



# RATIONALE ISO 29001:2020 SUPPLEMENTS TO ISO 9001:2015

## INTRODUCTION

ISO 29001:2020, *Petroleum, petrochemical and natural gas industries — Sector-specific quality management systems — Requirements for product and service supply organizations* supplements ISO 9001:2015, *Quality management systems — Requirements*. The supplementary requirements and guidance to ISO 9001:2015 have been developed to manage risks associated with the petroleum, petrochemical and natural gas industries and to provide a framework for aligning requirements with complementary standards employed within the industries. This document provides the rationale for each supplementary requirement in ISO 29001:2020.

## RATIONALE SUPPLEMENTARY REQUIREMENTS

| Clause | Rationale   |
|--------|---|
| 0.4    | <p>Reference to ISO/TS 9002 is added to make users aware of this document that was published after the publication of ISO 9001:2015.</p> <p>Reference to the correlation matrices is added to make users aware of the existence of this document that provides cross-references between ISO 29001:2020, ISO/TS 29001:2010, API Spec Q1 (9<sup>th</sup> edition) and API Spec Q2 (1<sup>st</sup> edition). The matrices have been developed to facilitate mapping of supplier quality management systems with the comparable supply chain quality management system standards</p>  |
| 1      | <p>The scope is supplemented to provide the specific context and scope which the supply chain of the petroleum, petrochemical and natural gas industries employs. .</p>   |
| 3      | <p>Definitions are added to define terms that are used in the supplementary requirements and/or sector-specific guidance not provided in ISO 9001:2015. Where available and appropriate, the definitions have been adopted from other ISO and/or IEC publications.</p>  |
| 4.1    | <p>Organizational context constantly evolves and informs the ongoing development of objectives, strategies and the quality management system. It is considered essential that organizations retain documented information of their understanding of the organization and its context as input to their planning and performance evaluation processes and as objective evidence for internal and interested party conformity assessment activities.</p>  |
| 4.2    | <p>The needs and expectations of stakeholders (interested parties) constantly change either through changes in organizational context and objectives or changing social, customer or regulatory expectations and obligations. It is considered essential that organizations retain documented information of their understanding of stakeholder expectations and obligations as input to their planning and performance evaluation processes and as objective evidence for internal and stakeholder conformity assessment activities.</p> <p>NOTE Normally, 'stakeholder' is the preferred term in the petroleum, petrochemical and natural gas industries instead of 'interested party'.</p> |
| 4.3    | <p>Requirement formalizes the principle that when required by regulatory obligation or contractual condition organizations shall inform stakeholders when requirements in this document and as such the organization's quality management system is not considered within the scope of activities. Requirement is aligned with ISO/TS 29001:2010 and with API Spec Q1 and API Spec Q2.</p>  |
| 4.4.3  | <p>Requirement formalizes the principles that organizations shall clearly define the scope boundaries and exclusions of the quality management system and its processes and the associated extent of maintained and retained documented information</p>   |

**Rationale ISO 29001:2020 supplements to ISO 9001:2015 (version 2020-01-29)**

| <b>Clause</b>       | <b>Rationale</b>  |
|---------------------|---|
| 5.3                 | Requirements for defining roles and documented information for responsibilities and authorities related to these roles are added as these elements are considered essential to be documented, also in view of conformity assessment activities.   |
| 6.1.3               | <p>Requirements for processes for managing risks and opportunities are added in view of the (potential) high risk associated with operations in the petroleum, petrochemical and natural gas industries, including the supply chain which can contain several providers following a 'cascading model' (e.g. contractors and sub-contractors), and to align the activities with the risk management methodology as described in ISO 31000.</p> <p>First note is added to inform user on the relationship between planning and operation.</p> <p>Second note is added to inform user that several practical guidance documents are available to manage risks and opportunities.</p> |
| 6.3                 | <p>Requirement for management of risks and opportunities associated with proposed changes is added as management of change is core principle in the petroleum, petrochemical and natural gas industries and underpins key frameworks, notably process safety.</p> <p>Requirement for documented information is added as management of changes is considered essential to be documented, also in view of conformity assessment activities.</p>   |
| 7.1.3.1 and 7.1.3.2 | <p>Requirements for documented information are added as infrastructure related products and services are considered essential to be documented, also in view of conformity assessment activities.</p> <p>NOTE Lessons learned from industry events demonstrate the need to maintain and retain documented information.</p>  |
| 7.1.3.3             | <p>The possibility of applying risk-based maintenance is added to enhance user's understanding of the concepts that are part of risk-based maintenance, which will be supportive in maintaining the infrastructure.</p> <p>Note is added to inform user that several practical guidance documents are available related to maintenance activities.</p>  |
| 7.1.5.1             | <p>Requirement for documented information is added as defining processes and controls related to monitoring and measuring resources is considered essential to be documented, also in view of conformity assessment activities.</p> <p>Note is added to inform user that a document specifying quality management requirements for laboratories is available.</p> <p>NOTE Although ISO 29001 cannot impose that laboratories are accredited to ISO/IEC 17025, it is common practice to require accreditation when performing laboratory activities, either internally or externally.</p>  |
| 7.1.5.2             | <p>Requirements for documented information are added as traceability of measuring equipment and actions taken in cases of inappropriate measurements are considered essential to be documented, also in view of conformity assessment activities.</p> <p>Note is added to inform user, also for recognition, that a measuring equipment register is commonly used in the petroleum, petrochemical and natural gas industries.</p>   |

| Clause    | Rationale   |
|-----------|---|
| 7.2.1     | <p>Requirement for validation of competency is added in view of the (potential) high risk associated with operations in the petroleum, petrochemical and natural gas industries, including the supply chain which can contain several providers following a 'cascading model (e.g. contractors and sub-contractors).</p> <p>Requirement for documented information is added as managing competencies is considered essential to be documented, also in view of conformity assessment activities.</p> <p>Second note is added to inform user on possible ways to manage competence of person(s) doing work under its control.</p> <p>Third note is added to inform user that guidelines on competency management are available.</p>  |
| 7.3       | <p>Requirement for awareness of specified regulated and customer quality requirements, risk mitigations and verification requirements related to work is added to align with ISO/TS 29001:2010 and with API Spec Q1 and API Spec Q2.</p>  |
| 7.5.3.3   | <p>Requirements for documented information are added as defining processes and controls for documented information and defining practices to integrate external specifications in their own operating processes are considered essential to be documented, also in view of conformity assessment activities.</p> <p>Note is added to inform user that several practical documents are available to manage (cyber) security as part of controlling documented information.</p>   |
| 8.1       | <p>Requirements related to operational planning and control are added to link these activities with risk treatments, including contingency plans where appropriate, and change management processes when planning the operations to ensure that product or service outcomes meet the requirements or obligations.</p> <p>Explanation is provided that documented information in this context is (better) known as quality plan, service quality plan or inspection and test plan.</p> <p>First note is added to inform user that practical guidance is available to develop quality plans.</p> <p>Second note is added to direct user to the informative annex that provides methods for assessing risk to the achievement of specified requirements and to the realization of improvement opportunities, and planning the controls to be put in place by providers to assure conformance with specified requirements</p> |
| 8.2.3.1.1 | <p>Requirement for documented information is added as defining processes for reviewing requirements related to the provision of products or services is considered essential to be documented, also in view of conformity assessment activities.</p> <p>Note is added to provide guidance in respect to the link between customer technical requirements and associated conformity assessment requirements.</p>   |
| 8.3.2     | <p>Requirement for activities for managing risks and opportunities is added to ensure coherence with the organizational and operational planning processes, also in view the (potential) high risk associated with operations in the petroleum, petrochemical and natural gas industries, including the supply chain which can contain several providers following a 'cascading model' (e.g. contractors and sub-contractors).</p> <p>Requirement for documented information is added as defining processes for planning and controlling design and development activities of products and/or services is considered essential to be documented, also in view of conformity assessment activities.</p>  |

**Rationale ISO 29001:2020 supplements to ISO 9001:2015 (version 2020-01-29)**

| <b>Clause</b> | <b>Rationale</b>  |
|---------------|---|
| 8.3.3         | <p>Statement related to performance requirements is added to enhance user's consideration of environmental and safety conditions as part of the performance requirements.</p> <p>Requirement for output of processes of managing risks and opportunities is added to ensure that this source is also considered in design and development inputs, also in view the (potential) high risk associated with operations in the petroleum, petrochemical and natural gas industries, including the supply chain which can contain several providers following a 'cascading model (e.g. contractors and sub-contractors).</p>   |
| 8.4.2.1       | <p>Requirement for assessing external provider performance is added as to ensure that changes in risk profiles are taken into account in defining and adjusting the type and extent of controls for externally provided processes, products and services, also in view the (potential) high risk associated with operations in the petroleum, petrochemical and natural gas industries, including the external providers following a 'cascading model (e.g. contractors and sub-contractors).</p> <p>Requirements for documented information are added as defining processes and controls for documented information and defining practices to integrate external specifications in their own operating processes are considered essential to be documented, also in view of conformity assessment activities.</p> <p>Note is added to direct user to the informative annex that provides methods for assessing risk to the achievement of specified requirements and to the realization of improvement opportunities, and planning the controls to be put in place by providers to assure conformance with specified requirements.</p> |
| 8.5.1.1       | <p>Requirement for the methods to be considered in the validation methods is added to align with ISO/TS 29001:2010 and with API Spec Q1 and API Spec Q2.</p> <p>Requirement for documented information is added as defining controls for meeting the production and service provision requirements is considered essential to be documented, also in view of conformity assessment activities.</p>  |
| 8.5.2.1       | <p>Requirement for documented information is added as defining processes to meet the identification and traceability requirements is considered essential to be documented, also in view of conformity assessment activities.</p>   |
| 8.5.3.1       | <p>Requirement for documented information is added as defining processes to meet the requirements of property belonging to customers or external providers is considered essential to be documented, also in view of conformity assessment activities.</p>  |
| 8.5.4         | <p>Requirement for documented information is added to ensure that essential information for risk-based preservation is defined and maintained, also to align with ISO/TS 29001:2010 and with API Spec Q1 and API Spec Q2.</p>   |
| 8.5.6         | <p>Requirements for control of changes in production or service provision, and possible communication for effect of these changes, are added to align with ISO/TS 29001:2010 and with API Spec Q1 and API Spec Q2.</p>  |
| 8.6           | <p>Requirement for documented information is added as defining processes to meet the requirements of release of products and services is considered essential to be documented, also in view of conformity assessment activities.</p>   |
| 8.7.1.1       | <p>Requirement for documented information is added as defining processes to meet the requirements of control of nonconforming outputs is considered essential to be documented, also in view of conformity assessment activities.</p>   |
| 9.1.1         | <p>Note is added to inform user that a practical documents is available to support performance measurement.</p>   |

| Clause  | Rationale  |
|---------|--|
| 9.1.2   | Requirement about documented information is added as defining processes to meet the customer satisfaction requirements is considered essential to be documented, also in view of conformity assessment activities.   |
| 9.1.3   | Requirement about documented information is added as defining processes for the identification, collection and analysis of data to demonstrate the suitability and effectiveness of the quality management system is considered essential to be documented, also in view of conformity assessment activities.  |
| 9.2.3   | Requirement related to planned intervals of internal audits is added to ensure that risks associated with the process and the results of performance evaluation are considered, also in view the (potential) high risk associated with operations in the petroleum, petrochemical and natural gas industries, including the supply chain which can contain several providers following a 'cascading model' (e.g. contractors and sub-contractors).<br><br>Note is added to hint user about the flexibility of planned intervals for internal audits. |
| 10.2    | Requirement about documented information is added as defining processes for implementing the nonconformity requirements is considered essential to be documented, also in view of conformity assessment activities.  |
| 10.3.1  | Requirement about considering implementation of improvement as a management of change process is added to ensure that this kind of implementations are taken into account as part of the plan-do-check-act cycle.<br><br>Requirement about documented information is added as defining processes for implementing the continual improvement requirements is considered essential to be documented, also in view of conformity assessment activities.   |
| Annex B | Reference to ISO/TS 9002 is added to make users aware of this document that was published after the publication of ISO 9001:2015.  |

Where it is stated that documented information is considered essential, a similar requirement was included in ISO/TS 29001:2010 and is included in API Spec Q1 and/or API Spec Q2.

#### RATIONALE SUPPLEMENTARY ANNEX

Annex C on risk and opportunity management and conformity assessment processes is added to provide the user methods for assessing risk to the achievement of specified requirements and to the realization of improvement opportunities, and for planning the controls to be put in place by providers to assure conformance with specified requirements. The methods enable customers to select their conformity assessment involvement, and organizations to identify their conformity assessment requirements for externally provided processes, products and services. Examples for criticality and conformity assessments are made available in revisable format to support the user in implementing the methods.

NOTE Annex C is based on the principles established in ISO/TR 13881, *Petroleum and natural gas industries — Classification and conformity assessment of products, processes and services*. In addition, the outcomes of JIP 33 'Standardization of equipment and packages' initiated by IOGP, the International Association of Oil and Gas Producers and A-liaison to ISO/TC 67, have been taken into account with respect to quality requirements.