

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

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Errata 3

Page 16, Section 5.7.2: The bulleted list shall be updated as follows:

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 and documentation, including required inspections, tests, and records, for conformance with requirements;
- c) identification and reference to control of outsourced activities;
- d) identification of each procedure, specification, or other document referenced or used in each activity; and
- e) identification of the required hold, witness, monitor, and document review points.

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

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Introduction

This specification has been developed to address quality management systems for organizations that manufacture products or provide manufacturing-related services under a product specification for use in the petroleum and natural gas industry. It defines the fundamental quality management system requirements for those claiming conformity to the requirements of this specification.

The requirements of this specification are consistent with those of other quality management system documents (e.g. API Q2). The requirements are structured in a way to minimize the likelihood of nonconformity. While this specification may include some elements of other management systems (such as those particular to environmental management, occupational health and safety management, financial management, or risk management), it does not include all requirements specific to those systems. This specification may be used either in conjunction with or independent of other industry-specified documents.

This specification can be used by internal and external parties, including certification bodies, to assess the organization's ability to meet customer, statutory, and regulatory requirements applicable to the product and the organization's own requirements.

This specification promotes the integration of a process approach into the application of specific sections 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 an 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 needs throughout the organization, provision of resources and product realization, identification of the proper sequence or order in a series of activities, monitoring and measuring the effectiveness of the activities performed, and applying changes or corrections to those activities as needed.

Goal of the Document

The goal of this specification 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 manufacturing organizations. It is designed to promote reliability in the manufacturing sector of the petroleum and natural gas industry. It is not the intent of this specification to imply uniformity in the structure of quality management systems or uniformity of documentation.

Applicability of API Specification Q1 and API Specification Q2

This specification establishes the API quality system requirements necessary for organizations to consistently and reliably manufacture products in accordance with API or other specifications for use in the petroleum and natural gas industry. This specification is also applicable to, and sets requirements for, all organizations desiring to acquire and maintain a license to use the API Monogram and applies at all times within the organization when a location has been licensed by the API Monogram Program. API Q1 applies to those activities that otherwise may be considered a service (such as heat treatment, threading, or testing) if these activities or the results of these activities are identified as an API monogramable product under any applicable API product specification in the API Monogram Program.

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

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

1 Scope

This specification establishes the minimum quality management system requirements for organizations that manufacture products or provide manufacturing-related processes under a product specification for use in the petroleum and natural gas industry.

This specification specifies the requirements of a quality management system for an organization to demonstrate its ability to consistently provide reliable products and manufacturing-related processes that meet customer and legal requirements.

If an organization performs activities addressed by this specification, no claims to exclusion of those activities are permitted. Where any requirement of this specification cannot be applied due to the nature of an organization, the requirement can be considered for exclusion. Where exclusions are made, the basis for claiming exclusions is to be identified. Furthermore, such exclusions cannot affect the organization's ability, or responsibility, to provide products and related servicing that meet customer and applicable regulatory requirements. Exclusions are limited to the following sections:

- 5.4, Design and Development;
- 5.7.1.2, Servicing;
- 5.7.1.5, Validation of Processes for Production and Servicing;
- 5.7.5, Customer-supplied Property;
- 5.8, Control of Testing, Measuring, and Monitoring Equipment.

The quality management system requirements specified in this specification are in alignment with the section requirements and format of document used for the provision of services and use of service-related product (API Q2). Information marked "NOTE" are not requirements but are provided for guidance in understanding or clarifying the associated requirement.

2 Normative References

The following referenced document is indispensable for the application of this document. For this dated reference, only the edition cited applies.

ISO 9000:2005, *Quality management systems—Fundamentals and vocabulary*

3 Terms, Definitions, and Abbreviations

3.1 Terms and Definitions

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

3.1.1

acceptance criteria

Specified limits of acceptability applied to process or product characteristics.