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## **EXAM PREPARATION GUIDE**

**PECB Certified ISO 9001 Lead Auditor**

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

Topic	Details
Topic 1	<ul style="list-style-type: none"> <li>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.</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>Closing an ISO 9001 audit: The topic focuses on concluding a QMS audit and conducting audit follow-up activities.</li> </ul>
Topic 4	<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>
Topic 5	<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 6	<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>

## PECB QMS ISO 9001:2015 Lead Auditor Exam Sample Questions (Q47-Q52):

### NEW QUESTION # 47

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

The organisation 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.

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

**Answer:**

**Explanation:**

You decide to raise a nonconformity.

Nonconformity report	
ISO 9001 Clause Number:	8.5.4
Nature of problem:	Cleaning and sanitising records are not
ISO 9001 requirement that has not been fulfilled:	ISO 9001 - "The organization shall implement production provision under controlled conditions."
Evidence:	40 clear

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.

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

8.5.4

Cleaning and sanitising not always completed.

Cleaning and sanitising are not always completed by trained staff.

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 planned arrangements, at appropriate stages, to verify that the product requirements have been met."

8.7

Cleaning and sanitising records are not available for every batch.

6.2.1

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 production provision under controlled conditions."
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 a text from the options below. Alternatively, you may drag and drop the options to the appropriate blank section.

#### NEW QUESTION # 48

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 and the name of the retailer supplied appears on the product packaging.

Sales turnover has increased significantly over the past five years.

You are interviewing the new Product Development Manager. You note that a software application called SWIFT is used to help control the product development process.

You have gathered audit evidence as outlined in the table. Match the ISO 9001 clause 8.3 extracts to the audit evidence.



## Audit evidence

## ISO 9001 Clause 8.3 extract

Half of all new products launched in the past 12 months were late.  
The NPD Manager explains he has not got enough people on his team to cope with the demand for new products.

The NPD Manager explains many changes are made to cosmetic formulations during product development owing to retailer feedback. Only when confirmed by the retailer is the agreed formulation documented on SWIFT.

The NPD Manager explains that the customer confirms their approval to proceed with a new formulation by email. These emails are kept on SWIFT.

The NPD Manager shows you evidence of consumer trials that are carried out for some new products prior to full-scale launch.

The NPD Manager explains that an approved external laboratory is used to perform shelf-life stability trials on some formulations during product development.

To complete the table click on the blank section you want to complete so it is highlighted in red and then click on the ISO 9001 clause 8.3 extracts listed below. Alternatively, drag and drop each clause to the audit evidence that applies.

"8.3.2 e) ... internal ... resource needs for the design and development of products ..."

"8.3.2 e) ... external ... resource needs for the design and development of products ..."

"8.3.4 d) ... conducted to ensure that the design and development outputs meet ..."

"8.3.5 ... retain documented information ..."

"8.3.6 ... retain documented information ..."

Answer:

Explanation:

## Audit evidence

Half of all new products launched in the past 12 months were late. The NPD Manager explains he has not got enough people on his team to cope with the demand for new products.

The NPD Manager explains many changes are made to cosmetic formulations during product development owing to retailer feedback. Only when confirmed by the retailer is the agreed formulation documented on SWIFT.

The NPD Manager explains that the customer confirms their approval to proceed with a new formulation by email. These emails are kept on SWIFT.

The NPD Manager shows you evidence of consumer trials that are carried out for some new products prior to full-scale launch.

The NPD Manager explains that an approved external laboratory is used to perform shelf-life stability trials on some formulations during product development.

## ISO 9001 Clause 8.3 extract

"8.3.2 e) ... internal ... resource needs for the design and development of products ..."

"8.3.6 ... retain documented information ..."

"8.3.5 ... retain documented information ..."

"8.3.4 d) ... conducted to ensure that the design and development outputs meet ..."

"8.3.2 e) ... external ... resource needs for the design and development of products ..."

To complete the table click on the blank section you want to complete so it is highlighted in red and then click on the ISO 9001 clause 8.3 extracts listed below. Alternatively, drag and drop each clause to the audit evidence that applies.

"8.3.2 e) ... internal ... resource needs for the design and development of products ..."

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"8.3.6 ... retain documented information ..."

## Audit evidence

Half of all new products launched in the past 12 months were late. The NPD Manager explains he has not got enough people on his team to cope with the demand for new products.

The NPD Manager explains many changes are made to cosmetic formulations during product development owing to retailer feedback. Only when confirmed by the retailer is the agreed formulation documented on SWIFT.

The NPD Manager explains that the customer confirms their approval to proceed with a new formulation by email. These emails are kept on SWIFT.

The NPD Manager shows you evidence of consumer trials that are carried out for some new products prior to full-scale launch.

The NPD Manager explains that an approved external laboratory is used to perform shelf-life stability trials on some formulations during product development.

## ISO 9001 Clause 8.3 extract

"8.3.2 e) ... internal ... resource needs for the design and development of products ..."

"8.3.6 ... retain documented information ..."

"8.3.5 ... retain documented information ..."

"8.3.4 d) ... conducted to ensure that the design and development outputs meet ..."

"8.3.2 e) ... external ... resource needs for the design and development of products ..."

To complete the table click on the blank section you want to complete so it is highlighted in red and then click on the ISO 9001 clause 8.3 extracts listed below. Alternatively, drag and drop each clause to the audit evidence that applies.



#### NEW QUESTION # 49

During an ISO 9001 audit of an electric cable manufacturer, you are reviewing the customer file for XYZ Construction in the Sales Department. This contract specifies that the installation configuration of the cable runs should meet national fire safety standards for Category A.

You discover that the customer later agreed to the approval of a less stringent Category B configuration instead.

The organization has the following quality policy document displayed in the reception area.

"This organization is committed to providing electric cables to customers' requirements, in accordance with statutory regulations for their use. Continual improvement is a permanent objective of the organization. This policy shall be communicated to all employees and, where required, to all interested parties." Referring to the scenario, select the two options for which the organization is meeting its policy commitments.

- A. The organization's processes deliver the intended products.
- **B. The organization communicates its policy to external parties.**
- **C. The organization satisfies its customers' requirements.**
- D. The organization has opportunities for continual improvement.
- E. The organization meets all statutory requirements.
- F. The organization has a strong customer approval rating.

**Answer: B,C**

#### NEW QUESTION # 50

Which action indicates that an organization is meeting the requirements of ISO 9001 regarding nonconforming outputs?

- A. Verifying conformity to the applicable requirements prior to correction of the nonconforming outputs.
- B. Allowing employees to handle nonconformities based on their own judgment without structured procedures.
- C. Retaining documented information only on the actions taken.
- **D. Taking appropriate action to nonconforming products and services detected after the delivery of products, during or after the provision of services.**

**Answer: D**

Explanation:

Comprehensive and Detailed In-Depth Explanation:

ISO 9001:2015 requires organizations to identify and control nonconforming outputs to prevent unintended use or delivery.

Clause References:

\* Clause 8.7 (Control of Nonconforming Outputs): Organizations must ensure that nonconforming outputs are identified and controlled to prevent unintended use or delivery.

\* Clause 10.2 (Nonconformity and Corrective Action): Requires organizations to take appropriate actions when nonconformities are found, including during or after service provision.

Why is the Correct Answer C?

\* If nonconforming products or services are identified after delivery or during service, organizations must take corrective actions to protect customers and stakeholders.

\* Actions may include recalls, rework, customer notifications, compensation, or process improvements.

\* This approach aligns with ISO 9001:2015, ensuring that products/services consistently meet requirements.

Why are the Other Options Incorrect?

\* A (Retaining documentation only) # While documentation is required, it alone does not ensure proper handling of nonconforming outputs.

\* B (Verifying conformity before correction) # While verification is good practice, ISO 9001 prioritizes corrective action over mere verification.

\* D (Allowing employees to handle nonconformities without structure) # ISO 9001 requires documented procedures for handling nonconformities (Clause 8.7).

#### NEW QUESTION # 51

In the context of a third-party audit, match the event with the responsibility for conducting it.

Event	Responsibility
Selecting audit team	
Conducting the audit	
Preparing the audit plan	
Requesting the audit	

To complete the table, 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 each option to the appropriate blank section.

Individual(s) managing the audit programme

Audit team

Audit team leader

Audit client

**Answer:**

**Explanation:**

Event	Responsibility
Selecting audit team	Individual(s) managing the audit programme
Conducting the audit	Audit team
Preparing the audit plan	Audit team leader
Requesting the audit	Audit client

To complete the table, 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 each option to the appropriate blank section.

Individual(s) managing the audit programme

Audit team

Audit team leader

Audit client

**Explanation:**

The correct answer is:

Event

Selecting audit team = Individual(s) managing the audit programme

Conducting the audit = Audit team

Preparing the audit plan = Audit team leader

Requesting the audit = Audit client

To complete the table, 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 each option to the appropriate blank section. Responsibility:- Individual(s) managing the audit programme Audit team Audit team leader Audit client According to ISO 19011:2018, clause 5.3, the individual(s) managing the audit programme are responsible for selecting the audit team, taking into account the competence and availability of the auditors and any experts needed. 1 According to clause 6.2, the audit team is responsible for conducting the audit, which includes collecting and verifying audit evidence, evaluating audit findings, and preparing the audit report. 1 According to clause 6.1, the audit team leader is responsible for preparing the audit plan, which includes defining the audit objectives, scope, criteria, and duration, as well as assigning roles and responsibilities to the audit team members. 1 According to clause 5.2, the audit client is the person or organization that requests the audit, which can be the auditee (the person or organization being audited) or any other person or organization that has an interest in the audit results. 1 References:

\* 1: ISO 19011:2018 - Guidelines for auditing management systems

## NEW QUESTION # 52

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