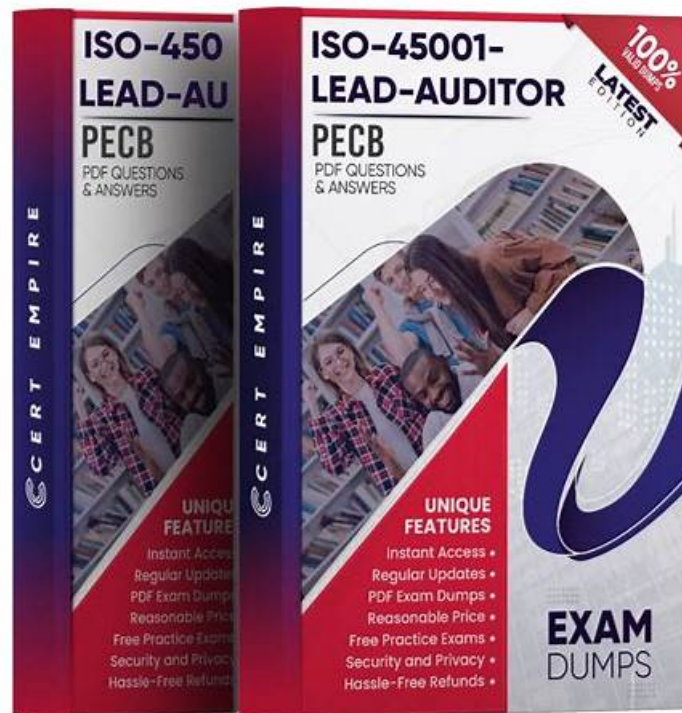


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PECB ISO-9001-Lead-Auditor Exam Syllabus Topics:

Topic	Details
Topic 1	<ul style="list-style-type: none">Closing an ISO 9001 audit: The topic focuses on concluding a QMS audit and conducting audit follow-up activities.
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">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 4	<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 5	<ul style="list-style-type: none">Conducting an ISO 9001 audit: It evaluates your skills to conduct a QMS audit.
Topic 6	<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.

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PECB QMS ISO 9001:2015 Lead Auditor Exam Sample Questions (Q28-Q33):

NEW QUESTION # 28

In the context of a third-party audit, select the issue which is not expected to be included in the audit plan.

- A. Scope of the audit
- **B. Expectations of the organisation's management**
- C. Number of sites to be audited
- D. Risk to achieving audit objectives

Answer: B

Explanation:

According to ISO 19011:2018, clause 6.3.2, the audit plan is a document that provides the basis for agreement regarding the conduct of the audit. The audit plan should include the following information1:

*the audit objectives, scope and criteria

*the audit team members and their roles and responsibilities

*the audit schedule, including the date, time and location of each audit activity

*the expected time and duration of meetings and interviews

*the allocation of appropriate resources to critical areas of the audit

*the identification of the audit client and the auditee

*the identification of the guides and observers, if any

*the documents and records to be reviewed before and during the audit

*the audit methods and tools to be used

*the audit language and terminology

*the audit report content, format, distribution and expected completion date

*the risk to achieving audit objectives and the contingency plan, if any Therefore, the issue which is not expected to be included in the audit plan is C, expectations of the organisation's management. This issue is not relevant to the conduct of the audit, as the audit is based on the audit criteria, not on the management's expectations. The management's expectations may be considered during the audit initiation or the audit programme management, but they are not part of the audit plan.

References: ISO 19011:2018(en), Guidelines for auditing management systems, How to create an ISO 9001 internal audit plan - Advisera

NEW QUESTION # 29

What competence, among others, should each audit team member have?

- **A. Knowledge of the risk-based approach to auditing.**
- B. Knowledge of the industry in which the auditee operates.
- C. A formal degree in quality management.
- D. Expertise in each domain to be audited.

Answer: A

Explanation:

Comprehensive and Detailed In-Depth Explanation:

Auditors must have competence in risk-based auditing to effectively assess an organization's QMS performance and compliance.

Clause References:

* ISO 19011:2018, Clause 7.2.3 - Determining Auditor Competence:

* Auditors must have knowledge of risk-based thinking to assess risk impact on processes.

* ISO 9001:2015, Clause 0.3.3 - Risk-Based Thinking:

* The standard emphasizes proactive risk management, which auditors must understand.

Why is the Correct Answer B?

* Risk-based auditing ensures audits focus on high-risk areas, improving audit effectiveness.

* Auditors must assess how organizations apply risk-based thinking in decision-making, process control, and improvement.

Why are the Other Options Incorrect?

* A (Industry knowledge) # While helpful, it is not mandatory for all auditors.

* C (Expertise in all domains) # Auditors are not required to be experts in all areas, just in audit methodology.

* D (Formal degree in quality management) # ISO does not require a formal degree, just competence in audit principles and methods.

Reference:

ISO 19011:2018, Clause 7.2.3 - Determining Auditor Competence

ISO 9001:2015, Clause 0.3.3 - Risk-Based Thinking

NEW QUESTION # 30

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.

Quality Improvement Request			QI/12/20/HR-3
To: HR Manager	QMS awareness training is to be included as part of the induction training for new employees.		Date: 12/12/20XX
Update by: 01/20XX	Update by: 02/20XX	Update by: 03/20XX	Action by: 31/03/20XX
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Signed: (QM)
Notes: Use of external resources for this action must be approved by senior management.			Action Completed: (Signature) Date:

After further auditing, the issues below were found. Select two statements that apply to the term 'nonconformity'.

- A. Limited knowledge of the content of Quality Improvement Requests by departmental staff.
- **B. Quality improvements not aligning with the quality policy.**
- C. Decisions on improvement action timescales not involving departmental managers.
- D. Top management claim not to be aware of the improvement request (QI/12/20/HR-3) initiated by the Quality Manager.
- **E. No quality objectives planned for the top management team**
- F. Evaluation of the results of the improvement action not always documented by the Quality Manager.

Answer: B,E

Explanation:

According to the ISO 9001:2015 standard, clause 10.2.1 defines nonconformity as the non-fulfilment of a requirement. A

requirement can be related to the quality management system, the products and services, the customer expectations, or the applicable statutory and regulatory requirements. Nonconformities can be detected through various sources, such as audits, inspections, tests, customer complaints, or internal reviews.

Nonconformities must be addressed by taking appropriate actions to correct them and prevent their recurrence.

In this scenario, the auditee has shown several issues that indicate nonconformities in their quality management system. Two statements that apply to the term nonconformity are:

A: No quality objectives planned for the top management team: According to ISO 9001, clause 6.2.1, the organization must establish quality objectives at relevant functions, levels, and processes. The quality objectives must be consistent with the quality policy and the strategic direction of the organization. The top management team is responsible for providing leadership and direction for the quality management system and ensuring its alignment with the organization's purpose and context. Therefore, the absence of quality objectives for the top management team is a nonconformity as it violates the requirement of clause 6.2.1.

E: Quality improvements not aligning with the quality policy: According to ISO 9001, clause 5.2.1, the quality policy is a statement of the organization's intentions and direction regarding quality, as formally expressed by top management. The quality policy must provide a framework for setting quality objectives and be compatible with the context and strategic direction of the organization. The quality policy must also be communicated, understood, and applied within the organization. Therefore, if the quality improvements are not aligned with the quality policy, it is a nonconformity as it violates the requirement of clause 5.2.1.

NEW QUESTION # 31

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 team's 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:

According to Scenario 7, one of the auditors requested permission from Sean to audit the department in which he worked on a daily basis. Should Sean grant the auditor permission?

- A. Yes, Sean should grant the auditor permission
- B. Yes, but Sean himself must be present in every audit activity
- C. No, internal auditors should be independent of the processes being audited

Answer: C

Explanation:

Comprehensive and Detailed In-Depth Explanation:

ISO 19011:2018, Clause 5.1 (Impartiality) states that:

* Internal auditors must be independent of the processes they audit to ensure objectivity.

* Auditing one's own department introduces bias and is not permitted.

Thus, Sean must not allow the auditor to audit their own department.

Reference:

ISO 19011:2018, Clause 5.1 (Impartiality)

NEW QUESTION # 32

You are carrying out an audit at an organisation seeking certification to ISO 9001 for the first time. The organisation offers regulatory

consultancy services to manufacturers of cosmetics. The business operates from ten regional offices.

You are nearing the end of the audit and need to decide if sufficient evidence of top management leadership and commitment with respect to the quality management system has been gathered.

Which four of the following would demonstrate top management leadership and commitment with respect to the quality management system?

- A. Not attending audit closing meeting
- B. Conducting staff disciplinary meetings
- C. Approving company car budgets for the fiscal year
- D. Chairing management review meetings
- E. Investing time and money in corrective actions arising from nonconformities
- F. Promoting the importance of following procedures
- G. Briefing staff on the development of an improvement culture

Answer: D,E,F,G

Explanation:

To demonstrate top management's leadership and commitment with respect to the quality management system, the following four actions would be indicative:

B: Briefing staff on the development of an improvement culture: This shows that top management is actively involved in promoting a culture of continuous improvement, which is a key aspect of the quality management system.

C: Chairing management review meetings: By leading these meetings, top management demonstrates their involvement in the quality management system's ongoing performance and commitment to its continual improvement.

E: Investing time and money in corrective actions arising from nonconformities: This indicates that top management is committed to addressing issues and ensuring that the quality management system is effective and continually improving.

G: Promoting the importance of following procedures: When top management emphasizes the importance of adherence to procedures, it reinforces the significance of the quality management system and its processes.

These actions align with the requirements of ISO 9001:2015, which emphasizes the need for top management to take accountability for the effectiveness of the quality management system and to promote a focus on continual improvement and customer satisfaction. Approving company car budgets, conducting disciplinary meetings, and not attending the audit closing meeting do not directly demonstrate leadership and commitment to the quality management system.

NEW QUESTION # 33

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