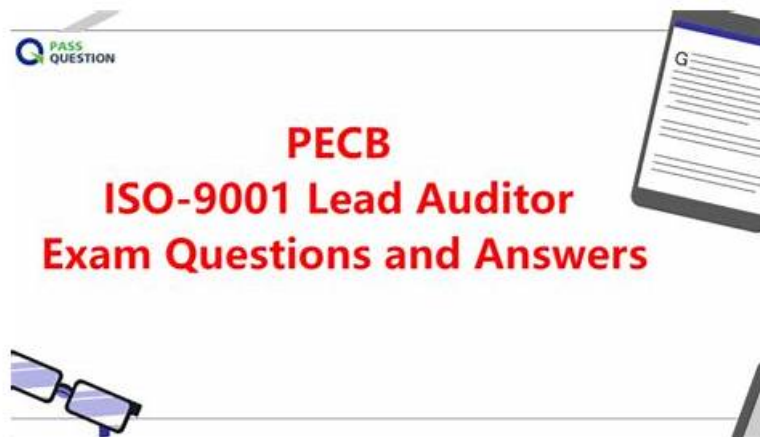


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PECB ISO-9001-Lead-Auditor Exam Syllabus Topics:

Topic	Details
Topic 1	<ul style="list-style-type: none"> Fundamental audit concepts and principles: Questions about interpreting and applying the main concepts and principles related to a QMS audit appear in this topic.
Topic 2	<ul style="list-style-type: none"> 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.
Topic 3	<ul style="list-style-type: none"> Preparing an ISO 9001 audit: This topic covers sub-topics related to preparing a quality management system audit.

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PECB QMS ISO 9001:2015 Lead Auditor Exam Sample Questions (Q213-Q218):

NEW QUESTION # 213

A small cleaning services organisation is about to start work on a hospital cleaning contract for the local Health Trust. You, as auditor, are conducting a Stage 2 audit to ISO 9001 and review the contract with the Service Manager. The contract requires that a

cleaning plan is produced.

You: "How was the cleaning plan for the contract developed?"

Service Manager: "We have a basic template that covers the materials, labour requirements and cleaning methods to be employed.

Some of that is specified by the customer." You: "How does the plan deal with locations like the intensive care wards and the operating theatres, which are included in the contract?"

Service Manager: "The basic plan covers general wards, but we will do more frequent cleaning in those areas if the hospital requests it." You: "Are you aware of the regulatory requirements for cleaning standards in hospitals?" Service Manager: "No. We depend on the hospital to look after that side of things in the contract." You decide to raise a non-conformity against section 8.2.2.a.1 of ISO 9001.

You decide to raise another non-conformity against section 8.2.4 of ISO 9001 when finding that the cleaning plan was amended without the agreement of the Health Trust. A different cleaning chemical was substituted to that specified in the contract. At the follow-up audit, the corrective action proposed was to

"obtain a concession from the Health Trust for use of the new chemical." Which one of the following options is the reason why you did not accept this action taken?

- A. The substitute chemical has not been used before in the Health Trust.
- B. The action assumes that the Health Trust will agree to the change.
- **C. The process for making changes to the contract has not been addressed.**
- D. Staff have not been trained in the use of the new chemical.
- E. The substitute chemical may not be as effective as the original.

Answer: C

NEW QUESTION # 214

You are preparing for interviews with two members of top management. Based on the information that you gathered about the organization, you conclude that it is the top management who takes all the important decisions and closely supervises and controls employees. Based on this, which management style is practiced in the organization?

- **A. Autocratic**
- B. Centralized
- C. Laissez-faire

Answer: A

Explanation:

Comprehensive and Detailed In-Depth Explanation:

An autocratic management style is characterized by:

- * Top management making all decisions without delegation.
- * Strict control over employees.
- * A lack of employee input in decision-making.

Centralized management (Answer C) refers to decision-making being concentrated at the top, but it does not necessarily imply strict control. Laissez-faire management (Answer B) allows employees high independence, which contradicts the scenario.

Reference:

ISO 9001:2015, Clause 5.1 (Leadership and Commitment)

NEW QUESTION # 215

Even though past audits have highlighted a consistently large number of nonconformities within an organisation's design team, the organisation has not varied the frequency or duration of audits on its audit plan.

The decision for whether this situation is acceptable or not should be governed by which of the following?

- A. The organization's reasoning behind the lack of change to the audit plan
- B. The availability of competent internal auditors
- C. The authority of the audit team leader
- **D. A risk-based approach to the audit programme**

Answer: D

NEW QUESTION # 216

You are conducting an ISO 9001 audit of a Materials Recycling Facility (MRF). The company processes waste plastics into raw material for plastic bottle manufacturers. You reach the manual picking line where operators are removing contaminant materials from incoming products, such as plastic bags, plastic film and badly contaminated items that would compromise the recycling process.

You interview the line supervisor.

You: "Why are these plastic items being rejected at this stage?"

Auditee: "They do not meet our processing standards."

You: "What is the reason for that?"

Auditee: "These items are likely to damage the machinery down the line. They can also compromise our quality standards. We need to protect our reputation for good quality output materials." You: "What happens to the rejected items?" Auditee: "Some get melted down in another process later on and some are disposed of as waste products that cannot be recycled." You: "What happens to the waste products?" Auditee: "I'm not sure. I suppose they go to landfill." After further auditing, you have gathered additional evidence.

Answer:

Explanation:

□ Explanation:

A # 8.4.3.a

B # 7.2.b

C # 10.2.2

D # 10.2.1

E # 6.2

Comprehensive and Detailed Explanation From Exact Extract:

A. There is no specification for incoming materials # 8.4.3.a

Clause 8.4.3(a) relates to the control of externally provided processes, products, and services, specifically the requirement to communicate appropriate specifications and requirements to suppliers:

"The organization shall ensure the adequacy of requirements prior to their communication to the external provider." Failure to specify requirements for incoming materials (e.g., what is acceptable waste plastic) risks compromising product quality.

B. The picking operators have been trained # 7.2.b

Clause 7.2(b) relates to Competence and mandates:

"Ensure that these persons are competent on the basis of appropriate education, training, or experience." Training is a critical part of establishing and maintaining operator competence in quality-affecting tasks.

C. The picked reject materials are not documented # 10.2.2

This clause focuses on the retention of documented information regarding nonconformities and actions taken:

"The organization shall retain documented information as evidence of: the nature of the nonconformities and any subsequent actions taken..." If rejects are not recorded, traceability and root cause analysis for quality failures are weakened.

D. The rejected materials are segregated # 10.2.1

Clause 10.2.1 relates to nonconformity and corrective action, including containment activities such as:

"Deal with nonconforming outputs in one or more of the following ways: correction; segregation, containment..." Segregation ensures nonconforming material doesn't contaminate acceptable output.

E. Management has set an objective for the level of rejects # 6.2

Clause 6.2 is about quality objectives. It requires organizations to:

"Establish quality objectives at relevant functions... The quality objectives shall be measurable..." Setting a measurable reject-level target aligns with improving process control and reducing waste.

References:

ISO 9001:2015 Clause 8.4.3.a - Information for External Providers

ISO 9001:2015 Clause 7.2.b - Competence

ISO 9001:2015 Clause 10.2.2 - Documentation of Nonconformity

ISO 9001:2015 Clause 10.2.1 - Control of Nonconforming Outputs

ISO 9001:2015 Clause 6.2 - Quality Objectives

NEW QUESTION # 217

According to ISO 9000, what is quality?

- A. The degree to which a set of inherent characteristics of an object fulfills requirements
- B. The ability of an object to realize an output that will fulfill the requirements for that output
- C. The efficiency with which resources are utilized in achieving objectives
- D. A set of conditions under which work is performed

Answer: A

