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

Topic	Details
Topic 1	<ul style="list-style-type: none"> Conducting an ISO 9001 audit: It evaluates your skills to conduct a QMS audit.
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"> 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.
Topic 5	<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 6	<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.

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PECB QMS ISO 9001:2015 Lead Auditor Exam Sample Questions (Q183-Q188):

NEW QUESTION # 183

According to the ISO 9001 standard, which one of the following is a defined responsibility of top management?

- A. Ensuring customer requirements are consistently met.
- **B. Establishing the Quality Management System quality policy.**
- C. Communicating the quality objectives needed for the Quality Management System.
- D. Planning actions to address risks and opportunities.

Answer: B

Explanation:

Top management is responsible for establishing, implementing, and maintaining the quality policy. The quality policy provides a framework for setting quality objectives and must be compatible with the context of the organization and support its strategic direction. It should also provide a commitment to satisfy applicable requirements and to continuous improvement.

References: ISO 9001:2015, Clause 5.2

NEW QUESTION # 184

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

Answer: C,D

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 # 185

Scenario 5: Mechanical-Electro (ME) Audit Stages

Mechanical-Electro, better known as ME, is an American company that provides mechanical and electrical services in China. Their services range from air-conditioning systems, ventilation systems, plumbing, to installation of electrical equipment in automobile plants, electronic manufacturing facilities, and food processing plants.

Due to the fierce competition from local Chinese companies and failing to meet customer requirements, ME's revenue dropped significantly. In addition, customers' trust and confidence in the company decreased, and the reputation of the company was damaged.

In light of these developments, the top management of ME decided to implement a quality management system (QMS) based on ISO 9001. After having an effective QMS in place for over a year, they applied for a certification audit.

A team of four auditors was appointed for the audit, including Li Na as the audit team leader. Initially, the audit team conducted a general review of ME's documents, including the quality policy, operational procedures, inventory lists, QMS scope, process documentation, training records, and previous audit reports.

Li Na stated that this would allow the team to maintain a systematic and structured approach to gathering documents for all audit stages. While reviewing the documented information, the team observed some minor issues but did not identify any major nonconformities. Therefore, Li Na claimed that it was not necessary to prepare a report or conduct a meeting with ME's representatives at that stage of the audit. She stated that all areas of concern would be discussed in the next phase of the audit.

Following the on-site activities and the opening meeting with ME's top management, the audit team structured an audit test plan to verify whether ME's QMS conformed to Clause 8.2.1 (Customer Communication) of ISO 9001.

To do so, they gathered information through group interviews and sampling. Li Na conducted interviews with departmental managers in the first group and then with top management. In addition, she chose a sampling method that sufficiently represented customer complaints from both areas of ME's operations.

The team members were responsible for the sampling procedure. They selected a sample size of 4 out of 45 customer complaints received weekly for electrical services and 2 out of 10 complaints for mechanical services.

Afterward, the audit team evaluated the evidence against the audit criteria and generated the audit findings.

After reviewing the documented information, Li Na claimed that it was not necessary to report the minor nonconformities that were identified; instead, they would be discussed in the next audit phase. Is this acceptable?

- A. Yes, all identified nonconformities throughout the audit need to be documented and communicated at the end of the audit.
- **B. No, identification of minor nonconformities or areas of concern that could become nonconformities need to be documented and communicated to the auditee before proceeding to the next audit phase.**
- C. Yes, during the review of documented information, only major nonconformities need to be documented if detected.

Answer: B

Explanation:

Comprehensive and Detailed In-Depth Explanation: As per ISO 9001:2015, Clause 10.2 (Nonconformity and Corrective Action), all identified nonconformities, including minor ones, must be documented and communicated to the auditee.

Minor nonconformities can lead to major issues if left unaddressed. The auditor must inform the organization before moving to the next audit phase so that corrective actions can be taken. Clause 9.2.2 (Internal Audit) states that audit findings should be reported without undue delay.

Since Li Na did not report the minor nonconformities immediately, her decision was incorrect. Minor nonconformities should always be documented and communicated before proceeding to the next phase.

NEW QUESTION # 186

The following are stages of an audit, put them in the order they would be conducted.

□

Answer:

Explanation:

□

Explanation:

□

Establishing the audit programme objectives
Determining and evaluating the audit programme risks and opportunities
Establishing the audit programme
Initiating the audit
Preparing all audit activity
Conducting the audit activities

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

Here is a brief explanation of each stage:

Establishing the audit programme objectives: This is the first stage of the audit process, where the purpose, scope, and criteria of the audit programme are defined. The audit programme objectives should be aligned with the strategic direction and policies of the organization, and should address the needs and expectations of the interested parties¹².

Determining and evaluating the audit programme risks and opportunities: This is the second stage of the audit process, where the factors that can affect the achievement of the audit programme objectives are identified and assessed. The audit programme risks and opportunities should consider the internal and external issues, the requirements and changes of the interested parties, and the results and feedback from previous audits¹².

Establishing the audit programme: This is the third stage of the audit process, where the audit programme is designed and implemented. The audit programme should include the audit programme procedures, the audit programme resources, the audit methods and techniques, the audit frequency and schedule, and the audit programme performance indicators¹².

Initiating the audit: This is the fourth stage of the audit process, where the audit is prepared and planned. The audit initiation involves selecting the audit team, establishing the contact with the auditee, defining the audit objectives, scope, and criteria, developing the audit plan, and conducting the document review¹²³.

Preparing all audit activity: This is the fifth stage of the audit process, where the audit activities are organized and coordinated. The audit preparation involves assigning the audit tasks, communicating with the auditee and the audit team, arranging the logistics, preparing the working documents, and conducting the opening meeting¹²³.

Conducting the audit activities: This is the sixth and final stage of the audit process, where the audit evidence is collected and evaluated. The audit conduct involves performing the audit activities, such as interviews, observations, document reviews, and tests, documenting the audit findings, preparing the audit conclusions, and conducting the closing meeting¹²³.

I hope this helps you with your ISO 9001 Lead Auditor objectives and content. If you have any further questions, please feel free to ask. # References: 1: ISO 19011:2018 - Guidelines for auditing management systems 2: Audit Process | Flowchart | Summary - Accountingdue 3: What are the Stages of the Auditing Process & Why it is Important ...

NEW QUESTION # 187

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:

Why is it important to discuss the audit findings with DC's top management prior to the closing meeting and the submission of the final audit report?

- A. To encourage the implementation of corrective actions as soon as possible
- B. To identify the persons responsible for the nonconformities
- C. To verify whether the audit objectives have been met

Answer: C

Explanation:

<https://drive.google.com/open?id=1V6T6ZUDxf6Ynrbz5EVzbCUNmHhoxnWPL>