

Test Questions



- **1. How many “Quality System Requirements” are included in “ISO 9001, Model for Quality Assurance in Design, Development, Production, Installation, and Servicing”?**
 - 17
 - 23
 - 20
 - 19

Feedback: The correct answer is “20.” ISO 9001, clause 4, has 20 sub-clauses, each a Quality System Requirement.

Test Questions



- 2. The “NOTES” appearing in ISO 9001 are requirements of the standard.

True

False

Feedback: The correct answer is “False.” Notes in ISO 9001 are for clarification purposes only.

Test Questions



- **3. ISO 9001 states that quality records will be retained for how long?**
 - 7 years
 - 10 years
 - 15 years
 - *As dictated by internal requirements, contracts with the customer, and regulatory requirements*

Feedback: The correct answer is “As dictated by internal requirements, contracts with the customer, and regulatory requirements.” ISO 9001 does not state how long records must be kept except to say that retention times shall be established and recorded. See ISO 9001, clause 4.16.

Test Questions



- **4. The Management Representative has defined authority for ensuring that a quality system is _____.**
 - **Established**
 - **Implemented**
 - **Maintained**
 - ***All of the above***

Feedback: The correct answer is “All of the above.” See ISO 9001, clause 4.1.2.3.

Test Questions



- 5. According to ISO 9001, how often should management's review of the quality system be performed?
 - Every 3 months
 - Every 6 months
 - At least once per year
 - *None of the above*

Feedback: The correct answer is “None of the above.” ISO 9001 states that the reviews will be held at defined intervals. See ISO 9001, clause 4.1.3.

Test Questions



- **6. A Quality Manual is a required part of the documentation for ISO 9001.**

True

False

Feedback: The correct answer is “True.” See ISO 9001, clause 4.2.1.

Test Questions



- **7. Which of the following model quality elements is contained in only the ISO 9001 Standard?**
 - **Document and Data Control**
 - ***Design Control***
 - **Inspection and Testing**
 - **None of the above**

Feedback: The answer is “Design Control.” ISO 9001 provides the model quality element for Design Control (4.4). The other standards do not require it. See Slides II-13 and II-14.

Test Questions



- **8. Guidance on quality manuals is given in which of the following?**
 - **ISO 10011**
 - **ISO 10012-1**
 - **ISO 10013**
 - **ISO 14000**

Feedback: The correct answer is “ISO 10013.” See ISO 9001 note to clause 4.2.1.

Test Questions



- **9. The management review of the quality system is held to determine which of the following?**
 - The continuing suitability of the system
 - The effectiveness of the system
 - *Both of the above*
 - Neither of the above

Feedback: The answer is “Both of the above.” See ISO 9001, clause 4.1.3.

Test Questions



- **10. The contract review is held to ensure which of the following?**
 - That all requirements are adequately defined
 - That the supplier has the capability to meet the contract
 - That the company will make adequate profit
 - That any differences between the contract and those in the tender are resolved
 - *That all requirements are adequately defined, that the supplier has the capability to meet the contract, and that any differences between the contract and those in the tender are resolved*

Feedback: The answer is “That all requirements are adequately defined, that the supplier has the capability to meet the contract, and that any differences between the contract and those in the tender are resolved.” See ISO 9001, clause 4.3.2.

Test Questions



- **11. Corrective action may result from which of the following?**
 - **Customer complaints**
 - **Internal scrap reports**
 - **Notification of a field failure**
 - ***All of the above***
 - **None of the above**
 - **Customer complaints and internal scrap reports**

**Feedback: The correct answer is “All of the above.”
See ISO 9001, clause 4.14.3.**

Test Questions



- **12. The document and data control procedure must call for a master list or equivalent, which, among other things, identifies the current revision status of all documents.**

True

False

Feedback: The correct answer is “True.” See ISO 9001, 4.5.2.

Test Questions



- **13. Which of the following describes changes to documents?**
 - **Must be done by the same functions/organizations that performed the original review and approval unless specifically designated**
 - **Must result in purging the system of obsolete documents and replacing them with revisions**
 - **Can be done by supervisors as they see fit**
 - **Must be done at least twice a year**
 - **None of the above**
 - ***Must be done by the same functions/organizations that performed the original review and approval unless specifically designated and must result in purging the system of obsolete documents and replacing them with revisions***

Feedback: The correct answer is “**Must be done by the same functions/organizations that performed the original review and approval unless specifically designated and must result in purging the system of obsolete documents and replacing them with revisions.**” See ISO 9001, clauses 4.5.2 and 4.5.3.

Test Questions



- **14. Which of the following describes incoming inspection on raw materials?**
 - **Must be done on all incoming shipments**
 - **Must be done on at least every third incoming shipment**
 - ***Is done in accordance with established procedures***
 - **Is always done on a random basis**

Feedback: The correct answer is “Is done in accordance with established procedures.” See ISO 9001, clause 4.10.2.

Test Questions



- 15. Processes requiring pre-qualification of their process capability are frequently referred to as _____.
 - *Special processes*
 - Pre-control processes
 - Statistical control processes
 - Calibrated processes

Feedback: The correct answer is “Special processes.” See note 16 in ISO 9001, clause 4.9.

Test Questions



- **16. Which of the following describes product identification and traceability?**
 - **Is necessary in all cases**
 - **Is necessary if it is a specified requirement (of the contract)**
 - **May be necessary because of Government regulations**
 - **All of the above**
 - **None of the above**
 - ***Is necessary if it is needed to adequately control product quality, is a specified requirement (of the contract), and may be necessary because of Government regulations***

Feedback: The correct answer is “Is necessary if it is needed to adequately control product quality, is a specified requirement (of the contract), and may be necessary because of Government regulations.” See ISO 9001, clause 4.8. Regulations may also require traceability.

Test Questions



- **17. Which of the following are inspection, measuring, and test equipment that must be controlled and calibrated?**
 - **All equipment that is used to demonstrate the conformance of product to the specified requirements**
 - **Software used as inspection devices**
 - **Any equipment used to assure the quality of the product or service**
 - ***All of the above***

Feedback: The correct answer is “All of the above.” See ISO 9001, clauses 4.11.1 and 4.11.2(b).

Test Questions



- **18. The Quality System Requirement for document and data control is found in which section/paragraph of ISO 9001?**
 - 4.4
 - 4.5
 - 4.6
 - 4.7

Feedback: The correct answer is “4.5.” See ISO 9001, clause 4.5.

Test Questions



- **19. Non-conforming product can be identified by which of the following?**
 - **Being locked in a cage**
 - **Physical segregation**
 - **Red tags**
 - **Being placed in a specifically marked area on the floor**
 - ***Any of the above as long as it is “suitable”***

Feedback: The correct answer is “Any of the above as long as it is “suitable.” See ISO 9001, clause 4.13.1.

Test Questions



- **20. Information on control of measuring equipment can be found in which of the following?**
 - **ISO 9006**
 - **ISO 10012-1**
 - **ISO 10011**
 - **ISO 10013**

Feedback: The correct answer is “ISO 10012-1.” See note 18 in ISO 9001, clause 4.11.2

Test Questions



- **21. Which of the following is true of non-conforming product?**
 - It may be reworked to meet the specified requirements.
 - It may be accepted with or without repair by concession.
 - It may be regraded for alternative applications.
 - It may be rejected or scrapped.
 - *All the above*
 - None of the above

Feedback: The correct answer is “All the above.”

Test Questions



- **22. Which of the following is true of corrective action?**
 - It must be done, no matter what the cost.
 - It is initiated only by the management review.
 - It never leads to revision of documents.
 - *It should be done with action and effort to a degree appropriate to the magnitude of problems and commensurate with the risks encountered.*

Feedback: The correct answer is “It should be done with action and effort to a degree appropriate to the magnitude of problems and commensurate with the risks encountered.” See ISO 9001, clause 4.14.1.

Test Questions



- **23. Which of the following describes delivery of products?**
 - The supplier is not responsible for product after it leaves his shipping dock.
 - The supplier is responsible for the product until it reaches the customer, regardless of the ownership of the transportation means.
 - The customer is always responsible for the transportation of the final product.
 - *The supplier is responsible for the product as contractually specified.*

Feedback: The correct answer is “The supplier is responsible for the product as contractually specified.” See ISO 9001, clause 4.15.6.

Test Questions



- **24. Quality records must not be in the form of electronic media?**

True

False

Feedback: The correct answer is “False.” Records may be in any type of media. See note 19 in ISO 9001, clause 4.16.

Test Questions



- **26. Which ISO documents are described as “requirements”?**
 - ISO 9001
 - ISO 9002
 - ISO 9003
 - ISO 9004
 - *ISO 9001, ISO 9002, and ISO 9003*
 - ISO 9001, ISO 9003, and ISO 9004

Feedback: The correct answer is “ISO 9001, ISO 9002, and ISO 9003.”

Test Questions



- **27. Which of the following is true of quality records?**
 - They are not an important part of the requirements of ISO 9001.
 - *They must be stored in a way that facilitates easy retrieval.*
 - They are not kept to demonstrate the effective operation of the quality system.
 - They are never made available to the customer or the customer's representative.

Feedback: The correct answer is “They must be stored in a way that facilitates easy retrieval.” See ISO 9001, clause 4.16.

Test Questions



- **29. In ISO 9001, which of the following is the clause/section/quality system requirement addressing inspection and test status?**
 - 4.3
 - 5.7
 - 4.6
 - 4.12
 - None of the above

Feedback: The correct answer is “4.12.” See ISO 9001, clause 4.12.

Test Questions



- **31. The ISO 9000 series documents can be classified as which of the following?**
 - ***Guidance or Conformance***
 - **Regulations or Requirements**
 - **Suggestions or Admonitions**
 - **None of the above**

Feedback: The correct answer is “Guidance or Conformance.”
Three of the documents are conformance documents; they are ISO 9001, ISO 9002, and ISO 9003. All others are guidance documents.

Test Questions



- **32. How many requirements/clauses are contained in ISO 9002?**
 - 10 requirements/clauses
 - 15 requirements/clauses
 - **19 requirements/clauses**
 - 20 requirements/clauses

Feedback: The correct answer is “19 requirements/clauses.”
ISO 9002 leaves out the requirement for Design Control.

Test Questions



- **33. Which of the following is covered by ISO 9000-3?**
 - **Processed materials**
 - **Software**
 - **Services**
 - **Quality improvement**

Feedback: The correct answer is “Software.” See ISO 9001, Annex A.

Test Questions



- **34. Which of the following is covered by ISO 10012-1?**
 - **Dependability**
 - **Auditing**
 - **Software**
 - ***Metrological confirmation (calibration) system***

Feedback: The correct answer is “Metrological confirmation (calibration) system.” See ISO 9001, Note 18 under clause 4.11.2.

Test Questions



- **35. ISO 9001 has requirements that address which of the following?**
 - **Documentation**
 - **Training**
 - **Record keeping**
 - **Maintenance of measuring equipment**
 - ***All of the above***
 - **Documentation and record keeping only**

Feedback: The correct answer is “All of the above.” See ISO 9001, clauses 4.5, 4.18, 4.11, and 4.16.

Test Questions



- **36. The supplier shall ensure that the quality policy is understood, implemented, and _____ at all levels of the organization.**
 - **Initiated**
 - ***Maintained***
 - **Processed**
 - **Defined**

Feedback: The correct answer is “Maintained.” See ISO 9001, clause 4.1.1.

Test Questions



- **37. The _____ has overall responsibility for the quality system and may include liaison with external parties on matters relating to the supplier's quality system.**
 - Purchasing agent
 - Chief inspector
 - *Management Representative*

**Feedback: The correct answer is “Management Representative.”
See ISO 9001, clause 4.1.2.3.**

Test Questions



- 38. _____ is the activity of defining and documenting how the requirements for quality will be met.
 - *Quality planning*
 - Goal setting
 - Contract review
 - Concession meeting

Feedback: The correct answer is “Quality planning.” See ISO 9001, clause 4.2.3.

Test Questions



- **39. Verification of quality at the vendor by the customer does not absolve the supplier of the responsibility to provide acceptable product.**

True

False

Feedback: The correct answer is “True.” See ISO 9001, clause 4.6.4.2.

Test Questions



- **40. The document to which a supplier registers if it engages in R&D, production, installation, and servicing is _____.**
 - **ISO 9004**
 - **ISO 9003**
 - **ISO 10013**
 - **ISO 9001**

Feedback: The correct answer is “ISO 9001.” See title page, ISO 9001.

Test Questions



- **41. Which of the following describes the relationship of the ISO 9000 series and Total Quality Management?**
 - *ISO is considered a subset of TQM.*
 - **TQM is considered a subset of ISO.**
 - **ISO and TQM are completely different.**
 - **ISO and TQM are incompatible.**

Feedback: The correct answer is “ISO is considered a subset of TQM.” ISO is only a portion of a complete TQM program.

Test Questions



- **42. For a person to be qualified as an internal auditor, ISO 9001 states which of the following?**
 - The person must be certified by the RAB.
 - ISO 9001 states nothing about the qualifications of an internal auditor.
 - The person must take a 36-hour course and pass an exam.
 - The person must work in the department he or she audits.
 - *None of the above*

Feedback: The correct answer is “None of the above.” ISO 9001 states that the supplier shall establish and maintain procedures for planning and implementing the internal audit system. It says nothing about the qualifications of internal auditors. See ISO 9001, clause 4.17.