Exam ISO-9001-Lead-Auditor Review & ISO-9001-Lead-Auditor Exam Study Solutions

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 ISO-9001-Lead-Auditor Exam Syllabus Topics:

Topic	Details
Topic 1	• Preparing an ISO 9001 audit: This topic covers sub-topics related to preparing a quality management system audit.
Topic 2	• Fundamental audit concepts and principles: Questions about interpreting and applying the main concepts and principles related to a QMS audit appear in this topic.

Topic 3	• 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.
Topic 4	• Closing an ISO 9001 audit: The topic focuses on concluding a QMS audit and conducting audit follow-up activities.
Topic 5	• Managing an ISO 9001 audit program: This topic evaluates your abilities to establish and managing a QMS audit program.

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PECB QMS ISO 9001:2015 Lead Auditor Exam Sample Questions (Q188-Q193):

NEW QUESTION # 188
What must the auditor consider in order to mitigate audit risks and obtain reasonable assurance?

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

Answer: D

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 # 189
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.

NEW QUESTION # 190

Scenario 2:
Bell is a Canadian food manufacturing company that operates globally. Their main products include nuts, dried fruits, and confections. Bell has always prioritized product quality and has maintained a good reputation for many years. However, the company's production error rate increased significantly, leading to more customer complaints.
To increase efficiency and customer satisfaction, Bell implemented a Quality Management System (QMS) based on ISO 9001. The top management established a QMS implementation team comprising five middle managers from various departments, including Leslie, the quality manager.
Leslie was responsible for assigning responsibilities and authorities for QMS-related roles. He also suggested including a top management representative in the QMS team, but top management declined due to other priorities.
The team defined the QMS scope as:
"The scope of the QMS includes all activities related to food processing." Leslie established a quality policy and presented it to the team for review before top management approval
. Top management also proposed a new strategy for handling customer complaints, requiring biweekly customer surveys to monitor customer perceptions.
The quality policy was established by Leslie and approved by top management. Is this acceptable?
Please refer to scenario 2.

- A. Yes, the quality policy can be established by the QMS implementation team and be approved by top management.
- B. No, the quality policy must be established and approved by top management.
- C. Yes, as long as top management is informed, the policy can be established by any responsible employee.
- D. No, the quality policy must be established and approved only by the quality manager.

Answer: B

Explanation:
Comprehensive and Detailed In-Depth Explanation:ISO 9001:2015, Clause 5.2.1 (Establishing the Quality Policy) states that top management must establish, implement, and maintain a quality policy.
In the scenario, the quality manager (Leslie) created the policy, but top management did not establish it themselves, which violates Clause 5.2.1. While the policy can be drafted by a team, top management must take full ownership of its development and approval.

NEW QUESTION # 191

Which one of the following documents addresses audit time calculation for third-party certification audits?

- A. ISO 17021-1
- B. ISO 19011
- C. ISO 9001
- D. ISO 9000

Answer: A

Explanation:
ISO/IEC 17021-1 is the standard that specifies requirements for bodies providing audit and certification of management systems. It includes provisions for determining audit time for third-party certification audits, ensuring that the audits are conducted in a consistent, comparable, and reliable manner, which can be applied to a variety of management systems, including ISO 9001.
References: ISO/IEC 17021-1; IAF Mandatory Document for the Determination of Audit Time of Quality and Environmental Management Systems Certification

NEW QUESTION # 192
Which two of the following auditors would not participate in a first-party audit?

- A. An auditor from a customer
- B. An auditor trained in the IRCA scheme
- C. An auditor certified by IRCA
- D. An auditor employed by an external consultancy organisation
- E. An auditor trained in-house
- F. An auditor from an interested party

Answer: A,D

Explanation:
A first-party audit is an internal audit conducted by auditors who are employed by the organization being audited but who have no vested interest in the audit results of the area being audited1. The purpose of a first-party audit is to assess the conformity of the organization's quality management system to the requirements of ISO 9001 and to identify opportunities for improvement2.
Therefore, the two auditors who would not participate in a first-party audit are:
*A. An auditor employed by an external consultancy organization: This auditor is not employed by the organization being audited, and therefore does not qualify as a first-party auditor. This auditor may be hired to conduct a second-party audit (if the external consultancy organization is a customer or supplier of the organization being audited) or a third-party audit (if the external consultancy organization is a certification body or registrar).
*F. An auditor from a customer: This auditor is not employed by the organization being audited, and therefore does not qualify as a first-party auditor. This auditor may be hired to conduct a second-party audit, as a customer is an interested party that has specific requirements for the organization being audited.
The other options are not correct, as they could participate in a first-party audit, as long as they are employed by the organization being audited and have no vested interest in the audit results of the area being audited:
*B. An auditor from an interested party: This auditor could be a first-party auditor, as long as the interested party is within the organization being audited. For example, an auditor from the finance department could audit the production department, as long as they are not involved in the production process or affected by its outcomes.
*C. An auditor trained in-house: This auditor could be a first-party auditor, as long as they are employed by the organization being audited and have no vested interest in the audit results of the area being audited. The source of the auditor's training is not relevant for determining the type of audit, as long as the auditor is competent and qualified to perform the audit.
*D. An auditor trained in the IRCA scheme: This auditor could be a first-party auditor, as long as they are employed by the organization being audited and have no vested interest in the audit results of the area being audited. The IRCA scheme is a professional certification scheme for auditors of management systems, which provides recognition of the auditor's competence and credibility3. However, being trained in the IRCA scheme does not determine the type of audit, as long as the auditor is competent and qualified to perform the audit.
*E. An auditor certified by IRCA: This auditor could be a first-party auditor, as long as they are employed by the organization being audited and have no vested interest in the audit results of the area being audited. Being certified by IRCA means that the auditor has met the requirements of the IRCA scheme and has demonstrated their competence and credibility as an auditor of management systems3. However, being certified by IRCA does not determine the type of audit, as long as the auditor is competent and qualified to perform the audit.
References: First Party Audits: The 5 Steps to Success - Sync Resource Inc, ISO 9001 Auditing Practices Group, IRCA - International Register of Certificated Auditors

NEW QUESTION # 193
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