

AQS 115 - Exam #2 (60 pts)

1. List three of the six phases for the corrective action process described in class and provide a summary of the activities that may take place in each phase. (10 pts)

Initiation  
Investigation  
Implementation  
Verification  
Effectiveness  
Closure

2. Describe the difference in audit scope between system, process and product. (6 pts)

System Audit – wide scope, narrow depth

Looks at entire quality system, encompasses all clauses of the standard and business operations

Process Audit - narrower scope, with increased depth

Rather than entire QMS, this audit focusses on a given business process across a variety of products or product families. (i.e. manufacturing line, purchasing, calibration, etc.)

Product Audit - narrowest scope, with greatest depth

This audit will focus on one product or product family, ensuring the QMS requirements have been met

3. Jane Smyth from Purchasing notified Larry Jones in Calibration that an internal audit would be performed in June. Who is the auditor and who is the auditee? (2 pts)

Auditor = Jayne Smyth

Auditee = Larry Jones (calibration)

4. The vendor (supplier) providing a critical component to company ABC's final product has been unable to reliably supply materials that meet specifications. An audit team has been assembled to visit their site, describe the responsibilities for the following team members (12 pts)

- a. Lead auditor - schedules the audit with the auditee, creates the work plan, determines who is on the team
- b. General auditor – performs the audit as directed by the Lead
- c. Auditor in-training - an observer in the process to learn and understand how to audit
- d. Subject matter expert - brings their technical expertise to a specific area, but doesn't contribute to the audit itself

5. 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

6. The purpose of quality auditing is to:

- a. Identify process or procedures that can be eliminated.
- b. Examine the effectiveness of the management system.
- c. Define an organizations mission and vision statements.
- d. Correct deficient areas.

Name \_\_\_\_\_

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7. Review each statement below and identify the related Clause # and whether it is true or false (40 pts)

	Clause	T / F
The measurement status of process output requirements shall be identified throughout production.	8.5.2	T
Post-delivery activities required by the customer do not need to be reviewed.	8.2.3.1a	F
To prevent unintended use or delivery, process outputs or products that do not conform to requirements are identified.	8.7.1	T
The criteria for selecting and monitoring the performance of a vendor's ability to provide products/services meeting specified requirements shall be determined.	8.4.1	T
Only the consequences of an unintended change need to be reviewed.	8.1.e 8.3.6 8.5.6	F
Processes outsourced to external providers are not within the control of the quality system.	8.4.2a	F
Communication regarding customer's perceptions is not required.	<del>8.2.1e</del> 9.1.2	F
Traceability to the person authoring release of the product must be documented.	8.6b	T
Ensuring that process outputs are preserved is only required during shipping.	8.5.4	F
Verification is conducted to ensure outputs meet input requirements; whereas validation is conducted to ensure products meet requirements for intended end use.	8.3.4c&d	T
Management review meetings shall be held quarterly to ensure the effectiveness of the quality management system.	9.3.1	F
Determining whether a non-conformance can occur elsewhere is not required.	10.2.1b	F
Improving products to address future needs is a requirement.	10.1a	T
Market share analysis is a method that can be used to monitor customer perceptions.	9.1.2	T
The corrective actions implemented as the result of audit findings must be completed within three months.	9.2.2e	F
Nonconforming product can be released to the customer if they provide written agreement	8.7.1c	T
When product manufactured using Customer supplied materials is found to be nonconforming it can be scrapped by the manufacturer without notification.	8.5.3	F
The availability of documented information regarding training for individual operators is required.	8.5.1e	T
The frequency of when a pressure gage used in the manufacturing process will be calibrated must be documented.	9.1.1c	T
Post-delivery requirements do not need to be agreed to prior to the manufacturer accepting the order.	8.2.3.1	F