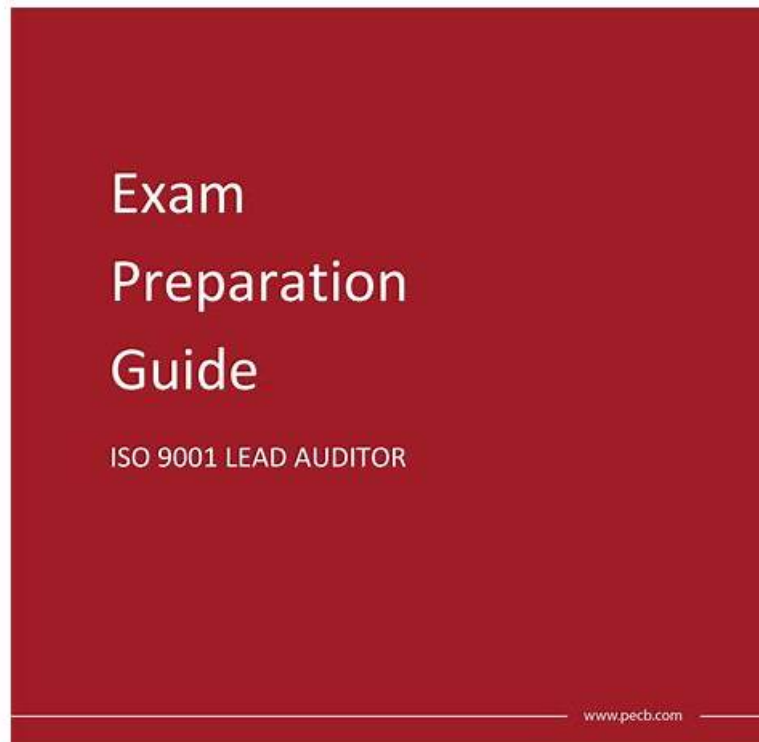


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PECB ISO-9001-Lead-Auditor Exam Syllabus Topics:

Topic	Details
Topic 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.
Topic 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.
Topic 3	<ul style="list-style-type: none">Managing an ISO 9001 audit program: This topic evaluates your abilities to establish and managing a QMS audit program.
Topic 4	<ul style="list-style-type: none">Closing an ISO 9001 audit: The topic focuses on concluding a QMS audit and conducting audit follow-up activities.
Topic 5	<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.

PECB QMS ISO 9001:2015 Lead Auditor Exam Sample Questions (Q186-Q191):

NEW QUESTION # 186

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

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

Answer: B

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 # 187

How much time is usually spent on the Stage 1 audit?

- A. 20% of the total audit time
- B. 40% of the total audit time
- C. 30% of the total audit time

Answer: C

Explanation:

Comprehensive and Detailed In-Depth Explanation:

According to ISO 17021-1:2015 (Conformity Assessment - Requirements for Certification Bodies), Clause 9.3.1.2, the Stage 1 Audit typically consumes around 30% of the total audit time.

This time is allocated to:

Reviewing documented information.

Assessing the readiness for Stage 2.

Identifying potential nonconformities.

A 20% allocation (Answer A) is too low, and 40% (Answer C) is excessive, as the majority of the audit should be spent on Stage 2 (on-site verification).

Reference:

ISO 17021-1:2015, Clause 9.3.1.2 (Determination of Audit Time)

NEW QUESTION # 188

XYZ Corporation employs 100 people, and during a Stage 1 certification audit, certain issues are identified with the Quality Management System (QMS). Which two options describe the circumstances in which you could raise a nonconformity against Clause 6.2 of ISO 9001:2015?

- A. Quality objectives were not established in alignment with the organisation's quality policy.
- B. The consultant has not interpreted ISO 9001 correctly.
- C. The organisation cannot afford to undertake quality objectives all at once.
- D. Quality objectives are not being implemented by the organisation's personnel.
- E. Establishing quality objectives did not include top management.
- F. Quality objectives are not maintained as documented information.

Answer: A,F

Explanation:

Understanding Clause 6.2 of ISO 9001:2015: Clause 6.2 (Quality Objectives and Planning to Achieve Them) specifies that organizations must:

Establish measurable and relevant quality objectives consistent with the quality policy (Clause 6.2.1).

Include objectives applicable to product/service conformity and customer satisfaction.

Document these objectives and their planning as documented information (Clause 6.2.1 & 6.2.2).

Plan how to achieve the objectives, including defining actions, resources, responsibilities, timelines, and methods for evaluation.

Analysis of Options:

A). Quality objectives are not being implemented by the organisation's personnel: Incorrect. While implementation is critical, this relates more to operational aspects rather than the direct requirements of Clause 6.2. Implementation issues would typically raise concerns under Clause 9.1 (Performance Evaluation).

B). The consultant has not interpreted ISO 9001 correctly: Incorrect. The consultant's interpretation of ISO 9001 is irrelevant in terms of Clause 6.2 compliance. The focus is on whether the organization aligns with the requirements, not the consultant's role.

C). Establishing quality objectives did not include top management: Incorrect. While top management involvement is vital for QMS effectiveness (Clause 5.1), this is not a direct requirement of Clause 6.2. Top management alignment is implied but not explicitly mandated for establishing quality objectives.

D). Quality objectives were not established in alignment with the organisation's quality policy: Correct. Clause 6.2.1 requires that quality objectives be consistent with the organization's quality policy, ensuring they reflect its purpose, strategic direction, and commitment to continual improvement. Misalignment would constitute a nonconformity.

E). The organisation cannot afford to undertake quality objectives all at once: Incorrect. Financial constraints are not directly addressed in Clause 6.2. The clause focuses on planning to achieve objectives, which includes defining the necessary resources but does not demand achieving all objectives simultaneously.

F). Quality objectives are not maintained as documented information: Correct. Clause 6.2.1 specifically requires that quality objectives be maintained as documented information. Failure to document the objectives is a direct violation of this clause.

Why Options D and F Are Correct:

D: Misalignment between the quality objectives and the quality policy directly violates Clause 6.2.1, which mandates that objectives

support the strategic direction of the organization.

F: Lack of documentation for quality objectives breaches the requirement to maintain them as documented information under Clause 6.2.1.

Relevant References:

Clause 6.2.1: Establishing quality objectives aligned with the quality policy.

Clause 6.2.2: Maintaining documented information for quality objectives and planning to achieve them.

Clause 5.1.1: Top management's responsibility to ensure alignment between the QMS and strategic direction.

NEW QUESTION # 189

You are carrying out an audit at an organisation seeking certification to ISO 9001 for the first time. The organisation offers health and safety training to customers. Training courses are offered either as open courses, delivered at a public venue, or online, or as courses that are tailored to meet specific requirements.

The business operates from a single office and those who deliver the training are either full-time employees or subcontractors.

You are interviewing the Training Manager (TM).

You: "What quality objectives apply to the training process?"

TM: "One of the quality objectives we aim for is a 90% minimum exam pass rate for all open training courses." You: "How do you measure this objective?" The Training Manager shows you a record on her computer and you see the following:

Month	Exam pass rates (%)					
	Course 1	Course 2	Course 3	Course 4	Course 5	Course 6
1	92	87	89	78	95	97
2	93	86	88	77	94	98
3	94	87	87	79	93	97
4	92	89	86	80	95	96
5	93	88	88	79	96	95
6	95	87	89	77	96	97

Which two of the following statements are true?

- A. You would determine how the exam pass rate figures were analysed.
- B. You would raise a nonconformity as a requirement in clause 8.7 has not been fulfilled.
- C. You would raise a nonconformity as a requirement in clause 10.2 has not been fulfilled.
- D. You would determine what corrective action was being taken to address the low pass rates.
- E. You would check the training of personnel.
- F. You would determine the relative difficulty of each training course by reviewing them.

Answer: A,D

Explanation:

In this scenario, the organization has set a quality objective of achieving a 90% minimum exam pass rate for all courses. The auditor's task is to assess whether this objective is being monitored effectively and if appropriate actions are taken when the objective is not met.

B: You would determine how the exam pass rate figures were analysed: ISO 9001:2015, particularly Clause 9.1 (Monitoring, measurement, analysis, and evaluation), requires organizations to evaluate performance data.

The auditor should verify how the organization analyses the pass rate data to ensure trends are identified, and corrective actions are planned based on this analysis.

D: You would determine what corrective action was being taken to address the low pass rates: When performance falls short of the objective, as seen with Course 4 (where the pass rate is below 90% in all months), Clause 10.2 (Nonconformity and corrective action) requires organizations to take corrective actions to address issues. The auditor would need to check if corrective actions have been initiated to address consistently low pass rates.

Statements A, C, E, and F do not directly address the monitoring and corrective action required under ISO 9001:2015 in this context.

NEW QUESTION # 190

Which of the following is a principle of maintaining audit work documents?

- A. Transparency
- B. Fair presentation
- **C. Completeness**

Answer: C

Explanation:

Comprehensive and Detailed Ir-Depth Explanation:Completeness ensures that all necessary audit evidence, observations, and findings are properly documented, which is critical for traceability and accountability in an audit.

While transparency and fair presentation are principles of auditing, completeness is specifically related to maintaining audit work documents, as required in ISO 19011:2018, Clause 6.5.4 (Preparing Audit Work Documents).

NEW QUESTION # 191

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