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

Topic	Details
Topic 1	<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 2	<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 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"> • Conducting an ISO 9001 audit: It evaluates your skills to conduct a QMS audit.
Topic 5	<ul style="list-style-type: none"> • Preparing an ISO 9001 audit: This topic covers sub-topics related to preparing a quality management system audit.

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PECB QMS ISO 9001:2015 Lead Auditor Exam Sample Questions (Q224-Q229):

NEW QUESTION # 224

An audit team leader arrives at a printing organisation to carry out a Stage 2 audit for a certification body. At a meeting with the Quality Manager, she is told that they have won their biggest contract from a computer manufacturer to print and compile computer documentation packages. They have leased the unit next door for space reasons but have never worked in this sector before. The Quality Manager wants the ISO 9001 certificate to cover the new contract.

During the audit, a team member finds that a number of print jobs have been rejected by several clients over a number of months due to spelling errors in the print run. The Print Manager blames the new employees they had to take on because of a big contract. The auditor raises a nonconformance against clause 10.2.1.b of ISO 9001.

Which one of the evidence statements would support this finding?

- A. There was no record that the organisation evaluated the effectiveness of the training given to new employees.
- B. The organisation did not provide the correct resources to prevent nonconformity.
- C. The actions taken to deal with customer complaints did not prevent recurrence of the problem
- D. There was no evidence that a check of spelling took place before the release of printing to the client.

Answer: C

Explanation:

According to clause 10.2.1.b of ISO 9001:2015, the organization should evaluate the need for action to eliminate the causes of nonconformities, in order to prevent their recurrence. This means that the organization should identify and address the root causes and contributing factors of the nonconformities, and implement appropriate corrective actions that are effective and proportional to the impact of the nonconformities. In this case, the evidence statement that supports the finding of nonconformance is C, because it shows that the organization did not take effective actions to prevent the recurrence of the spelling errors in the print run, which resulted in repeated customer rejections and dissatisfaction. The other options are not directly related to clause 10.2.1.b, although they may indicate other nonconformities or weaknesses in the organization's QMS.

For example, option A may relate to clause 7.2 on competence, option B may relate to clause 8.6 on release of products and services, and option D may relate to clause 7.1 on resources. References: ISO 9001:2015, [ISO 9001 Auditing Practices Group Guidance on Nonconformity and Corrective Action], ISO 9001 Clause 10.

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NEW QUESTION # 225

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. Requirements of ISO 9001

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

Answer: A,B

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 effectively¹

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 # 226

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.

After further auditing, the issues below were found. Select three statements that apply to the term 'audit trail'

- A. Decisions on improvement action timescales not involving departmental managers.
- B. The single quality objective set for the organisation by the Quality Manager.
- C. Quality improvements not aligning with the quality policy.
- D. Top management claim not to be aware of the improvement request (QI/12/20/HR-3) initiated by the Quality Manager.
- E. Evaluation of the results of the improvement action not always documented by the Quality Manager.
- F. Limited knowledge of the content of Quality Improvement Requests by departmental staff.

Answer: A,E,F

Explanation:

Based on the scenario and the concept of an 'audit trail' within the context of ISO 9001, the three statements that apply would likely be:

A: Decisions on improvement action timescales not involving departmental managers. This indicates a lack of involvement and communication with those responsible for implementing the improvements, which is a key part of an effective audit trail¹.

B: Evaluation of the results of the improvement action not always documented by the Quality Manager.

Proper documentation is essential for an audit trail, as it provides evidence that actions have been evaluated and are effective¹.

C: Limited knowledge of the content of Quality Improvement Requests by departmental staff. An audit trail should ensure that all relevant parties are aware of and understand the actions being taken, which is not the case here¹.

These points suggest issues with the communication, documentation, and involvement of relevant personnel in the quality management system processes, which are crucial for maintaining an effective audit trail and, by extension, a robust quality management system.

NEW QUESTION # 227

What type of audit evidence are policies and guidelines?

- A. Confirmative evidence.
- **B. Documentary evidence.**
- C. Technical evidence.

Answer: B

Explanation:

Comprehensive and Detailed In-Depth Explanation:

Policies and guidelines are considered documentary evidence because they are written records that demonstrate how an organization complies with ISO 9001 requirements.

Clause References:

* ISO 19011:2018, Clause 6.4.6 - Audit Evidence:

* Documentary evidence includes manuals, procedures, and policies.

Why is the Correct Answer C?

* Documentary evidence includes written records such as policies, procedures, and documented instructions that support QMS implementation.

* Auditors review policies to verify conformance with ISO 9001.

Why are the Other Options Incorrect?

* A (Confirmative evidence) # Not a recognized category in ISO auditing.

* B (Technical evidence) # Technical evidence refers to measurements, test results, or product data, not policies.

NEW QUESTION # 228

Scenario 4:

TD Advertising is a print management company based in Chicago. The company offers design services, digital printing, storage, and distribution. As TD expanded, its management recognized that success depended on adopting new technologies and improving quality.

To ensure customer satisfaction and quality improvement, the company decided to pursue ISO 9001 certification.

After implementing the QMS, TD hired a well-known certification body for an audit. Anne Key was appointed as the audit team leader. She received a document listing the audit team members, audit scope, criteria, duration, and audit engagement limits.

Anne reviewed the document and approved the audit mandate. The certification body and TD's top management signed the certification agreement.

Before contacting TD, Anne reviewed the audit scope and noticed that TD made changes to it due to the adoption of new printing equipment. However, Anne disagreed with the changes, stating they would affect the audit timeline. She considered withdrawing from the audit.

In scenario 4, the audit team determined the audit feasibility by considering only the resources available for the audit. Is this acceptable?

- A. Yes, considering only the resources available for the audit is sufficient for determining the audit feasibility.
- B. No, the audit feasibility should be determined by TD's top management.
- C. Yes, because the audit team leader has final authority over audit feasibility.
- **D. No, because other factors should be considered when determining the audit feasibility, such as information needed to plan the audit, the cooperation of the auditee, duration of the audit, etc.**

Answer: D

Explanation:

Comprehensive and Detailed In-Depth Explanation:

An audit's feasibility must be assessed using multiple factors, not just resource availability.

Clause References:

* ISO 19011:2018, Clause 5.3 - Establishing the Audit Program: Requires consideration of logistical, technical, and cooperation factors when assessing audit feasibility.

* ISO/IEC 17021-1:2015, Clause 9.1.3 - Determining Feasibility of the Audit: Requires evaluating more than just resources to ensure a successful audit.

Why is the Correct Answer B?

* Audit feasibility should consider:

* Availability of information (documents, records).

* Cooperation from the auditee.

- ### Why are the Other Options Incorrect?

- ### NEW QUESTION # 229

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