Quality Management System Requirements for Organizations Providing Products for the Petroleum and Natural Gas Industry

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Introduction

This specification has been developed to address quality management systems for organizations in the petroleum and natural gas industry. It defines the fundamental quality management system requirements for organizations claiming conformity to this specification.

This specification may be applied by organizations that provide product (3.1.16) for use in the petroleum and natural gas industry. As defined in 3.1.16, this specification uses the term “product” to refer to the “output of an organization intended to be provided to a customer”. Previous editions of this specification limited the application to organizations which manufactured a physical product, performed servicing on a physical product, or performed manufacturing-related processes. This edition addresses the following types of organizations in the petroleum and natural gas industry.

— manufacturing

— engineering/design

— physical product realization activity providers such as those performing:

  — welding

  — heat treating

  — coating/plating

  — machining

  — inspection

  — testing

  — servicing

— physical product-related activity providers such as those performing:

  — distribution

  — logistics

  — software development

The requirements of this specification are consistent with those of other quality management system documents. The requirements are intended 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 Specification

The goal of this specification is to provide the minimum requirements for the development of a quality management system that promotes reliability and provides for continual improvement, emphasizes prevention of nonconformities, and strives to minimize variation and waste. It is not the intent of this specification to imply uniformity in the structure of quality management systems or uniformity of documentation.

Significant Changes from the Ninth Edition to the Tenth Edition

Highlights of some of the significant changes between the ninth and tenth editions include:

— Alignment with the requirements of ISO 9001:2015

— Change of scope to include companies that provide product related activities

— Change definition of “product” to align with expanded scope

— Record retention period expanded to ten years

— Reference to outdated version of ISO 9000 removed

— Added alternatives to traditional Quality Manual

— “Design and Development” changed to “Design”

— Clarification on validation of processes

— Revised wording around product inspection and final acceptance process

— Revised supplier evaluation process

— Removed preventive action section

— Added and revised definitions

Quality Management System Requirements for Organizations Providing Products for the Petroleum and Natural Gas Industry

1 Scope

This specification establishes minimum quality management system requirements for organizations that provide products for use in the petroleum and natural gas industry.

2 Normative References

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

ISO[1] 9000:2015, *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 requirements of acceptability applied to product or process characteristics.

3.1.2
acceptance inspection
Demonstration through monitoring or measurement that the product conforms to specified requirements.

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

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

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

3.1.5
critical
Deemed by the organization, product specification, or customer to be of significant importance and requiring specific action.

3.1.6
delivery
Point in time at which the agreed transfer of ownership takes place.

[1] International Organization for Standardization, ISO Central Secretariat, Chemin de Blandonnet 8, CP 401, 1214 Vernier, Geneva, Switzerland, www.iso.org.