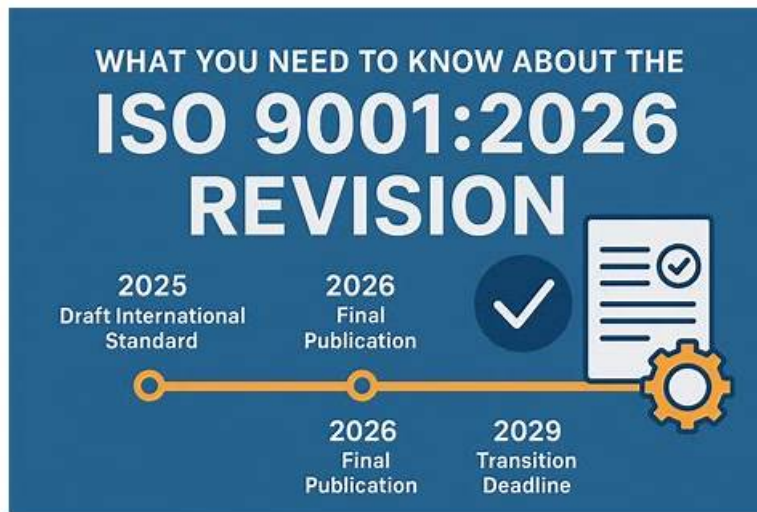


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## PECB ISO-9001-Lead-Auditor Exam Syllabus Topics:

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

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## PECB QMS ISO 9001:2015 Lead Auditor Exam Sample Questions (Q65-Q70):

### NEW QUESTION # 65

What must the auditor consider in order to mitigate audit risks and obtain reasonable assurance?

- A. The needs and expectations of internal interested parties.
- **B. The processes deemed material to the auditee.**
- C. The previous audit results.
- D. The financial risks associated with QMS implementation.

**Answer: B**

Explanation:

Comprehensive and Detailed In-Depth Explanation:

Auditors must focus on key processes that impact QMS effectiveness to ensure audit risks are minimized.

Clause References:

ISO 19011:2018, Clause 6.3 - Managing Audit Risk: Auditors should prioritize critical processes to obtain reasonable assurance.

Why is the Correct Answer A?

Some processes are critical (e.g., production quality, customer complaints handling).

If these material processes fail, the QMS could collapse.

Why are the Other Options Incorrect?

B (Needs of internal parties) # Important, but not the primary focus for reducing audit risk.

C (Previous audit results) # Useful for improvement but does not directly reduce current audit risks.

D (Financial risks) # ISO 9001 focuses on quality risks, not financial risks.

Reference:

ISO 19011:2018, Clause 6.3 - Managing Audit Risk

### NEW QUESTION # 66

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.

After reviewing the documented information, Li Na claimed that it was not necessary to report the minor nonconformities that were identified; instead, they would be discussed in the next audit phase. Is this acceptable?

- A. Yes, all identified nonconformities throughout the audit need to be documented and communicated at the end of the audit.
- B. Yes, during the review of documented information, only major nonconformities need to be documented if detected.
- **C. No, identification of minor nonconformities or areas of concern that could become nonconformities need to be documented and communicated to the auditee before proceeding to the next audit phase.**

**Answer: C**

Explanation:

Comprehensive and Detailed In-Depth Explanation:

As per ISO 9001:2015, Clause 10.2 (Nonconformity and Corrective Action), all identified nonconformities, including minor ones, must be documented and communicated to the auditee.

Minor nonconformities can lead to major issues if left unaddressed. The auditor must inform the organization before moving to the next audit phase so that corrective actions can be taken. Clause 9.2.2 (Internal Audit) states that audit findings should be reported without undue delay.

Since Li Na did not report the minor nonconformities immediately, her decision was incorrect. Minor nonconformities should always be documented and communicated before proceeding to the next phase.

Reference:

ISO 9001:2015, Clause 9.2.2 (Internal Audit Reporting)

ISO 9001:2015, Clause 10.2 (Nonconformity and Corrective Action)

#### **NEW QUESTION # 67**

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:

Ten employees of POLKA were part of the audit team that conducted the internal audit. Is this acceptable?

- A. Yes, it is a requirement of ISO 9001 to include employees of the company in the internal audit
- **B. Yes, members of the company can join the internal audit team**
- C. No, ISO 9001 requires hiring a professional team of auditors who are not part of the company to conduct the internal audit

**Answer: B**

Explanation:

Comprehensive and Detailed In-Depth Explanation:

According to ISO 9001:2015, Clause 9.2 (Internal Audit):

Internal audits are conducted by employees of the company who are trained as auditors.

External auditors are not mandatory unless required by the organization.

Thus, A is the correct answer.

Reference:  
ISO 9001:2015, Clause 9.2 (Internal Audit)

**NEW QUESTION # 68**

In the context of a third-party certification audit, it is very important to have effective communication. Which is not the responsibility of the audit team leader?

- A. Confirming formal communication channels between the audit team and the auditee during the opening meeting.
- B. Planning formal communication arrangements, so an auditee can communicate with the auditor any time during the audit.
- C. If audit objectives are unattainable, reporting the reasons to the accreditation body.
- D. Communicating the progress, any significant findings and any concerns to the auditee and audit client, as appropriate.

**Answer: C**

**NEW QUESTION # 69**

You are carrying out an audit at an organisation seeking certification to ISO 9001 for the first time. The organisation offers health and safety training to customers.

You are interviewing the Quality Systems Manager (QSM).

You: "What risks and opportunities have the business identified?"

QSM: "I'll show you. This was discussed with the Managing Director at the latest management review." Narrative: The QSM shows you the latest management review record and points to the following table:

Reference	Risks and Opportunities
1	Nine of the 10 employed trainers are retiring within next 12 months
2	Changes to health and safety legislation imminent
3	Market information indicates increasing preference for technology-driven, self-paced training
4	Customer feedback highlights need for multi-language health and safety training

You: "How is the business planning to address these risks and opportunities?" QSM: "The MD said that they already knew about them so it was not necessary."

You decide to raise a non-conformity.

Non-conformity report	
ISO 9001 Clause Number:	
Nature of problem:	
ISO 9001 requirement that has not been fulfilled:	

To complete the non-conformity report, 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 the options to the appropriate blank section.

6.1.1      6.1.2 a      Several risks and opportunities have not been determined.

Actions to address risks and opportunities not recorded.      ISO 9001 - "The organization shall consider the requirements referred to in 4.2 and determine the risks and opportunities that need to be addressed."

ISO 9001 - "The organization shall plan actions to address risks and opportunities."      ISO 9001 - "The organization shall establish quality objectives needed for the quality management system."      6.1.2 b

Actions to address risks and opportunities not planned.

**Answer:**

Explanation:

You decide to raise a non-conformity.

Non-conformity report	
ISO 9001 Clause Number:	6.1.1
Nature of problem:	Several risks and opportunities have not been determined.
ISO 9001 requirement that has not been fulfilled:	ISO 9001 - "The organization shall consider the requirements referred to in 4.2 and determine the risks and opportunities that need to be addressed."

To complete the non-conformity report, click on the blank section of the report, click on the applicable text from the options below. Alternatively, you may drag and drop the options to the appropriate blank section.

6.1.1	6.1.2 a	Several risks and opportunities have not been determined.
Actions to address risks and opportunities not recorded.	ISO 9001 - "The organization shall consider the requirements referred to in 4.2 and determine the risks and opportunities that need to be addressed."	
ISO 9001 - "The organization shall plan actions to address risks and opportunities."	ISO 9001 - "The organization shall establish quality objectives needed for the quality management system."	6.1.2 b
Actions to address risks and opportunities not planned.		

Explanation:

Non-Conformity Report:

ISO 9001 Clause Number

Nature of Problem

ISO 9001 Requirement That Has Not Been Fulfilled

6.1.1

Several risks and opportunities have not been determined.

"The organization shall consider the requirements referred to in 4.2 and determine the risks and opportunities that need to be addressed."

6.1.2 (a)

Actions to address risks and opportunities not planned.

"The organization shall plan actions to address risks and opportunities." Step-by-Step Reasoning:

Clause 6.1.1 - Determining Risks and Opportunities:

Requirement: The organization must determine risks and opportunities that are relevant to its Quality Management System (QMS).

This ensures that the QMS achieves intended results and prevents undesired effects.

Problem Identified: While some risks and opportunities were discussed, the organization did not perform a systematic evaluation of all risks (e.g., health and safety legislation changes, retiring trainers).

Clause 6.1.2 (a) - Planning Actions for Risks and Opportunities:

Requirement: The organization must plan actions to address identified risks and opportunities. These actions should be integrated into the QMS processes to ensure continuous improvement.

Problem Identified: The Quality Systems Manager confirmed that no plans were made to address the risks and opportunities because the Managing Director deemed it unnecessary. This violates the requirement to plan actions.

Correct Options Selected:

Clause 6.1.1 with the nature of the problem as: "Several risks and opportunities have not been determined." Clause 6.1.2 (a) with the nature of the problem as: "Actions to address risks and opportunities not planned." ISO 9001 Requirements Not Fulfilled:

For 6.1.1: "The organization shall consider the requirements referred to in 4.2 and determine the risks and opportunities that need to be addressed." For 6.1.2 (a): "The organization shall plan actions to address risks and opportunities."

NEW QUESTION # 70

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