



www.jimshell.com

ISO9001 Introduction Quiz Parts 3 and 4

Name: _____

Date: _____

1. How often are ISO9001 Recertification Audits

- _____ Annually
- _____ Every Calendar Year
- _____ Every Three Years
- _____ Determined by the Organization

Well, typically these are annually, but the correct answer is “determined by the organization.” You may choose to have your audits done every six months.

2. Who determines the “acceptance criteria” (specifications) for products and services
- The Organization
 - The Government
 - The Organization, in consultation with the customers and other interested parties
 - The Auditor

If you are doing business with the government, it is possible that the government can determine the acceptance criteria, and you, the organization, have to comply. But, a better answer for most organizations is “the organization.” It’s up to you to determine whether you did your job properly.

3. What must an organization do before committing to provide products or services
- Create a Catalogue
 - Create a Price List
 - Conduct a Review
 - Hold a Sales Meeting

Have a review. There’s no requirement anywhere in the standard for a “meeting>”

4. The organization must retain records of the Order Review
- True False

This is true. It’s up to the organization to determine the controls for this record.

5. What are good reasons for Design Controls? (Select one or more)
- Assures that the design met the customer expectations
 - Protects the engineer from undisclosed design changes
 - Provides a record of validation and verification of the design
 - Slows down the design process to make it slower and better
 - Reduces design costs

The first three are correct. The intent of the design controls may slow the process down, but may also speed it up by setting deadlines and applying focused effort. It may also reduce design costs by encouraging the designer not to be distracted by chasing something interesting, rather than something useful.

6. Design and Development Controls are developed by:

- The Registrar
- The Auditor
- The Organization
- The Customer
- The Organization in consultation with the Customer as needed

The Organization is primarily responsible for developing the design controls. The customer may also provide design control guidance, and the organization may have, as part of its design controls, the requirement that the customers sign off on design outputs. It's the responsibility of "the organization" to establish the design process.

7. What is required when a design output doesn't meet the requirements?

- Rework the design
- Report back to the Customer
- Cancel the Project
- Change the Design Requirement
- Could be any of the above, depending on the design plan.

The best answer to this is the last one, could be any of the above. It's up to you, the organization to decide what to do if your design output doesn't meet the requirements. It may be possible that you're close enough to the customer requirements that they will accept the product.

8. Who determines the controls for externally provided materials or services? (Purchasing Controls?)

- The Registrar
- The Auditor
- The Organization
- The Customer
- The Organization in consultation with the Customer as needed

In most cases it's up to you, the organization, to make this determination, and you may get the customer involved if the contract or sales order calls for it.

9. In what way are purchasing controls normally passed to the Supplier?

- Phone Call
- Email
- Verbally
- Depends on "The Organization's" communication requirements
- Other

It's up to "the organization" to determine the means of supplier communication, but the supplier may also have requirements for accepting orders (example: via email or through a portal of some kind) and these may be laid out in the supplier agreement.

10. When it requires the supplier to provide testing or other verification activities, what does "the organization" need to do? (one or more may apply)

- Inform the Supplier
- Require a C of A
- Require an OK Stamp or other markings
- To be determined by the Organization

The best answer is the last one. It's up to "the organization" to inform the supplier whether there are any testing or verification activities to be done at their place. This may vary by the material.

11. When should a product inspection be done?

- At the end of the process
- At the appropriate stages (as determined by the organization)
- Before Packaging

According to the ISO standard, it's the second one, at "appropriate stages" determined by you. You may choose not to do one at all, depending on what it is you're selling.

12. At what point must the status of outputs (good or not good) be identified?

- Throughout the process
- At the end of the process
- In the finished goods warehouse

The correct answer is "throughout the process." You are required as part of the standard to be able to identify the status of the output "throughout production or service provision."

13. When externally owned property is lost, damaged, or compromised, what is the requirement for "the organization?"

- Ignore
- Notify in writing
- Notify verbally, and keep a record
- Depends on the agreement with the external party

The better answer is the last one, usually when an external party trusts you with something they tell you what to do with it if you destroy it.

14. Employee personal data is considered externally owned property.

- True
- False

It's true, and you'd better have some rules in place to keep it protected.

15. An employee makes a process change that differs from what is called for in the operating specification. Which of the following things need to happen.

- _____ Nothing. The employee can change what he or she wants
- _____ Tell his or her supervisor
- _____ Get written permission from the Supervisor
- _____ Get written permission from an authorized approval authority
- _____ Depends on the organization's rules. Several of these may apply.

The correct answer is the last one. Depending on the process it's up to the organization to lay out the rules for changing processes. It's good practice to do the middle three, which is to tell someone and/or get approval, but not a requirement of the standard.

16. Which of the following are required activities in the event of nonconforming products or services?

- _____ Throw in trash
- _____ Correct and reinspect
- _____ Segregate
- _____ Release
- _____ Release with customer concession (Maintain records)
- _____ Maintain record of the authority deciding the action

The only "required activity" is the last one, at least as applied to the standard. You may have rules in place to do any or all of the other ones, and if you do, you're required to make a record of who made the decision.

17. Can a company make a claim that it is ISO conformant without being ISO certified?

- _____ Yes
- _____ No

Sure. But they're not "certified" until a "certified registrar" says so.

18. The Organization is required to conduct Customer Surveys

_____ True _____ False

False. It's up to "the organization" to determine how to gather customer surveys. If they require themselves to do so, they can, but it's not a requirement of the standard.

19. What is the "required interval" for an internal ISO9001 Audit?

- _____ Once a year
- _____ Every three years
- _____ Up to the Organization to decide based on various factors

It's up to the organization to decide. The word "annual" never appears in the standard anywhere.

20. What is the "Required Interval" for the Management Review Meeting

- _____ Once a Year
- _____ Quarterly
- _____ Up to the Organization
- _____ There is no requirement for a meeting.

The last two are correct. If you can find a way to document that the management "reviewed" the management review inputs, and generated action items, there is no requirement in the standard for a "meeting."

It's usually done that way though.

21. The organization is required to take a corrective action in the event of a non-conformity.

_____ True _____ False

False. The organization is required to determine the action, whatever it may be. The organization is only required to take "necessary" corrections and corrective actions. If "the organization" decides that no action is "necessary" they may do so. Be sure to document the decision not to take action.