Training on

API SPEC Q1 9th Edition

American Petroleum Institute - Overview

API,

- Is standards organization.
- Maintains more than 600 standard and recommended practices.

API History

- API traces its beginnings to world war – I.
- Oil & gas companies created in 1911 after the discussion of standard oil.
- API established on March 20, 1919.

API was established to,

- Afford a means of cooperation with the government in all matters of national concern.
- Foster foreign & domestic trade in American Petroleum products.

What is Q1 & Q2 Specification

Q1 ➤ Specification for **Quality Management System** Requirements for Manufacturing Organizations for the Petroleum & Natural Gas Industry.
(For OEM)

Q2 ➤ Specification for Quality Management System Requirements for Service Supply Organization for the Petroleum and Natural Gas Industries.

Specification for Servicing of **Upstream equipments**

Upstream : Exploration of crude
Midstream : Transporting of crude
Downstream : Refining of crude
(For oil well site)

API Spec Q1

1986

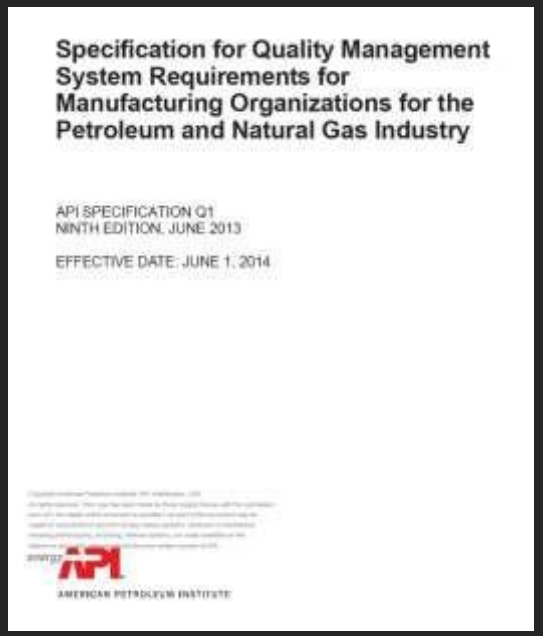
Released to Industry

2007

8th Edition is Released

2013

9th Edition is Released


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

API SPECIFICATION Q1
NINTH EDITION, JUNE 2013

EFFECTIVE DATE: JUNE 1, 2014

API
AMERICAN PETROLEUM INSTITUTE

API Specification Series

2 For offshore structures

5 Pipes, Tubes, Casing, Tubing

6 High Pressure refining valves

7 Chain

(API Specification Series : 2 to 20)

API Specification Q1 9th Edition

Clauses	: 6 + Annexure A
Sub clauses	: 99
Documented Procedures	: 30
Documents	: 14
Records	: 36

API Spec Q1 9th Edition
Mandatory Documented Procedures

Sr. No.	Clause No.	Description
1	4.3.2.1	Human Resource General
2	4.4.1	Documentation Requirements General
3	4.4.3	Control of Documents
4	4.4.4	Use of External Documents in Product Realization
5	4.5	Control of Records
6	5.1.1	Contract Review General
7	5.3	Risk Assessment & management
8	5.4.1	Design & Development Planning
9	5.5.1	Contingency Planning General
10	5.6.1.1	Purchasing Control - Procedure
11	5.6.3	Verification Of Purchased Products or activities
12	5.7.1.1	Control of Production & Servicing - Production
13	5.7.1.2	Servicing
14	5.7.1.5	Validation of Process for Production & Servicing
15	5.7.3	Identification & traceability

API Spec Q1 9th Edition
Mandatory Documented Procedures (Contd..)

Sr. No.	Clause No.	Description
16	5.7.4	Product Inspection/Test Status
17	5.7.5	Customer-supplied Property
18	5.7.6.1	Preservation of Product - General
19	5.7.7.1	Inspection & Testing - General
20	5.7.7.2	In-process Inspection and Testing
21	5.7.7.3	Final Inspection and Testing
22	5.7.8	Preventive Maintenance
23	5.8	Control of Testing, Measuring & Monitoring Equipment
24	5.9	Product Release
25	5.10.1	Control of Nonconforming Product - General
26	6.2.1	Customer Satisfaction
27	6.2.2.1	Internal Audit - General
28	6.3	Analysis of Data
29	6.4.2	Corrective Action
30	6.4.3	Preventive Action

API Q1 9th Edition
Mandatory Records

Sr. No.	Clause No.	Description
1	4.3.2.3	Training and Awareness
2	4.4	Documentation Requirements
3	4.4.1	General
4	4.5	Control of Records
5	5.1.2	Determination of Requirements
6	5.1.3	Review of Requirements
7	5.2	Planning
8	5.3	Risk Assessment & management
9	5.4.2	Design and Development Inputs
10	5.4.3	Design and Development Outputs
11	5.4.4	Design and Development Review
12	5.4.5	Design and Development Verification and Final Review
13	5.4.6	Design and Development Validation and Approval
14	5.4.7	Design and Development Changes
15	5.6.1.5	Supplier Evaluation—Records
16	5.6.1.6	Outsourcing
17	5.6.3	Verification Of Purchased Products or activities
18	5.7.1.4	Product Realization capability Documentation

API Q1 9th Edition
Mandatory Records (Contd..)

Sr. No.	Clause No.	Description
19	5.7.1.5	Validation of Process for Production & Servicing
20	5.7.2	Product Quality Plans
21	5.7.3	Identification & traceability
22	5.7.5	Customer-supplied Property
23	5.7.6.2	Storage and Assessment
24	5.7.7.1	Inspection & Testing - General
25	5.7.8	Preventive Maintenance
26	5.8	Control of Testing, Measuring & Monitoring Equipment
27	5.9	Product Release
28	5.10.4	Customer Notification
29	5.10.5	Records
30	5.11.1	General
31	6.2.1	Customer Satisfaction
32	6.2.2.2	Performance of Internal Audit
33	6.2.2.3	Audit Review and Closure
34	6.4.2	Corrective Action
35	6.4.3	Preventive Action
36	6.5.3	Output Requirements

Clause No. 4

Quality Management System Requirements

Quality Management System Requirements (Clause No. 4)

2. Quality Policy

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. The policy shall include commitment to comply with requirements and continually improve the effectiveness of the QMS.

3. Quality Objectives

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

Quality Management System Requirements (Clause No. 4) contd.

4.1.4 Planning

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

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

5. Communication

1. **Internal :** Ensure that the organization is aware of all relevant customer, legal and other applicable requirements.
2. **External :** To manage risk that occurs throughout the execution of the contract.

Quality Management System Requirements (Clause No. 4) contd.

2. Management Responsibility

4.2.1 General

The responsibility of the management within the organization is to provide evidence of its commitment to the development & implementation of the QMS and to continuously improve its effectiveness.

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

b) Conducting management reviews

2. Responsibility and Authority

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

3. Management Representative

- **Establishing the QMS**
- **Implementing the QMS**
- **Maintaining the QMS**

Quality Management System Requirements (Clause No. 4) contd.

3. Organization Capability

1. Provision of Resources

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

2. Human Resources

1. General

Procedure shall include provisions for determining and documenting the effectiveness of the training or other actions taken toward the achievement of required competency.

2. Personnel Competence

Personnel shall be competent based on the appropriate education, training, skills, and experience needed to meet product and customer requirements.

Quality Management System Requirements (Clause No. 4) contd.

4.3.2.3 Training and Awareness

The organization shall:

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

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

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

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

e) Maintain appropriate records of education, training, skills, and experience

4.3.3 Work Environment : Includes,

Building, Workspace, Associated utilities, Process equipment, Supporting service, Physical and environment conditions.

Quality Management System Requirements (Clause No. 4) contd.

4.4 Documentation Requirements

4.4.1 General

The quality management system documentation shall include:

a) Statements of quality policy and quality objectives;

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

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

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

3) Identification of processes that require validation; and

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

c) Documented procedures;

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

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

Quality Management System Requirements (Clause No. 4) contd.

4. Documentation Requirements

2. Procedures

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

3. Control of Documents

The organization shall maintain a documented procedure for the identification, distribution and control of documents required by the quality management system.

a) reviewed and approved for adequacy prior to issue and use,
b) identify changes and revision status,
c) remain legible and readily identifiable, and
d) are available where the activity is being performed

Obsolete documents shall be removed from all points of issue or use.

Quality Management System Requirements (Clause No. 4) contd.

5. Control of Records

- The organization shall maintain a documented procedure to identify the controls and responsibilities needed for the identification, collection, storage, protection, retrieval, retention time and disposition of records.
- Records shall be retained for a minimum of **five years** or as required by customer, legal and other applicable requirements, **whichever is longer.**

Clause No. 5

Product Realization

Product Realization (Clause No. 5)

5.1 Contract Review

The organization shall maintain a documented procedure for the review of equipments related to the provision of products and required servicing. The first step in the manufacturing or servicing a product is to review the contract.
It is important to review contract requirements **prior to the manufacturing or servicing a product.**

5.1.2 Determination of Requirements

The organization shall determine;

- Customer requirements (Documented)
- Legal & Applicable requirements
- Customer requirements(Undocumented but requirement for the product)

3. Review of Requirements

The organization shall review the requirements related to provision of products. This review shall be conducted prior to the organization‘s commitment to deliver product to the customer and shall ensure that:
a) requirements are identified and documented;
b) requirements differing from those previously identified are resolved;
c) the organization has the capability to meet the documented requirements.

Product Realization (Clause No. 5) Contd.

2. Planning

Planning of product realization shall be consistent with the requirements of the other processes of the quality management system

In planning, the organization shall address the following:

a)required resources and work environment management;

b) product and customer-specified requirements;

c) legal and other applicable requirements;

d) contingencies based on risk assessment;

e) design and development requirements;

f)required verification, validation, monitoring, measurement, inspection, and test activities specific to

the product and the criteria for product acceptance;

g) management of change (MOC); and

h) records needed to provide evidence that the product realization processes meet requirements

Product Realization (Clause No. 5) Contd.

5.3 Risk Assessment and Management

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

Risk assessment associated with product delivery shall include:
a) facility/equipment availability and maintenance; and
b) supplier performance and material availability/supply.
Risk assessment associated with product quality shall include, as applicable:
c) delivery of nonconforming product
d) availability of competent personnel.

Records of risk assessment and management including actions taken shall be maintained

Product Realization (Clause No. 5) Contd.

5.4 Design and Development

5.4.1 Design and Development Planning

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

a) The Plan(s), Including Plan Updates: plan and control procedures must include the design and development plans and plan updates.

b) The design and development stages : Under this subpart, organization are required to identify the D & D stage in its plan and control procedure.

API Q1 PRODUCTS

Product Realization (Clause No. 5) Contd.

c)The resources, responsibilities, authorities : plan & control procedure must include the resources, responsibilities, authorities and there interfaces to ensure effective communication for the D & D activities.

d) The review activities : In addition to identifying the different D & D stages in the plan and control procedure , organizations must include the review, verification, and validation activities necessary to complete each design and development stage.

e) Final review : The plan and control procedure the requirements for a final review of the design.

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

Product Realization (Clause No. 5) Contd.

4. Design and Development

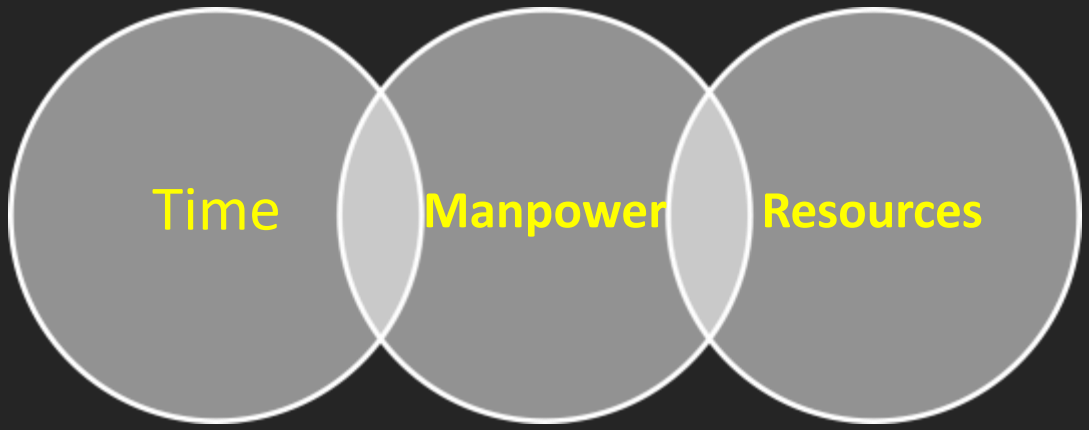
1. Design and Development Planning
2. Design and Development Inputs
3. Design and Development Outputs
4. Design and Development Review
5. Design and Development Verification and Final Review
6. Design and Development Validation and Approval
7. Design and Development Changes

Product Realization (Clause No. 5) Contd.

5. Contingency Planning

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

The contingency plan shall include, at a minimum:
a)actions required in response to significant risk scenarios to mitigate effects of disruptive incidents;
b) identification and assignment of responsibilities and authorities and
c) internal and external communication controls
Contingency planning takes,



RISKS	CONTINGENCIES
NATURAL DISASTERS	
WEATHER	•Alternate regional distribution points •Drop shipments from supplier facilities
WIND (e.g. hurricane)	
WATER (e.g. storm, tsunami)	
SNOW/ICE	
EARTHQUAKE, VOLCANO	
AVAILABILITY OF TRANSPORTATION	Qualify multiple transport suppliers
WORK PLACE	
STRIKE	Increase product inventory, negotiations
UTILITIES	Institute a failover system (e.g. generators)
COMMUNICATION	Identify alternate communication modalities
VENDOR ISSUES	Qualify multiple suppliers

Product Realization (Clause No. 5) Contd.

5.6 Purchasing

5.6.1 Purchasing Control : This section reviews API Q1 9th edition purchasing requirements

5.6.1.1 Procedure

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

The procedure shall address:

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

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

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

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

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

f) type and extent of control to be applied to outsourced activities

Product Realization (Clause No. 5) Contd.

2. Initial Supplier Evaluation—Critical Purchases

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

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

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

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

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

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

Product Realization (Clause No. 5) Contd.

3.Initial Supplier Evaluation—Noncritical Purchases

For purchase of noncritical products, components, or activities that impact product realization or the final product, the criteria for evaluation of suppliers by the organization shall meet the requirements of 5.6.1.2 or satisfy one or more of the following:

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

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

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

Product Realization (Clause No. 5) Contd.

4. Supplier Reevaluation

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

5. Supplier Evaluation—Records

Records of the results of all evaluations and any necessary actions arising from the evaluations shall be maintained

6. Outsourcing

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

Product Realization (Clause No. 5) Contd.

2. Purchasing Information

Purchasing information provided to the supplier shall be documented and adequately describe the product or activity to be purchased, including acceptance criteria, and where appropriate:

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

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

c) requirements for qualification of supplier's personnel and

d) quality management system requirements.

3. Verification of Purchased Products or Activities

- The organization shall maintain a documented procedure for the verification or other activities necessary for ensuring that purchased products or activities meet specified purchase requirements.
- Where the organization or its customer intends to perform verification at the supplier's premises, the organization shall state the intended verification arrangements and method of product release in the purchasing information.
- The organization shall ensure and provide evidence that purchased products and activities conform to specified requirements.

Product Realization (Clause No. 5) Contd.

5.7 Production and Servicing Provision

5.7.1 Control of Production and Servicing

5.7.1.1 Production

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

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

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

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

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

e) the availability of work instructions, when applicable;

f) process control documents;

g) implementation of monitoring and measurement activities; and

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

Product Realization (Clause No. 5) Contd.

5.7.1.2 Servicing

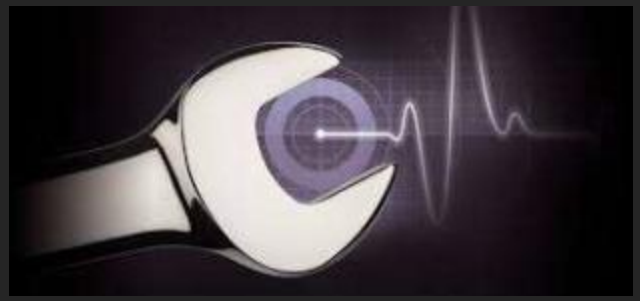
The organization shall maintain a documented procedure that describes controls associated with the servicing of products. The procedure shall address the following:

a) review and implementation of the organization's, customer-specific, product servicing, and other servicing requirements;
b) the availability and use of suitable servicing, testing, monitoring, and measurement equipment;
c) the availability of work instructions, when applicable;
d) ensuring identification and traceability requirements are maintained throughout the servicing process;
e) the implementation of monitoring and measurement activities;
f) process control documents; and
g) requirements for release of the product that was serviced

5.7.1.3 Process Control Documents

Process controls shall be documented in

- Routings,
- Travelers,
- Checklists,
- Process sheets, or
- Equivalent controls required by the organization



Product Realization (Clause No. 5) Contd.

5.7.1.4 Product Realization Capability Documentation

Develop & maintain the documentation that includes but is not limited to

- Product Realization Plan
- Record or Review/Verification
- Validation
- Monitoring
- Measurement
- Inspection
- Test activities
- Criteria of Product acceptance

5.7.1.5 Validation of Processes for Production and Servicing

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

Product Realization (Clause No. 5) Contd.

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

a)required equipment;

b) qualification of personnel;

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

d) identification of acceptance criteria;

e) requirements for records (see 4.5); and

f) revalidation.

5.7.2 Product Quality Plans

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

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

a) Description of the product to be manufactured;

b) Required processes;

c) Control of outsourced activities;

d) Identification of each procedure, specification, or other document referenced or used in each activity; and

e) Hold, witness, monitor, and document review points.

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

Product Realization (Clause No. 5) Contd.

5.7.3 Identification and Traceability

The organization shall maintain a documented procedure for identification and traceability while the product is under control of the organization as required by the organization, the customer, and/or the applicable product specifications throughout the product realization process, including applicable delivery and post-delivery activities. The procedure shall include requirements for maintenance or replacement of identification and/or traceability marks.

Documented procedure for:

- Identification
- Traceability
- Maintenance/replacement of marks

Required by :

- Organization
- Customer
- Product specification

5.7.4 Product Inspection/Test Status

The organization shall maintain a documented procedure for the identification of product inspection and/or test status throughout the product realization process that indicates the conformity or nonconformity of product with respect to inspections and/or tests performed.

Product Realization (Clause No. 5) Contd.

5.7.5 Customer-supplied Property

The organization shall maintain a documented procedure for

- Identification,
- verification
- safeguarding
- preservation
- maintenance
- control

of customer-supplied property, including intellectual property and data, while under control of the organization.

5.7.6 Preservation of Product

Preservation shall include identification and traceability marks, transportation, handling, packaging, and protection.

The procedure shall identify the requirements for storage and assessment. The organization shall use designated storage areas or stock rooms to prevent damage or deterioration of product, pending use or delivery. In order to detect deterioration, the condition of product in stock shall be assessed at specified intervals identified by the procedure. The interval shall be appropriate to the products being assessed.

Product Realization (Clause No. 5) Contd.

7. Inspection and Testing

The organization shall maintain a documented procedure for inspection and testing to verify that product requirements have been met. The procedure shall include requirements for in-process and final inspection and testing.

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

Types of inspection/ verification

- Quantity, Description : size, weight, diameter, length
- 100 % or sampling, Visual inspection, Gauging
- Nondestructive examination, Mechanical testing, PMI, Review of reports.

8. Preventive Maintenance

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

a) Type of equipment to be maintained (Hydraulic, Pneumatic)

b) Frequency (Daily/weekly, Monthly/ Quarterly, Annually)

c) responsible personnel (operator, maintenance personal, manufacturer/ 3rd party)

Preventive maintenance can be based on risk, system reliability, usage history, experience, industry recommended practices, relevant codes and standards, Original Equipment manufacturer guidelines.

Product Realization (Clause No. 5) Contd.

8. Control of Testing, Measuring, and Monitoring Equipment (TMME)

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

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

a)unique identifier;

b) calibration status;

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

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

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

f) acceptance criteria;

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

Product Realization (Clause No. 5) Contd.

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

5.8 Control of Testing, Measuring, and Monitoring Equipment (Contd..)

Testing, measuring, and monitoring equipment shall:

1) Be calibrated or verified, or both, against measurement standards
2) have the calibration status identifiable by the user for the activities being performed at all times;
3) be safeguarded from adjustments that would invalidate the measurement result or the calibration status;
4) be protected from damage and deterioration during handling, maintenance, and storage; and
5) be used under environmental conditions that are suitable for the calibrations, inspections, measurements, and tests being carried out.

Product Realization (Clause No. 5) Contd.

9. Product Release

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

10. Control of Nonconforming Product

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

a) product identification to prevent unintended use or delivery;
b) addressing the detected nonconformity (see 5.10.2)
c) taking action to preclude its original intended use or delivery and
d) authorizing its use, release, or acceptance under concession by relevant authority and, where applicable, by the customer

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

1)identifying, documenting, and reporting nonconformance's or product failure identified after delivery

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

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

Product Realization (Clause No. 5) Contd.

10. Control of Nonconforming Product (Contd..)

2. Nonconforming Product

The organization shall address nonconforming product by performing one or more of the following:

a) repair or rework with subsequent inspection to meet specified requirements;

b) re-grade for alternative applications;

c) release under concession (see 5.10.3); and/or

d) reject or scrap.

3. Release of Nonconforming Product Under Concession

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

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

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

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

Product Realization (Clause No. 5) Contd.

10. Control of Nonconforming Product (Contd..)

4. Customer Notification

The organization shall notify customers of product not conforming to DAC or contract requirements, that has been delivered. The organization shall maintain records of such notifications

5. Records

Records of the nature of nonconformities and any subsequent actions taken, including concessions obtained, shall be maintained

11. Management of Change (MOC)

5.11.1 General

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

Product Realization (Clause No. 5) Contd.

11. Management of Change (MOC) (Contd..)

5.11.2 MOC Implementation

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

a) changes in the organizational structure
b) changes in key or essential personnel
c) changes in critical suppliers
d) changes to the management system procedures, including changes resulting from corrective and preventive actions

5.11.3 MOC Notification

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

Clause No. 6

Quality Management System Monitoring, Measurement, Analysis, and Improvement

Quality Management System Monitoring, Measurement, Analysis, and Improvement (Clause No. 6)

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

1. **General**

   The organization shall plan and implement the monitoring, measurement, analysis, and improvement processes needed to ensure conformity of the quality management system to the requirements of this specification and to continually improve the effectiveness of the quality management system. This shall include determination of applicable methods, techniques for the analysis of data, the extent of their use.

2. **Monitoring, Measuring, and Improving**

   1. **Customer Satisfaction**

The organization shall maintain a documented procedure to measure customer satisfaction that must include the following items,

- Frequency of measurement
- Customer feedback
- Key Performance Indicators
- Other information to determine requirements are satisfied

Quality Management System Monitoring, Measurement, Analysis, and Improvement (Clause No. 6)

2. Internal Audit

1. General

All processes claiming conformity to API Q1, 9th Edition shall be audited at least every 12 months. Outsource activities that impact the quality of the product shall be include as a part of internal audit of the organization.

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.

•All management system processes shall be audited prior to claiming conformance to API Q1, 9th Edition.

3. Audit Review and Closure

Response Time

Results & status reported in management review

Quality Management System Monitoring, Measurement, Analysis, and Improvement (Clause No. 6)

6.2.3 Process Evaluation

Process Evaluation

The organization shall apply suitable evaluation methods to demonstrate the ability of the quality management system processes to achieve planned results, including conformity to product requirements.

6.3 Analysis of Data

The organization shall maintain a documented procedure for,

Data

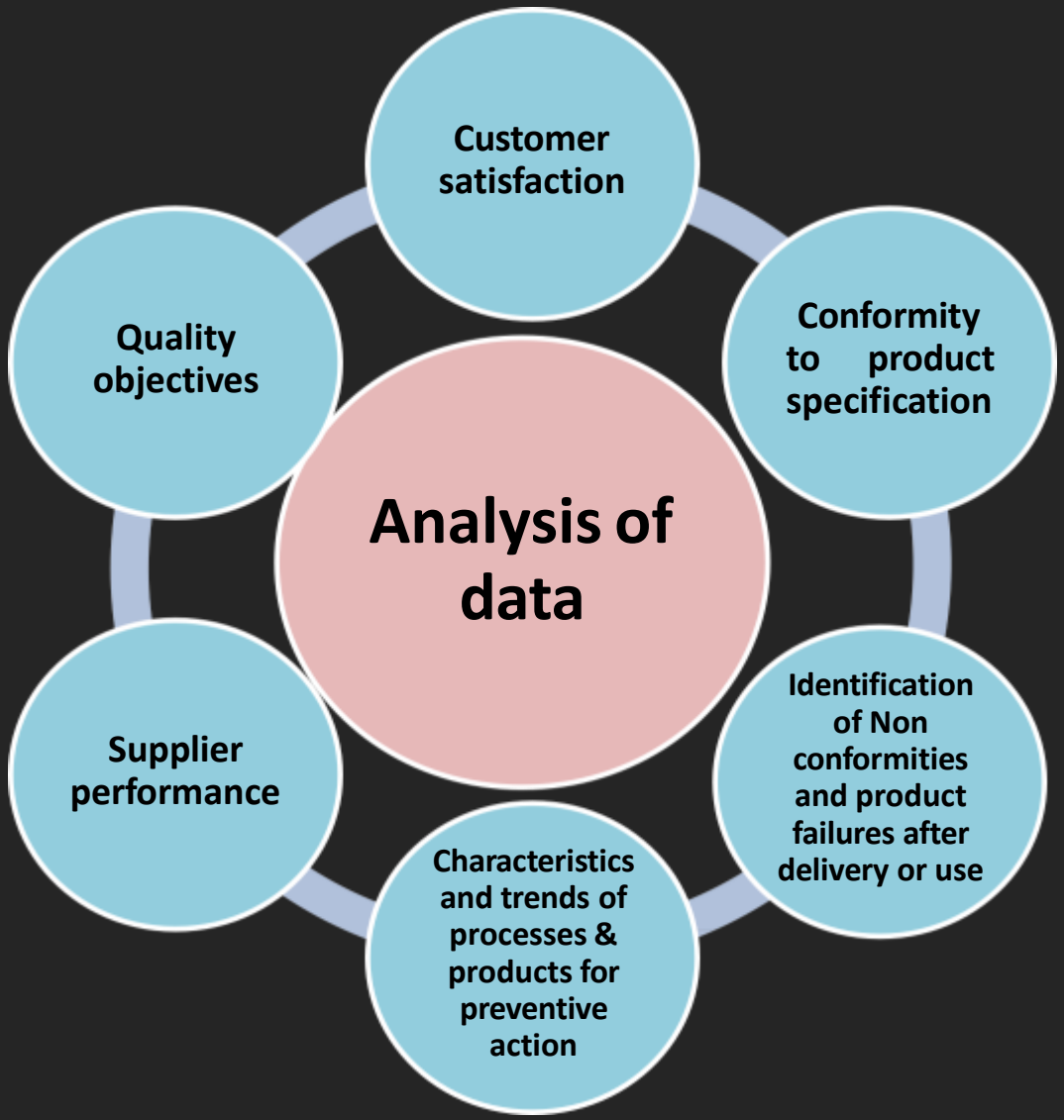
- Identification
- Collection
- Analysis

Management System

- Suitability
- Effectiveness

Quality Management System Monitoring, Measurement, Analysis, and Improvement (Clause No. 6) Contd..

6.3 Analysis of Data (Contd..)



Quality Management System Monitoring, Measurement, Analysis, and Improvement (Clause No. 6) Contd..

6.4 Improvement

1. General

Continually improve Effectiveness of the Quality Management System through,

- Use of quality policy, objectives, audit results, analysis of data, corrective and preventive actions.

6.4.2 Corrective Action

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

MOC when the corrective action require new Or change controls with in QMS

Quality Management System Monitoring, Measurement, Analysis, and Improvement (Clause No. 6) Contd..

6.4.2 Corrective Action : The procedure shall identify requirements for

Quality Management System Monitoring, Measurement, Analysis, and Improvement (Clause No. 6) Contd..

3. Preventive Action

The organization shall maintain a documented procedure to Determine and implement Preventive actions, both internally and with in the supply chain to eliminate the Potential nonconformities in order to Minimize the likelihood of their occurrence.

The procedure shall identify requirements for

- Identifying opportunities for improvements.
- Identifying a potential nonconformity and its potential causes.
- Evaluating the need for preventive action, including any immediate or short-term action required, to prevent occurrence of a nonconformity.
- Identifying the timeframe and responsible person for implementing a preventive action.

MOC when the corrective action require new or change controls with in QMS

Quality Management System Monitoring, Measurement, Analysis, and Improvement (Clause No. 6) Contd..

6.5 Management Review

6.5.1 General

The organization's quality management system shall be reviewed at least every 12 months by the organization management to evaluate the quality management system's,

- Continued suitability
- Adequacy
- 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.

Quality Management System Monitoring, Measurement, Analysis, and Improvement (Clause No. 6) Contd..

6.5.2 Input Requirements

- Effectiveness of actions resulting from previous management reviews
- Results of Audits
- Changes that could affect the Quality management system
- Analysis of Customer satisfaction
- Process performance
- Results of risk assessment
- Status of corrective & preventive action
- Analysis of supplier performance
- Review of the analysis of product conformity, including nonconformities identified after delivery or use
- Recommendations for improvement

Quality Management System Monitoring, Measurement, Analysis, and Improvement (Clause No. 6) Contd..

3. Output Requirements

Management Review OUTPUTS

- Summary assessment
- Required changes
- Resources
- Required Actions
- Improvement to products

Annexure A

Use Of API Monogram by Licensees

Annexure A
Use of API Monogram by Licensees

1. Scope

Registered certification mark:

- New products
- Meet product specification
- Manufactured under an API Q1 management

Representation and warranty

- To API and purchaser
- Program licenses issued after on site audit
- Only licensed manufacturers can apply the API monogram to their programs

A.3 Terms and Definitions

A.3.1 API Monogrammable product

Product that has been manufactured by an API Licensee utilizing a fully implemented API Q1 compliant quality management system and that meets all the API-specified requirements of the applicable API product specification(s) and/or standard(s)

Annexure A
Use of API Monogram by Licensees

A.3.2 API Product specification

Prescribed set of rules, conditions, or requirements attributed to a specified product that address the definition of terms; classification of components; delineation of procedures; specified dimensions; manufacturing criteria; material requirements, performance testing, design of activities and the measurement of quality and quantity with respect to materials; products, processes, services, and/or
Practices

A.3.4 Design package

Records and documents required to provide evidence that the applicable product has been designed in accordance with API Q1 and the requirements of the applicable product specification(s) and/or standard(s).

Licensee

Organization that has successfully completed the application and audit process and has been issued a license by API

A.4 Quality Management System Requirements

An organization applying the API Monogram to products shall develop, maintain, and operate at all times a quality management system conforming to API Q1.

Annexure A
Use of API Monogram by Licensees

5. Control of the Application and Removal of the API Monogram

API Monogram marking procedure

- Define the authority responsible for application and removal of API monogram
- Define the methods used to apply the monogram
- Identify the location on the product where API monogram is to be applied
- Require the application of licensee's license number and date of manufacture of the product in conjunction with the use of API monogram.
- Require that the date of manufacture at a minimum be two digits representing the month and two digits representing the year.
- Require controls for the application of additional API product specifications and standard marking requirements, as applicable.

Applying the API Monogram

only an API licensee apply the monogram and its license number to API monogrammable products.

Annexure A
Use of API Monogram by Licensees

Site- specific Monogram

The API monogram license when issued, is site specific and shall only be applied at that site specific licensed facility location.

Removal of Monogram

Monogram is applied during production process but shall be removed if the product is out of conformance with any of the requirements of the applicable API product specifications / standards.

6. Design Package Requirements

- Maintain design product package
- Meets the most current product specifications
- Available during API audits

7. Manufacturing Capability

Demonstrated ability to manufacture in accordance with specifications

API shall,

- Refuse licensing
- Suspend licensing
- Perform additional audits
- Perform subcontractor audits

Based on a facility's level of manufacturing capability.

Annexure A
Use of API Monogram by Licensees

8. API Monogram Program: Nonconformance Reporting

API solicits information

- Non confirming product
- Field failures
- Malfunctions

Related to

- Specification deficiencies
- Non confirmative with requirements

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

Correlation to API Q1, 9th Edition *"Soft" Requirements (as applicable, if necessary, etc.)*	
API Q1, 9th Edition	**API Q1, 8th Edition**
4.1 Quality Management System	
4.1.1 General	
4.1.1 Establish, document, implement, and maintain QMS at all times	4.1, 4.1 c), 7.1
4.1.1 Measure effectiveness and improve QMS	4.1 c), 8.5.1
4.1.2 Quality Policy	
4.1.2 Top management defines, documents, and approves policy	5.1 b), 5.3.1
4.1.2 Policy reviewed to ensure appropriate and basis for quality objectives	5.3 a), 5.3 c)
4.1.2 Communicated, understood, implemented, and maintained	5.3 d)
4.1.2 Statement of commitment to comply and improve QMS	5.3 b)
4.1.3 Quality Objectives	
4.1.3 Management and top management establish	5.1 c), 7.1 a)
4.1.3 Established at relevant functions and levels	5.4.1
4.1.3 Measureable and consistent with quality policy	5.4.1
4.1.4 Planning	
4.1.4 a) Criteria and methods of QMS determined and effective	4.1, 4.1 a), 7.1
4.1.4 b) Planning of QMS carried out to meet requirements	4.1, 4.1 a), 5.4.2 a)

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

Correlation to API Q1, 9th Edition *"Soft" Requirements (as applicable, if necessary, etc.)*	
API Q1, 9th Edition	**API Q1, 8th Edition**
4.1.5 Communication	
4.1.5.1 Internal	
Communication processes established	5.5.3
Effectiveness of QMS communicated	5.5.3
4.1.5.1 a) Requirements communicated within the organization	5.1 a)
4.1.5.1 b) Data analysis results communicated within organization	*No Requirement*
4.1.5.2 External	
Determine, document, and implement external communication process	5.2, 7.2.3
4.1.5.2 a) For execution of inquiries, contracts, and amendments	7.2.3 b)
4.1.5.2 b) For product information and nonconformities	7.2.3 a)
4.1.5.2 c) For addressing feedback and complaints	7.2.3 c)
4.1.5.2 d) Quality plans and changes	*No Requirement*
4.2 Management Responsibility	
4.2.1 Organization Structure	
Top management ensures availability of resources	4.1 d), 5.1 e)
Management commitment to QMS and its improvement	5.1
4.2.1 a) Management ensures objects established including KPIs	5.1 c)

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

Correlation to API Q1, 9th Edition *"Soft" Requirements (as applicable, if necessary, etc.)*	
API Q1, 9th Edition	**API Q1, 8th Edition**
4.2.1 b) Management conducts management reviews	5.1 d)
4.2.2 Responsibility and Authority	
Responsibilities and authorities defined	5.5.1
4.2.3 Management Representative	
Top management appoints management representative who:	5.5.2
4.2.3 a) Ensures processes established, implemented and maintained	5.5.2 a)
4.2.3 b) Reports to top management on performance of QMS	5.5.2 b)
4.2.3 c) Initiates actions to minimize nonconformances	*No Requirement*
4.2.3 d) Ensure promotion of awareness of customer requirements	5.5.2 c)
4.3 Organization Capability	
4.3.1 Provision of Resources	
Determine and allocate resources needed for QMS	6.1, 7.1 b)
4.3.2 Human Resources	
4.3.2.1 General	
Procedure for competency and training	6.2.2.1, 6.2.2 a), 6.2.2 b)
Procedure includes provisions for determining effectiveness	6.2.2 c)
4.3.2.2 Personnel Competence	
Personnel competent to meet requirements	6.2.1
Records of competency determination	*No Requirement*
4.3.2.3 Training and Awareness	
4.3.2.3 a) QMS and job training for personnel	6.2.2.1
4.3.2.3 b) Allow for customer-specified/provided training	*No Requirement*
4.3.2.3 c) Frequency and content identified	6.2.2.1
4.3.2.3 d) Personnel aware of importance of activities and contribution	6.2.2 d)
4.3.2.3 e) Records maintained	6.2.2 e)

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

Correlation to API Q1, 9th Edition *"Soft" Requirements (as applicable, if necessary, etc.)*	
API Q1, 9th Edition	**API Q1, 8th Edition**
4.3.3 Work Environment	
Determine, provide, manage, and maintain work environment, including:	6.3, 6.4
4.3.3 a) Buildings, workspace, and utilities	6.3 a)
4.3.3 b) Process equipment	6.3 b)
4.3.3 c) Support services	6.3 c)
4.3.3 d) Physical, environment, and other factors	6.4
4.4 Documentation Requirements	
4.4.1 General	
4.4.1 a) Statements of policy and objectives	4.2.1 a)
4.4.1 b) Quality manual that includes:	4.2.1 b), 4.2.2.1
4.4.1 b) 1) Scope or QMS and justifications for exclusions	4.2.2 a)
4.4.1 b) 2) Interaction of processes of QMS	4.1 b), 4.2.2 c)
4.4.1 b) 3) Identification of processes requiring validation	*No Requirement*
4.4.1 b) 4) Reference to procedures of the QMS	4.2.2 b)
4.4.1 c) Procedures for the QMS	4.2.1 c)
4.4.1 d) Documents/records for planning, operation, and control of QMS	4.2.1 d), 7.1 b)
4.4.1 e) Legal and other applicable requirements	*No Requirement*
4.4.2 Procedures	
Procedures established, documented, implemented, and maintained	*No Requirement*
4.4.3 Control of Documents	
Procedure for control of documents, including external documents	4.2.3
Procedure specifies responsibilities for approval and re-approval	4.2.3 a), 4.2.3 b), 4.2.3.2
4.4.3 a) Documents reviewed and approved before use	4.2.3 a), 4.2.3 b)
4.4.3 b) Changes and revision status identified	4.2.3 c)

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

Correlation to API Q1, 9th Edition *"Soft" Requirements (as applicable, if necessary, etc.)*	
API Q1, 9th Edition	**API Q1, 8th Edition**
4.4.3 c) Documents remain legible and identifiable	4.2.3 e)
4.4.3 d) Documents available where activity performed	4.2.3 d)
External document controlled to ensure correct version used	4.2.3 f)
Obsolete documents removed or identified	4.2.3 g)
Procedures, work instructions, and forms controlled	*No Requirement*
4.4.4 Use of External Documents in Product Realization	
Procedure to translate requirements into the product realization process	7.1.1
4.5 Control of Records	
Procedure for records control and identification of responsibilities	4.2.3, 4.2.4, 4.2.4.1
Identify, collect, store, protect, retrieve, retain, and dispose records	4.2.4
Records including outsourced activities provide evidence of conformity	*No Requirement*
Records legible, identifiable, and retrievable	4.2.4
Records maintained for five years minimally or per specification	4.2.4.1
5 Product Realization	
5.1 Contract Review	
5.1.1 General	
Procedure for review of requirements and provision of products and servicing	7.2.2.1
5.1.2 Determination of Requirements	
5.1.2 a) Determine requirements specified by customer	7.2.1 a)
5.1.2 b) Determine legal requirements	7.2.1 c), 7.2.1 d)
5.1.2 c) Determine requirements not stated by customer but needed	7.2.1 b), 7.2.2
When no documented requirements, organization confirms and maintains records	7.2.2
5.1.3 Review of Requirements	
Review the requirements related to provision of products	7.2.2
Review conducted before commitment to deliver product	7.2.2
5.1.3 a) Requirements identified and documented	7.2.2 a)
5.1.3 b) Requirement differences resolved	7.2.2 b)
5.1.3 c) Organization has capability to meet requirements	7.2.2 c)

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

Correlation to API Q1, 9th Edition *"Soft" Requirements (as applicable, if necessary, etc.)*	
API Q1, 9th Edition	**API Q1, 8th Edition**
When changed, documents amended and personnel notified	7.2.2
Records maintained	7.2.2
5.2 Planning	
Plan processes needed for product realization	7.1
Planning consistent with requirements of other processes of QMS	7.1
5.2 a) Address required resources and work environment	7.1 b)
5.2 b) Address product and customer-specified requirements	7.1 a)
5.2 c) Address legal and other requirements	*No Requirement*
5.2 d) Address contingencies based on risk assessment	*No Requirement*
5.2 e) Address design requirements	7.1 a)
5.2 f) Address required verification, validation, monitoring, inspection, and testing	7.1 c)
5.2 g) Address management of change	*No Requirement*
5.2 h) Address records	7.1 d)
Planning output updated with changes	*No Requirement*
Planning suitable for organization	7.1
5.3 Risk Assessment and Management	
Procedure to: identify and control risk	*No Requirement*
identify techniques and tools	*No Requirement*
5.3 a) Product delivery risk includes facility/equipment availability and maintenance	*No Requirement*
5.3 b) Product delivery risk includes supplier performance and material availability	*No Requirement*
5.3 c) Product quality risk includes delivery of nonconforming product	*No Requirement*

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

Correlation to API Q1, 9th Edition *"Soft" Requirements (as applicable, if necessary, etc.)*	
API Q1, 9th Edition	**API Q1, 8th Edition**
5.3 d) Product quality risk includes availability of competent personnel	*No Requirement*
Records of risk assessment and actions taken maintained	*No Requirement*
5.4 Design and Development	
5.4.1 Design and Development Planning	
Procedure to plan and control design and development	7.3.1.1
5.4.1 a) Plans and updates	7.3.1
5.4.1 b) Design and development stages	7.3.1 a)
5.4.1 c) Resources, responsibilities, authorities, and interfaces	7.3.1, 7.3.1 c)
5.4.1 d Review, verification, and validation activities	7.3.1 b)
5.4.1 e) Final review of design	7.3.4.1
Controls for other organization design locations impacting design	*No Requirement*
Controls for outsourced design activities	7.3.1.1
5.4.2 Design and Development Inputs	
Inputs identified and reviewed for adequacy and completeness	7.3.2, 7.3.2.1
Inputs include functional and technical requirements	7.3.2 a), 7.3.2 d)
5.4.2 a) Customer-specified requirements	7.3.2.1
5,4.2 b) External sources (API specifications)	7.3.2 d)
5.4.2 c) Environmental and operational conditions	7.3.2 d)
5.4.2 d) Methods, assumption, and formulae documentation	7.3.1.2
5.4.2 e) Historical performance	7.3.2 c)
5.4.2 f) Legal requirements	7.3.2 b)
5.4.2 g) Risk assessment	*No Requirement*
Records maintained	7.3.2.1

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

Correlation to API Q1, 9th Edition *"Soft" Requirements (as applicable, if necessary, etc.)*	
API Q1, 9th Edition	**API Q1, 8th Edition**
5.4.3 Design and Development Outputs	
Outputs verified against input requirements	7.3.3
5.4.3 a) Meet input requirements	7.3.3 a)
5.4.3 b) Provide purchasing, production, and post-delivery information	7.3.3 b)
5.4.3 c) Design acceptance criteria	7.3.3 c)
5.4.3 d) Critical products or components	*No Requirement*
5.4.3 e) Results of calculations	7.3.1.2
5.4.3 f) Specify characteristics essential for safe and proper use	7.3.3 d)
Records maintained	7.3.3.1
5.4.4 Design and Development Review	
5.4.4 a) Review for adequacy to meet requirements	7.3.4 a)
5.4.4 b) Identify problems and propose actions	7.3.4 b)
Participants from concerned functions	7.3.4
Records maintained of review	7.3.4
5.4.5 Design and Development Verification and Final Review	
Conduct final design review and verification to ensure output meets input	7.3.4.1, 7.3.5
Records maintained of final review and verification	7.3.4, 7.3.5
5.4.6 Design and Development Validation and Approval	
Product capable of meeting specified requirements	7.3.6
Performed prior to delivery	7.3.6
Completed designs approved after validation	*No Requirement*
Competent person other than design developer approves final design	7.3.4.1
Records maintained for validation and approval	7.3.6
5.4.7 Design and Development Changes	
Changes identified	7.3.7
Changes reviewed, verified and validated, and approved	7.3.7

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

Correlation to API Q1, 9th Edition *"Soft" Requirements (as applicable, if necessary, etc.)*	
API Q1, 9th Edition	**API Q1, 8th Edition**
Evaluation of the effect of changes on product and parts delivered	7.3.7
Changes require same controls as original design	7.3.7.1
Records maintained	7.3.7
5.5 Contingency Planning	
5.5.1 General	
Procedure for contingency planning to address risk	*No Requirement*
Based on assessed risk	*No Requirement*
Output documented and communicated	*No Requirement*
5.5.2 Planning Output	
5.5.2 a) Includes actions required in response to significant risk	*No Requirement*
5.5.2 b) Includes identification and assignment of responsibilities	*No Requirement*
5.5.2 c) Includes internal and external communications controls	*No Requirement*
5.6 Purchasing	
5.6.1 Purchasing Control	
5.6.1.1 Procedure	
Procedure for control of purchase products and outsourced activities	4.1, 4.1.1, 7.4.1, 7.4.1.1
5.6.1.1 a) Determine criticality	*No Requirement*
5.6.1.1 b) Initial evaluation and selection of suppliers	7.4.1
5.6.1.1 c) Type/extent of control on supplier based on criticality	*No Requirement*
5.6.1.1 d) Criteria, scope, frequency, and methods for reassessment	7.4.1
5.6.1.1 e) List of approved suppliers	*No Requirement*
5.6.1.1 e) List of approved supplier scope	*No Requirement*
5.6.1.1 f) Control of outsourced activities	4.1, 4.1.1, 7.4.1.3
5.6.1.2 Initial Supplier Evaluation—Critical Purchases	

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

Correlation to API Q1, 9th Edition *"Soft" Requirements (as applicable, if necessary, etc.)*	
API Q1, 9th Edition	**API Q1, 8th Edition**
Criteria for initial evaluation of critical suppliers	*No Requirement*
5.6.1.2 a) Supplier QMS conforms to specified requirements	7.4.1.2 d)
5.6.1.2 b) i) Assessment by on-site evaluation of supplier, or	7.4.1.2 a)
5.6.1.2 b) ii) Assessment by first article inspection, or	*No Requirement*
5.6.1.2 b) iii) Identifying how product conforms to legal or contractual requirements	*No Requirement*
5.6.1.3 Initial Supplier Evaluation—Noncritical Purchases	
Meeting the requirements 5.6.1.2, or	*No Requirement*
5.6.1.3 a) Assessment of supplier to meet purchase requirements, or	7.4.1.2 c)
5.6.1.3 b) Supplier QMS conforms to specified requirements, or	7.4.1.2 d)
5.6.1.3 c) Assessment of supplier upon delivery of product	7.4.1.2 b)
5.6.1.4 Supplier Reevaluation	
Reevaluation requirements follow those of 5.6.1.3	7.4.1.2
5.6.1.5 Supplier Evaluation—Records	
Supplier evaluation records maintained	7.4.1
5.6.1.6 Outsourcing	
Organization's applicable QMS requirements satisfied	4.1
Maintain responsibility for product conformance to requirements	4.1.1
Records maintained	*No Requirement*
5.6.2 Purchasing Information	
Ensure adequacy of information	7.4.2
Information documented and includes:	7.4.2, 7.4.2.1
Acceptance criteria	7.4.2 a)
5.6.2 a) Requirements for approval of supplier procedures	7.4.2 a)
5.6.2 b) Applicable versions of documents	7.4.2.1
5.6.2 c) Requirements for supplier personnel qualification	7.4.2 b)

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

Correlation to API Q1, 9th Edition *"Soft" Requirements (as applicable, if necessary, etc.)*	
API Q1, 9th Edition	**API Q1, 8th Edition**
5.6.2 d) QMS requirements	7.4.2 c)
5.6.3 Verification of Purchased Products or Activities	
Procedure for verification of products or activities	7.4.3.1
Control for verification at supplier's premises	7.4.3
Products or activities conform to requirements	7.4.3
Records maintained	7.4.3.1
5.7 Production and Servicing Provision	
5.7.1 Control of Production and Servicing	
5.7.1.1 Production	
Procedure for production of products and includes:	7.5.1.1
5.7.1.1 a) Information on characteristics of product	7.5.1 a)
5.7.1.1 b) Implementation of quality plans	*No Requirement*
5.7.1.1 c) Design requirements satisfied	*No Requirement*
5.7.1.1 d) Availability and use of equipment	7.5.1 c), 7.5.1 d)
5.7.1.1 e) Availability of work instructions	7.5.1 b)
5.7.1.1 f) Process control documents	*No Requirement*
5.7.1.1 g) Implementation of monitoring and measurement activities	7.5.1 e)
5.7.1.1 h) Implementation of product release, delivery, and post-delivery	7.5.1 f)
5.7.1.2 Servicing	
Procedure for servicing of products and includes:	7.5.1.1
5.7.1.2 a) Implementation of servicing requirements	7.5.1 a)
5.7.1.2 b) Availability and use of equipment	7.5.1 c), 7.5.1 d)
5.7.1.2 c) Availability of work instructions	7.5.1 b)
5.7.1.2 d) Ensure identification and traceability maintained	*No Requirement*
5.7.1.2 e) Implementation of monitoring and measurement activities	7.5.1 e)
5.7.1.2 f) Process control documents	*No Requirement*
5.7.1.2 g) Implementation of product release	7.5.1 f)

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

Correlation to API Q1, 9th Edition *"Soft" Requirements (as applicable, if necessary, etc.)*	
API Q1, 9th Edition	**API Q1, 8th Edition**
5.7.1.3 Process Control Documents	
Controls in routings, travelers, checklists, etc.	7.5.1.2
Controls include API product specifications or equivalent	*No Requirement*
Reference instructions and acceptance criteria	7.5.1.2
Customer's inspection hold or witness points	*No Requirement*
5.7.1.4 Product Realization Capability Documentation	
Maintain evidence of capability to meet product requirements	*No Requirement*
5.7.1.5 Validation of Processes for Production and Servicing	
Validate process where output cannot be subsequently verified	7.5.2
Validation shows processes achieve planned results	7.5.2
Outsourced processes require same controls	7.4.1.3
Procedure established and includes:	7.5.2
5.7.1.5 a) Required equipment	7.5.2 b)
5.7.1.5 b) Qualification of personnel	7.5.2 b)
5.7.1.5 c) Use of methods, including operating parameters	7.5.2 c)
5.7.1.5 d) Identification of acceptance criteria	7.5.2 a)
5.7.1.5 e) Requirements for records	7.5.2 d)
5.7.1.5 f) Revalidation	7.5.2 e)
Validation processes identified in product specifications	7.5.2.1
Otherwise validate nondestructive examination, welding, heat treating	7.5.2.1
5.7.2 Product Quality Plan	
Plan developed for QMS and resource requirements	*No Requirement*

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

Correlation to API Q1, 9th Edition *"Soft" Requirements (as applicable, if necessary, etc.)*	
API Q1, 9th Edition	**API Q1, 8th Edition**
5.7.2 a) Description of product to be manufactured	*No Requirement*
5.7.2 b) Required processed, including records	*No Requirement*
5.7.2 c) Control of outsourced activities	*No Requirement*
5.7.2 d) Identification of procedures	*No Requirement*
5.7.2 e) Identification of hold/witness points	*No Requirement*
Plans and revisions approved by organization	*No Requirement*
Plans and revisions communicated to customer	*No Requirement*
5.7.3 Identification and Traceability	
Procedure for identification and traceability while with organization	7.5.3, 7.5.3.1
Maintenance and replacement of identification and traceability	7.5.3.2
Records maintained	7.5.3
5.7.4 Product Inspection/Test Status	
Procedure for identification of product inspection/test status	7.5.3, 7.5.3.3
Ensure product meets requirements or	*No Requirement*
Product released under concession	8.3 b)
5.7.5 Customer-supplied Property	
Procedure for control of customer property	7.5.4.1
ID, verify, safeguard, preserve, maintain, and control customer property	7.5.4
Controls for reporting loss, damage, or unsuitability to customer	7.5.4
Records maintained	7.5.4
5.7.6 Preservation of Product	
5.7.6.1 General	
Procedure for preservation of product and parts	7.5.5.1
Procedure for ID, traceability, marks, transportation, handling, packaging, and protection	7.5.5.1

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

Correlation to API Q1, 9th Edition *"Soft" Requirements (as applicable, if necessary, etc.)*	
API Q1, 9th Edition	**API Q1, 8th Edition**
5.7.6.2 Storage and Assessment	
Procedure for storage and assessment	7.5.5.1
Use of designated storage areas	*No Requirement*
Assessment of stock at specified intervals	7.5.5.2
Intervals appropriate to the product/part being assessed	*No Requirement*
Records of assessment maintained	*No Requirement*
5.7.7 Inspection and Testing	
5.7.7.1 General	
Procedure for inspection and testing	8.2.4.1
Requirement for in-process and final inspection/testing	8.2.4
Records maintained	8.2.4
5.7.7.2 In-process Inspection and Testing	
Inspect and test at planned stages	8.2.4
Evidence of conformity maintained	8.2.4
5.7.7.3 Final Inspection and Testing	
Final inspection based on plan or procedures to validate and document results	*No Requirement*
Independent personnel performs final acceptance inspection	8.2.4.2
5.7.8 Preventive Maintenance	
Procedure for preventive maintenance of manufacturing equipment	*No Requirement*
5.7.8 a) Requirements for type of equipment to be maintained	*No Requirement*
5.7.8 b) Requirements for frequency	*No Requirement*
5.7.8 c) Requirements for responsible person	*No Requirement*
Records maintained	*No Requirement*
5.8 Control of Testing, Measuring, and Monitoring Equipment	
Determine the testing, monitoring, and measurement requirements	7.6

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

Correlation to API Q1, 9th Edition *"Soft" Requirements (as applicable, if necessary, etc.)*	
API Q1, 9th Edition	**API Q1, 8th Edition**
Procedure for calibration of equipment include:	7.6.1
5.8 a) Unique identifier	7.6 c), 7.6.1
5.8 b) Calibration status	7.6 c)
5.8 c) Equipment traceability	7.6 a)
5.8 c) Where no standard exists, basis for calibration recorded	7.6 a)
5.8 d) Frequency of calibration	7.6 a), 7.6.1
5.8 e) Calibration method, including adjustments and readjustments	7.6.1, 7.6 b)
5.8 f) Acceptance criteria	7.6.1
5.8 g) Control of out-of-calibration equipment	7.6
5.8 h) Assess measurements when equipment is out of calibration	7.6
5.8 h) Records of assessment and customer notification	7.6
5.8 1) Calibrated/verified against standards	7.6 a)
5.8 2) Calibration status identified	7.6 c)
5.8 3) Safeguard equipment from adjustments	7.6 d)
5.8 4) Protected from damage and deterioration	7.6 e)
5.8 5) Used in suitable environment	7.6.2
Confirmation of software when used in measurement	7.6
Verification of externally provided equipment	*No Requirement*
Registry of equipment, including unique identification	*No Requirement*
Records of calibration maintained	7.6
5.9 Product Release	
Procedure for release of product under planned arrangements	8.2.4.1
Approved for release by customer under concession	8.2.4
Records maintained	8.2.4

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

Correlation to API Q1, 9th Edition *"Soft" Requirements (as applicable, if necessary, etc.)*	
API Q1, 9th Edition	**API Q1, 8th Edition**
5.10 Control of Nonconforming Product	
5.10.1 General	
Procedure(s) to control nonconforming product and identify responsibilities, including:	8.3
5.10.1 a) Product identification and unintended use	8.3
5.10.1 b) Addressing nonconformity	8.3 a)
5.10.1 c) Take action to preclude intended use	8.3 c)
5.10.1 d) Authorizing use under concession	8.3 b)
Procedures for control nonconforming product after delivery	8.3
5.10.1.1) Identifying and reporting nonconformances	8.3.2
5.10.1 2) Analysis of product failure if evidence available	8.3.2
5.10.1 3) Taking action appropriate to the effects	8.3 d)
5.10.2 Nonconforming Product	
5.10.2 a) Repair or re-work and reinspected to meet requirements	8.3
5.10.2 b) Re-grade for alternative applications	*No Requirement*
5.10.2 c) Accept under concession	*No Requirement*
5.10.2 d) Reject/scrap	*No Requirement*
5.10.3 Release of Nonconforming Product Under Concession	
5.10.3 a) Products continue to meet DAC	8.3.1 a)
5.10.3 b) Violated MAC categorized as not needed to meet DAC/customer requirements	8.3.1 a)
5.10.3 c) DAC is changed	8.3.1 b)
5.10.4 Customer Notification	
Notify customers if products do not meet requirements after delivery	8.3.3
Records of customer notification maintained	8.3.3
5.10.5 Records	
Records of nonconformities and subsequent actions maintained	8.3

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

Correlation to API Q1, 9th Edition *"Soft" Requirements (as applicable, if necessary, etc.)*	
API Q1, 9th Edition	**API Q1, 8th Edition**
5.11 Management of Change (MOC)	
5.11.1 General	
Process for MOC	*No Requirement*
QMS integrity maintained when changes are planned/implemented	5.4.2 b)
Identify risks associated with change	*No Requirement*
Identify approvals prior to introduction of changes	*No Requirement*
Records maintained	*No Requirement*
5.11.2 MOC Implementation	
5.11.2 a) MOC for changes in organizational structure	*No Requirement*
5.11.2 b) MOC for changes in essential personnel	*No Requirement*
5.11.2 c) MOC for changes in critical suppliers	*No Requirement*
5.11.2 d) MOC for changes for management system procedures	*No Requirement*
5.11.3 MOC Notification	
Notify relevant personnel	*No Requirement*
Notify customer when required by contract	*No Requirement*
6 QMS Monitoring, Measurement, Analysis, and Improvement	
6.1 General	
Monitor and measure QMS for conformity and continually improve	4.1, 8.1 b), 8.1 c), 8.5.1
Methods include techniques for analysis of data and their use	8.1
6.2 Monitoring, Measuring, and Improving	
6.2.1 Customer Satisfaction	
Procedure for customer satisfaction	6.1 b), 8.2.1
Determine frequency of measurement, feedback, KPIs	8.2.1
Records maintained	*No Requirement*

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

Correlation to API Q1, 9th Edition *"Soft" Requirements (as applicable, if necessary, etc.)*	
API Q1, 9th Edition	**API Q1, 8th Edition**
6.2.2.1 General	
Procedure for responsibilities for planning and conducting internal audits	8.2.2
Verification of implementation of QMS to requirements	8.2.2 a), 8.2.2 b)
Planning considers results of previous audits	8.2.2
Identify criteria, scope frequency, and methods	8.2.2
Audits performed at least every 12 months	8.2.2.1
On-site outsourced activities subject to internal audits	*No Requirement*
6.2.2.2 Performance of Internal Audit	
Performed by competent personnel independent of area audited	8.2.2, 8.2.2.1
Records maintained	8.2.2
QMS processes audited before claiming conformance to specification	*No Requirement*
6.2.2.3 Audit Review and Closure	
Identify response times for addressing nonconformities	8.2.2, 8.2.2.2
Management of audited areas take corrective actions	8.2.2
Results of audits and corrective actions reported to management	5.6.2 a)
Records maintained	8.2.2
6.2.3 Process Evaluation	
Evaluation methods used to show QMS achieves results	4.1 e), 4.1 f), 8.2.3
When results not achieved, correction/corrective action taken	8.2.3
6.3 Analysis of Data	
Procedure for collecting and analyzing data	8.4.1, 4.1 c)
Includes data from monitoring/measurement, audits, and management reviews	8.4
6.3 a) Output includes information on customer satisfaction	8.4 a)
6.3 b) Output includes information on conformity to product requirements	8.4 b)

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

Correlation to API Q1, 9th Edition *"Soft" Requirements (as applicable, if necessary, etc.)*	
API Q1, 9th Edition	**API Q1, 8th Edition**
6.3 c) Output includes information on nonconformities	*No Requirement*
6.3 d) Output includes information on trends of processes and products	8.4 c)
6.3 e) Output includes information on supplier performance	8.4 d)
6.3 f) Output includes information on objectives	*No Requirement*
Use data for continual improvement	8.4
6.4 Improvement	
6.4.1 General	
Continually improve effectiveness of QMS	8.5.1
6.4.2 Corrective Action	
Procedure for process nonconformances	8.5.2
Corrective actions appropriate to effects of the nonconformities	8.5.2
6.4.2 a) Review nonconformity and customer complaints	8.5.2 a)
6.4.2 b) Determine and implement corrections	8.5.2 c), 8.5.2 d)
6.4.2 c) Identify root cause and evaluate need for corrective action	8.5.2 b), 8.5.2 c)
6.4.2 d) Implement corrective action	8.5.2 d)
6.4.2 e) Identify timeframe and personnel	8.5.2.2
6.4.2 f) Verification of effectiveness	8.5.2 f), 8.5.2.1
6.4.2 g) MOC when corrective actions require new controls	*No Requirement*
Records maintained	8.5.2 e)
Records identify activities performed to verify effectiveness	*No Requirement*
6.4.3 Preventive Action	
Procedure for process potential nonconformances	8.5.3
Preventive actions appropriate to effects of the nonconformities	8.5.3
6.4.3 a) Identify need for improvements	8.5.3 c)
6.4.3 b) Identify potential nonconformity and cause(s)	8.5.3 a)
6.4.3 c) Evaluate need for preventive action	8.5.3 b)
6.4.3 d) Identify timeframe and personnel	*No Requirement*
6.4.3 e) Verification of effectiveness	8.5.3 e), 8.5.3.1
6.4.3 f) MOC when preventive actions require new controls	*No Requirement*
Records maintained	8.5.3 d)

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

Correlation to API Q1, 9th Edition *"Soft" Requirements (as applicable, if necessary, etc.)*	
API Q1, 9th Edition	**API Q1, 8th Edition**
6.5 Management Review	
6.5.1 General	
QMS suitability reviewed at least every 12 months by management	5.6.1.1
Review includes improvement opportunities and need for change to QMS	5.6.1, 5.3 e)
6.5.2 Input Requirements	
6.5.2 a) Effectiveness of actions resulting from previous reviews	5.6.2 e)
6.5.2 b) Results of audits	5.6.2 a)
6.5.2 c) Changes to QMS, including legal	5.6.2 f)
6.5.2 d) Customer satisfaction/customer feedback	5.6.2 b)
6.5.2 e) Process performance	*No Requirement*
6.5.2 f) Results of risk assessment	*No Requirement*
6.5.2 g) Status of corrective and preventive actions	5.6.2 d)
6.5.2 h) Analysis of supplier performance	*No Requirement*
6.5.2 i) Analysis of product conformity and nonconformity after delivery	5.6.2 c)
6.5.2 j) Recommendations for improvement	5.6.2 g)
6.5.3 Output Requirements	
Summary of effectiveness of QMS	5.6.3 a)
Required changes to processes	5.6.3 a)
Required resources	5.6.3 c)
Improvements in meeting customer requirements	5.6.2 b)
Top management review output of management reviews	5.6.1
Reviews documented and records maintained	5.6.1


Thank You