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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"> • Closing an ISO 9001 audit: The topic focuses on concluding a QMS audit and conducting audit follow-up activities.
Topic 3	<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.
Topic 4	<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 5	<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 6	<ul style="list-style-type: none"> • Conducting an ISO 9001 audit: It evaluates your skills to conduct a QMS audit.

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PECB QMS ISO 9001:2015 Lead Auditor Exam Sample Questions (Q227-Q232):

NEW QUESTION # 227

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.

How do you assess the situation presented in the last paragraph of scenario 4?

- A. TD should have agreed with the certification body and Anne about any change in the audit scope.
- B. Anne has full authority to reject any scope changes, even if TD and the certification body agree.
- C. TD cannot make any change to the audit scope once it has been defined.
- D. Anne cannot withdraw from the audit once the audit mandate is accepted.

Answer: A

Explanation:

Comprehensive and Detailed In-Depth Explanation:

ISO 9001:2015 requires collaboration between the auditee (TD Advertising), the certification body, and the audit leader when making changes to audit scope.

Clause References:

* ISO/IEC 17021-1:2015, Clause 9.2.3 - Conducting the Audit: Any change in audit scope must be agreed upon by all parties before proceeding.

Why is the Correct Answer C?

* TD cannot unilaterally change the scope without agreement from the certification body and audit leader.

* The certification body must ensure the scope remains relevant and that resources are allocated properly.

Why are the Other Options Incorrect?

* A (Anne cannot withdraw) # Incorrect, Anne CAN withdraw if the changes make the audit unfeasible, but she must consult with the certification body first.

* B (TD cannot change the scope) # Incorrect, scope changes are allowed but must be formally approved.

* D (Anne has full authority to reject scope changes) # Incorrect, scope changes require mutual agreement among all parties.

Reference:

ISO/IEC 17021-1:2015, Clause 9.2.3 - Conducting the Audit

NEW QUESTION # 228

Put the following steps of a third-party audit into the correct sequence in which they happen.

Answer:

Explanation:

Explanation:

Sequence:

Stage 1 Audit

Stage 2 Opening Meeting

Interviews

Stage 2 Closing Meeting

Close-out of Stage 2 Audit Findings

Issue Certificate

Surveillance Audit

Follow-up Audit

To complete the sequence, you can drag and drop the options to the appropriate blank section.

Here is a brief explanation of each step:

Stage 1 Audit: This is the initial audit that aims to assess the readiness of the organization for the stage 2 audit. It involves reviewing the documentation of the quality management system, evaluating the scope and objectives of the audit, and identifying any major gaps or nonconformities³⁴.

Stage 2 Opening Meeting: This is the meeting that marks the start of the stage 2 audit. It involves confirming the audit plan, the audit criteria, the audit scope, and the audit team. It also provides an opportunity for the auditee to ask any questions or raise any concerns³⁴.

Interviews: This is the main activity of the stage 2 audit, where the audit team collects evidence by interviewing the personnel involved in the quality management system, observing the processes and activities, and examining the records and documents. The audit team uses various techniques, such as sampling, measurement, analysis, and evaluation, to verify the conformity and effectiveness of the quality management system^{34,5}.

Stage 2 Closing Meeting: This is the meeting that marks the end of the stage 2 audit. It involves presenting the audit findings, the audit conclusions, and the audit report to the auditee. It also provides an opportunity for the auditee to provide feedback, ask questions, or dispute any findings³⁴.

Close-out of Stage 2 Audit Findings: This is the process of verifying that the auditee has taken appropriate corrective actions to address any nonconformities or opportunities for improvement identified during the stage 2 audit. The audit team may request evidence or conduct a follow-up visit to confirm the effectiveness of the corrective actions³⁴.

Issue Certificate: This is the process of issuing a certificate of conformity to the auditee, if the audit team is satisfied that the quality management system meets the requirements of the standard and that there are no major nonconformities or unresolved issues. The certificate is valid for a specified period, usually three years, and is subject to periodic surveillance audits³⁴.

Surveillance Audit: This is the process of conducting periodic audits, usually once a year, to monitor the continued conformity and effectiveness of the quality management system. It involves reviewing the changes, improvements, and performance of the quality management system, and identifying any new nonconformities or opportunities for improvement³⁴.

Follow-up Audit: This is the process of conducting an additional audit, usually in response to a significant change, a complaint, or a major nonconformity, to verify the impact and the corrective actions taken by the auditee. It may result in the suspension, withdrawal, or renewal of the certificate, depending on the outcome of the audit³⁴.

NEW QUESTION # 229

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 not accept the legal compliance expert answering the question.
- B. I would ask the consultant to leave the meeting since he is not an employee of the organisation.
- C. I would ask for a different guide instead of the legal compliance expert.
- **D. I would ask to audit the Technical Manager by phone.**
- **E. I would look for evidence that the actions resulting from the risk assessment had been taken.**
- F. I would delay the audit until the return of the technical manager

Answer: D,E

Explanation:

* D. I would look for evidence that the actions resulting from the risk assessment had been taken.

* According to ISO 9001:2015, Clause 6.1.2 requires the organization to plan actions to address risks and opportunities. The organization must integrate and implement these actions into its quality management system and evaluate their effectiveness. The auditor should seek evidence that the organization has assessed the risks and taken appropriate actions.

* B. I would ask to audit the Technical Manager by phone.

* As the Technical Manager is responsible for this process and is absent due to illness, it is reasonable to attempt to contact him to obtain accurate information. This ensures that the audit process is not unduly delayed and that the information is obtained from the appropriate person.

* A. I would not accept the legal compliance expert answering the question.

* While the legal compliance expert might not be the best source for technical details, outright rejecting their input is not appropriate. It is better to first verify if the expert can provide relevant information.

* C. I would delay the audit until the return of the Technical Manager.

* This would be an inefficient approach. Contacting the Technical Manager by phone is a more practical and reasonable option.

* E. I would ask for a different guide instead of the legal compliance expert.

* The guide's role is not necessarily to answer technical questions but to facilitate the audit. Since Jack is already familiar with the situation, replacing him may not add value.

* F. I would ask the consultant to leave the meeting since he is not an employee of the organization.

* This is inappropriate and could disrupt the audit process. There is no rule in ISO 9001 preventing a consultant from assisting in the audit if authorized by the organization.

Why Not the Other Options:

NEW QUESTION # 230

You work for an organisation, 'A', which provides packaged food to the public. You are asked to lead a team (you as the leader and two other auditors) to audit a supplier, 'B', which provides packaging materials to your organisation. It is 4 p.m. and the audit is close to an end; you are having an internal meeting with the team to decide what will be presented to the auditee during the Closing meeting.

The Closing meeting was scheduled for 5 p.m.

You, as audit team leader, audited top management, the laboratory, and the storage of raw materials.

Auditor 1 audited the two manufacturing lines and dispatch areas.

You to Auditor 1: "What findings would you report?"

Auditor 1: "When reviewing the Dispatch records, I noticed that during the morning two different trucks (Number 011 and 025) delivered the same batch number of the product (Batch 33555). Truck 011 left the plant at 9.15 am and Truck 025 left the plant at 11.30 am. Procedure P-02 Rev.3 says

that trucks should carry a complete batch. The batch number, once on the truck, is captured using a QR device." You: "OK, what do you think?" Auditor 2: "I think that this is a nonconformity." You: "OK. How would you describe the evidence on which the nonconformity will be based"?

Identify which one of the following statements best describes the identified nonconformity.

- A. Dispatch personnel do not always carry out its activities in conformance with Procedure P-02 rev 3.
- B. A product delivered to the client was not identified as required in P-02 Rev 3.

- C. The batch 33555 was delivered split in two different trucks (011 and 025).
- D. Dispatch personnel are not fully aware of the need to conform to written procedures.

Answer: C

Explanation:

According to the definition in ISO 9000, a nonconformity is "non-fulfillment of a requirement". There are three parts to a well-documented nonconformity: the audit evidence to support auditor findings; a record of the requirement against which the nonconformity is detected; and the statement of nonconformity¹. In this case, the audit evidence is the dispatch records that show the same batch number of the product being delivered by two different trucks at different times. The requirement is the procedure P-02 Rev.3 that says that trucks should carry a complete batch. The statement of nonconformity is that the batch 33555 was delivered split in two different trucks (011 and 025), which does not conform to the procedure. Therefore, option C best describes the identified nonconformity, as it includes all three parts of a well-documented nonconformity.

Option A is not correct, as it does not state the audit evidence or the requirement. Option B is not correct, as it does not specify the audit evidence or the statement of nonconformity. Option D is not correct, as it does not match the audit evidence or the requirement. References: 1: ISO 9001 Auditing Practices Group Guidance on Nonconformity - Documenting.

NEW QUESTION # 231

ISO 9001 is based on quality management principles. Match each of the following quality management principles to the related activity.

Answer:

Explanation:

Explanation:

Related Activity

Correct Quality Management Principle

Communicate client needs and expectations throughout the organisation.

Customer focus

Encourage an organisation-wide commitment to quality.

Leadership

Empower staff to determine constraints to performance and to take the initiative without fear.

Engagement of people

Establish authority, responsibility, and accountability for managing processes.

Process approach

Continuously educate and train people at all levels on how to apply basic tools and methodologies to achieve objectives.

Improvement

Determine, measure, and monitor key indicators to demonstrate the organisation's performance.

Evidence-based decision making

Determine relevant interested parties (such as providers, partners, customers, investors, employees, or society as a whole) and their connection with the organisation.

Relationship management

1. Customer focus

ISO 9001 states that organizations must understand and consistently meet customer needs and expectations.

Communicating client needs throughout the organization ensures alignment and customer satisfaction.

Reference: Clause 0.2; Clause 5.1.2 (Customer focus)

2. Leadership

Leadership establishes unity of purpose and direction and promotes a culture of quality across the organization.# Encouraging organization-wide commitment to quality is a core leadership responsibility.

Reference: Clause 0.2; Clause 5.1 (Leadership and commitment)

3. Engagement of people

ISO emphasizes that competent, empowered, and engaged people at all levels enhance organizational capability.# Empowering staff to identify constraints and act without fear reflects true engagement.Reference:

Clause 0.2; Clause 7.3 (Awareness)

4. Process approach

The process approach requires clear definition of responsibilities, authorities, inputs, outputs, and controls.# Establishing authority, responsibility, and accountability for processes is fundamental to this principle.

Reference: Clause 0.2; Clause 4.4 (QMS and its processes)

5. Improvement

Organizations must continually improve products, services, and system effectiveness.# Ongoing education and training enable

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