

# HOT Sample ISO-9001-Lead-Auditor Test Online - PECB QMS ISO 9001:2015 Lead Auditor Exam - Latest Exam ISO-9001-Lead-Auditor Outline

## ISO 9001 Lead Auditor Sample Exam Questions and Answers:

There are 4 sections in the ISO 9001 QMS Lead Auditor examination as illustrated in table 1 below. In this ISO 9001 lead auditor sample exam questions and answer article, we will examine one question per section and provide their answers.

In table 1 you can find the question break-ups and the passing scores.

*Table 1: ISO 9001 Exam Section and Question break-up*

Section	No of Questions	Minimum Pass Mark	Maximum Pass Mark
1	5	4.5	10
2	4	9.5	20
3	3	14.5	30
4	3	14.5	30
Total	15	62.5	90

Table 1 shows us the total available and minimum marks to pass each section. It is mandatory to pass each section. For example: if you have scored 6 marks on section 1, 18 marks on section 2, 10 marks on section 3 & 30 marks on section 4, your subtotal would be 64 marks. Though you have scored a total of 64 marks, since you haven't scored the minimum passing marks on section 3, it will still be considered a failure.

Now let's look at a few sample exam questions in each section.

### Section 1:

This section has 5 questions and each carries 2 marks,

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### PECB QMS ISO 9001:2015 Lead Auditor Exam Sample Questions (Q175-Q180):

#### NEW QUESTION # 175

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. No, because the decision for the deadline should have been suggested by the top management
- C. Yes, because a deadline from 10 to 60 days is a best practice for the submission of action plans

**Answer: C**

Explanation:

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)

#### NEW QUESTION # 176

During a third-party surveillance audit, the auditor finds that the management review meeting minutes record that the improvement actions set by the previous review have not been completed for a second year running. It states that a new Quality Manager has been brought in at the middle management level to rectify the situation.

You learn that top management is not involved in the QMS other than being copied into the minutes of the management review

meeting.

The audit reveals that the new Quality Manager was given responsibility by top management to:

- a) take accountability for the effectiveness of the QMS,
- b) select, approve, and monitor improvement actions without involving and reporting to top management, c) promote the improvement of the QMS, and d) make efficient use of the limited financial and personnel resources allocated for the QMS by top management.

The auditor considers whether there is a nonconformity against clause 5.1.1 of ISO 9001:2015.

Select two options of the evidence required for such a nonconformity:

- **A. Top management is not accountable for the effectiveness of the QMS.**
- **B. The Quality Manager does not have access to the resources needed for the QMS.**
- C. The Chief Executive never attends the management review meetings in person.
- D. The Quality Manager avoids giving improvement actions to the Chief Executive.
- E. The Quality Manager is on target to complete only half of the improvement actions.
- F. The Quality Manager only reports to one designated senior manager.

**Answer: A,B**

Explanation:

Comprehensive and Detailed In-Depth Explanation:

Clause 5.1.1 of ISO 9001:2015 - Leadership and Commitment - specifically mandates that top management must take accountability for the effectiveness of the QMS. They are also responsible for ensuring:

- \* Integration of the QMS into business processes (5.1.1 c)
- \* Promotion of customer focus and continual improvement (5.1.1 d, i)
- \* Availability of necessary resources (5.1.1 e)
- \* That the QMS achieves its intended results (5.1.1 g)

Let's analyze the selected options:

# A. Top management is not accountable for the effectiveness of the QMS.

This directly violates clause 5.1.1 a, which explicitly requires top management to take accountability for the effectiveness of the QMS. Delegating this to a middle-level Quality Manager, as described in the scenario, constitutes a nonconformity.

# F. The Quality Manager does not have access to the resources needed for the QMS.

According to clause 5.1.1 e, top management must ensure the availability of required resources for maintaining and improving the QMS. If the Quality Manager is resource-constrained, it indicates top management has failed to meet this requirement.

Now, why the other options are incorrect in terms of direct clause 5.1.1 nonconformity:

# B. Avoiding giving improvement actions to the Chief Executive - While this may reflect poor communication, it is not, by itself, a clear breach of 5.1.1 unless linked directly to top management's lack of accountability or commitment.

# C. Chief Executive never attending meetings - ISO 9001 does not require physical attendance of the Chief Executive at management reviews. What matters is whether top management is fulfilling their roles, not how.

# D. Completing only half of improvement actions - This indicates performance issues but does not necessarily indicate top management's lack of accountability, unless they failed to monitor progress entirely.

# E. Reporting to one designated senior manager - This is not inherently nonconforming unless that senior manager does not fulfill top management's responsibilities under 5.1.1.

Relevant ISO 9001:2015 Reference:

\* Clause 5.1.1 a, e, g, h:

"Top management shall demonstrate leadership and commitment with respect to the quality management system by:

- a) taking accountability for the effectiveness of the quality management system; e) ensuring that the resources needed for the quality management system are available..."

## NEW QUESTION # 177

Knowledge and skills are requirements of the auditor's competence. Select two from the following topics of knowledge that apply to every member of an audit team auditing an ISO 9001 quality management system.

- **A. ISO 19011 Audit principles**
- B. Organisation's processes
- C. Organisation's market sector
- **D. Requirements of ISO 9001**
- E. Requirements of auditee's interested parties other than customers
- F. Organisation's invoicing and profits of the last 5 years

**Answer: A,D**

Explanation:

According to ISO 9001:2015, clause 7.2, an auditor shall have the competence to:

- \* Understand the requirements of ISO 9001 and how they relate to the audit
- \* Understand the organization's quality management system and its processes
- \* Understand the applicable legal, regulatory, contractual and other requirements that affect the audit
- \* Understand the needs and expectations of interested parties other than customers
- \* Plan and conduct audits in accordance with ISO 19011
- \* Evaluate audit evidence and draw appropriate conclusions
- \* Communicate audit findings effectively<sup>1</sup>

Therefore, knowledge of ISO 9001 requirements and ISO 19011 audit principles are essential for every member of an audit team auditing an ISO 9001 quality management system.

References:

- \* ISO 9001:2015 - Quality management systems - Requirements
- \* ISO 19011:2018 - Guidelines for auditing management systems

### NEW QUESTION # 178

When should the certification body accept the audit?

- A. Only if the auditee has no previous major nonconformities.
- B. After considering the nature of the operations of the auditee.
- C. After considering the integrity and reputation of the auditee.
- **D. Both A and B.**

**Answer: D**

Explanation:

Comprehensive and Detailed In-Depth Explanation:

Before accepting an audit, the certification body must assess the integrity of the auditee and the nature of its operations to ensure compliance feasibility.

Clause References:

\* ISO/IEC 17021-1:2015, Clause 9.1.2 - Audit Planning:

\* The certification body must review the auditee's background, reputation, and operational complexity before accepting the audit.

Why is the Correct Answer C?

- \* The auditee's integrity and reputation impact the credibility of certification.
- \* The nature of operations determines audit complexity and resource allocation.

Why are the Other Options Incorrect?

- \* A (Integrity and reputation only) # Correct but incomplete; nature of operations is equally important.
- \* B (Nature of operations only) # Integrity is also a factor, not just operations.
- \* D (No previous major nonconformities required) # Auditees with past major nonconformities can still be audited if corrective actions are taken.

Reference:

ISO/IEC 17021-1:2015, Clause 9.1.2 - Audit Planning

### NEW QUESTION # 179

You are conducting a third-party audit to ISO 9001 and interviewing the Training Manager. She explains that training is more important than ever because the organisation has had to reduce the number of staff employed. Many of the remaining staff are now required to be 'multi-skilled'. You ask to see plans for the multi-skilling training and are shown plans that look comprehensive, and include both 'on the job' training and internal and external training courses.

The records indicate that several staff required parts of their training to be repeated one month after the first training was provided. You ask why this was needed and are told that an investigation of customer complaints identified that several staff members did not complete certain tasks in the correct manner. The extra training was therefore recommended as a corrective action.

Based on this interview, which two of the following audit trails would be the most appropriate to follow?

Select the two most appropriate audit trails from the following.

- A. Determine whether customers were consulted about the risks associated with the multi-skilling training.
- **B. Ask if customer complaints had ceased since the multi-skilled training finished.**
- C. Ask the members of staff whether they found the training received useful.
- D. Determine whether management has assessed the impact of staff reduction on the organisation's ability to meet its

objectives.

- E. Review records to assess if all planned training has been completed.
- F. Assess whether Quality objectives are being met.

**Answer: B,E**

Explanation:

When conducting a third-party audit to ISO 9001, especially in the context of training and corrective actions taken due to customer complaints, the most appropriate audit trails to follow would be:

A: Ask if customer complaints had ceased since the multi-skilled training finished. This audit trail is relevant because it directly relates to the effectiveness of the corrective action taken. If customer complaints have decreased or ceased, it could indicate that the additional training was effective<sup>1</sup>.

F: Review records to assess if all planned training has been completed. This trail is important to ensure that the training plan has been fully implemented and to verify that all staff members have received the necessary training. It also helps in assessing the adequacy of the training in terms of content, frequency, and outcomes<sup>1</sup>.

These two trails, A and F, are closely linked to the issue of customer complaints and the organization's response to them. They provide insight into whether the actions taken were suitable and whether they have led to improvements in staff performance and customer satisfaction<sup>1</sup>. The other options, while potentially useful, do not directly address the immediate concern of the effectiveness of the corrective actions taken in response to the customer complaints<sup>1</sup>.

## NEW QUESTION # 180

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