UNCONTROLLED

ENGINE SYSTEMS, INC.

QUALITY ASSURANCE MANUAL

6th EDITION

REVISION 1, 01/24/24

APPROVED BY:

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1-24-2024
Date

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1-24-2024
Date

Revision	Date	Page	Paragraph	Description
5th Edition, Rev. 0	July 13, 2007	All	All	Added NQA-1 (1989) requirements throughout manual.
		All	All	Renumbered throughout manual.
			Section 17	Revised Internal Quality Audits section in its entirety to meet current standards and practices.
		21-25	Glossary	Updated definitions to current standards
6th Edition, Rev. 0	February 20, 2018	All	All	Updated to ASME NQA-1 2008/09a requirements throughout. Updated to ISO 9001:2015 requirements throughout.
6th Edition, Rev. 1	January 24, 2024	Cover	-	Changed "General Manager" to "Vice President".
		6	1.1	Changed "General Manager" to "Vice President" in 2 places.
		7	1.5	Changed "General Manager" to "Vice President" in 2 places.
		11	4.3	Added the 4th sentence in this paragraph.

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QUALITY SYSTEM DESCRIPTION
FOR THE
DESIGN/DEVELOPMENT, PRODUCTION, INSTALLATION, INSPECTION, TESTING, AND SERVICING OF POWER GENERATING SYSTEMS

It is intended that all items and services provided by Engine Systems, Inc. (ESI) comply with the requirements of the Quality Program described in this manual.

For Nuclear Safety Related items and services, this manual, based on the requirements of 10CFR50 Appendix B, ANSI N45.2, NQA-1-2008/2009a, IEEE 323 & 344 and 10CFR21, is mandatory. The dedication of spare parts is controlled by Parts and Service Procedures.

NOTE: For Nuclear Safety Related items and services, Welding Procedures and Welding operators must meet all requirements of ASME Section IX or AWS. Nondestructive testing must meet ASNT-TC-1A.

For all other work the requirements of this manual, based on ISO 9001:2015 are mandatory.

The Engine Systems Quality Assurance Manual defines the Quality System. The system is dynamic and receptive to changing conditions and, as a result, the manual is designed to incorporate revisions and changes promptly as the need arises. Requests for changes should be forwarded to the Manager, Quality Assurance (MQA), preferably in the form of a proposed draft. The MQA will arrange for evaluation, appropriate approval and distribution of the proposed change. Any changes to responsibilities and authorities shall be defined and communicated within the organization.

QUALITY POLICY

Engine Systems, Inc. specializes in the design, procurement, manufacture, inspection, testing, and installation of specialized diesel generation equipment. This equipment and related aftermarket services are supplied to various markets. The nature of ESI's activities places particular emphasis upon experience, expertise, capability, reliability and safety. ESI is open, value oriented, reflective, and in pursuit of quality.

The prime objective of ESI is to provide this equipment and the associated services in a manner that conforms to the contractual and regulatory requirements and meets all customer expectations. ESI management is committed to satisfy applicable requirements and continually improve the quality management system.

In order to achieve this objective, it is the policy of ESI to establish and maintain an efficient and effective Quality Assurance Program, planned and developed in conjunction with all company functions. Determination of conformance of work to contract and regulatory requirements is verified on the basis of objective evidence of quality.

The Quality Manual and associated supplementary procedures outline the system to ensure that all quality and regulatory requirements are recognized and that a consistent and uniform control of these requirements is adequately maintained.

Top management shall ensure this policy performs the following:

a) Is appropriate to the purpose and context of the organization and supports its strategic direction;
b) Provides a framework for setting quality objectives;
c) Is available and maintained as documented information;
d) Is communicated, understood, and applied within the organization;
e) Is available to relevant interested parties, where appropriate.

Adequate provision of resources shall be provided to implement and maintain the quality management system, continually improve its effectiveness, and to enhance customer satisfaction by meeting customer requirements.

The Company shall determine and select opportunities for improvement and implement any necessary actions to meet customer requirements and enhance customer satisfaction. These shall include:

a) improving products and services to meet requirements as well as to address future needs and expectation;
b) correcting, preventing, or reducing undesired effects;
c) improving the performance and effectiveness of the quality management system.

The Company shall consider the results of analysis and evaluation, and the outputs from management review to determine opportunities to continually improve the suitability, adequacy, and effectiveness of the quality management system.

Section 1 QAM-1 Organization

1.1 MANAGEMENT RESPONSIBILITY AND AUTHORITY

ESI has established and maintains a documented procedure that defines the organizational structure, responsibility, levels of authority, and lines of communication for activities affecting quality.

The Vice President of ESI has delegated the necessary authority to the management group to effectively implement the Quality System. Evidence of top management's leadership and commitment to the quality management system shall be provided by:

a) taking accountability for the effectiveness of the quality management system;
b) ensuring that the quality policy and quality objectives are established and are compatible with the context and strategic direction of the organization;
c) ensuring the integration of the quality management system requirements into ESI's business processes;
d) promoting the use of the process approach and risk-based thinking;
e) ensuring that the resources needed for the quality management system are available;
f) communicating the importance of effective quality management and of conforming to the quality management system requirements;
g) ensuring that the quality management system achieves its intended results;
h) engaging, directing, and supporting persons to contribute to the effectiveness of the quality management system;
i) promoting improvement;
j) supporting other relevant management roles to demonstrate their leadership as it applies to their areas of responsibility.

The Manager Quality Assurance (MQA) is hereby given authority and responsibility for the preparation, approval, revision, and control of this Quality Manual and the associated supplementary procedures. The Manager Quality Assurance is also given the authority, responsibility, and organizational freedom to implement the Quality Program. When a disagreement exists between departments, it shall be brought to the attention of the Vice President for resolution within the guidelines of this program and regulatory requirements.

1.2 MANAGEMENT REPRESENTATIVE

ESI's top management has appointed the Manager of Quality Assurance who, irrespective of other responsibilities, has the responsibility and authority that includes:

a) ensuring that processes needed for the quality management system are delivering their intended outputs;
b) reporting to top management on the performance of the quality management system and any opportunities for improvement;
c) ensuring the promotion of awareness of customer focus throughout ESI;
d) ensuring that the planning of the quality management system is carried out in order to meet the requirements listed in Section 2.1 as well as the quality objectives;
e) ensuring the integrity of the quality management system is maintained when changes are planned and implemented.

1.3 ORGANIZATIONAL FREEDOM

The organization is structured to provide the organizational freedom and authority for personnel who need to:

a) initiate action to prevent the occurrence of product nonconformity,
b) identify and record any product quality problems,
c) initiate, recommend, or provide solutions through designated channels,
d) verify the implementation of solutions,
e) control further processing, delivery, or installation of nonconforming product until the deficiency or unsatisfactory condition has been corrected.

1.4 VERIFICATION RESOURCES

ESI has determined the knowledge necessary for the operation of its processes and to achieve conformity of products and services. This knowledge is maintained within the implementation procedures, standards libraries, and various other sources. All knowledge maintained by ESI is made available to personnel to the extent necessary. When addressing changes to needs and trends, ESI shall consider its current knowledge and determine how to acquire or access any necessary additional knowledge and required updates.

ESI has identified the necessary verification activities within the system implementation procedures. It is management's responsibility to provide an adequate number of properly trained personnel to accomplish verification activities and ensure that quality objectives, including those needed to meet requirements for product are established at relevant functions, levels, and processes needed for the quality management system. The quality objectives shall:

a) be consistent with the quality policy;
b) be measurable;
c) take into account applicable requirements;
d) be relevant to conformity of products and services and to enhancement of customer satisfaction;
e) be monitored;
f) be communicated;
g) be updated as appropriate.

Verification for nuclear safety related activities shall always be performed by personnel who have organizational freedom sufficiently independent from cost and schedule considerations and who are not directly responsible for performing the work. Personnel performing work affecting product quality shall be competent on the basis of appropriate education, training, skills and experience.

1.5 MANAGEMENT REVIEW

All business activities including the quality system shall be reviewed on a monthly basis to ensure its continuing suitability and effectiveness unless cancelled or postponed by the Vice President. The Vice President or his designee shall chair the Management Review Meeting. The purpose of the meeting is to ensure the suitability and effectiveness of current business practices, including, but not limited to, the quality program. Meeting Review topics (Input) will include, but not limited to:

a) the status of actions from previous management reviews,
b) changes in external and internal issues that are relevant to the quality management system,
c) the adequacy of resources,
d) status of corrective actions,
e) the effectiveness of actions taken to address risks and opportunities,
f) opportunities for improvement, and
g) other topics as deemed necessary.

The results (Output) from the management review meeting shall include any decisions and actions related to:

a) opportunities for improvement;
b) any need for changes to the quality management system;
c) resource needs.

The Management Review Meeting information shall be retained as evidence of the results of the review. The documentation shall include, but not be limited to:

a) highlights and deficiencies,
b) recommended corrective action,
c) focus of system goals,
d) required actions, such as; system changes, priorities, goals and corrective actions, and
e) responsibilities for corrective action designated during the meeting.

Status of all required actions will be addressed in subsequent Management Review meetings.

Section 2 QAM-2 Quality System

2.1 ESI's quality program is implemented by means of the system defined in this manual and any supporting supplementary procedures, as applicable. This documented information will identify the processes needed for the quality system as well as their application throughout the organization, and shall:

- Determine the inputs required and the outputs expected from these processes.
- Determine the methods and criteria needed to ensure that both the operation and control of these processes are effective.
- Ensure the availability of information and resources necessary to support the operation and monitoring of these processes.
- Assign the responsibilities and authorities for these processes.
- Monitor, measure and analyze these processes and implement actions necessary to achieve planned results and continual improvement.
- Address the risks and opportunities to prevent or reduce undesired effects and achieve improvement.

2.2 GENERAL

Engine Systems, Inc. has designed this quality system to meet the necessary regulatory requirements.

The quality system consists of this Quality Manual, and Supplementary Procedures. Management shall regularly assess the adequacy and effective implementation of the quality assurance program. The quality system provides:

a) control over activities affecting quality to an extent consistent with their importance,
b) monitoring activities against acceptance criteria in a manner sufficient to provide assurance that the activities affecting quality are performed satisfactorily,
c) for the planning and accomplishment of activities affecting quality under suitably controlled conditions. These conditions include the use of appropriate equipment, suitable environmental conditions for accomplishing the activity, and assurance that prerequisites for the given activity have been satisfied.
d) for any special controls, processes, test equipment, tools, and skills to attain the required quality of activities and items and for verification of that quality.
e) processes to detect and correct quality problems,
f) indoctrination, training, and qualification as necessary, of personnel performing or managing activities affecting quality to assure that suitable proficiency is achieved and maintained.

The Quality Assurance Manual defines the scope of the quality management system, taking into consideration:

a) External and internal issues that affect the ability to achieve intended results
b) Identification and requirements of relevant interested parties
c) Products and services provided by ESI

The Supplementary Procedures are the mechanism for system implementation describing the effective planning, operation, process controls and validation records.

Qualification, Indoctrination & Training:

a) Qualification Requirements:

Engine Systems, Inc. will designate those activities that require qualified personnel and the minimum requirements for such personnel. ESI shall establish written procedures for the qualification of personnel and for the assurance that only those who meet these requirements are permitted to perform these activities.

b) Indoctrination and Training:

Indoctrination and training shall be commensurate with scope, complexity, importance of the activities, and the education, experience, and proficiency of the person. Initial capabilities of a candidate shall be determined by an evaluation of the candidate's education, experience, training, and either test results or capability demonstration. Personnel performing or managing activities affecting quality shall 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. The need for a formal training program shall be determined, and such training activities shall be conducted as required to qualify personnel who perform inspections and tests. On-the-job training shall also be included in the program, with emphasis on the first-hand experience gained through actual performance of inspections and tests.

2.3 SYSTEM DESIGN CONSIDERATIONS

The Quality Assurance Manual and Supplementary Procedures are prepared in accordance with specified requirements, which include ISO9001: 2015, NQA-1-2008/09a, 10CFR50 Appendix B, 10CFR21, IEEE 323 & 344, ANSI N45.2, ASME Section IX or AWS, and ASNT-TC-1A.

Quality Plans may be developed for a specific project as required by contract or as determined by ESI's management group.

The organization will plan, implement, and control the processes needed to meet the requirements for the provision of products and services. These actions shall be implemented by:

a) determining the requirements for the products and services;
b) establishing criteria for the processes and acceptance of products and services;
c) determining the resources needed to achieve conformity to the requirements;
d) implementing control of the processes in accordance with the criteria;
e) determining, maintaining, and retaining documented information to the extent necessary to demonstrate conformity to the requirements, and to have confidence that the processes have been carried out as planned.

Section 3 QAM-3 Contract Review

3.1 CONTRACT REVIEW

Contract review shall determine:

- that any applicable statutory and regulatory requirements for products and services are defined;
- that requirements considered necessary by ESI are defined;
- that ESI can meet the requirements for the products and services.

Each contract shall be reviewed to identify:

- requirements specified by the customer including the requirements for delivery and post-delivery activities;
- requirements not stated by the customer, but necessary for the specified or intended use, when known;
- any requirements determined by ESI;
- statutory and regulatory requirements applicable to the products and services;
- contract or order requirements differing from those previously expressed;
- that the terms and conditions are acceptable.

This review shall be conducted prior to ESI's commitment to supply a product or service to the customer. Where the customer provides no documented statement of requirements, the customer requirements shall be confirmed by ESI before acceptance. Where product requirements are changed, ESI shall ensure that the relevant documents are amended and that relevant personnel are made aware of the change.

3.2 ORDER ENTRY

All new orders shall be formally entered into the order entry system. At this point the order will be processed by the appropriate department(s) as necessary.

3.3 PROJECT PLANNING

Formal project planning for major projects begins once the order is accepted and entered. Formal project planning is directed as required by ESI management.

The project planning shall consist of the design, procurement, manufacturing, inspection, testing, and scheduling activities as required by the complexity of the contract. Each of these activities shall be planned and assigned to qualified staff, equipped with adequate resources, as necessary.

- The design, consisting of the design inputs and design outputs shall identify the required design and verification activities. It shall also generate the required bill of material.
- The purchasing planning shall identify the required sources of supply and shall provide the required schedule input.
- The manufacturing planning shall identify the project task requirements; provide schedule inputs and process controls.
- The quality planning shall identify the project quality and inspection requirements and provide schedule input. The project quality requirements shall include internal and external hold and witness point activities and documentation requirements.
- The project schedule shall incorporate the planning, and submittal requirements into an integrated plan. The schedule shall be a dynamic tool to monitor and control the project.

Section 4 QAM-4 Design Control

4.1 GENERAL

The design shall be defined, controlled and verified. Applicable design inputs shall be appropriately specified on a timely basis and correctly translated into design documents. Design and development activities for projects shall be planned and updated as required. These activities shall be assigned to qualified personnel who possess adequate resources. The interfaces necessary to accomplish these activities shall be defined and all the necessary information shall be documented, transmitted and regularly reviewed. Design changes shall be governed by control measures commensurate with those applied to the original design.

Design inputs shall be properly identified and documented and their selection reviewed and approved. The design input shall be specified to the level of detail necessary to permit the design activities to be carried out in a correct manner and to provide a consistent basis for making design decisions, accomplishing design verification measures, and evaluating design changes. Incomplete, ambiguous, or conflicting requirements shall be resolved by the Production and Engineering departments.

Design outputs shall be properly verified by competent personnel, other than those who designed the item.

- Project design outputs shall be expressed in terms of code or standard, and specification requirements, calculations, and analyses. Design outputs shall:
    - Meet the design input requirements
    - Contain or reference acceptance criteria, conform to appropriate regulatory requirements whether or not these have been stated in the input information
    - Identify those characteristics of the design that are crucial to the safe and proper functioning of the product.
- Design documents shall support facility design, construction, and operation. Appropriate quality standards shall be identified and documented, and their selection reviewed and approved. Changes from specified quality standards, including the reasons for the changes, shall be identified, approved, documented, and controlled. Design methods, materials, parts, equipment, and processes that are essential to the function of the items shall be selected and reviewed for suitability of application. Applicable information derived from experience, as set forth in reports or other documentation, shall be made available to cognizant design personnel. The final design (approved design output documents and approved changes thereto) shall:
    - Be relatable to the design input by documentation in sufficient detail to permit design verification.
    - Specify required inspections and tests and include or reference appropriate acceptance criteria.
    - 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 that, prior to its installation, is modified or selected by special inspection and/or testing to requirements that are more restrictive than the Supplier's published product description, the component part shall be represented as different from the commercial grade item in a manner traceable to a documented definition of the difference.

4.2 DESIGN ANALYSES

Design analyses shall be sufficiently detailed such that a person technically qualified in the subject can review and understand the analyses and verify the adequacy of the results without recourse to the originator. Documentation of design analyses shall include the following:

- The objective of the analyses
- Design inputs and their sources
- Results of literature searches or other applicable background data
- Assumptions and indication of those assumptions that must be verified as the design proceeds
- Identification of any computer calculation, including identification of the computer type, computer program name, and revision, inputs, outputs, evidence of or reference to computer program verification, and the bases supporting application of the computer program to the specific physical problem
- Review and approval

4.3 DESIGN VERIFICATION

Design verifications shall be applied to verify the adequacy of design by one or more of the following methods: the performance of design reviews, the use of alternate calculations, or the performance of qualification tests. Verification of computer programs shall include appropriate testing. The method of verification shall be identified and documented. When qualification testing is utilized, the testing shall demonstrate adequacy of performance under conditions that simulate the most adverse design conditions. The results of design verification shall be clearly documented with the identification of the verifier clearly indicated. Design verification shall be performed by any competent individual(s) or group(s) other than those who performed the original design but who may be from the same organization. This verification may be performed by the originator's supervisor, provided the supervisor did not specify a singular design approach or rule out certain design considerations and did not establish the design inputs used in the design or, provided the supervisor is the only individual in the organization competent to perform the verification. Cursory supervisor reviews do not satisfy this intent. Verification shall be performed in a timely manner. Design verification, for the level of design activity accomplished, shall be performed prior to release for procurement, manufacture, construction, or release to another organization for use in other design activities except in those cases where this timing cannot be met, such as when insufficient data exist. In those cases, the unverified

portion of the design shall be identified and controlled. In all cases the design verification shall be completed prior to relying upon the component, system, structure, or computer program to perform its function.

If the design is modified to resolve verification findings, the modified design shall be verified prior to release or use.

The extent of the design verification required is a function of the importance to safety, the complexity of the design, the degree of standardization, the state of the art, and the similarity with previously proven designs. Where the design has been subjected to a verification process, the verification process need not be duplicated for identical designs. However, the applicability of standardized or previously proven designs, with respect to meeting pertinent design inputs, shall be verified for each application. Known problems affecting the standard or previously proven designs and their effects on other features shall be considered.

The original design and associated verification measures shall be adequately documented and referenced in the files of subsequent application of the design. Where changes to previously verified designs have been made, design verification shall be required for the changes, including evaluation of the effects of those changes on the overall design and on any design analyses upon which the design is based that are affected by change to previously verified design.

4.4 CHANGE CONTROL

Changes to design inputs, final designs, field changes, and temporary and permanent modifications shall be justified and subject to design control measures commensurate with those applied to the original design. These measures shall include evaluation of effects of those changes on the overall design and on any analysis upon which the design is based. Changes shall be approved by the same affected groups or organizations that reviewed and approved the original design documents. The design organization approving the change shall have demonstrated competence in the specific design area of interest and have an adequate understanding of the requirements and intent of the original design. When a design change is approved other than by revision to the affected design documents, measures shall be established to incorporate the change into these documents, where such incorporation is appropriate. Where a significant design change is necessary because of an incorrect design, the design process and verification procedure shall be reviewed and modified as necessary.

4.5 INTERFACE CONTROL

Interface controls include assignment of responsibility and establishment of procedures among participating design organizations for review, approval, release, distribution, and revision of documents involving design interfaces. Design information transmitted across interfaces shall identify the status of the design information or document provided, and identify incomplete items that require further evaluation, review, or approval. Where it is necessary to initially transmit design information orally or by other informal means, the transmittal shall be confirmed promptly by a controlled document.

Section 5 QAM-5 Instructions, Procedures, Drawings, & Document Control

Activities affecting quality shall be prescribed by and performed in accordance with documented instructions, procedures, or drawings that include or reference appropriate quantitative or qualitative acceptance criteria for determining the prescribed activities have been satisfactorily accomplished. The activity shall be described to a level of detail commensurate with the complexity of the activity and the need to assure consistent and acceptable results. The need for, and level of detail in, written procedures or instructions shall be determined based upon complexity of the task, the significance of the item or activity, work environment, and worker proficiency and capability (education, training, experience). This section defines the document control requirements for all documents related to ESI's quality system. These documents include:

- Quality Assurance Manual, Supplementary Procedures and Work Instructions,
- Design Outputs, Drawings, Dedication Reports, and Test Procedures,
- Purchase Requisitions, Purchase Orders, and Approved Suppliers List,
- OEM Documentation.

The preparation, issue, and change of documents that specify quality requirements or prescribe activities affecting quality such as instructions, procedures, and drawings shall be controlled to ensure that correct documents are being employed. All required documents shall be reviewed and approved for adequacy by authorized personnel prior to issue. The following controls shall be applied to documents and changes:

- The identification of controlled documents.
- The specified distribution of controlled documents for use at the appropriate locations where operations essential to the effective functioning of the quality system are performed.
- The identification of individuals responsible for the preparation, review, approval, and distribution of controlled documents.
- Review of controlled documents for adequacy, completeness, and approval prior to distribution.
- A method to ensure the correct documents are being used.

Document revisions shall receive the same review and approval process as the original. This process shall be performed by designated personnel who have access to all pertinent background information. The nature of the document revision shall be identified in the document. Control of documents shall preclude the use of non-applicable documents.

Section 6 QAM-6 Procurement & Control of Purchased Items and Services

6.1 PROCUREMENT DOCUMENT CONTROL

Applicable design bases and other requirements necessary to assure adequate quality shall be included or referenced in documents for procurement of items and services. Procurement documents shall include the quality program requirements as necessary.

A list of approved suppliers shall be maintained. This list will define the scope of supply. Selection of suppliers to be included on this list shall be dependent on the type of product or service to be provided. The quality system requirement and method of selection shall be commensurate with the criticality of the product or service to be provided.

Purchasing documents shall contain data describing the item or service ordered including, where applicable:

- The type, class, style, grade, or precise identification.
- The scope of work to be performed by the Supplier
- Technical requirements, specified, as appropriate, by reference to specifications, drawings, codes, standards, regulations, process requirements, inspection instructions, and other relevant technical data, including requirements for approval or qualification of product, procedures, process equipment and personnel.
- Appropriate test, inspection, and acceptance criteria for determining acceptability of the item or service.
- Quality assurance program requirements, including appropriate requirements for sub-tier.
- Access to the Supplier's and sub-tier Supplier's facilities and records for surveillance, inspection, or audit by ESI or is designated representative.
- Documentation required to be submitted for information, review, or approval by ESI.
- Requirements for the Supplier's reporting of nonconformances.
- Requirements for identification of spare and replacement parts or assemblies and the related data required for ordering these parts of assemblies.

Purchase documents, and changes thereto, shall be reviewed and approved prior to award. Procurement document changes affecting the technical or quality assurance program requirements shall be subject to the same degree of control as utilized in the preparation of the original documents. Conformity of products to specified requirements shall be verified by ESI. This verification may be accomplished at the supplier's facility by source inspection or at ESI by receipt inspection.

When specified in the contract, a customer representative shall be afforded the right to verify that subcontracted products conform to specified requirements. Such verification shall not be used by ESI as evidence of effective control of quality by the supplier. Verification by the customer shall not absolve ESI of the responsibility to provide acceptable product, nor shall it preclude subsequent rejection by the customer.

6.2 CONTROL OF PURCHASED ITEMS AND SERVICES

6.2.1 Safety Related Items and Services

Suppliers of safety related items and services are evaluated and selected for their capability to provide items or services in accordance with the requirements of procurement documentation. Controls are implemented to ensure that the submittal and evaluation of Supplier-generated documents and changes are accomplished in accordance with the procurement document requirements. Verification activities for the item or service being furnished shall be a function of the relative importance, complexity and quantity of the item or service procured and the Supplier's quality performance. Methods used to accept an item or service shall be one more of the following.

Certificate of Conformance

When a certificate of conformance is used, the following requirements must be met:

- The certificate shall identify the purchased material or equipment, such as by the purchase order number.
- The certificate shall identify the specific procurement requirements met by the purchased material or equipment, such as codes, standards, and other speicfications.
- The certificate shall identify any procurement requirements that have not been met, together with an explanation and the means for resolving the nonconformances.
- The certificate shall be signed or otherwise authenticated by a person who is responsible for this quality assurance function and whose function and position are described in the Supplier's quality assurance program.
- The certification system, including the procedures to be followed in filling out a certificate and the administrative procedures for review and approval of the certificates, shall be described in the Purchaser's or Supplier's quality assurance program.
- Means shall be provided to verify the validity of supplier certificates and the effectiveness of the certification system, such as during the performance of audits of the Supplier or independent inspection or test of the items. Such verification shall be conducted by ESI at intervals commensurate with the supplier's past quality performance.

Source Verification

When source verification is used, it shall be performed at intervals consistent with the importance and complexity of the item or service, and shall include monitoring, witnessing, or observing selected activities. Source verification shall be implemented in accordance with plans to perform inspections, examinations, or tests at predetermined points. Upon purchaser acceptance of source verification, documented evidence of acceptance shall be furnished to the receiving destination of the item, the purchaser, and the supplier.

Receiving Inspection

When receiving inspection is used purchased items shall be inspected as necessary to verify conformance to specified requirements, taking into account source verification and audit activities and the demonstrated quality performance of the supplier. Receiving inspection shall verify by objective evidence such features as

- Configuration
- Identification
- Dimensional, physical, and other characteristics
- Freedom from shipping damage
- Cleanliness

Receiving inspection shall be coordinated with review of supplier documentation to be furnished prior to receiving inspection.

6.2.2 Commercial Grade Items and Services

For purchased commercial grade items and services supplied as safety related by ESI, controls shall be implemented to provide reasonable assurance that the item or service will perform its intended safety function. These controls shall include the following:

- Determination that the item or service performs a safety function.
- Confirmation that the item or service meets the applicable commercial grade item definitions.
- Identification and documentation of the critical characteristics, including acceptance criteria.
- Selection, performance, acceptance, and documentation, of the dedication method(s) for determining compliance with acceptance criteria
- Verification that critical characteristics meet the acceptance criteria

Only items that perform a safety function and meet the commercial grade definitions shall be considered for commercial grade dedication. A dedication plan shall be developed for the item or service that identifies the critical characteristics and dedication methods, including acceptance criteria. Dedication plans may be developed for a specific item, service, or for a generic group of items or services. Dedication requirements shall be included in applicable procurement and technical documents as necessary to support dedication. Specific implementation of the ESI dedication process is addressed within applicable procedures and dedication reports.

Section 7 QAM-7 Customer Supplied Products

Customer supplied products shall be inspected to verify compliance with requirements prior to assignment to work.

Customer supplied product falls into the following categories:

- CORE Returns
- Warranty Returns
- Repair and Return Work
- Customer Supplied Material

Section 8 QAM-8 Product Identification and Traceability

All products shall be properly identified during all stages of receipt, storage, production, delivery and installation. Identification shall be maintained on the items or in documents traceable to the items, or in a manner that assures that identification is established and maintained. Physical identification shall be used to the maximum extent possible. Where physical identification on the item is either impractical or insufficient, physical separation, procedural control, or other appropriate means shall be employed. Identification markings shall be applied using materials and methods that provide a clear and legible identification and do not degrade the function or service life of the item. Markings shall be transferred to each part of an identified item when subdivided and shall not be obliterated or hidden by surface treatment or coating unless other means of identification are substituted. Where traceability is a specified requirement, individual product or batches shall have unique identification and traceability control.

Section 9 QAM-9 Process Control

Production and installation processes shall be identified and planned in the manufacturing plan, and/or approved procedures and work instructions. These processes shall be carried out under the following controlled conditions:

- Documented work instructions defining the manner of production and installation, where the absence of such instructions would adversely affect quality, use of suitable production and installation equipment, suitable working environment, compliance with reference standards/codes, OEM manuals and instructions, and quality plans.
- Monitoring and control of suitable process and product characteristics during production and installation.
- The approval of processes and equipment, as appropriate.
- Criteria for workmanship which shall be stipulated, to the greatest practicable extent, in written standards or by means of representative samples.
- Suitable maintenance of equipment to ensure continuing process capability.

Special processes that control or verify quality such as those used in welding, heat treating, and nondestructive examination, shall be completed by qualified personnel using qualified procedures and qualified equipment in accordance with specified requirements.

Section 10 QAM-10 Inspection and Testing

10.1 GENERAL

Inspections and testing shall be completed in accordance with the quality plan, procedures, or work instructions and shall include as a minimum all operations necessary to assure quality. Inspections, monitoring, witnessing and other verification activities shall be performed by individuals other than those who performed or directly supervised the activity being inspected. When hold points are required, they shall be indicated in appropriate documents and work shall not proceed beyond these points without specific consent of the designated representative, the specific hold points shall be indicated in appropriate documents. Consent to waive specified hold points shall be recorded prior to continuation of work beyond the designated hold point. Inspection and test acceptance criteria shall be defined. When customer witness is required by customer contract specification, the customer will be notified of the upcoming event.

10.2 TEST REQUIREMENTS

Test requirements and acceptance criteria shall be provided or approved by the responsible design organization. Required tests, including, as appropriate, prototype qualification tests, productions tests, proof tests, pre-operational tests, operational tests, computer program tests such as software design verification, factory acceptance tests, site acceptance tests, and in-use tests shall be controlled. Required tests shall be controlled under appropriate environmental conditions using the tools and equipment necessary to conduct the test in a manner to fulfill test requirements and acceptance criteria. The tests performed shall obtain the necessary data with sufficient accuracy for evaluation and acceptance. Test requirements and acceptance criteria shall be based upon specified requirements contained in applicable design documents, or other pertinent technical documents that provide approved requirements.

10.3 TEST PROCEDURES

Test procedures shall include or reference test objectives and provisions for assuring that prerequisites for the given test have been met, that adequate instrumentation is available and used, that necessary monitoring is performed, and that suitable environmental conditions are maintained. Prerequisites shall include the following, as applicable: calibrated equipment, appropriate equipment, trained personnel, condition of test equipment and the item to be tested, suitable environmental conditions, and provisions for data acquisition. In lieu of specially prepared written test procedures, appropriate sections of related documents, such as ASTM methods, supplier manuals, equipment maintenance instructions, or approved drawings or travelers with acceptance criteria, can be used. Such documents shall include adequate instructions to assure the required quality of work.

10.4 RECEIVING INSPECTION AND TESTING

Incoming products shall undergo inspection and test in accordance with the procedural requirements.

10.5 IN-PROCESS INSPECTION AND TESTING

Products in process shall undergo inspection and test in accordance with the procedural requirements.

Dedication inspection and test shall be accomplished in accordance with the Product Dedication Report.

Process monitoring and control methods shall be used to establish product conformance to specified requirements.

Products shall be held until required inspection and testing has been satisfactorily completed. Nonconforming products shall be properly identified.

10.6 FINAL INSPECTION AND TESTING

Final inspection and testing shall be completed in accordance with procedural requirements.

All in-process inspection and testing shall be completed prior to final inspection. Completed items shall be inspected for completeness, markings, calibration, adjustments, protection from damage, cleanliness, or other characteristics as required to verify the quality and conformance of the item specified requirements. Acceptance of the item shall be approved by authorized personnel.

Products shall not be dispatched until all inspection and test is satisfactorily completed and documentation is available and authorized.

Section 11 QAM-11 Measuring and Test Equipment

ESI has established and maintains a documented procedure that defines the control of measuring and test equipment. ESI, where necessary, shall:

- Identify the measurements to be made, the accuracy required, and select the appropriate, measuring, and test equipment.
- Identify, calibrate, and adjust all, measuring and test equipment, and devices that can affect quality at prescribed intervals, or prior to use, against and traceable to certified equipment or reference standards having a known valid relationship to nationally recognized standards; where no such standards exist, the basis used for calibration shall be documented.
- Reference standards shall have a minimum accuracy four times greater than that of the measuring and test equipment being calibrated to ensure that the reference standards contribute no more than one-fourth of the allowable calibration tolerance. Where this 4:1 ratio cannot be maintained, the basis for selection of the standard in question shall be technically justified.
- Establish, document, and maintain calibration procedures, including details of equipment type, identification number, location, frequency of checks, check method, acceptance criteria, and the action to be taken when results are unsatisfactory.
- Calibration procedures shall identify or reference required accuracy and shall define methods and frequency of checking accuracy.
- Ensure that the measuring and test equipment is capable of the accuracy and precision necessary.
- Identify measuring and test equipment with a suitable indicator or approved identification record to show the calibration status.
- Maintain calibration records for measuring and test equipment.

- Assess and document the validity of previous test results when measuring and test equipment is found to be out of calibration.
- Ensure that the environmental conditions are suitable for the calibrations, measurements, and test being carried out.
- Safeguard measuring and test equipment from adjustments, damage, or deterioration that would invalidate the calibration status and subsequent measurement results..
- Verify the capability of test hardware and software prior to use in production or installation.

Section 12 QAM-12 Inspection and Test Status

The inspection and test status of products shall be identified. This status shall:

- Be on the items or in documents traceable to the items.
- Maintained through indicators, such as physical location and tags, markings, shop travelers, stamps, inspection records, or other suitable means.
- Indicate the conformance of products with regard to inspection and tests performed.
- Be maintained throughout the production and installation to ensure that products have passed the required inspection and tests.

Authority for application and removal of tags markings, labels, and stamps shall be specified. The inspection authority responsible for the release of conforming product shall be defined.

Section 13 QAM-13 Control of Nonconforming Product

Products that do not conform to specified requirements shall be documented, identified, and segregated, where practical, to prevent inadvertent use or installation.

- Nonconforming items shall be identified by legible marking, tagging, or other methods not detrimental to the item, on either the item, the container, or the package containing the item.
- Nonconforming items shall be segregated, when practical, by placing them in a clearly identified and designated hold area until properly dispositioned. When segregation is impractical or impossible due to physical conditions such as size, weight, or access limitations, other precautions shall be employed to preclude inadvertent use of a nonconforming item.

Nonconforming items shall be evaluated and recommended dispositions shall be proposed. Further processing, delivery, installation, or use of a nonconforming item shall be controlled pending the evaluation and an approved disposition by authorized personnel.

- The responsibility and authority for the evaluation and disposition of nonconforming items shall be defined.
- Responsibility for the control of further processing, delivery, installation, or use of nonconforming items shall be designated in writing.
- Personnel performing evaluations to determine a disposition shall have demonstrated competence in the specified area they are evaluating, have an adequate understanding of the requirements, and have access to pertinent background information.

A disposition, such as use-as-is, reject, repair, or rework, of nonconforming items shall be made and documented. Technical justification for the acceptability of a nonconforming item, dispositioned repair, or use-as-is shall be documented. Nonconformance to design requirements dispositioned use-as-is or repair shall be subject to design control measures commensurate with those applied to the original design. Required as-built records shall reflect the use as-is or repair condition.

Reworked items shall be reexamined in accordance with applicable procedures and with the original acceptance criteria. Repaired items shall be reexamined in accordance with applicable procedures and with the original acceptance criteria unless the nonconforming item disposition has established alternate acceptance criteria.

Section 14 QAM-14 Corrective Action

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 ESI shall take action to eliminate the cause in order to prevent reoccurrence. Corrective actions are appropriate to the effects of the nonconformities encountered. All information regarding the nature of the condition, any subsequent actions taken, and the results of the corrective action will be documented within the Corrective Action Report (CAR). To adequately address any such condition, ESI shall:

a) Take action to control and correct the nonconformance;
b) Evaluate the need for action to eliminate the cause of the nonconformance, so that it does not recur;
c) Review and analyze the nonconformance;
d) Determine the cause of the nonconformity;
e) Determine if similar nonconformities exist, or could potentially occur;
f) Determine and implement any action needed;
g) Review the effectiveness of any corrective action taken;
h) Update risks and opportunities determined during planning, if necessary;
i) Make changes to the quality management system, if necessary.

Section 15 QAM-15 Handling, Storage, Packaging and Delivery

15.1 GENERAL

Handling, storage, packaging, shipping, and preservation of items shall be controlled to prevent damage or loss and to minimize deterioration. These activities shall be conducted in accordance with established work and inspection instructions, or other pertinent documents or procedures specified for use in conducting the activity.

15.2 HANDLING

ESI shall provide the method and means of handling that prevents damage or deterioration of products.

15.3 STORAGE

ESI shall provide secure storage areas to prevent damage or deterioration of product, pending use, or delivery. Receipt of products into storage shall be authorized. Dispatch of product to and from storage shall be controlled. Storage conditions of product shall be assessed at appropriate intervals.

15.4 PACKAGING

ESI shall control packing, preservation, and identification of products to ensure conformance to specified requirements. ESI shall identify, preserve, and protect all products from receipt to delivery.

15.5 DELIVERY

ESI shall arrange for the protection of the quality of products after final inspection and test until delivery.

Section 16 QAM-16 Quality Records

Quality Assurance records shall furnish documentary evidence that items or activities meet specified quality requirements. The effective operation of this product shall be specified, prepared, maintained, legible, identifiable, and retrievable. These records shall be protected against damage, deterioration, loss, and unintended alteration. Requirements and responsibilities for record access, retrieval, use, transmittal, distribution, retention, maintenance, and disposition shall be established and documented. Quality records shall be identified by the quality system defined in this manual, supplementary procedures, or quality plans. Quality records shall be made available to the customer prior to being destroyed.

Section 17 QAM-17 Internal Quality Audits

ESI shall complete a comprehensive system of planned and documented internal quality audits to verify that the quality system is effectively implemented within the guidelines of this manual and the supplementary procedures.

ESI's audit program is planned, takes into consideration the status and importance of the processes and of the areas to be audited, as well as the results of previous audits. The audit criteria, scope, frequency and methods are defined.

Selection of auditors and conduct of audits ensure objectivity and impartiality of the audit process. Audits shall be performed by qualified personnel, independent of those personnel having direct responsibility for the activity being audited. The responsibilities and requirements for planning and conducting audits, and for reporting results and maintaining records are defined in a documented procedure.

The management responsible for the area being audited ensures that actions are taken without undue delay to eliminate detected nonconformities and their causes. Follow-up activities include the verification of the actions taken and the reporting of verification results.

Section 18 QAM-18 Training

The training needs for personnel performing activities affecting quality shall be identified. The management of ESI shall:

a) determine the necessary competence of person(s) doing work under its control that affects the performance and effectiveness of the quality management system;
b) ensure that these persons are competent on the basis of appropriate education, training, or experience;
c) where applicable, take actions to acquire the necessary competence, and evaluate the effectiveness of the actions taken;
d) retain appropriate documented information as evidence of competence.

The management of ESI shall also ensure that personnel are made aware of:

a) their roles and responsibilities in achieving conformance with the quality policy and procedures and with the requirements of the quality system,
b) the significant impact of their work activities on quality,
c) the benefits of improved personal performance, and
d) the potential consequences of departure from specified procedures.

Section 19 QAM-19 Servicing

ESI implements any service requirement under controlled conditions. Controlled conditions include, as applicable:

a) the availability of documented information that describes the characteristics of the product, services, or activities, as well as the results to be achieved;
b) the availability and use of suitable monitoring and measuring resources;
c) the implementation of monitoring and measurement activities at appropriate stages to verify that criteria for control of processes or outputs, and acceptance criteria for products and services, have been met;
d) the use of suitable infrastructure and environment for the operation of processes;
e) the appointment of competent persons, including any required qualification;
f) the validation, and periodic revalidation, of the ability to achieve planned results of the processes for service provision, where the resulting output cannot be verified by subsequent monitoring or measurement;
g) the implementation of actions to prevent human error;
h) the implementation of release, delivery, and post-delivery activities.

Servicing at ESI includes; Field Service, Engineering Services, and External Training. Procedures that stipulate performance and verification activities for servicing shall be utilized. The servicing goals at ESI include:

- Customer satisfaction
- Continuous improvement
- Consideration for the safety of society
- Consideration for the environment
- Efficiency

Section 20 QAM-20 Statistical Techniques

ESI analyses and evaluates appropriate data and information to demonstrate the suitability and effectiveness of the quality system. This includes data generated as a result of monitoring and measurement and from other relevant sources. The results of analysis shall be used to evaluate:

- Conformity of products and services;
- The degree of customer satisfaction;
- The performance and effectiveness of the quality management system;
- If planning has been implemented effectively;
- The effectiveness of actions taken to address risks and opportunities;
- The performance of external providers;
- The need for improvements to the quality management system.

Trend analysis of discrepancies found in nonconforming product is performed on a defined, regular basis and results are utilized as input for corrective and preventive action.