ISO 9001:2015/Amd 1:2024   Test of Understanding
Level 2 – Professional

Test Syllabus

The main purpose of the ISTO Test of Understanding (the "Test") is to offer an evidence-based qualification to professionals who have demonstrated an appreciation of the intent and an accurate understanding of the requirements (and the non-requirements) of the standard, including its applicability and underlying management principles. Such knowledge and skills are crucial in providing a value-adding service related to the standard, be it implementation, advisory or auditing.

The Test of Understanding is not an auditor qualification. There are no questions directly related to auditing.

The topics set out in 1.1 to 1.3 are not intended to limit the subject matter or be all inclusive of what might be covered in the Test. Candidates will be expected to apply their knowledge to organizations with different sizes and complexity.

1.1. Applicability (A)
- ISO 9001 purpose
- ISO 9001 intended outcomes
- Scope and boundaries of a quality management system
- ISO 9001 Applicability (Clause 4.3)

1.2. Concepts, principles and Terminologies (Co, T)
Quality
- Prevention over inspection, concepts of quality assurance & quality management
- Commonly known legal requirements relevant to a sector
  (E.g. Personnel competence; license(s) to operate)
- Typical measurements of quality performance.
  (E.g. Customer satisfaction index, complaint ratio, process yield, equipment reliability; on-time ratio)

Seven Quality Management Principles (the "QMPs")
- Customer focus
- Leadership
- Engagement of people
- Process approach
- Improvement
- Evidence-based decision making
- Relationship management.

ISO 9000:2015 terms and definitions
- Terms related to person or people
  (E.g. top management)
- Terms related to organization
  (E.g. context of the organization, interested party, customer)
- Terms related to activity
  (E.g. continual improvement, quality management, quality assurance)
- Terms related to process
  (E.g. process, outsource, design and development)
- Terms related to system
  (E.g. infrastructure, management system, work environment, quality policy)
- Terms related to requirement
  (E.g. quality, requirement, nonconformity, traceability)
- Terms related to result
  (E.g. objective, output, product, service, performance, risk, efficiency, effectiveness)
- Terms related to data, information and document
  (E.g. document, documented information, verification, validation)
- Terms related to customer
  (E.g. customer satisfaction, complaint)
- Terms related to characteristic
  (E.g. characteristic, competence)
- Terms related to determination
  (E.g. determination, review, monitoring, measurement)
- Terms related to action
  (E.g. corrective action, concession, release)
- Terms related to audit
  (E.g. audit, audit programme)

Management Systems
- Risk-based thinking
- The hierarchy and interrelationship of documented information within the management system, as well as the associated risks
- Root cause analysis and simple analytical tools such as Pareto chart
- The application of the Plan-Do-Check-Act cycle within the management system
- Typical measurements of management system performance
  (E.g. Training hours; achievement of objectives, improvements achieved; number of nonconformities)

ISO 9001 QMS requirements structure
- Interrelationship between leadership and commitment, policy, objectives, planning, resources, operations, monitoring and measurement, analysis and evaluation and continual improvement
- Sequence of activities in the requirements of the standard

1.3. Clause reference, Requirements and Unspecified requirements (C, U, R, Ac, E)

Clause Reference (C)
- Identify the clause reference of a particular ISO 9001 requirement.
  (E.g. The requirement to determine competence is given in clause 7.2a.)

Requirements versus Unspecified requirements (R, U)
- Requirements specified in the ISO 9001 standard
  (E.g. Conduct management review)
- Differentiate from non-requirements
  (E.g. Clause 5.1 does not require a strategic plan; Clause 6.1 does not require a formal method for risk management or a documented risk management process.)

Key requirements of the ISO 9001 QMS: **Management System related**
Planning
- Context, interested parties' requirements, risks/opportunities & actions to address; consideration of climate change
- Leadership and commitment
- Quality policy, objectives and actions to achieve
- Roles, responsibilities and authorities
- System changes control

Performance evaluation and improvement
- Monitoring and measurement
- Customer perception monitoring
- Analysis and evaluation
- Internal audit
- Management review
- Corrective action
- Improvement
- Management system non-requirements

Key requirements of the ISO 9001 QMS: **Operations related**
Support
- Resources
- Infrastructure & process environment
- Monitoring and measuring resources; measurement traceability
- Organizational knowledge
- Competence and awareness
- Communication
- Documented information creation and control, and to maintain and retain

Operation
- Operational planning
- Product and services requirements
- Design and development
- External provision control
- Operational control; changes control
- Identification, traceability & preservation
- Customers' or external providers' property
- Release and post-delivery
- Control of nonconforming outputs
- Support and operational non-requirements

Actual documented information requirements versus Erroneous Requirements (Ac, E)

In order to provide flexibility to organizations of different sizes and background, ISO 9001 is written with minimal documentation requirements. Based on their contextual factors, organization shall determine the complexity of their documented information required to support their QMS.

- Requirements specified in the ISO 9001 standard
  (E.g. competence documented information)
- Differentiate from non-documentation requirements.
  (E.g. management system manual; documented procedure; approved supplier list)

Reference sources

The reference sources and sites detailed in this section contain information that will support your learning and better position you to pass your ISTO Test.

ISO 9000:2015
Quality management systems — Fundamentals and vocabulary

ISO 9001:2015/Amd 1:2024
Quality management systems — Requirements

ISO/TS 9002:2016
Quality management systems — Guidelines for the application of ISO 9001:2015

Reference sites *(free of charge)*

ISO Annex SL Appendix 2 (2024)	https://www.iso.org/committee/54996.html?t=-Duqtv8H-DoUiDQTNCpLN0UhREpjaZ130Orwm4_WLY97n2yln9bslL_OpNRJZCit&view=documents#section-isodocuments-top *(Note: The link above provides access to the 2024 version of Annex SL Appendix 2. It should be noted that the contents of ISO 9001:2015/Amd 1:2024 may not necessarily incorporate all the latest Annex SL changes. The ISTO Test of Understanding is based on the ISO Management System Standards (MSS) and not on Annex SL Appendix 2.)*
Seven Quality Management Principles - ISO	https://www.iso.org/files/live/sites/isoorg/files/store/en/PUB100080.pdf
Guidance on implementing ISO 9001:2015	A paper on ISO 9001 and Risk https://committee.iso.org/files/live/sites/tc176sc2/files/documents/ISO%209001%202015%20-%20Implementation%20guidance%20docs/ISO9001_2015_and_Risk.docx A presentation on ISO 9001 and Risk Based Thinking https://committee.iso.org/files/live/sites/tc176sc2/files/documents/ISO%209001%202015%20-%20Implementation%20guidance%20docs/ISO9001_2015_Risk_Based_Thinking.pptx Guidance on the requirements for Documented Information of ISO 9001:2015 https://committee.iso.org/files/live/sites/tc176sc2/files/documents/ISO%209001%202015%20-%20Implementation%20guidance%20docs/ISO9001_2015_Guidance_on_Documented_Information.docx How Change is addressed within ISO 9001:2015 https://committee.iso.org/files/live/sites/tc176sc2/files/documents/ISO%209001%202015%20-

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	%20Implementation%20guidance%20docs/ISO9001_2015_Managing_Change.docx A paper on the Process Approach in ISO 9001:2015 https://committee.iso.org/files/live/sites/tc176sc2/files/documents/ISO%209001%202015%20-%20Implementation%20guidance%20docs/ISO9001_2015_Guidance_on_the_Process_Approach.docx A presentation on the Process Approach in ISO 9001:2015 https://committee.iso.org/files/live/sites/tc176sc2/files/documents/ISO%209001%202015%20-%20Implementation%20guidance%20docs/ISO9001_2015_Process_Approach_Presentation.pptx Frequently Asked Questions (FAQs) https://committee.iso.org/files/live/sites/tc176sc2/files/documents/ISO%209001%202015%20-%20Implementation%20guidance%20docs/ISO9001_2015_Frequently_Asked_Questions.docx
Interpretations of ISO 9001	https://committee.iso.org/files/live/sites/tc176sc2/files/documents/Interpretations/ISO9001_2015_Approved_Interpretations.doc
ISO 9001:2015: How to use it	https://committee.iso.org/files/live/sites/tc176sc2/files/documents/iso_9001-2015_-_how_to_use_it.pdf.pdf
ISO 9001 Auditing Practice Group	https://committee.iso.org/home/tc176/iso-9001-auditing-practices-group.html *(Note: documentation focuses on auditing however they are good references from an implementation perspective)*
Glossary – Guidance on selected words used in the ISO 9000 family of standards	https://www.iso.org/files/live/sites/isoorg/files/standards/docs/en/terminology-ISO9000-family.pdf
IRCA ISO 9001:2015 white paper	https://www.quality.org/content/download-iso-90012015-white-paper
NSI – ISO 9001 clause by clause	http://www.nsi.org.uk/wp-content/uploads/2012/11/Annex-A-Step-by-Step-Guide-for-ISO-9001-2015-NG-FG-AG.pdf
The ISO 9001 Help Company – ISO 9001 clause by clause	https://www.iso9001help.co.uk/Clause-by-clause%20Interpretation.pdf

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