Quality Management System Requirements for Organizations Providing Products for the Petroleum and Natural Gas Industry

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Introduction

This specification has been developed to address quality management systems for organizations in the petroleum and natural gas industry. It defines the fundamental quality management system requirements for organizations claiming conformity to this specification.

This specification may be applied by organizations that provide product (3.1.~~17~~16) for use in the petroleum and natural gas industry. As defined in 3.1.~~17~~16, this specification uses the term “product” to refer to the “output of an organization intended to be provided to a customer”. Previous editions of this specification limited the application to organizations which manufactured a physical product, performed servicing on a physical product, or performed manufacturing-related processes. This edition addresses the following types of organizations in the petroleum and natural gas industry.

- manufacturing
- engineering/design
- physical product realization activity providers such as those performing:
  - welding
  - heat treating
  - coating/plating
  - machining
  - inspection
  - testing
  - servicing
- physical product-related activity providers such as those performing:
  - distribution
  - logistics
  - software development

The requirements of this specification are consistent with those of other quality management system documents. The requirements are intended to minimize the likelihood of nonconformity. While this specification may include some elements of other management systems (such as those particular to environmental management, occupational health and safety management, financial management, or risk management), it does not include all requirements specific to those systems. This specification may be used either in conjunction with or independent of other industry-specified documents.

This specification can be used by internal and external parties, including certification bodies, to assess the organization's ability to meet customer, statutory, and regulatory requirements applicable to the product and the organization's own requirements.

This specification promotes the integration of a process approach into the application of specific sections when developing, implementing, and improving the effectiveness of a quality management system. This provides for continuous control over the stated requirements, as well as facilitating the overlap of processes.

For an organization to function effectively, it has to determine and manage numerous linked activities. An activity that transforms inputs into outputs can be considered a process. Process activities include determination of needs throughout the organization, provision of resources and product realization, identification of the proper sequence or order in a series of activities, monitoring and measuring the effectiveness of the activities performed, and applying changes or corrections to those activities as needed.

Goal of the Specification

The goal of this specification is to provide the minimum requirements for the development of a quality management system that promotes reliability and provides for continual improvement, emphasizes prevention of nonconformities, and strives to minimize variation and waste. It is not the intent of this specification to imply uniformity in the structure of quality management systems or uniformity of documentation.

Significant Changes from the Ninth Edition to the Tenth Edition

Highlights of some of the significant changes between the ninth and tenth editions include:

- Alignment with the requirements of ISO 9001:2015
- Change of scope to include companies that provide product related activities
- Change definition of "product" to align with expanded scope
- Record retention period expanded to ten years
- Reference to outdated version of ISO 9000 removed
- Added alternatives to traditional Quality Manual
- "Design and Development" changed to "Design"
- Clarification on validation of processes
- Revised wording around product inspection and final acceptance process
- Revised supplier evaluation process
- Removed preventive action section
- Added and revised definitions

1 Scope

This specification establishes minimum quality management system requirements for organizations that provide products for use in the petroleum and natural gas industry.

2 Normative References

The following document is referred to in the text in such a way that some or all of the content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any addenda) applies.

ISO [1] 9000:2015, *Quality management systems—Fundamentals and vocabulary*

3 Terms, Definitions, and Abbreviations

3.1 Terms and Definitions

[1] International Organization for Standardization, ISO Central Secretariat, Chemin de Blandonnet 8, CP 401, 1214 Vernier, Geneva, Switzerland, www.iso.org.

For the purposes of this specification, the terms and definitions given in ISO 9000 and the following shall apply. When identical terms are defined in ISO 9000 and this specification, the following definitions shall apply.

3.1.1
acceptance criteria
Specified requirements of acceptability applied to product or process characteristics.
3.1.2
acceptance inspection
Demonstration through monitoring or measurement that the product conforms to specified requirements.
3.1.3
calibration
Process of comparison to a standard of known accuracy, comparison of results against TMMDE (testing, measuring, monitoring, and detection equipment) acceptance criteria, and, if applicable, making needed adjustment(s).

NOTE Calibration of non-adjustable equipment can be referred to as verification.

3.1.4
compliance
Act of satisfying (verb) or the status of having satisfied (noun) legal requirements.
3.1.5
critical
Deemed by the organization, product specification, or customer to be of significant importance and requiring specific action.
3.1.6
delivery
Point in time at which the agreed transfer of ownership takes place.
3.1.7
design acceptance criteria
DAC
Requirements applied to characteristics or combinations of those characteristics, of materials, products, or components to achieve conformity to the specified design requirements and/or required design performance.

NOTE 1 DAC can be equal to MAC.

NOTE 2 Required design performance is often stated in technical specifications.

3.1.8
design validation
Process of proving a design by testing to demonstrate that the product conforms to design requirements and performs as intended.

NOTE Design validation can include one or more of the following (this is not an all-inclusive list):

a) prototype tests,

b) functional and/or operational tests,

c) tests specified by industry standards and/or regulatory requirements,

d) field performance tests and reviews.

3.1.9
design verification
Process of examining design outputs to determine conformity with specified requirements.

NOTE Design verification activities can include one or more of the following (this is not an all-inclusive list):

a) confirming the accuracy of design results through the performance of alternative calculations,

b) review of design output documents resulting from design activities,

c) comparing new designs to similar proven designs.

3.1.10
key performance indicator
KPI
Quantifiable measure that an organization uses to gauge or compare performance.

3.1.11
legal requirement
Statutory or regulatory requirements.

3.1.12
Management personnel ~~[noun]~~
A person or group of persons with authority and responsibility for the conduct and control of all or part of an organization.

NOTE For some organizations, top management (see ISO 9000) and management personnel are the same.

3.1.13
manufacturing acceptance criteria
MAC
Requirements applied to characteristics or combinations of those characteristics, of materials, products, or components to achieve conformity to the applicable DAC (see 3.1.7) and other product manufacturing requirements.

NOTE 1 MAC can be equal to DAC.

NOTE 2 For services, product realization can be substituted for product manufacturing.

3.1.14
outsource
[outsourced activity]
Function or process that is performed by an external supplier on behalf of the organization.

~~**3.1.15**~~
~~**preventive maintenance**~~
~~Systematic servicing of equipment, machines and/or facilities for the purpose of maintaining a satisfactory operating condition.~~

3.1.~~16~~15
procedure
Organization's documented method for performing an activity under controlled conditions to achieve conformity to specified requirements.

NOTE 1 This definition was previously identified as a "control feature" in earlier editions of this specification.

NOTE 2 A procedure can be in many forms, e.g. work instructions, flow diagrams and manuals.

3.1.~~17~~16
product
Output of an organization intended to be provided to a customer.

NOTE As used in this document, the term 'product' can include, but is not limited to, hardware, software, production activities, or product related activities such as: servicing, storage, distribution, and logistics.

3.1.17~~8~~
product realization
Set of interrelated or interacting activities ~~(processes)~~ necessary to provide product.

3.1.18~~9~~
remote assessment
Assessment conducted by person(s) not physically present at the location being assessed.
3.1.19~~20~~
risk
A situation or circumstance that has both a probability of occurring and a potentially negative consequence.
3.1.20~~1~~
servicing
Maintenance, adjustment, and/or repair performed ~~on a product~~ after delivery and/or on-site installation.

3.1.~~22~~21
supply chain
Suppliers and associated sub-supplier(s) required for product realization.

3.2 Abbreviations

For the purposes of this specification, the following abbreviations shall apply.

DAC design acceptance criteria
ITP inspection test plan
KPI key performance indicator
MAC manufacturing acceptance criteria
MOC management of change
MPS manufacturing process specification
PCP process control plan
QAP quality activity plan
QMS quality management system
QP quality plan
TMMDE testing, measuring, monitoring, and detection equipment

4 Quality Management System Requirements

4.1 Quality Management System

4.1.1 General

The organization shall plan, establish, document, implement, and maintain at all times a quality management system in accordance with the requirements of this specification for product provided within the scope defined by the organization (see 4.1.4.1). The organization shall measure and improve the effectiveness of the quality management system.

4.1.2 Quality Policy

The organization's policy for its commitment to quality shall be defined, documented, reviewed, and approved by top management.

The quality policy shall:

a) be appropriate to the organization and support its strategic direction,

b) be the basis for the development of quality objectives (see 4.1.3),

c) be communicated, understood, implemented, and maintained within the organization,

d) be available to relevant interested parties, as specified by the organization, and

e) include a commitment to conform to requirements and continually improve the effectiveness of the quality management system.

4.1.3 Quality Objectives

Quality objectives, including those needed to meet product and customer requirements, shall be established at relevant functions and levels within the organization by management personnel with approval from top management. The quality objectives shall be measurable, communicated, and consistent with the quality policy.

4.1.4 Planning the Quality Management System

4.1.4.1 General

Planning of the quality management system shall be performed. The organization shall:

a) define the scope of the quality management system, that identifies product(s) covered (see 3.1.~~17~~16) and includes any limitations and exclusions (see 4.1.4.2);

b) identify external and internal issues relevant to the organization's long-term or overall objectives and goals;

c) determine relevant interested parties and their requirements for the quality management system;

d) determine the sequence and interaction between the processes of the quality management system;

e) determine and manage the criteria and methods needed for the effective operation and control of quality management system processes;

f) identify quality objectives, including actions, resources, responsibilities, timeframe, and how results are monitored and evaluated;

g) address identified risks (see 5.3);

h) address identified opportunities for improvement (see 6.4); and

i) identify key personnel.

4.1.4.2 Exclusions

If an organization performs activities addressed by this specification, including activities which are outsourced (see 5.5.1.7), no claims to exclusion of those activities shall be permitted. Excluded activities shall not affect the organization's ability, or responsibility, to provide product that satisfies customer and legal requirements. Where exclusions are claimed, the justification shall be documented [see 4.4.1, Item a)].

Allowable exclusions shall be limited to the following sections of this specification:

— 5.4, Design

— 5.6.4, Validation of Processes

— 5.6.7, Externally Owned Property

— 5.6.8, Preservation of Product

— 5.8, Testing, Measuring, Monitoring, and Detection Equipment (TMMDE)

4.1.5 Communication

4.1.5.1 Internal

The organization shall establish internal communication processes.

The processes shall include communicating at relevant levels and functions within the organization:

a) the importance of satisfying customer, legal, and other applicable requirements; and

b) the results of analysis of data (see 6.3).

4.1.5.2 External

The organization shall establish and implement a process for communicating with external organizations, including customers.

The process shall address:

a) execution of inquiries, contracts, or order handling and amendments (see 5.1);

b) determining and understanding requirements throughout contract execution and product realization (see 5.1.2);

c) provision of product information, including nonconformities (see 5.9.3 and 5.9.4);

d) feedback and customer complaints (see 6.2.1);

e) communication of quality plans including subsequent changes (see 5.6.2); and

f) communicating changes and associated risks (see 5.10.3).

4.2 Management Responsibility

4.2.1 General

Top management shall demonstrate leadership and commitment to the establishment, implementation, maintenance, and improvement of the quality management system by:

a) approving establishment of quality objectives (see 4.1.3) at relevant functions and levels within the organization;

b) providing resources needed for the quality management system;

NOTE Resources can include human resources and specialized skills, organizational infrastructure, financial resources, and technology.

c) engaging and supporting personnel in the implementation and maintenance of the quality management system; and

d) assigning responsibilities and authorities for ensuring the processes achieve intended outputs.

4.2.2 Responsibility and Authority

Responsibilities, authorities, and accountabilities of personnel within the scope of the organization's quality management system shall be defined, documented, and communicated throughout the organization.

4.2.3 Management Representative

Top management shall appoint and maintain a member of the organization's management personnel who, irrespective of other responsibilities, shall have responsibility and authority that includes:

a) ensuring that the quality management system conforms to the requirements of this specification;

b) ensuring that processes needed for the quality management system are established, implemented, and maintained;

c) reporting to top management on the performance of the quality management system and any need for improvement;

d) ensuring initiation of action(s) to address nonconformities (see 6.4.2); and

e) ensuring the promotion of awareness of customer requirements throughout the organization.

4.3 Organization Capability

4.3.1 Resources and Knowledge

4.3.1.1 Resources

The organization shall determine and allocate the resources needed to implement, maintain, and improve the effectiveness of the quality management system.

4.3.1.2 Knowledge

The organization shall determine the knowledge needed to provide continued operation of its processes (see 5.6) and achieve ongoing conformity of products (see 5.1). This knowledge shall be maintained and made available as determined by the organization.

NOTE Knowledge can be acquired through experience, study, training, lessons learned, best practices, or other sources.

4.3.2 Human Resources

4.3.2.1 Personnel Competence

The organization's personnel whose responsibilities fall within the scope of the quality management system shall be competent. The organization shall maintain a documented procedure addressing personnel competence. The procedure shall address:

a) how required competencies are identified and documented;

b) how required education, training, experience, or other actions to achieve competence are identified;

c) evaluation of effectiveness of actions taken to acquire competencies;

d) criteria and methods for assessing, maintaining and, re-assessing competencies; and

e) personnel responsible for assessing competency.

Records of personnel competence shall be maintained (see 4.5).

4.3.2.2 Training

The organization shall develop and maintain a procedure for training that shall address:

a) identification of the content and frequency of training required;

b) provision of quality management system training;

c) provision of job training including personnel awareness of the relevance and importance of their activities and how they contribute to the achievement of the organization's quality objectives;

d) provision of customer-specified training and/or customer-provided training, when required;

e) evaluation of effectiveness of training; and

f) identification of required training records.

Records of personnel training shall be maintained (see 4.5).

4.3.3 Work Environment

The organization shall determine, provide, manage, and maintain the work environment needed to achieve conformity of the product. Work environment shall include:

a) buildings, workspace, and associated utilities;

b) process equipment (both hardware and software) (see 5.6.10);

c) supporting services (e.g. transport, communication, information systems); and

d) conditions under which work is performed such as physical, environmental, or other factors.

4.4 Documentation Requirements

4.4.1 General

The quality management system documentation shall include:

a) the scope of the quality management system that identifies product(s) covered (see 3.1.~~17~~16) and includes justification for any exclusions (see 4.1.4.2);

b) statements of quality policy and quality objectives;

c) identification of legal and other applicable requirements to which the organization claims compliance that are needed to achieve product conformity;

~~d) identification of how the quality management system addresses each requirement of this specification;~~

~~e~~d) identification of processes that require validation (see 5.6.4); and

~~f~~e) procedures, documents, and records necessary for the planning, operation, and control of its processes and conformance with specified requirements.

NOTE Some of the above documentation has been traditionally included as part of a quality manual but can be many different formats and can be either a single document or multiple documents.

4.4.2 Procedures

All procedures (see 3.1.1~~6~~5) required by this specification shall describe the organization's method for performing an activity and shall be documented, implemented, and maintained for continued suitability.

NOTE A single procedure can address the requirements for one or more documented procedures. Any requirement for a documented procedure can be satisfied by more than one procedure.

4.4.3 Control of Internal Documents

The organization shall maintain a documented procedure for the identification, distribution, and control of internal documents required by the quality management system and this specification, including revisions, translations, and updates.

The procedure shall address:

a) responsibilities for approval and re-approval;

b) review and approval for adequacy prior to issue and use;

c) reviews for continued suitability and revision(s) as necessary;

d) identification of changes and current revision status;

e) legibility and identification of documents; and

f) availability where the activity is being performed.

Obsolete documents shall be removed from all points of issue or use, or otherwise identified to prevent unintended use if they are retained for any purpose.

Procedures, work instructions, and forms required by the quality management system shall be controlled.

4.4.4 Control and Use of External Documents

The organization shall maintain a documented procedure for the control of documents of external origin required for product realization and used by the organization, including API or other external specifications. The procedure shall address:

a) identification and documentation of required documents;

b) access and distribution of required documents, including relevant versions;

c) integration of requirements into product realization and any other affected processes;

d) process for identifying when changes to required documents have occurred, including addenda, errata, and updates;

e) assessment of impact of changes; and

f) integration of applicable changes.

NOTE Normative references that are identified within API product or other external specifications and are required during product realization can also be considered an external document.

4.5 Control of Records

Records, including those originating from outsourced activities (see 5.5.1.7), shall be established and controlled to provide evidence of conformity to requirements and the organization's quality management system.

The organization shall maintain a documented procedure to identify the controls and responsibilities for records. The procedure shall address record:

a) identification;

b) collection;

c) legibility;

d) correction;

e) storage;

f) protection from unintended alteration, damage, or loss;

g) retrieval;

h) retention time; and

i) disposition.

Records shall be retained for a minimum of ten years or as required by customer, legal, and other applicable requirements, whichever is longer.

5 Product Realization

5.1 Contract Review

5.1.1 General

The organization shall maintain a documented procedure for the review of requirements related to the provision of product. The procedure shall address:

a) determination of requirements;

b) review of requirements; and

c) changes to requirements.

5.1.2 Determination of Requirements

The organization shall determine:

a) requirements specified by the customer;

b) legal and other applicable requirements; and

c) requirements not stated by the customer but considered necessary by the organization for the provision of product.

Where the customer provides no documented statement of the requirements, the customer requirements shall be confirmed by the organization and records maintained (see 4.5).

5.1.3 Review of Requirements

The organization shall review the requirements related to provision of product. This review shall be conducted prior to the organization's commitment to deliver product to the customer and shall confirm that:

a) requirements are identified and documented;

b) requirements differing from those previously identified are resolved; and

c) the organization has the capability to meet the documented requirements.

Where contract requirements are changed, the organization shall amend the relevant documents and make relevant personnel aware of the changed requirements.

Records of the results of the review, including resulting actions, shall be maintained (see 4.5).

5.2 Planning

The organization shall identify and plan the processes and documents needed for product realization.

In planning, the organization shall address the following:

a) required resources and work environment management (see 4.3);

b) product and customer-specified requirements (see 5.1);

c) legal and other applicable requirements;

d) design requirements (see 5.4);

e) contingency planning (see 5.3.3);

f) required verification, validation, monitoring, measurement, inspection, and test activities specific to the product and the criteria for acceptance;

g) management of change (MOC) (see 5.10); and

h) records needed to provide evidence that product realization conforms to requirements (see 4.5).

The output of planning shall be documented and updated as changes occur. The plans shall be maintained in a structure suitable for the organization's method of operations.

5.3 Risk Management

5.3.1 General

The organization shall maintain a documented procedure to identify and control risk associated with product delivery and product quality.

The procedure shall address:

a) risk identification and assessment techniques;

b) risk assessment tools and their application;

c) criteria to determine risk severity including potential consequences of product failure;

d) risk mitigation actions;

e) assessment of remaining risk; and

f) contingency planning, including when a contingency plan is required based on assessment of remaining risks.

NOTE 1 Risk assessment can include consideration of severity, probability of occurrence, and detectability.

NOTE 2 Risk assessment can be an activity associated with corrective action.

5.3.2 Risk Assessment

5.3.2.1 Product Delivery

Risk assessment associated with product delivery shall include:

a) facility/equipment availability including maintenance; and

b) supplier delivery performance and material availability/supply.

5.3.2.2 Product Quality

Risk assessment associated with product quality shall include:

a) delivery of nonconforming product (see 5.9); and

b) availability of competent personnel.

5.3.2.3 Changes Impacting Product Quality

If any of the following changes can negatively impact the quality of the product (see 5.10.2), risk assessment associated with product quality (see 5.3.2.2) shall be performed:

a) changes in the organizational structure (see 4.2.2);

b) changes in key personnel (see 4.1.4.1);

c) changes in the supply chain of critical products, components, or activities (see 5.5.1.1);

d) changes to the management system scope or procedures (see 4.4.1); and

e) changes to the organization's capability to perform the process(es) required for product realization.

NOTE Changes can be of internal or external origin.

5.3.3 Contingency Planning

When the organization determines a contingency plan is required based on assessed risk, the contingency plan shall include, at a minimum:

a) actions required to reduce effects of disruptive incidents;

b) identification and assignment of responsibilities and authorities; and

c) internal and external communication controls (see 4.1.5).

The contingency plan(s) shall be documented, communicated to the relevant personnel, and updated as needed.

5.3.4 Records

Records of risk assessment and management including actions taken shall be maintained (see 4.5).

5.4 Design

5.4.1 General

When the organization is responsible for the design of products, the requirements of 5.4 shall apply. ~~The design requirements of 5.4 shall not apply if the product is production activities, servicing, storage, distribution, or logistics (see 3.1.17).~~

NOTE In previous editions the term “design” was referred to as “design and development”.

5.4.2 Design Planning

The organization shall maintain a documented procedure to plan and control the design process. The procedure shall address:

a) the plan(s), including plan updates, used for design;

b) the design stages;

c) the resources, responsibilities, authorities, and their interfaces;

d) the review, verification, and validation activities necessary to complete each design stage;

e) the requirements for a final review of the design (see 5.4.6); and

f) the review and approval requirements for design changes (see 5.4.8).

When design activities are outsourced or performed at different locations within the organization, the procedure shall identify the controls to ensure that the requirements of 5.4 are satisfied. When design activities are outsourced, the organization shall remain responsible for the design and demonstrate that the supplier conforms to the requirements of 5.5.1.7.

NOTE Design review, verification, and validation each have distinct purposes but can be conducted and recorded separately or in any combination, as suitable for the product and the organization.

5.4.3 Design Inputs

Inputs shall be identified and reviewed for adequacy, completeness, lack of ambiguity, and lack of conflict. Any identified issues shall be addressed.

Inputs shall include functional and technical requirements, and the following, as applicable:

a) customer-specified requirements (see 5.1);

b) requirements provided from external sources, including API product specifications;

c) environmental and operational conditions;

d) methodology, assumptions, and formulae documentation;

e) historical performance and other information derived from previous similar designs;

f) legal requirements; and

g) consequences of potential product failure, when required by legal requirements, industry standards, customers, or deemed necessary by the organization.

Records of design inputs shall be maintained (see 4.5).

5.4.4 Design Outputs

Outputs shall be documented to allow verification against the design input requirements.

Outputs shall:

a) meet the input requirements for design;

b) provide information for purchasing, production, inspection, testing, and servicing, as applicable;

c) identify or reference design acceptance criteria (DAC);

d) include identification of, or reference to, products, components, and/or activities deemed critical to the design;

e) include results of applicable calculations; and

f) specify the characteristics of the product that are essential for its intended purpose and its safe and proper function.

Records of design outputs shall be maintained (see 4.5).

NOTE Identification of criticality of products, components, and/or activities can be maintained outside of the design process.

5.4.5 Design Review

At suitable stages, review(s) shall be performed:

a) to evaluate the suitability, adequacy, and effectiveness of the results of design stages to meet specified requirements; and

b) to identify any problems and propose necessary actions.

Participants in such review(s) shall include representatives of functions concerned with the design stage(s) being reviewed.

Records of the results of the review(s) and any necessary actions shall be maintained (see 4.5).

5.4.6 Design Verification and Final Review

To ensure that the design outputs have satisfied the design input requirements, design verification and a final review shall be conducted and documented as identified within the organization's procedure (see 5.4.2).

Records of design verification, any necessary actions, and the final review shall be maintained (see 4.5).

5.4.7 Design Validation and Approval

Design validation shall be performed in accordance with the organization's procedure (see 5.4.2) to ensure that the resulting product is capable of satisfying the specified requirements. Validation shall be completed prior to the delivery of the product, when possible.

The completed design shall be approved after validation. Competent (see 4.3.2.1) individual(s) other than the person or persons who developed the design shall approve the final design.

Records of the design validation, approval, and any necessary actions shall be maintained (see 4.5).

5.4.8 Design Changes

Design changes shall be identified. The changes shall be reviewed, verified, and validated, as appropriate, and approved before implementation.

The review of design changes shall include evaluation of the effect of the changes on the product and their component parts in affected stages of product realization, as well as product already delivered. The review of design changes shall include an evaluation to determine if customer notification is required when design changes negatively affect the specified performance capability of the product.

Design changes, including changes to design documents, shall be in accordance with the organization's procedure (see 5.4.2).

Records of design changes, reviews of those changes, and any necessary actions shall be maintained (see 4.5).

5.5 Purchasing

5.5.1 Purchasing Control

5.5.1.1 Procedure

The organization shall maintain a documented procedure for the purchase of products, components, and/or activities required for product realization.

The procedure shall address:

a) determination of critical products, components, and/or activities;

b) initial evaluation and selection of suppliers;

c) use of identified risk to determine initial assessment method of supplier's capability for critical purchases [see 5.5.1.2, Item c)];

d) type and extent of control applied to the supply chain for critical products, components, or activities;

NOTE Section 5.5.1.7 contains additional requirements for outsourced activities.

e) criteria, scope, frequency, and methods for re-evaluation of suppliers;

f) identification of approved suppliers and scope of approval; and

g) identification of customer specified suppliers and suppliers limited by proprietary, and/or legal requirements when 5.5.1.3 applies.

5.5.1.2 Initial Supplier Evaluation—Critical Purchases

For the purchase of critical products, components or activities, the initial evaluation of suppliers (not previously approved) shall address the scope of supply, be site-specific for each supplier and include the following:

a) verification of the supplier's quality management system implementation and conformity to the quality system requirements specified for suppliers by the organization;

b) verification of the type and extent of control applied by the supplier, internally and to their supply chain, to meet the organization's requirements [see 5.5.1.1, Item d)];

c) assessment of the supplier's capability to meet the organization's specified requirements by one or more of the following based on identified risk [see 5.5.1.1, Item c)]:

   1) performing an on-site assessment to verify that relevant product realization processes are being performed in accordance with process controls, and are effective in achieving conformity to requirements,

   2) performing a remote assessment (see 3.1.1~~9~~8) to verify that relevant product realization processes are being performed in accordance with process controls and are effective in achieving conformity to requirements,

   3) performing inspection, testing, or verification of relevant characteristics of a received product.

For suppliers of critical purchases with high-risk severity [see 5.3.1 Item c)] identified by the organization for which an on-site assessment per 5.5.1.2, Item c) 1) is not performed, the assessment of the supplier's capability [see 5.5.1.2, Item c)] shall include performing a remote assessment per 5.5.1.2, Item c) 2) and performing inspection, testing, or verification per 5.5.1.2, Item c) 3).

When performed, remote assessment [see 5.5.1.2, Item c) 2)] shall include verification of objective evidence through real-time audio/visual observation of required activities and documentation using information and communication technology.

Evaluation of a supplier shall also be performed in accordance with the requirements of this section for any additions to a supplier's scope of approval or change from an approved site to a new site of supply.

5.5.1.3 Initial Supplier Evaluation – Critical Purchases – Customer Specified, Proprietary, and/or Legal Limited

For the purchase of critical products, components, or activities where the supplier is specified by the customer or involves proprietary and/or legal requirements that limit application of 5.5.1.2, the initial evaluation shall include the following:

a) verification of the supplier's quality management system implementation and conformity to quality system requirements specified for suppliers by the organization and/or the customer's requirements; and

b) identifying how the supplied product, component or activity conforms to specified requirements.

The scope of approval for customer-specified suppliers shall be limited to the relevant customer contract when assessment per 5.5.1.2, Item c) has not been performed.

5.5.1.4 Initial Supplier Evaluation—Noncritical Purchases

For the purchase of noncritical products, components, or activities that impact product realization or the final product, the criteria for evaluation of suppliers by the organization shall meet the requirements of 5.5.1.2 or satisfy one or more of the following:

a) verification that the supplier's quality management system conforms to the quality system requirements specified for suppliers by the organization;

b) assessment of the supplier to meet the organization's purchasing requirements;

c) assessment of the product or component upon delivery, or activity upon completion.

5.5.1.5 Supplier Reevaluation

For previously approved suppliers of products, components, or activities the organization shall determine the supplier reevaluation frequency based on identified risk (see 5.3) and supplier quality performance.

For the re-evaluation of suppliers of critical products, components or activities, the requirements of 5.5.1.2 shall apply.

For the re-evaluation of suppliers of critical products, components or activities for customer specified suppliers and suppliers limited by proprietary, and/or legal requirements, the requirements of 5.5.1.3 shall apply.

For the re-evaluation of suppliers of noncritical products, components, or activities that impact product realization or the final product, the requirements of 5.5.1.4 shall apply.

5.5.1.6 Records

Records of the results of evaluations including objective evidence and any necessary actions arising from the evaluations shall be maintained (see 4.5).

Records of identification of approved suppliers, customer specified suppliers, and suppliers limited by proprietary, and/or legal requirements shall be maintained (see 4.5).

5.5.1.7 Outsourcing

When an organization chooses to outsource a process or activity of its quality management system, the organization shall verify that the supplier satisfies the applicable requirements of the organization's quality management system.

When an organization chooses to outsource a product realization process or activity, the organization shall maintain responsibility for product conformance to specified requirements, including applicable API or other external specifications.

NOTE See 5.6.4 for requirements when a process requiring validation is outsourced.

Records of outsourced activities shall be maintained (see 4.5) and shall include evidence of conformity (see 5.5.3).

5.5.2 Purchasing Information

The organization shall ensure the adequacy of specified purchasing information prior to communication to the supplier. Purchasing information provided to the supplier shall be documented and describe the product, component, or activity to be purchased, including as applicable:

a) acceptance criteria;

b) requirements for approval of supplier's procedures, processes, and equipment;

c) applicable version of specifications, drawings, process requirements, inspection instructions, traceability requirements, and other relevant technical data;

d) requirements for qualification of supplier's personnel;

e) quality management system requirements;

f) requirements for approval of product release; and

g) the intended verification requirements if the organization or its customer performs verification (see 5.5.3) on the supplier's premises.

NOTE Applicable specifications may include or be derived from the customer, API specifications, design output, and/or industry standards.

5.5.3 Verification of Purchased Products, Components or Activities

5.5.3.1 General

The organization shall maintain a documented procedure defining the verification necessary for determining that purchased products, components or activities conform to specified purchase requirements.

5.5.3.2 Critical Purchases

For critical products, components or activities, the organization's procedure for verification shall address:

a) review of the organization's required documentation from the supplier;

b) verification that the applicable versions were used when specifications, drawings, process requirements, inspection instructions, traceability requirements, and other relevant technical data are specified per 5.5.2, Item c); and

c) inspection, testing and/or verification requirements including methods, frequency, and responsible party. The organization shall determine the methods, frequency, and responsible party based on identified risk (see 5.3) and supplier quality performance.

5.5.3.3 Noncritical Purchases

Noncritical products, components or activities shall be verified in accordance with the organization's documented procedure.

5.5.3.4 Records

Records of verification activities and evidence of conformity to specified requirements shall be maintained (see 4.5).

5.6 Control of Product Realization

5.6.1 General

The organization shall maintain a documented procedure that describes controls associated with product realization. The procedure shall address the following:

a) determination and implementation of manufacturing acceptance criteria (MAC) (see 3.1.13);

b) identification and documentation of processes critical to product realization;

c) implementation of the quality plan, when applicable (see 5.6.2);

d) conformance to design requirements and related changes, when applicable (see 5.4);

e) the availability and use of product realization equipment and TMMDE (unless TMMDE has been excluded, see 4.1.4.2);

f) the use of applicable work instructions;

g) process control documents (see 5.6.3);

h) maintenance of identification and traceability requirements throughout product realization (see 5.6.5);

i) implementation of monitoring and measurement activities;

j) implementation of product release (see 5.8), including applicable delivery and post-delivery activities; and

k) review and control of product realization changes, required approvals, and records.

5.6.2 Quality Plan

When required by contract, the organization shall develop a quality plan that specifies the processes of the quality management system (including product realization) and the resources to be applied to a product.

The quality plan shall address each of the following as a minimum:

a) description of the product (see 3.1.~~17~~16) or scope of quality plan;

b) required processes and documentation, including required inspections, tests, and records, for conformance with requirements;

c) identification of outsourced activities and reference to their control;

d) identification of each procedure, specification, or other document referenced or used in each activity; and

e) identification of the required hold, witness, monitor, and document review points.

The quality plan and any revisions to it shall be documented and approved by the organization.

The quality plan and any revisions shall be communicated to the customer.

NOTE 1 A quality plan can be comprised of one or several different documents.

NOTE 2 A quality plan can be referred to by other terms and refer to other quality management system documents. Examples of other terms include product quality plan (PQP), inspection and test plan (ITP), manufacturing process specification (MPS), process control plan (PCP), and quality activity plan (QAP).

5.6.3 Process Control Documents

The organization shall document process controls. Process controls shall include or reference:

a) requirements for verifying conformance with applicable quality plans (see 5.6.2), API product specifications, customer requirements, and/or other applicable product standards/codes;

b) instructions and acceptance criteria for processes, tests, inspections, and

c) when applicable, customer's inspection hold, witness, monitor, and document review points.

NOTE Process controls can include routings, travelers, checklists, process sheets, or equivalent controls and can be electronic or hard copy.

5.6.4 Validation of Processes

The organization shall validate processes when the resulting output cannot be verified by subsequent monitoring or measurement, and consequently, deficiencies become evident after the product has been delivered or is in use. Validation shall demonstrate the ability of these processes to achieve planned results.

Validation of processes shall be based on 5.6.4, Item a) or 5.6.4, Item b), as follows:

a) If a product specification identifies specific processes requiring validation, then only those processes specified shall require validation for the applicable product.

   NOTE At its discretion, an organization can validate other processes in addition to those identified in a product specification.

b) If there is no applicable product specification or the product specification does not identify processes that require validation, then processes requiring validation, if applicable to the product, shall include, at a minimum:

   — nondestructive examination (NDE)/nondestructive test (NDT);

   — welding;

   — heat treating; and

   — coating and plating (when identified by the product specification or by the organization as critical to product performance).

   The organization shall maintain a documented procedure for the validation of processes, including the methods used for review and approval. The procedure shall address:

c) required equipment;

d) qualification of personnel;

e) use of specific methods, including identified operating parameters;

f) identification of process acceptance criteria;

g) requirements for records (see 4.5); and

h) revalidation.

If an organization outsources (see 5.5.1.7) a process that requires validation, the organization shall maintain evidence that the requirements of 5.6.4 have been satisfied.

5.6.5 Identification and Traceability

The organization shall:

a) establish and maintain identification throughout product realization, including applicable delivery and post-delivery activities;

b) identify the traceability requirements as specified by the organization, the customer, and/or the applicable product specifications;

c) maintain a documented procedure for identification and traceability while the product is under control of the organization that addresses:

   1) methods of identification;

   2) when required, information needed for traceability;

   3) requirements for maintenance and/or reapplication of identification and/or traceability; and

   4) actions required to address loss of identification and/or traceability.

Records (see 4.5) of traceability shall be maintained.

NOTE Product can include components or input (raw) materials.

5.6.6 Inspection/Test Status

The organization shall maintain a documented procedure for the identification of inspection and/or test status throughout product realization that indicates product conformity or nonconformity.

5.6.7 Externally Owned Property

The organization shall maintain a documented procedure for control of externally (including customer) owned property that is incorporated into the product, while the property is under the organization's control. Externally owned property shall include intellectual property and data that are not publicly available. The procedure shall address:

a) identification;

b) verification;

c) safeguarding;

d) preservation;

e) maintenance; and

f) reporting loss, damage, or unsuitability for use to the external owner.

Records for the control and disposition of externally owned property shall be maintained (see 4.5).

5.6.8 Preservation of Product

The organization shall maintain a documented procedure describing the methods used to preserve the product and component parts throughout product realization and delivery. The procedure shall address the following:

a) identification and traceability marking;

b) storage, including the use of designated storage areas or stock rooms;

c) assessment of condition at intervals specified by the organization;

d) transportation;

e) handling;

f) packaging; and

g) protection.

Records of the results of assessments shall be maintained (see 4.5).

5.6.9 Inspection, Testing, and Verification

5.6.9.1 General

The organization shall maintain a documented procedure for inspection, testing, and/or verification of product to confirm that requirements have been satisfied.

The procedure shall address:

a) in-process inspection, testing, and/or verification methods and their application (see 5.6.9.2);

b) final inspection, testing, and/or verification methods and their application (see 5.6.9.3); and

c) record(s) creation and retention (see 5.6.9.4).

NOTE In-process and final inspection can be performed as one or more activities. Some product characteristics can require final inspection/verification during product realization.

5.6.9.2 In-process Inspection, Testing, and Verification

The organization shall inspect, test, and/or verify product at planned stages as required by the quality plan (see 5.6.2), process control documents (see 5.6.3), and/or documented procedures. Evidence of conformity with the acceptance criteria shall be maintained.

5.6.9.3 Final Inspection, Testing, and Verification

The organization shall perform final inspection, testing, and/or verification of product in accordance with the quality plan (see 5.6.2), process control documents (see 5.6.3), and/or documented procedures to determine and document conformity of the finished product to the specified requirements.

Unless performed by an automated system (see 5.8.3), personnel other than those who performed or directly supervised the product realization shall perform final acceptance inspection at planned stages of the product realization process.

5.6.9.4 Records

Records of all required inspection, testing, verification, and final acceptance shall be maintained (see 4.5).

5.6.10 Preventive Maintenance

The organization shall maintain a documented procedure for preventive maintenance of equipment used for product realization. The procedure shall address requirements for:

a) type of equipment to be maintained;

b) frequency; and

c) responsible personnel.

Records of preventive maintenance shall be maintained (see 4.5).

NOTE Preventive maintenance can be based on risk, system reliability, usage history, experience, industry recommended practices, relevant codes and standards, original equipment manufacturer's guidelines, or other applicable requirements.

5.7 Product Release

The organization shall maintain a documented procedure to address release of product to the customer. Release shall not proceed until the planned arrangements (see 5.6) have been satisfactorily completed. The organization shall only release product that conforms to requirements or that is authorized under concession (see 5.9.3).

Records shall be maintained to enable identification of the individual releasing the product (see 4.5).

5.8 Testing, Measuring, Monitoring, and Detection Equipment (TMMDE)

5.8.1 General

The organization shall determine the testing, measuring, monitoring, and detection requirements and the TMMDE needed to provide evidence of conformity to those requirements.

TMMDE owned and maintained by the organization, employee-owned equipment, and TMMDE from other sources (e.g. third-party, proprietary, and customer-owned) used to provide evidence of product conformity and/or monitor process parameters identified by the organization that impact product conformance shall be controlled.

TMMDE shall be calibrated at specified intervals. When the specified interval is based on the date of first use, the date of first use shall be documented.

5.8.2 Procedure

The organization shall maintain a documented procedure for the control of TMMDE. The procedure shall include requirements for the specific equipment type and shall address:

a) unique identification;

b) calibration status;

c) traceability to international or national measurement standards; where no such standards exist, the basis used for calibration shall be recorded (see 4.5);

d) calibration method and acceptance criteria;

e) frequency of calibration, and when the calibration interval begins;

f) documentation of the calibration measurements prior to adjustment and measurements after any adjustments during calibration;

NOTE Calibration measurements prior to adjustment can be referred to as 'as-found'. Calibration measurements after any adjustments can be referred to as 'as-left'. When no adjustments are made, 'as-found' and 'as-left' are the same.

g) actions taken to prevent unintended use of TMMDE identified as out-of-calibration, beyond calibration interval, or not in-service;

h) when the TMMDE is found to be out of calibration, an assessment of the validity of previous measurements and actions to be taken on the TMMDE and product, including maintaining records and evidence of notification to the customer (see 4.1.5.2) if suspect product has been shipped;

i) use of third-party, proprietary, employee-owned, and customer-owned TMMDE;

j) maintenance; and

k) suitability for the planned monitoring and measurement activities.

5.8.3 Equipment

TMMDE identified in 5.8.1 shall:

a) be calibrated (see 3.1.3);

b) have the calibration status identifiable by the user prior to and during use;

c) be safeguarded from adjustments or modification that would invalidate the measurement result or the calibration status;

d) be protected from damage and deterioration during handling, maintenance, and storage; and

e) be used under environmental conditions that are suitable for the calibrations, inspections, measurements, and tests being performed.

When used in the testing, monitoring, measurement, or detection of specified requirements, the ability of computer software to satisfy the intended application shall be confirmed prior to initial use and reconfirmed, as necessary.

5.8.4 TMMDE Equipment from Other Sources

When TMMDE is third-party, proprietary, or customer-owned, the organization shall confirm the equipment is in calibration prior to use. When limited by customer, contract, or licensing agreement, the requirements of 5.8.2, Item c), 5.8.2, Item d), 5.8.2, Item e), 5.8.2, Item f), 5.8.2, Item j), and 5.8.2, Item k) shall not apply.

5.8.5 Records

The organization shall maintain a registry of the TMMDE identified in 5.8.1 that includes a unique identification, specific to each piece of equipment.

Results of calibration per 5.8.2 shall be recorded and maintained (see 4.5).

When calibration of the third-party, proprietary, and customer TMMDE to the requirements of 5.8 is limited by customer, contract, or licensing agreement, the organization shall maintain records (see 4.5) of the limitations imposed.

5.9 Control of Nonconforming Product

5.9.1 Procedure

5.9.1.1 General

The organization shall maintain a documented procedure addressing the controls and related responsibilities and authorities for nonconforming product during product realization and after delivery.

5.9.1.2 Nonconforming Product During Product Realization

The procedure for addressing nonconforming product identified during product realization shall include requirements for:

a) product identification and control to prevent unintended use or delivery;

b) addressing the detected nonconformity (see 5.9.2);

c) taking action to preclude its original intended use or delivery; and

d) authorizing its use, release, or acceptance under concession by relevant authority and, when required, by the customer (see 5.9.3).

5.9.1.3 Nonconforming Product After Delivery

The procedure for addressing nonconforming product delivered to the customer shall include requirements for:

a) identifying, documenting, and reporting nonconforming product;

b) the analysis of nonconforming product, provided the product or documented evidence supporting the nonconformity is available to facilitate the determination of the cause (see 6.4.2);

c) taking action appropriate to the effects, or potential effects, of the nonconformity; and

d) authorizing its use or acceptance under concession by relevant authority and, when required, by the customer (see 5.9.3).

5.9.2 Nonconforming Product

The organization shall address nonconforming product by performing one or more of the following:

a) repair or rework with subsequent inspection to meet specified requirements;

b) re-grade for alternative applications;

c) release under concession (see 5.9.3); and/or

d) reject or scrap.

5.9.3 Release of Nonconforming Product Under Concession

The release under concession of nonconforming product that does not satisfy manufacturing acceptance criteria (MAC) shall be permitted when the organization's relevant authority has conducted an evaluation, and authorized release provided that:

a) products continue to satisfy the applicable DAC and customer criteria; or

b) the violated MAC is determined as unnecessary to satisfy the applicable DAC and/or customer criteria; or

c) the DAC is changed (see 5.4.8) and the affected products satisfy the revised DAC and associated MAC requirements. When the DAC was previously agreed with customer, the DAC change shall be authorized by the customer.

The organization shall not release product not conforming to DAC or contract requirements without customer authorization.

5.9.4 Customer Notification of Nonconforming Product

The organization shall notify customers of product not conforming to DAC or contract requirements, that has been delivered. The organization shall maintain records of such notifications (see 4.5).

5.9.5 Records

Records of nonconformities shall be maintained (see 4.5) and shall include:

a) the description of the nonconformity;

b) subsequent actions taken, including concessions obtained;

c) rationale to support release of product under concession (5.9.3); and

d) relevant authority.

5.10 Management of Change (MOC)

5.10.1 General

The organization shall maintain a documented procedure for MOC to maintain integrity of the quality management system when changes occur (see 5.10.2). The MOC procedure shall address:

a) description of, and the need for, the change;

b) availability and allocation of resources (including personnel);

c) potential risks (see 5.3) that may arise from implementing the change;

d) review, approval, and implementation of the change;

e) notifications (see 5.10.3); and

f) verification of the completion of MOC activities and impact on the QMS.

5.10.2 MOC Application

The organization shall use MOC for changes that may negatively impact the quality of the product (see 5.3.2.3).

5.10.3 MOC Notification

The organization shall notify relevant internal personnel of the change and associated risk. When required by contract, the organization shall notify the customer of the change and associated risk. MOC Notifications shall be documented.

5.10.4 Records

Records of MOC activities shall be maintained (see 4.5).

6 Quality Management System Monitoring, Measurement, Analysis, and Improvement

6.1 General

The organization shall plan and implement the monitoring, measurement, analysis, and improvement processes needed to ensure conformity of the quality management system to the requirements of this specification and to continually improve the effectiveness of the quality management system.

Quality management system monitoring, measurement, analysis, and improvement shall include determination of applicable methods, including techniques for the analysis of data, and the extent of their use.

6.2 Monitoring, Measuring, and Improving

6.2.1 Customer Satisfaction

The organization shall maintain a documented procedure to monitor customer satisfaction. The procedure shall address:

a) the frequency and methods of determining customer satisfaction; and

b) key performance indicators of customer satisfaction.

Records of the results of customer satisfaction information shall be maintained (see 4.5).

6.2.2 Internal Audit

6.2.2.1 General

The organization shall conduct internal audits to provide information on whether the quality management system is implemented, maintained, and conforms to the requirements of this specification and the organization's own quality management system requirements. The organization shall maintain a documented procedure to define responsibilities for planning, conducting, and documenting internal audits.

The organization shall identify the audit criteria, scope, frequency, and methods. The planning of audits shall take into consideration the results of previous audits (internal and external), the criticality of the process being audited, and changes made to the quality management system. All processes of the quality management system shall be audited at least every 12 months (not later than the end of the same calendar month as the prior year audit).

NOTE The entire quality management system does not need to be audited at the same time or in one consolidated audit.

When the entire quality management system is not audited as one consolidated audit, the time between audits of each part of the quality management system shall not exceed 12 months.

For those processes performed by the organization and identified as critical to product realization [see 5.6.1, Item b)], audits shall include observation of the activity being performed and evaluate whether the activity conforms with requirements.

6.2.2.2 Performance of Internal Audit

Audits shall be performed by competent personnel (see 4.3.2.1) independent of those who performed or directly supervised the activity being audited to ensure objectivity and impartiality of the audit process.

Records of the audits shall provide objective evidence that the quality management system is implemented and maintained (see 4.5).

NOTE Product specification requirements can be embedded throughout the quality management system processes and audited in conjunction with one or more quality management system processes.

6.2.2.3 Audit Review and Closure

The organization shall identify response times for addressing detected nonconformities. The management personnel responsible for the area being audited shall ensure that any necessary corrections and corrective actions follow the requirements of 6.4.2. Records of internal audits shall be maintained (see 4.5).

6.3 Analysis of Data

The organization shall maintain a documented procedure for the identification, collection, and analysis of data, to demonstrate the suitability and effectiveness of the quality management system. The analysis shall include data generated from monitoring and measurement, internal audits (see 6.2.2), audits of the organization by external parties, management reviews (see 6.5), and other relevant sources.

The data analysis output shall provide information, including trends, relating to:

a) customer satisfaction (see 6.2.1);

b) nonconformity to product requirements during product realization;

c) nonconformities (see 5.9) and product failures identified after delivery or use, provided the product or documented evidence is available to facilitate the determination of the cause:

d) process performance;

e) supplier performance (see 5.5); and

f) achieving quality objectives (see 4.1.3).

The organization shall use data to evaluate where continual improvement of the effectiveness of the quality management system can be made.

6.4 Improvement

6.4.1 General

The organization shall continually improve the effectiveness of the quality management system by evaluating, selecting, and implementing opportunities for improvement through the use of the quality objectives, internal audit, analysis of data, corrective action, and management review.

6.4.2 Corrective Action

The organization shall maintain a documented procedure to address nonconformities, including any resulting from customer complaints, and to take corrective actions, both internally and with suppliers. Corrective actions shall be appropriate to the effect(s) of the nonconformity encountered.

NOTE Corrective action can apply to both quality management system processes and nonconforming product trends.

The procedure shall address:

a) criteria for determining when the corrective action process is initiated;

b) reviewing the nonconformity;

c) determining and implementing corrections;

d) identifying the root cause of the nonconformity and evaluating the need for corrective actions;

e) implementing corrective action to reduce the likelihood that a nonconformity recurs;

f) identifying the timeframe and responsible person(s) for addressing corrections and corrective action;

g) verification of the effectiveness of the corrections and corrective action taken;

h) criteria for updating the risks and opportunities ~~determined~~ identified during planning (see 4.1.4);~~,~~

i) MOC (see 5.10) when the corrective actions require new or changed controls within the quality management system; and

j) evaluating similar, potential nonconformities and implementing action to reduce the likelihood of occurrence, as appropriate.

Records of corrective action process activities shall be maintained (see 4.5). Records shall identify the activities performed to verify effectiveness of the corrective actions taken.

6.5 Management Review

6.5.1 General

The organization's quality management system shall be reviewed at least every 12 months (not later than the end of the same calendar month as the prior year review) by the organization's management personnel to evaluate the quality management system's continuing suitability, adequacy, and effectiveness. This review shall include assessing opportunities for improvement, adequacy of resources, and the need for changes to the quality management system, including the quality policy and quality objectives.

6.5.2 Input Requirements

The input to management review shall include, as a minimum:

a) status and effectiveness of actions resulting from previous management reviews;

b) results of internal audits (see 6.2.2) and audits of the organization by external parties;

c) changes that could affect the quality management system, including:

1) changes to legal and other applicable requirements (such as industry standards); and

2) changes in external and internal issues that are relevant to the quality management system.

d) analysis of customer satisfaction (see 6.2.1);

e) relevant feedback from customers and other interested parties (see 4.1.5);

f) process performance [see 6.3, Item d)];

g) results of risk assessment and the effectiveness of actions taken to address risks (see 5.3);

h) status of corrective actions (see 6.2.2.3 and 6.4.2);

i) analysis of supplier performance (see 5.5);

j) review of the analysis of product conformity, including nonconformities identified after delivery or use (see 5.9);

k) actual performance compared with quality objectives; and

l) recommendations for improvement.

6.5.3 Output Requirements

The output from the management review shall include:

a) a summary assessment of the effectiveness of the quality management system,

b) any required changes (see 5.10) to the processes,

c) decisions and actions,

d) required resources, and

e) any improvement to products in satisfying customer requirements.

Top management shall review and approve the output of management reviews.

Management reviews shall be documented, and records of these reviews shall be maintained (see 4.5).

Annex A

(informative)

API Monogram Program—Use of the API Monogram by Licensees

A.1 Scope

The API Monogram® is a registered certification mark owned by the American Petroleum Institute (API) and authorized for licensing by the API Board of Directors. Through the API Monogram Program, API licenses product manufacturers to apply the API Monogram to new products which comply with product specifications and have been manufactured under a quality management system that meets the requirements of API Spec Q1. API maintains a complete, searchable list of all Monogram licensees on the API Composite List website (https://compositelist.api.org).

The application of the API Monogram and license number on products constitutes a representation and warranty by the licensee to API and to purchasers of the products that, as of the date indicated, the products were manufactured under a quality management system conforming to the requirements of API Spec Q1 and that the product conforms in every detail with the applicable standard(s) or product specification(s). API Monogram Program licenses are issued only after on-site audits have verified that an organization has implemented and continually maintained a quality management system that meets the requirements of API Spec Q1 and that the resulting products satisfy the requirements of the applicable API product specification(s) and/or standard(s). Although any manufacturer may claim that its products meet API product requirements without monogramming them, only manufacturers with a license from API can apply the API Monogram to their products.

Together with the requirements of the API Monogram license agreement, this annex establishes the requirements for those organizations who wish to voluntarily obtain an API license to provide API monogrammed products that satisfy the requirements of the applicable API product specification(s) and/or standard(s) and API Monogram Program requirements.

For information on becoming an API Monogram Licensee, please contact API, Monogram Program, 200Massachusetts Avenue, NW, Washington, DC 20001 at Certification@api.org.

A.2 Normative References

For Licensees under the Monogram Program, the latest version of this document shall be used. The requirements identified therein are mandatory.

A.3 Terms and Definitions

For purposes of this annex, the following terms and definitions apply.

A.3.1

API monogrammable product

Product that has been newly manufactured by an API Licensee utilizing a fully implemented API Spec Q1 compliant quality management system and that meets all the API-specified requirements of the applicable API product specification(s) and/or standard(s).

A.3.2

API product specification

Prescribed set of rules, conditions, or requirements attributed to a specified product that address the definition of terms; classification of components; delineation of procedures; specified dimensions; manufacturing criteria; material requirements, performance testing, design of activities; and the measurement of quality and quantity with respect to materials; products, processes, services, and/or practices.

A.3.3

API-specified requirements

Requirements, including performance and Licensee-specified requirements, set forth in API Spec Q1 and the applicable API product specification(s) and/or standard(s).

NOTE Licensee-specified requirements include those activities necessary to satisfy API-specified requirements.

A.3.4

design package

Records and documents required to provide evidence that the applicable product has been designed in accordance with API Spec Q1 and the requirements of the applicable product specification(s) and/or standard(s).

A.3.5

licensee

Organization that has successfully completed the application and audit process and has been issued a license by API to use the API Monogram Mark.

A.4 Quality Management System Requirements

An organization applying the API Monogram to products shall develop, maintain, and operate at all times a quality management system conforming to API Spec Q1.

A.5 Control of the Application and Removal of the API Monogram

Each licensee shall control the application and removal of the API Monogram in accordance with the following:

a) Products that do not conform to API specified requirements shall not bear the API Monogram.

b) Each licensee shall develop and maintain an API Monogram marking procedure that documents the marking/monogramming requirements specified by this annex and any applicable API product specification(s) and/or standard(s). The marking procedure shall:

   1) define the authority responsible for application and removal of the API Monogram and license number;

   2) define the method(s) used to apply the Monogram and license number;

   3) identify the location on the product where the API Monogram and license number are to be applied;

   4) require the application of the date of manufacture of the product in conjunction with the use of the API Monogram and license number;

   5) require that the date of manufacture, at a minimum, be two digits representing the month and two digits representing the year (e.g. 05-12 for May 2012) unless otherwise stipulated in the applicable API product specification(s) or standard(s); and

   6) define the application of all other required API product specification(s) and/or standard(s) marking requirements.

c) Only an API licensee shall apply the API Monogram and its designated license number to API monogrammable products.

d) The API Monogram and license number, when issued, are site-specific and subsequently the API Monogram shall only be applied at that site specific licensed facility location.

e) The API Monogram may be applied at any time appropriate during the production process but shall be removed in accordance with the licensee's API Monogram marking procedure if the product is subsequently found to be out of conformance with any of the requirements of the applicable API product specification(s) and/or standard(s) and API Monogram Program.

For certain manufacturing processes or types of products, alternative API Monogram marking procedures may be acceptable. Requirements for alternative API Monogram marking are detailed in the *API Alternative Marking Agreement (AMA)*, which is available on the API Monogram Program website.

A.6 Design Package Requirements

Each licensee and/or applicant for licensing shall maintain a current design package for all of the applicable products that fall under the scope of each Monogram license. The design package information shall provide objective evidence that the product design meets the requirements of the applicable and most current API product specification(s) and/or standard(s). The design package(s) shall be made available during API audits of the facility.

In specific instances, the exclusion of design activities is allowed under the Monogram Program, as detailed in Advisory # 6, available on the API Monogram Program website.

A.7 Manufacturing Capability

The API Monogram Program is designed to identify facilities that have demonstrated the ability to manufacture equipment that conforms to API specifications and/or standards. API may refuse initial licensing or suspend current licensing based on a facility's level of manufacturing capability. If API determines that additional review is warranted, API may perform additional audits (at the organization's expense) of any primary subcontractors to ensure their compliance with applicable specifications.

Facilities with capabilities that are limited to the processes or activities defined below do not meet the manufacturing capability requirements to produce new products, and therefore, shall not be licensed or be the basis for licensing under the API Monogram Program:

— Capabilities that are limited to performing final inspection and testing of the product;

— Buying, selling and/or distributing finished products and materials;

— Design and development activities;

— Tearing-down and/or re-assembling of products/components; and

— Repairing or remanufacturing of existing, used, worn or damaged products.

In all instances where requirements for manufacturing or manufacturing facilities are explicitly identified within the API product specification, those requirements shall take precedence over this advisory.

A.8 Product Marking Requirements

A.8.1 General

These marking requirements shall apply only to those API Licensees wishing to mark applicable products in conjunction with the requirements of the API Monogram Program.

A.8.2 Product Specification Identification

Manufacturers shall mark products as specified by the applicable API specifications or standards. Marking shall include reference to the applicable API specification and/or standard. Unless otherwise specified, reference to the API specifications and/or standards shall be, as a minimum, “API [Document Number]” (e.g. API 6A, or API 600). Unless otherwise specified, when space allows, the marking may include use of “Spec” or “Std”, as applicable (e.g. API Spec 6A or API Std 600).

A.8.3 Units

Products shall be marked with units as specified in the API specification and/or standard. If not specified, equipment shall be marked with U.S. customary (USC) units. Use of dual units [USC units and metric (SI) units] may be acceptable if such units are allowed by the applicable product specification and/or standard.

A.8.4 Nameplates

Nameplates, when applicable, shall be made of a corrosion-resistant material unless otherwise specified by the API specification and/or standard. Nameplate shall be located as specified by the API specification and/or standard. If the location is not specified, then the licensee shall develop and maintain a procedure detailing the location to which the nameplate shall be applied. Nameplates may be attached at any time during the manufacturing process.

The API Monogram and license number shall be marked on the nameplate, in addition to the other product marking requirements specified by the applicable product specification and/or standard.

A.8.5 License Number

The API Monogram license number shall not be used unless it is marked in conjunction with the API Monogram. The license number shall be used in close proximity to the API Monogram.

A.9 API Monogram Program—Nonconformance Reporting

API solicits information on products that are found to be nonconforming with API specified requirements, as well as field failures (or malfunctions), which are judged to be caused by either specification and/or standard deficiencies or nonconformities against API specified requirements. Customers are requested to report to API all problems with API monogrammed products. A nonconformance may be reported using the API Nonconformance Reporting System available at https://ncr.api.org/ncr.aspx.

Bibliography

[1] API Specification Q2, *Quality Management System Requirements for Service Supply Organizations for the Petroleum and Natural Gas Industries*

[2] ISO 9001, *Quality management systems—Requirements*

[3] ISO 9004, *Quality management - Quality of an organization - Guidance to achieve sustained success*

[4] ISO 10005, *Quality management systems—Guidelines for quality plans*

[5] ISO 10013, *Quality management systems - Guidance for documented information*

[6] ISO 10015, *Quality management—Guidelines for competence management and people development*

[7] ISO 10017, *Guidance on statistical techniques for ISO 9001:2015*

[8] ISO 19011, *Guidelines for auditing management systems*

[9] ISO 29001, *Petroleum, petrochemical and natural gas industries—Sector-specific quality management systems—Requirements for product and service supply organizations*

[10] ISO 31000, *Risk management—Guidelines*

[11] ISO 13880, *Petroleum and natural gas industries—Content and drafting of a technical specification*

[12] ISO 13879, *Petroleum and natural gas industries—Content and drafting of a functional specification*