Guidance on Changes to API Q1, Ninth Edition

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Suggested revisions are invited and should be submitted to the Standards Department, API, 1220 L Street, NW, Washington, DC 20005, standards@api.org.

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Guidance on Changes to API Q1, Ninth Edition

1 Scope

This document is written for experienced quality professionals seeking to implement the new requirements of API Q1, Ninth Edition (Q1, 9th) and to gain a deeper understanding of the requirements with an overall view to improving their quality management system (QMS) and conformance to Q1, 9th.

While Q1, 9th was created independently of ISO 9001:2008, the specification continues to satisfy those requirements and the supplemental requirements in API Q1, Eighth Edition (Q1, 8th). The formatting of Q1, 9th was revised to align with API Q2, First Edition and to follow a chronological order in the production and delivery of the product.

2 Normative References

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

API Specification Q1, *Specification for Quality Programs for the Petroleum, Petrochemical and Natural Gas Industry*, Eighth Edition

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

API Specification Q2, *Specification for Quality Management System Requirements for Service Supply Organizations for the Petroleum and Natural Gas Industry*

3 Terms, Definitions, Acronyms, and Abbreviations

3.1 Terms and Definitions

For the purposes of this document, the terms and definitions given in API Q1 apply.

3.2 Acronyms and Abbreviations

DAC	design acceptance criteria
KPI	key performance indicator
MOC	management of change
Q1, 8th	API Specification Q1, Eighth Edition
Q1, 9th	API Specification Q1, Ninth Edition
QMS	quality management system

4 Changes from Previous Edition

1 Scope

Intent of Section

The intent of this section is to outline the areas to which the specification applies.

Changes from Previous Edition

— Q1, 8th included provisions for service supply organizations, which are now covered by API Q2.

— Added 5.8 to the list as an excludable section.

3 Terms, Definitions, and Abbreviations

Intent of Section

The intent of this section is to specify terms and definitions in addition to those given in ISO 9000.

Changes from Previous Edition

Q1, 9th eliminated 2 terms, added 12 new terms, expanded on 2 terms, and renamed 1 term. Abbreviations were added to Q1, 9th that were not present in Q1, 8th.

Eliminated the following Q1, 8th terms:

— 3.1.9 field nonconformity,

— 3.1.11 tender.

Added the following terms to Q1, 9th:

— 3.1.4 collection,

— 3.1.5 compliance,

— 3.1.6 critical,

— 3.1.11 first article,

— 3.1.12 key performance indicator (KPI),

— 3.1.13 legal requirement,

— 3.1.14 management [*noun*],

— 3.1.16 outsource [outsourced activity],

— 3.1.17 preventive maintenance,

— 3.1.19 risk,

— 3.1.20 service,

— 3.1.21 servicing.

Expanded the following terms:

— 3.1.9 design validation was modified to include a note that provides examples of design validation that were previously in Q1, 8th, 7.3.6;

— 3.1.10 design verification was modified to include a note that provides examples of design verification that were previously in Q1, 8th, 7.3.5.

Renamed the following term:

— in Q1, 8th, 3.1.4 control feature was renamed 3.1.18 procedure.

4 Quality Management System Requirements

This section consolidated requirements from Sections 4, 5, and 6 of Q1, 8th.

4.1 Quality Management System

4.1.1 General

Intent of Section

The intent of this section is to establish requirements related to the QMS.

Changes from Previous Edition

— Added the terms “at all times” and “for all products and servicing provided for use in the petroleum and natural gas industry.”

4.1.2 Quality Policy

Intent of Section

The intent of this section is to establish requirements related to the quality policy.

Changes from Previous Edition

— Added the requirement for the quality policy to be communicated, understood, implemented, and maintained at all relevant functions and levels within the organization.

4.1.3 Quality Objectives

Intent of Section

The intent of this section is to establish requirements related to the quality objectives.

Changes from Previous Edition

— Changed the responsibility for establishing quality objectives from top management to management with approval from top management.

— Expanded the requirement for quality objectives to include customer requirements.

4.1.4 Planning

Intent of Section

The intent of this section is to establish requirements related to planning for the QMS.

Changes from Previous Edition

— Changed responsibility for QMS planning from top management to management.

4.1.5 Communication

4.1.5.1 Internal

Intent of Section

The intent of this section is to establish requirements related to internal communication for the QMS.

Changes from Previous Edition

— Changed the responsibility for internal communication from top management to management.

— Added requirement 4.1.5.1 b) results of analysis of data need to be communicated at relevant levels.

4.1.5.2 External

Intent of Section

The intent of this section is to establish requirements related to external communication for the QMS.

Changes from Previous Edition

— Added requirement 4.1.5.2 d) information required by product quality plans is to be provided when required by contract

4.2 Management Responsibility

Some of the responsibilities that were assigned to top management in Q1, 8th have been assigned to management in Q1, 9th.

4.2.1 General

Intent of Section

The intent of this section is to establish responsibilities for top management and management in an organization.

Changes from Previous Edition

— Added the use of KPIs for data analysis.

4.2.2 Responsibility and Authority

Intent of Section

The intent of this section is to establish the responsibility, authority, and accountability of personnel within the scope of the QMS.

Changes from Previous Edition

— Expanded the requirement for ensuring that responsibility and authority are defined and communicated to include accountability.

— The application of this requirement is now specified to be personnel within the QMS.

— Added the requirement for documentation.

4.2.3 Management Representative

Intent of Section

The intent of this section is to establish responsibilities and authorities for the management representative.

Changes from Previous Edition

— Added requirement 4.2.3 c) management representative is to ensure that actions are taken to reduce the likelihood of the occurrence of nonconformities.

— Added the requirement for top management to maintain a management representative.

4.3 Organization Capability

4.3.1 Provision of Resources

Intent of Section

The intent of this section is to establish responsibility for appropriate resource allocation to implement, maintain, and improve the effectiveness of the QMS.

Changes from Previous Edition

— Removed the word “continually” from the requirement to improve the effectiveness of the QMS [Q1, 8th, 6.1 a)].

— Removed the requirement to provide the resources needed to enhance customer satisfaction by meeting customer requirements [Q1, 8th, 6.1 b)].

4.3.2 Human Resources

4.3.2.1 General

Intent of Section

The intent of this section is to establish the requirement for a procedure defining personnel competency and identifying training requirements and other actions necessary to achieve personnel competency.

Changes from Previous Edition

— Separated personnel competence from training and awareness.

— Added the requirement for a documented procedure defining personnel competence.

4.3.2.2 Personnel Competence

Intent of Section

The intent of this section is to establish the requirements for personnel competence and the associated records.

Changes from Previous Edition

— Added the requirement for personnel to be competent to meet customer requirements.

— Added the requirement to maintain records of the determination of personnel competence.

4.3.2.3 Training and Awareness

Intent of Section

The intent of this section is to establish requirements for QMS and job training.

Changes from Previous Edition

— Added requirement 4.3.2.3 b) customer-specified training and/or customer-provided training (when required).

— Added requirement 4.3.2.3 c) identification of training content to the requirement to identify training frequency.

4.3.3 Work Environment

Intent of Section

The intent of this section is to establish the requirements for an organization to identify and manage the conditions of the work environment needed to achieve conformity of product.

Changes from Previous Edition

— Merged the requirements for infrastructure and work environment into one section, “Work Environment.”

— Incorporated the note that was in Q1, 8th into this section to expand the work environment requirements to achieve conformity to the manufacture of the product.

— Expanded 4.3.3 b) to include maintenance of process equipment.

4.4 Documentation Requirements

4.4.1 General

Intent of Section

The intent of this section is to establish the minimum documentation requirements for an organization’s QMS.

Changes from Previous Edition

— Included the quality manual section under general instead of a separate section.

— Added requirement 4.4.1 b), Item 3) identification of processes that require validation.

— Expanded requirement 4.4.1 d) to include compliance with specified requirements.

— Added requirement 4.4.1 e) identification of legal and other applicable requirements.

4.4.2 Procedures

Intent of Section

The intent of this section is to establish the requirement that procedures be documented and maintained.

Changes from Previous Edition

— This is a new section.

4.4.3 Control of Documents

Intent of Section

The intent of this section is to establish the requirements for document control.

Changes from Previous Edition

— Removed the requirement for a master list or equivalent.

— Removed the requirement for document changes to be reviewed and approved by the original function.

— Added translations and updates.

— Specified “documents” to be controlled as procedures, forms, and work instructions.

— Included identification and distribution requirements to the documented procedure.

4.4.4 Use of External Documents in Production Realization

Intent of Section

The intent of the section is to establish the requirement for control of external documents used in product realization.

Changes from Previous Edition

— Added requirement for a documented procedure for the integration of external documents into the product realization process and any other affected processes.

4.5 Control of Records

Intent of Section

The intent of this section is to establish the requirements for control of records needed for the QMS.

Changes from Previous Edition

— Added the requirement to establish and control records, including those originating from outsourced activities.

— Modified the retention time requirement by the addition of customer, legal, or other requirements, if applicable.

5 Product Realization

5.1 Contract Review

5.1.1 General

Intent of Section

The intent of this section is to establish the requirements related to contract review.

Changes from Previous Edition

— Expanded the requirement to include any required servicing.

5.1.2 Determination of Requirements

Intent of Section

The intent of this section is to define the requirements that an organization needs to determine during contract review.

Changes from Previous Edition

— There are no new requirements.

5.1.3 Review of Requirements

Intent of Section

The intent of this section is to establish review requirements related to the provision of products.

Changes from Previous Edition

— Clarified that review requirements were related to provision of products instead of product requirements.

— Added the requirement for documentation of requirements.

5.2 Planning

Intent of Section

The intent of this section is to establish the minimum requirements for product realization planning.

Changes from Previous Edition

— Added requirement 5.2 c) address legal and other requirements.

— Added requirement 5.2 d) contingencies based on risk assessment.

— Added requirement 5.2 g) address management of change (MOC).

— Added requirement to have a documented plan that is updated when changes occur.

5.3 Risk Assessment and Management

Intent of Section

The intent of this section is to establish requirements for identification and mitigation of risks associated with product quality and delivery.

Changes from Previous Edition

— This is a new requirement.

5.4 Design and Development

5.4.1 Design and Development Planning

Intent of Section

The intent of this section is to establish the minimum planning requirements for the design and development process.

Changes from Previous Edition

— Added the requirement to identify final design review requirements.

— Added the requirement to identify controls when design and development activities are performed at different locations within the same organization.

5.4.2 Design and Development Inputs

Intent of Section

The intent of this section is to establish required design and development inputs.

Changes from Previous Edition

— Use of the word “technical,” which was implied in Q1, 8th, is now made explicit as a design and development input.

— 5.4.2 b) API product specifications have been identified as a potential external source for design inputs.

— 5.4.2 c) the environmental and operational conditions are now specifically listed to form part of the inputs to the design and development process.

— 5.4.2 e) historical performance is now identified as an input.

— 5.4.2 g) the results from risk assessments are design inputs.

5.4.3 Design and Development Outputs

Intent of Section

The intent of this section is to establish requirements for design and development outputs.

Changes from Previous Edition

— Replaced product acceptance criteria by design acceptance criteria (DAC).

— Added the requirement 5.4.3 d) identification or reference to critical product/components.

5.4.4 Design and Development Review

Intent of Section

The intent of this section is to establish the requirements for design and development reviews.

Changes from Previous Edition

— In 5.4.4 a), “suitability, adequacy and effectiveness” replaced “ability” of design and development results to meet specified requirements.

5.4.5 Design and Development Verification and Final Review

Intent of Section

The intent of this section is to establish requirements for design and development verification and final review.

Changes from Previous Edition

— There are no changes from the previous edition.

5.4.6 Design and Development Validation and Approval

Intent of Section

The intent of this section is to establish the requirements for design and development validation and approval.

Changes from Previous Edition

— Specified that design approval is after design validation.

— Added the requirement for competent individuals to approve the final design.

5.4.7 Design and Development Changes

Intent of Section

The intent of this section is to establish requirements for the identification, review, performance, and approval of all changes to existing designs prior to implementation of the change.

Changes from Previous Edition

— There are no changes from the previous edition.

5.5 Contingency Planning

Intent of Section

The intent of this section is to ensure that contingency planning based on previously identified risks is conducted and communicated. The section requires a documented procedure for contingency planning with minimum requirements for planning output.

Changes from Previous Edition

— This is a new requirement.

5.6 Purchasing

5.6.1 Purchasing Control

5.6.1.1 Procedure

Intent of Section

The intent of this section is to have the organization maintain a documented procedure in regards to purchased products or outsourced activities in order to meet specified requirements.

Changes from Previous Edition

— Added requirement 5.6.1.1 a) determination of the criticality of the activities or products as they are applicable.

— Added requirement 5.6.1.1 c) type and extent of control applied to the supplier based on the criticality of the product or activity.

— Added requirement 5.6.1.1 d) scope, frequency, and methods for reassessment of suppliers.

— Added requirement 5.6.1.1 e) maintaining a list of approved suppliers and scope of approval.

5.6.1.2 Initial Supplier Evaluation—Critical Purchases

Intent of Section

The intent of this section is to establish the criteria for the initial evaluation of suppliers deemed to be critical with details regarding verification of the supplier's QMS and manufacturing capabilities in order to meet specified requirements.

Changes from Previous Edition

— This is a new section.

5.6.1.3 Initial Supplier Evaluation—Noncritical Purchases

Intent of Section

The intent of this section is to establish the criteria for the initial evaluation of suppliers deemed to be noncritical with details regarding verification of the supplier's QMS and manufacturing capabilities in order to meet specified requirements upon delivery or completion.

Changes from Previous Edition

— Although this is a new section, the concept was included in Q1, 8th.

5.6.1.4 Supplier Reevaluation

Intent of Section

The intent of this section is to establish the requirements for reevaluating critical and noncritical suppliers.

Changes from Previous Edition

— Although this is a new section, the concept was included in Q1, 8th.

5.6.1.5 Supplier Evaluation—Records

Intent of Section

The intent of this section is to establish the necessity to record evaluation, perform actions from the evaluations, and maintain the records.

Changes from Previous Edition

— Although this is a new section, the concept was included in Q1, 8th.

5.6.1.6 Outsourcing

Intent of Section

The intent of this section is hold the manufacturing organization responsible for product conformance based on customer- and API-specified requirements for products and activities that are outsourced.

Changes from Previous Edition

— Although this is a new section, the concept was included in Q1, 8th. The requirement that records of outsourced activities be maintained (4.5) is a new requirement.

5.6.2 Purchasing Information

Intent of Section

The intent of this section is to specify the purchasing information requirements that describe the product or activity to be purchased; acceptance criteria; and other requirements for the supplier regarding processes, the qualification of personnel, and QMS.

Changes from Previous Edition

— This section combines Q1, 8th, Sections 7.4.2 and 7.4.2.1.

— Added traceability to the list of applicable versions of purchasing information.

5.6.3 Verification of Purchased Products or Activities

Intent of Section

The intent of this section is to state the requirements for a documented procedure for the verification of purchased products or activities in order to ensure that they meet specified requirements by performing verifications at the supplier's premises and maintaining records of these activities.

Changes from Previous Edition

— This section combines Q1, 8th, Sections 7.4.3 and 7.4.3.1.

5.7 Production and Servicing Provision

This section has been rewritten from Q1, 8th, where 7.5.1 addressed the requirements for "Control of Production and Service Provision." In Q1, 9th, this section has been separated into subsections "Production" and "Servicing." The word "service" applies to API Q2, and the word "servicing" applies to API Q1. See the definition of "servicing" in Section 3, Terms, Definitions, and Abbreviations.

5.7.1 Control of Production and Servicing

5.7.1.1 Production

Intent of Section

The intent of this section is to establish the requirement of a documented procedure for the controls associated with the production of products.

Changes from Previous Edition

— 5.7.1.1 d) adds production and testing to Q1, 8th, 7.5.1 e).

— Added requirement 5.7.1.1 b) implementation of the product quality plan, when applicable (Q1, 9th, 5.7.2).

— Added requirement 5.7.1.1 c) ensuring design requirements and related changes are satisfied, when applicable (Q1, 9th, 5.4).

5.7.1.2 Servicing

Intent of Section

The intent of this section is to establish the requirement of a documented procedure for the controls associated with the performance of servicing of products.

Changes from Previous Edition

— Q1, 8th, 7.5.1 was split into two separate sections in Q1, 9th: 5.7.1.1 and 5.7.1.2. This change was made to differentiate between production and servicing. This change was also made to allow exclusion of servicing.

— Added requirement 5.7.1.2 a) review and implementation of the organization's, customer-specific, product servicing, and other servicing requirements.

— 5.7.1.2 b) added servicing and testing to Q1, 8th, 7.5.1 e).

— Added requirement 5.7.1.2 d) ensuring identification and traceability requirements are maintained throughout the servicing process.

5.7.1.3 Process Control Documents

Intent of Section

The intent of this section is to establish the requirement for documentation of process controls.

Changes from Previous Edition

— Added the requirement for process controls to include requirements for verifying conformance to applicable API product specifications and customer requirements.

5.7.1.4 Product Realization Capability Documentation

Intent of Section

The intent of this section is to establish the requirement to develop and maintain documentation for demonstrating an organization's capability to satisfy product and/or servicing requirements.

Changes from Previous Edition

— This is a new requirement.

5.7.1.5 Validation of Processes for Production and Servicing

Intent of Section

The intent of this section is to establish the additional controls required for processes that cannot be verified by subsequent monitoring.

Changes from Previous Edition

— Added the requirement for a documented procedure.

— Added the requirement for “identified operating parameters” for the required specific methods that must be part of the control requirements.

5.7.2 Product Quality Plans

Intent of Section

The intent of this section is to provide an organization the minimum expectations that need to be included in a product quality plan when required by contract to show how the organization will meet customer-specified requirements. Product quality plans can be created in several ways depending on each organization’s production and servicing complexities and customer-specified requirements/formats.

Changes from Previous Edition

— This is a new requirement.

5.7.3 Identification and Traceability

Intent of Section

The intent of this section is to establish the basic procedural requirements for identification and traceability of a product while under control of the organization if required by the organization, the customer, or the product specification.

Changes from Previous Edition

— Combined two supplemental requirements, Sections 7.5.3.1 and 7.5.3.2 from Q1, 8th, into the basic requirement in Q1, 9th.

5.7.4 Product Inspection and Test Status

Intent of Section

The intent of this section is to enable organizations to establish a method of identifying and maintaining the product inspection and test status of the product.

Changes from Previous Edition

— Combined Q1, 8th requirements 7.5.3.3, 8.3 b), and portions of 8.2.4 to form this section in Q1, 9th to emphasize the importance of product status.

— Added the requirement to ensure that only product meeting product requirements or authorized by concession is released.

5.7.5 Customer-supplied Property

Intent of Section

The intent of the section is to provide requirements for the control of customer-supplied property.

Changes from Previous Edition

— Added the word “preservation” to the controls required for customer property.

— The requirement to include intellectual property and data was changed from being a note in Q1, 8th, 7.5.4 to being a requirement.

— Removed the word “personal” so as not to limit the scope of customer data.

— Strengthened the requirement for records to include records of control and disposition of customer-supplied property while under control of the organization. Q1, 8th only required records to be maintained for property that was lost, damaged, or unsuitable for use.

5.7.6 Preservation of Product

5.7.6.1 General

Intent of Section

The intent of the section is to provide requirements for the preservation of product including constituent parts through manufacturing, finished product storage, and delivery (transfer of ownership).

Changes from Previous Edition

— Expanded the requirements for preservation to include “traceability marks” and “transportation.”

5.7.6.2 Storage and Assessment

Intent of Section

The intent of the section is to provide requirements for storing and assessing product pending use or delivery.

Changes from Previous Edition

— Added the requirement to use designated storage areas or stock rooms.

— Added the requirement to make assessment intervals appropriate to the product or constituent part being assessed.

— Added the requirement to maintain records of the assessment.

5.7.7 Inspection and testing

5.7.7.1 General

Intent of Section

The intent of the section is to require an organization to maintain a documented procedure that provides requirements for the inspection and testing of product and the associated records.

Changes from Previous Edition

— Clarified the term “at appropriate stages of the product realization process” to include in-process and final inspection.

5.7.7.2 In-process Inspection and Testing

Intent of Section

The intent of the section is to provide requirements for in-process inspection and testing of product.

Changes from Previous Edition

— Replaced the phrase “appropriate stages of product realization process in accordance with planned arrangements” from Q1, 8th, 8.2.4 with the phrase “at planned stages as required by the product quality plan, process control documents, and/or documented procedures.”

5.7.7.3 Final Inspection and Testing

Intent of Section

The intent of the section is to provide requirements for final inspection and testing of product.

Changes from Previous Edition

— Replaced the phrase “planned arrangements” from Q1, 8th, 8.2.4 to the phrase “product quality plan and/or documented procedures.”

— Clarified that maintenance of evidence of conformity is a documented record.

— Added note to provide clarification regarding single step inspection and testing activity.

5.7.8 Preventive Maintenance

Intent of Section

The intent of this section is to establish the minimum requirements for a preventive maintenance program and complement 4.3.3 and 5.3 a) in Q1, 9th.

Changes from Previous Edition

— This is a new section that was developed to expand an inferred requirement in Q1 8th, 6.3 regarding the maintenance of infrastructure.

5.8 Control of Testing, Measuring, and Monitoring Equipment

Intent of Section

The intent of this section is to establish minimum requirements for control of testing, measuring, and monitoring equipment including verification, calibration, traceability, safeguarding from unintended adjustments, and protection from damage or deterioration.

Changes from Previous Edition

— Added the requirement for verification of externally provided equipment (including third-party, proprietary, employee, and customer owned).

— Added the requirement for the creation of an equipment registry.

— Added the requirement to control equipment identified as out of calibration [5.8 g)] to prevent unintended use.

— Added the requirement of evidence of notification to the customer in 5.8 h).

— Q1, 8th, 7.6 c) was modified in 5.8, Item 2) to clarify that calibration status was not required to be identified on the instrument itself.

— Added Notes 1 and 2 for clarification.

5.9 Product Release

Intent of Section

The intent of this section is to provide requirements for product release to customer.

Changes from Previous Edition

— This is a new section; however, the requirements have not changed from those in Q1, 8th (8.2.4).

5.10 Control of Nonconforming Product

5.10.1 General

Intent of Section

The intent of the section is to require an organization to maintain a documented procedure that provides controls, responsibilities, and authorities for nonconforming products.

Changes from Previous Edition

— Introduced the phrases “identified during product realization” and “identified after delivery.”

— The requirements in Q1, 9th, 5.10.1 a) to 5.10.1 d) are found in Q1, 8th, 8.3.

— The requirements in Q1, 9th, 5.10.1.1, 5.10.1.2, and 5.10.1.3 are a consolidation of the requirements in Q1, 8th, 8.3 and 8.3.2.

5.10.2 Nonconforming Product

Intent of Section

The intent of this section is to identify specific methods to address nonconforming product.

Changes from Previous Edition

— Included scrapping of product as a method to address nonconforming product.

— Introduced the term “regrade,” which meets the intent of Q1, 8th, 8.3.1 b).

5.10.3 Release of Nonconforming Product under Concession

Intent of Section

The intent of this section is to define requirements for concessions.

Changes from Previous Edition

— Relocated the requirement of Q1, 8th, 8.3 b) to Q1, 9th, 5.10.3.

— Added the phrase “and/or customer criteria” to 5.10.3 a) and 5.10.3 b) in addition to the DAC.

5.10.4 Customer Notification

Intent of Section

The intent of this section is to define requirements for customer notification when product not meeting DAC or contract requirements has been delivered.

Changes from Previous Edition

— There are no changes from the previous edition.

5.10.5 Records

Intent of Section

The intent of this section is to define record requirements for nonconformances.

Changes from Previous Edition

— There are no changes from the previous edition.

5.11 Management of Change (MOC)

5.11.1 General

Intent of Section

The intent of this section is to establish the requirement to ensure that the integrity of the QMS is maintained when changes are planned and implemented. Keywords in this section are “maintain a process” as opposed to requiring a documented procedure.

Changes from Previous Edition

— This is a new requirement.

5.11.2 MOC Implementation

Intent of Section

The intent of this section is to establish the types of changes that would require a MOC.

Changes from Previous Edition

— This is a new requirement.

5.11.3 MOC Notification

Intent of Section

The intent of this section is to establish the requirement to notify relevant personnel of the change, including any new or residual risk due to the changes. Customers are notified when required by contract.

Changes from Previous Edition

— This is a new requirement.

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

6.1 General

Intent of Section

The intent of this section is to provide the general QMS requirements for monitoring, measuring, analyzing, and continual improvement.

Changes from Previous Edition

— There are no changes from the previous edition.

6.2 Monitoring, Measuring, and Improving

6.2.1 Customer Satisfaction

Intent of Section

The intent of this section is to establish the requirement to have a documented procedure for the measurement of customer satisfaction.

Changes from Previous Edition

— Added the requirement to have a documented procedure and to maintain records of customer satisfaction information.

— Added the requirement for the procedure to address the frequency of measurement, data sources, and KPIs.

6.2.2 Internal Audit

6.2.2.1 General

Intent of Section

The intent of this section is to establish the requirements for a documented procedure and responsibilities for internal QMS audits.

Changes from Previous Edition

— Changed the requirement to conduct audits annually to at least every 12 months.

— Added requirement for on-site outsourced activities impacting product quality to be part of the internal audit.

6.2.2.2 Performance of Internal Audit

Intent of Section

The intent of this section is to establish the competency and independence requirements for internal auditors.

Changes from Previous Edition

— Added requirement for competent personnel.

— Expanded the requirement for records to provide objective evidence that the QMS was implemented and maintained.

— Added requirement to audit all QMS processes prior to claiming conformance to Q1, 9th.

6.2.2.3 Audit Review and Closure

Intent of Section

The intent of this section is to establish and assign responsibility for responding to internal audit nonconformities.

Changes from Previous Edition

— Added the requirement for corrections and corrective actions to follow the requirements of Q1, 9th, 6.4.2.

— This section now ties the results and corrective action to the management review.

6.2.3 Process Evaluation

Intent of Section

The intent of this section is to establish the requirement for evaluation of the QMS to achieve planned results and conformity to product requirements.

Changes from Previous Edition

— Added note to explain that the performance of internal audits and management reviews satisfies this requirement.

— The ISO note in Q1, 8th, 8.2.3 regarding conformity to product requirements was brought into this section as a requirement.

6.3 Analysis of Data

Intent of Section

The intent of this section is to require data analysis to demonstrate the suitability and effectiveness of the QMS and to evaluate where improvements can be made.

Changes from Previous Edition

Q1, 9th added two new sources of data:

— internal audits,

— management reviews.

There are two new additions to the output of data analysis:

— product failures identified after delivery or use,

— information relating to quality objectives.

6.4 Improvement

6.4.1 General

Intent of Section

The intent of this section is to identify methods for the organization to use to improve the effectiveness of the QMS.

Changes from Previous Edition

— Added note to refer to ISO 9000 for definitions of correction, corrective action, and preventive action.

6.4.2 Corrective Action

Intent of Section

The intent of this section is to establish the requirements for a documented procedure for managing nonconformities.

Changes from Previous Edition

— Added the phrase “both internally and within the supply chain” to emphasize that corrective actions are applicable both internally and externally to the organization.

— Added a note to clarify that corrective action applies both to QMS processes and products.

— 6.4.2 e) added the requirement for identifying responsible persons to address corrections and corrective actions.

— 6.4.2 g) was added to require MOC when corrective actions require new or changed controls within the QMS.

— Added the requirements for records to be maintained of the activities for control of a nonconforming process and to identify the activities performed to verify effectiveness of corrective actions taken.

6.4.3 Preventive Action

Intent of Section

The intent of this section is to establish the requirements for a documented procedure for managing potential nonconformities.

Changes from Previous Edition

— Added the phrase “both internally and within the supply chain” to emphasize that corrective actions are applicable both internally and externally to the organization.

— Added a note to clarify that preventive action applies both to QMS processes and products.

— Expanded 6.4.3 c) to include immediate and short-term actions.

— Added requirement 6.4.3 a) identifying opportunities for improvement.

— Added requirement 6.4.3 d) identifying the timeframe and responsible person(s) for implementing a preventive action.

— Added requirement 6.4.3 f) MOC when the preventive action require new or changed controls within the QMS.

— Added requirement for maintaining records of the activities for control of potential process nonconformities.

6.5 Management Review

6.5.1 General

Intent of Section

The intent of the section is to provide requirements for a review of the organization's QMS.

Changes from Previous Edition

— Changed requirement for review intervals from annual to at least every 12 months.

6.5.2 Input Requirements

Intent of Section

The intent of the section is to provide management review input requirements.

Changes from Previous Edition

— 6.5.2 a) adds the review of the effectiveness of the actions taken instead of just to "follow-up actions from previous management reviews" [Q1, 8th, 5.6.2 e)].

— 6.5.2 c) is an expansion of Q1, 8th, 5.6.2 f) and includes Note 2, adding legal and other applicable requirements.

— 6.5.2 d) is an expansion of Q1, 8th, 5.6.2 b) adding analysis of customer satisfaction.

— 6.5.2 f) is a new requirement.

— 6.5.2 h) is a new requirement.

— 6.5.2 i) is an expansion and combination of Q1, 8th, 5.6.2 c), Note 1 and Note 3.

6.5.3 Output Requirements

Intent of Section

The intent of the section is to provide management review output requirements.

Changes from Previous Edition

— The output now requires a summary assessment of the effectiveness of the QMS, including any required changes to the QMS.

— Added requirement for top management review and approval of management review output.

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