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

| Topic | Details |
|---------|---|
| Topic 1 | <ul style="list-style-type: none">Managing an ISO 9001 audit program: This topic evaluates your abilities to establish and managing a QMS audit program. |
| Topic 2 | <ul style="list-style-type: none">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. |

| | |
|---------|---|
| Topic 3 | <ul style="list-style-type: none"> • Conducting an ISO 9001 audit: It evaluates your skills to conduct a QMS audit. |
| Topic 4 | <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. |

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PECB QMS ISO 9001:2015 Lead Auditor Exam Sample Questions (Q151-Q156):

NEW QUESTION # 151

(When raising a non-conformity during an audit, which two of the following items should you include in the non-conformity statement?)

- **A. Relevant audit evidence**
- B. A target time to implement the corrective action
- C. The name of the technical expert of the audit team that confirmed the existence of the non-conformity
- D. Action the auditee has to implement to eliminate the non-conformity
- E. The name of the person (auditee) responsible for the non-conformity
- **F. A description of or reference to audit criteria**

Answer: A,F

Explanation:

ISO 9001:2015 requires that nonconformities be objective, evidence-based, and referenced against defined requirements, not personal, prescriptive, or solution-driven.

When a nonconformity is raised, it must clearly show what requirement was not met and what objective evidence demonstrates this failure.

Why D (Audit criteria) is required

* A nonconformity must reference the requirement that was not fulfilled (e.g., ISO 9001 clause, procedure, contract, or legal requirement).

* ISO 9001 defines nonconformity as "non-fulfilment of a requirement".

* Without audit criteria, there is no basis for declaring a nonconformity.

Supported by:

* Clause 9.2.2 - Internal audits must determine whether the QMS conforms to requirements

* Clause 10.2.2 - Documented information shall describe the nature of the nonconformity

Why E (Relevant audit evidence) is required

* ISO 9001 requires decisions and conclusions (including audit findings) to be based on evidence.

* Audit evidence ensures objectivity and prevents subjective or opinion-based findings.

Supported by:

* Clause 9.1.3 - Analysis and evaluation shall be based on data and information

* Clause 9.2.2 - Audit results must demonstrate conformity or nonconformity based on evidence

Why the other options are NOT correct

* A (Name of person responsible)ISO 9001 focuses on system and process failures, not blaming individuals.

* B (Target time for corrective action)This is part of corrective action planning, not the nonconformity statement itself (Clause 10.2).

* C (Name of technical expert)ISO 9001 does not require identifying auditors or experts in the nonconformity statement.

* F (Action to eliminate the nonconformity)Auditors must not prescribe solutions. The auditee determines corrective actions (Clause 10.2).

NEW QUESTION # 152

Scenario 7: POLKA is a car manufacturing company based in Stockholm, Sweden. The company has around 14,000 employees working in different sectors which help with the design, painting, assembling, and test drives of the final product. The company is widely known for its qualitative products and affordable prices. In order to retain their reputation, POLKA implemented a quality management system (QMS) based on ISO 9001.

Before applying for certification, the company decided to conduct an internal audit to check whether there are any nonconformities in their QMS and if the requirements of ISO 9001 are being fulfilled.

The top management appointed Sean, the internal auditor, as the team leader of the internal audit team. Sean required from the top management to have unrestricted access to the employees and executives of POLKA and to the documented information.

Furthermore, Sean required to establish a team with a large number of auditors, considering the size and the complexity of the organization. The top management of POLKA agreed with Sean's requirements.

The top management, in cooperation with Sean, assigned 10 more employees to the audit team.

Following that, Sean planned the audit activities and assigned the roles and responsibilities to each auditor. They began by interviewing employees of different manufacturing departments to check whether they are aware of the process of the QMS implementation. While conducting these activities, one of the auditors asked Sean for permission to audit the department in which he worked on a daily basis, as he was very familiar with the processes of the department.

Along the way, the teams findings showed that the staff were trained, documented information was updated, and the QMS fulfilled the requirements of ISO 9001. The internal audit took three weeks to complete, and on the last week the audit team held a final meeting. The team shared their results and together drafted the audit report. This report was submitted to the top management of the company. The report was maintained as documented information, and was available to the relevant interested parties.

Based on the scenario above, answer the following question:

Based on Scenario 7, the team worked together to draft the final audit report. Is this acceptable?

- A. No, it is the responsibility of the audit team leader to draft the audit report
- B. No, audit team members should draft separate reports for their findings and conclusions
- C. Yes, audit team members should contribute to drafting one general report for the findings and conclusions

Answer: C

Explanation:

Comprehensive and Detailed In-Depth Explanation:

According to ISO 19011:2018, Clause 6.4.9 (Audit Conclusions & Reporting):

* One consolidated audit report should be drafted based on all team members' findings.

* Each auditor does not draft separate reports (B) unless explicitly required.

Thus, A is the correct answer.

Reference:

ISO 19011:2018, Clause 6.4.9 (Audit Conclusions & Reporting)

NEW QUESTION # 153

Select the phrase that best describes the purpose of a quality management system to ISO 9001 in relation to the performance of an organization.

- A. Improves the performance
- B. Dictates the performance
- C. Manages the performance
- D. Monitors the performance

Answer: A

Explanation:

* Understanding the Purpose of a Quality Management System (QMS): The primary objective of ISO 9001:2015 is to improve the overall performance of the organization by:

* Ensuring consistent delivery of products and services that meet customer and regulatory requirements.

* Focusing on enhancing customer satisfaction.

* Promoting continual improvement of the organization's processes and practices.

Reference: Clause 0.1 (General) of ISO 9001:2015 specifies that a QMS enables organizations to achieve better performance by consistently meeting customer needs and improving their processes. It further highlights that continual improvement is a cornerstone of the standard (Clause 10.3).

Option Analysis:

A: Manages the performance:Incorrect. A QMS provides a framework to manage processes, not directly manage performance. The improvement of performance is an outcome of managing processes effectively.

B: Monitors the performance:Incorrect. Monitoring is a component of performance evaluation (Clause 9.1) but does not define the overall purpose of the QMS.

C: Dictates the performance:Incorrect. ISO 9001 does not "dictate" performance but allows organizations to set their own objectives and improve their operations based on their specific context and goals.

D: Improves the performance:Correct. The fundamental purpose of a QMS as per ISO 9001 is continual improvement of the organization's performance. This includes improving operational efficiency, customer satisfaction, and product/service quality.

Why Option D is Correct:ISO 9001:2015 emphasizes the Plan-Do-Check-Act (PDCA) cycle and risk- based thinking, which are designed to drive improvements in organizational performance. Continuous assessment of processes and customer feedback ensures that the organization can adapt, innovate, and improve its effectiveness over time.

Clause 0.1: Purpose of the QMS.

Clause 10.3: Continual improvement ensures that the QMS remains effective and aligned with organizational objectives.

Clause 4.1: Context of the organization, which requires the QMS to align with organizational strategies and improve outcomes.

NEW QUESTION # 154

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

Answer: A

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 # 155

In the context of a third-party management system certification audit, which two of the following statements are correct?

- A. The Stage 2 audit cannot include remote access to electronic site(s) that contain information relevant to the audit of the management system.
- B. The purpose of a Stage 2 audit is to certify an organisation to ISO 9001.
- **C. The purpose of a Stage 2 audit is to evaluate the implementation of the auditee's management system.**
- **D. The Stage 2 audit should include an opening meeting at the start of the audit and a closing meeting at the conclusion of the audit.**

- Answer: C,D**

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