

ISO-9001-Lead-Auditor Exam Blueprint & Valid Dumps

ISO-9001-Lead-Auditor Sheet

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	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.
Topic 2	Managing an ISO 9001 audit program: This topic evaluates your abilities to establish and managing a QMS audit program.
Topic 3	Closing an ISO 9001 audit: The topic focuses on concluding a QMS audit and conducting audit follow-up activities.
Topic 4	Fundamental audit concepts and principles: Questions about interpreting and applying the main concepts and principles related to a QMS audit appear in this topic.

PECB QMS ISO 9001:2015 Lead Auditor Exam Sample Questions (Q128-Q133):

NEW QUESTION # 128

Among others, what does Clause 4.4 (Quality Management System and Its Processes) of ISO 9001 require from organizations?

- **A. To continually improve the QMS**
- B. To review the QMS annually
- C. To change the QMS quarterly
- D. To conduct a QMS gap analysis every two years

Answer: A

Explanation:

Comprehensive and Detailed In-Depth Explanation:

ISO 9001:2015 emphasizes continual improvement as a fundamental requirement of an effective Quality Management System (QMS).

Clause Reference:

* Clause 4.4.1 (Quality Management System and Its Processes) states that organizations must:

- * Determine processes needed for the QMS
- * Establish criteria and methods for process effectiveness
- * Ensure continual improvement of the system

Why is the Correct Answer C?

- * Continual improvement is a core principle of ISO 9001.
- * Organizations must regularly assess and enhance their QMS to adapt to new challenges and maintain effectiveness.

Why are the Other Options Incorrect?

- * A (To change the QMS quarterly) # ISO 9001 does not mandate a specific frequency for system changes.
- * B (To review the QMS annually) # QMS reviews must be conducted as needed, not strictly annually.
- * D (To conduct a QMS gap analysis every two years) # Gap analysis is useful but is not a mandatory requirement under Clause 4.4.

Reference:

ISO 9001:2015, Clause 4.4 - Quality Management System and Its Processes

NEW QUESTION # 129

The following are stages of an audit, put them in the order they would be conducted.

The following are stages of an audit, put them in the order they would be conducted.

The first and last stages have been done for you.

To complete the sequence 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.

1. Establishing the audit programme objectives
2.
3.
4.
5.
6. Conducting the audit activities

Determining and evaluating the audit programme risks and opportunities	Preparing all audit activity	Initiating the audit	Establishing the audit programme
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Answer:

Explanation:

The following are stages of an audit, put them in the order they would be conducted.

The first and last stages have been done for you.

To complete the sequence 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.

1. Establishing the audit programme objectives

Determining and evaluating the audit programme risks and opportunities

3. Establishing the audit programme

4. Initiating the audit

5. Preparing all audit activity

6. Conducting the audit activities

Determining and evaluating the audit programme risks and opportunities	Preparing all audit activity	Initiating the audit	Establishing the audit programme
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Explanation:

Establishing the audit programme objectives

Determining and evaluating the audit programme risks and opportunities

Establishing the audit programme

Initiating the audit

Preparing all audit activity

Conducting the audit activities

According to ISO 19011:2018, clause 5, the audit programme is a set of one or more audits planned for a specific time frame and directed towards a specific purpose. The audit programme includes all activities necessary to plan, organize, and conduct the audits.

The audit programme management involves the following steps 1:

Establishing the audit programme objectives: The audit programme objectives define the intended outcomes of the audit programme, such as verifying conformity, evaluating performance, identifying improvement opportunities, etc. The audit programme objectives should be aligned with the strategic direction and policies of the organization and the needs and expectations of the interested parties.

Determining and evaluating the audit programme risks and opportunities: The audit programme risks and opportunities are the factors that can affect the achievement of the audit programme objectives, such as changes in the internal or external context, availability of resources, competence of auditors, etc. The audit programme risks and opportunities should be identified, analyzed, and evaluated to determine the appropriate actions to address them.

Establishing the audit programme: The audit programme is established by defining the audit programme scope, criteria, methods, and resources. The audit programme scope defines the extent and boundaries of the audit programme, such as the processes, functions, sites, activities, etc. that will be audited. The audit programme criteria are the set of policies, procedures, or requirements used as a reference for the audits. The audit programme methods are the techniques used to conduct the audits, such as interviews, observations, document review, sampling, etc. The audit programme resources are the human, technical, and financial resources needed to implement the audit programme.

Initiating the audit: The audit initiation is the process of formally establishing the arrangements for an individual audit within the audit programme. The audit initiation involves contacting the auditee and the audit client, confirming the audit objectives, scope, and criteria, and obtaining the necessary information and access for the audit.

Preparing all audit activity: The audit preparation is the process of developing the audit plan and the audit work documents for an individual audit. The audit plan is a document that provides the basis for agreement regarding the conduct of the audit, such as the audit schedule, the audit team, the audit methods, the audit language, the audit report, etc. The audit work documents are the

records that provide evidence of the audit activities, such as the audit checklist, the audit notes, the audit findings, etc.
Conducting the audit activities: The audit activities are the processes of collecting and verifying audit evidence and evaluating it against the audit criteria to make the audit conclusions. The audit activities include the opening meeting, the communication during the audit, the roles and responsibilities of the audit team and the auditee, the audit evidence collection and verification, the audit findings generation and recording, the closing meeting, and the audit report preparation and distribution.
References: ISO 19011:2018(en), Guidelines for auditing management systems

NEW QUESTION # 130

When monitoring customer perceptions, which analysis is helpful to use?

- A. Competitive benchmarking
- B. PEST analysis
- C. Market-share analysis
- D. Gap analysis

Answer: D

Explanation:

Comprehensive and Detailed In-Depth Explanation:

ISO 9001:2015 requires organizations to measure and monitor customer perceptions to determine whether customer requirements are being met.

Clause Reference:

* Clause 9.1.2 - Customer Satisfaction states that organizations must monitor customer perceptions using relevant methods such as customer surveys, feedback forms, and complaint analysis.

* One of the most effective ways to do this is gap analysis, which identifies differences between customer expectations and actual service or product performance.

Why is the Correct Answer C?

* Gap analysis helps determine discrepancies between current performance and customer expectations, allowing organizations to improve quality.

* It is a standard quality improvement tool used to assess customer satisfaction.

Why are the Other Options Incorrect?

* A (PEST analysis) # Focuses on external macroeconomic factors (Political, Economic, Social, Technological) rather than customer satisfaction.

* B (Market-share analysis) # Examines business performance relative to competitors, not customer perceptions.

* D (Competitive benchmarking) # Involves comparing processes with competitors but does not directly monitor customer perceptions.

NEW QUESTION # 131

Which two of the following work documents are not required for audit planning by an auditor conducting a certification audit?

- A. An organization's financial statement
- B. An evidence sampling strategy
- C. A list of interested parties
- D. A checklist
- E. A career history of the quality manager
- F. An audit plan

Answer: A,E

NEW QUESTION # 132

During a third-party audit of a pharmaceutical organisation (CD9000) site of seven COVID-19 testing laboratories in various terminals at a major international airport, you interview the CD 9000's General Manager (GM), who was accompanied by Jack, the legal compliance expert. Jack is acting as the guide in the absence of the Technical Manager due to him contracting COVID-19. You: "What external and internal issues have been identified that could affect CD9000 and its quality management system?" GM: "Jack guided us on this. We identified issues like probable competition of another laboratory organisation in the airport, legal requirements on COVID-19 continuously changing, the shortage of competent laboratory analysts, the epidemic declining soon, shortage of chemicals for the analysis. It was quite a good experience." You: "Did you document these issues?" GM: "No. Jack said

that ISO 9001 does not require us to document these issues." You: "How did you determine the risks associated with the issues and did you plan actions to address them?" GM: "I am not sure. The Technical Manager is responsible for this process. Jack may be able to answer this question in his absence." Select two options for how you would respond to the General Manager's suggestion:

- A. I would ask for a different guide instead of the legal compliance expert.
- B. I would delay the audit until the return of the technical manager
- C. I would ask the consultant to leave the meeting since he is not an employee of the organisation.
- D. I would look for evidence that the actions resulting from the risk assessment had been taken.
- E. I would not accept the legal compliance expert answering the question.
- F. I would ask to audit the Technical Manager by phone.

Answer: A,D

Explanation:

According to the ISO 9001:2015 standard, clause 4.1 requires organizations to determine the external and internal issues that are relevant to their purpose and that affect their ability to achieve the intended outcomes of their quality management system. Clause 6.1 requires organizations to plan actions to address the risks and opportunities associated with these issues. These actions must be integrated into the quality management system processes and evaluated for effectiveness.

In this scenario, the General Manager of the pharmaceutical organization has shown a lack of understanding and involvement in the process of identifying and addressing the external and internal issues that affect their quality management system. The General Manager has relied on the legal compliance expert, who is not an employee of the organization, to guide them on this process. The General Manager has also admitted that they did not document these issues, which is contrary to the requirement of retaining documented information on the context of the organization. The General Manager has also delegated the responsibility of determining and planning the actions to address the risks and opportunities to the Technical Manager, who is absent due to COVID-19.

Based on this information, you can respond to the General Manager's suggestion by taking two options:

B: I would ask for a different guide instead of the legal compliance expert: You can request to have a different guide who is an employee of the organization and who is familiar with the quality management system processes and the external and internal issues that affect them. The legal compliance expert may not have the necessary knowledge and authority to answer your questions or provide you with the relevant evidence.

C: I would look for evidence that the actions resulting from the risk assessment had been taken: You can verify whether the organization has implemented and evaluated the actions to address the risks and opportunities associated with the external and internal issues. You can look for evidence such as records of risk analysis, action plans, monitoring and review results, and improvement measures.

These two options would help you to assess the conformity and effectiveness of the organization's quality management system with respect to the requirements of clauses 4.1 and 6.1.

NEW QUESTION # 133

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