements. A memo stating the accomplishment of the review and any revision requirements, is written to the Quality Systems Manager.	Added a means to document the required reviews.	Enhances the commitments to §71.113
QP-5	B	6/272016	Instructions, Procedures, and Drawings	3.7.1 GA Designs/GA Approved Designs. GA products shall be constructed to released GA design specifications, GA drawings, and/or GA approved supplier design specifications and drawings (see QP 3 and P/RPM). Actual production work shall be accomplished to approved planning or assembly procedures, based on such released design documents.	3.7.1 Updated to include QDI 3-1	4.7.1 GA Designs/GA Approved Designs. GA products shall be constructed to released GA design specifications, GA drawings, and/or GA approved supplier design specifications and drawings (see QP 3, QDI 3-1, and the P/RPM). Actual production work shall be accomplished to approved planning or assembly procedures, based on such released design documents.	Needed to reference a specific QDI that applies to this procedure.	Clarification that does not reduce commitments.
QP-6	B	6/272016	Document Control	None	Added New Section : Applicable QP's and QDI's and adjusted numbering sequence	Added a list of the applicable Quality procedures and the Quality Division instructions that apply to the QP	Needed to show which QPs and QDI's applied to this procedure.	Clarification that does not reduce commitments.
QP-7	B	414/2016	Control of Purchased Items	None	Added New Section : Applicable QP's and QDI's and adjusted numbering sequence	Added a list of the applicable Quality procedures and the Quality Division instructions that apply to the QP	Needed to show which QPs and QDI's applied to this procedure.	Clarification that does not reduce commitments.
QP-7	B	414/2016	Control of Purchased Items	3.1.3 Evaluation by Survey. QA shall perform surveys to determine the capability of potential suppliers to satisfactorily control conformance of products and services to GA procurement requirements. Surveys shall evaluate the supplier's facilities, personnel, and QA Program implementation.	Referenced QDI 7-2	4.1.3 Evaluation by Survey. QA shall perform surveys to determine the capability of potential suppliers to satisfactorily control conformance of products and services to GA procurement requirements. Surveys shall evaluate the supplier's facilities, personnel, and QA Program implementation (See QDI 7-2, Supplier Surveys).	Needed to reference a specific QDI that applies to this procedure.	§71.115 Enhances the commitment to approving suppliers.

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QP-7	B	414/2016	Control of Purchased Items	3.1.6 Surveys, Evaluations, and Audits by Others. 3.1.6.1 The services of others may be engaged to perform surveys, evaluations, and audits when they have been reviewed and approved by GA QA. Review and approval of the services of others include GA QA verification of the individual's qualifications for performing the evaluation, and GA QA approval of the survey/audit plan, checklists, and final report. 3.1.6.2 Surveys, evaluations, or audits performed by consortiums of multiple companies or some government agencies (e.g., NRC) of the company may be used providing GA QA reviews and approves of the group/company, including GA QA verification of the individuals' qualifications for performing the evaluation, and GA QA approval of the survey/audit plan, checklists, and final report.	3.1.6.1	4.1.6 Surveys, Evaluations, and Audits by Others (Third Party Audits). 4.1.6.1 The services of others may be engaged to perform surveys, evaluations, and audits when they have been reviewed and approved by GA QA. Review and approval of the services of others include: 1) A lead nuclear auditor in GA QA reviews and accepts the group's/company's/government agencies' audit package, to determine if the supplier is qualified for the NTM division's particular needs; 2) The audit package meets the requirements of an equivalent QA audit of the supplier's Quality Assurance Program, and 3) at least one of the team of auditors is qualified as a lead nuclear auditor and the remaining audit team members are legitimate auditors or technical specialists trained on auditing techniques. 4.1.6.2 Surveys, evaluations, or audits performed by consortiums of multiple companies (e.g., NIAC, ILAC, NUPIC, etc.), individual partner companies (e.g., Westinghouse, etc.) or some government agencies (e.g., INL, NRC, etc.) may be used by GA TP QA to qualify a supplier for placement on the GA QA TP ASL, provided the consortium, company, or government agency is willing to provide the complete audit package to GA and the scope of the third party audit is equivalent to the scope of goods or services to be provided to GA by the audited company. The questions/subject areas on the Third Party Audit Evaluation checklist in QDI 7-2, may be used to assist in qualifying a supplier to be placed on the GA QA TP ASL. For example, the Nuclear Industry Assessment Committee (NIAC) audits of QAL I safety-related suppliers are acceptable for meeting the requirements of this procedure in that member companies receive a copy of all assessment data, including the assessment report, assessment checklist, and all identified findings and observations. In addition, NIAC only uses lead auditors for performances of audits, all of which are qualified via a written	Requested by external auditors. This change elaborates on the requirements for reviewing and accepting third party audits by others for use in qualifying a supplier to be approved by GA as qualified to be placed on the GA safety-related Approved Suppliers List.	§71.115 Enhances the commitment to approving suppliers.
QP-7	B	414/2016	Control of Purchased Items	3.1.7.2 Supplier evaluation may be waived when it is necessary to place a procurement with a supplier or customer who will provide safety-related items or services, but is not listed on the QA ASL. In such instances, specific provisions to assure full compliance with the quality requirements before beginning fabrication or services, must be specified on the purchase order. The purchase order must be approved by the Director, Quality Assurance.	3.1.7.2	4.1.7.2 Supplier evaluation may be waived on a one-time basis when it is necessary to place a procurement with a supplier or customer who will provide safety-related items or services, but is not listed on the QA ASL. In such instances, specific provisions to assure full compliance with the quality requirements before beginning fabrication or services, must be specified on the purchase order. The purchase order must be approved by the Director, Quality Assurance. Should additional procurements be needed from the same company, the company shall be audited by QA prior to future purchases.		
QP-8	B	6/272016	Identification and Control of Items	None	Added New Section : Applicable QP's and QDI's and adjusted numbering sequence	Added a list of the applicable Quality procedures and the Quality Division instructions that apply to the QP	Needed to show which QPs and QDI's applied to this procedure.	Clarification that does not reduce commitments.
QP-9	B	6/272016	Control of Processes	None	Added New Section : Applicable QP's and QDI's and adjusted numbering sequence	Added a list of the applicable Quality procedures and the Quality Division instructions that apply to the QP	Needed to show which QPs and QDI's applied to this procedure.	Clarification that does not reduce commitments.
QP-10	B	4/14/2016	Inspection	None	Added New Section : Applicable QP's and QDI's and adjusted numbering sequence	Added a list of the applicable Quality procedures and the Quality Division instructions that apply to the QP	Needed to show which QPs and QDI's applied to this procedure.	Clarification that does not reduce commitments.

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QP-10	B	4/14/2016	Inspection	3.4.3 When inspection is to be performed, the scope and type of inspections to be performed, the characteristics to be inspected, the inspection methods, and the acceptance criteria shall be specified in inspection planning (see QP 5) provided by the cognizant quality engineer. Inspection results shall be documented on the applicable inspection plan, or the intergraded shop traveler.	3.4.3	4.4.3 When inspection is to be performed, the scope and type of inspections to be performed, the characteristics to be inspected, the inspection methods, and the acceptance criteria shall be specified in inspection planning (see QP 5) provided by the cognizant quality engineer. Inspection results, including the M&TE used during the inspection, shall be documented on the applicable inspection plan, or the intergraded shop traveler.	Added to document which specific M&TE was/were used during inspections to improve traceability in the future in the event of an M&TE calibration/out-of-tolerance issue	Increases meeting the requirements in §71.125
QP-10	B	4/14/2016	Inspection	3.12 4. Type of observation (as applicable, note exactly what was verified, witnessed, etc.).		4.12 4. A list of all NRs or Supplier's Disposition Requests with a disposition of "Repair" or "Use As Is."	Wanted to start including additional records for more complete data packages.	Enhances the commitment to this section. §71.135
QP-11	B	4/14/2016	Test Control	None	Added New Section : Applicable QP's and QDI's and adjusted numbering sequence	Added a list of the applicable Quality procedures and the Quality Division instructions that apply to the QP	Needed to show which QPs and QDI's applied to this procedure.	Clarification that does not reduce commitments.
QP-11	B	4/14/2016	Test Control	3.3.5 Test procedures may be prepared by the supplier for those tests specified to be performed at the supplier's facility. GA shall specify the pertinent requirements of this QP in purchase orders to the supplier. The purchase orders for such tests shall require the contractor to submit test procedures to GA for acceptance prior to testing. The test procedures, upon receipt at GA, shall be processed as required in QP-3 for supplier design documents in.	Sec. 3.3.5	4.3.5 Test procedures may be prepared by the supplier for those tests specified to be performed at the supplier's facility. GA shall specify the pertinent requirements of this QP and QDI 4-1, "Standard Quality Clauses," in purchase orders to the supplier. The purchase orders for such tests shall require the contractor to submit test procedures to GA for acceptance prior to testing. The test procedures, upon receipt at GA, shall be processed as required in QP-3 for supplier design documents.	Needed to enhance the requirements in QP-11 and reference a specific QDI that applies to this procedure.	§71.123 Enhances the commitment to this section.
QP-11	B	4/14/2016	Test Control	3.8.1 1. A description of the test, referencing the test procedure number, revision, test equipment identification, and location. 5. Description of the equipment used and serial numbers. 6. Description of the test parameters and test results (See Para. 3.9 below). 7. Signature of the Tester.	Sec. 3.8.1	4.8.1 1. A description of the test, referencing the test specification, the test plan, the test procedures, test equipment identification, and location. 5. Description of the equipment used and serial numbers. 6. M&TE used in executing the test procedure(s) including the Asset No. and the Calibration Due Date. 7. Description of the test parameters and test results (See Para. 3.9 below). 8. Signature of the Tester.	Needed to increase the documentation requirements, especially to include identification of the M&TE used during testing.	§71.123 Enhances the commitment to this section.
QP-12	B	8/26/2016	Control of Measuring and Test Equipment	None	Added New Section : Applicable QP's and QDI's and adjusted numbering sequence	Added a list of the applicable Quality procedures and the Quality Division instructions that apply to the QP	Needed to show which QPs and QDI's applied to this procedure.	Clarification that does not reduce commitments.
QP-13	B	8/26/2016	Handling, Storage, and Shipping	None	Added New Section : Applicable QP's and QDI's and adjusted numbering sequence	Added a list of the applicable Quality procedures and the Quality Division instructions that apply to the QP	Needed to show which QPs and QDI's applied to this procedure.	Clarification that does not reduce commitments.
QP-14	B	8/26/2016	Inspection, Test, and Operating Status	None	Added New Section : Applicable QP's and QDI's and adjusted numbering sequence	Added a list of the applicable Quality procedures and the Quality Division instructions that apply to the QP	Needed to show which QPs and QDI's applied to this procedure.	Clarification that does not reduce commitments.

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QP-15	B	4/14/2016	Control of Nonconforming Items	None	Added New Section : Applicable QP's and QDI's and adjusted numbering sequence	Added a list of the applicable Quality procedures and the Quality Division instructions that apply to the QP	Needed to show which QPs and QDI's applied to this procedure.	Clarification that does not reduce commitments.
QP-15	B	4/14/2016	Control of Nonconforming Items	3.3.1.3 The QA Records Center (QARC) administrator is responsible for issuing blocks of serial numbers and nonconformance report forms to Project Quality Engineers. Project Quality Engineers are responsible for maintaining a log which indicates the status of all NRs and NOD tags including serialized number, disposition, and the close-out date.	3.3.1.3	4.3.1.3 The QA Records Center (QARC) administrator is responsible for issuing blocks of Production Control (PC) serial numbers and Nonconformance Report numbers to Project Quality Engineers (PQE). PQEs are responsible for maintaining a log, which indicates the status of all project NRs and NOD tags, including serialized number, disposition, and the close-out date.	Needed to document the responsibility by the QARC to issue specific types of numbers used for tracking and identification purposes.	Clarification that does not reduce commitments.
QP-15	B	4/14/2016	Control of Nonconforming Items	3.8.1 MRB Membership. The MRB is a board of engineers, consisting of at least one project engineer and one quality engineer. MRBs are chaired by the QA member. Engineering MRB members for each major hardware item shall be selected and documented by the appropriate design engineering functions. In the case of internal orders for QAL III items via properly authorized service requests, the requestor shall be the engineering MRB member when no other documented selection is made. If required by contract, a customer representative is also a member of the MRB.	3.8.1	4.8.1 MRB Membership. The MRB is a board of engineers, consisting of at least one project engineer and one quality engineer and the Nuclear Compliance Working Group (NCWG Chair). MRBs are chaired by the QA member. Engineering MRB members for each major hardware item shall be selected and documented by the appropriate design engineering functions. In the case of internal orders for QAL III items via properly authorized service requests, the requestor shall be the engineering MRB member when no other documented selection is made. If required by contract, a customer representative is also a member of the MRB.	Change was requested by external auditors. They wanted written proof that the Chair of the Nuclear Compliance Working Group was indeed reviewing Nonconformances in light of the 10CFR21 requirements and that the review was getting documented on the Nonconformance report forms.	Enhances requirements in §71.131
QP-15	B	4/14/2016	Control of Nonconforming Items	None	Added Section 4.8.2.3	4.8.2.3 The NCWG Chairperson is responsible to investigate 10CFR21 problems regarding defects of items performing a safety function (i.e. basic components).	Change was made to document the responsibility of investigating potential 10CFR21 problems.	Enhances requirements in §71.131
QP-15	B	4/14/2016	Control of Nonconforming Items	3.11.1 Discrepancies, which pertain to "Significant Deficiencies" or 10CFR21 type defects and nonconformances, are discussed in QP 16.	3.11.1	4.11.1 Discrepancies, which pertain to "Significant Deficiencies" or 10 CFR 21 type defects and nonconformances, are discussed in QP 16. The requirement for the reporting of 10 CFR 21 defects are found in Company Policies CP-207, 1200.207.	Change was made to identify the company policies which contain the requirements for investigating and reporting 10CFR21 issues.	Enhances requirements in §71.131
QP-15	B	4/14/2016	Control of Nonconforming Items	3.12.2 Purchasing shall receive the SDR from the supplier and refer it to the cognizant quality engineer. The quality engineer and design engineer, and members of the MRB, if necessary, shall review the request and approve, disapprove, or provide requested information in accordance with QP-15 for nonconforming items or QP-3 for design changes. The quality engineer shall return the signed SDR to Purchasing for transmittal to the supplier.	3.12.2	4.12.2 Purchasing shall receive the SDR from the supplier and refer it to the cognizant PQE. The PQE shall then refer the SDR to the applicable MRB, whose members shall review the request and approve, disapprove, or provide requested information in accordance with QP-15 for nonconforming items or QP-3 for design changes. The MRB Chair shall return the signed SDR to the PQE and Purchasing for transmittal to the supplier.	Change requires the chair of the MRB to give the signed SDR to the PQE for follow up, if that person has it when it is completed and signed.	Enhances requirements in §71.131
QP-16	C	4/14/2016	Corrective Action	None	Added New Section : Applicable QP's and QDI's and adjusted numbering sequence	Added a list of the applicable Quality procedures and the Quality Division instructions that apply to the QP	Needed to show which QPs and QDI's applied to this procedure.	Clarification that does not reduce commitments.
QP-16	C	4/14/2016	Corrective Action	3.1 Nonconforming Items The process for maintaining control of nonconforming items and for obtaining definitive corrective action by means of the Nonconformance Report (NR, Form No. GA 663) is specified in QP 15.	3.1 Added reference to QDI.	4.1 Nonconforming Items The process for maintaining control of nonconforming items and for obtaining definitive corrective action by means of the Nonconformance Report (NR, Form No. GA 663) is specified in QP 15 (also see QDI 15-1).	Added the reference to the specific QDI that the controls the use of the Nonconformance Report form.	Enhances requirements in §71.131

Summary of Changes to GA's Quality Assurance Program

QP No.	Rev. No.	Effective Date	Title	Previous	Changed Section	Change	Reason for the change	Basis for Concluding that the Revised Program Incorporating the Change Continues to Satisfy the Applicable Requirements of Subpart H of 10CFR71
QP-16	C	4/14/2016	Corrective Action	**3.3.1** Significant noncompliance with systems and procedures affecting quality may be discovered under circumstances other than formal audit or inspection. All GA employees have the authority to request corrective action on quality-related matters. Anyone who discovers a system noncompliance (e.g., an individual, organization, or supplier which consistently does not follow established procedures) may initiate corrective action in accordance with Section 3.4. If the discovering function is outside QA, the discovering individual's manager may notify Quality Systems and request that Quality Systems take the action described in Section 3.4.	3.3.1	4.3.1 Significant noncompliance with systems and procedures affecting quality may be discovered under circumstances other than formal audit or inspection. All GA employees have the authority to request corrective action on quality-related matters. Anyone who discovers a system noncompliance (e.g., an individual, organization, or supplier which consistently does not follow established procedures) may initiate corrective action in accordance with Section 4.4. If the discovering function is outside QA, the discovering individual's manager may notify Quality Systems and request that Quality Systems take the action described in Section 4.4	Change made to update a Cross reference Section number	Clarification that does not diminish any requirements in §71.133
QP-16	C	4/14/2016	Corrective Action	3.4.4 If the individual initiating the CAR is within QA, the Quality Systems CAR administrator shall log the problem and assign a CAR number. The initiator shall prepare the applicable sections of the CAR in accordance with the instructions on the reverse of the CAR, identify the CAR with the assigned number, and forward it to Quality Systems for distribution, completion, and closeout.	3.4.4 Added "Or Designee"	4.4.4 If the individual initiating the CAR is within QA, the Quality Systems Manager, or designee, shall log the problem under the assigned CAR number. The initiator shall prepare the applicable sections of the CAR in accordance with the instructions on the reverse side of the CAR, (QDI 16-5), identify the CAR with the assigned number, and forward it to the Quality Systems Manager , or designee, for distribution, completion, and closeout.	Change was made to provide for specific individuals to perform the work, as there is no longer a CAR Administrator.	Does not diminish requirements in §71.133 by making sure the work is still performed.
QP-16	C	4/14/2016	Corrective Action	Section 3.5.2 1. Identification of the root cause of the deficiency as it exists in that organization's area of responsibility.	3.5.2	Section 4.5.2 1. Identification of the root cause of the deficiency as it exists in that organization's area of responsibility (see QDI 16-7).	Added the reference to the specific QDI that requires identification of the root cause of a deficiency.	Clarification that does not reduce commitments.
QP-16	C	4/14/2016	Corrective Action	3.10.1 Any employee of GA who detects what the employee considers to be a "significant deficiency," (See Definitions) shall promptly inform the Director, Quality Assurance and furnish all available pertinent facts regarding the problem. When a supplier detects such discrepancies, he shall inform the buyer, who shall inform the Director, Quality Assurance.	3.10.1	4.10.1 Any employee of GA who detects what the employee considers to be a "significant deficiency," (See Definitions in the Introduction in this QA Manual) shall promptly inform the Director, Quality Assurance and furnish all available pertinent facts regarding the problem. When a supplier detects such discrepancies, he shall inform the buyer , who shall inform the PQE and the Director, Quality Assurance.	Updated the definitions section and included additional personnel when reporting deficiencies.	Does not reduce commitments, but is an administrative improvement.
QP-16	C	4/14/2016	Corrective Action	3.11 10CFR21-Type Defects and Noncompliances Any GA employee who becomes aware of what appears to be a defect in a basic component that has been supplied for use in an NRC-licensed facility, or a noncompliance within the meaning of 10CFR21, (i.e., a deviation from the technical requirements included in the procurement document or a noncompliance with a rule or license provision - see Definitions) that in each case (i.e., deviation or noncompliance) relates to or could create a substantial safety hazard at an NRC-licensed facility, shall report it immediately to his or her supervisor and to the Chairman, Nuclear Defects and Noncompliance Committee who shall proceed in accordance with Company Policy CP-212.	3.11	4.11 10 CFR 21-Type Defects and Noncompliances Any GA employee who becomes aware of what appears to be a defect in a basic component that has been supplied for use in an NRC-licensed facility, or a noncompliance within the meaning of 10 CFR 21 (i.e., a deviation from the technical requirements included in the procurement document or a noncompliance with a rule or license provision - see Definitions in the introduction to this Quality Assurance Manual), that in each case (i.e., deviation or noncompliance) relates to or could create a substantial safety hazard at an NRC-licensed facility, shall report it immediately to his or her supervisor and to the Chairman, Nuclear Defects and Noncompliance Committee who shall proceed in accordance with Company Policies CP-207, and CP-1200.207 (see QDI 16-4).	Updated to include references to definitions, company policy, and specific QDIs.	Clarification that does not reduce commitments.
QP-17	B	8/26/2016	Quality Assurance Records	None	Added New Section : Applicable QP's and QDI's and adjusted numbering sequence	Added a list of the applicable Quality procedures and the Quality Division instructions that apply to the QP	Needed to show which **QPs and QDI's applied to this** procedure.	Editorial change that does not reduce commitments.

Summary of Changes to GA's Quality Assurance Program

QP No.	Rev. No.	Effective Date	Title	Previous	Changed Section	Change	Reason for the change	Basis for Concluding that the Revised Program Incorporating the Change Continues to Satisfy the Applicable Requirements of Subpart H of 10CFR71
QP-17	B	8/26/2016	Quality Assurance Records	3.9.2.2 Quality Assurance Records Center (QARC). The QARC manages Quality Assurance (QA) records, provides electronic scanning, storage, protection, and retrieval services for selected documents generated/processed by QA (e.g., inspection documents, procedures, manufacturing planning, personnel qualifications, certifications, etc.), and provides storage, protection, and retrieval services for legacy microfilmed and scanned QA records.	3.9.2.2	4.9.2.2 Quality Assurance Records Center (QARC). The QARC Administrator manages Quality Assurance (QA) records, provides electronic scanning, storage, protection, and retrieval services for selected documents generated/processed by QA (e.g., inspection documents, procedures, manufacturing planning, personnel qualifications, certifications, etc.), and provides storage, protection, and retrieval services for legacy microfilmed and scanned QA records.	Added title of Administrator	Editorial change that does not reduce commitments.
QP-17	B	8/26/2016	Quality Assurance Records	3.11.3 Completed quality assurance records shall be maintained, preserved, and protected in accordance with ASME NQA 1 from the time they are received until they are transmitted to the customer, or if retained at GA, until the established retention time expires.	3.11.3	4.11.3 Completed quality assurance records shall be maintained, preserved, and protected in accordance with ASME NQA 1 Requirement 17, from the time they are received until they are transmitted to the customer, or if retained at GA, until the established retention time expires.	Added Requirement 17 as the source of the requirement.	Clarification that does not reduce commitments.
QP-18	B	4/14/2016	Audits	None	Added New Section : Applicable QP's and QDI's and adjusted numbering sequence	Added a list of the applicable Quality procedures and the Quality Division instructions that apply to the QP	Needed to show which QPs and QDI's applied to this procedure.	Clarification that does not reduce commitments.
QP-18	B	4/14/2016	Audits	3.3.1 Elements. Each element of the GA QA Program and each organization involved in safety-related activities shall be scheduled for audit at least once each year or at least once during the life of the activity, whichever is shorter. Nonsafety-related quality activities shall be audited at a frequency commensurate with the status and importance of the activities. In intervening years, an annual evaluation of the supplier shall be performed and documented. To remain on the QA Approved Suppliers List, each supplier shall be audited at 3 year intervals.	Sec. 3.3.1	4.3.1 Elements. Each element of the GA QA Program and each organization involved in safety-related activities shall be scheduled for audit at least once each year or at least once during the life of the activity, whichever is shorter. Nonsafety-related quality activities shall be audited at a frequency commensurate with the status and importance of the activities. In intervening years, an annual evaluation of the supplier shall be performed and documented. To remain on the QA Approved Suppliers List, each safety-related supplier shall be audited at 3 year intervals.	Added the words to identify specifically which suppliers get audited at three year intervals.	Clarification that does not reduce commitments.
QP-18	B	4/14/2016	Audits	3.4.1 Audit Plan. The Lead Auditor shall develop, document, and utilize an audit plan for each audit. This plan shall identify the audit objective, scope, requirements, audit personnel, activities to be audited, organizations to be notified, applicable documents, schedule, and checklists. The plan shall take into account the results of any relevant prior audits, special concerns reported to Quality Systems. The audit checklists shall contain the specific requirements against which the applicable QA Program elements are to be evaluated.	Sec. 3.4.1 Change from Lead Auditor to Lead Nuclear Auditor	4.4.1 Audit Plan. The Lead Nuclear Auditor shall develop, document, and utilize an audit plan for each audit. This plan shall identify the audit objective, scope, requirements, audit personnel, activities to be audited, organizations to be notified, applicable documents, schedule, and checklists. The plan shall take into account the results of any relevant prior audits, special concerns reported to Quality Systems. The audit checklists shall contain the specific requirements against which the applicable QA Program elements are to be evaluated.	Added the word nuclear to differentiate the NQA-1 nuclear auditors from the ISO auditors.	Clarification that does not reduce commitments.
QP-18	B	4/14/2016	Audits	3.5.1 Audits shall be performed by Lead Auditors or by auditors/auditor trainees under the direct supervision of Lead Auditors qualified in accordance with QP-2. Lead Auditors shall be assigned by the Manager, Quality Systems; however, Lead Auditors who are to perform audits of Quality Systems activities shall be assigned by the Director, Quality Assurance.	Sec. 3.5.1 Updated Lead Auditor to Lead Nuclear Auditor	4.5.1 Audits shall be performed by Lead Nuclear Auditors or by auditors/auditor trainees under the direct supervision of Lead Auditors qualified in accordance with QP-2. Lead Nuclear Auditors shall be assigned by the Manager, Quality Systems; however, Lead Nuclear Auditors who are to perform audits of Quality Systems activities shall be assigned by the Director, Quality Assurance.	Added the word nuclear to differentiate the NQA-1 nuclear auditors from the ISO auditors.	Clarification that does not reduce commitments.

Summary of Changes to GA's Quality Assurance Program

QP No.	Rev. No.	Effective Date	Title	Previous	Changed Section	Change	Reason for the change	Basis for Concluding that the Revised Program Incorporating the Change Continues to Satisfy the Applicable Requirements of Subpart H of 10CFR71
QP-18	B	4/14/2016	Audits	3.5.2 Auditors and Lead Auditors shall be independent of, and shall have no direct responsibility for, the activity to be audited. They shall have sufficient authority and organizational freedom to make the audit process meaningful and effective.	Sec. 3.5.2 Updated Lead Auditor to Lead Nuclear Auditor	4.5.2 Auditors and Lead Nuclear Auditors shall be independent of, and shall have no direct responsibility for, the activity to be audited. They shall have sufficient authority and organizational freedom to make the audit process meaningful and effective.	Added the word nuclear to differentiate the NQA-1 nuclear auditors from the ISO auditors.	Clarification that does not reduce commitments.
QP-18	B	4/14/2016	Audits	3.5.3 Selection of Audit Team. The audit team shall be identified prior to the beginning of the audit, and shall consist of one or more auditors one being designated Lead Auditor who organizes and directs the audit. The audit team shall have experience, or training commensurate with, the scope, complexity, or special nature of the activities to be audited.	Sec. 3.5.3 Updated Lead Auditor to Lead Nuclear Auditor	4.5.3 Selection of Audit Team. The audit team shall be identified prior to the beginning of the audit, and shall consist of one or more auditors, with one being designated the Lead Nuclear Auditor who organizes and directs the audit. The audit team shall have experience, or training commensurate with, the scope, complexity, or special nature of the activities to be audited.	Added the word nuclear to differentiate the NQA-1 nuclear auditors from the ISO auditors.	Clarification that does not reduce commitments.
QP-18	B	4/14/2016	Audits	3.6.1 Notification and Pre Audit Conference. The auditor shall provide advance written notice to the management of the activities to be audited, and shall conduct and document pre audit conferences.	Sec. 3.6.1 Updated Lead Auditor to Lead Nuclear Auditor	4.6.1 Notification and Pre Audit Conference. The Lead Nuclear Auditor shall provide advance written notice to the management of the activities to be audited, and shall conduct and document pre audit conferences.	Added the word nuclear to differentiate the NQA-1 nuclear auditors from the ISO auditors.	Clarification that does not reduce commitments.
Addendum 1	F	5/27/2016	Adendum 1	Not in previous version	Definitions	Added Definition: Basic Component - structure, system, or component, or part thereof that affects a Nuclear Power Plant (NPP's) safety function necessary to assure: (A) The integrity of the reactor coolant pressure boundary; (B) The capability to shut down the reactor and maintain it in a safe shutdown condition; (C) The capability to prevent or mitigate the consequences of accidents which could result in potential offsite exposures. Basic Components can only come from a Vendor with a Quality Assurance Program that meets 10CFR50, Appendix B	Definition was added due to the preparation of a new QDI titled "Commercial Grade Dedication"	Does not reduce commitments to the previously approved QA program. Enhances commitment to safety performance.