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### PECB ISO-9001-Lead-Auditor Exam Syllabus Topics:

Topic	Details
Topic 1	<ul style="list-style-type: none"><li>Conducting an ISO 9001 audit: It evaluates your skills to conduct a QMS audit.</li></ul>
Topic 2	<ul style="list-style-type: none"><li>Preparing an ISO 9001 audit: This topic covers sub-topics related to preparing a quality management system audit.</li></ul>

Topic 3	<ul style="list-style-type: none"> <li>Quality management system (QMS) requirements: It assesses your abilities to point out and explain different requirements for a quality management system based on ISO 9001.</li> </ul>
Topic 4	<ul style="list-style-type: none"> <li>Managing an ISO 9001 audit program: This topic evaluates your abilities to establish and managing a QMS audit program.</li> </ul>
Topic 5	<ul style="list-style-type: none"> <li>Fundamental audit concepts and principles: Questions about interpreting and applying the main concepts and principles related to a QMS audit appear in this topic.</li> </ul>

## PECB QMS ISO 9001:2015 Lead Auditor Exam Sample Questions (Q61-Q66):

### NEW QUESTION # 61

Match each of the following statements into the table below to show whether they apply to first-party audits, second-party audits or third-party audits:

#### Answer:

Explanation:

Explanation:

Table

Statement

First-party audits

Second-party audits

Third-party audits

The audit scope is typically determined by the organisation being audited.

Yes

No

No

The outcome of the audit is typically certification to a recognised standard.

No

No

Yes

The audit scope is typically confined to service/product provision capability.

No

Yes

No

Here is a brief explanation of each statement:

The audit scope is typically determined by the organisation being audited: This statement applies to first-party audits, also known as internal audits, where the organisation audits its own processes and activities to ensure conformity and improvement<sup>1</sup>. The organisation can decide the scope of the audit based on its own needs and objectives<sup>2</sup>. This statement does not apply to second-party audits, where the customer audits the supplier, or third-party audits, where an independent body audits the organisation. In these cases, the audit scope is determined by the customer or the certification body, respectively<sup>3,4</sup>.

The outcome of the audit is typically certification to a recognised standard: This statement applies to third-party audits, where an independent body audits the organisation to verify that it meets the requirements of a specific standard, such as ISO 9001, and issues a certificate of conformity if the audit is successful<sup>3,4</sup>. This statement does not apply to first-party audits or second-party audits, where the outcome of the audit is not certification, but rather self-improvement or supplier qualification<sup>1,3</sup>.

The audit scope is typically confined to service/product provision capability: This statement applies to second-party audits, where the customer audits the supplier to ensure that they are meeting the requirements specified in the contract, such as service or product quality, delivery, or performance<sup>3,4</sup>. The audit scope is usually focused on the specific aspects of the service or product that are of interest to the customer<sup>3</sup>. This statement does not apply to first-party audits or third-party audits, where the audit scope is broader and covers the entire quality management system or the relevant clauses of the standard<sup>1,4</sup>.

### NEW QUESTION # 62

XYZ Corporation is an organisation that employs 100 people. As audit team leader, you are conducting a certification audit at Stage 1. When reviewing the quality management system (QMS) documentation, you find that quality objectives have been set for every

employee in the organisation except top management.

The Quality Manager complains that this has created a lot of resistance to the QMS, and the Chief Executive is asking questions about how much it will cost. He asks for your opinion on whether this is the correct method of setting objectives.

Three months after Stage 1, you return to XYZ Corporation to conduct a Stage 2 certification audit as Audit Team Leader with one other auditor. You find that the Quality Manager has cancelled the previous quality objectives for all employees and replaced them with a single objective for himself. This states that "The Quality Manager will drive multiple improvements in the QMS in the next year". The Quality Manager indicates that this gives him the authority to issue instructions to department managers when quality improvement is needed. He says that this approach has the full backing of senior management. He shows you the latest Quality Improvement Request that was included in the last management review.

After further auditing, the issues below were found. Select three statements that apply to the term 'audit trail'

- A. Decisions on improvement action timescales not involving departmental managers.
- B. Top management claim not to be aware of the improvement request (QI/12/20/HR-3) initiated by the Quality Manager.
- C. Evaluation of the results of the improvement action not always documented by the Quality Manager.
- D. Quality improvements not aligning with the quality policy.
- E. Limited knowledge of the content of Quality Improvement Requests by departmental staff.
- F. The single quality objective set for the organisation by the Quality Manager.

**Answer: A,C,E**

Explanation:

Based on the scenario and the concept of an 'audit trail' within the context of ISO 9001, the three statements that apply would likely be:

A: Decisions on improvement action timescales not involving departmental managers. This indicates a lack of involvement and communication with those responsible for implementing the improvements, which is a key part of an effective audit trail.

B: Evaluation of the results of the improvement action not always documented by the Quality Manager.

Proper documentation is essential for an audit trail, as it provides evidence that actions have been evaluated and are effective.

C: Limited knowledge of the content of Quality Improvement Requests by departmental staff. An audit trail should ensure that all relevant parties are aware of and understand the actions being taken, which is not the case here.

These points suggest issues with the communication, documentation, and involvement of relevant personnel in the quality management system processes, which are crucial for maintaining an effective audit trail and, by extension, a robust quality management system.

### NEW QUESTION # 63

Below are four of the seven principles on which ISO 9000 series are based. Match a potential benefit to each of the quality management principles (QMP).

**Answer:**

Explanation:

Explanation:

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According to the ISO 9000:2015 document, the seven quality management principles are:

Customer focus

Leadership

Engagement of people

Process approach

Improvement

Evidence-based decision making

Relationship management

For each principle, the document provides a statement, a rationale, key benefits, and actions you can take to apply the principle in your organization.

Based on the document, here is a possible way to match a potential benefit to each of the four quality management principles you mentioned:

Table

Quality management principle

Potential benefit

Customer focus

Increased revenue and market share

Engagement of people  
Enhanced trust and collaboration throughout the organization  
Improvement  
Enhanced drive for innovation  
Evidence-based decision making  
Increased ability to demonstrate effectiveness of past actions

#### NEW QUESTION # 64

You are carrying out an audit at a single-site organisation seeking certification to ISO 9001 for the first time.

The organisation manufactures cosmetics for major retailers.

You are interviewing the Manufacturing Manager (MM).

You: "I would like to begin by looking at the cleaning controls."

MM: "We record the cleaning of the equipment at the end of every batch. This document details the minimum cleaning frequency and the procedures to follow for all areas and each item of equipment. The person who carries out the cleaning puts their initial on the document and records the time and date alongside." Narrative: You sample production records over 3-days and note down evidence of nonconformity as per the table below.

□

**Answer:**

Explanation:

□

#### NEW QUESTION # 65

Scenario 2:

Bell is a Canadian food manufacturing company that operates globally. Their main products include nuts, dried fruits, and confections. Bell has always prioritized product quality and has maintained a good reputation for many years. However, the company's production error rate increased significantly, leading to more customer complaints.

To increase efficiency and customer satisfaction, Bell implemented a Quality Management System (QMS) based on ISO 9001. The top management established a QMS implementation team comprising five middle managers from various departments, including Leslie, the quality manager.

Leslie was responsible for assigning responsibilities and authorities for QMS-related roles. He also suggested including a top management representative in the QMS team, but top management declined due to other priorities.

The team defined the QMS scope as:

"The scope of the QMS includes all activities related to food processing." Leslie established a quality policy and presented it to the team for review before top management approval

. Top management also proposed a new strategy for handling customer complaints, requiring biweekly customer surveys to monitor customer perceptions.

The quality policy was established by Leslie and approved by top management. Is this acceptable?

Please refer to scenario 2.

- A. Yes, the quality policy can be established by the QMS implementation team and be approved by top management.
- B. Yes, as long as top management is informed, the policy can be established by any responsible employee.
- **C. No, the quality policy must be established and approved by top management.**
- D. No, the quality policy must be established and approved only by the quality manager.

**Answer: C**

Explanation:

Comprehensive and Detailed In-Depth Explanation:

ISO 9001:2015, Clause 5.2.1 (Establishing the Quality Policy) states that top management must establish, implement, and maintain a quality policy.

In the scenario, the quality manager (Leslie) created the policy, but top management did not establish it themselves, which violates Clause 5.2.1. While the policy can be drafted by a team, top management must take full ownership of its development and approval.

Reference:

ISO 9001:2015, Clause 5.2.1 - Establishing the Quality Policy

## NEW QUESTION # 66

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