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

Topic	Details
Topic 1	<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 2	<ul style="list-style-type: none">Conducting an ISO 9001 audit: It evaluates your skills to conduct a QMS audit.
Topic 3	<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 4	<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 (Q180-Q185):

NEW QUESTION # 180

Which one of the following options is the definition of the context of an organisation?

- A. Comparison of internal and external issues that can have an effect on an organisation's desire to achieve its objectives.
- B. Complexity of internal and external issues that can have an effect on an organisation's approach to developing and achieving its purpose.
- **C. Combination of internal and external issues that can have an effect on an organisation's approach to developing and achieving its objectives.**
- D. Coordination of internal and external issues that can have a positive or negative effect on an organisation's success.

Answer: C

NEW QUESTION # 181

Select the term which best describes the quality management system process of modifying a non-conforming product to bring it within acceptance criteria.

- A. Corrective action
- **B. Correction**
- C. Preventive action
- D. Concession

Answer: B

Explanation:

According to the ISO 9000:2015 - Quality management systems - Fundamentals and vocabulary, correction is defined as "action to eliminate a detected nonconformity". A nonconformity is defined as "non-fulfilment of a requirement". Therefore, the process of modifying a non-conforming product to bring it within acceptance criteria is a correction, as it eliminates the non-fulfilment of the product specification. The other options are not correct, as they have different definitions and purposes:

*Concession: permission to release or use a nonconforming product, service or process

*Corrective action: action to eliminate the cause of a nonconformity and to prevent recurrence

*Preventive action: action to eliminate the cause of a potential nonconformity or other undesirable potential situation
References: ISO 9000:2015 - Quality management systems - Fundamentals and vocabulary, ISO 9001 nonconforming product: How to understand dispositions - Advisera

NEW QUESTION # 182

Scenario 3:

Fin-Pro is a financial institution in Austria offering commercial banking, wealth management, and investment services. The company faced a significant loss of customers due to failing to improve service quality as they expanded.

To regain customer confidence, top management implemented a QMS based on ISO 9001. After a year, they contacted ACB, a local certification body, to pursue ISO 9001 certification.

The audit team was led by Emilia, an experienced lead auditor, and included three auditors. After an agreement was reached, ACB sent the audit objectives to the audit team.

The audit team began by gathering information about Fin-Pro's understanding of ISO 9001 requirements.

While reviewing documented information, they noticed missing records of training and awareness sessions. They conducted employee interviews to verify attendance.

The team also reviewed the organizational chart and job descriptions to confirm employee competence.

They observed the company's working environment (social, psychological, and physical conditions).

The audit team analyzed the evidence and prepared an audit report with findings and conclusions.
Which statement below represents the level of responsibility demonstrated by the audit team in scenario 3?

- A. Ordinary negligence, the audit team has demonstrated lack of diligence.
- B. Willful misconduct, the audit team intentionally disregarded audit procedures.
- **C. No negligence, the audit team has demonstrated diligence during the audit and followed the best practices.**
- D. Gross negligence, the audit team has demonstrated a total lack of diligence.

Answer: C

Explanation:

Comprehensive and Detailed In-Depth Explanation:

ISO 19011:2018 requires auditors to conduct audits professionally and diligently.

Clause References:

* ISO 19011:2018, Clause 4.4 - Professional Care: Auditors must exercise due diligence in conducting audits.

* ISO 9001:2015, Clause 9.2 - Internal Audit: Requires objective and systematic audits to evaluate QMS effectiveness.

Why is the Correct Answer A?

* The audit team followed best practices by gathering verifiable audit evidence through interviews, document reviews, and observations.

* They ensured fair presentation of findings in the final audit report.

* They complied with ISO 9001 and ISO 19011 guidelines for audit procedures.

Why are the Other Options Incorrect?

* B (Ordinary negligence) # No evidence of negligence; the team followed structured audit processes.

* C (Gross negligence) # No indication that the auditors ignored important responsibilities.

* D (Willful misconduct) # The auditors acted professionally and did not intentionally disregard rules.

Reference:

ISO 19011:2018, Clause 4.4 - Professional Care

ISO 9001:2015, Clause 9.2 - Internal Audit

NEW QUESTION # 183

What are the objectives of the Stage 2 audit?

- A. To gather information regarding the scope of the QMS
- **B. To evaluate whether the QMS is effectively implemented**
- C. To review the auditee's management system documented information

Answer: B

Explanation:

Comprehensive and Detailed In-Depth Explanation: The Stage 2 audit (ISO 17021-1:2015, Clause 9.3.1.3) is conducted to:

* Verify whether the QMS is effectively implemented and operational.

* Ensure compliance with ISO 9001 requirements in actual practice.

* Identify nonconformities that may impact certification.

Reviewing documented information (Answer B) is part of Stage 1, and gathering scope information (Answer C) is done before the certification audit.

NEW QUESTION # 184

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. Yes, because a deadline from 10 to 60 days is a best practice for the submission of action plans
- B. No, because the decision for the deadline should have been suggested by the top management
- C. No, because the deadline for the client to present a corrective action plan is at least within 7 days

Answer: A

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 # 185

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