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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>Fundamental principles and concepts of a quality management system: The main objective of this domain is to evaluate your skills of explaining and applying ISO 9001 principles and concepts.</li></ul> |
| Topic 4 | <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>                   |

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### PECB QMS ISO 9001:2015 Lead Auditor Exam Sample Questions (Q44-Q49):

#### NEW QUESTION # 44

Which one of the following is not an ISO 9000:2015 quality management principle?

- A. Leadership
- **B. Risk-based approach**
- C. Evidence-based decision-making
- D. Process approach

**Answer: B**

Explanation:

According to the ISO 9000:2015 quality management principles document1, risk-based approach is not one of the seven quality management principles that ISO 9000, ISO 9001 and other related quality management standards are based on. The seven quality management principles are:

- \* Customer focus
- \* Leadership
- \* Engagement of people
- \* Process approach
- \* Improvement
- \* Evidence-based decision making
- \* Relationship management

Therefore, risk-based approach is not a quality management principle under ISO 9001:2015.

References: ISO - Quality management principles

#### NEW QUESTION # 45

Match the process descriptions below to the process names:

Match the process descriptions below to the process names:

|   |                      |
|---|----------------------|
| The process by which the accuracy of test equipment is checked against a known standard.                | <input type="text"/> |
| The process by which a product or service is visually examined to determine conformity to requirements. | <input type="text"/> |
| The process by which data is examined in detail to reach a specific answer or answers.                  | <input type="text"/> |
| The process by which a parameter of a product or service is examined to determine a specific value.     | <input type="text"/> |

To complete the table click on the blank section you want to complete so it is highlighted in red and then click on the applicable text from the options below. Alternatively you may drag and drop each of the following process names to the descriptions:

**Answer:**

Explanation:

Match the process descriptions below to the process names:

The process by which the accuracy of test equipment is checked against a known standard.

The process by which a product or service is visually examined to determine conformity to requirements.

The process by which data is examined in detail to reach a specific answer or answers.

The process by which a parameter of a product or service is examined to determine a specific value.

To complete the table click on the blank section you want to complete so it is highlighted in red and then click on the applicable text from the options below. Alternatively you may drag and drop each of the following process names to the descriptions:

Explanation:

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The process by which the accuracy of test equipment is checked against a known standard.

The process by which a product or service is visually examined to determine conformity to requirements.

The process by which data is examined in detail to reach a specific answer or answers.

The process by which a parameter of a product or service is examined to determine a specific value.

#### NEW QUESTION # 46

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 and the name of the retailer supplied appears on the product packaging. Sales turnover has increased significantly over the past five years. The organisation uses a software programme called SWIFT, which is used to record sales, plan production, purchase supplies, print despatch notes, track new product development, perform traceability exercises, carry out mass balance checks, raise invoices, create budgets, and support financial control.

You are nearing the end of the audit and you are reviewing your audit notes. You notice a recurring trend concerning the SWIFT database as shown below:

| Your audit notes  | Status               |
|---|----------------------|
| Production Planner: SWIFT database version 202          | Requires audit trail |
| Manufacturing Manager: SWIFT database version 169       | Requires audit trail |
| Manufacturing Supervisor: SWIFT database version 169    | Requires audit trail |
| Product Development Manager: SWIFT database version 169 | Requires audit trail |
| Logistics Supervisor: SWIFT database version 182        | Requires audit trail |
| Quality Manager: SWIFT database version 205             | Requires audit trail |

You ask the Quality Manager to explain how the SWIFT database is controlled. You learn that the Operations Director is responsible for determining and progressing SWIFT software updates. You decide to meet the Operations Director (OD).

You: "Good afternoon."

OD: "Good afternoon."

You: "What responsibility do you have concerning the SWIFT database?"

OD: "I maintain it. If anyone wishes to propose an update to the database, they send me an email with details of their proposal. I then either process the database update myself, or I send the request to the consultant who designed the database 20 years ago. The necessary software changes are made, and the amended software is immediately released to users." You: "Would you explain how the software amendments are controlled?" OD: "Of course. I personally update every computer myself." You: "Do you inform the database users of the changes?" OD: "No I don't. They find out for themselves by using the software, or they come to see me if they have any questions." You: "How do you ensure that the database users use the latest version?" OD: "That's easy, I update every computer myself." You: "During the audit, I noted there were several versions of SWIFT in use (you refer to your audit notes)." OD: "I know. That's because some versions work better than others, and depending on user needs and experiences, we allow users to revert to using an earlier version if they find it works better for them." Based on the scenario, which two of the following statements are true? There is evidence of nonconformity with a requirement defined in ...

- A. clause 7.1.3 Infrastructure

- B. ... clause 7.5.2 Documented information - Creating and updating
- **C. clause 7.5.1 Documented information - General**
- D. ... clause 7.1.4 Environment for the operation of processes
- **E. ... clause 7.5.3 Control of documented information**

**Answer: C,E**

Explanation:

Based on the scenario provided, there is evidence of nonconformity with the requirements defined in:

C: Clause 7.5.1 Documented information - General: The scenario indicates that there is no formal process for informing users about updates to the SWIFT database, which suggests a lack of control over documented information. This could lead to users being unaware of important changes and not using the latest version of the software, which is required by the quality management system<sup>1</sup>.

E: Clause 7.5.3 Control of documented information: The Operations Director's approach to updating the SWIFT database and the lack of communication to users about these updates indicate that the documented information is not adequately controlled. Allowing users to revert to earlier versions of the software at their discretion further suggests that the organization does not have a proper mechanism in place to ensure the integrity and suitability of documented information<sup>2</sup>.

These clauses are part of the ISO 9001:2015 standard, which requires organizations to have a systematic approach to controlling and managing documented information as part of their quality management system.

The scenario described shows a casual approach to managing critical software updates, which could affect the organization's ability to consistently meet customer and regulatory requirements.

## NEW QUESTION # 47

Scenario 5: Mechanical-Electro (ME) Audit Stages

Mechanical-Electro, better known as ME, is an American company that provides mechanical and electrical services in China. Their services range from air-conditioning systems, ventilation systems, plumbing, to installation of electrical equipment in automobile plants, electronic manufacturing facilities, and food processing plants.

Due to the fierce competition from local Chinese companies and failing to meet customer requirements, ME's revenue dropped significantly. In addition, customers' trust and confidence in the company decreased, and the reputation of the company was damaged.

In light of these developments, the top management of ME decided to implement a quality management system (QMS) based on ISO 9001. After having an effective QMS in place for over a year, they applied for a certification audit.

A team of four auditors was appointed for the audit, including Li Na as the audit team leader. Initially, the audit team conducted a general review of ME's documents, including the quality policy, operational procedures, inventory lists, QMS scope, process documentation, training records, and previous audit reports.

Li Na stated that this would allow the team to maintain a systematic and structured approach to gathering documents for all audit stages. While reviewing the documented information, the team observed some minor issues but did not identify any major nonconformities. Therefore, Li Na claimed that it was not necessary to prepare a report or conduct a meeting with ME's representatives at that stage of the audit. She stated that all areas of concern would be discussed in the next phase of the audit.

Following the on-site activities and the opening meeting with ME's top management, the audit team structured an audit test plan to verify whether ME's QMS conformed to Clause 8.2.1 (Customer Communication) of ISO 9001.

To do so, they gathered information through group interviews and sampling. Li Na conducted interviews with departmental managers in the first group and then with top management. In addition, she chose a sampling method that sufficiently represented customer complaints from both areas of ME's operations.

The team members were responsible for the sampling procedure. They selected a sample size of 4 out of 45 customer complaints received weekly for electrical services and 2 out of 10 complaints for mechanical services.

Afterward, the audit team evaluated the evidence against the audit criteria and generated the audit findings.

According to general principles of sampling procedure, did the audit team select a valid sample for electrical services?

- A. Yes, the selected sample size is proportionate to the population.
- B. No, the selected sample size is high compared to the population, as for a population from 13 to 52 the minimum sample size should be 10.
- **C. No, the selected sample size is low compared to the population, as for a population from 13 to 52 the minimum sample size should be 5.**

**Answer: C**

Explanation:

Comprehensive and Detailed In-Depth Explanation:

The audit team selected 4 out of 45 customer complaints for electrical services, which is too low based on standard statistical

sampling methods. According to ISO 19011:2018 (Guidelines for Auditing Management Systems), for a population size between 13 and 52, a minimum sample size should be 5 to achieve a reasonable level of confidence.

This means the selected sample (4 complaints) was insufficient and did not align with standard sampling procedures. Therefore, the correct answer is A.

Reference:

ISO 19011:2018, Clause 6.4.5 (Sampling Methods in Auditing)

### NEW QUESTION # 48

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 only by the quality manager.
- **D. No, the quality policy must be established and approved by top management.**

**Answer: D**

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.

### NEW QUESTION # 49

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