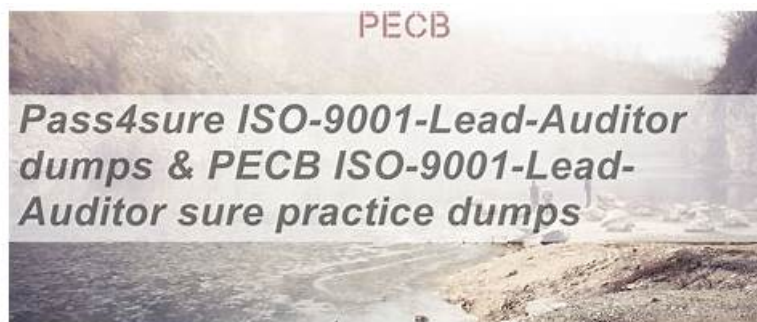


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PECB ISO-9001-Lead-Auditor Exam Syllabus Topics:

Topic	Details
Topic 1	<ul style="list-style-type: none">Preparing an ISO 9001 audit: This topic covers sub-topics related to preparing a quality management system audit.
Topic 2	<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 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">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.

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PECB QMS ISO 9001:2015 Lead Auditor Exam Sample Questions (Q217-Q222):

NEW QUESTION # 217

In the context of a third-party audit, match the event with the responsibility for conducting it.

Answer:

Explanation:

Explanation:

The correct answer is:

Event

Selecting audit team = Individual(s) managing the audit programme

Conducting the audit = Audit team

Preparing the audit plan = Audit team leader

Requesting the audit = Audit client

To complete the table, click on the blank section you want to complete so that it is highlighted in red, and then click on the applicable text from the options below. Alternatively, drag and drop each option to the appropriate blank section. Responsibility:- Individual(s) managing the audit programme Audit team Audit team leader Audit client According to ISO 19011:2018, clause 5.3, the individual(s) managing the audit programme are responsible for selecting the audit team, taking into account the competence and availability of the auditors and any experts needed. 1 According to clause 6.2, the audit team is responsible for conducting the audit, which includes collecting and verifying audit evidence, evaluating audit findings, and preparing the audit report. 1 According to clause 6.1, the audit team leader is responsible for preparing the audit plan, which includes defining the audit objectives, scope, criteria, and duration, as well as assigning roles and responsibilities to the audit team members. 1 According to clause 5.2, the audit client is the person or organization that requests the audit, which can be the auditee (the person or organization being audited) or any other person or organization that has an interest in the audit results. 1 References:

* 1: ISO 19011:2018 - Guidelines for auditing management systems

NEW QUESTION # 218

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 delay the audit until the return of the technical manager
- B. I would ask to audit the Technical Manager by phone.
- 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 for a different guide instead of the legal compliance expert.

Answer: D,E

Explanation:

According to clause 4.1 of ISO 9001:2015, the organization should determine external and internal issues that are relevant to its purpose and its strategic direction and that affect its ability to achieve the intended results of its quality management system. The organization should monitor and review these issues and update them as necessary. Although the standard does not explicitly require documented information of these issues, it does require documented information as evidence of the implementation of the actions taken to address risks and opportunities, as per clause 6.1. The organization should also retain documented information as evidence of the results of the monitoring, measurement, analysis and evaluation of its QMS, as per clause 9.1. Therefore, the auditor should not accept the legal compliance expert answering the question, as he is not the person responsible for the process and may not have the necessary competence or knowledge of the QMS. The auditor should also look for evidence that the actions resulting from the risk assessment had been taken, as this is a requirement of the standard and a way to verify the effectiveness of the QMS. The other

options are not appropriate courses of action for the auditor, because they do not address the audit objective or criteria, or they may compromise the audit integrity or impartiality. For example, option B may not be feasible or reliable, as the Technical Manager may not be available or able to provide the necessary evidence by phone. Option C may cause unnecessary delay and inconvenience for the audit process and the auditee. Option E may not solve the problem, as the guide is not the main source of evidence or information for the audit. Option F may be disrespectful or unprofessional, as the consultant may have a legitimate role or interest in the audit.

References: ISO 9001:2015, ISO 9001 Auditing Practices Group Guidance on Context of the Organization, ISO 9001 Auditing Practices Group Guidance on Audit Evidence

NEW QUESTION # 219

Which of the following three options could be considered potential threats to impartiality in an audit context?

- A. Competence
- B. Self-audit
- C. Experience
- D. Intimidation
- E. Familiarity

Answer: B,D,E

Explanation:

Questions no: 1 Verified answer: = C, D, E Comprehensive But Short Explanation: = Potential threats to impartiality in an audit context include familiarity (having a close relationship with the auditee), intimidation (being coerced or feeling pressured), and self-audit (auditing one's own work). These factors can compromise the auditor's objectivity and the audit's integrity. References: = The information is based on the ISO 9001 Auditing Practices Group documents which discuss threats to auditor impartiality and how they may compromise an auditor's objectivity123.

NEW QUESTION # 220

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.

What type of evidence has been collected by the ACB's audit team, as presented in scenario 3?

- A. Verbal, documentary, physical.
- B. Documentary, confirmative, verbal.
- C. Physical, verbal, analytical.
- D. Observational, secondary, qualitative.

Answer: A

Explanation:

Comprehensive and Detailed In-Depth Explanation:

Audit evidence includes information collected through different methods to assess compliance with ISO 9001:2015 requirements.

Clause References:

* ISO 19011:2018, Clause 6.4.6 - Audit Evidence: Audit evidence must be objective, verifiable, and based on facts.

* ISO 9001:2015, Clause 9.1.1 - Monitoring, Measurement, Analysis, and Evaluation: Requires organizations to collect and analyze data from multiple sources to verify effectiveness.

Types of Audit Evidence Collected in Scenario 3:

- * Verbal Evidence - Employee interviews regarding training and awareness sessions.
- * Documentary Evidence - Organizational charts, job descriptions, training records.
- * Physical Evidence - Workplace observations to assess working conditions.

Why is the Correct Answer B?

- * The audit team used a combination of verbal (interviews), documentary (records), and physical (site observations) evidence.
- * This triangulation approach enhances audit reliability and ensures compliance verification.

Why are the Other Options Incorrect?

- * A (Confirmative evidence) # Not a formal audit term in ISO 9001 or ISO 19011.
- * C (Analytical evidence) # Incorrect, as analysis was not a primary method used.
- * D (Qualitative evidence only) # Incorrect because the audit involved both qualitative (interviews) and quantitative (documents, physical) evidence.

Reference:

ISO 19011:2018, Clause 6.4.6 - Audit Evidence

ISO 9001:2015, Clause 9.1.1 - Monitoring, Measurement, Analysis, and Evaluation

NEW QUESTION # 221

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

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

Reference:

ISO 9001:2015, Clause 9.1.2 - Customer Satisfaction

NEW QUESTION # 222

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