Specification for Quality Management System Requirements for Manufacturing Organizations for the Petroleum and Natural Gas Industry

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Introduction

This specification has been developed to address quality management systems for organizations that manufacture products or provide manufacturing-related services under a product specification for use in the petroleum and natural gas industry. It defines the fundamental quality management system requirements for those claiming conformity to the requirements of this specification.

The requirements of this specification are consistent with those of other quality management system documents (e.g. API Q2). The requirements are structured in a way 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 Document

The goal of this specification is to provide the minimum requirements for the development of a quality management system that provides for continual improvement, emphasizes defect prevention, and strives to minimize variation and waste from manufacturing organizations. It is designed to promote reliability in the manufacturing sector of the petroleum and natural gas industry. It is not the intent of this specification to imply uniformity in the structure of quality management systems or uniformity of documentation.

Applicability of API Specification Q1 and API Specification Q2

This specification establishes the API quality system requirements necessary for organizations to consistently and reliably manufacture products in accordance with API or other specifications for use in the petroleum and natural gas industry. This specification is also applicable to, and sets requirements for, all organizations desiring to acquire and maintain a license to use the API Monogram and applies at all times within the organization when a location has been licensed by the API Monogram Program. API Q1 applies to those activities that otherwise may be considered a service (such as heat treatment, threading, or testing) if these activities or the results of these activities are identified as an API monogrammable product under any applicable API product specification in the API Monogram Program.

API Q2 (*Specification for Quality Management System Requirements for Service Supply Organizations for the Petroleum and Natural Gas Industries*) establishes the API quality system requirements necessary for service supply organizations to consistently and reliably provide services that meet customer, legal, and other applicable requirements. This specification applies to service-related activities in oil and gas well construction, intervention, production, and abandonment, as well as equipment repair/maintenance. This specification does not apply to the API Monogram Program or any product that is identified by license as eligible for marking with the API Monogram.

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Specification for Quality Management System Requirements for Manufacturing Organizations for the Petroleum and Natural Gas Industry

1 Scope

This specification establishes the minimum quality management system requirements for organizations that manufacture products or provide manufacturing-related processes under a product specification for use in the petroleum and natural gas industry.

This specification specifies the requirements of a quality management system for an organization to demonstrate its ability to consistently provide reliable products and manufacturing-related processes that meet customer and legal requirements.

If an organization performs activities addressed by this specification, no claims to exclusion of those activities are permitted. Where any requirement of this specification cannot be applied due to the nature of an organization, the requirement can be considered for exclusion. Where exclusions are made, the basis for claiming exclusions is to be identified. Furthermore, such exclusions cannot affect the organization's ability, or responsibility, to provide products and related servicing that meet customer and applicable regulatory requirements. Exclusions are limited to the following sections:

— 5.4, Design and Development;

— 5.7.1.2, Servicing;

— 5.7.1.5, Validation of Processes for Production and Servicing;

— 5.7.5, Customer-supplied Property;

— 5.8, Control of Testing, Measuring, and Monitoring Equipment.

The quality management system requirements specified in this specification are in alignment with the section requirements and format of document used for the provision of services and use of service-related product (API Q2). Information marked "NOTE" are not requirements but are provided for guidance in understanding or clarifying the associated requirement.

2 Normative References

The following referenced document is indispensable for the application of this specification. The latest edition of the referenced document (including any amendments) applies.

ISO 9000, *Quality management systems—Fundamentals and vocabulary*

3 Terms, Definitions, and Abbreviations

3.1 Terms and Definitions

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 limits of acceptability applied to process or product characteristics.

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3.1.2
acceptance inspection
Demonstration through monitoring or measurement that the product conforms to specified requirements.

3.1.3
calibration
Comparison to a standard of known accuracy and making any needed adjustment(s).

3.1.4
collection
Process of obtaining, assembling, and/or organizing applicable information with the intent of meeting the requirements of 4.5.

3.1.5
compliance
Act or process of satisfying the legal and other applicable requirements of a regulation or regulatory body.

3.1.6
critical
That deemed by the organization, product specification, or customer as mandatory, indispensable or essential, needed for a stated purpose or task, and requiring specific action.

3.1.7
delivery
Point in time and physical location at which the agreed transfer of ownership takes place.

3.1.8
design acceptance criteria
DAC
Defined limits placed on characteristics of materials, products, or services established by the organization, customer, and/or applicable specifications to achieve conformity to the product design.

3.1.9
design validation
Process of proving a design by testing to demonstrate conformity of the product to design requirements.

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 of production products,

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

d) field performance tests and reviews.

3.1.10
design verification
Process of examining the result of design and development output 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 independent of activities of design and development,

c) comparing new designs to similar proven designs.

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3.1.11
first article
Representative sample of a product, component, or output from a process used to verify that prescribed activities have satisfied the requirements as specified by the organization.

NOTE Samples can include trial purchases and prototypes.

3.1.12
key performance indicator
KPI
Quantifiable measure that an organization uses to gauge or compare performance.

3.1.13
legal requirement
Obligation imposed on an organization, including those that are statutory or regulatory.

3.1.14
management [*noun*]
Person or group of people, as defined by the organization, who directs and controls all or part of a facility, location, department, or other function; has the fiscal responsibility for the organization, and is accountable for ensuring compliance with legal and other applicable requirements.

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

3.1.15
manufacturing acceptance criteria
MAC
Defined limits placed on characteristics of materials, products, and services established by the organization to achieve conformity to the manufacturing or servicing requirements.

3.1.16
outsource
[outsourced activity]
Function or process that is performed by an external supplier on behalf of the organization.

3.1.17
preventive maintenance
Planned action to minimize the likelihood of equipment failure and unscheduled interruptions

3.1.18
procedure
Organization's documented method for performing an activity under controlled conditions to achieve conformity to specified requirements.

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

3.1.19
risk
Situation or circumstance that has both a likelihood of occurring and a potentially negative consequence.

3.1.20
service
Performance of an activity by one function or organization for another.

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3.1.21
servicing
Product maintenance, adjustment, repair, and/or on-site installation when installation is required by applicable product specifications.

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
QM	quality manual
QMS	quality management system
QP	quality plan

4 Quality Management System Requirements

4.1 Quality Management System

4.1.1 General

The organization shall establish, document, implement, and maintain at all times a quality management system for all products and servicing provided for use in the petroleum and natural gas industry. The organization shall measure the effectiveness and improve upon the quality management system in accordance with the requirements of this specification.

4.1.2 Quality Policy

The organization's policy for its commitment to quality shall be defined, documented, and approved by top management. The organization's top management shall review the quality policy to ensure that it is appropriate to the organization, is the basis for the development of quality objectives (see 4.1.3), and is communicated, understood, implemented, and maintained at all relevant functions and levels within the organization. The policy shall include a commitment to comply with requirements and continually improve the effectiveness of the quality management system.

4.1.3 Quality Objectives

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

4.1.4 Planning

Management shall ensure that:

a) criteria and methods needed for the operation and control of all quality management system processes are determined, managed, and effective; and

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b) planning of the quality management system is carried out in order to meet the requirements of this specification.

4.1.5 Communication

4.1.5.1 Internal

Management shall ensure that appropriate communication processes are established within the organization and the effectiveness of the quality management system is communicated.

The organization shall establish processes to ensure that:

a) importance of meeting customer, legal, and other applicable requirements is communicated at relevant functions within the organization; and

b) results of analysis of data (see 6.3) are communicated at relevant levels and functions within the organization.

4.1.5.2 External

The organization shall determine and implement a process for communicating with external organizations, including customers, to ensure requirements are understood throughout contract execution and product realization. The communication process shall address:

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

b) provision of product information, including product nonconformities identified after delivery to the customer (see 5.10.4);

c) feedback and customer complaints (see 6.2.1); and

d) when required by contract, providing information required by product quality plans and subsequent changes to those plans (see 5.7.2).

4.2 Management Responsibility

4.2.1 General

Top management shall ensure the availability of resources essential to establish, implement, maintain, and improve the quality management system.

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

Management shall provide evidence of its commitment to the development and implementation of the quality management system and continually improve its effectiveness by:

a) ensuring that quality objectives are established including key performance indicators for use in data analysis; and

b) conducting management reviews (see 6.5).

4.2.2 Responsibility and Authority

Responsibilities, authorities, and accountabilities of personnel within the scope of this document shall be defined, documented, and communicated throughout the organization.

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4.2.3 Management Representative

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

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

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

c) ensuring initiation of action(s) to minimize the likelihood of the occurrence of nonconformities (see 6.4.3); and

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

4.3 Organization Capability

4.3.1 Provision of Resources

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

4.3.2 Human Resources

4.3.2.1 General

The organization shall maintain a documented procedure for defining personnel competency and identifying training requirements or other actions to achieve the necessary competency of personnel whose responsibilities fall within the scope of the quality management system. The procedure shall include provisions for determining and documenting the effectiveness of the training or other actions taken toward the achievement of required competency.

4.3.2.2 Personnel Competence

Personnel shall be competent based on the appropriate education, training, skills, and experience needed to meet product and customer requirements. Evidence of the determination of competence of personnel shall be recorded and maintained (see 4.5).

4.3.2.3 Training and Awareness

The organization shall:

a) provide for quality management system training and job training;

b) ensure that customer-specified training and/or customer-provided training, when required, is included in the training program;

c) ensure that the frequency and content of training is identified;

d) ensure that its personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the quality objectives; and

e) maintain appropriate records of education, training, skills, and experience (see 4.5).

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4.3.3 Work Environment

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

a) buildings, workspace, and associated utilities;

b) process equipment and its maintenance (both hardware and software) (see 5.7.8);

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) statements of quality policy and quality objectives;

b) a quality manual that addresses each requirement of this specification and includes:

   1) the scope of the quality management system, including justification for any exclusions to specific quality management system elements (see Section 1);

   2) a description of the sequence and interaction between the processes of the quality management system;

   3) identification of processes that require validation (see 5.7.1.5); and

   4) reference to documented procedures that control the quality management system processes;

c) documented procedures established for the quality management system;

d) documents and records to ensure the effective planning, operation, and control of its processes and compliance with specified requirements; and

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

4.4.2 Procedures

All procedures referenced within this specification shall be established, documented, implemented, and maintained for continued suitability.

NOTE 1 A single document can address the requirements of one or more procedures.

NOTE 2 A requirement for documented procedures can be satisfied by more than one document.

4.4.3 Control of Documents

The organization shall maintain a documented procedure for the identification, distribution, and control of documents required by the quality management system and this specification, including required documents of an origin external to the organization.

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The procedure shall specify responsibilities for approval and re-approval and shall identify the controls needed to ensure that the documents required by the quality management system, including revisions, translations, and updates:

a) are reviewed and approved for adequacy prior to issue and use,

b) identify changes and revision status,

c) remain legible and readily identifiable, and

d) are available where the activity is being performed.

Documents of external origin shall be controlled to ensure that the relevant versions are used and maintained.

Obsolete documents shall be removed from all points of issue or use, or otherwise identified to ensure against 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 Use of External Documents in Product Realization

When API product or other external specification requirements, including addenda, errata, and updates, are used in the design or manufacture of the product, the organization shall maintain a documented procedure for the integration of these requirements into the product realization process and any other affected processes.

4.5 Control of Records

The organization shall maintain a documented procedure to identify the controls and responsibilities needed for the identification, collection, storage, protection, retrieval, retention time, and disposition of records.

Records, including those originating from outsourced activities (see 5.6.1.6), shall be established and controlled to provide evidence of conformity to requirements and the organization's quality management system.

Records shall remain legible, identifiable, and retrievable. Records shall be retained for a minimum of five 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 products and required servicing.

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 the product.

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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 products. This review shall be conducted prior to the organization's commitment to deliver product to the customer and shall ensure 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 ensure that relevant documents are amended and that relevant personnel are made 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. Planning of product realization shall be consistent with the requirements of the other processes of the quality management system (see 4.1.4).

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) contingencies based on risk assessment (see 5.3 and 5.5);

e) design and development requirements (see 5.4);

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

g) management of change (MOC) (see 5.11); and

h) records needed to provide evidence that the product realization processes meet 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 Assessment and Management

The organization shall maintain a documented procedure to identify and control risk associated with impact on delivery and quality of product. The procedure shall identify the techniques, tools and their application for risk identification, assessment, and mitigation.

NOTE Risk assessment can include consideration of severity, detection methods, and probability of occurrence.

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Risk assessment associated with product delivery shall include:

a) facility/equipment availability and maintenance; and

b) supplier performance and material availability/supply.

Risk assessment associated with product quality shall include, as applicable:

c) delivery of nonconforming product (see 5.10.1);

d) availability of competent personnel.

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

NOTE 1 The output of risk assessment may be used in the development of contingency plans (see 5.5).

NOTE 2 Risk assessment can be an activity associated with corrective and/or preventive action.

5.4 Design and Development

5.4.1 Design and Development Planning

The organization shall maintain a documented procedure to plan and control the design and development of the product.

The procedure shall identify:

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

b) the design and development stages;

c) the resources, responsibilities, authorities, and their interfaces to ensure effective communication;

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

e) the requirements for a final review of the design (see 5.4.5).

When design and development activities are performed at different locations within the same organization, the procedure shall identify the controls required to ensure that the designs meet the requirements of 5.4.

When design and development are outsourced, the organization shall ensure the supplier meets the requirements of 5.6.1.6.

NOTE Design and development 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.

5.4.2 Design and Development Inputs

Inputs shall be identified and reviewed for adequacy, completeness, and lack of conflict.

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

a) customer-specified requirements (see 5.1);

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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) results from risk assessments (see 5.3).

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

5.4.3 Design and Development Outputs

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

Outputs shall:

a) meet the input requirements for design and development;

b) provide appropriate information for purchasing, production, and servicing;

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

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

e) include results of applicable calculations; and

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

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

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

5.4.4 Design and Development Review

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

a) to evaluate the suitability, adequacy, and effectiveness of the results of design and development 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 and development stage(s) being reviewed. Records of the results of the review(s) and any necessary actions shall be maintained (see 4.5).

5.4.5 Design and Development Verification and Final Review

To ensure that the design and development outputs have met the design and development input requirements, design and development verification and a final review shall be conducted and documented in accordance with planned arrangements (see 5.4.1).

Records of design and development verification and the final review shall be maintained (see 4.5).

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5.4.6 Design and Development Validation and Approval

Design and development validation shall be performed in accordance with planned arrangements (see 5.4.1) to ensure that the resulting product is capable of meeting 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 4.3.2.2) individual(s) other than the person or persons who developed the design shall approve the final design.

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

5.4.7 Design and Development Changes

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

The review of design and development changes shall include evaluation of the effect of the changes on product and/or their constituent parts already delivered.

Design and development changes, including changes to design documents, shall require the same controls as the original design and development.

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

5.5 Contingency Planning

5.5.1 General

The organization shall maintain a documented procedure for contingency planning needed to address risk associated with impact on delivery and quality of product.

Contingency planning shall be based on assessed risks (see 5.3), and output shall be documented and communicated to the relevant personnel and updated as required.

5.5.2 Planning Output

The contingency plan shall include, at a minimum:

a) actions required in response to significant risk scenarios to mitigate effects of disruptive incidents;

b) identification and assignment of responsibilities and authorities; and

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

5.6 Purchasing

5.6.1 Purchasing Control

5.6.1.1 Procedure

The organization shall maintain a documented procedure to ensure that purchased products or outsourced activities conform to specified requirements.

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The procedure shall address:

a) determination of the criticality of the activities or products as they are applicable to conformance to product or customer specifications;

b) initial evaluation and selection of suppliers based on their ability to supply products or activities in accordance with the organization's requirements (see 5.6.1.2 and 5.6.1.3);

c) type and extent of control applied to the supplier based on the criticality of the product or activity;

d) criteria, scope, frequency, and methods for reassessment of suppliers;

e) maintaining a list of approved suppliers and scope of approval; and

f) type and extent of control to be applied to outsourced activities (see 5.6.1.6).

5.6.1.2 Initial Supplier Evaluation—Critical Purchases

For purchase of critical products, components or activities, the criteria for the initial evaluation of suppliers by the organization shall be site-specific for each supplier and shall include the following:

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

b) assessment of the supplier to ensure its capability to meet the organization's purchasing requirements by:

   i) performing an on-site evaluation of relevant activities, or

   ii) performing first article inspection to ensure conformance to stated requirements, or

   iii) identifying how the supplied product conforms to stated requirements when limited by proprietary, legal, and/or contractual arrangements.

5.6.1.3 Initial Supplier Evaluation—Noncritical Purchases

For 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 5.6.1.2 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; or

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

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

5.6.1.4 Supplier Reevaluation

For reevaluation of all suppliers (critical and noncritical), the requirements of 5.6.1.3 shall apply.

5.6.1.5 Supplier Evaluation—Records

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

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5.6.1.6 Outsourcing

Where an organization chooses to outsource any activity within the scope of its quality management system, the organization shall ensure that all applicable elements of its quality management system are satisfied and shall maintain responsibility for product conformance to specified requirements, including applicable API product specifications, associated with product realization.

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

5.6.2 Purchasing Information

The organization shall ensure the adequacy of specified purchasing information prior to their communication to the supplier. Purchasing information provided to the supplier shall be documented and adequately describe the product or activity to be purchased, including acceptance criteria, and where appropriate:

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

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

c) requirements for qualification of supplier's personnel; and

d) quality management system requirements.

5.6.3 Verification of Purchased Products or Activities

The organization shall maintain a documented procedure for the verification or other activities necessary for ensuring that purchased products or activities meet specified purchase requirements.

Where the organization or its customer intends to perform verification at the supplier's premises, the organization shall state the intended verification arrangements and method of product release in the purchasing information.

The organization shall ensure and provide evidence that purchased products and activities conform to specified requirements.

The organization shall maintain records of verification activities (see 4.5).

5.7 Production and Servicing Provision

5.7.1 Control of Production and Servicing

5.7.1.1 Production

The organization shall maintain a documented procedure that describes controls associated with the production of products. The procedure shall address the following:

a) the availability of information that describes the characteristics of the product;

b) implementation of the product quality plan, when applicable (see 5.7.2);

c) ensuring design requirements and related changes are satisfied, when applicable (see 5.4);

d) the availability and use of suitable production, testing, monitoring, and measurement equipment;

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e) the availability of work instructions, when applicable;

f) process control documents (see 5.7.1.3);

g) implementation of monitoring and measurement activities; and

h) implementation of product release (see 5.9), including applicable delivery and post-delivery activities.

5.7.1.2 Servicing

The organization shall maintain a documented procedure that describes controls associated with the servicing (see 3.1.21) of products. The procedure shall address the following:

a) review and implementation of the organization's, customer-specific, product servicing, and other servicing requirements;

b) the availability and use of suitable servicing, testing, monitoring, and measurement equipment;

c) the availability of work instructions, when applicable;

d) ensuring identification and traceability requirements are maintained throughout the servicing process;

e) the implementation of monitoring and measurement activities;

f) process control documents (see 5.7.1.3); and

g) requirements for release of the product that was serviced (see 5.9).

5.7.1.3 Process Control Documents

Process controls shall be documented in routings, travelers, checklists, process sheets, or equivalent controls required by the organization and shall include requirements for verifying conformance with applicable product quality plans (see 5.7.2), API product specifications, customer requirements, and/or other applicable product standards/codes. The process control documents shall include or reference instructions and acceptance criteria for processes, tests, inspections, and required customer's inspection hold or witness points.

5.7.1.4 Product Realization Capability Documentation

The organization shall develop and maintain documentation that includes but is not limited to product realization plans (see 5.2) and records of review/verification, validation, monitoring, measurement, inspection, and test activities, including criteria for product acceptance that demonstrates the capability of the organization to satisfy specified product and/or servicing requirements.

NOTE Product realization documentation is evidence of the capability of the organization to manufacture products or families of products and does not extend to every work order or individual product manufactured.

5.7.1.5 Validation of Processes for Production and Servicing

The organization shall validate processes for production and servicing where the resulting output cannot be verified by subsequent monitoring or measurement, and as a consequence, deficiencies become apparent only after the product is in use or the servicing has been delivered. Validation shall demonstrate the ability of these processes to achieve planned results. Where an organization chooses to outsource a process that requires validation, the organization shall require that the supplier conform to these requirements (see 5.6.1.6).

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The organization shall maintain a documented procedure to address methods for review and approval of the processes including:

a) required equipment;

b) qualification of personnel;

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

d) identification of acceptance criteria;

e) requirements for records (see 4.5); and

f) revalidation.

The organization shall validate those processes identified by the applicable product specification as requiring validation. If these processes are not identified, or there is no product specification involved, the processes requiring validation shall include, as a minimum, nondestructive examination, welding, and heat treating, if applicable to the product.

5.7.2 Product Quality Plans

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

The product quality plan required by contract shall address each of the following as a minimum:

a) description of the product to be manufactured;

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

c) identification and reference to control of outsourced activities;

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.

These product quality plans and any revisions to them shall be documented and approved by the organization to ensure customer requirements are met.

These product quality plans and any revisions shall be communicated to the customer.

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

NOTE 2 A product quality plan is sometimes referred by other terms—such as quality plan (QP), inspection and test plan (ITP), manufacturing process specification (MPS), process control plan (PCP), and quality activity plan (QAP)—and often makes references to parts of the quality manual or to procedure documents.

5.7.3 Identification and Traceability

The organization shall maintain a documented procedure for identification and traceability while the product is under control of the organization as required by the organization, the customer, and/or the applicable product specifications throughout the product realization process, including applicable delivery

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and post-delivery activities. The procedure shall include requirements for maintenance or replacement of identification and/or traceability marks.

Records (see 4.5) of identification and traceability shall be maintained.

5.7.4 Product Inspection/Test Status

The organization shall maintain a documented procedure for the identification of product inspection and/or test status throughout the product realization process that indicates the conformity or nonconformity of product with respect to inspections and/or tests performed. The organization shall ensure that only product that meets requirements or that is authorized under concession (see 5.10.3), is released.

5.7.5 Customer-supplied Property

The organization shall maintain a documented procedure for the identification, verification, safeguarding, preservation, maintenance, and control of customer-supplied property, including intellectual property and data, while under control of the organization. The procedure shall include requirements for reporting to the customer any loss, damage, or unsuitability for use of customer-supplied property.

Records for the control and disposition of customer-supplied property shall be maintained (see 4.5).

5.7.6 Preservation of Product

5.7.6.1 General

The organization shall maintain a documented procedure describing the methods used to preserve the product and constituent parts throughout product realization and delivery to the intended destination in order to maintain conformity to requirements. As applicable, preservation shall include identification and traceability marks, transportation, handling, packaging, and protection.

5.7.6.2 Storage and Assessment

The procedure shall identify the requirements for storage and assessment. The organization shall use designated storage areas or stock rooms to prevent damage or deterioration of product, pending use or delivery.

In order to detect deterioration, the condition of product or constituent parts in stock shall be assessed at specified intervals identified by the procedure. The interval shall be appropriate to the products or constituent parts being assessed.

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

5.7.7 Inspection and Testing

5.7.7.1 General

The organization shall maintain a documented procedure for inspection and testing to verify that product requirements have been met. The procedure shall include requirements for in-process and final inspection and testing. Records of required inspection and testing shall be maintained per documented procedures (see 4.5).

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5.7.7.2 In-process Inspection and Testing

The organization shall inspect and test the product at planned stages as required by the product quality plan (see 5.7.2), process control documents (see 5.7.1.3), and/or documented procedures. Evidence of conformity with the acceptance criteria shall be maintained.

5.7.7.3 Final Inspection and Testing

The organization shall perform all final inspection and testing in accordance with the product quality plan (see 5.7.2) and/or documented procedures to validate and document conformity of the finished product to the specified requirements.

Personnel other than those who performed or directly supervised the production of the product shall perform final acceptance inspection at planned stages of the product realization process.

NOTE For single step manufacturing processes (e.g. threading), in-process and final inspection and testing can be performed as one activity.

5.7.8 Preventive Maintenance

The organization shall maintain a documented procedure for the establishment of preventive maintenance for equipment used in product realization. The procedure shall identify 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.

5.8 Control of Testing, Measuring, and Monitoring Equipment

The organization shall determine the testing, monitoring, and measurement requirements and the associated equipment needed to provide evidence of conformity to those requirements.

The organization shall maintain a documented procedure in order to ensure that testing, measurement, and monitoring equipment is calibrated and maintained and that the equipment is used in a manner that is consistent with monitoring and measurement requirements.

The procedure shall include requirements for the specific equipment type that addresses:

a) unique identifier;

b) calibration status;

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

d) frequency of calibration, at specific intervals or prior to use;

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e) calibration or verification method, including adjustments and readjustments, as necessary;

f) acceptance criteria;

g) control of equipment identified as out-of-calibration in order to prevent unintended use; and

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

Testing, measuring, and monitoring equipment shall:

1) be calibrated or verified, or both, against measurement standards;

NOTE 1 Verification against identified acceptance criteria is performed on nonadjustable equipment.

2) have the calibration status identifiable by the user for the activities being performed at all times;

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

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

5) be used under environmental conditions that are suitable for the calibrations, inspections, measurements, and tests being carried out.

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

NOTE 2 Verification of the suitability of proprietary measurement equipment and evidence of its conformity to the requirements of 5.8 may be limited by contract or licensing agreement; however, the licensee is required to demonstrate the limitations imposed by the contract in order to meet 5.8 c), 5.8 d), 5.8 e), and 5.8 f).

When the equipment is provided from a source external to the organization, including third-party, proprietary, employee- and customer-owned equipment, the organization shall verify that the equipment is suitable and provide evidence of conformity to the requirements of this section.

The organization shall maintain a registry of the required testing, measurement and monitoring equipment used to determine product conformity to requirements that includes a unique identification, specific to each piece of equipment.

Records of the results of calibration and verification shall be maintained (see 4.5).

5.9 Product Release

The organization shall maintain a documented procedure to ensure release of product to the customer shall not proceed until the planned arrangements (see 5.7) have been satisfactorily completed, unless otherwise approved by a relevant authority and, where applicable, by the customer.

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

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5.10 Control of Nonconforming Product

5.10.1 General

The organization shall maintain (a) documented procedure(s) to identify the controls and related responsibilities and authorities for addressing nonconforming product.

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

a) product identification to prevent unintended use or delivery;

b) addressing the detected nonconformity (see 5.10.2);

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, where applicable, by the customer (see 5.10.3).

The procedure for addressing nonconforming product identified after delivery shall include controls for:

1) identifying, documenting, and reporting nonconformances or product failure identified after delivery;

2) ensuring the analysis of product nonconformance or failure, provided the product or documented evidence supporting the nonconformity is available to facilitate the determination of the cause (see 6.4.2);

3) taking action appropriate to the effects, or potential effects, of the nonconformance when nonconforming product is detected after delivery.

5.10.2 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 5.10.3); and/or

d) reject or scrap.

5.10.3 Release of Nonconforming Product Under Concession

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

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

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

c) the DAC are changed and the products satisfy the revised DAC and associated MAC requirements.

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5.10.4 Customer Notification

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).

5.10.5 Records

Records of the nature of nonconformities and any subsequent actions taken, including concessions obtained, shall be maintained (see 4.5).

5.11 Management of Change (MOC)

5.11.1 General

The organization shall maintain a process for MOC. The organization shall ensure that the integrity of the quality management system is maintained when changes to the quality management system are planned and implemented. For MOC, the organization shall identify the potential risks (see 5.3) associated with the change and any required approvals prior to the introduction of such changes. The organization shall maintain records of MOC activities (see 4.5).

5.11.2 MOC Implementation

The organization shall use the MOC process for any of the following that may negatively impact the quality of the product:

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

b) changes in key or essential personnel (see 4.3.2);

c) changes in critical suppliers (see 5.6.1.1); and/or

d) changes to the management system procedures, including changes resulting from corrective and preventive actions (see 6.4).

5.11.3 MOC Notification

The organization shall notify relevant personnel, including the customer when required by contract, of the change and residual or new risk due to changes that have either been initiated by the organization or requested by the customer.

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.

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6.2 Monitoring, Measuring, and Improving

6.2.1 Customer Satisfaction

The organization shall maintain a documented procedure to measure customer satisfaction. The procedure shall address the frequency of measurement, obtaining customer feedback, key performance indicators (KPIs), and other information that the organization uses to determine whether the organization has satisfied customers in meeting identified requirements. 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 maintain a documented procedure to define responsibilities for planning, conducting, and documenting internal audits. Audits shall verify that the quality management system is effectively implemented and maintained and conforms to the requirements of this specification. The planning of internal audits shall take into consideration the results of previous audits and criticality of the process being audited.

The organization shall identify the audit criteria, scope, frequency, and methods to ensure that all processes of the quality management system claiming conformity to the requirements of this specification are audited at least every 12 months.

Outsourced activities that impact the quality of the product and that are performed at the organization's facility shall be included as part of the internal audit of the organization.

6.2.2.2 Performance of Internal Audit

Audits shall be performed by competent personnel (see 4.3.2.2) 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).

All processes of the quality management system required to meet this specification shall be audited prior to claiming conformance to the requirements of this specification.

NOTE Product specification requirements may 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 responsible for the area being audited shall ensure that any necessary corrections and corrective actions follow the requirements of 6.4.2. The results of internal audits and the status of corrective actions shall be reported in the management review (see 6.5). Records of internal audits shall be maintained (see 4.5).

6.2.3 Process Evaluation

The organization shall apply suitable evaluation methods to demonstrate the ability of the quality management system processes to achieve planned results, including conformity to product requirements. When planned results are not achieved, correction and corrective action shall be taken (see 6.4.2), as appropriate.

NOTE Performance of internal audits and management reviews satisfy this requirement.

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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), management reviews (see 6.5), and other relevant sources.

The data analysis output shall provide information relating to:

a) customer satisfaction (see 6.2.1);

b) conformity to product requirements;

c) nonconformities and product failures identified after delivery or use, provided the product or documented evidence is available to facilitate the determination of the cause (see 5.10);

d) characteristics and trends of processes and products including opportunities for preventive action (see 6.4.3);

e) supplier performance (see 5.6); and

f) 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 through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions, and management review.

NOTE See ISO 9000 for definitions of correction, corrective action, and preventive action.

6.4.2 Corrective Action

The organization shall maintain a documented procedure to correct nonconformities and to take corrective actions, both internally and within the supply chain, to eliminate the causes of nonconformities in order to minimize the likelihood of its recurrence. 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 identify requirements for:

a) reviewing a process nonconformity (including customer complaints);

b) determining and implementing corrections;

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

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

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

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

g) MOC (see 5.11) when the corrective actions require new or changed controls within the quality management system.

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

6.4.3 Preventive Action

The organization shall maintain a documented procedure to determine and implement preventive actions, both internally and within the supply chain, to eliminate the causes of potential nonconformities in order to minimize the likelihood of their occurrence. Preventive actions shall be appropriate to the effect(s) of the potential problems.

NOTE Preventive action can apply to both quality management system processes and product analysis.

The procedure shall identify requirements for:

a) identifying opportunities for improvements;

b) identifying a potential nonconformity and its potential cause(s);

c) evaluating the need for preventive action, including any immediate or short-term action required, to prevent occurrence of a nonconformity;

d) identifying the timeframe and responsible person(s) for implementing a preventive action;

e) reviewing the effectiveness of the preventive action taken; and

f) MOC (see 5.11) when the preventive action require new or changed controls within the quality management system.

Records of the activities for control of potential process nonconformities shall be maintained (see 4.5).

6.5 Management Review

6.5.1 General

The organization's quality management system shall be reviewed at least every 12 months by the organization's management to evaluate the quality management system's continuing suitability, adequacy, and effectiveness. This review shall include assessing opportunities for improvement 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) effectiveness of actions resulting from previous management reviews;

b) results of audits (see 6.2.2);

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c) changes that could affect the quality management system, including changes to legal and other applicable requirements (such as industry standards);

d) analysis of customer satisfaction, including customer feedback (see 6.2.1);

e) process performance [see 6.2.3 and 6.3 d)];

f) results of risk assessment (see 5.3);

g) status of corrective and preventive actions (see 6.4.2 and 6.4.3);

h) analysis of supplier performance (see 5.6);

i) review of the analysis of product conformity, including nonconformities identified after delivery or use (see 5.10); and

j) recommendations for improvement.

6.5.3 Output Requirements

The output from the management review shall include a summary assessment of the effectiveness of the quality management system. The assessment shall include any required changes (see 5.11) to the processes and any decisions and actions, required resources, and improvement to products in meeting 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).

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Annex A
(informative)

Use of API Monogram by Licensees

A.1 Scope

The API Monogram® is a registered certification mark owned by API and authorized for licensing by the API Board of Directors. Through the API Monogram Program (www.api.org/certification-programs/api-monogram-program-and-apiqr.aspx), API licenses product manufacturers to apply the API Monogram to new products that comply with product specifications and have been manufactured under a quality management system that meets the requirements of API Q1. API maintains a complete, searchable list of all Monogram Licensees on the API Composite List website (http://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 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 an on-site audit has verified that an organization has implemented and continually maintained a quality management system that meets the requirements of API 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, Certification Programs, 1220 L Street, NW, Washington, DC 20005 or call 202-682-8145 or by email at certification@api.org.

A.2 Normative References

API Q1, *Specification for Quality Management System Requirements for Manufacturing Organizations for the Petroleum and Natural Gas Industry*

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 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

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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 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 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.

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 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;

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

3) identify the location on the product where the API Monogram is to be applied;

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

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) require controls for the application of the additional API product specification(s) and/or standard(s) marking requirements, as applicable.

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

d) The API Monogram license, when issued, is 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 Policy, *API Monogram Program Alternative Marking of Products License Agreement*, available on the API Monogram Program website at http://www.api.org/alternative-marking.

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). 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 API Monogram Program website at http://www.api.org/advisories.

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 subcontractors to ensure their compliance with the requirements of the applicable API product specification(s) and/or standard(s).

A.8 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 deficiencies or nonconformities with 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 http://compositelist.api.org/ncr.asp.

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Annex B
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Cross-reference from API Q1, 9th Edition to API Q1, 8th Edition

With this current edition of API Q1, the reference citations are renumbered. For existing quality management systems, there is no requirement to meet a specific quality management system ***format*** or ***numbering system***. This annex is created to provide a ready cross-reference between the requirements of API Q1, 8th and 9th Editions. This will allow an organization to maintain its existing formatting and numbering system, if desired, and identify those requirements that have been added to the new edition of the specification.

NOTE Where "No Requirement" is identified in the matrix below, it is an indication that this is a new requirement in the API Q1, 9th Edition that has no corresponding requirement in the API Q1, 8th Edition.

Correlation to API Q1, 9th Edition *"Soft" Requirements (as applicable, if necessary, etc.)*	
API Q1, 9th Edition	**API Q1, 8th Edition**
4.1 Quality Management System	
4.1.1 General	
4.1.1 Establish, document, implement, and maintain QMS at all times	4.1, 4.1 c), 7.1
4.1.1 Measure effectiveness and improve QMS	4.1 c), 8.5.1
4.1.2 Quality Policy	
4.1.2 Top management defines, documents, and approves policy	5.1 b), 5.3.1
4.1.2 Policy reviewed to ensure appropriate and basis for quality objectives	5.3 a), 5.3 c)
4.1.2 Communicated, understood, implemented, and maintained	5.3 d)
4.1.2 Statement of commitment to comply and improve QMS	5.3 b)
4.1.3 Quality Objectives	
4.1.3 Management and top management establish	5.1 c), 7.1 a)
4.1.3 Established at relevant functions and levels	5.4.1
4.1.3 Measureable and consistent with quality policy	5.4.1
4.1.4 Planning	
4.1.4 a) Criteria and methods of QMS determined and effective	4.1, 4.1 a), 7.1
4.1.4 b) Planning of QMS carried out to meet requirements	4.1, 4.1 a), 5.4.2 a)
4.1.5 Communication	
4.1.5.1 Internal	
Communication processes established	5.5.3
Effectiveness of QMS communicated	5.5.3
4.1.5.1 a) Requirements communicated within the organization	5.1 a)
4.1.5.1 b) Data analysis results communicated within organization	*No Requirement*
4.1.5.2 External	
Determine, document, and implement external communication process	5.2, 7.2.3
4.1.5.2 a) For execution of inquiries, contracts, and amendments	7.2.3 b)
4.1.5.2 b) For product information and nonconformities	7.2.3 a)
4.1.5.2 c) For addressing feedback and complaints	7.2.3 c)
4.1.5.2 d) Quality plans and changes	*No Requirement*
4.2 Management Responsibility	
4.2.1 General	
Top management ensures availability of resources	4.1 d), 5.1 e)
Management commitment to QMS and its improvement	5.1
4.2.1 a) Management ensures objects established including KPIs	5.1 c)

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Correlation to API Q1, 9th Edition *"Soft" Requirements (as applicable, if necessary, etc.)*	
API Q1, 9th Edition	**API Q1, 8th Edition**
4.2.1 b) Management conducts management reviews	5.1 d)
4.2.2 Responsibility and Authority	
Responsibilities and authorities defined	5.5.1
4.2.3 Management Representative	
Top management appoints management representative who:	5.5.2
4.2.3 a) Ensures processes established, implemented and maintained	5.5.2 a)
4.2.3 b) Reports to top management on performance of QMS	5.5.2 b)
4.2.3 c) Initiates actions to minimize nonconformances	*No Requirement*
4.2.3 d) Ensure promotion of awareness of customer requirements	5.5.2 c)
4.3 Organization Capability	
4.3.1 Provision of Resources	
Determine and allocate resources needed for QMS	6.1, 7.1 b)
4.3.2 Human Resources	
4.3.2.1 General	
Procedure for competency and training	6.2.2.1, 6.2.2 a), 6.2.2 b)
Procedure includes provisions for determining effectiveness	6.2.2 c)
4.3.2.2 Personnel Competence	
Personnel competent to meet requirements	6.2.1
Records of competency determination	*No Requirement*
4.3.2.3 Training and Awareness	
4.3.2.3 a) QMS and job training for personnel	6.2.2.1
4.3.2.3 b) Allow for customer-specified/provided training	*No Requirement*
4.3.2.3 c) Frequency and content identified	6.2.2.1
4.3.2.3 d) Personnel aware of importance of activities and contribution	6.2.2 d)
4.3.2.3 e) Records maintained	6.2.2 e)
4.3.3 Work Environment	
Determine, provide, manage, and maintain work environment, including:	6.3, 6.4
4.3.3 a) Buildings, workspace, and utilities	6.3 a)
4.3.3 b) Process equipment	6.3 b)
4.3.3 c) Support services	6.3 c)
4.3.3 d) Physical, environment, and other factors	6.4
4.4 Documentation Requirements	
4.4.1 General	
4.4.1 a) Statements of policy and objectives	4.2.1 a)
4.4.1 b) Quality manual that includes:	4.2.1 b), 4.2.2.1
4.4.1 b) 1) Scope or QMS and justifications for exclusions	4.2.2 a)
4.4.1 b) 2) Interaction of processes of QMS	4.1 b), 4.2.2 c)
4.4.1 b) 3) Identification of processes requiring validation	*No Requirement*
4.4.1 b) 4) Reference to procedures of the QMS	4.2.2 b)
4.4.1 c) Procedures for the QMS	4.2.1 c)
4.4.1 d) Documents/records for planning, operation, and control of QMS	4.2.1 d), 7.1 b)
4.4.1 e) Legal and other applicable requirements	*No Requirement*
4.4.2 Procedures	
Procedures established, documented, implemented, and maintained	*No Requirement*
4.4.3 Control of Documents	
Procedure for control of documents, including external documents	4.2.3
Procedure specifies responsibilities for approval and re-approval	4.2.3 a), 4.2.3 b), 4.2.3.2
4.4.3 a) Documents reviewed and approved before use	4.2.3 a), 4.2.3 b)
4.4.3 b) Changes and revision status identified	4.2.3 c)

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Correlation to API Q1, 9th Edition *"Soft" Requirements (as applicable, if necessary, etc.)*	
API Q1, 9th Edition	**API Q1, 8th Edition**
4.4.3 c) Documents remain legible and identifiable	4.2.3 e)
4.4.3 d) Documents available where activity performed	4.2.3 d)
External document controlled to ensure correct version used	4.2.3 f)
Obsolete documents removed or identified	4.2.3 g)
Procedures, work instructions, and forms controlled	*No Requirement*
4.4.4 Use of External Documents in Product Realization	
Procedure to translate requirements into the product realization process	7.1.1
4.5 Control of Records	
Procedure for records control and identification of responsibilities	4.2.3, 4.2.4, 4.2.4.1
Identify, collect, store, protect, retrieve, retain, and dispose records	4.2.4
Records including outsourced activities provide evidence of conformity	*No Requirement*
Records legible, identifiable, and retrievable	4.2.4
Records maintained for five years minimally or per specification	4.2.4.1
5 Product Realization	
5.1 Contract Review	
5.1.1 General	
Procedure for review of requirements and provision of products and servicing	7.2.2.1
5.1.2 Determination of Requirements	
5.1.2 a) Determine requirements specified by customer	7.2.1 a)
5.1.2 b) Determine legal requirements	7.2.1 c), 7.2.1 d)
5.1.2 c) Determine requirements not stated by customer but needed	7.2.1 b), 7.2.2
When no documented requirements, organization confirms and maintains records	7.2.2
5.1.3 Review of Requirements	
Review the requirements related to provision of products	7.2.2
Review conducted before commitment to deliver product	7.2.2
5.1.3 a) Requirements identified and documented	7.2.2 a)
5.1.3 b) Requirement differences resolved	7.2.2 b)
5.1.3 c) Organization has capability to meet requirements	7.2.2 c)
When changed, documents amended and personnel notified	7.2.2
Records maintained	7.2.2
5.2 Planning	
Plan processes needed for product realization	7.1
Planning consistent with requirements of other processes of QMS	7.1
5.2 a) Address required resources and work environment	7.1 b)
5.2 b) Address product and customer-specified requirements	7.1 a)
5.2 c) Address legal and other requirements	*No Requirement*
5.2 d) Address contingencies based on risk assessment	*No Requirement*
5.2 e) Address design requirements	7.1 a)
5.2 f) Address required verification, validation, monitoring, inspection, and testing	7.1 c)
5.2 g) Address management of change	*No Requirement*
5.2 h) Address records	7.1 d)
Planning output updated with changes	*No Requirement*
Planning suitable for organization	7.1
5.3 Risk Assessment and Management	
Procedure to: identify and control risk	*No Requirement*
identify techniques and tools	*No Requirement*
5.3 a) Product delivery risk includes facility/equipment availability and maintenance	*No Requirement*
5.3 b) Product delivery risk includes supplier performance and material availability	*No Requirement*
5.3 c) Product quality risk includes delivery of nonconforming product	*No Requirement*

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API Q1, 9th Edition	**API Q1, 8th Edition**
5.3 d) Product quality risk includes availability of competent personnel	*No Requirement*
Records of risk assessment and actions taken maintained	*No Requirement*
5.4 Design and Development	
5.4.1 Design and Development Planning	
Procedure to plan and control design and development	7.3.1.1
5.4.1 a) Plans and updates	7.3.1
5.4.1 b) Design and development stages	7.3.1 a)
5.4.1 c) Resources, responsibilities, authorities, and interfaces	7.3.1, 7.3.1 c)
5.4.1 d Review, verification, and validation activities	7.3.1 b)
5.4.1 e) Final review of design	7.3.4.1
Controls for other organization design locations impacting design	*No Requirement*
Controls for outsourced design activities	7.3.1.1
5.4.2 Design and Development Inputs	
Inputs identified and reviewed for adequacy and completeness	7.3.2, 7.3.2.1
Inputs include functional and technical requirements	7.3.2 a), 7.3.2 d)
5.4.2 a) Customer-specified requirements	7.3.2.1
5,4.2 b) External sources (API specifications)	7.3.2 d)
5.4.2 c) Environmental and operational conditions	7.3.2 d)
5.4.2 d) Methods, assumption, and formulae documentation	7.3.1.2
5.4.2 e) Historical performance	7.3.2 c)
5.4.2 f) Legal requirements	7.3.2 b)
5.4.2 g) Risk assessment	*No Requirement*
Records maintained	7.3.2.1
5.4.3 Design and Development Outputs	
Outputs verified against input requirements	7.3.3
5.4.3 a) Meet input requirements	7.3.3 a)
5.4.3 b) Provide purchasing, production, and post-delivery information	7.3.3 b)
5.4.3 c) Design acceptance criteria	7.3.3 c)
5.4.3 d) Critical products or components	*No Requirement*
5.4.3 e) Results of calculations	7.3.1.2
5.4.3 f) Specify characteristics essential for safe and proper use	7.3.3 d)
Records maintained	7.3.3.1
5.4.4 Design and Development Review	
5.4.4 a) Review for adequacy to meet requirements	7.3.4 a)
5.4.4 b) Identify problems and propose actions	7.3.4 b)
Participants from concerned functions	7.3.4
Records maintained of review	7.3.4
5.4.5 Design and Development Verification and Final Review	
Conduct final design review and verification to ensure output meets input	7.3.4.1, 7.3.5
Records maintained of final review and verification	7.3.4, 7.3.5
5.4.6 Design and Development Validation and Approval	
Product capable of meeting specified requirements	7.3.6
Performed prior to delivery	7.3.6
Completed designs approved after validation	*No Requirement*
Competent person other than design developer approves final design	7.3.4.1
Records maintained for validation and approval	7.3.6
5.4.7 Design and Development Changes	
Changes identified	7.3.7
Changes reviewed, verified and validated, and approved	7.3.7

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API Q1, 9th Edition	**API Q1, 8th Edition**
Evaluation of the effect of changes on product and parts delivered	7.3.7
Changes require same controls as original design	7.3.7.1
Records maintained	7.3.7
5.5 Contingency Planning	
5.5.1 General	
Procedure for contingency planning to address risk	*No Requirement*
Based on assessed risk	*No Requirement*
Output documented and communicated	*No Requirement*
5.5.2 Planning Output	
5.5.2 a) Includes actions required in response to significant risk	*No Requirement*
5.5.2 b) Includes identification and assignment of responsibilities	*No Requirement*
5.5.2 c) Includes internal and external communications controls	*No Requirement*
5.6 Purchasing	
5.6.1 Purchasing Control	
5.6.1.1 Procedure	
Procedure for control of purchase products and outsourced activities	4.1, 4.1.1, 7.4.1, 7.4.1.1
5.6.1.1 a) Determine criticality	*No Requirement*
5.6.1.1 b) Initial evaluation and selection of suppliers	7.4.1
5.6.1.1 c) Type/extent of control on supplier based on criticality	*No Requirement*
5.6.1.1 d) Criteria, scope, frequency, and methods for reassessment	7.4.1
5.6.1.1 e) List of approved suppliers	*No Requirement*
5.6.1.1 e) List of approved supplier scope	*No Requirement*
5.6.1.1 f) Control of outsourced activities	4.1, 4.1.1, 7.4.1.3
5.6.1.2 Initial Supplier Evaluation—Critical Purchases	
Criteria for initial evaluation of critical suppliers	*No Requirement*
5.6.1.2 a) Supplier QMS conforms to specified requirements	7.4.1.2 d)
5.6.1.2 b) i) Assessment by on-site evaluation of supplier, or	7.4.1.2 a)
5.6.1.2 b) ii) Assessment by first article inspection, or	*No Requirement*
5.6.1.2 b) iii) Identifying how product conforms to legal or contractual requirements	*No Requirement*
5.6.1.3 Initial Supplier Evaluation—Noncritical Purchases	
Meeting the requirements 5.6.1.2, or	*No Requirement*
5.6.1.3 a) Assessment of supplier to meet purchase requirements, or	7.4.1.2 c)
5.6.1.3 b) Supplier QMS conforms to specified requirements, or	7.4.1.2 d)
5.6.1.3 c) Assessment of supplier upon delivery of product	7.4.1.2 b)
5.6.1.4 Supplier Reevaluation	
Reevaluation requirements follow those of 5.6.1.3	7.4.1.2
5.6.1.5 Supplier Evaluation—Records	
Supplier evaluation records maintained	7.4.1
5.6.1.6 Outsourcing	
Organization's applicable QMS requirements satisfied	4.1
Maintain responsibility for product conformance to requirements	4.1.1
Records maintained	*No Requirement*
5.6.2 Purchasing Information	
Ensure adequacy of information	7.4.2
Information documented and includes:	7.4.2, 7.4.2.1
Acceptance criteria	7.4.2 a)
5.6.2 a) Requirements for approval of supplier procedures	7.4.2 a)
5.6.2 b) Applicable versions of documents	7.4.2.1
5.6.2 c) Requirements for supplier personnel qualification	7.4.2 b)

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API Q1, 9th Edition	**API Q1, 8th Edition**
5.6.2 d) QMS requirements	7.4.2 c)
5.6.3 Verification of Purchased Products or Activities	
Procedure for verification of products or activities	7.4.3.1
Control for verification at supplier's premises	7.4.3
Products or activities conform to requirements	7.4.3
Records maintained	7.4.3.1
5.7 Production and Servicing Provision	
5.7.1 Control of Production and Servicing	
5.7.1.1 Production	
Procedure for production of products and includes:	7.5.1.1
5.7.1.1 a) Information on characteristics of product	7.5.1 a)
5.7.1.1 b) Implementation of quality plans	*No Requirement*
5.7.1.1 c) Design requirements satisfied	*No Requirement*
5.7.1.1 d) Availability and use of equipment	7.5.1 c), 7.5.1 d)
5.7.1.1 e) Availability of work instructions	7.5.1 b)
5.7.1.1 f) Process control documents	*No Requirement*
5.7.1.1 g) Implementation of monitoring and measurement activities	7.5.1 e)
5.7.1.1 h) Implementation of product release, delivery, and post-delivery	7.5.1 f)
5.7.1.2 Servicing	
Procedure for servicing of products and includes:	7.5.1.1
5.7.1.2 a) Implementation of servicing requirements	7.5.1 a)
5.7.1.2 b) Availability and use of equipment	7.5.1 c), 7.5.1 d)
5.7.1.2 c) Availability of work instructions	7.5.1 b)
5.7.1.2 d) Ensure identification and traceability maintained	*No Requirement*
5.7.1.2 e) Implementation of monitoring and measurement activities	7.5.1 e)
5.7.1.2 f) Process control documents	*No Requirement*
5.7.1.2 g) Implementation of product release	7.5.1 f)
5.7.1.3 Process Control Documents	
Controls in routings, travelers, checklists, etc.	7.5.1.2
Controls include API product specifications or equivalent	*No Requirement*
Reference instructions and acceptance criteria	7.5.1.2
Customer's inspection hold or witness points	7.5.1.2
5.7.1.4 Product Realization Capability Documentation	
Maintain evidence of capability to meet product requirements	*No Requirement*
5.7.1.5 Validation of Processes for Production and Servicing	
Validate process where output cannot be subsequently verified	7.5.2
Validation shows processes achieve planned results	7.5.2
Outsourced processes require same controls	7.4.1.3
Procedure established and includes:	7.5.2
5.7.1.5 a) Required equipment	7.5.2 b)
5.7.1.5 b) Qualification of personnel	7.5.2 b)
5.7.1.5 c) Use of methods, including operating parameters	7.5.2 c)
5.7.1.5 d) Identification of acceptance criteria	7.5.2 a)
5.7.1.5 e) Requirements for records	7.5.2 d)
5.7.1.5 f) Revalidation	7.5.2 e)
Validation processes identified in product specifications	7.5.2.1
Otherwise validate nondestructive examination, welding, heat treating	7.5.2.1
5.7.2 Product Quality Plan	
Plan developed for QMS and resource requirements	*No Requirement*

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Correlation to API Q1, 9th Edition

"Soft" Requirements (as applicable, if necessary, etc.)

API Q1, 9th Edition	API Q1, 8th Edition
5.7.2 a) Description of product to be manufactured	*No Requirement*
5.7.2 b) Required processed, including records	*No Requirement*
5.7.2 c) Control of outsourced activities	*No Requirement*
5.7.2 d) Identification of procedures	*No Requirement*
5.7.2 e) Identification of hold/witness points	*No Requirement*
Plans and revisions approved by organization	*No Requirement*
Plans and revisions communicated to customer	*No Requirement*
5.7.3 Identification and Traceability	
Procedure for identification and traceability while with organization	7.5.3, 7.5.3.1
Maintenance and replacement of identification and traceability	7.5.3.2
Records maintained	7.5.3
5.7.4 Product Inspection/Test Status	
Procedure for identification of product inspection/test status	7.5.3, 7.5.3.3
Ensure product meets requirements or	*No Requirement*
Product released under concession	8.3 b)
5.7.5 Customer-supplied Property	
Procedure for control of customer property	7.5.4.1
ID, verify, safeguard, preserve, maintain, and control customer property	7.5.4
Controls for reporting loss, damage, or unsuitability to customer	7.5.4
Records maintained	7.5.4
5.7.6 Preservation of Product	
5.7.6.1 General	
Procedure for preservation of product and parts	7.5.5.1
Procedure for ID, traceability, marks, transportation, handling, packaging, and protection	7.5.5.1
5.7.6.2 Storage and Assessment	
Procedure for storage and assessment	7.5.5.1
Use of designated storage areas	*No Requirement*
Assessment of stock at specified intervals	7.5.5.2
Intervals appropriate to the product/part being assessed	*No Requirement*
Records of assessment maintained	*No Requirement*
5.7.7 Inspection and Testing	
5.7.7.1 General	
Procedure for inspection and testing	8.2.4.1
Requirement for in-process and final inspection/testing	8.2.4
Records maintained	8.2.4
5.7.7.2 In-process Inspection and Testing	
Inspect and test at planned stages	8.2.4
Evidence of conformity maintained	8.2.4
5.7.7.3 Final Inspection and Testing	
Final inspection based on plan or procedures to validate and document results	*No Requirement*
Independent personnel performs final acceptance inspection	8.2.4.2
5.7.8 Preventive Maintenance	
Procedure for preventive maintenance of manufacturing equipment	*No Requirement*
5.7.8 a) Requirements for type of equipment to be maintained	*No Requirement*
5.7.8 b) Requirements for frequency	*No Requirement*
5.7.8 c) Requirements for responsible person	*No Requirement*
Records maintained	*No Requirement*
5.8 Control of Testing, Measuring, and Monitoring Equipment	
Determine the testing, monitoring, and measurement requirements	7.6

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Correlation to API Q1, 9th Edition *"Soft" Requirements (as applicable, if necessary, etc.)*	
API Q1, 9th Edition	**API Q1, 8th Edition**
Procedure for calibration of equipment include:	7.6.1
5.8 a) Unique identifier	7.6 c), 7.6.1
5.8 b) Calibration status	7.6 c)
5.8 c) Equipment traceability	7.6 a)
5.8 c) Where no standard exists, basis for calibration recorded	7.6 a)
5.8 d) Frequency of calibration	7.6 a), 7.6.1
5.8 e) Calibration method, including adjustments and readjustments	7.6.1, 7.6 b)
5.8 f) Acceptance criteria	7.6.1
5.8 g) Control of out-of-calibration equipment	7.6
5.8 h) Assess measurements when equipment is out of calibration	7.6
5.8 h) Records of assessment and customer notification	7.6
5.8 1) Calibrated/verified against standards	7.6 a)
5.8 2) Calibration status identified	7.6 c)
5.8 3) Safeguard equipment from adjustments	7.6 d)
5.8 4) Protected from damage and deterioration	7.6 e)
5.8 5) Used in suitable environment	7.6.2
Confirmation of software when used in measurement	7.6
Verification of externally provided equipment	*No Requirement*
Registry of equipment, including unique identification	*No Requirement*
Records of calibration maintained	7.6
5.9 Product Release	
Procedure for release of product under planned arrangements	8.2.4.1
Approved for release by customer under concession	8.2.4
Records maintained	8.2.4
5.10 Control of Nonconforming Product	
5.10.1 General	
Procedure(s) to control nonconforming product and identify responsibilities, including:	8.3
5.10.1 a) Product identification and unintended use	8.3
5.10.1 b) Addressing nonconformity	8.3 a)
5.10.1 c) Take action to preclude intended use	8.3 c)
5.10.1 d) Authorizing use under concession	8.3 b)
Procedures for control nonconforming product after delivery	8.3
5.10.1.1) Identifying and reporting nonconformances	8.3.2
5.10.1 2) Analysis of product failure if evidence available	8.3.2
5.10.1 3) Taking action appropriate to the effects	8.3 d)
5.10.2 Nonconforming Product	
5.10.2 a) Repair or re-work and reinspected to meet requirements	8.3
5.10.2 b) Re-grade for alternative applications	*No Requirement*
5.10.2 c) Accept under concession	*No Requirement*
5.10.2 d) Reject/scrap	*No Requirement*
5.10.3 Release of Nonconforming Product Under Concession	
5.10.3 a) Products continue to meet DAC	8.3.1 a)
5.10.3 b) Violated MAC categorized as not needed to meet DAC/customer requirements	8.3.1 a)
5.10.3 c) DAC is changed	8.3.1 b)
5.10.4 Customer Notification	
Notify customers if products do not meet requirements after delivery	8.3.3
Records of customer notification maintained	8.3.3
5.10.5 Records	
Records of nonconformities and subsequent actions maintained	8.3

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Correlation to API Q1, 9th Edition *"Soft" Requirements (as applicable, if necessary, etc.)*	
API Q1, 9th Edition	**API Q1, 8th Edition**
5.11 Management of Change (MOC)	
5.11.1 General	
Process for MOC	*No Requirement*
QMS integrity maintained when changes are planned/implemented	5.4.2 b)
Identify risks associated with change	*No Requirement*
Identify approvals prior to introduction of changes	*No Requirement*
Records maintained	*No Requirement*
5.11.2 MOC Implementation	
5.11.2 a) MOC for changes in organizational structure	*No Requirement*
5.11.2 b) MOC for changes in essential personnel	*No Requirement*
5.11.2 c) MOC for changes in critical suppliers	*No Requirement*
5.11.2 d) MOC for changes for management system procedures	*No Requirement*
5.11.3 MOC Notification	
Notify relevant personnel	*No Requirement*
Notify customer when required by contract	*No Requirement*
6 QMS Monitoring, Measurement, Analysis, and Improvement	
6.1 General	
Monitor and measure QMS for conformity and continually improve	4.1, 8.1 b), 8.1 c), 8.5.1
Methods include techniques for analysis of data and their use	8.1
6.2 Monitoring, Measuring, and Improving	
6.2.1 Customer Satisfaction	
Procedure for customer satisfaction	6.1 b), 8.2.1
Determine frequency of measurement, feedback, KPIs	8.2.1
Records maintained	*No Requirement*
6.2.2 Internal Audit	
6.2.2.1 General	
Procedure for responsibilities for planning and conducting internal audits	8.2.2
Verification of implementation of QMS to requirements	8.2.2 a), 8.2.2 b)
Planning considers results of previous audits	8.2.2
Identify criteria, scope frequency, and methods	8.2.2
Audits performed at least every 12 months	8.2.2.1
On-site outsourced activities subject to internal audits	*No Requirement*
6.2.2.2 Performance of Internal Audit	
Performed by competent personnel independent of area audited	8.2.2, 8.2.2.1
Records maintained	8.2.2
QMS processes audited before claiming conformance to specification	*No Requirement*
6.2.2.3 Audit Review and Closure	
Identify response times for addressing nonconformities	8.2.2, 8.2.2.2
Management of audited areas take corrective actions	8.2.2
Results of audits and corrective actions reported to management	5.6.2 a)
Records maintained	8.2.2
6.2.3 Process Evaluation	
Evaluation methods used to show QMS achieves results	4.1 e), 4.1 f), 8.2.3
When results not achieved, correction/corrective action taken	8.2.3
6.3 Analysis of Data	
Procedure for collecting and analyzing data	8.4.1, 4.1 c)
Includes data from monitoring/measurement, audits, and management reviews	8.4
6.3 a) Output includes information on customer satisfaction	8.4 a)
6.3 b) Output includes information on conformity to product requirements	8.4 b)

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Correlation to API Q1, 9th Edition *"Soft" Requirements (as applicable, if necessary, etc.)*	
API Q1, 9th Edition	**API Q1, 8th Edition**
6.3 c) Output includes information on nonconformities	*No Requirement*
6.3 d) Output includes information on trends of processes and products	8.4 c)
6.3 e) Output includes information on supplier performance	8.4 d)
6.3 f) Output includes information on objectives	*No Requirement*
Use data for continual improvement	8.4
6.4 Improvement	
6.4.1 General	
Continually improve effectiveness of QMS	8.5.1
6.4.2 Corrective Action	
Procedure for process nonconformances	8.5.2
Corrective actions appropriate to effects of the nonconformities	8.5.2
6.4.2 a) Review nonconformity and customer complaints	8.5.2 a)
6.4.2 b) Determine and implement corrections	8.5.2 c), 8.5.2 d)
6.4.2 c) Identify root cause and evaluate need for corrective action	8.5.2 b), 8.5.2 c)
6.4.2 d) Implement corrective action	8.5.2 d)
6.4.2 e) Identify timeframe and personnel	8.5.2.2
6.4.2 f) Verification of effectiveness	8.5.2 f), 8.5.2.1
6.4.2 g) MOC when corrective actions require new controls	*No Requirement*
Records maintained	8.5.2 e)
Records identify activities performed to verify effectiveness	*No Requirement*
6.4.3 Preventive Action	
Procedure for process potential nonconformances	8.5.3
Preventive actions appropriate to effects of the nonconformities	8.5.3
6.4.3 a) Identify need for improvements	*No Requirement*
6.4.3 b) Identify potential nonconformity and cause(s)	8.5.3 a)
6.4.3 c) Evaluate need for preventive action	8.5.3 b)
6.4.3 d) Identify timeframe and personnel	*No Requirement*
6.4.3 e) Verification of effectiveness	8.5.3 e), 8.5.3.1
6.4.3 f) MOC when preventive actions require new controls	*No Requirement*
Records maintained	8.5.3 d)
6.5 Management Review	
6.5.1 General	
QMS suitability reviewed at least every 12 months by management	5.6.1.1
Review includes improvement opportunities and need for change to QMS	5.6.1, 5.3 e)
6.5.2 Input Requirements	
6.5.2 a) Effectiveness of actions resulting from previous reviews	5.6.2 e)
6.5.2 b) Results of audits	5.6.2 a)
6.5.2 c) Changes to QMS, including legal	5.6.2 f)
6.5.2 d) Customer satisfaction/customer feedback	5.6.2 b)
6.5.2 e) Process performance	5.6.2 c)
6.5.2 f) Results of risk assessment	*No Requirement*
6.5.2 g) Status of corrective and preventive actions	5.6.2 d)
6.5.2 h) Analysis of supplier performance	*No Requirement*
6.5.2 i) Analysis of product conformity and nonconformity after delivery	5.6.2 c)
6.5.2 j) Recommendations for improvement	5.6.2 g)
6.5.3 Output Requirements	
Summary of effectiveness of QMS	5.6.3 a)
Required changes to processes	5.6.3 a)
Required resources	5.6.3 c)

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Correlation to API Q1, 9th Edition *"Soft" Requirements (as applicable, if necessary, etc.)*	
API Q1, 9th Edition	**API Q1, 8th Edition**
Improvements in meeting customer requirements	5.6.2 b)
Top management review output of management reviews	5.6.1
Reviews documented and records maintained	5.6.1

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Annex C[1]
(informative)

Cross-reference from API Q1, 8th Edition to API Q1, 9th Edition

With this current edition of API Q1, the reference citations are renumbered. For existing quality management systems, there is no requirement to meet a specific quality management system ***format*** or ***numbering system***. This annex is created to provide a ready cross-reference between the requirements of API Q1, 8th and 9th Editions. This will allow an organization to maintain its existing formatting and numbering system, if desired, and identify those requirements that have been added to the new edition of the specification.

Please note that use of this annex does not provide a gap analysis between API Q1, 8th and 9th Editions. Annex B facilitates the identification of all new additional requirements found in API Q1, 9th Edition.

NOTE Where "No Requirement" is identified in the matrix below, it is an indication that this is a new requirement in the API Q1, 9th Edition that has no corresponding requirement in the API Q1, 8th Edition.

Correlation to API Q1, 8th Edition (ISO/TS 29001 and ISO 9001) *"Soft" Requirements (as applicable, if necessary, etc.) Not Applicable to ISO 9001:2008*	
API Q1, 8th Edition (ISO/TS 29001 and ISO 9001)	**API Q1, 9th Edition**
4.1 General Requirements	
4.1 Establish, document, implement, and maintain QMS	4.1.1, 6.1
4.1 a) Determine processes	4.1.4 a), 4.1.4 b)
4.1 b) Determine process sequence	4.4.1 b) 2)
4.1 c) Determine criteria for effectiveness	4.1.1
4.1 d) Availability of resources	4.2.1
4.1 e) Monitor and measure processes	6.2.3, 6.3 d)
4.1 f) Implement actions	6.1, 6.2.3
4.1 Manage processes	4.1.4 a), 4.1.4 b)
4.1 Control (and its identification within QMS) of outsourced processes	5.6.1.1, 5.6.1.6
4.1 Outsources process control defined	5.6.1.1 f)
4.1.1 Responsibility for outsourced processes	5.6.1.6
4.2 Documentation Requirements	
4.2.1 General	
4.2.1 a) Documentation includes quality policy	4.4.1 a)
4.2.1 b) Documentation includes quality manual	4.4.1 b)
4.2.1 c) Documentation includes procedures and records	4.4.1 c)
4.2.1 d) Documentation includes that for planning and control	4.4.1 d)
4.2.1 e) Records	4.4.1 d)
4.2.2 Quality Manual	
4.2.2 a) QM includes scope and exclusions	4.4.1 b) 1)
4.2.2 b) QM includes procedures	4.4.1 b) 4)
4.2.2 c) QM includes description of process interaction	4.4.1 b) 2)
4.2.2.1 QM identifies controls for each requirement	4.4.1 b)
4.2.3 Control of Documents	
4.2.3 Documents controlled	4.4.3
4.2.3 Records controlled	4.5

[1] As a reminder, Annex C does not identify the new elements of API Q1, 9th Edition of Risk Assessment and Management (5.3), Contingency Planning (5.5), Product Quality Plans (5.7.2), Preventive Maintenance (5.7.8), Product Release (5.9), and Management of Change (5.11). In addition, there are new requirements in several individual sections already found in API Q1. See Annex B or API Q1, 9th Edition for details on those new requirements.

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API Q1, 8th Edition (ISO/TS 29001 and ISO 9001)	**API Q1, 9th Edition**
4.2.3 Document procedure established	4.4.3
4.2.3 a) Document approval	4.4.3, 4.4.3 a)
4.2.3 b) Document review, update, and re-approval	4.4.3
4.2.3 c) Document changes identified	4.4.3 b)
4.2.3 d) Documents available at point of use	4.4.3 d)
4.2.3 e) Documents legible	4.4.3 c)
4.2.3 f) Documents (external) identified and controlled	4.4.3
4.2.3 g) Documents (obsolete) identified	4.4.3
4.2.3.1 Document master list established	*No Requirement*
4.2.3.2 Document changes approved by same as original	*No Requirement*
4.2.4 Control of Records	
4.2.4 Records established and controlled	4.5
4.2.4 Records procedure established	4.5
4.2.4 Records identified, stored, protected, retrieved, retention time ID'd and disposed	4.5
4.2.4 Records legible, identifiable, and retrievable	4.5
4.2.4.1 Records procedure identifies responsible persons	4.5
4.2.4.1 Records retained for time specified in product specifications	4.5
4.2.4.1 Records retained for minimum of five years	4.5
5.1 Management Commitment	
5.1 Top management commits to QMS	4.2.1
5.1 a) Top management communicates customer's requirements	4.1.5.1 a)
5.1 b) Top management establishes quality policy	4.1.2
5.1 c) Top management establishes objectives	4.1.3, 4.2.1 a), 4.2.1 b)
5.1 d) Top management conducts management reviews	4.2.1 b), 6.5.1
5.1 e) Top management ensures resources available	4.2.1
5.2 Customer Focus	
5.2 Top management determines customer needs/satisfaction	4.1.5.2
5.3 Quality Policy	
5.3 a) Quality policy is appropriate	4.1.2
5.3 b) Quality policy includes commitment to comply	4.1.2
5.3 c) Quality policy provides framework for objectives	4.1.2
5.3 d) Quality policy communicated and understood	4.1.2
5.3 e) Quality policy reviewed for continuing suitability	6.5.1
5.3.1 Top management documents approval of quality policy	4.1.2
5.4 Planning	
5.4.1 Top management establishes objectives at functions	4.1.3
5.4.1 Quality objectives measureable and consistent with policy	4.1.3
5.4.2 a) Top management plans the QMS	4.1.4 b)
5.4.2 b) Top management ensure integrity of QMS when changed	5.11
5.5 Responsibility Authority and Communication	
5.5.1 Top management ensures responsibilities are defined	4.2.2
5.5.2 a) Management representative maintains processes	4.2.3 a)
5.5.2 b) Management representative reports to top management	4.2.3 b)
5.5.2 c) Management representative promotes customer awareness	4.2.3 d)
5.5.3 Top management establishes communication processes	4.1.5.1
5.6 Management Review	
5.6.1 Top management reviews quality system	6.5.1
5.6.1 Review includes improvement, changes, policy, and objectives	6.5.1
5.6.1 Records of management reviews maintained	6.5.3

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API Q1, 8th Edition (ISO/TS 29001 and ISO 9001)	**API Q1, 9th Edition**
5.6.1.1 Reviews conducted annually	6.5.1
5.6.2 a) Input includes results of audits	6.5.2 b)
5.6.2 b) Input includes customer feedback	6.5.2 d)
5.6.2 c) Input includes process performance/product conformity	6.5.2 e), 6.5.2 i)
5.6.2 d) Input includes corrective/preventive actions	6.5.2 g)
5.6.2 e) Input includes follow-ups from previous reviews	6.5.2 a)
5.6.2 f) Input includes changes to the QMS	6.5.2 c)
5.6.2 g) Input includes recommendation for improvement	6.5.2 j)
5.6.3 a) Output includes effectiveness of QMS	6.5.3
5.6.3 b) Output includes improvements of product	6.5.3
5.6.3 c) Output includes resource needs	6.5.3
6.1 Provision of Resources	
6.1 a) Resources provided to implement QMS	4.3.1
6.1 b) Resources to enhance customer satisfaction	6.2.1
6.2 Human Resources	
6.2.1 Personnel competent	4.3.2.1, 4.3.2.2
6.2.2 a) Determine competence	4.3.2.1
6.2.2 b) Provide training or other action	4.3.2.1
6.2.2 c) Evaluate effectiveness of actions taken	4.3.2.1
6.2.2 d) Personnel aware of importance of activities	4.3.2.3 d)
6.2.2 e) Maintain records	4.3.2.3 e)
6.2.2.1 Training control features established	4.3.2.1
6.2.2.1 Training include QMS training	4.3.2.3 a)
6.2.2.1 Frequency of training defined	4.3.2.3 c)
6.3 Infrastructure	
6.3 a) Infrastructure includes buildings, workspace, and utilities	4.3.3 a)
6.3 b) Infrastructure includes process equipment	4.3.3 b)
6.3 c) Infrastructure includes support services	4.3.3 c)
6.4 Work Environment	
6.4 Organization manages work environment	4.3.3, 4.3.3 d)
7.1 Planning of Product Realization	
7.1 Plan processes	4.1.4 a), 4.1.4 b), 5.2
7.1 Planning consistent with processes of QMS	4.1.4 a), 5.2
7.1 a) Planning includes objectives and product requirements	4.1.3, 5.2 b)
7.1 b) Planning includes processes and resources	4.3.1, 4.4.1 d), 5.2 a)
7.1 c) Planning includes verification, validations, and monitoring	5.2 f)
7.1 d) Planning includes records	5.2 h)
7.1 Planning output suitable for operations	5.2
7.1.1 Control features for implementing external requirements	4.4.4
7.2 Customer Related Processes	
7.2.1 a) Determine customer requirements	5.1.2 a)
7.2.1 b) Determine unstated customer requirements	5.1.2 c)
7.2.1 c) Determine statutory requirements	5.1.2 b)
7.2.1 d) Determine additional requirements	5.1.2 b)
7.2.2 Review requirements related to product	5.1.3
7.2.2 Review conducted prior to commitment to manufacture	5.1.3
7.2.2 a) Review includes product requirements defined	5.1.3 a)
7.2.2 b) Review includes resolution of differences	5.1.3 b)
7.2.2 c) Review ensures organization capable	5.1.3 c)

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API Q1, 8th Edition (ISO/TS 29001 and ISO 9001)	**API Q1, 9th Edition**
7.2.2 Review records maintained	5.1.3
7.2.2 Confirm undocumented requirements	5.1.2
7.2.2 With changes, documents are amended/personnel notified	5.1.3
7.2.2.1 Product review control features established	5.1.1
7.2.3 a) Communicate product requirements	4.1.5.2 b)
7.2.3 b) Communicate contract handling	4.1.5.2 a)
7.2.3 c) Communicate feedback and complaints	4.1.5.2 c)
7.3 Design and Development	
7.3.1 Plan design of product	5.4.1
7.3.1 a) Planning includes stages	5.4.1 b)
7.3.1 b) Planning includes review, verification, and validation stages	5.4.1 d)
7.3.1 c) Planning includes responsibilities	5.4.1 c)
7.3.1 Manage interfaces	5.4.1 c)
7.3.1 Planning updated as design progresses	5.4.1 a)
7.3.1.1 Design control features established	5.4.1
7.3.1.2 Documentation includes methods, assumptions, etc.	5.4.2 d), 5.4.3 d)
7.3.2 Inputs determined and records maintained	5.4.2
7.3.2 a) Input includes functional and performance requirements	5.4.2
7.3.2 b) Input includes statutory requirements	5.4.2 f)
7.3.2 c) Input includes information from similar designs	5.4.2 e)
7.3.2 d) Input includes essential requirements	5.4.2, 5.4.2 b), 5.4.2 c)
7.3.2 Inputs reviewed for adequacy	5.4.2
7.3.2 Inputs complete, unambiguous	5.4.2
7.3.2.1 Identify, document, and review inputs	5.4.2
7.3.2.1 Inputs include customer-specified requirements	5.4.2 a)
7.3.3 Output in suitable form	5.4.3
7.3.3 Output approved	5.4.6
7.3.3 a) Outputs meet input requirements	5.4.3 a)
7.3.3 b) Outputs provide purchasing information	5.4.3 b)
7.3.3 c) Outputs contact/reference acceptance criteria	5.4.3 c)
7.3.3 d) Output specifies characteristics for safe and proper use	5.4.3 f)
7.3.3.1 Outputs documented	5.4.3
7.3.4 Perform review at planned stages	5.4.4
7.3.4 a) Design reviews performed to evaluate design	5.4.4 a)
7.3.4 b) Design reviews performed to identify problems	5.4.4 b)
7.3.4 Design reviews include all applicable participants	5.4.4
7.3.4 Design review results maintained	5.4.4
7.3.4.1 Final design review conducted and documented	5.4.5
7.3.4.1 Final design review conducted by independent personnel	5.4.6
7.3.5 Design verification performed	5.4.5
7.3.5 Design verification records maintained	5.4.5
7.3.6 Design validation performed	5.4.6
7.3.6 Designed validation performed before delivery	5.4.6
7.3.6 Design validation records maintained	5.4.6
7.3.7 Design changes identified and maintained	5.4.7
7.3.7 Design changes reviewed, verified, and validated	5.4.7
7.3.7 Changes includes effect on parts and delivered product	5.4.7
7.3.7 Design change records maintained	5.4.7
7.3.7.1 Design changes include same controls as original	5.4.7
7.4 Purchasing	

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API Q1, 8th Edition (ISO/TS 29001 and ISO 9001)	**API Q1, 9th Edition**
7.4.1 Purchased product conforms to requirements	5.6.1.1
7.4 1 Purchase control depends on effect in product realization	5.6.1.1, 5.6.1.1 c)
7.4.1 Evaluate and select suppliers	5.6.1.1 b)
7.4.1 Criteria for supplier selection established	5.6.1.1 d)
7.4.1 Records of evaluations maintained	5.6.1.5
7.4.1.1 Purchasing control features established	5.6.1.1
7.4.1.2 a) Selection criteria include inspection at supplier facility	5.6.1.2 b) i)
7.4.1.2 b) Selection criteria include inspection upon delivery	5.6.1.3 c)
7.4.1.2 c) Selection criteria include surveillance of supplier	5.6.1.3 a)
7.4.1.2 d) Selection criteria include supplier conformance to QMS	5.6.1.2 a), 5.6.1.3 b)
7.4.1.3 Outsourced supplier conform to 7.5.2	5.6.1.1 f), 5.7.1.5
7.4.2 a) Information includes approval requirements	5.6.2 a)
7.4.2 b) Information includes personnel qualification requirements	5.6.2 c)
7.4.2 c) Information include QMS requirements	5.6.2 d)
7.4.2 Adequacy of requirements determined	5.6.2
7.4.2.1 Information documented and describes product	5.6.2
7.4.2.1 a) Information includes type, class, or other information	5.6.2 b)
7.4.2.1 b) Information includes applicable specifications	5.6.2 b)
7.4.3 Inspection activities established	5.6.3
7.4.3 On-site supplier verification arrangements identified	5.6.3
7.4.3.1 Verification of product control features and records established	5.6.3
7.5 Production and Service Provision	
7.5.1 Production and service controlled	5.7.1.1
7.5.1 a) Controls include characteristic of product	5.7.1.1 a)
7.5.1 b) Controls include availability of work instructions	5.7.1.1 e)
7.5.1 c) Controls include suitable equipment	5.7.1.1 d)
7.5.1 d) Controls include use of monitoring and measuring devices	5.7.1.1 d)
7.5.1 e) Controls include monitoring and measurement	5.7.1.1 g)
7.5.1 f) Controls include release and post-delivery activities	5.7.1.1 h)
7.5.1.1 Production control features established	5.7.1.1
7.5.1.2 Process controls documented in routings, etc.	5.7.1.3
7.5.1.2 Process control documents include acceptance criteria	5.7.1.3
7.5.2 Validate processes where output cannot be verified	5.7.1.5
7.5.2 Validation demonstrates ability to achieve results	5.7.1.5
7.5.2 a) Process validation includes defined criteria	5.7.1.5 d)
7.5.2 b) Process validation includes approval of equipment/personnel	5.7.1.5 a), 5.7.1.5 b)
7.5.2 c) Process validation includes used of procedures	5.7.1.5 c)
7.5.2 d) Process validation includes records	5.7.1.5 e)
7.5.2 e) Process validation includes revalidation	5.7.1.5 f)
7.5.2.1 Process validation includes heat treating, welding, and nondestructive examination	5.7.1.5
7.5.3 Identify the product	5.7.3
7.5.3 Identify product status	5.7.4
7.5.3 Control traceability and maintain records	5.7.3
7.5.3.1 Product identification control features established	5.7.3
7.5.3.2 Controls for replacement or maintenance of identification	5.7.3
7.5.3.3 Product status control features established	5.7.4
7.5.4 Care for customer property	5.7.5
7.5.4 Identify, verify, protect, and safeguard customer property	5.7.5
7.5.4 Report to customer lost or damaged property and records maintained	5.7.5

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"Soft" Requirements (as applicable, if necessary, etc.) Not Applicable to ISO 9001:2008

API Q1, 8th Edition (ISO/TS 29001 and ISO 9001)	API Q1, 9th Edition
7.5.4.1 Customer property control features	5.7.5
7.5.5 Preserve product during processing	5.7.6.1
7.5.5 Preservation includes ID, handling, packaging, storage, and protection	5.7.6.1, 5.7.6.2
7.5.5 Preservation applies to constituent parts	5.7.6.2
7.5.5.1 Preservation control features established	5.7.6.1
7.5.5.2 Product and parts assessed at specified intervals	5.7.6.2
7.6 Control of Monitoring and Measurement Equipment	
7.6 Determine measurements and equipment needed	5.8
7.6 Establish processes for measuring and monitoring	5.8
7.6 a) Equipment calibrated at specified intervals against standards	5.8 c), 5.8 d)
7.6 b) Equipment adjusted and readjusted	5.8 e)
7.6 c) Equipment identified	5.8 a), 5.8 b)
7.6 d) Equipment safeguarded from adjustments	5.8 3)
7.6 e) Equipment protected	5.8 4)
7.6 Assess results if equipment out of calibration	5.8 h)
7.6 Take action on equipment and product if out of calibration	5.8 h)
7.6 Calibration records maintained	5.8
7.6 Computer software confirmed for intended use	5.8
7.6 Computer software verified before use	5.8
7.6.1 Calibration control features established	5.8
7.6.1 Controls include ID, location, frequency, method, and acceptance	5.8 a), 5.8 d), 5.8 e), 5.8 f)
7.6.2 Environmental conditions controlled.	5.8 5)
8.1 Measurement, Analysis, and Improvement—General	
8.1 a) Measurement to demonstrate conformity of product	6.3 b)
8.1 b) Measurement to ensure conformity to QMS	6.1
8.1 c) Measurement to continually improve QMS	6.1
8.1 Measurement includes statistical techniques	6.1
8.2 Monitoring and Measurement	
8.2.1 Monitor customer satisfaction	6.2.1
8.2.1 Methods for determining customer satisfaction	6.2.1
8.2.2 Conduct audits a planned intervals	6.2.2.1
8.2.2 a) Audit to check conformity to QMS requirements	6.2.2.1
8.2.2 b) Audit to check QMS implemented	6.2.2.1
8.2.2 Audits consider results of previous audits	6.2.2.1
8.2.2 Audit scope, criteria, methods, and frequency defined	6.2.2.1
8.2.2 Auditors and audits remain objective	6.2.2.2
8.2.2 Auditors do not audit own work	6.2.2.2
8.2.2 Audit procedure established	6.2.2.1
8.2.2 Audit records maintained	6.2.2.2, 6.2.2.3
8.2.2 Audited areas followed up without delay	6.2.2.3
8.2.2 Audit follow-ups include verification of actions taken	6.2.2.3
8.2.2.1 Audits conducted annually by independent personnel	6.2.2.1
8.2.2.2 Response times for nonconformities identified	6.2.2.3
8.2.3 Monitor and measure QMS processes	6.2.3
8.2.3 Demonstration of ability of processes to achieve results	6.2.3
8.2.3 When results not achieved, corrective action taken	6.2.3
8.2.4 Monitor and measure product conducted	5.7.7.1
8.2.4 Monitor and measure product at planned stages	5.7.7.1, 5.7.7.2
8.2.4 Evidence of conformity maintained	5.7.7.2
8.2.4 Records indicate person releasing product	5.9
8.2.4 Release of product after requirements met/OK by customer	5.9

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API Q1, 8th Edition (ISO/TS 29001 and ISO 9001)	**API Q1, 9th Edition**
8.2.4.1 Product monitor/measure control features established	5.7.7.1
8.2.4.2 Final inspection by independent personnel	5.7.7.3
8.3 Control of Nonconforming Product	
8.3 Nonconforming product identified and controlled	5.10.1, 5.10.1 a)
8.3 Nonconforming product procedure established	5.10.1
8.3 a) Controls for action to eliminate nonconformity	5.10.1 b)
8.3 b) Controls for release under concession	5.7.4, 5.10.1 d), 5.10.2 c)
8.3 c) Controls for action to preclude use	5.10.1 c)
8.3 Controls for action after product delivered	5.10.1 3)
8.3 Nonconforming product reverified after corrected	5.10.2 a)
8.3 Records of nonconformity actions maintained	5.10.5
8.3.1 a) Release of products not meeting MAC	5.10.3 a), 5.10.3 b)
8.3.1 b) Release of products not meeting DAC	5.10.3 c)
8.3.2 Controls for field nonconformities	*No Requirement*
8.3.2 Controls for evaluation of field nonconformities	*No Requirement*
8.3.3 Notification when delivered product not meeting design	5.10.4
8.3.3 Records of customer notification	5.10.4
8.4 Analysis of Data	
8.4 Collect and analyze data	6.3
8.4 Data from monitoring, measurement, and other sources	6.3
8.4 a) Data analysis includes customer satisfaction	6.3 a)
8.4 b) Data analysis includes product conformity	6.3 b)
8.4 c) Data analysis includes process trends	6.3 d)
8.4 d) Data analysis includes suppliers	6.3 e)
8.4.1 Data analysis control features established	6.3
8.5 Improvement	
8.5.1 Continually improve effectiveness of the QMS	6.1, 6.4.1
8.5.2 Eliminate causes of nonconformities	6.4.2
8.5.2 Corrective actions appropriate to effects	6.4.2
8.5.2 Procedure for corrective actions established	6.4.2
8.5.2 a) Review nonconformities	6.4.2 a)
8.5.2 b) Determine cause of nonconformities	6.4.2 c)
8.5.2 c) Evaluate need for action	6.4.2 c)
8.5.2 d) Determine and implement need for action	6.4.2 b), 6.4.2 d)
8.5.2 e) Records of actions taken	6.4.2
8.5.2 f) Review corrective action	6.2.4 f)
8.5.2.1 Corrective action effective	6.2.4 f)
8.5.2.2 Identify response times for corrective actions	6.4.2 e)
8.5.3 Eliminate the potential cause of nonconformities	6.4.3
8.5.3 Procedure for preventive action established	6.4.3
8.5.3 a) Determine potential nonconformities	6.4.3 b)
8.5.3 b) Evaluate need for action	6.4.3 c)
8.5.3 c) Determine and implement need for action	6.4.3 c)
8.5.3 d) Records of action taken	6.4.3
8.5.3 e) Review effectiveness of preventive action	6.4.3 e)
8.5.3.1 Ensure preventive action effective	6.4.3 e)

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2 British Standards Institution, Chiswick High Road, London W4 4AL, United Kingdom, www.bsi-global.com.

3 International Organization for Standardization, 1, ch. de la Voie-Creuse, Case postale 56, CH-1211 Geneva 20, Switzerland, www.iso.org.

4 U.S. Department of Labor, Occupational Safety and Health Administration, 200 Constitution Avenue, NW, Washington, DC 20210, www.osha.gov.

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