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

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Contents

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.

Applicability of API Specification Q2

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

It is the responsibility of the service supply organization to ensure that an adequate quality management system (QMS) is in place for outsourced activities, including those associated with repair and remanufacture of service-related product. This could be in conformance to API Q1, API Q2, ISO 9001, or a system defined by the service supply organization that is appropriate for the scope of work. Conformance to API Q2 for outsourced activities is not required by this specification.

Changes from the First Edition to the Second Edition

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

— alignment with API Q1 verbiage where applicable;

— removal of the reference to the outdated version of ISO 9000;

— addition of requirements a) through e) to Human Resources section (4.3.2);

— addition of supply chain to Purchasing Control (5.6.1);

— alignment of Control of Testing, Measuring, Monitoring, and Detection Equipment with API Q1 (5.8);

— addition of Control of TMMDE to list of exclusions;

— removal of Preventive Actions section.

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

1 Scope

This specification defines 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.

If an organization performs activities addressed by this specification, including the provision of service-related product (SRP) and outsourced activities, no claims to exclusion of those requirements are permitted. Where SRP is not required for the execution of the applicable service, the basis for claiming exclusions is to be identified. Furthermore, such exclusions cannot affect the organization's ability or responsibility to meet customer and applicable regulatory requirements. Exclusions are limited to requirements within the following clauses:

— 5.7.3 Identification and Traceability;

— 5.7.4 SRP Status;

— 5.7.6 Preservation of SRP;

— 5.7.7 Validation of SRP;

— 5.7.8 Preventive Maintenance, Inspection; and Test Process.

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

Where claims of conformity are made, exclusions will be identified in conjunction with these claims.

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, *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 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 requirements.

3.1.3
calibration
The comparison to a standard of known accuracy or comparison of results against testing, measuring, monitoring, and detection equipment (TMMDE), and making any needed adjustments.

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

3.1.4
collection
The process of obtaining, assembling, and/or organizing applicable documented information with the intent of meeting the requirements for control of records (see 4.5).

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

3.1.6
critical spare part
A spare part whose individual failure would cause the inability of a critical service-related product to perform its designated function.

3.1.7
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).

3.1.8
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).

3.1.9
critical supplier
A supplier providing critical SRP or critical service.

3.1.10
critical success factor
CSF
An element of service that is essential to achieve goals or stated objectives.

3.1.11
design acceptance criteria
Defined limits placed on the characteristics or condition of materials, products, or services established by the organization, customer, and/or applicable specifications to achieve conformity.

3.1.12
document *(noun)*
A piece of written, printed, or electronic matter that provides information or evidence, or that serves as an official record.

3.1.13
key performance indicator
KPI
A quantifiable measure that an organization uses to gauge or compare performance.

3.1.14
legal requirement
An obligation imposed on an organization, including those that are statutory or regulatory.

3.1.15
management *(noun)*
A person or group of people defined by the organization who directs and controls all or part of a facility, location, department, or other function, has the fiscal responsibility for the organization, and is accountable for ensuring compliance with legal and other applicable requirements.

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

3.1.16
outsourced activities
Activities or processes performed by an external supplier on behalf of the organization.

3.1.17
personnel
Individuals employed or contracted by the organization involved in the execution of services.

3.1.18
preventive maintenance
A planned action to minimize the likelihood of equipment failure and unscheduled interruptions.

3.1.19
procedure
An organization’s documented method for performing an activity under controlled conditions to achieve conformity to specified requirements.

3.1.20
residual risk
Remaining risk after mitigation that may affect service execution.

3.1.21
risk
A situation or circumstance that has both a likelihood of occurring and a potentially negative consequence.

3.1.22
service
Performance of an activity by one function or organization for another.

3.1.23
service quality plan
SQP
A document that establishes procedures, resources, processes, and any required sequence of activities identifying and controlling the quality requirements.

3.1.24
service-related product
SRP
Materials, equipment, and software required for the execution of a service.

3.1.25
supply chain
The suppliers and associated sub-supplier(s) required for execution of service or service-related product provision.

3.1.26
testing, measuring, monitoring, and detection equipment (TMMDE) verification
A comparison to a standard of known accuracy and comparison of results against TMMDE acceptance criteria.

3.2 Abbreviations and Acronyms

For the purposes of this specification, the following abbreviations 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 General

4.1.1 Quality Management System

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

4.1.2 Quality Policy

The organization’s policy for its commitment to quality shall be defined, documented, and approved by top management. The organization’s top management shall review the quality policy (see 6.5.1) to ensure that it is appropriate to the organization, is the basis for the development of quality objectives (see 4.1.3), and is communicated, understood, implemented, and maintained at all relevant functions and levels within the organization. The quality policy shall be available externally, as appropriate. The policy shall include a commitment to conform to requirements and continually improve the effectiveness of the QMS.

4.1.3 Quality Objectives

Management, with approval from top management, shall ensure that quality objectives required for service and service-related product (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

When planning the quality management system, management shall ensure that:

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

b) the planning of the QMS is performed to meet the requirements of this specification;

c) the integrity of the QMS is maintained while changes are implemented; and

d) the planning to achieve quality objectives includes actions, resources, responsibilities, time frame, and how results will be evaluated.

NOTE Additionally, see 5.2, 5.4.1, 5.5, 5.7.2, 6.1, and 6.2.2 for other planning requirements.

4.1.5 Communication

4.1.5.1 Internal

Management 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, including nonconforming services and SRP (see 6.3), 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 to ensure requirements are understood throughout service execution. The communication process shall address, as applicable:

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

b) control of service and SRP information, including service-related nonconformities (see 5.10);

c) service quality plans (SQPs) and subsequent changes (see 5.7.2);

d) feedback and complaints (see 6.2.1); and

e) communication of residual risk (see 5.3).

4.2 Management Responsibility

4.2.1 General

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

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

Management shall provide evidence of its commitment to the development and implementation of the QMS and continually improving its effectiveness by:

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

b) conducting management reviews (see 6.5).

4.2.2 Responsibility and Authority

Roles, responsibilities, authorities, and accountabilities of personnel within the scope of this specification shall be defined, documented, assigned, and communicated throughout the organization.

4.2.3 Management Representative

The organization's management shall appoint a member(s) of the organization’s management who, irrespective of other responsibilities, shall have defined roles, responsibilities, and authority that includes:

a) ensuring that the QMS meets 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 minimize the likelihood of the occurrence of nonconformities; and

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

4.3 Organization Capability

4.3.1 Provision of Resources

The organization shall determine and provide the resources needed to establish, implement, maintain, and improve the effectiveness of the QMS.

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. Competency shall be achieved through education, training, skills, or experience. The organization shall maintain a documented procedure addressing personnel competence.

The procedure shall address:

a) identification and documentation of required competencies and methods for achievement;

b) criteria and methods for assessing and, if applicable, reassessing required competencies;

c) evaluation of effectiveness of training or actions taken to acquire the necessary competencies;

d) how required competencies are maintained; and

e) personnel responsible for assessing competency.

The organization shall maintain records of personnel competence (see 4.5).

4.3.2.2 Training and Awareness

The organization shall provide for QMS training and job training of the organization's personnel who affect execution of service or provision of SRP, and shall ensure that:

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

b) the frequency and content of training is identified and complies with legal and other applicable requirements;

c) personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the quality objectives; and

d) appropriate records of education, training, skills, and experience are maintained (see 4.5).

4.3.3 Work Environment

The organization shall determine, provide, manage, and maintain the work environment needed to achieve conformity to applicable 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) statements of quality policy and quality objectives;

b) a quality manual or other documentation that addresses the scope of the QMS and each requirement of this document, and that includes the identification and justifications of allowable exclusions;

c) documented procedures established, implemented, and maintained for the QMS;

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

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

NOTE A single document can address the requirements for one or more procedures. A requirement for documented procedures can be covered by more than one document.

4.4.2 Control of Documents

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

The procedure shall identify responsibilities for approval and reapproval and the controls needed to ensure that documents, including relevant revisions, translations, and updates:

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

b) identify changes that are made;

c) remain legible and readily identifiable; and

d) are available 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.

A master list or equivalent shall be established to identify the current revision status of documents.

4.5 Control of Records

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

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

Records shall remain legible, identifiable, and readily retrievable. Records required by this specification shall be retained for a minimum of five 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 or provision of SRPs.

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 provision of SRP.

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

5.1.3 Review of Requirements

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

a) requirements are defined and documented;

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

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

Where contract requirements are changed, the organization shall ensure that relevant documents are amended and that relevant personnel are made aware of the changed requirements.

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

5.2 Planning

The organization shall identify and plan the processes and documents needed for 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) service design 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 Assessment and Management

The organization shall maintain a documented procedure to control risk throughout the execution of a service.

The procedure shall address the identification, communication, and management of:

a) risks associated with services and SRPs;

b) work environment;

c) risk management tools and techniques;

d) implementation of the mitigation or preventive control measures to reduce or avoid exposure to loss; and

e) notification to the customer of residual risks that may impact the service.

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

5.4 Design and Development of Service

5.4.1 Design and Development Planning

The organization shall maintain a documented procedure to plan and control the design and development of the service, including the use of SRPs.

The procedure shall identify:

a) the design and development stages;

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

c) the interfaces between different groups involved in design and development; and

d) the responsibilities and authorities for the design and development activities.

When design and development are outsourced, the organization shall ensure the supplier meets the requirements of 5.4 and provide objective evidence that the supplier has met these requirements.

5.4.2 Design and Development Inputs

Inputs relating to design of the service shall be determined and records maintained (see 4.5). These inputs shall include:

a) customer-specified requirements (see 5.1);

b) legal requirements; and

c) other applicable requirements, including:

    1) requirements provided from an external source;

    2) SRP, including its functional and technical requirements;

    3) environmental and operational conditions;

    4) results from risk assessments (see 5.3); and

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

5.4.3 Design and Development Outputs

The outputs of design and development shall be documented to allow verification against the design and development input requirements.

Design and development outputs shall:

a) meet the input requirements for design and development;

b) provide information for purchasing of any required 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 SRPs; and

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

5.4.4 Design and Development 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 and development outputs have met the design and development input requirements. Records of the results of the verification shall be maintained (see 4.5).

5.4.5 Design and Development Final Review and Approval

A final design and development 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 and development 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 and Development Changes

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

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).

5.6 Purchasing

5.6.1 Purchasing Control

5.6.1.1 Procedure

The organization shall maintain a documented procedure to ensure that SRP and outsourced services conform to specified requirements.

The procedure shall address:

a) the determination and identification of critical services and SRPs;

b) the evaluation and selection of suppliers based on their ability to supply services and SRP in accordance with the organization‘s requirements;

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

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

e) maintaining a listing of approved suppliers and scope of approval.

5.6.1.2 Initial Supplier Evaluation—Critical Purchases

For critical services or 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—Noncritical Purchases

For the initial evaluation of suppliers for non-critical services or SRP by the organization, 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 product or service.

5.6.1.4 Supplier Re-evaluation

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

Re-evaluation of suppliers of critical services and/or SRP 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).

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.

For the re-evaluation of suppliers of noncritical services and/or SRP, the requirements of 5.6.1.3 shall apply.

5.6.1.5 Supplier Evaluation—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).

5.6.1.6 Outsourcing

Where an organization chooses to outsource a process or activity of its QMS, the organization shall ensure that applicable elements of its QMS are satisfied.

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) QMS requirements.

5.6.3 Verification of Purchased Services and SRP

The organization shall maintain a documented procedure for defining the verification criteria and other activities necessary for ensuring that the purchased service and SRP meet specified purchase requirements. The organization shall maintain records of verification activities (see 4.5).

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

5.7 Execution of Service

5.7.1 Control of Service Execution

5.7.1.1 General

The organization shall maintain a documented procedure that describes the integration of the following, at a minimum, into the development of an SQP (see 5.7.2):

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).

5.7.1.2 Documentation

Controls for execution of the service shall be documented and include requirements for verifying conformance with quality plans, procedures, and applicable standards/codes. The control documents shall include or reference instructions and acceptance criteria for processes, tests, inspections, and customer's inspection hold or witness points.

5.7.2 Service Quality Plan (SQP)

5.7.2.1 General

The organization shall develop an SQP that controls the execution of services and use of SRPs.

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.

5.7.2.2 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 updated when any of the plan content changes.

5.7.2.3 Plan Approval

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

When required by contract, the SQP and revisions shall be communicated to the customer.

5.7.3 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 5.7.8) and the original manufacturer.

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

5.7.4 SRP Status

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

5.7.5 Customer Property

The organization shall maintain a documented procedure to identify, verify, store, and safeguard customer property provided for use in the service and/or with the SRP while under control of the organization. Customer property shall include customer-derived intellectual property and customer-specific data. Control of customer property shall include the controls required for reporting to the customer any loss, damage, or unsuitable use of customer property.

Records for the organization’s control and disposition of customer property shall be maintained (see 4.5).

5.7.6 Preservation of SRP

The organization shall maintain a documented procedure describing the methods used to preserve the SRP during internal processing through execution of service. As applicable, preservation shall include identification and traceability, transportation, handling, packaging, storage, and protection. Preservation shall also apply to the constituent parts of the SRP.

To detect deterioration, the condition of the SRP or constituent parts in stock shall be assessed at intervals specified in the procedure.

5.7.7 Validation of SRP

SRP shall be validated to the extent needed to confirm capability to meet planned service requirements prior to execution of service. The validation shall be appropriate to the criticality of the SRP. Records of the validations and validation results shall be maintained (see 4.5).

5.7.8 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) list of critical spare parts requirements by the customer and/or technical requirements considering those recommended by the original equipment manufacturer;

e) controls that ensure SRP integrity to the organization's defined performance requirements and design acceptance criteria are maintained for SRP and constituent components; and

f) frequency or condition that requires maintenance, inspection, and/or testing.

Records of PMITP shall be maintained (see 4.5).

Defined performance requirements 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 Control of Testing, Measuring, Monitoring, and Detection Equipment (TMMDE)

The organization shall determine the required testing, measurement, monitoring, and detection equipment (TMMDE) to be controlled and necessary to provide evidence that the service or SRP meets specified requirements.

Calibrations shall be in accordance with an international or national recognized standard; where no such standards exist, the basis used for calibration shall be recorded (see 4.5).

The organization shall maintain a documented procedure to ensure that TMMDE is identified, calibrated, and maintained for the execution of the service or in the provision of the SRP. The procedure shall include requirements for the specific equipment type that addresses:

a) unique identifier;

b) calibration status;

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

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

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

f) confirmation of TMMDE accuracy additional to the required calibration, if required by the organization or product specification;

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

g) acceptance criteria;

h) control of equipment identified as out-of-calibration or not in-service, to prevent unintended use; and

i) when the equipment is found to be out-of-calibration, an assessment of the validity of the previous measurements shall be confirmed and the customer shall be notified of potential impact to the service or SRP.

TMMDE shall:

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

NOTE Verification against identified acceptance criteria is performed on non-adjustable equipment.

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

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

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

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

When used in the testing, measuring, monitoring, and 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.

When TMMDE is externally provided, the organization shall verify that the equipment is suitable to provide evidence of conformity of service or SRP to specified requirements.

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

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

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 5.7.2). 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 Nonconformities

5.10.1 General

The organization shall maintain a documented procedure to define the controls for identifying, documenting, and reporting nonconforming service execution and SRPs during all phases of service execution, including nonconformances discovered after 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 nonconformances.

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

The organization shall notify customers in the event that the service execution does not conform to service design requirements or when nonconforming SRPs 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). Such records shall include the description of the nonconformity, subsequent actions taken (including concessions obtained), and relevant authority.

5.11 Management of Change (MOC)

5.11.1 General

The organization shall maintain a documented procedure for the MOC process to ensure that the integrity of the QMS is maintained when changes to the QMS occur (see 5.11.2). For the MOC, the organization shall identify the potential risks (see 5.3) associated with the change and any required approvals prior to the introduction of such changes. The organization shall maintain records (see 4.5) of MOC activities.

5.11.2 MOC Implementation

The organization shall use the MOC process for any of the following that may negatively impact the execution of a service:

a) changes or proposed changes in the organizational structure;

b) changes in key or essential personnel;

c) changes in critical suppliers;

d) changes to the QMS procedures, including temporary changes and improvements resulting from corrective actions (see 6.4);

e) changes to the original equipment manufacturer's specifications, applications, and/or software for SRP;

f) changes in approved design (see 5.4), including those that were originally agreed upon by the customer;

g) changes including legal, industry, and other applicable requirements;

h) deviations from applicable procedures or requirements on a temporary basis to address a specific situation; and

i) changes in the work environment.

5.11.3 MOC Evaluation, Notification, and Controls

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

The organization shall ensure that relevant documents are amended.

6 QMS 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 QMS, and to continually improve its effectiveness.

QMS 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 the frequency and methods of obtaining customer feedback, key performance indicators (KPIs), and other information that the organization monitors to determine whether the organization has met customer requirements. Records of the results of customer satisfaction information shall be maintained (see 4.5).

6.2.2 Internal Audit

6.2.2.1 General

The organization shall maintain a documented procedure to define responsibilities for planning, conducting, and documenting internal audits. Audits shall verify that the QMS is effectively implemented and maintained, and conforms to the requirements of this specification. The planning of internal audits shall take into consideration the results of previous audits, criticality of the process being audited, and applicable changes affecting the QMS (see 5.11.2).

The organization shall identify the audit criteria, scope, frequency, and methods to ensure that all processes of the QMS for the organization claiming conformity to the requirements of this specification are audited at least every 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 suitable 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.

6.2.2.3 Audit Review and Closure

The organization shall identify response times for addressing detected nonconformities. The management responsible for the area being audited shall ensure that any necessary corrections and corrective actions 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 and use of the techniques for the analysis of data. The organization shall determine, collect, and analyze appropriate data to demonstrate the suitability and effectiveness of the QMS and to evaluate where continual improvement of the effectiveness of the QMS can be made. This shall include data generated from monitoring and measurement, internal audits (see 6.2.2), external audits, and management reviews (see 6.5), and from other relevant sources.

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

a) customer satisfaction (see 6.2.1);

b) nonconformity to service design requirements (see 5.4);

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

d) supplier performance (see 5.6); and

e) KPIs, CSFs, and quality objectives (see 4.1.3).

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

6.4 Improvement

6.4.1 General

The organization shall continually improve the effectiveness of the QMS 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 correct nonconformities and to take corrective actions, both internally and with suppliers, to eliminate the causes of nonconformities to minimize the likelihood of their recurrence.

NOTE Corrective action can apply to both QMS processes and nonconforming trends.

The procedure shall define requirements for:

a) reviewing nonconformities (including customer complaints);

b) determining and implementing corrections;

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

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

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

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

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

Where corrective action identifies the need for new or changed controls that may negatively impact execution of service, the procedure shall require that the MOC process (see 5.11) be applied to the proposed action.

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 QMS shall be reviewed at least every 12 months by the organization’s management to evaluate the QMS’s continuing suitability, adequacy, and effectiveness. This review shall include assessing opportunities for improvement and the need for changes to the QMS, including the quality policy, KPIs, CSFs, 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 audits (see 6.2.2);

c) changes that could affect the QMS, including legal and other applicable requirements;

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

e) feedback from relevant interested parties;

f) process effectiveness;

g) results of risk assessment (see 5.3);

h) status of corrective actions (see 6.4.2);

i) analysis of supplier performance [see 6.3.d) and 5.6];

j) review and analysis of failures in service and/or SRPs (see 5.10); and

k) recommendations for improvement (see 6.3)

6.5.3 Output Requirements

The output from the management review shall include a summary assessment of the effectiveness of the QMS. The assessment shall include any required changes to the processes and any decisions and actions, required resources, and improvement of service and SRPs in meeting 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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