

Quality Program for Suppliers: General Industry

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The American Society of
Mechanical Engineers

Quality Program for Suppliers: General Industry

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Date of Issuance: May 20, 2021

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FOREWORD

On August 6, 2019, the ASME Board on Conformity Assessment authorized the formation of a Project Team to address complaints against suppliers who are feeding items of poor quality into the pressure equipment supply chain. The scope of work was further expanded to permit ASME to take an active role in the supply chain for general industry. The QPS standard was developed specifically by and for ASME to establish a level playing field by which ASME, Suppliers, and Purchasers can work together on improving the quality of items entering the supply chain. The goal is to establish a global network of ASME suppliers for general industry which can be relied upon to supply items in conformance to the technical and quality requirements identified on an ASME certificate.

This Standard is an ASME certification product based on agreements with entities seeking to improve quality within the general industry supply chain. The standard was developed by a Project Team of subject matter experts from various industries; it is neither a consensus standard nor an American National Standard. ASME has approved its issuance and publication as a certification product under the purview of the Board on Conformity Assessment on April 26, 2021.

ASME gratefully acknowledges the time, effort, and dedication of the many people and organizations that assisted and contributed in the development of this Standard. The following deserve special recognition for their work on the standard.

- P. Williams, QRCS, Ltd.
- A. Appleton, Alloy Stainless Products Co., Inc.
- J. Cameron, The Hartford Steam Boiler Inspection and Insurance Co.
- G. Gobbi, 3HCSI Srls
- D. Jensen, Optimum Performance Solutions
- C. Smith, Smith Associates Consulting Group LLC
- R. R. Stevenson, Richard R. Stevenson, P.E., and Associates, LLC
- D. Tuttle, Emerson

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E. Whittle, *Ex-Officio Member*, OneCIS Insurance Co., a Bureau Veritas Co.
R. V. Wielgoszinski, *Ex-Officio Member*, The Hartford Steam Boiler Inspection and Insurance Co.
C. Smith, *Contributing Member*, Smith Associates Consulting Group, LLC

QPS PROJECT TEAM

P. Williams, *Project Team Manager*, QRCS, Ltd.
A. Appleton, Alloy Stainless Products Co., Inc.
J. Cameron, The Hartford Steam Boiler Inspection and Insurance Co.
G. Gobbi, 3HCSI Srls
D. Jensen, Optimum Performance Solutions

P. Lang, The American Society of Mechanical Engineers
G. Moino, The American Society of Mechanical Engineers
J. Pang, The American Society of Mechanical Engineers
C. Smith, Smith Associates Consulting Group, LLC
R. R. Stevenson, Richard R. Stevenson, P.E., and Associates, LLC
D. Tuttle, Emerson

CORRESPONDENCE WITH ASME

General. ASME codes and standards are developed and maintained with the intent to represent the consensus of concerned interests. As such, users of this Standard may submit inquiries seeking clarification or propose revisions and attend meetings. Correspondence should be addressed to:

Secretary, Board on Conformity Assessment
The American Society of Mechanical Engineers
Two Park Avenue
New York, NY 10016-5990
<http://go.asme.org/Inquiry>

Attending Committee Meetings. The Board on Conformity Assessment regularly holds meetings and/or telephone conferences that are open to the public. Persons wishing to attend any meeting and/or telephone conference should contact the Secretary of the Board on Conformity Assessment.

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Chapter 1

Introduction, Scope, Definitions, and References

1-1 INTRODUCTION

(a) *General.* This Standard identifies the basic requirements to be addressed under a Quality Program Supplier (QPS) Certificate. The QPS Certificate Holder shall establish a formalized set of controlled documents such as a Quality Manual, procedures, instructions, forms, and other discretionary documents that are specific to each of their processes. This formalized set of controlled documents establishes the quality program that has been implemented and proven to provide, on a consistent basis, products satisfying the specified requirements in a technical job file. The 17 essential requirements addressed in [Chapter 2](#) of this Standard shall be addressed in a Quality Manual; elements that do not apply shall be identified in the manual with rationale supporting the basis for their exclusion.

(b) *Requirements.* The requirements of this Standard, in total, shall be addressed in a quality program. These requirements should be addressed in a stand-alone quality program. When integrating into an existing quality management system or quality program, the Certificate Holder shall document and demonstrate how all 17 essential requirements in [Chapter 2](#) of this Standard are fully addressed. The established quality program is to be developed, maintained, and implemented to ensure the outputs of each process are in compliance with the mandatory requirements specified in this Standard and the original source specification for the product, i.e., the customer agreement or a product specification. The Certificate Holder shall notify the ASME Conformity Assessment Department of any significant changes that may affect conformance with this Standard and seek ASME approval prior to implementation.

(c) *Implementation.* The implementation of the quality program described in this Standard emphasizes the importance of

- (1) producing a technical job file to provide quality products under a controlled environment
- (2) management's commitment to fostering an atmosphere of continual process improvements
- (3) providing necessary and adequate resources to maintain a quality program in a well-maintained and properly staffed and equipped facility

(d) *Definitions.* As used in this Standard and in the Certificate Holder's established quality program, the following terms shall have the following meanings:

- (1) The word "shall" denotes a mandatory requirement.
- (2) The word "should" denotes a recommendation.
- (3) The word "may" indicates a permission. It is neither a requirement nor a recommendation.
- (4) The word "can" indicates a possibility or capability. It is neither a requirement nor a recommendation.

(e) *Health and Safety.* This Standard does not purport to address all of the safety concerns, if any, associated with its use. It is the responsibility of the user of this Standard to establish appropriate safety and health practices and determine the applicability of any regulatory limitations prior to use.

(f) *ASME Certification.* An organization desiring to become a Certificate Holder under ASME QPS shall make an application through the ASME Conformity Assessment Department. The issuance, preservation/maintenance, renewal, suspension, or withdrawal of a QPS Certificate is determined by ASME based on the results of surveys, audits, surveillance, and investigations conducted by ASME-certified auditors. The Certificate Holder is permitted to certify its products through issuance of a Certificate of Conformance (CofC), identifying its ASME Certificate number under the terms of the signed ASME agreement. The product shall not be stamped with any ASME-registered markings or contain statements in the Certificate of Conformance indicating product certification by ASME.

1-2 SCOPE

This Standard establishes the essential requirements of a quality program for the manufacture of products used within the general commercial and industrial sectors to facilitate commerce of goods and services. As defined in this Standard, a product can be a service or a physical item. The product may range from raw materials to the finished product used by the end user, an in-process item or material requiring additional processing by one or more organizations, or an item produced for inventory purposes.

1-3 TERMS AND DEFINITIONS

The following are terms and definitions used in this Standard.

annual: a 12-month period in which an event is to occur in the same month for each successive year. The specific month completing the 12-month cycle and identified as “month 12” is initially established and identified under the Certificate Holder’s quality program. Other than the number of days in a given month, there is no allowance for a grace period unless specifically permitted under ASME QPS.

authorized personnel: as documented within the Certificate Holder’s quality program, identified personnel or role titles given specific authorization to perform a specific activity, function, process, or special process.

customer agreement: a document, inclusive of any amendments, annexes, or attachments, that is issued by the customer to the Certificate Holder and specifies a product, including its technical and quality requirements; may also be known as a “contract” or “customer purchase order.”

Certificate Holder: an organization having or renewing a QPS Certificate issued by ASME, or an organization operating under a QPS Certificate issued by ASME.

competency examination: a written or practical test, or a combination of both, administered to determine an individual’s knowledge and competence.

competency requirements: attributes necessary to perform a task or process satisfactorily, such as specific skills, abilities, personal attributes, training, experience, knowledge, or any combination thereof when identified in the quality program. These attributes may be further grouped as requisites or prerequisites.

competency matrix: a document identifying a specific task or process and the elements of the competency requirements that must be satisfied by an individual. The specific task or process is undertaken by someone who meets the competency requirements.

credentialed person: see *credentialed personnel*.

credentialed personnel:

(a) an individual having current documentary evidence of proven competency in a specific subject area, which is achieved via attainment of a post-secondary degree, license, professional registration, or certification. Credentials may be gained in-house or via a creditable recognized third party. Proven competency is based on successfully passing a competency examination.

(b) an individual having documentary evidence of completing an educational or training program on a specific subject area through a certificate. Credentials may be gained in-house or via a creditable recognized third party.

discrepant: a condition outside of an established tolerance or requirement.

executive management: a person or group of people who direct and control the Certificate Holder’s activities at the highest level. The person ultimately responsible for the establishment of the quality program need not be physically situated at the location where activities are performed. This is a generic term used to establish a functional role and may not be the actual title assigned by the Certificate Holder; the title of the person or group is established by the Certificate Holder and identified in its organizational chart.

grace period: an allowance that modifies the term “annual” by a maximum period of plus or minus 3 months when specifically permitted by this Standard. The performance of an activity within the bounds of this allowance does not change the original 12-month cycle or “month 12” as defined under the term “annual.”

inspection: activities performed by authorized personnel to verify that a product is in conformance with the requirements of this Standard and the technical job file. Nondestructive examination (NDE) activities are considered to be an inspection.

internal audit: an activity initiated by the Certificate Holder to provide impartial assurance that its quality program has been properly documented and is being effectively implemented as documented in the quality program manual and subtier documents.

manufacture: an all-inclusive term for one or more of the following processes to produce a product: certification, design, assembly, fabrication, installation, purchasing, testing, inspection, quality control, quality assurance.

monitor: to observe or check an individual’s performance or the operation of a process for compliance with the requirements specified in the technical job file, this Standard, or the Certificate Holder’s quality program.

nondestructive examination (NDE): the development and application of technical methods to examine products in ways that do not impair future usefulness and serviceability in order to detect, locate, measure, interpret, and evaluate flaws.

purchase order: a document, inclusive of any amendments, annexes or attachments, prepared by the Certificate Holder and issued to a supplier that specifies a product, including its technical and quality requirements.

procurement: the activities performed within a Certificate Holder's internal organizational structure for selection of a suitable supplier or sources and generation of a purchase order.

product:

(a) the item or service to be supplied by the Certificate Holder in conformance with the requirements of this Standard and the requirements specified in the technical job file. The final output under a QPS Certificate will produce a physical hardware item, a software item, a certified document reporting the results of services performed, or any combination thereof.

(b) an item, service, or material procured by the Certificate Holder and used as an input in the manufacturing process.

quality manager: an individual who has been appointed by the executive management to be responsible for the implementation of an effective quality program based on the established competency requirements of the Certificate Holder's quality program. This is a generic term used to establish a person's function and may not necessarily be the actual title assigned by the Certificate Holder; this person's title is established by the Certificate Holder and identified in its organizational chart.

quality personnel: individuals who are employed by the Certificate Holder and report directly or indirectly to the quality manager.

quality requirements: documentation establishing the performance of assurance and verification activities to ensure the product's conformance with its original source specification.

significant change: a change that could potentially affect continued conformance with the specific requirements of this Standard or the ASME certificate; such changes could include, but may not be limited to

- (a) organizational structure changes
- (b) personnel changes within the management team
- (c) substantial changes to the Certificate Holder's quality program processes
- (d) the introduction of new processes or equipment (for example, moving from a manual to an automated process)
- (e) a change in address

special process: a process whose output is highly dependent on the control of the process or the skill of the individual performing the process, or both, and the specified quality of the product cannot be readily determined by inspection or test; or a process that is deemed critical, requiring the use of qualified and approved procedures by personnel who have been qualified to perform the process.

technical job file: the conversion of the product's original source specification either from a customer agreement or a product specification into documents controlled under the Certificate Holder's quality program. These controlled documents are identified or assembled to establish the manufacturing processes and acceptance criteria required to manufacture the product in conformance with the original source specification. The documents, which ensure the product's technical and quality requirements will be achieved and verified by the Certificate Holder's personnel, include but are not limited to the customer agreement, drawings, instructions, specifications, standards, process sheets, travelers, labels and tags, and product specification.

technical manager: an individual who has been appointed by the executive management to be responsible for the Certificate Holder's technical activities based on the established competency requirements of the Certificate Holder's quality program. This is a generic term used to establish a person's function and may not necessarily be the actual title assigned by the Certificate Holder; this person's title is established by the Certificate Holder and identified in its organizational chart.

technical personnel: individuals who are knowledgeable of the product specified in the customer agreement or product specification and understand the technical requirements of the product. The individual is knowledgeable in the methodology and equipment, tooling, and machinery needed to fabricate the product.

technical requirements: documentation defining the product's functional requirements, which include design requirements, physical characteristics, chemical composition, features, performance requirements, intended purpose, or any combination thereof.

test: an element of verification that determines the capability of a product to meet its technical requirements by subjecting the product to specified physical, chemical, environmental, or operating conditions.

1-4 REFERENCE

The following publication is referenced in this Standard. The latest edition shall apply.

ISO/IEC 17025, General requirements for the competence of testing and calibration laboratories

Publisher: International Organization for Standardization (ISO), Central Secretariat, Chemin de Blandonnet 8,
Case Postale 401, 1214 Vernier, Geneva, Switzerland (www.iso.org)

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Chapter 2

Quality Program Requirements

2-1 QUALITY PROGRAM

2-1.1 General

(a) A description of the Certificate Holder's quality program shall be documented in a manual. The manual shall include a statement of policy and authority indicating executive management support for implementing an effective quality program. An organizational chart identifying the functional responsibilities and authority of the individuals affecting quality in the Certificate Holder's organization shall also be included.

(b) The quality program shall provide for indoctrination and, when required, training of personnel performing activities affecting quality to ensure that suitable competency and proficiency (competency requirements) are achieved and maintained. The defined competency requirements shall identify the qualitative and quantitative traits that are appropriate and suitable for the scope and complexity of the quality program, including where credentialed personnel may be required. The competency matrix shall identify tasks or processes and personnel who meet the defined competency requirements to undertake each task or process.

2-1.2 Quality Manual

(a) The manual shall identify the scope of activities and products to which it applies and shall address the role and activities undertaken by ASME in protecting the integrity of the ASME certificate. The establishment of the quality program shall include consideration of the technical aspects of the activities affecting quality. The quality program shall provide control over activities affecting quality to an extent consistent with their importance.

(b) The manual shall include a definition of "significant change" appropriate to the Certificate Holder's business and a process for ensuring ASME approval is sought and obtained for any significant changes falling under this definition prior to implementation.

(c) The manual shall be auditable and shall address the essential controls for each requirement within this Standard. The use of flowcharts, matrices, tables, and charts is encouraged when they can accurately depict how conformance with the requirements of this Standard is achieved.

(d) The manual shall be supported by procedures, work instructions, forms, and other documentation, as necessary, to define and manage the controls and measures established to ensure the product manufactured by the Certificate Holder conforms to the requirements of this Standard and the technical job file.

(e) The documents identified under (a), (c), and (d) form the quality program, which shall be implemented to provide for the planning and accomplishment of activities affecting quality under suitable controlled conditions. Controlled 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. The quality program shall provide for any special controls, processes, test equipment, tools, and skills to attain the required quality and for verification of quality.

2-1.3 Delegation of Duty

Individual management roles identified on the organizational chart may delegate a duty when controls for such role assignments are established under the quality program to ensure the delegate is competent to perform the delegated activities. The manager delegating a duty shall be accountable for determining the delegate's competency for completing the assignment satisfactorily and retain responsibility for all delegated duties.

2-1.4 Authorized Personnel

Authorized personnel shall be used to control

(a) access to financial or other resources or to documents related to the implementation of the quality program. Authorization levels shall be assigned to authorized personnel and documented in the quality program.

(b) the initiation or discontinuation of a specific task or process under the quality program. Prior to initiation, measures shall be in place for the use of authorized personnel who are identified on the competency matrix as meeting the defined competency requirements for the specific task or process.

(c) the quality of work through requirements for individuals to undergo additional training and development to improve productivity or performance.

2-2 ORGANIZATION

2-2.1 General

(a) The organizational structure, functional responsibilities, levels of authority, and lines of communication for activities affecting quality shall be documented. Executive management involved in the monitoring of the quality program under [section 2-15](#) shall be identified in the organizational structure. An individual from executive management shall be responsible for assuring that an appropriate quality program is established.

(b) All personnel shall have sufficient authority, access to work areas, and organizational freedom to identify quality problems.

(c) Technical and quality personnel, in particular, shall be responsible for verifying that all activities affecting quality have been correctly performed to meet the requirements specified by the approved technical job file.

2-2.2 Credentialed Personnel

Roles, processes, or tasks requiring credentialed personnel shall be identified within the quality program and defined as part of the competency requirements. As a minimum, the following roles shall require the use of credentialed personnel:

- (a) quality manager
- (b) nondestructive inspection personnel
- (c) welders; brazers; and welding, brazing and fusing operators
- (d) internal auditors and auditors

2-2.3 Competency Requirements — Quality Manager

The competency requirements established for the quality manager within the quality program manual shall include the requirement that the person be credentialed through the completion of a formal ASME training course on the QPS standard. The competency requirements shall provide assurance that the individual has the necessary experience in the field of quality and a background aligned with the scope and complexity of the quality program.

2-2.4 Competency Requirements — Technical Manager

The competency requirements established for the technical manager within the quality program manual shall require a competent person suitable for the scope and complexity of work performed under the quality program. The competency requirements shall provide assurance that the individual has the necessary technical qualifications, background, knowledge and understanding of the Certificate Holder's products, including related design standards and manufacturing processes.

2-2.5 Assessment of Resources by Executive Management

The executive management shall ensure that it has sufficient resources to fully and effectively implement the activities defined within its quality program. The executive management shall undertake a periodic review, at least on an annual basis (see [section 2-15](#)), to determine whether

- (a) personnel resource levels remain at an adequate level or if there is a need for recruitment
- (b) existing personnel require additional training and development to improve capability, capacity, productivity, or performance

2-3 DOCUMENT CONTROL

2-3.1 General

(a) The preparation, approval, issuance, and change of internally established documents that specify quality requirements or prescribe activities affecting quality shall be controlled to ensure correct and approved documents are used. These documents shall be reviewed for adequacy and approval prior to release by authorized personnel. Changes to these documents shall be reviewed and approved by defined authorized personnel.

(b) Externally established documents, such as customer agreements, normative references, and standards, shall be reviewed for adequacy by authorized personnel prior to release as an approved document for use under the Certificate Holder's quality program or the technical job file.

2-3.2 Competency Matrix

The competency matrix shall identify the types of documents and the individuals who meet the competency requirements to prepare, approve, and issue such documents for use under the Certificate Holder's quality program.

2-3.3 Access to Controlled Documents

(a) Measures shall be in place to ensure that the current version of approved documents are accessible and used as follows:

- (1) by production personnel to achieve conformance
- (2) by technical and quality personnel to verify the achievement of conformance

(b) The documents that shall be controlled under [section 2-3](#), include, but are not limited to, the following:

- (1) Quality Program Manual and subtier documents such as, but not limited to, procedures, work instructions, drawings, forms, tags, and labels
- (2) technical job file
- (3) ASME agreement and ASME certificate
- (4) product specification document
- (5) normative references, standards referenced under the quality program, customer agreement, and product specification document
- (6) purchase orders
- (7) competency matrix
- (8) approved suppliers list

2-4 TECHNICAL JOB FILE REQUIREMENTS

2-4.1 General

There shall be a technical job file for each product produced under the Certificate Holder's quality program that identifies the technical and quality requirements to be achieved and verified.

2-4.2 Preparation, Review, and Approval of Technical Job Files

(a) The technical job file shall be prepared by technical and quality personnel as a controlled document. Technical and quality personnel shall transcribe the technical and quality requirements of the product as specified in the original source specification, from either the customer agreement or a product specification, as process requirements. The technical and quality requirements shall be defined through, but not limited to, drawings, procedures, work instructions, process sheets, forms, travelers, labels, and tags. The personnel involved in performing the prescribed activities shall have access to these controlled documents, as appropriate to their job function and responsibilities.

(b) The technical job file shall identify the processes where credentialed personnel are required.

(c) Technical and quality personnel shall determine the type of inspections and testing (quality control activities) required to verify the achievement of quality. The completed technical job file shall be verified by authorized personnel for accuracy and correctness to the original source specification for the product. The competency matrix shall identify personnel who satisfy the defined competency requirements to prepare, review, and approve the technical job file.

(d) Certificate Holders not performing or assuming design responsibility shall have technical personnel control use of the customer's design documents, including customer approved changes, within its technical job file.

2-5 INSTRUCTIONS, PROCEDURES, AND DRAWINGS

2-5.1 General

Activities affecting quality shall be prescribed by and performed in accordance with documented instructions, procedures, or drawings of a type appropriate to the circumstances. These documents shall include or reference appropriate quantitative or qualitative acceptance criteria for determining that prescribed activities have been satisfactorily accomplished.

2-5.2 Preparation, Review and Approving for Use

Documented instructions, procedures, internal specifications, or drawings shall be reviewed for adequacy and approved for release in accordance with [section 2-3](#). The competency matrix shall identify personnel who meet the defined competency requirements to perform the prescribed activities.

2-6 PROCUREMENT DOCUMENT CONTROL

2-6.1 General

(a) The procurement process begins with the selection of a supplier in accordance with [section 2-7](#). The activities of the supplier shall be specified through the issuance of a purchase order.

(b) Purchase orders shall contain sufficient technical and quality requirements to ensure the procured product or products meet the specifications identified in the technical job file or, when procured for inventory as a future manufacturing input, the product specification. Additional detailed requirements affecting delivery and schedules shall be specified in the purchase order.

2-6.2 Preparation, Review, and Approval for Release of Purchase Orders

(a) In accordance with [section 2-3](#) the Certificate Holder shall establish controls for the provision of purchase orders, including updates, to ensure they are correct and approved prior to release to suppliers.

(b) Prior to issue, each purchase order shall be reviewed by authorized personnel to ensure all specifications contained in either a technical job file or, when procured for inventory as a future manufacturing input, the product specification have been appropriately documented.

(c) The competency matrix shall identify personnel who meet the defined competency requirements to prepare, approve, and release purchase orders.

2-7 CONTROL OF PROCURED PRODUCTS

2-7.1 General

Procured products for inventory as a future manufacturing input or as inputs for the realization of the final product(s) under a technical job file shall be obtained from an approved supplier, a supplier specified by the customer, or from the customer themselves.

2-7.2 Procurement of Product From an Approved Supplier

The Certificate Holder shall be responsible for product(s) procured from an approved supplier. The Certificate Holder shall have measures for controlling the identification, handling, and storage of such product(s) from receipt until use as an input in the manufacturing process.

2-7.3 Procurement of Product From a Supplier Specified by the Customer

Where the customer agreement requires the use of a specific supplier, the Certificate Holder shall be responsible for the inspection of the products received. The Certificate Holder shall have measures for controlling the identification, handling, and storage of such product(s) from receipt until use as an input in the manufacturing process.

2-7.4 Customer Supplied Product

Where products are provided by a customer, generally known as “customer supplied products,” the Certificate Holder shall be responsible for receiving inspection to ensure the product or products conform to the requirements of the technical job file and are suitable as an input in the manufacturing process. The Certificate Holder shall have measures

for controlling the identification, handling, and storage of the customer supplied product(s) from the time of receipt until use as an input in the manufacturing process.

2-7.5 Approved Supplier Evaluation

The process for identifying a supplier as an approved supplier shall be controlled to ensure conformance with the requirements of this Standard and the specifications established in the technical job file or, in the case of procuring product for inventory, a product specification. The selection and evaluation of a supplier to be included on or removed from the approved supplier list shall be based on the documented results of one or more of the following tasks, performed as appropriate to the complexity and risk associated with the product:

(a) verification that an ASME Certificate provided by the supplier is acceptable for the scope of product to be procured. If so verified, those suppliers holding an ASME Certificate under this Standard may be considered approved suppliers without further action.

(b) review and acceptance of objective evidence of quality and conformance furnished by the supplier. This task shall be performed by personnel identified on the competency matrix as meeting the defined competency requirements for supplier evaluations.

(c) audit of the supplier's quality program, to be performed by a certified auditor (refer to [para. 2-15.3](#)).

(d) evaluation of the supplier's past performance history. This shall be performed by authorized personnel based on any or a combination of the following:

(1) source inspections at the supplier's facility performed by personnel identified on the competency matrix as meeting the defined competency requirements for source inspections

(2) surveillance at the supplier's facility performed by personnel identified on the competency matrix as meeting the defined competency requirements for surveillance

(3) inspection or testing, or both, of products upon delivery or completion performed by personnel identified on the competency matrix as meeting the defined competency requirements for inspection or testing (refer to [para. 2-10.6](#))

2-7.6 Source Documentation Package

The documents providing details on the product's conformance to the purchase order, or technical job file for customer supplied products, shall be obtained from the source supplier. The source supplier may transmit documents electronically or separately from the products when the documents can be traced back to the products.

2-7.7 Supplier Performance Management

When the Certificate Holder's quality program requires a supplier to be reviewed for the purposes of identifying an approved supplier, or for the performance management of a supplier specified by the customer, the task of conducting a supplier review shall be performed by authorized personnel.

(a) The task of conducting an audit of a supplier's quality program shall be undertaken by certified auditors identified in the competency matrix as satisfying the defined competency requirements for supplier audits. The quality program shall establish the competency requirements for personnel undertaking supplier audits (refer to [para. 2-15.3](#)). The frequency and extent of supplier audits shall be defined through a documented audit schedule, the extent of which will depend on the scope and complexity of the quality program and the production schedule of the supplier. The audit schedule shall be established by the quality manager to make the audits meaningful.

(b) The task of conducting a source inspection or surveillance shall be undertaken by personnel identified in the competency matrix as satisfying the defined competency requirements for source inspections and surveillance. The quality program shall identify the competency requirements for personnel undertaking source inspections and surveillance.

(c) The task of conducting inspections or tests, or both, upon delivery or completion shall be undertaken by personnel identified in the competency matrix as satisfying the defined competency requirements for inspections and tests. The quality program shall identify the competency requirements for personnel undertaking inspections and tests.

2-7.8 Receiving Inspection

Receipt inspection shall be performed when both the product and the associated source documentation package are available for inspection. For multiple items produced and procured under the same heat, lot, or batch, receipt inspection may be performed on a sample. If a 100% inspection is not used, the number of samples and selection of samples shall be based on a sample plan developed and approved by quality personnel.

(a) All products procured from an approved supplier or the supplier specified by the customer shall be subjected to verification that the purchase order requirements have been met. Verification can include inspection or testing of products, or both, upon completion at the source supplier's facility or on delivery.

(b) All products supplied by the customer as inputs for further processing under the customer agreement shall be inspected or tested to ensure the items received have been properly identified, are associated with proper documentation, and meet the specifications established in the technical job file.

The competency matrix shall identify quality personnel who satisfy the defined competency requirements to undertake receiving inspections and, when part of the Certificate Holder's quality program, the development and approval of an inspection sampling plan.

2-8 CONTROL AND IDENTIFICATION OF PRODUCTS

Controls shall be established to ensure that only correct and accepted products, procured products, and in-process products are used as inputs to produce the final product specified in the technical job file. Products used as inputs for the realization of the final product shall be identified and controlled while in the custody of the Certificate Holder. Identification shall be established and always maintained

(a) on the products, or

(b) in documents traceable to the products

2-9 CONTROL OF PROCESSES

2-9.1 General

(a) All processes and tasks affecting the quality of product shall be controlled and performed by competent personnel. The Certificate Holder's quality program shall establish the competency requirements for personnel undertaking production activities that transform the properties or function of the product. The competency matrix shall identify these processes, including special processes, and tasks and identify the individuals satisfying the competency requirements specified in the technical job file.

(b) Products shall be manufactured using documentation such as process sheets, shop procedures, checklists, travelers, or equivalent documents identifying the technical and quality requirements specified in the technical job file. Products manufactured for inventory shall also meet the requirements of this Standard and the relevant technical job file.

2-9.2 Identifying and Controlling a Special Process

Special processes shall be identified in the quality program manual and include but are not limited to heat treatment, welding, brazing, fusing, and surface treatment. Special processes shall be performed by authorized personnel using the qualified and approved procedures specified in the technical job file.

(a) Authorized personnel performing a special process shall be those who meet the defined competency requirements and demonstrate competency by producing satisfactory results using the qualified and approved procedures specified in the technical job file. The achievement of satisfactory results shall be verified as a quality control function through inspection or testing, or both, in accordance with [section 2-10](#).

(b) The quality program shall have measures for authorized personnel performing a special process to maintain or renew their proficiency.

(c) When credentialed personnel are used to perform a special process, the documented competency requirements specified under [para. 2-1.1\(b\)](#) shall

(1) identify the type of credentials required

(2) identify the organization or type of organization issuing the credentials

(3) establish the requirements for maintaining and renewing the defined credentials or proficiency

2-9.3 Planned Maintenance

A planned maintenance system shall be in place. When maintenance and repairs are conducted internally, personnel shall be identified on the competency matrix. When maintenance and repairs are subcontracted, an approved supplier shall be used in accordance with [para. 2-7.5](#) for the procurement of a service under a purchase order identifying the technical and quality requirements for the maintenance or repair of machinery and equipment.

2-10 INSPECTIONS AND TESTS

2-10.1 General

Inspections and tests shall be established to ensure conformance with the requirements of this Standard and the technical job file. For products manufactured in batches, lots or heats, a sampling plan can be used when permitted by the quality program. The sampling plan shall be documented and verified by quality personnel to provide a suitable level of confidence in conformance.

2-10.2 Inspections

Inspections required to verify conformance of a product to specified requirements shall be planned. Characteristics to be inspected, methods to be used, and the acceptance criteria shall be specified by technical personnel and documented. The inspection results shall be documented by the person performing the inspection, and their conformance with acceptance criteria shall be evaluated by personnel identified in the competency matrix.

2-10.3 Tests

Tests required to verify conformance to the technical job file requirements shall be planned. Characteristics to be tested, test methods to be used, and the acceptance criteria shall be specified by technical personnel and documented. Test results shall be documented by the person performing the test, and their conformance with acceptance criteria shall be evaluated by personnel identified in the competency matrix.

2-10.4 Testing Laboratory

(a) When a test is subcontracted, the testing laboratory shall be accredited to the requirements of ISO/IEC 17025 by an accreditation body. Measures shall be in place to verify the laboratory is providing work under the scope of its accreditation and under an accreditation that has not expired nor been withdrawn or suspended.

(b) As an alternative, organizations performing testing activities shall as a minimum meet the requirements of ISO/IEC 17025. The placement of a supplier on the approved supplier list as a testing laboratory shall involve the quality manager implementing [paras. 2-7.2, 2-7.5, and 2-7.7](#) to evaluate, at a minimum, the results of the annual supplier audits to determine the supplier's capability of meeting ISO/IEC 17025.

2-10.5 Inspection and Test Status Indicators

The status of inspection and test activities performed as a quality control activity shall be identified either on the products or in documents traceable to the products where it is necessary to ensure that required inspections and tests are performed.

(a) Nonconforming or deficient products, tooling, equipment, and machinery shall be properly identified to avoid being inadvertently installed, used, or operated.

(b) Inspection and test status shall be maintained through indicators such as physical location and tags, markings, shop travelers, stamps, inspection records, barcode, quick response (QR) code, radio frequency identification (RFID), or other suitable means.

2-10.6 Competency Requirements — Inspection and Test Personnel, Production and Quality Personnel

(a) In-process checks may be performed by personnel performing the work as a function of production. Final process checks should be performed by persons other than those who performed or directly supervised the work. Inspections and tests performed as a quality control function for acceptance and release from hold points shall be performed by competent personnel. The quality program shall establish the competency requirements for personnel undertaking inspections and tests. The competency matrix shall identify these inspections and tests and indicate the individuals satisfying the competency requirements.

(b) The documented competency requirements specified under [para. 2-1.1\(b\)](#) shall be based on the intricacy and complexity of the inspections and tests to be conducted and instruments or equipment to be used. When credentialed personnel are used to perform an inspection or test, the documented competency requirements shall

- (1) identify the type of credentials required
- (2) identify the organization or type of organization issuing the credentials
- (3) establish the requirements for maintaining and renewing the defined credentials or proficiency

For nondestructive examination activities, the competency requirements for each method and technique shall require the activity to be performed by credentialed personnel.

2-11 CONTROL OF MEASURING AND TESTING EQUIPMENT

2-11.1 General

Controls shall be in effect to ensure that tools, gauges, instruments, and other measuring and testing equipment used for production activity or as a quality control activity are calibrated and properly adjusted at specific periods or use intervals to maintain accuracy within necessary limits. The frequency at which measuring and testing equipment is to be calibrated and adjusted to maintain accuracy within necessary limits shall be specified. Periodic checks on these devices shall be performed to determine that calibration is maintained. Calibration records shall be traceable to the equipment.

2-11.2 Calibration of Measuring and Testing Equipment

(a) Calibration shall be made against certified calibration standards having known valid relationships and documented traceability to nationally recognized standards, where such standards exist. If no known nationally recognized standard exists, the basis for calibration shall be documented.

(b) When the Certificate Holder performs calibration activities in-house, an individual shall be appointed and designated as the responsible manager. The competency requirements for this manager shall ensure knowledge and understanding of ISO/IEC 17025 principles and the manager preferably shall have experience in calibration. The in-house calibration activities are to be performed by individuals trained in the required calibration methodology and shall be identified in the competency matrix. The depth of training for these individuals shall be identified and documented based on the intricacy of the calibration activities and the complexity of the measuring and testing equipment under calibration.

2-11.3 Calibration Laboratory

(a) When calibration is subcontracted, the calibration laboratory shall be accredited to the requirements of ISO/IEC 17025 by an accreditation body. Measures shall be in place to verify the laboratory is providing work under the scope of its accreditation and under an accreditation that has not expired nor been withdrawn or suspended.

(b) As an alternative, organizations performing calibration activities shall as a minimum meet the requirements of ISO/IEC 17025. The placement of a supplier on the approved supplier list as a calibration laboratory shall involve the quality manager implementing [paras. 2-7.2, 2-7.5, and 2-7.7](#) to evaluate, at a minimum, the results of the annual supplier audits to determine the supplier's capability of meeting ISO/IEC 17025.

2-11.4 Calibration Status Indicators

Control measures shall include provisions for measuring and testing equipment identification and determining calibration status. The identification shall provide sufficient visual information to personnel without personnel having to obtain the current calibration status elsewhere.

2-11.5 Discrepancies in Measuring and Testing Equipment

When discrepancies beyond an acceptable tolerance range for measuring and testing equipment are found during calibration, the discrepant measuring and testing equipment shall be processed as a nonconformity per [section 2-13](#). Appropriate corrective actions shall be taken and shall include the evaluation of past products (including shipped products) measured or tested since the previous calibration period to determine conformance with the requirements of this Standard and the established tolerances in the technical job file.

2-12 HANDLING, STORAGE, AND SHIPPING

Measures for the handling, storage, cleaning, packaging, shipping, and preservation of products to maintain the quality of the product shall be established. These measures shall be evaluated and approved by technical personnel.

2-13 CONTROL OF NONCONFORMITY

2-13.1 General

(a) Products or processes that do not conform to this Standard, the Certificate Holder's quality program, the technical job file, or the purchase order shall be controlled to prevent inadvertent installation, use, or operation.

(b) Adequate measures shall be provided for the identification, documentation, evaluation, segregation when practical, and disposition of nonconforming products or processes, and for notification to affected organizations. Technical and quality personnel shall be jointly responsible for the disposition of the nonconforming products and processes.