Quality Management System Requirements for Service Supply Organizations for the Petroleum and Natural Gas Industries

API SPECIFICATION Q2

THIRD EDITION 202X

Introduction

This specification has been developed to address the development and implementation of quality management systems for service supply organizations working in the upstream petroleum and natural gas industries. This specification defines the fundamental requirements of quality management systems for those service supply organizations claiming conformity to this specification.

The requirements of this specification are consistent with those of other quality management system documents. This specification provides additional requirements that target the execution of services or provision of service-related products in the execution of the service. The requirements are structured in a way to minimize the likelihood of nonconformity during the execution of a service and/or provision of service-related product.

While this specification may include some elements of other quality 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 and legal requirements applicable to service execution and the organization's own requirements.

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

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

Goal of the Specification

The goal of this specification is to identify the minimum requirements for the development of a quality management system that provides for continual improvement, emphasizes the prevention of nonconformities, and strives to minimize variation and waste from service supply organizations. It is designed to promote reliability in service supply organizations for the upstream petroleum and natural gas industries.

Changes from the Second Edition to the Third Edition

Highlights of some of the significant changes between the second and third editions include:

- alignment with API Q1 verbiage where applicable;
- change of scope;
- Elimination of exclusions;
- Revised applicability statement that identifies examples of what is not applicable;
- Introduction of deferrals or Concession under PMITP;
- Record retention period expanded to ten years;
- new definition of performance acceptance criteria (PAC)
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1 Scope

1.1 General

This specification defines the quality system requirements necessary for upstream service sector supply organizations to consistently and reliably provide and manage services that meet customer, legal, and other applicable requirements.

~~the quality management system (QMS) requirements for service supply organizations for the petroleum and natural gas industries. It is intended to apply to the execution of services for the petroleum and natural gas industry. This includes, but is not limited to, activities such as well construction, intervention, production, and abandonment as well as repair/maintenance/configuration of service-related product.~~

1.2 Applicability

This specification was developed to apply to organizations that provide well site services and services associated with well site activities in oil and gas well construction, intervention, production, and abandonment.

This specification was not developed to apply to organizations that only provide calibration, engineering and design, training/technical consulting, SRP repair without accompanying service, inspection and testing, transportation, project management, rental of equipment, provision of software, or manufacturing and/or product realization services. Those organizations that do not provide well site services associated with well site activities may adopt other API or international standards.

Note: Examples of API or international standards can include but are not limited to API Q1, ISO 9001, or ISO 29001.

Information marked “NOTE” are not requirements but are for guidance in understanding or clarifying the associated requirement.

2 Normative References

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

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

3 Terms, Definitions, Abbreviations, and Acronyms

3.1 Terms and Definitions

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

3.1.1
acceptance criteria
Specified limits of acceptability applied to service, process, service-related product, or component characteristics.
3.1.2
acceptance inspection

Demonstration through monitoring, evaluation, or measurement that the service or service-related product (SRP) conforms to specified acceptance criteria.

3.1.3
calibration
Process of comparison to a standard of known accuracy, comparison of results against TMMDE (testing, measuring, monitoring, and detection equipment) acceptance criteria, and, if applicable, making needed adjustment(s).

NOTE 1 Calibration of non-adjustable equipment can be referred to as verification.

NOTE 2 The term verification is defined in 9000:2015

3.1.4
compliance
Act of satisfying (verb) or the status of having satisfied (noun) legal requirements.

3.1.5
critical spare part
A spare part whose individual failure would cause the inability of a critical service-related product to perform its designated function.

3.1.6
critical service-related product
critical SRP
An SRP whose failure is likely to cause non-productive time (NPT), failure to provide required service deliverables, release of hydrocarbons, or serious injury or fatality (SIF).

3.1.7
critical service
A service whose failure to be executed successfully is likely to cause non-productive time (NPT), failure to provide required service deliverables, release of hydrocarbons, or serious injury or fatality (SIF).

3.1.8
critical success factor
CSF
An element of service that is essential to achieve goal(s) or stated objectives.

3.1.9
key performance indicator
KPI
Quantifiable measure that an organization uses to gauge or compare performance.

3.1.10
legal requirement
Statutory or regulatory requirements.

3.1.11
management personnel
A person or group of persons with authority and responsibility for the conduct and control of all or part of an organization.

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

3.1.12
performance acceptance criteria (PAC)

Requirements applied to characteristics or combinations of those characteristics, of Service-Related Product (SRP) to achieve conformity to design of service.

3.1.13
procedure
Organization's documented method for performing an activity under controlled conditions to achieve conformity to specified requirements**.**

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

3.1.14
risk
A situation or circumstance that has both a likelihood of occurring and a potentially negative consequence.

3.1.15
service
Execution of an activity by one function or organization for another.

3.1.16
service-related product
SRP
Materials, equipment, and software required for the execution of the organization's primary service to support well site activities.

3.1.17
supply chain
suppliers and associated sub-supplier(s) required for execution of service or service-related product provision.

3.2 Abbreviations and Acronyms

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

CSF	critical success factor
KPI	key performance indicator
MOC	management of change
NPT	non-productive time
PMITP	preventive maintenance, inspection, and test program
QMS	quality management system
SIF	serious injury or fatality
SRP	service-related product
SQP	service quality plan
TMMDE	testing, measuring, monitoring, and detection equipment

4 Quality Management System (QMS) Requirements

4.1 Quality Management System

4.1.1 General

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

4.1.2 Quality Policy

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

The quality policy shall:

a) be appropriate to the organization,

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

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

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

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

4.1.3 Quality Objectives

Management personnel, with approval from top management, shall ensure that quality objectives required for service and SRP are established at relevant functions and levels within the organization. At a minimum, the organization shall consider the output from 6.3 (Analysis of Data) when establishing the quality objectives. The quality objectives shall be measurable, communicated, and consistent with the quality policy.

4.1.4 Planning of the Quality Management System

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

a) define the scope of the quality management system, that identifies service and SRP covered (see 3.1.16);

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

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

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

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

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

g) address identified risks (see 5.3);

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

i) identify key personnel.

NOTE Additionally, see 5.2, 5.4.1, 5.5, 5.7.1, 6.1, and 6.2.2 for other planning requirements.

4.1.5 Communication

4.1.5.1 Internal

Management personnel shall ensure that appropriate communication processes are established and implemented within the organization and the effectiveness of the QMS is communicated.

The organization shall establish processes to ensure that:

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

b) the results of analysis of data (see 6.3), including nonconforming services and SRP (see 5.10), are communicated to relevant functions within the organization.

4.1.5.2 External

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

The process shall address:

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

b) determining and understanding requirements throughout contract execution, and realization of service and if applicable, SRP;

c) provision of service and if applicable, SRP information, including service-related nonconformities (see 5.10);

e) d)feedback and customer complaints (see 6.2.1); communication of service quality plans (SQPs) including subsequent changes (see 5.7.1); and

f) communicating changes and associated risks (see 5.3).

4.2 Management Personnel Responsibility

4.2.1 General

Top management shall demonstrate leadership and commitment to the establishment, implementation,

maintenance, and improvement of the quality management system by:

a) approving establishment of quality objectives including key performance indicators at relevant functions and levels within the organization;

b) providing resources needed for the quality management system;

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

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

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

4.2.2 Responsibility and Authority

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

4.2.3 Management Representative

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

a) ensuring that the QMS conforms to the requirements of this specification;

b) ensuring that processes needed for the QMS are established, implemented, and maintained;

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

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

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

4.3 Organization Capability

4.3.1 Resources and Knowledge

4.3.1.1 Resources

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

4.3.1.2 Knowledge

The organization shall determine the knowledge needed to provide continued operation of its processes and achieve ongoing conformity of service and applicable, SRP (see 3.1.15). This knowledge shall be maintained and made available as determined by the organization.

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

4.3.2 Human Resources

4.3.2.1 Personnel Competence

The organization's personnel whose responsibilities fall within the scope of the QMS shall be competent. The organization shall maintain a documented procedure addressing personnel competence.

The procedure shall address:

a) how required competencies are identified and documented;

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

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

d) criteria and methods for assessing, maintaining and, re-assessing competencies; and
e) personnel responsible for assessing competency.

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

4.3.2.2 Training

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

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

b) provision of quality management system training;

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

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

e) evaluation of effectiveness of training; and

f) identification of required training records.

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

4.3.3 Work Environment

The organization shall determine, provide, and assess the work environment needed to achieve conformity to service or SRP requirements. Work environment shall include, as applicable:

a) buildings, workspace, and associated utilities;
b) process equipment (both hardware and software);
c) supporting services (such as transport, communication, or information systems); and
d) conditions under which work is performed, including physical, environmental, and other factors.

4.4 Documentation Requirements

4.4.1 General

The QMS documentation shall include:

a) the scope of the quality management system that identifies service and SRP covered (see 3 1.16);

b) statements of quality policy and quality objectives;

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

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

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

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

NOTE Some of the documentation in 4.4.1 has been traditionally included as part of a quality manual but can be in different formats and can be either a single document or multiple documents.

4.4.2 Procedures

All procedures required by this specification shall describe the organization's method for performing an activity and shall be documented, implemented, and maintained for continued suitability.
NOTE A single procedure can address the requirements for one or more documented procedures. Any requirement for a documented procedure can be satisfied by more than one procedure.

4.4.3 Control of Internal Documents

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

The procedure shall address:

a) responsibilities for approval and re-approval;

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

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

e) identification of changes and current revision status;

f) legibility and identification of documents; and

g) availability where the activity is being performed.

Obsolete documents shall be removed from all points of issue or use, or otherwise identified to prevent unintended use if they are retained for any purpose. Procedures, work instructions, and forms required by the quality management system shall be controlled.

4.4.4 Control and Use of External Documents

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

The procedure shall address:

a) identification and documentation of required documents;

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

c) integration of requirements into service and related processes and products (SRP);

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

e) assessment of impact of changes; and

f) integration of applicable changes.

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

4.5 Control of Records

Records, including those originating from outsourced activities, shall be established and controlled to provide evidence of conformity to requirements and the organization's quality management system. The organization shall maintain a documented procedure to identify the controls and responsibilities for records.

The procedure shall address record:

a) identification;

b) collection;

c) legibility;

d) correction;

e) storage;

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

g) retrieval;

h) retention time; and

i) disposition.

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

5 Realization of Service and Service-related Product

5.1 Contract Review

5.1.1 General

The organization shall maintain a documented procedure for the review of requirements related to the execution of services and required SRP. The procedure shall address:

a) determination of requirements;

b) review of requirements; and

c) changes to requirements.

5.1.2 Determination of Requirements

The organization shall determine:

a) requirements specified by the customer;

b) legal and other applicable requirements; and

c) requirements not stated by the customer but considered necessary by the organization for the execution of service and required SRP.

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

5.1.3 Review of Requirements

The organization shall review the requirements related to execution of the service and required SRP. This review shall be conducted prior to the organization‘s commitment to provide a service and/or SRP to the customer and shall confirm that:

a) requirements are defined and documented;

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

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

d) relevant personnel are notified of requirements.

5.1.4 Changes to Requirements

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

5.1.5 Records

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 service and SRP realization.

In planning, the organization shall address the following:

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

b) customer-specified requirements (see 5.1), including critical success factors (CSFs);

c) legal and other applicable requirements;

d) initial risk assessment (see 5.3);

e) contingency planning (see 5.5);

f) design of service and provisions of SRP (see 5.4);

g) key performance indicators;

h) required verification, validation, monitoring, measurement, inspection, and test activities (including the use of suitable TMMDE) specific to the service and SRP and the criteria for acceptance;

i) management of interfaces with other party’s SRP;

j) management of change (see 5.11); and

k) records needed to provide evidence that the 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 Management

5.3.1 General

The organization shall maintain a documented procedure to identify and control risk associated with quality of service execution and SRP. The procedure shall address:

a) risk identification and assessment techniques;

b) risk assessment tools and their application;

c) criteria to determine risk severity including potential consequences of service execution and SRP failure;

d) risk mitigation actions;

e) assessment of remaining risk; and

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

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

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

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

5.4 Design of Service

5.4.1 Design Planning

The organization shall maintain a documented procedure to plan and control the design of the service, including the identification and configuration of required SRP. The procedure shall identify:

a) the design stages;

b) the activities required for completion, review, and verification of each stage of design;

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

d) the responsibilities and authorities for the design activities;

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

When design of service activities, including the identification and configuration of required SRP, are outsourced or performed at different locations within the organization, the procedure shall identify the controls to ensure that the requirements of 5.4 and 5.6.1.7 are satisfied. When design activities are outsourced, the organization shall remain responsible for the design.

5.4.2 Design Inputs

Inputs shall be identified and reviewed for adequacy, completeness, lack of ambiguity, and lack of conflict. Any identified issues shall be addressed. Inputs shall include functional and technical requirements, and the following, as applicable:

a) customer-specified requirements (see 5.1);

b) legal requirements;

c) requirements provided from an external source;

d) required SRP;

e) environmental and operational conditions;

f) methodology, assumptions, and formulae documentation;

g) identified risks associated with design impacting the well, service, or SRP performance; and

h) historical performance data and other information derived from previous similar service designs.

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

5.4.3 Design Outputs

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

a) meet the input requirements for design;

b) provide information for purchasing of any required services and SRP;

c) provide controls for the execution of the service, including allowable variations in the service execution parameters;

d) include or reference acceptance criteria for the completion of the service;

e) identify critical services and SRPs; and

f) specify the PAC for SRP that are essential for execution of service.

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

5.4.4 Design Verification

Verification of the design of the service shall be performed in accordance with planned arrangements (see 5.4.1) to ensure that the design outputs have met the design input requirements. Records of the results of the verification shall be maintained (see 4.5).

5.4.5 Design Review and Approval

A design review and approval shall be conducted and documented. Competent individual(s) other than the person or persons who developed the design shall review and approve the final design outputs.

Records of the results of the final review, including the closure of any necessary actions, and approval shall be maintained (see 4.5).

5.4.6 Design Changes

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

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

NOTE Management of changes in the approved design are further addressed in 5.11.

5.5 Contingency Planning

5.5.1 General

The organization shall maintain a documented procedure for contingency planning. The procedure shall include incident and disruption prevention and mitigation measures. Contingency planning shall be integrated into services and supporting processes of the organization, its suppliers, and the customer.

5.5.2 Planning Output

Contingency planning output shall be documented and communicated to the relevant personnel and updated as required to minimize the likelihood or duration of disruption of execution of service. The contingency plan shall be based on assessed risks (see 5.3) and shall include, at a minimum:

a) actions required in response to significant risk scenarios (see 5.3);

b) actions required to reduce effects of incidents causing service disruptions;

c) identification and assignment of resources, responsibilities, and authorities; and

d) internal and external communications controls (see 4.1.5).

Records of contingency planning shall be maintained (see 4.5).

5.6 Purchasing

5.6.1 Purchasing Control

5.6.1.1 Procedure

The organization shall maintain a documented procedure for the purchase of SRP and outsourced services that directly impact execution of service.

The procedure shall address:

a) the determination of critical services and SRP;

b) the evaluation and selection of suppliers;

c) the type and extent of control applied to the supply chain for services and SRPs, based on the criticality and identified risk of the service and SRP;

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

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

f) identification of customer specified suppliers and suppliers limited by proprietary, and/or legal requirements when 5.6.1.3 applies.

g) defining the verification criteria and other activities necessary for ensuring that the purchased service and SRP meet specified purchase requirements

f) identification of customer specified suppliers and suppliers limited by proprietary, and/or legal requirements when 5.6.1.3 applies.

5.6.1.2 Initial Supplier Evaluation—Critical Purchases

For critical services or critical SRP, the criteria for the initial evaluation and selection of suppliers by the organization shall include the following prior to initiation of the purchase agreement:

a) on-site assessment of the supplier's activities to ensure their capability to meet the organization's purchasing requirements;

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

c) verification of the type and extent of control applied by the supplier, internally and to their supply chain, to meet the organization's requirements.

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

For the purchase of critical services or SRP, where the supplier is specified by the customer or involves proprietary and/or legal requirements, the initial evaluation requirements shall be as follows:

a) where suppliers are specified by the customer are not part of the organization's approved suppliers, evaluation shall not be required by the organization. The scope of approval for customer-specified suppliers shall be limited to the relevant customer contract.

b) When limited by proprietary, legal, and/or contractual arrangements, the organization shall identify how the supplied service-related processes and/or SRP conform to stated requirements.

5.6.1.4 Initial Supplier Evaluation—Noncritical Purchases

For the initial evaluation of suppliers by the organization for non-critical services or SRP, one or more of the following shall apply:

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

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

c) assessment of the supplier upon delivery of the SRP or service.

5.6.1.5 Supplier Re-evaluation

The organization shall determine the supplier re-evaluation frequency based on supplier risk and quality performance.

Re-evaluation of suppliers for critical purchases shall include:

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

b) verification of the type and extent of control applied by the supplier, internally and to their supply chain, to meet the organization's requirements (see 5.6.1.1.c); and

c) evaluation method of the supplier's continued capability to meet the organization's specified requirements.

The evaluation method shall be based on risk and quality performance using one or both of the following:

1) performing an assessment to verify that relevant service-related processes are in accordance with process controls, and are effective in achieving conformity to service or SRP requirements;

NOTE The assessment may be on site or remote.

2) performing inspection, function testing, or verification of relevant characteristics of product, component, or activity as applicable (see 5.6.3).

For the re-evaluation of customer specified, proprietary, and/or legal limited suppliers for critical purchases, the requirements of 5.6.1.3 shall apply.

For the re-evaluation of suppliers of noncritical services and/or SRP, the requirements of 5.6.1.4 shall apply.

5.6.1.6 Records

Records of the results of evaluations and any necessary actions arising from these evaluations (see 6.4.2) shall be maintained (see 4.5).

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

5.6.1.7 Supplier QMS Requirements for Outsourced Activities

The organization shall define quality management system (QMS) requirements for outsourced activities, including those associated with repair, inspection activities, and remanufacture of SRP.

NOTE The supplier's QMS may conform to API Q1, API Q2, ISO 9001, or a system defined by the organization that is appropriate for the scope of work.

Where an organization chooses to outsource a service or SRP or activity, the organization shall maintain responsibility for service or SRP conformance to specified requirements, including applicable industry specifications.

Records of outsourced activities shall be maintained (see 4.5), including evidence of conformity (see 5.6.3).

5.6.2 Purchasing Information

Purchasing information provided to the supplier shall be documented and describe the services or SRP to be purchased, including where appropriate:

a) requirements for acceptance criteria of service and SRP;

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

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

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

e) any QMS requirements defined by the organization.

5.6.3 Verification of Purchased Services and SRP

The organization shall ensure and provide evidence that outsourced services and SRPs conform to specified requirements.

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

5.7 Control of Service Execution

5.7.1 Service Quality Plan (SQP)

5.7.1.1. General

The organization shall develop an SQP that controls the execution of services and use of SRPs. The input to development of the service quality plan shall include, as a minimum:

a) personnel training and competence (see 4.3.2);

b) defined contract requirements (see 5.1);

c) risk assessment and management (see 5.3);

d) information that describes the characteristics of the service and SRPs and ensuring design requirements are satisfied (see 5.4); and

e) identification of testing, measuring, monitoring, and detection equipment (TMMDE) (see 5.8).

NOTE An SQP is often referred to as a "quality plan" or "service delivery plan," and can be developed according to the service type, well, project, or geographic region as deemed appropriate by the organization and the customer requirements. It may be comprised of one or several different documents.

5.7.1.2 Plan Content

The SQP shall address each of the following:

a) required activities and documentation for compliance with customer and legal requirements;

b) identification of responsible functions for each activity, including external parties;

c) identification and reference to controls for outsourcing activities critical to execution of service;

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

e) identification of the requirements to perform acceptance inspection for each activity, including hold, witness, monitor, and document review points for representatives of the organization and the customer;

f) identification of required testing, measuring, monitoring, and detection equipment (TMMDE) (see 5.8);

g) identification and controls of risk (see 5.3);

h) identification of critical services and critical SRP, including where these are outsourced;

i) identification of the required deliverables; and

j) identification of the required records (see 4.5).

The SQP shall be revised when any of the plan content changes.

5.7.1.3 Plan Approval

SQPs and any revisions to them shall be documented and approved by the organization.

When API Q2 conformance is required by contract, the SQP and service quality related changes shall be communicated to the customer.

5.7.2 Identification and Traceability

The organization shall maintain a documented procedure for identification and traceability of SRPs. The procedure shall include identification controls at all stages of delivery, installation, repair, and redress as required by the organization and the customer. The procedure shall include requirements for maintenance or replacement of identification and traceability marks.

SRPs shall be identified. Critical SRPs shall be identified and traceable to the Preventative Maintenance, Inspection, and Test Program (PMITP) records (see 4.5 and 5.7.7) and the original equipment manufacturer (OEM).

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

5.7.3 SRP Status

The organization shall maintain a documented procedure for the identification of SRP status at all stages of service execution.

NOTE: Status can refer to acceptability for use, readiness, certification, conformity, or nonconformity.

5.7.4 Externally Owned Property

The organization shall maintain a documented procedure for control of externally (including customer) owned property that is provided for use in the service and/or SRP, while the property is under the organization's control. Externally owned property shall include intellectual property and data that are not publicly available.

The procedure shall address:

a) identification;

b) verification;

c) safeguarding;

d) preservation;

e) maintenance; and

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

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

5.7.5 Preservation of SRP

The organization shall maintain a documented procedure describing the methods used to preserve the SRP and constituent parts during internal processing through execution of service and delivery. The procedure shall address the following:

a) identification and traceability marking;

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

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

d) transportation;

e) handling;

f) packaging; and

g) protection.

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

5.7.6 Validation of SRP

SRP shall be validated to the extent needed to confirm SRP meets PAC prior to and/or during execution of service. The validation shall be appropriate to the criticality of the SRP including use. Records of the validations and validation results shall be maintained (see 4.5).

5.7.7 Preventive Maintenance, Inspection, and Test Program (PMITP)

The organization shall maintain a documented procedure for the PMITP. The procedure shall address inspection, maintenance, redress, repair, makeup, testing, and acceptance criteria for SRP. At a minimum, the PMITP shall include:

a) actions that address corrective maintenance;

b) actions that address preventive or predictive maintenance;

c) reports that document usage history, repairs or redress, modifications, remanufacturing, and inspection, and test activities that allow direct verification for reuse of product;

d) recommended requirements by the customer and/or technical requirements considering those recommended by the original equipment manufacturer, including critical spare parts;

e) controls that ensure SRP integrity to the organization's defined PAC are maintained for SRP and constituent components; f) frequency or condition that requires maintenance, inspection, and/or testing; and

g) actions to address customer driven maintenance deferral or concession

Records of PMITP shall be maintained (see 4.5).

Defined performance requirements for SRP that cannot be met shall undergo the MOC process (see 5.11) for continued use.

NOTE The PMITP can be based on risk, system reliability, usage history, experience, industry recommended practices, relevant codes and standards, original equipment manufacturing guidelines, or other applicable requirements.

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

5.8.1 General

The organization shall determine the testing, measuring, monitoring, and detection requirements and the TMMDE needed to provide evidence of conformity to those requirements. TMMDE shall be calibrated, verified or both as necessary.

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

5.8.2 Procedure

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

a) unique identification;

b) calibration status;

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

d) calibration method and acceptance criteria;

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

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

NOTE Confirmation or verification of TMMDE accuracy additional to the required calibration is not considered calibration.

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

h) actions to be taken when the TMMDE is found to be out of calibration:

1. assessing the validity of previous measurements;

2. actions to be taken on the TMMDE, affected service, and SRP including maintaining records and notifications to the customer (see 4.1.5.2) if suspect SRP has been shipped or affected service has been performed;

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

j) maintenance; and

k) suitability for the planned monitoring and measurement activities.

5.8.3 Equipment

TMMDE identified in 5.8.1 shall:

a) be calibrated (see 3.1.3) and/or verified;

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

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

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

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

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

5.8.4 Equipment from Other Sources

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

5.8.5 Records

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

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

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

5.9 Service Performance Validation

The organization shall maintain a documented procedure to validate the execution of the service performance to confirm that requirements were achieved.

This shall be performed at appropriate stages during the execution of the service in accordance with design requirements (see 5.4) and the SQP (see 5.7.1). Evidence of conformity with established acceptance criteria, including KPIs and CSFs that are part of service execution, shall be maintained.

Records of the service performance validation shall be maintained, including identification of the person(s) accepting the results (see 4.5).

5.10 Control of Nonconforming Service Execution and SRP

5.10.1 General

The organization shall maintain a documented procedure to define the controls for identifying, documenting, and reporting nonconforming service execution, SRP and/or failure to meet PAC during all phases of service execution, including nonconformities discovered after validation of SRP (see 5.7.6) and validation of the service (see 5.9). The level of response shall be proportionate to the severity of the nonconformity and its effect on the execution of the service. The procedure shall include identification of related responsibilities and authorities for addressing the nonconformities.

5.10.2 Nonconforming Service Execution and SRPs

The organization shall address nonconforming service execution or SRPs by the following sequence of activities:

a) by taking action to correct the nonconformity;

b) when 5.10.2.a) is not possible or appropriate, by taking action to identify and preclude the use of the SRP from its intended use or application; or

c) when 5.10.2.a) and 5.10.2.b) are not appropriate, by authorizing release or acceptance under concession by a relevant authority and/or by the customer.

For nonconforming service execution or SRP, the organization shall take corrective action in accordance with 6.4.2 that is appropriate to the effects, or potential effects, of the nonconformity.

5.10.3 Verification

When nonconforming services and/or SRPs are corrected, they shall be subject to verification to demonstrate conformity to the requirements.

5.10.4 Customer Notification of Nonconforming service and SRP

The organization shall notify customers in the event that the service execution does not conform to applicable service design and SQP requirements or when nonconforming SRPs and TMMDE have been delivered or used in the execution of the service. The organization shall maintain records of such notifications (see 4.5).

5.10.5 Records

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

a) the description of the nonconformity;

b) subsequent actions taken, including concessions obtained;

c) rationale to support release of service or SRP under concession (5.9.3); and

d) relevant authority.

5.11 Management of Change (MOC)

5.11.1 General

The organization shall maintain a documented procedure for MOC to maintain integrity of the quality management system when changes occur. The organization shall identify the potential risks (see 5.3) associated with the change and any required approvals prior to the implementation of such changes.

The MOC procedure shall address:

a) description of, and the need for, the change.
b) availability and allocation of resources (including personnel);
c) potential risks (see 5.3) that may arise from implementing the change;
d) review approval, and implementation of the change;
e) notifications (see 5.11.3); and
f) verification of the completion of MOC activities and impact on the QMS.

5.11.2 MOC Application

The organization shall apply the MOC process, as a minimum, to any of the following changes that may negatively impact the execution of a service or SRP:

a) organizational structure;
b) key or essential personnel;
c) suppliers of critical services or critical SRP
d) QMS procedures, including temporary changes and improvements resulting from corrective actions (see 6.4);
e) original equipment manufacturer's specifications, applications, and/or software for SRP;
f) Approved design (see 5.4), including those that were originally agreed upon by the customer;
g) Legal, industry, and other applicable requirements;
h) deviations from applicable procedures or requirements on a temporary basis to address a specific situation; and
i) work environment (including operational conditions).

5.11.3 MOC Notification

The organization shall notify relevant parties of the change and residual or new risk due to changes managed by the organization.

NOTE Relevant parties can include internal personnel and/or external personnel such as suppliers or customers.

5.11.4 Records

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

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

6.1 General

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

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

6.2 Monitoring, Measuring, and Improving

6.2.1 Customer Satisfaction

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

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

b) key performance indicators of customer satisfaction.

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

6.2.2 Internal Audit

6.2.2.1 General

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

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

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

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

Audit techniques shall include observation of the execution of inspection, assembly, testing, and maintenance processes.

Outsourced activities that impact the quality of services or SRPs performed at the organization's facility or worksite 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. The audit shall apply observation and evaluation methods to ensure the effectiveness of the area or process being audited.

An audit of all elements of the QMS shall be conducted prior to claiming conformance to the requirements of this specification.

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

6.2.2.3 Audit Review and Closure

The organization shall identify response times for addressing detected nonconformities. The management personnel responsible for the area being audited shall ensure that any necessary corrections and corrective actions are taken to eliminate detected nonconformities and their causes. Follow-up activities shall include the verification of the actions taken (see 6.4.2).

Records of the internal audits shall be maintained (see 4.5).

6.3 Analysis of Data

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

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

a) customer satisfaction (see 6.2.1);

b) nonconformities to service design (see 5.4) and SQP (see 5.7.1) requirements;

c) process performance;

d) service execution and SRP performance (see 5.10, 6.4.2,);

e) supplier performance (see 5.6); and

f) KPIs, CSFs, and 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 quality objectives, assessment and management of risks, MOC, audit results, analysis of data, corrective actions, and management review.

The organization shall also consider improvement to service execution to meet customer requirements and improve customer satisfaction.

6.4.2 Corrective Action

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

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

The procedure shall address:

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

b) reviewing nonconformities (including customer complaints);

c) determining and implementing corrections;

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

e) implementing corrective action to reduce the likelihood that nonconformities recur;

f) identifying the time frame and responsible person(s) for making corrections and taking corrective action;

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

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

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

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

6.5 Management Review

6.5.1 General

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

6.5.2 Input Requirements

The input to management review shall include, but not be limited to:

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

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

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

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

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

d) relevant feedback from customers and other interested parties;

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

f) status of corrective actions (see 6.4.2);

g) results of analysis of data (see 6.3); and

h) recommendations for improvement

6.5.3 Output Requirements

The output from the management review shall include:

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

b) any required changes (see 5.11) to the processes,

c) decisions and actions,

d) required resources, and

e) any improvement to service execution and SRP in satisfying customer requirements.

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

Management reviews shall be documented and communicated to the organization. Records of these reviews shall be maintained (see 4.5).

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