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## PECB QMS ISO 9001:2015 Lead Auditor Exam Sample Questions (Q181-Q186):

### NEW QUESTION # 181

Match the following potential audit client options to the type of audit.

First-party Management System audit	Second-party Management System audit

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, drag and drop each option to the appropriate blank section.

Options:

- Accreditation body
- Interested parties of an organisation
- Functions of an organisation that has been audited
- Top management of an audited organisation
- All members of an audited organisation
- Certification body

**Answer:**

**Explanation:**

First-party Management System audit	Second-party Management System audit
All members of an audited organisation	Interested parties of an organisation

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, drag and drop each option to the appropriate blank section.

Options:

- Accreditation body
- Interested parties of an organisation
- Functions of an organisation that has been audited
- Top management of an audited organisation
- All members of an audited organisation
- Certification body

**Explanation:**

First-party Management System audit # All members of an audited organisation  
 Second-party Management System audit # Interested parties of an organisation  
 According to ISO 19011:2018 (Guidelines for Auditing Management Systems) and as reinforced in ISO

9001 Lead Auditor training materials, audit types are defined as:

- \* First-party audit - conducted by the organization itself, or on its behalf (internal audit).# The audit client is all members of the audited organisation, because the audit is internal, involving all functional areas under the organization's control.
- \* Second-party audit - conducted by a customer or other person on behalf of a customer (external but not by a certification body).# The audit client includes interested parties of an organisation, such as customers who want to verify if their suppliers meet contractual or regulatory requirements.

These definitions are directly aligned with ISO 19011:2018, Clause 3.13 - Types of audits.

Why Other Options Are Incorrect:

- \* Certification body / Accreditation body # These relate to third-party audits, not first or second.
- \* Top management / Functions of an audited organisation # Refer to auditees or audit participants, not the audit client itself

References:

ISO 19011:2018 Clause 3.13 - Types of audits

ISO 9001:2015 Clause 9.2 - Internal audit

ISO Definitions for First-party, Second-party, and Third-party audits

**NEW QUESTION # 182**

State the correct sequence of events in the certification process for an organisation to obtain third-party accredited certification to ISO 9001.

State the correct sequence of events in the certification process for an organisation to obtain third-party accredited certification to ISO 9001.

Event	
1	
2	
3	
4	

To complete the sequence, click on the blank section you want to complete so that it is highlighted in red, and then click on the applicable text from the options below. Alternatively, drag and drop the options to the appropriate blank section.

Conduct certification audit stages    Accredited Certification Body    Award ISO 9001 certificate    Programme initial certification audit

**Answer:**

**Explanation:**

State the correct sequence of events in the certification process for an organisation to obtain third-party accredited certification to ISO 9001.

Event	
1	Programme initial certification audit
2	Conduct certification audit stages
3	Award ISO 9001 certificate
4	Accredit Certification Body

To complete the sequence, click on the blank section you want to complete so that it is highlighted in red, and then click on the applicable text from the options below. Alternatively, drag and drop the options to the appropriate blank section.

Conduct certification audit stages    Accredited Certification Body    Award ISO 9001 certificate    Programme initial certification audit

Reference: ISO 9001:2015 Clause 9.2 emphasizes the planning of audits and their scheduling to achieve desired results.

Step 2: Conduct Certification Audit StagesThe certification process includes a two-stage audit.

Stage 1 Audit: Review of documentation to verify readiness and understanding of the Quality Management System (QMS).

Stage 2 Audit: A detailed evaluation of the implementation and effectiveness of the QMS against ISO 9001 requirements.Reference: Clause 8.1 of ISO 9001:2015 discusses operational planning and control, which includes the preparation for audit activities.

Step 3: Award ISO 9001 CertificateAfter successfully completing the certification audits and resolving any identified non-conformities, the certification body awards the ISO 9001 certificate. This certificate demonstrates that the organization's QMS meets the ISO 9001 standard.Reference: Clause 10 of ISO 9001:

2015 focuses on continual improvement and conformity, which leads to the certification issuance.

Step 4: Accredited Certification BodyCertification bodies must be accredited to ensure they meet international standards for certification. Accreditation is conducted by bodies like UKAS (United Kingdom Accreditation Service) or ANAB (ANSI National Accreditation Board), ensuring the credibility and global acceptance of the certification process.Reference: Clause 7.1.5 of ISO 9001 covers resource monitoring, which supports the integrity of the certification process.

By following these steps, organizations can ensure an effective and compliant certification process, achieving ISO 9001 certification.

**NEW QUESTION # 183**

You are carrying out an audit at a single-site organisation seeking certification to ISO 9001 for the first time.

The organization manufactures cosmetics for major retailers.

You are interviewing the Manufacturing Manager (MM).

You: "I would like to begin by looking at the cleaning controls."

MM: "We record the cleaning of the equipment at the end of every batch. This document details the minimum cleaning frequency and the procedures to follow for all areas and each item of equipment. The person who carries out the cleaning puts their initial on the document and records the time and date alongside." Narrative: You sample production records over 3-days and note down evidence of nonconformity as per the table below.

Date	Batches of product made	Production line to be cleaned	Cleaned by	Number of cleaning records
10/XX	10	Line 1	DS	6
	14	Line 2	HM	8
11/XX	12	Line 1	WR	7
	12	Line 2	DD	9
12/XX	15	Line 1	DS	10

You decide to raise a nonconformity.

Nonconformity report	
ISO 9001 Clause Number:	<input type="text"/>
Nature of problem:	<input type="text"/>
ISO 9001 requirement that has not been fulfilled:	<input type="text"/>
Evidence:	40 cleaning records are available for 63 batches.

To complete the nonconformity 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.

Cleaning and sanitising not always completed.

**ISO 9001** - "The organization shall implement planned arrangements, at appropriate stages, to verify that the product requirements have been met."

Cleaning and sanitising records are not available for every batch.

8.7

8.5.4

**ISO 9001** - "The organization shall preserve the outputs during production provision to the extent necessary to ensure conformity to requirements."

**ISO 9001** - "The organization shall implement production provision under controlled conditions."

Cleaning and sanitising are not always completed by trained staff.

6.2.1

**Answer:**

**Explanation:**

You decide to raise a nonconformity.

Nonconformity report	
ISO 9001 Clause Number:	8.5.4
Nature of problem:	ISO 9001 - "The organization shall implement planned arrangements, at appropriate stages, to verify that the product requirements have been met." 33 batches.
ISO 9001 requirement that has not been fulfilled:	
Evidence:	

To complete the nonconformity 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.

The interface shows several options to be dragged into the report fields:

- Clause 8.5.4:** ISO 9001 - "The organization shall implement planned arrangements, at appropriate stages, to verify that the product requirements have been met."
- Clause 8.7:** ISO 9001 - "The organization shall preserve the outputs during production provision to the extent necessary to ensure conformity to requirements."
- Clause 6.2.1:** ISO 9001 - "The organization shall implement production provision under controlled conditions."
- Evidence:** Cleaning and sanitising are not always completed by trained staff.
- Problem:** Cleaning and sanitising records are not available for every batch.
- Problem:** Cleaning and sanitising not always completed.

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Explanation:

Nonconformity report

ISO 9001 Clause Number: 8.5.4 Nature of problem: Cleaning and sanitising records are not available for every batch. ISO 9001 requirement that has not been fulfilled: ISO 9001 - "The organization shall implement planned arrangements, at appropriate stages, to verify that the product requirements have been met." Evidence: 40 cleaning records are available for 63 batches.

#### NEW QUESTION # 184

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

Answer: B

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.

#### NEW QUESTION # 185

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:

Sean requested unrestricted access to the employees, executives, and documented information of POLKA. Is this in accordance with audit best practices?

- A. Yes, unrestricted access for the internal auditor should be provided by the company
- B. Yes, but the internal auditor should make such a request to the CEO directly as only the CEO of the company can approve such a request
- C. No, such requests are acceptable only if a third-party audit is being conducted

**Answer: A**

Explanation:

Comprehensive and Detailed In-Depth Explanation: According to ISO 19011:2018, Clause 5.3.2 (Access to Information), internal auditors must have unrestricted access to:

\* Employees and executives for interviews and observations.

\* Documented information to verify compliance with ISO 9001.

This ensures a transparent and objective audit process. The CEO's approval (B) is not required unless restricted information is involved.

## NEW QUESTION # 186

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