SUPPLEMENT TO ISO 9000 (ANSI/ISO/ASQ Q9000) QUALITY SYSTEMS FOR CRITICAL/COMPLEX PROCUREMENTS

The organization shall establish and maintain a quality assurance program in accordance with ISO 9000:1994 (ANSI/ISO/ASQ Q9000) Quality Systems Models or ISO 9001:2000/2008/2015 (ANSI/ISO/ASQ Q9001) Quality Management Systems as modified and amended herein which shall apply on contracts invoking this document.

Paragraph references correspond to the 1994 revisions of ISO 9001 and ISO 9002 (ANSI/ISO/ASQ Q9001/9002) or the 2000/2008/2015 revision of ISO 9001 (ANSI/ISO/ASQ Q9001). This has been done as a convenience only and the issuing agency assumes no liability whatsoever for any inaccuracies in these notations.

To support the preferred implementation of ISO 9001:2000/2008/2015, the terminology used to describe the supply chain in ISO 9001:2000/2008/2015 has been incorporated herein. When the 1994 version is applied, replace "organization" with "supplier" and "supplier" with "subcontractor." When the 2015 version is applied replace "supplier" with "external provider." When the 2015 version is applied, the term "documented information" refers to documentation, quality manual, documented procedures, and records.

1. Organization Quality System

a. 1994 - Add to QUALITY SYSTEM - General: Paragraph 4.2.1

2000
2008 - Add to Quality management system - General requirements: Paragraph 4.1
2015 - Add to Context of the organization - Quality management system and its processes: Paragraph 4.4

The organization shall provide and maintain a quality assurance program that ensures that the product meets the contract requirements and that is acceptable to Customer and Government. The organization shall notify the customer in writing of any change, other than editorial, to the quality manual.

2. **Coordinated Government/Organization Actions and Use of Organization Inspection Facilities**

a. 1994 - Add to Purchasing data: Paragraph 4.6.3

2000
2008 - Add to Purchasing information: Paragraph 7.4.2
2015 - Add to Information for external providers: Paragraph 8.4.3

When, under authorization of the Government Representative, copies of the purchasing document are to be furnished directly by the supplier or organization to the Government Representative at their facility rather than through Government channels, the organization shall add to their purchasing document a statement substantially as follows:

> "On receipt of this order, promptly furnish a copy to the Government Representative who normally services your plant. In the event the representative or office cannot be located, our purchasing agent should be notified immediately."

All documents and referenced data for purchases applying to a Government contract shall be available for review by the Government Representative to determine compliance with the requirements for control of such purchases. Copies of purchasing documents required for Government inspection purposes shall be furnished in accordance with the instructions of the Government Representative.

b. 1994 - Add to Receiving inspection and testing: Paragraph 4.10.2.1

2000
2008 - Add to Verification of purchased product: Paragraph 7.4.3
2015 - Add to Type and extent of control: Paragraph 8.4.2

The organization shall make available to the Government Representative reports of any nonconformance found on Government source-inspected supplies and shall (when requested) require their suppliers to coordinate with their Government Representative on corrective action.

c. 1994 - Add to INSPECTION AND TESTING - General: Paragraph 4.10.1

2000
2008 - Add to Monitoring and measurement of product: Paragraph 8.2.4
2015 - Add to Release of products and services: Paragraph 8.6

When required, the organization's measuring and testing equipment shall be made available for use by the Government Representative to determine conformance of product with contract requirements. In addition, if conditions warrant, organization's personnel shall be made available for operation of such devices and for verification of their accuracy and condition.

The organization shall repeat any measurement or test that the customer, or Government Representative when Government Source Inspection is required, may reasonably request to substantiate that the order requirements are met.

3. **Independence of Inspection and Test Personnel**

a. 1994 - Add to Resources: Paragraph 4.1.2.2

2000
2008 - Add to Human resources - General: Paragraph 6.2.1
2015 - Add to Competence: Paragraph 7.2

Unless otherwise specified, contractually required inspections and tests shall be performed by a qualified person(s) other than the person(s) who performed the work being inspected or tested.

b. 1994 - Add to TRAINING: Paragraph 4.18

2000
2008 - Add to Competence, awareness and training: Paragraph 6.2.2
2015 - Add to Competence: Paragraph 7.2

Performance of qualified inspection and test personnel will be periodically assessed by the organization. Appropriate records of qualifications and periodic assessments shall be maintained.

4. **Records**

a. 1994 - Add to CONTROL OF QUALITY RECORDS: Paragraph 4.16

2000
2008 - Add to Monitoring and measurement of product: Paragraph 8.2.4
2015 - Add to Release of products and services: Paragraph 8.6

All records of contractually required inspection and test operations, and those records of manufacturing and assembly operations critical to safety, function, reliability or interchangeability of the component, shall be signed off by the individual completing the operation. The signature shall denote certification that the operation has been completed. The operation being signed for shall be clearly identified. When it is not practical for the individual completing the final step of the operation to sign, a supervisor may sign if, at the time of signature, there is objective evidence to substantiate that the operation has been completed. The sign-off should be performed using a permanent, legible signature or unique, protected identifier traceable to that individual. Protection from unauthorized changes of recorded data shall be provided. Guidelines for use of electronic signatures, when used, are identified in Addendum (1). The organization shall document how this requirement is implemented.

5. **Quality Audits**

a. 1994 - Add to INTERNAL QUALITY AUDITS: Paragraph 4.17

2000
2008 - Add to Internal audit: Paragraph 8.2.2
2015 - Add to Internal audit: Paragraph 9.2

The organization shall perform periodic, independent reinspection and retest of product previously inspected and/or tested, to confirm the acceptability of the previous inspection and test results.

6. **Interpretation of Limits**

a. 1994 – Add to Quality planning: Paragraph 4.2.3

2000
2008 – Add to Planning of product realization: Paragraph 7.1
2015 – Add to Operational planning and control: Paragraph 8.1

Where not otherwise contractually invoked, all specified limits for machining services and for dimensional control of deliverable parts and assemblies shall be interpreted as absolute limits as defined by ASTM E29, Standard Practice for Using Significant Digits in Test Data to Determine Compliance with Specifications. Unless otherwise specified in the contract, for all other observed, measured or calculated product characteristics (e.g. for material suppliers, material distributors, services other than machining) specified limits shall be interpreted using round-off method as defined by ASTM E29.

7. **NDT Program Requirements**

a. 1994 – Add Verification of nondestructive testing: Paragraph 4.6.4.3

2000
2008 – Add to Verification of purchased product: Paragraph 7.4.3
2015 – Add to Type and extent of control: Paragraph 8.4.2

The organization shall ensure the adequacy of all subcontracted nondestructive testing by using a qualified test examiner or similarly skilled individual, or by using external providers who have demonstrated acceptable performance, or by alternate methods agreed to by the customer.

8. **Documented Information**

a. 2015 – Add to Documented information – General: Paragraph 7.5.1

The organization shall create a documented procedure to define the control(s) needed for NNPP documented

information.

b. 2015 - Add to Management review inputs: Paragraph 9.3.2

The organization shall retain the management review inputs as documented information.

9. Corrective Actions

a. 2015 - Add to Monitoring, measurement, analysis and evaluation - General: Paragraph 9.1.1

The organization shall take corrective action as appropriate when planned results are not achieved.

b. 2015 - Add to Nonconformity and corrective action: Paragraph 10.2

The organization shall create a documented procedure for reacting to nonconformities including identifying the nonconformities, determining the causes of the nonconformities, evaluating the need for actions to prevent reoccurrence of the nonconformities, implementing the required actions to correct the nonconformities, reviewing of the effectiveness of the corrective action taken to prevent reoccurrence of the nonconformances, updating risks and opportunities as necessary, and making changes to the quality management system as necessary.

Addendum 1 to STR-ISO 9000 Supplement A

Electronic Signature Guidelines

Where signatures are required by contract and will be provided electronically, the following guidelines should be used:

1. Definitions

1.1 Electronic Signature - the electronic signature is equivalent to a person's handwritten signature . It indicates approval or certification of information or action(s) in the same manner as pen-and-ink signature.

1.2 Electronic Identification - is an electronic means of identifying a signer of an electronic record, document transaction, or instrument. It is unique and attributable to only one person. Examples of various electronic identifications include but are not limited to; an identifying keystroke, a password, a personal identification number (PIN), or a token or magnetic key.

2. Electronic Signature Process Controls - The controls for the electronic signature process should provide:

(a) the signer to take a distinct action to "sign" electronically.

(b) a means to delegate signature authority which allows the delegated individual to utilize their own electronic identification (i.e., integrity of each person's electronic signature must be preserved.)

(c) a means to identify the electronic signer by name on the electronic or paper version of the document and be maintained for the retention life of the electronic record.

(d) prevention of unauthorized access to electronic identifications.

(e) an established password policy to change electronic identification and not share electronic identification.

(f) reviews to ensure proper use of electronic signatures.

(g) a means to identify an electronic signature on a record as an electronic signature.

3. Electronic Identification/Authentication - One method of authentication is required to be provided at the time of signature. The authentication method must be based on something known only to the signer (e.g., a password) or based on something only the signer possesses (e.g., a card or other device).