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

Topic	Details
Topic 1	<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 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">Preparing an ISO 9001 audit: This topic covers sub-topics related to preparing a quality management system audit.

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PECB QMS ISO 9001:2015 Lead Auditor Exam Sample Questions (Q97-Q102):

NEW QUESTION # 97

Which of the following two documents does an auditor need to prepare and complete prior to the on-site audit?

- A. Checklist / Prompts
- B. Audit Report
- C. Procedures
- D. Findings
- E. Risk Matrices
- F. Audit Plan

Answer: A,F

Explanation:

According to ISO 19011:2018, clause 6.3, the audit plan is a document that provides the basis for agreement regarding the conduct of the audit. The audit plan should include the information listed in my previous response, such as the audit objectives, scope, criteria, schedule, team, methods, report, etc. The audit plan should be prepared and completed prior to the on-site audit, and should be communicated to the audit team and the auditee1.

According to ISO 19011:2018, clause 6.4.3, the checklist / prompts are documents that list the questions or topics that need to be covered during an audit. The checklist / prompts can help the auditor to collect and verify information relevant to the audit criteria, and to ensure the consistency and completeness of the audit.

The checklist / prompts should be prepared and completed prior to the on-site audit, and should be based on the audit plan and the audit scope and objectives1.

Therefore, the two documents that an auditor needs to prepare and complete prior to the on-site audit are B and D, as they are essential for planning and conducting the audit. The other options are not correct, as they are either prepared or completed after the on-site audit, or not required by the standard:

*A. Audit Report: The audit report is a document that provides a complete, accurate, concise, and clear record of the audit. The audit report should include the information listed in my previous response, such as the audit objectives, scope, criteria, findings, conclusions, etc. The audit report should be prepared and completed after the on-site audit, and should be distributed to the audit client and the auditee1.

*C. Procedures: Procedures are documents that specify the way activities are to be performed. Procedures may be part of the audit criteria, if they are part of the organization's management system, or part of the audit programme, if they are part of the certification body's or registrar's requirements. Procedures are not prepared or completed by the auditor prior to the on-site audit, but rather reviewed or followed by the auditor during the audit1.

*E. Risk Matrices: Risk matrices are tools that help to assess and prioritize the risks and opportunities associated with the audit programme or the audit. Risk matrices may be part of the audit programme management, if they are used to determine and evaluate the audit programme risks and opportunities, or part of the audit preparation, if they are used to determine and evaluate the audit risks and opportunities. Risk matrices are not prepared or completed by the auditor prior to the on-site audit, but rather used or updated by the auditor during the audit programme management or the audit preparation1.

*F. Findings: Findings are the results of the evaluation of the collected audit evidence against the audit criteria. Findings can indicate either conformity or nonconformity, as well as positive aspects or opportunities for improvement. Findings are not prepared or completed by the auditor prior to the on-site audit, but rather generated and recorded by the auditor during the audit activities1.

References: ISO 19011:2018(en), Guidelines for auditing management systems

NEW QUESTION # 98

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

Answer: C

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.

NEW QUESTION # 99

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.

Which stages of the audit were performed?

- A. Stage 2 audit and surveillance audit.
- **B. Stage 1 and stage 2 audit.**
- C. Audit follow-up and stage 1 audit.

Answer: B

Explanation:

Comprehensive and Detailed In-Depth Explanation:

Understanding Audit Stages Based on ISO/IEC 17021-1:2015

ISO certification audits consist of two main stages:

* Stage 1 Audit (Readiness Review)

* The organization's documented information is reviewed to assess readiness for Stage 2.

* This ensures that the QMS is developed, implemented, and prepared for full assessment.

* Stage 2 Audit (On-Site Evaluation)

* Auditors assess process implementation and effectiveness through interviews, observations, and evidence collection.

* The audit team verifies if the organization meets ISO 9001 requirements in practice.

Why is the Correct Answer B?

* The audit team reviewed ME's documents, which is a Stage 1 activity.

* The audit team performed interviews, sampling, and on-site verification, which is a Stage 2 activity.

* There was no mention of an audit follow-up or a surveillance audit, which occur post-certification.

Why are the Other Options Incorrect?

* A (Audit follow-up and Stage 1 Audit) # Follow-up audits occur after certification, which was not the case here.

* C (Stage 2 Audit and Surveillance Audit) # Surveillance audits are post-certification audits and were not conducted yet.

NEW QUESTION # 100

An organisation decides to purchase products and services only from ISO 9001 certified suppliers.

Match the four organisational functions to a potential benefit.

□

Answer:

Explanation:

□

Explanation:

Reduced incoming inspection # A. Quality

Improved communication with suppliers # B. Procurement

Purchased materials received on time # C. Logistics

Reduced variability within processes # D. Production

According to ISO 9001:2015, Clause 8.4 - Control of externally provided processes, products and services, organisations are required to ensure that externally provided products and services conform to specified requirements. When an organisation sources from ISO 9001 certified suppliers, there is greater assurance of consistency in quality, delivery, and communication. This enhances internal operations across various functions:

* Reduced incoming inspection (Quality): ISO 9001 certified suppliers have robust quality controls (Clause 8.4.2), reducing the need for repeated inspections upon receipt. This aligns with Quality's responsibility for incoming inspection and verification.

* Improved communication with suppliers (Procurement): Clause 8.4.3 emphasizes the communication of detailed requirements to external providers. Procurement plays a key role in ensuring these requirements are understood and met.

* Purchased materials received on time (Logistics): Timely deliveries are often a result of structured supplier evaluation and selection (Clause 8.4.1). Logistics benefits through fewer delays and better scheduling of internal processes.

* Reduced variability within processes (Production): Consistency of supplied materials supports stable and predictable production processes, which is a key aspect of Clause 8.5 - Production and service provision.

References:

ISO 9001:2015 Clause 8.4.1 - General

ISO 9001:2015 Clause 8.4.2 - Type and extent of control

ISO 9001:2015 Clause 8.4.3 - Information for external providers

NEW QUESTION # 101

Which one of the following options is the definition of the context of an organisation?

- A. Combination of internal and external issues that can have an effect on an organisation's approach to developing and achieving its objectives.
- B. Coordination of internal and external issues that can have a positive or negative effect on an organisation's success.
- C. Complexity of internal and external issues that can have an effect on an organisation's approach to developing and achieving its purpose.
- D. Comparison of internal and external issues that can have an effect on an organisation's desire to achieve its objectives.

Answer: A

NEW QUESTION # 102

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