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

Topic	Details
Topic 1	• Conducting an ISO 9001 audit: It evaluates your skills to conduct a QMS audit.
Topic 2	• Preparing an ISO 9001 audit: This topic covers sub-topics related to preparing a quality management system audit.
Topic 3	• Managing an ISO 9001 audit program: This topic evaluates your abilities to establish and managing a QMS audit program.

Topic 4	• 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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PECB QMS ISO 9001:2015 Lead Auditor Exam Sample Questions (Q98-Q103):

NEW QUESTION # 98
"A set of interrelated or interlacing elements of an organization to establish policies and objectives, and processes to achieve those objectives" is the definition of a/an:

- A. Standard
- B. Quality manual
- C. Management system
- D. Organization scope

Answer: C

Explanation:
Comprehensive and Detailed In-Depth Explanation:
According to ISO 9000:2015, which provides definitions for terms used in ISO 9001:2015, a management system is defined as a set of interrelated or interacting elements of an organization to establish policies, objectives, and processes to achieve those objectives.
A Quality Management System (QMS) is a type of management system that ensures organizations meet customer and regulatory requirements while improving performance.
Clause 3.5.3 of ISO 9000:2015 clearly defines "management system" and aligns with this question. The other options do not fit the definition:
* Standard refers to an established norm or requirement.
* Organization scope defines the boundaries of a QMS but is not a system itself.
* Quality manual is a document (optional under ISO 9001:2015) that describes a QMS but is not the system itself.
Reference:
ISO 9000:2015, Clause 3.5.3 - Management System
ISO 9001:2015, Clause 4.4 - QMS and its Processes

NEW QUESTION # 99
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:

The audit team delayed audit activities until DC's top management submitted their action plans. Is this acceptable?

- A. Yes, DC's top management promised the submission of action plans within a short period of time
- B. Yes, the audit report can be prepared once the auditee submits the action plans in cases of minor nonconformities
- C. No, the audit report should be prepared and submitted to the certification body prior to the submission of action plans by the auditee

Answer: C

Explanation:
Comprehensive and Detailed In-Depth Explanation:
According to ISO 17021-1:2015, Clause 9.4.8 (Audit Reporting):
* The audit report must be submitted to the certification body regardless of corrective actions.
* Corrective actions are reviewed after the audit, but the audit process should not be delayed.
* Certification decisions should be made based on the audit findings and evidence, not pending corrective actions.
Thus, delaying audit activities until corrective actions are submitted is not acceptable.
Reference:
ISO 17021-1:2015, Clause 9.4.8 (Audit Reporting)

NEW QUESTION # 100

Which statement regarding the drafting of the audit conclusions is correct?

- A. The audit conclusions must be drafted based on observation
- B. The audit conclusions must be based on evidence that is examined and evaluated in terms of quantity and quality
- C. The audit conclusions must not include the revisions that resulted from the closing meeting

Answer: B

Explanation:
Comprehensive and Detailed In-Depth Explanation:
According to ISO 19011:2018, Clause 6.4.9 (Audit Conclusions):
* Audit conclusions must be based on verified evidence.
* The evidence must be evaluated both quantitatively and qualitatively to ensure accuracy.
* Observations alone (A) are insufficient; conclusions must be supported by objective evidence.
Thus, B is the correct answer.
Reference:
ISO 19011:2018, Clause 6.4.9 (Audit Conclusions)

NEW QUESTION # 101

In the context of a second-party audit, match the activity with the party responsible for conducting it.

In the context of a second-party audit, match the **activity** with the **party responsible** for conducting it.

Activity	Party responsible
Define the audit scope	
Develop the audit plan	
Respond to the audit findings	
Conduct the audit	

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.

Customer	Audit team leader	External provider	Audit team

Answer:

Explanation:

In the context of a second-party audit, match the **activity** with the **party responsible** for conducting it.

Activity	Party responsible
Define the audit scope	Customer
Develop the audit plan	Audit team leader
Respond to the audit findings	External provider
Conduct the audit	Audit team

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.

Customer	Audit team leader	External provider	Audit team

Explanation:
Here is the correct matching of the activities with the responsible parties in the context of a second-party audit:
* Define the audit scope: Customer
* Develop the audit plan: Audit team leader
* Respond to the audit findings: External provider
* Conduct the audit: Audit team
This reflects the typical division of responsibilities in a second-party audit, where the customer (the party commissioning the audit) sets the scope, the audit team leader manages the planning, the external provider responds to findings, and the audit team carries out the audit.

NEW QUESTION # 102
An internal auditor of a manufacturer of polystyrene packaging products for the electronics industry raised a nonconformity against section 10.3 of ISO 9001 in Report IA202. The nonconformity (NC 3) stated:
"The reject rate of 'finished' product of 9.7% needs improvement as it doesn't meet the stated objective of top management of 5%."
Just before the Closing meeting of a third-party audit, the audit team leader is invited to a meeting with the Quality Manager. He tells the audit team leader that a member of the audit team was seen taking photographs of the factory on his phone during the day and wants him suspended from the Closing meeting with any nonconformities raised by him rescinded. The issue of photographs was not discussed during the opening meeting.
Select the three options for how the audit team leader might deal with this situation.

- A. Insist that the nonconformities must stand since they have been agreed by the team from other evidence gathered
- B. State that the auditor will take no further part in the audit and all his photographs will be deleted
- C. Apologise for the situation and ensure the Quality Manager that all photographs will be deleted during the Closing meeting
- D. Advise the Quality Manager that he, as audit team leader, needs to speak to the auditor about the situation and he will report back to the Quality Manager once this is done

- E. Advise the Quality Manager that the auditor will be reported to Head Office
- F. Delay the Closing meeting until the audit team leader has consulted his audit programme manager at Head Office

Answer: A,B,D

Explanation:
The audit team leader should deal with this situation in a professional and ethical manner, while maintaining the integrity and credibility of the audit process and the audit findings. The audit team leader should also try to resolve the conflict with the Quality Manager in a constructive and respectful way, without compromising the audit objectives or the audit team's independence and impartiality.
According to the ISO 9001 Lead Auditor Reference Materials guides and documents, the possible actions that the audit team leader might take are:
*A. Insist that the nonconformities must stand since they have been agreed by the team from other evidence gathered. This action is consistent with the principle of evidence-based approach, which states that the audit team should collect and verify information that is appropriate, sufficient, and reliable to support the audit findings and conclusions. The audit team leader should explain to the Quality Manager that the nonconformities are not based solely on the photographs, but on other audit evidence that corroborates them. The audit team leader should also remind the Quality Manager that the nonconformities are subject to review and approval by the certification body, and that any attempt to influence or interfere with the audit results would be considered a breach of the audit agreement and the certification rules.
*D. State that the auditor will take no further part in the audit and all his photographs will be deleted. This action is consistent with the principle of confidentiality, which states that the audit team should exercise discretion in the use and protection of information acquired during the audit. The audit team leader should acknowledge that the auditor's behavior was inappropriate and unprofessional, and that he violated the audit rules and the auditee's rights. The audit team leader should apologize for the inconvenience and the discomfort caused by the auditor, and assure the Quality Manager that the auditor will be removed from the audit team and that his photographs will be erased from his phone and any other device or media. The audit team leader should also inform the auditor of his misconduct and the consequences, and report the incident to the audit program manager and the certification body.
*F. Advise the Quality Manager that he, as audit team leader, needs to speak to the auditor about the situation and he will report back to the Quality Manager once this is done. This action is consistent with the principle of communication, which states that the audit team should exchange information with the auditee in a timely, open, honest, and respectful manner. The audit team leader should express his concern and his willingness to address the issue with the auditor, and ask for the Quality Manager's patience and cooperation. The audit team leader should also explain that the audit process is not finished yet, and that the Closing meeting is an opportunity to present and discuss the audit findings and conclusions, and to seek feedback and clarification from the auditee. The audit team leader should then speak to the auditor privately, and follow the steps described in action D.
The other options are not appropriate or effective ways to deal with this situation, because they either:
*B. Delay the Closing meeting until the audit team leader has consulted his audit program manager at Head Office. This action would disrupt the audit schedule and the audit plan, and create unnecessary delays and costs for both the audit team and the auditee. It would also show a lack of leadership and decision-making skills from the audit team leader, and undermine his authority and credibility. The audit team leader should be able to handle the situation on site, and consult his audit program manager only if the situation escalates or becomes unmanageable.
*C. Advise the Quality Manager that the auditor will be reported to Head Office. This action would escalate the conflict and create a hostile and defensive atmosphere between the audit team and the auditee. It would also imply that the audit team leader is not capable or willing to resolve the issue himself, and that he is threatening or punishing the auditee for raising a legitimate concern. The audit team leader should try to defuse the tension and restore the trust and the rapport with the Quality Manager, and report the auditor to Head Office only after the audit is completed and the audit report is submitted.
*E. Apologise for the situation and ensure the Quality Manager that all photographs will be deleted during the Closing meeting. This action would not address the root cause of the problem, and would not prevent the auditor from taking more photographs or using them for other purposes. It would also expose the audit team and the auditee to unnecessary risks and liabilities, and compromise the confidentiality and the security of the audit information. The audit team leader should delete the photographs as soon as possible, and not wait until the Closing meeting.
References: ISO 9001:2015, ISO 19011:2018, PECB Certified ISO 9001 Lead Auditor, Common Audit Problems and How to Deal with Them, The Auditor's Guide to Conflict Resolution, Conflict Resolution in your Audit Career, How to Be a Good Auditor as a Team Leader

NEW QUESTION # 103

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