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

Upstream Segment

API SPECIFICATION Q2
FIRST EDITION, DECEMBER 2011

energy API
AMERICAN PETROLEUM INSTITUTE

Special Notes

API publications necessarily address problems of a general nature. With respect to particular circumstances, local, state, and federal laws and regulations should be reviewed.

Neither API nor any of API's employees, subcontractors, consultants, committees, or other assignees make any warranty or representation, either express or implied, with respect to the accuracy, completeness, or usefulness of the information contained herein, or assume any liability or responsibility for any use, or the results of such use, of any information or process disclosed in this publication. Neither API nor any of API's employees, subcontractors, consultants, or other assignees represent that use of this publication would not infringe upon privately owned rights.

API publications may be used by anyone desiring to do so. Every effort has been made by the Institute to assure the accuracy and reliability of the data contained in them; however, the Institute makes no representation, warranty, or guarantee in connection with this publication and hereby expressly disclaims any liability or responsibility for loss or damage resulting from its use or for the violation of any authorities having jurisdiction with which this publication may conflict.

API publications are published to facilitate the broad availability of proven, sound engineering and operating practices. These publications are not intended to obviate the need for applying sound engineering judgment regarding when and where these publications should be utilized. The formulation and publication of API publications is not intended in any way to inhibit anyone from using any other practices.

Any manufacturer marking equipment or materials in conformance with the marking requirements of an API standard is solely responsible for complying with all the applicable requirements of that standard. API does not represent, warrant, or guarantee that such products do in fact conform to the applicable API standard.

Foreword

Nothing contained in any API publication is to be construed as granting any right, by implication or otherwise, for the manufacture, sale, or use of any method, apparatus, or product covered by letters patent. Neither should anything contained in the publication be construed as insuring anyone against liability for infringement of letters patent.

Shall: As used in a standard, "shall" denotes a minimum requirement in order to conform to the specification.

Should: As used in a standard, "should" denotes a recommendation or that which is advised but not required in order to conform to the specification.

This document was produced under API standardization procedures that ensure appropriate notification and participation in the developmental process and is designated as an API standard. Questions concerning the interpretation of the content of this publication or comments and questions concerning the procedures under which this publication was developed should be directed in writing to the Director of Standards, American Petroleum Institute, 1220 L Street, NW, Washington, DC 20005. Requests for permission to reproduce or translate all or any part of the material published herein should also be addressed to the director.

Generally, API standards are reviewed and revised, reaffirmed, or withdrawn at least every five years. A one-time extension of up to two years may be added to this review cycle. Status of the publication can be ascertained from the API Standards Department, telephone (202) 682-8000. A catalog of API publications and materials is published annually by API, 1220 L Street, NW, Washington, DC 20005.

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

Contents

Introduction

This document has been developed to address quality management systems for the service supply organizations for the upstream petroleum and natural gas industries. It defines the fundamental quality management system requirements for those claiming conformity to the requirements of this document. When coupled with customer-specific requirements, the document creates a basis for the quality management system. Although quality management system requirements for service supply organizations may be addressed in other management system documents, this document has been created to provide specific guidance to facilitate quality management system development and implementation for service supply organizations.

The requirements of this document are consistent with those of many other quality management system documents (for example, API Spec Q1). These generic requirements are supplemented by 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 in the execution of a service.

While this document may include some elements of other management systems, it does not include all requirements specific to those systems, such as those particular to environmental management, occupational health and safety management, financial management or risk management. This document may be used either in conjunction with or independent of other industry-specified documents.

This document 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 the service and the organization's own requirements.

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

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

Goal of the document

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

It is not the intent of this document to imply uniformity in the structure of quality management systems or uniformity of documentation.

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

1 Scope

1.1 Application

This document defines the quality management system requirements for service supply organizations for the petroleum, and natural gas industries. It is intended to apply to the execution of upstream services during exploration, development and production in the oil and gas industry. This includes activities involved in oil and gas well construction, intervention, production, and abandonment. This document applies to activities associated with well servicing, equipment repair/maintenance, and inspection activities.

This document specifies requirements of a quality management system for an organization to demonstrate its ability to consistently provide services that meet customer, legal, and other applicable requirements.

This document was developed by a group of upstream technical experts. While this document and/or portions thereof could be applicable to other industry segments, it is recommended that other segments carefully review these requirements to determine their applicability and if necessary develop a segment annex identifying any segment-specific requirements.

1.2 Exclusions

When an organization performs activities addressed by this document, including the provision of service-related product, all requirements shall be performed and no claims to exclusion of those requirements shall be permitted. Where exclusions may be possible or where service-related product is not provided, the basis for claiming exclusions shall be identified and such exclusions shall not affect the organization's ability, or responsibility, to meet customer and applicable regulatory requirements. Exclusions shall be limited to requirements within the following clauses:

— 5.7.3 *Identification and Traceability*

— 5.7.4 *Service-related Product Status*

— 5.7.6 *Preservation of Service-related Product*

— 5.7.7 *Validation of Service-related Product*

— 5.7.8 *Preventive Maintenance, Inspection and Test Program*

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

The quality management system requirements specified in this document are complementary to requirements for services. Informational statements marked "NOTE" are not requirements but are provided for guidance in understanding or clarifying the associated requirement.

2 Normative References

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies, except that new editions may be used on issue and shall become mandatory 6 months from the date of the revision.

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

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

3 Terms, Definitions, Abbreviations, and Acronyms

3.1 Terms and Definitions

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

3.1.1
acceptance criteria
Specified limits of acceptability applied to process, service, or product characteristics.

3.1.2
acceptance inspection
Demonstration through monitoring, evaluation, or measurement that the service or service-related product conforms to specified requirements.

3.1.3
calibration
Comparison and adjustment to a standard of known accuracy.

3.1.4
collection
Process of obtaining, assembling, and/or organizing applicable documentation with the intent of meeting the requirements for control or records.

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

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

3.1.7
critical success factor
Element of service that is essential to achieve goals or stated objectives.

3.1.8
key performance indicator
KPI
Metric by which an organization measures the manner or quality of the functioning of its processes, service, or service-related product.

3.1.9
legal requirement
Obligation imposed on an organization, including those that are statutory or regulatory.

3.1.10
management
Person or group of people who directs and controls an organization, 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 may be the same.

3.1.11
outsourced
Business function or process which is contracted to an external supplier.

3.1.12
preventive maintenance
Planned action to minimize the likelihood of causes of equipment failure and unscheduled interruptions to planned events.

3.1.13
risk
Situation or circumstance that has both a likelihood of occurring and a potentially negative consequence.

3.1.14
service
Performance of an activity by one function or organization for another.

3.1.15
service quality plan
Document that establishes procedures, resources, processes, and any required sequence of activities identifying and controlling the quality requirements.

3.1.16
service-related product
Materials, equipment, and software used in the execution of a service.

3.2 Abbreviations and acronyms

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

API	American Petroleum Institute
ISO	International Organization for Standardization
KPI	key performance indicator
MOC	management of change
PMITP	preventive maintenance, inspection and test program

4 Quality Management System Requirements

4.1 General

4.1.1 Quality Management System

The organization shall establish, document, implement, maintain, measure the effectiveness of, and improve upon a quality management system in accordance with the requirements of this document.

The organization shall ensure that legal and other applicable requirements with which the organization claims compliance are taken into account in its quality management system.

4.1.2 Quality Policy

The organization's policy for its commitment to quality shall be defined, documented, and approved by top management. The organization's top management shall review the quality policy to ensure that it is appropriate to the

organization, is the basis for the development of quality objectives (see 4.1.3), and is communicated, understood, implemented, and maintained at all relevant functions and levels within the organization.

4.1.3 Objectives

Management shall ensure that quality objectives, including those needed to meet requirements for the service and service-related product, are established at relevant functions and levels within the organization. The quality objectives shall be measurable and consistent with the quality policy.

4.1.4 Planning

Management shall ensure that:

a) the planning of the quality management system is carried out in order to meet the requirements of this document, and

b) the integrity of the quality management system is maintained when changes to the quality management system are planned and implemented.

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 Communications

4.1.5.1 Internal

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

The organization shall establish processes to ensure that customer and legal and other applicable requirements are communicated at relevant levels within the organization.

The organization shall establish processes to ensure that the results of data analysis (see 6.3) are communicated at relevant levels within the organization.

4.1.5.2 External

The organization shall determine, document, and implement the process for communicating with external organizations to ensure requirements are fully understood and risk is managed (see 5.3) throughout execution of contract and execution of services including activities such as:

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

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

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

d) addressing feedback and complaints (see 6.2.1).

4.2 Management Responsibility

4.2.1 Organization Structure

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

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

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

a) communicating to the organization the importance of meeting customer as well as legal and other applicable requirements;

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

c) conducting management reviews (see 6.5).

4.2.2 Responsibility and Authority

Roles, responsibilities and authorities shall be defined, documented, assigned within, and communicated throughout the organization.

The organization's management shall appoint a specific management representative(s) from within the organization who shall have defined roles, responsibilities and authority for:

a) ensuring that the quality management system is established, implemented and maintained in accordance with the requirements of this document;

b) initiating action(s) to minimize the likelihood of the occurrence of nonconformities; and

c) reporting to management on the performance of the quality management system for review, including recommendations for improvement.

4.3 Organization Capability

4.3.1 Provision of Resources

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

4.3.2 Human Resources

4.3.2.1 General

The organization shall maintain a documented procedure for defining personnel competency within the organization and identifying training requirements. The procedure shall provide for the training of all personnel. The procedure shall include provisions for ensuring the effectiveness of the actions taken to achieve the necessary competency of personnel.

4.3.2.2 Personnel Competence

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

4.3.2.3 Training and Awareness

The organization shall:

a) provide for quality management system training and for job training of the organization's personnel and contractors who affect the execution of services or provision of service-related products;

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

c) ensure that the frequency and content of training complies with legal and other applicable requirements;

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

e) identify and provide training on legal and other applicable requirements; and

f) maintain appropriate records of education, training, skills and experience (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 service-related product requirements. Work environment includes, as applicable:

a) buildings, workspace, and associated utilities;

b) process equipment (both hardware and software);

c) supporting services (such as transport or 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 quality management system documentation shall include:

a) statements of quality policy and quality objectives;

b) a quality manual that addresses each requirement of this document and includes the following:

1) scope of the quality management system,

2) description of the interaction between the processes of the quality management system, including the reference to documented procedures,

3) allowable exclusions and the basis for claiming those exclusions (see 1.2), and

4) identification of legal and other applicable requirements to which the organization claims compliance;

c) documented procedures established for the quality management system; and

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

Procedures required by this document and the quality management system shall be established, documented, implemented and maintained.

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 quality management system and this document, including required documents of an origin external to the organization.

The procedure shall define the controls needed:

a) to ensure that documents required by the quality management system, including revisions, translations, and updates, are reviewed and approved for adequacy prior to issue and use;

b) to define responsibilities for approval and re-approval of documents;

c) to identify changes to the documents;

d) to ensure that documents remain legible and readily identifiable; and

e) to ensure relevant versions of applicable documents 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 initiation, identification, collection, storage, protection, retrieval, retention time, and disposition of records.

Records, including those from outsourced activities, shall be established and controlled to provide evidence of conformity to requirements and of the effective operation of the quality management system.

Records shall remain legible, identifiable, and readily retrievable. Records shall be retained for a minimum of five years or as required by customer, legal and other applicable requirements, whichever is longer.

5 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 service-related products.

5.1.2 Determination of Requirements

The organization shall determine:

a) requirements specified by the customer, including the requirements for service planning, execution, and evaluation;

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 service-related product.

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

5.1.3 Review of Requirements

The organization shall review the requirements related to execution of the service or provision of service-related products. This review shall be conducted prior to the organization's commitment to provide a service to the customer and shall ensure that:

a) requirements are defined,

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

c) the organization has the capability to meet the defined 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 service-related product realization.

In planning, the organization shall address the following:

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

b) key performance indicators;

c) legal and other applicable requirements;

d) initial risk assessment (see 5.3);

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

f) service and/or service-related product design (see 5.4);

g) contingency planning (see 5.5);

h) management of change (see 5.11); and

i) records needed to provide evidence that the realization processes meet requirements (see 4.5).

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:

a) identify risks (potential or real) associated with services and service-related products;

b) identify and use risk management tools and techniques;

c) select, communicate and implement the mitigation or preventive control measures to reduce or avoid exposure to loss; and

d) notify the customer of remaining risks that may impact the service.

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

5.4 Design and Development

5.4.1 Design and Development Planning

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

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) requirements for service-related products, including its functional and technical requirements,

   3) environmental and operational conditions,

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

5) historical performance 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 service-related product;

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; and

e) identify critical service-related product.

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. 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 and approval shall be maintained (see 4.5).

5.4.6 Control of Design and Development Changes

Changes in the approved design shall be reviewed and verified by the management of change process (see 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 between the organization, its suppliers and the customer.

5.5.2 Planning Output

Contingency planning output shall be documented and communicated to the relevant operational 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,

b) actions required to mitigate the effects of disruptive incidents,

c) identification and assignment of responsibilities and authorities, and

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

5.6 Purchasing

5.6.1 Purchasing Control

The organization shall maintain a documented procedure to ensure that purchased or outsourced services and service-related products conform to specified requirements.

The procedure shall address:

a) the determination of the criticality of the services and/or service-related products obtained;

b) the evaluation and selection of suppliers based on their ability to supply services and service-related product in accordance with the organization's requirements;

c) the type and extent of control applied to the supplier and service and/or service-related product based on the criticality of the service and service-related product;

d) criteria, scope, frequency, and methods used when performing an assessment on a supplier; and

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

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

1) assessment of the supplier at supplier's facility to meet the organization's purchasing requirements, and

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

For re-evaluation of suppliers and the initial evaluation of suppliers for non-critical services or service-related product by the organization, one or more of the following shall apply:

i) assessment of the supplier to meet the organization's purchasing requirements,

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

iii) assessment of the supplier upon delivery of the product or service.

Records of the results of assessments and any necessary actions arising from the evaluation shall be maintained (see 4.5). Where supplier assessment results in the need for corrective actions, evidence of effective implementation of such actions shall be maintained in accordance with 6.4.2.

5.6.2 Purchasing Information

Purchasing information provided to the supplier shall be documented and describe the services or service-related product to be purchased, including where appropriate:

a) requirements for acceptance criteria of service and service-related product;

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

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

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

e) quality management system requirements.

5.6.3 Verification of Purchased Services and Service-related Product

The organization shall maintain a documented procedure for the verification or other activities necessary for ensuring that purchased service and service-related product meets 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 service-related products 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, as a minimum, into the development of a service quality plan (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 service-related products and ensuring design requirements are satisfied (see 5.4); and

e) identification of equipment, including required testing, measuring, monitoring, and detection devices (see 5.8).

5.7.1.2 Documentation

Controls for execution of the service shall be documented in routings, travelers, checklists, process sheets, or other types of documents and shall include requirements for verifying conformity to quality plans, procedures, and applicable standards/codes. The control documents shall include or reference instructions, workmanship, and acceptance criteria for processes, tests, inspections, and customer's inspection hold or witness points.

5.7.2 Service Quality Plan

5.7.2.1 General

The organization shall develop a service quality plan that controls the execution of services or use of service-related products.

NOTE A service quality plan is often referred to as a quality plan or service delivery plan.

5.7.2.2 Plan Content

The service quality plan 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 control of subcontractors;

d) identification of the relevant revision for each 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) service equipment and monitoring devices (see 5.8);

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

h) identification of critical services and service-related product;

i) identification of the required deliverables; and

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

The service quality plan shall be updated when any of the plan content changes.

5.7.2.3 Plan Approval

Service quality plans and any revisions to them shall be documented and approved by the organization.

When required by contract, the service quality plan and any 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 service-related product. 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, and records (see 4.5).

Service-related product shall be identified. Critical service-related product shall be identified and traceable to preventive maintenance, inspection, and test program (PMITP) records (see 4.5 and 5.7.8) and the original manufacturer.

5.7.4 Service-related Product Status

The organization shall maintain a documented procedure for the identification of service-related product status.

5.7.5 Customer Property

The organization shall maintain a documented procedure for the identification, verification, storage, preservation, maintenance, and protection of customer property, while under control of the organization. Customer property shall include customer-derived intellectual property and customer-specific data. Control of customer property shall include reporting to the customer any loss, damage, or unsuitable use of customer-supplied property.

The organization shall identify, verify, protect, and safeguard customer property provided for use in the service and/or with the service-related product. Records for the control and disposition of customer supplied property shall be maintained (see 4.5).

5.7.6 Preservation of Service-related Product

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

In order to detect deterioration, the condition of the service-related product or constituent parts in stock shall be assessed at intervals specified in the procedure.

5.7.7 Validation of Service-related Product

Validation of the service-related product shall be completed prior to the execution of the service. Records of the results of validation, when performed, shall be maintained (see 4.5).

5.7.8 Preventive Maintenance, Inspection, and Test Program

The organization shall maintain a documented procedure for the establishment of a PMITP. The procedure shall address record keeping requirements (see 4.5), inspection, maintenance, redress, repair, make-up, testing, and acceptance criteria for service-related product.

As a minimum, the PMITP shall include:

a) actions which address preventive maintenance;

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

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

d) controls that ensure equipment integrity to original performance requirements and design acceptance criteria are maintained.

Original 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

The organization shall determine the required testing, measurement, monitoring, and detection equipment to be controlled and necessary to provide evidence that service or service-related product meets specified requirements.

The organization shall maintain a documented procedure to ensure that testing, measurement, monitoring, and detection equipment is calibrated and maintained for the execution of the service or in the provision of the service-related product.

The procedure shall address equipment traceability, frequency of calibration, calibration method, acceptance criteria and suitable environmental conditions. The procedure shall identify required assessments and maintain records (see 4.5) when the validity of the previous testing, measuring, monitoring, or detection results are found not to conform to calibration requirements. The organization shall take appropriate action on the equipment and any service affected.

Testing, measuring, monitoring, and detection equipment shall:

a) be calibrated or verified, or both, at specified intervals, or prior to use, against measurement standards traceable to international or national measurement standards; where no such standards exist, the basis used for calibration or verification shall be recorded (see 4.5);

b) have identification in order to determine its calibration status;

c) be safeguarded from adjustments that would invalidate the measurement result; and

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

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

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

The organization shall maintain a registry of the required testing, measurement, monitoring, and detection equipment that includes an unambiguous form of identification, specific to each piece of equipment.

Records of the results of calibration and verification 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 carried out at appropriate stages during the execution of the service in accordance with design requirements (see 5.4) and the service quality plan (see 5.7.2). Evidence of conformity with established acceptance criteria, including KPIs and critical success factors, 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 and related responsibilities and authorities for addressing nonconforming service execution and service-related product. The level of response shall be proportionate to the severity of the nonconformity and its effect on the execution of the service.

5.10.2 Nonconforming Service Execution and Service-related Product

The organization shall address nonconforming service execution or service-related product by the following sequence of activities:

a) by taking action to correct the nonconformity; or

b) when 5.10.2.a) is not possible or appropriate, by taking action to preclude the use of service-related product 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, 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 and Documentation

When nonconforming services and/or service-related product are corrected they shall be subject to verification to demonstrate conformity to the requirements.

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

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 service-related product has been delivered or used in the execution of the service. The organization shall maintain records of such notifications (see 4.5).

5.11 Management of Change

5.11.1 General

The organization shall maintain a documented procedure for management of change (MOC). For the management of change, 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.

5.11.2 MOC Implementation

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

a) changes or proposed changes in the organizational structure;

b) changes in key or essential personnel, whose absence or departure could negatively impact the service;

c) changes in critical suppliers whose absence or departure could negatively impact the service;

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

e) changes to original equipment manufacturer's specifications, applications, and/or software for service-related product; and

f) changes in approved design (see 5.4) including those that were originally agreed upon by the customer and those required by changes in legal and other applicable requirements.

5.11.3 MOC Evaluation, Notification and Controls

The organization shall conduct a risk assessment (see 5.3) when evaluating a potential change. 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. The organization shall maintain records (see 4.5) of MOC activities.

6 Quality Management System 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, and to continually improve the effectiveness of the quality management system.

Quality management system 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 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 and conducting internal audits. The planning of internal audits shall take into consideration the results of previous audits and criticality of the process.

The organization shall define the audit criteria, scope, frequency, and methods to ensure that all elements of the management system claiming conformity to the requirements of this document are audited at least annually.

Outsourced suppliers that impact the quality of services or service-related product, located at the organization's facility, shall be included as part of the internal audit of the organization.

6.2.2.2 Performance of Internal Audit

The organization shall conduct internal audits to determine whether the quality management system conforms to the requirements of this document and is effectively implemented and maintained.

Audits shall be performed by competent personnel (see 4.3.2.2) independent of those who performed or directly supervised the activity being audited.

An audit of all elements of the management system shall be conducted prior to claiming conformance to the requirements of this document.

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 audits and their results 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 quality management system and to evaluate where continual improvement of the effectiveness of the quality management system can be made. This shall include data generated as a result of monitoring and measurement and from other relevant sources.

The analysis of data shall provide information relating to customer satisfaction (see 6.2.1), conformity to service design requirements (see 5.4), characteristics and trends of processes and service-related products including opportunities for preventive action (see 6.4.1 and 6.4.3), supplier performance (see 5.6), and quality objectives (see 4.1.3).

6.4 Improvement

6.4.1 General

The organization shall maintain a documented procedure that identifies the methods used to monitor, evaluate and improve the effectiveness and implementation of the quality management system processes for the execution of the service and use of the service-related product.

The procedure shall identify how the organization uses the quality policy, quality objectives, customer feedback, audit results, analysis of data, corrective and preventive actions, and management review for the continual improvement of the effectiveness of the quality management system.

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

6.4.2 Corrective action

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

The procedure shall define requirements for:

a) reviewing nonconformities (including customer complaints),

b) identifying the root cause of the nonconformity and implementing corrections,

c) evaluating the need for corrective action to reduce the likelihood that nonconformities recur,

d) identifying the timeframe and responsible person(s) for making corrections and taking corrective action,

e) reviewing and ensuring the effectiveness of the corrections and corrective action taken, and

f) maintaining records of the corrections and corrective action taken (see 4.5).

When the corrective action identifies the need for new or changed controls, the procedure shall require that the MOC process (see 5.11) be applied to the proposed action.

6.4.3 Preventive action

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

The procedure shall define requirements for:

a) identifying potential nonconformities and their potential causes;

b) evaluating the need for preventive action, including any immediate or short term action required, to prevent occurrence of nonconformities;

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

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

e) maintaining records of results of preventive action taken (see 4.5).

When the preventive action identifies the need for new or changed controls, the procedure shall require that the MOC process (see 5.11) be applied to the proposed action.

6.5 Management Review

6.5.1 General

The organization's quality management system shall be reviewed at least annually by the organization's management to evaluate the quality management system's continuing suitability, adequacy and effectiveness. This review shall include assessing opportunities for improvement and the need for changes to the quality management system, including the quality policy and quality objectives.

6.5.2 Input Requirements

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

a) effectiveness of actions resulting from previous management reviews;

b) results of internal audits (see 6.2.2);

c) changes, including legal and other applicable requirements, that could affect the quality management system;

d) customer feedback (see 6.2.1);

e) process effectiveness, including the results of risk assessment (see 5.3);

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

g) review and analysis of failures in service and/or service-related products (see 6.3).

6.5.3 Output Requirements

The output from the management review shall include a summary assessment of the status of the quality management system. The assessment shall include any required changes to the processes and any decisions and actions, required resources, and improvement of service and service-related products in meeting customer requirements.

Top management shall review and approve the output of management reviews. Management reviews shall be documented and records of these reviews shall be maintained (see 4.5).

Bibliography

[1] API Specification Q1, *Specification for Quality Programs for the Petroleum, Petrochemical, and Natural Gas Industry*

[2] OHSAS 18001 [2], *Occupational health and safety management systems—Requirements*

[3] ISO 9001 [1], *Quality management systems—Requirements*

[4] ISO 9004, *Managing for the sustained success of an organization—A quality management approach*

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

[6] ISO/TR 10013, *Guidelines for quality management system documentation*

[7] ISO 10015, *Quality management—Guidelines for training*

[8] ISO/TR 10017, *Guidance on statistical techniques for ISO 9001:2000*

[9] ISO 19011, *Guidelines for quality and/or environmental management systems auditing*

[10] ISO/TS 29001, *Specification for Quality Programs for the Petroleum, Petrochemical and Natural Gas Industry*

[11] ISO 31000, *Risk management—Principles and guidelines*

[12] 29 *CFR* 1910.119 [3], *Process safety management*

[2] Occupational Health & Safety Advisory Services, Navy House, King James IV Road, Rosyth Business Park, Rosyth, Fife, KY11 2BJ, England, www.ohsas.org.

[3] The *Code of Federal Regulations* is available from the U.S. Government Printing Office, Washington, DC 20402.

AMERICAN PETROLEUM INSTITUTE

2011 PUBLICATIONS ORDER FORM

Effective January 1, 2011. API Members receive a 30% discount where applicable. The member discount does not apply to purchases made for the purpose of resale or for incorporation into commercial products, training courses, workshops, or other commercial enterprises.

Online Orders www.api.org/pubs
Phone Orders 1-800-854-7179 (Toll-free in the U.S. and Canada) | (+1) 303-397-7956 (Local and International)
Fax Orders (+1) 303-397-2740

Date: _____ ☐ **API Member** (Check if Yes)

Invoice To (☐ Check here if same as "Ship To")

Name:
Title:
Company:
Department:
Address:
City: State/Province:
Zip/Postal Code: Country:
Telephone:
Fax:
Email:

Ship To (UPS will not deliver to a P.O. Box)

Name:
Title:
Company:
Department:
Address:
City: State/Province:
Zip/Postal Code: Country:
Telephone:
Fax:
Email:

Quantity	Title	SO★	Unit Price	Total
	Spec Q1, Specification for Quality Programs for the Petroleum and		$102.00	
	Natural Gas Industry			

Subtotal
Applicable Sales Tax (see below)
Rush Shipping Fee (see below)
Shipping and Handling (see below)
Total (in U.S. Dollars)

☐ Payment Enclosed ☐ P.O. No. (Enclose Copy) _____
☐ Charge My IHS Account No. _____
☐ VISA ☐ MasterCard ☐ American Express
☐ Diners Club ☐ Discover
Credit Card No.:
Print Name (As It Appears on Card):
Expiration Date:
Signature:

★ To be placed on Standing Order for future editions of this publication, place a check mark in the SO column and sign here:

_____

Pricing and availability subject to change without notice.

Mail Orders – Payment by check or money order in U.S. dollars is required except for established accounts. State and local taxes, $10 processing fee, and 5% shipping must be added. Send mail orders to: **API Publications, IHS, 15 Inverness Way East, c/o Retail Sales, Englewood, CO 80112-5776, USA.**

Purchase Orders – Purchase orders are accepted from established accounts. Invoice will include actual freight cost, a $10 processing fee, plus state and local taxes.

Telephone Orders – If ordering by telephone, a $10 processing fee and actual freight costs will be added to the order.

Sales Tax – All U.S. purchases must include applicable state and local sales tax. Customers claiming tax-exempt status must provide IHS with a copy of their exemption certificate.

Shipping (U.S. Orders) – Orders shipped within the U.S. are sent via traceable means. Most orders are shipped the same day. Subscription updates are sent by First-Class Mail. Other options, including next-day service, air service, and fax transmission are available at additional cost. Call 1-800-854-7179 for more information.

Shipping (International Orders) – Standard international shipping is by air express courier service. Subscription updates are sent by World Mail. Normal delivery is 3-4 days from shipping date.

Rush Shipping Fee – Next Day Delivery orders charge is $20 in addition to the carrier charges. Next Day Delivery orders must be placed by 2:00 p.m. MST to ensure overnight delivery.

Returns – All returns must be pre-approved by calling the IHS Customer Service Department at 1-800-624-3974 for information and assistance. There may be a 15% restocking fee. Special order items, electronic documents, and age-dated materials are non-returnable.

THERE'S MORE WHERE THIS CAME FROM.

API Monogram® Licensing Program
Sales: (+1) 713-964-2662
Service: (+1) 202-962-4791
Fax: (+1) 202-682-8070
Email: certification@api.org
Web: www.api.org/monogram

API Quality Registrar (APIQR®)
- ISO 9001
- ISO/TS 29001
- ISO 14001
- OHSAS 18001
- API Spec Q1®
- API QualityPlus®
- Dual Registration

Sales: (+1) 713-964-2662
Service: (+1) 202-962-4791
Fax: (+1) 202-682-8070
Email: certification@api.org
Web: www.api.org/apiqr

API Individual Certification Programs (ICP®)
Sales: (+1) 713-964-2662
Service: (+1) 202-682-8064
Fax: (+1) 202-682-8348
Email: icp@api.org
Web: www.api.org/icp

API Engine Oil Licensing and Certification System (EOLCS)
Sales: (+1) 713-964-2662
Service: (+1) 202-682-8516
Fax: (+1) 202-962-4739
Email: eolcs@api.org
Web: www.api.org/eolcs

API Training Provider Certification Program (API TPCP™)
Sales: (+1) 713-964-2662
Service: (+1) 202-682-8075
Fax: (+1) 202-682-8070
Email: tpcp@api.org
Web: www.api.org/tpcp

API Perforator Design Registration Program
Sales: (+1) 713-964-2662
Service: (+1) 202-682-8490
Fax: (+1) 202-682-8070
Email: perfdesign@api.org
Web: www.api.org/perforators

API Credit Exchange (ACE™)
Service: (+1) 202-682-8192
Fax: (+1) 202-682-8070
Email: exchange@api.org
Web: www.api.org/ace

API Diesel Exhaust Fluid Certification Program
Phone: (+1) 202-682-8516
Fax: (+1) 202-962-4739
Email: info@apidef.org
Web: www.apidef.org

API WorkSafe™
Sales: (+1) 713-964-2662
Service: (+1) 202-682-8469
Fax: (+1) 202-682-8348
Email: apiworksafe@api.org
Web: www.api.org/worksafe

API-U
Phone: (+1) 202-682-8053
Fax: (+1) 202-682-8070
Email: training@api.org
Web: www.api-u.org

API Data™
Phone: (+1) 202-682-8499
Fax: (+1) 202-962-4730
Email: apidata@api.org
Web: www.APIDataNow.org

API Publications
Online: www.api.org/pubs
Phone: 1-800-854-7179
(Toll-free: U.S./Canada)
(+1) 303-397-7956
(Local/International)
Fax: (+1) 303-397-2740

API Standards
Phone: (+1) 202-682-8148
Fax: (+1) 202-962-4797
Email: standards.org
Web: www.api.org/standards

Request a Quotation: www.api.org/quote

API
AMERICAN PETROLEUM INSTITUTE

AMERICAN PETROLEUM INSTITUTE

1220 L Street, NW
Washington, DC 20005-4070
USA

202-682-8000

Additional copies are available online at www.api.org/pubs

Phone Orders: 1-800-854-7179 (Toll-free in the U.S. and Canada)
303-397-7956 (Local and International)
Fax Orders: 303-397-2740

Information about API publications, programs and services is available on the web at www.api.org.

Product No. G0Q201