

有效的最新ISO-9001-Lead-Auditor考證和資格考試中的 領導者和非常好的PECB QMS ISO 9001:2015 Lead Auditor Exam



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PECB ISO-9001-Lead-Auditor 考試大綱：

主題	簡介
主題 1	<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.
主題 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.
主題 3	<ul style="list-style-type: none">• Preparing an ISO 9001 audit: This topic covers sub-topics related to preparing a quality management system audit.
主題 4	<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.
主題 5	<ul style="list-style-type: none">• Conducting an ISO 9001 audit: It evaluates your skills to conduct a QMS audit.

>> 最新ISO-9001-Lead-Auditor考證 <<

PECB ISO-9001-Lead-Auditor考題寶典，ISO-9001-Lead-Auditor真題材料

PECB的ISO-9001-Lead-Auditor考試認證是屬於那些熱門的IT認證，也是雄心勃勃的IT專業人士的夢想，這部分考生需要做好充分的準備，讓他們在ISO-9001-Lead-Auditor考試中獲得最高分，使自己的配置檔相容市場需求。

最新的 ISO 9001 ISO-9001-Lead-Auditor 免費考試真題 (Q206-Q211):

問題 #206

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 financial risks associated with QMS implementation.
- C. The previous audit results.
- **D. The processes deemed material to the auditee.**

答案: D

解題說明:

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

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

Reference:

ISO 19011:2018, Clause 6.3 - Managing Audit Risk

問題 #207

Scenario 6: Davis Clinic (DC) is an American medical center focused on integrated health care. Since its establishment DC was committed to providing qualitative services for its clients, which is the reason why the company decided to implement a quality management system (QMS) based on ISO 9001. After a year of having an active QMS in place, DC applied for a certification audit.

A team of five auditors, from a well-known certification body, was selected to conduct the audit. Eva was appointed as the audit team leader. After three days of auditing, the team gathered to review and examine their findings. They also discussed the audit findings with DC's top management and then drafted the audit conclusions.

In the closing meeting, which was held between the audit team and the top management of DC. Eva presented two nonconformities that were detected during the audit. Eva stated that the company did not retain documented information regarding its outsourced services for an analysis laboratory and regarding the conducted management reviews. During the closing meeting, the audit team required from DC's top management to come up with corrective action plans within two weeks. Although the top management did not agree with the audit findings, the audit team insisted that the auditee must submit corrective actions within the given time frame in order for the audit activities to continue.

Once the action plans were evaluated, the audit team began preparing the audit report. Eva required from the team to provide accurate descriptions of the audit findings and the audit conclusions. The report was then distributed to all the interested parties involved in the audit, including the certification body. Based on the report, the certification body together with Eva, as the audit team leader, made the certification decision.

Based on the scenario above, answer the following question:

According to Scenario 6, the audit team required DC's top management to submit corrective action plans within two weeks. Is this action acceptable?

- A. No, because the deadline for the client to present a corrective action plan is at least within 7 days
- **B. Yes, because a deadline from 10 to 60 days is a best practice for the submission of action plans**
- C. No, because the decision for the deadline should have been suggested by the top management

答案: B

解題說明:

Comprehensive and Detailed In-Depth Explanation:

ISO 17021-1:2015, Clause 9.4.9 (Corrective Actions) states:

* The auditor can set a reasonable deadline for corrective actions.

* 10 to 60 days is a best practice timeframe for the auditee to respond.

* The auditee must propose corrective actions, but the audit team has the authority to set the deadline

A 7-day deadline (A) is too short, and the audit team-not the auditee-determines the timeframe (B).

Reference:

ISO 17021-1:2015, Clause 9.4.9 (Corrective Actions)

問題 #208

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

答案: D,F

解題說明:

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.

問題 #209

You are the supervisor in Production of a medium size manufacturing organisation. You are qualified as an internal auditor. The Quality Manager asks you to lead the next internal audit of Production and Logistics Dispatch. The audit team includes two other internal auditors.

You are the supervisor in Production of a medium size manufacturing organisation. You are qualified as an internal auditor. The Quality Manager asks you to lead the next internal audit of Production and Logistics / Dispatch. The audit team includes two other internal auditors.

*if practicable

*You should not ...

You need not ...

You must ...

You must not ...

You should ...

To complete the sentences 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 the options to the appropriate blank section.

audit production carry out a formal opening meeting raise audit findings if necessary change the audit team send the audit report to the Quality Manager

答案:

解題說明:

You are the supervisor in Production of a medium size manufacturing organisation. You are qualified as an internal auditor. The Quality Manager asks you to lead the next internal audit of Production and Logistics / Dispatch. The audit team includes two other internal auditors.

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audit production carry out a formal opening meeting raise audit findings if necessary change the audit team send the audit report to the Quality Manager

Explanation:

Here is the correct matching of actions to the statements in the context of leading the internal audit:

- * If practicable carry out a formal opening meeting
- * You should not audit production (as you are a supervisor in that area, and this would compromise audit objectivity)
- * You need not change the audit team (unless there is a specific reason, such as conflict of interest)
- * You must raise audit findings if necessary (this is a key responsibility of an auditor when nonconformities are found)
- * You must not send the audit report to the Quality Manager (the audit report must be reviewed first; it is typically part of the internal audit process to go through necessary channels before final submission)
- * You should send the audit report to the Quality Manager (after appropriate reviews and approvals) This reflects key principles of conducting an internal audit according to ISO 9001:2015, ensuring objectivity, proper documentation, and clear reporting procedures.

問題 #210

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."

Cleaning and sanitising are not always completed by trained staff.

6.2.1

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

答案:

解題說明:

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." 63 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.

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.

問題 #211

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