

**AQS 115 – Introduction To Quality and Auditing
Challenge Exam
(100 pts total)**

PASS CRITERIA:

Overall score of 78% required.

DESCRIPTION / OBJECTIVE:

This course provides an introduction to various industry (both manufacturing and service) international and US regulatory quality system standards. This course will also provide instruction on the audit process and principles. Students will learn the components of a quality system used in both manufacturing and service industries. The International Organization of standardization (ISO) library of standards for Quality Systems and Auditing Principles will be explored. Students will learn to identify commonality between the standards, along with industry specific differences; demonstrating their knowledge using auditing tools. Students will learn about the formal audit cycle: scope, planning (preparation), execution (performing the audit), reporting and follow-up actions.

OUTCOME ASSESSMENTS:

Category	Objective	Question Type			Points Available
		Matching	T/F – Multi choice	Short Answer	
1	Demonstrate an ability to identify and interpret the ISO standards (e.g. ISO 9001:2015 or ISO 13485:2016) and FDA regulations (e.g. 21 CFR 210/211 or 820) used for a variety of manufacturing and service industries, including automotive (TS/ISO 16949), aerospace (AS9001), food manufacture, pharmaceutical, etc.	1, 2, 3, 4	5, 6, 7, 8, 9, 11, 13, 14, 15, 16, 17, 18, 22, 24, 25, 26, 27, 35, 43		75
2	Demonstrate the ability to explain and distinguish different audit types		19, 20, 23, 29, 44		5
3	Demonstrate the ability to differentiate the components of an audit and choose the appropriate tools		21, 32, 33, 37, 41, 42, 45, 46, 49, 50		10
4	Express and practice audit techniques, utilizing graphs and charts to communicate results.		28, 30, 31, 34, 36, 37, 39, 40, 47, 48		10

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1. Match the following terms as defined by ISO9000:2015 (2pt each, 22 total)

Term	Answer	Definition
Management System	d	A. Degree to which a set of characteristics fulfill requirements
Quality	a	B. Need that is stated.
Organization	e	C. Result of a process
Policy	i	D. Set of interrelated elements to establish policies and process to achieve those objectives.
Objective	j	E. Group of people that has its own function with authorities to achieve objectives.
Process	h	F. Distinguishing feature
Characteristic	f	G. Effect of uncertainty
Requirement	b	H. Set of interacting activities that use inputs to deliver intended output
Top Management	k	I. Intention of organization as formally expressed by top management
Output	c	J. Result to be achieved
Risk	g	K. Person who directs an organization at the highest level

2. Match the following quality management principles and their application (2pt each, 14 total)

Principle	Answer	Application
Customer Focus	e	A. React to changes in internal and external conditions
Leadership	d	B. Recognize and employ individual skills and knowledge
Engagement of the People	b	C. Manage interested part interactions to optimize performance impact
Process Approach	f	D. Create unity of purpose, direction and engagement.
Improvement	a	E. Understand interested party future needs
Evidence-based Decision making	g	F. Understand how all resources and controls produce results
Relationship management	c	G. Understand cause and effect relationships

3. Match the following product with the appropriate standard (2pt each, 6 total)

Product	Answer	Standard
ISO 9001:2015	C	A. Knee joint
ISO 13485:2016	A	B. Diesel engine parts
ISO 16949:20??	B	C. Skateboard

4. Match the following statements to the appropriate section of ISO 9001:2015 (2pt each, 12 total)

Principle	Answer	Application
Audit report results shall be reported to relevant management	e	A 8.5.2
Methods for monitoring, measuring and analysis shall be determined.	d	B 7.1.5.2b
Status of measurement equipment shall be identified	b	C 10.2.1.a.1
Quality objectives must be documented and maintained.	f	D 9.1.1b
When traceability is a requirement, the unique identification shall be controlled.	a	E 9.2.2b
The organization shall take action to control and correct customer complaints	c	F 6.2.1

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5. The organization shall determine evaluation criteria for external providers based on service requirements. T F
6. A customer's post-delivery requirements do not require review. T F
7. Pharmaceutical manufacturers in the US are required to follow 21CFR 210 requirements. T F
8. The status of monitoring and measurement requirements shall be identified throughout the process. T F
9. When unintended production changes occur the organization shall identify the consequences. T F
10. Random selection of a sample means each item in the batch has an equal chance of being selected. T F
11. Outsourced production processes are not within the control of the Quality Management System. T F
12. After successful implementation of a corrective action, further follow-up is necessary to extend the fix to other products/services. T F
13. Medical device manufacturers in the US are required to follow ISO 13485:2016. T F
14. Documented information shall include traceability to personnel responsible for product release. T F
15. What are the basic elements of a process?
 - a. Input, activities, output
 - b. Sources, personnel, equipment
 - c. Training, time, materials
 - d. Cost, productivity, throughput
16. What does validation mean?
 - a. Confirmation by examination that specified design requirements have been met.
 - b. Confirmation by examination that the requirements for intended use are satisfied.
 - c. Predefined scripted set of tests with expected results
 - d. Process through which equipment is made per documented design specifications
17. What does verification mean?
 - a. Confirmation by examination that specified design requirements have been met.
 - b. Confirmation by examination that the requirements for intended use are satisfied.
 - c. Predefined scripted set of tests with expected results
 - d. Process through which equipment is made per documented design specifications
18. What should be consistent with the quality policy, be measurable and improve customer satisfaction?
 - a. Corrective actions
 - b. Internal audits
 - c. Management review
 - d. Quality objectives
19. The primary purpose of conducting internal audits is to
 - a. Find problems
 - b. Interview staff
 - c. Review the effectiveness of the QMS
 - d. Identify issues with procedures
20. In order to evaluate the internal effectiveness of the customer order planning function, which of the following audits would be appropriate?
 - a. Product audit
 - b. Process audit
 - c. Management audit
 - d. System audit
21. In flow charts, the diamond symbol is used to represent
 - a. Process steps
 - b. Decision branch
 - c. Start of a process
 - d. Continuation

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22. When comparing internal and external customers, one finds that
- a. **Feedback is essential in both areas**
 - b. The requirements of internal customers must be more clearly defined
 - c. An external customer may have less flexibility to make a change
 - d. There are no significant differences
23. The most extensive audit category is which of the following?
- a. Product audit
 - b. Internal audit
 - c. **System audit**
 - d. Process audit
24. When should product and service requirements be reviewed?
- a. When shipping the order
 - b. After starting production
 - c. While negotiating costs
 - d. **Before accepting the order**
25. Improvement and planning is part of which category for cost of quality?
- a. **Prevention**
 - b. Internal
 - c. External
 - d. Appraisal
26. What is a process?
- a. A sequence of un-related events
 - b. **A chain of value-added activities that deliver a product.**
 - c. A set of directions
 - d. A system of tasks that provide support to a organization
27. The best evidence of acceptable quality is
- a. Complete compliance to design requirements
 - b. A low rejection rate
 - c. **A satisfied customer**
 - d. Long-term usefulness
28. A conflict of interest threatens which of the following audit attributes?
- a. **Objectivity**
 - b. Performance
 - c. Completion
 - d. Clarity
29. Which audit listed below would typically require more time to prepare?
- a. Process
 - b. Procedure
 - c. Product
 - d. **Quality System**
30. An auditor's responsibilities include
- a. Taking action on important audit findings
 - b. **Complying with audit standards and procedures**
 - c. Providing resources needed by the audit team
 - d. Determining the audit need scope and purpose.

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31. Audit team members are responsible for
 - a. Recommending specific corrective actions
 - b. Initiating most second party audits
 - c. **Collecting audit evidence**
 - d. Defining the scope and purpose of the audit.
32. During audit preparation, an audit team would
 - a. Prepare an exit meeting summary
 - b. **Review available and appropriate documentation**
 - c. Conduct interviews
 - d. Schedule any anticipate follow-up audits
33. The audit agenda is typically prepared
 - a. In the opening meeting with the auditee
 - b. At the same time as the annual audit schedule
 - c. By the audit team
 - d. **By the audit team leader**
34. When performing the audit which of the following is considered
 - a. **Is the audit progressing as planned**
 - b. What sampling plans must be developed
 - c. How many auditors are needed
 - d. What are the cost considerations for the audit
 - e.
35. A system for controlling nonconforming material should have the procedures for
 - a. **Identification, segregation, and disposition**
 - b. Segregation, disposition and reapplication
 - c. Segregation, reapplication, and investigation
 - d. Investigation, disposition and revision
36. The forward-tracing technique has which of the following advantages
 - a. Allows for auditee personnel to be juggled
 - b. **Assists the auditor to understand process flow**
 - c. Is practical for follow-up audits
 - d. Permits maximum audit flexibility
37. Which of the following would be considered objective evidence?
 - a. Non-electronic control of documents
 - b. Key operator comments about specification violations
 - c. **Auditor observation of revision controlled blueprints being used**
 - d. No operating training recorded in last six months
38. Checklists are useful during audits because
 - a. **They promote an economical use of time**
 - b. They promote flexibility
 - c. They permit randomness in audit overage
 - d. They can be substituted for an audit report
39. During an audit, an auditor discovers a set of unapproved, handwritten work instructions. As a result of this observation, he auditor should
 - a. Add more questions to the checklist
 - b. **Determine if this is an isolated incident or chronic deficiency**
 - c. Ask that the work instruction be reviewed and approved
 - d. Keep the document as evidence of the deficiency

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40. Following an audit and report-out, checklists should be
- a. **Maintained a reference of the auditee's response and documentation**
 - b. Discarded, as the audit report is the only required deliverable
 - c. Copied and sent to the auditee
 - d. Shredded to ensure that proprietary information remains intact
41. The audit report should include
- a. Details of how the audit team was selected
 - b. Identification of person(s) who prepared the checklists
 - c. **A summary of audit results and findings**
 - d. Qualifications of personnel who performed the audit
42. Risk analysis planning should
- a. **Be done at the beginning of the project**
 - b. Eliminate all associated contingency plans
 - c. Identify and implement a metrics program
 - d. Be updated upon project completion
43. The product costs resulting from re-inspection because of quality issues detected prior to shipping would be considered
- a. Appraisal costs
 - b. External costs
 - c. **Internal costs**
 - d. Preventive costs
44. An audit is an organized method of
- a. Pinpointing responsibility for error
 - b. Writing checklists
 - c. Assuring that personnel are adequately trained
 - d. **Finding out how business is actually being conducted**
45. Audit schedules should be
- a. **Periodically reviewed and modified**
 - b. Established annually and rarely modified
 - c. Approved by all subcontractors
 - d. Established by top management
46. Flowcharting of activities and systems is most helpful in detecting
- a. An inappropriate use of brainstorming techniques
 - b. Deficiencies in the organizational structure
 - c. **Holes or gaps in the control system**
 - d. The improper use of statistical methods
47. When observing recorded data from various sources and formats, outliers are noted to be:
- a. Below the lower control limit in a control chart
 - b. **Unusual observations in any data arrangement**
 - c. Higher than the average value on a data sheet
 - d. Data not fitting into a bell shaped curve
48. The best description of sampling used when auditing is
- a. Contained in ANSI/ASQ Z1.4
 - b. Taking a few representative pieces off the top
 - c. **The selection of random items**
 - d. A sequential selection process

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49. The most widely used technique for distinguishing between chronic and insignificant problems is:
- a. **Pareto diagram**
 - b. Control chart
 - c. Cause and effect diagram
 - d. Scatter diagram
50. Which of the following best describes the auditee?
- a. The organization, individual or firm performing the audit.
 - b. **The organization, individual or firm being audited.**
 - c. The organization, individual or firm that is paying for the audit.
 - d. The organization, individual or firm that first receives the audit report.