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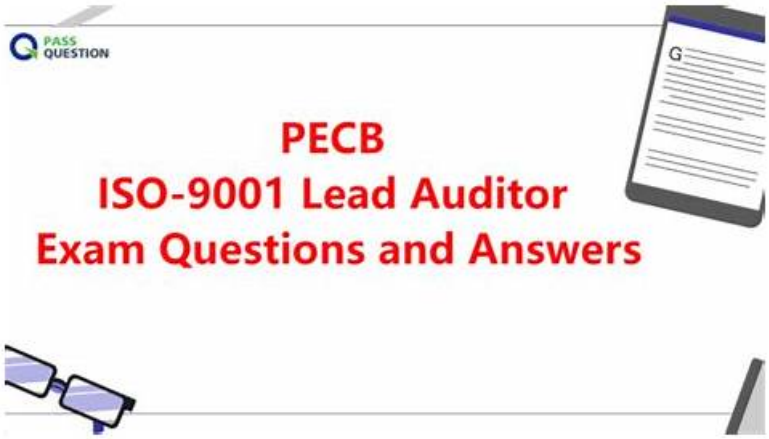

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PECB ISO-9001-Lead-Auditor Exam Syllabus Topics:

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	• Conducting an ISO 9001 audit: It evaluates your skills to conduct a QMS audit.

Topic 4	• 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 5	• Closing an ISO 9001 audit: The topic focuses on concluding a QMS audit and conducting audit follow-up activities.

PECB QMS ISO 9001:2015 Lead Auditor Exam Sample Questions (Q153-Q158):

NEW QUESTION # 153
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. Top management claim not to be aware of the improvement request (QI/12/20/HR-3) initiated by the Quality Manager.
- C. Quality improvements not aligning with the quality policy.
- D. Evaluation of the results of the improvement action not always documented by the Quality Manager.
- E. No quality objectives planned for the top management team
- F. Limited knowledge of the content of Quality Improvement Requests by departmental staff.

Answer: C,E

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 # 154
(From the following, select six tasks you would expect to be completed during the audit team meeting of a second-party audit in preparation for the closing meeting of a four-day audit being performed by organisation ABC to an external provider.)

- A. The audit team leader holds daily virtual meetings with ABC's Quality Manager to review any timetable issues and potential findings and their impact on the audit for other team members.
- B. The audit team agrees on the audit opportunities for improvement to be presented to the supplier.
- C. The audit team leader writes all audit finding reports, taking into account the inputs provided by each auditor.
- D. Each audit team member completes the report of their individual findings.
- E. The audit team leader completes the final report to be signed by all members of the audit team and of the supplier's top management.
- F. The audit team review any points raised by the auditee-nominated representative during the audit.
- G. The audit team agrees on the roles of each audit team member for the closing meeting.
- H. The audit team leader informs ABC's Procurement Manager that the closing meeting is ready to be held.
- I. The audit team leader refuses to review corrective actions taken to address non-conformities identified during the audit, as required by the supplier.
- J. The audit team agrees on the conformities and non-conformities to be included in the final audit report.

Answer: B,C,D,F,G,J

Explanation:
Comprehensive and Detailed Explanation From ISO 9001 / ISO 19011 Guidance:
ISO 9001:2015 requires audits to be planned and conducted objectively, but it refers auditors to ISO 19011 for detailed guidance on audit activities, including audit team meetings and preparation for closing meetings.
ISO 19011:2018 describes the purpose of the audit team meeting before the closing meeting as ensuring alignment, consistency, and clarity of audit conclusions and messages to the auditee.
Explanation of the selected tasks:
C). The audit team review any points raised by the auditee-nominated representative during the audit.
ISO 19011 requires the audit team to consider and evaluate information and concerns raised by the auditee to ensure audit findings are accurate, fair, and evidence-based before the closing meeting.
E). The audit team agrees on the audit opportunities for improvement to be presented to the supplier.
Before the closing meeting, the audit team must align on opportunities for improvement so that these are presented consistently and clearly, without contradiction between auditors.
F). The audit team agrees on the roles of each audit team member for the closing meeting.
ISO 19011 requires clear allocation of responsibilities within the audit team. Agreeing who will present findings, nonconformities, or conclusions is a normal and expected preparation activity.
G). The audit team leader writes all audit finding reports, taking into account the inputs provided by each auditor.
The audit team leader is responsible for consolidating audit inputs and ensuring consistency of reporting, even though individual auditors contribute evidence and findings.
H). Each audit team member completes the report of their individual findings.
ISO 19011 expects each auditor to document their findings and provide them to the audit team leader for consolidation into the final audit report.
J). The audit team agrees on the conformities and non-conformities to be included in the final audit report.
Before the closing meeting, the audit team must reach consensus on audit conclusions to ensure findings are clear, justified, and consistently communicated.
Explanation of why the other options are not selected:
* A: Daily meetings with the auditee's Quality Manager are not part of an internal audit team meeting and may compromise independence.
* B: The final audit report is not completed and signed during the audit team meeting prior to the closing meeting.
* D: Refusing to review corrective actions is inappropriate; however, corrective actions are normally reviewed after the audit, not during preparation for the closing meeting.
* I: Informing the Procurement Manager is an administrative action, not a task of the audit team meeting.

ISO-aligned conclusion:
An audit team meeting prior to the closing meeting focuses on alignment, consolidation of findings, agreement on conclusions, and preparation for clear communication. The six correct tasks are therefore C, E, F, G, H, and J.

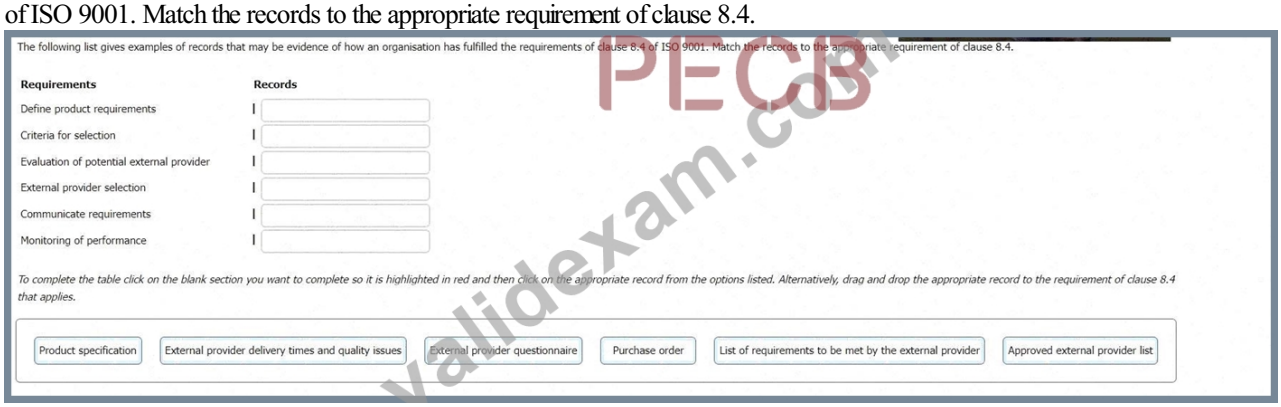
NEW QUESTION # 155
What should the auditor document during the Stage 1 audit?

- A. The observations that could result in nonconformities during the on-site audit
- B. The main processes of the auditee
- C. The interviews with the auditee's employees

Answer: A

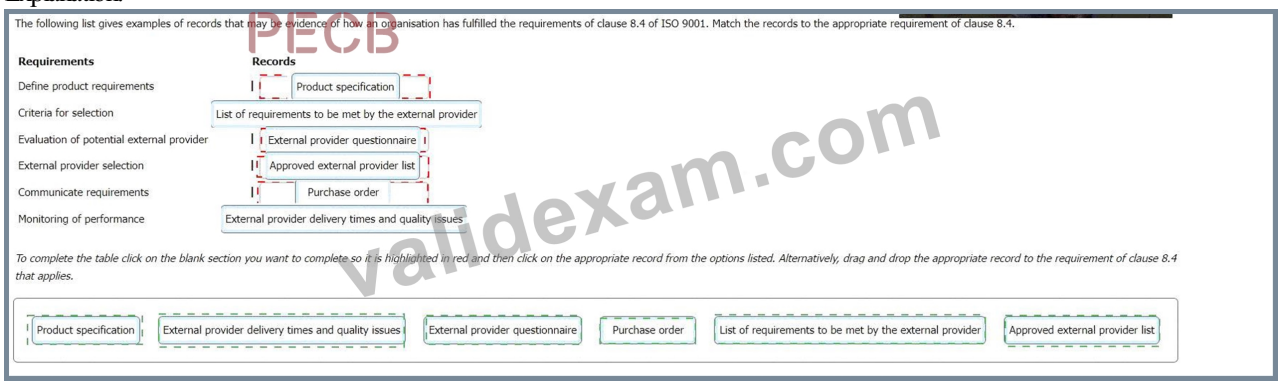
Explanation:
Comprehensive and Detailed In-Depth Explanation:Stage 1 Audit (ISO 9001:2015, Clause 9.2.2) is a documentation review to assess the readiness for a Stage 2 Audit. The auditor must document:
* Observations that could lead to nonconformities, ensuring they are addressed before Stage 2.
* Areas needing improvement, such as missing documented information or unclear process definitions
.
While understanding the auditee's main processes is important, documenting interviews is not a requirement at Stage 1.

NEW QUESTION # 156
The following list gives examples of records that may be evidence of how an organisation has fulfilled the requirements of clause 8.4 of ISO 9001. Match the records to the appropriate requirement of clause 8.4.



Answer:

Explanation:



Explanation:

The following table shows the possible matching of the records to the requirements of clause 8.4:
Table
Requirements
Records
Define product requirements
Product specification
Criteria for selection
List of requirements to be met by the external provider
Evaluation of potential external provider
External provider questionnaire
External provider selection
Approved external provider list
Communicate requirements
Purchase order
Monitoring of performance
External provider delivery times and quality issues
Comprehensive and Detailed Explanation: = According to clause 8.4 of ISO 9001:2015, the organization should ensure that externally provided processes, products, and services conform to the specified requirements. To do so, the organization should:
Define the product requirements that are relevant for the external provision, such as specifications, drawings, standards, codes, etc. These should be documented and communicated to the external provider. A record of the product specification can be used as evidence of this requirement.
Establish the criteria for the selection, evaluation, and re-evaluation of external providers, based on their ability to provide processes, products, and services in accordance with the requirements. The criteria should be documented and applied consistently. A record of the list of requirements to be met by the external provider can be used as evidence of this requirement.
Evaluate the potential external providers before selecting them, using the established criteria. The evaluation methods may include questionnaires, audits, references, samples, etc. The results of the evaluation should be documented and reviewed. A record of the external provider questionnaire can be used as evidence of this requirement.
Select the external providers that have demonstrated their competence and conformity to the requirements.
The selection should be based on the evaluation results and the organization's needs. The selection should be documented and approved. A record of the approved external provider list can be used as evidence of this requirement.
Communicate the requirements for the processes, products, and services to be provided by the external provider, including the verification and validation activities, the acceptance criteria, the documentation requirements, the changes control, etc. The communication methods may include purchase orders, contracts, agreements, etc. The communication should be clear, complete, and timely. A record of the purchase order can be used as evidence of this requirement.
Monitor the performance and conformity of the external provider, using the established criteria and methods.
The monitoring methods may include inspections, tests, audits, feedback, complaints, etc. The monitoring results should be documented and analyzed. A record of the external provider delivery times and quality issues can be used as evidence of this requirement.
References: ISO 9001:2015, [ISO 9001 Auditing Practices Group Guidance on Scope], Mastering the Scope of ISO 9001 Quality Management Systems

NEW QUESTION # 157
Scenario 2:
Bell is a Canadian food manufacturing company that operates globally. Their main products include nuts, dried fruits, and

confections. Bell has always prioritized product quality and has maintained a good reputation for many years. However, the company's production error rate increased significantly, leading to more customer complaints.
To increase efficiency and customer satisfaction, Bell implemented a Quality Management System (QMS) based on ISO 9001. The top management established a QMS implementation team comprising five middle managers from various departments, including Leslie, the quality manager.
Leslie was responsible for assigning responsibilities and authorities for QMS-related roles. He also suggested including a top management representative in the QMS team, but top management declined due to other priorities.
The team defined the QMS scope as:
"The scope of the QMS includes all activities related to food processing." Leslie established a quality policy and presented it to the team for review before top management approval
. Top management also proposed a new strategy for handling customer complaints, requiring biweekly customer surveys to monitor customer perceptions.
The quality policy was established by Leslie and approved by top management. Is this acceptable?
Please refer to scenario 2.

- A. Yes, the quality policy can be established by the QMS implementation team and be approved by top management.
- B. No, the quality policy must be established and approved by top management.
- C. Yes, as long as top management is informed, the policy can be established by any responsible employee.
- D. No, the quality policy must be established and approved only by the quality manager.

Answer: B

Explanation:
Comprehensive and Detailed In-Depth Explanation:ISO 9001:2015, Clause 5.2.1 (Establishing the Quality Policy) states that top management must establish, implement, and maintain a quality policy.
In the scenario, the quality manager (Leslie) created the policy, but top management did not establish it themselves, which violates Clause 5.2.1. While the policy can be drafted by a team, top management must take full ownership of its development and approval.

NEW QUESTION # 158
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