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

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certainly appear in the next PECB ISO-9001-Lead-Auditor test.

PECB QMS ISO 9001:2015 Lead Auditor Exam Sample Questions (Q221-Q226):

NEW QUESTION # 221
Will the auditee be subject to an audit follow-up if a minor nonconformity has been reported by the audit team leader in the audit conclusions?

- A. No, the auditee will be subject to an audit follow-up only if a major nonconformity is detected
- B. No, the audit team should suggest a recommendation only, in which it suggests an adequate corrective action for the nonconformity
- C. Yes, there should be an audit follow-up regardless of the type of nonconformities that are detected during the audit

Answer: A

Explanation:
Comprehensive and Detailed In-Depth Explanation:According to ISO 17021-1:2015, Clause 9.4.9 (Corrective Actions):
* Minor nonconformities do not require a follow-up audit but must be corrected before the next surveillance audit.
* Follow-up audits are required only for major nonconformities.
* The audit team should recommend corrective actions, not enforce immediate follow-ups for minor nonconformities.
Thus, A is the correct answer.

NEW QUESTION # 222
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. Willful misconduct, the audit team intentionally disregarded audit procedures.
- B. No negligence, the audit team has demonstrated diligence during the audit and followed the best practices.
- C. Gross negligence, the audit team has demonstrated a total lack of diligence.
- D. Ordinary negligence, the audit team has demonstrated lack of diligence.

Answer: B

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

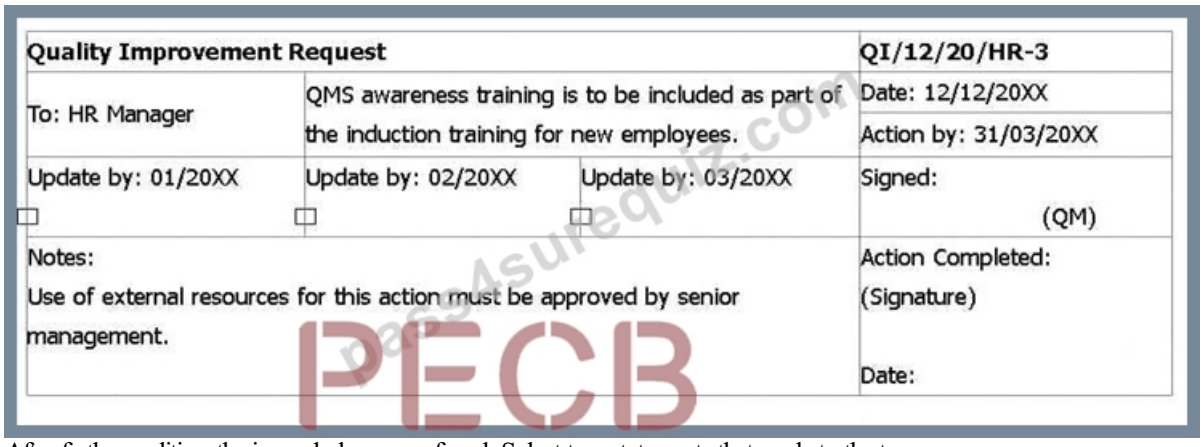
NEW QUESTION # 223
Scenario 6: Davis Clinic (DC) is an American medical center focused on integrated health care. Since its establishment DC was committed to providing qualitative services for its clients, which is the reason why the company decided to implement a quality management system (QMS) based 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 DCs 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. No, because the decision for the deadline should have been suggested by the top management
- B. No, because the deadline for the client to present a corrective action plan is at least within 7 days
- C. Yes, because a deadline from 10 to 60 days is a best practice for the submission of action plans

Answer: C

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 # 224
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.



Quality Improvement Request			QI/12/20/HR-3
To: HR Manager	QMS awareness training is to be included as part of the induction training for new employees.		Date: 12/12/20XX Action by: 31/03/20XX
Update by: 01/20XX	Update by: 02/20XX	Update by: 03/20XX	Signed: (QM)
Notes: Use of external resources for this action must be approved by senior management.			Action Completed: (Signature) Date:

After further auditing, the issues below were found. Select two statements that apply to the term `nonconformity'.

- A. Decisions on improvement action timescales not involving departmental managers.
- B. Evaluation of the results of the improvement action not always documented by the Quality Manager.
- C. No quality objectives planned for the top management team
- D. Quality improvements not aligning with the quality policy.
- E. Top management claim not to be aware of the improvement request (QI/12/20/HR-3) initiated by the Quality Manager.
- F. Limited knowledge of the content of Quality Improvement Requests by departmental staff.

Answer: C,D

Explanation:
According to the ISO 9001:2015 standard, clause 10.2.1 defines nonconformity as the non-fulfilment of a requirement. A requirement can be related to the quality management system, the products and services, the customer expectations, or the applicable statutory and regulatory requirements. Nonconformities can be detected through various sources, such as audits, inspections, tests, customer complaints, or internal reviews.
Nonconformities must be addressed by taking appropriate actions to correct them and prevent their recurrence.
In this scenario, the auditee has shown several issues that indicate nonconformities in their quality management system. Two statements that apply to the term nonconformity are:
A: No quality objectives planned for the top management team: According to ISO 9001, clause 6.2.1, the organization must establish quality objectives at relevant functions, levels, and processes. The quality objectives must be consistent with the quality policy and the strategic direction of the organization. The top management team is responsible for providing leadership and direction for the quality management system and ensuring its alignment with the organization's purpose and context. Therefore, the absence of quality objectives for the top management team is a nonconformity as it violates the requirement of clause 6.2.1.
E: Quality improvements not aligning with the quality policy: According to ISO 9001, clause 5.2.1, the quality policy is a statement of the organization's intentions and direction regarding quality, as formally expressed by top management. The quality policy must provide a framework for setting quality objectives and be compatible with the context and strategic direction of the organization. The quality policy must also be communicated, understood, and applied within the organization. Therefore, if the quality improvements are not aligned with the quality policy, it is a nonconformity as it violates the requirement of clause 5.2.1.

NEW QUESTION # 225
What is an advantage of group interviews?

- A. Equal duration of time for each interviewee to answer questions
- B. Less time-consuming
- C. Auditors pay more attention to each interviewee

Answer: B

Explanation:
Comprehensive and Detailed In-Depth Explanation:
Group interviews allow auditors to gather more information in less time by:
* Obtaining input from multiple participants simultaneously.
* Encouraging discussions that might highlight inconsistencies.
* Reducing the number of individual interviews needed.
While auditors strive for fairness, equal time for each interviewee is not guaranteed, and paying attention to each individual is more

difficult in a group setting.
Reference:
ISO 19011:2018, Clause 6.4.6 (Conducting Interviews)

NEW QUESTION # 226
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