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ISO9001 Introduction Quiz Parts 1 and 2

Name: _____

Date: _____

1. ISO Certification means that the products you make are certified by a third party registrar

_____ True _____ False

False is correct. The ISO certification says nothing about the product. It certifies the quality system to conformity to the ISO standard. It's up to the client to make it effective.

2. ISO Certification is performed by a third party organization called a Registrar

_____ True _____ False

True. You may be audited by a third party auditor, but it will only count toward your internal audit requirement, if your internal auditing procedure allows it.

3. The ISO Auditor is required to be certified by the Registrar

_____ True _____ False

False. The auditor is certified by another certification body that certifies the auditor. It's to prevent conflict of interest

4. ISO9001 is the “Entry Level” Quality Systems Standard

True False

True. The system is all “harmonized” to the same structure as ISO9001

5. Choose any of the following that denotes a requirement

Shall

Can

May

Should

Could

Shall is the only correct answer. Everything else is a suggestion.

6. When something “necessary” is required, who decides what is “necessary?”

The Auditor

The Organization

The auditor’s lone job is to determine the organization’s conformity to the standard. It’s up to “the organization” to determine what is “necessary” or “appropriate” or “timely” or “undue”

7. Who defines the scope of an organization’s Quality Management System?

The Registrar

The Auditor

The Organization

It’s the organization again. The registrar and auditor use the Organization’s scope statement to understand the boundaries of the system.

8. Who defines the “Processes” in the quality management system?

- The Registrar
- The Auditor
- The Organization

It’s up to “the organization” to develop and document the processes.

9. Who is accountable for the effectiveness of the Quality Management System?

- Top Management
- Anybody Else

You’d think this was obvious, but 5.1.1 gives this responsibility to the top management.

10. What are the required commitments within the Quality Policy

- Meeting Requirements
- Continually Improving
- Cost Effectiveness
- Customer Satisfaction

The correct answers are “meeting requirements” and “continually improving.”

11. Audit findings are written against a requirement in the standard

- True
- False

This is true. A client-derived requirement may be cited as evidence during the documentation process, however.

12. Major non-conformities in an ISO audit can require a follow up audit

- True
- False

This is also true. It’s a good reason for not getting one.

13. It's the auditors job to make the ISO registration decision

_____ True _____ False

False. The auditor, a contractor or employee of the registrar, can only make a recommendation, backed up by a lot of evidence that he or she gathered during the audit.

14. Who determines the rules for responding to a finding in an ISO audit?

_____ The Organization

_____ The Auditor

_____ The Registrar

The registrar sets the rules for findings and their responses.

15. Whose job is it to determine Risks and Opportunities

_____ The Organization

_____ The Auditor

_____ The Registrar

As it applies to the requirements in 6.1 of the standard, it's the organization, however, since the implementation of "risk based thinking" both the registrar and auditor both make risk determinations. The auditor estimates risk when he or she decides how big of a sample is taken during the audit. The registrar may also designate "high risk" auditors based on internal criteria.

16. What are the requirements for the Quality Objectives (Select one or more)

_____ Consistent with the Quality Policy (Conform to Requirements and Improving)

_____ Measurable

_____ Measures cost effectiveness

_____ Takes into account requirements

_____ Be Monitored

_____ Be the same every year

_____ Be communicated

All of the above except “cost effectiveness” and “be the same every year.” The Organization can and should change objectives to focus on a specific problem. They may include cost effectiveness, but the standard requires the other five.

17. If you don't meet your quality objectives, what are you required to do?

- Do corrections, corrective actions and make necessary improvements
- TBD by the organization
- Ignore, do better next time.

You do want to do corrections or corrective actions. The standard requires you to make “necessary” improvements. If you choose not to make any improvements, document this decision somehow.

18. When there are changes in the Management System, how must the change be done?

- By Top Management
- Randomly
- In a Planned Manner

In a planned manner. You, the organization, set the rules for dealing with a change.