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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">Managing an ISO 9001 audit program: This topic evaluates your abilities to establish and managing a QMS audit program.

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.
Topic 4	<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 5	<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 (Q165-Q170):

NEW QUESTION # 165

Technical experts must operate under the supervision of:

- A. The auditee
- B. The audit team leader only
- C. An auditor

Answer: C

Explanation:

Comprehensive and Detailed In-Depth Explanation:

According to ISO 19011:2018, Clause 5.5 (Determining Audit Team Competence), technical experts:

- * Provide specialized knowledge in an audit.
- * Must operate under the supervision of an auditor to ensure compliance with audit protocols.
- * Cannot work independently or under the auditee's supervision, as they are not responsible for the audit's findings.

The audit team leader has overall responsibility, but technical experts are supervised by an auditor during the audit process.

Reference:

ISO 19011:2018, Clause 5.5 (Determining Audit Team Competence)

NEW QUESTION # 166

Which of the following three options could be considered potential threats to impartiality in an audit context?

- A. Experience
- B. Familiarity
- C. Intimidation
- D. Competence
- E. Self-audit

Answer: B,C,E

Explanation:

Questions no: 1 Verified answer: = C, D, E Comprehensive But Short Explanation: = Potential threats to impartiality in an audit context include familiarity (having a close relationship with the auditee), intimidation (being coerced or feeling pressured), and self-audit (auditing one's own work). These factors can compromise the auditor's objectivity and the audit's integrity. References: = The information is based on the ISO 9001 Auditing Practices Group documents which discuss threats to auditor impartiality and how

they may compromise an auditor's objectivity¹²³.

NEW QUESTION # 167

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

Answer: A

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.

Reference:

ISO/IEC 17021-1:2015, Clause 9.3.1 - Initial Certification Audit (Stage 1 & 2)

NEW QUESTION # 168

Match each of the following statements into the table below to show whether they apply to first-party audits, second-party audits or

third-party audits:

Answer:

Explanation:

Explanation:

Table

Statement

First-party audits

Second-party audits

Third-party audits

The audit scope is typically determined by the organisation being audited.

Yes

No

No

The outcome of the audit is typically certification to a recognised standard.

No

No

Yes

The audit scope is typically confined to service/product provision capability.

No

Yes

No

Here is a brief explanation of each statement:

The audit scope is typically determined by the organisation being audited: This statement applies to first-party audits, also known as internal audits, where the organisation audits its own processes and activities to ensure conformity and improvement¹. The organisation can decide the scope of the audit based on its own needs and objectives². This statement does not apply to second-party audits, where the customer audits the supplier, or third-party audits, where an independent body audits the organisation. In these cases, the audit scope is determined by the customer or the certification body, respectively^{3,4}.

The outcome of the audit is typically certification to a recognised standard: This statement applies to third-party audits, where an independent body audits the organisation to verify that it meets the requirements of a specific standard, such as ISO 9001, and issues a certificate of conformity if the audit is successful⁴. This statement does not apply to first-party audits or second-party audits, where the outcome of the audit is not certification, but rather self-improvement or supplier qualification^{1,3}.

The audit scope is typically confined to service/product provision capability: This statement applies to second-party audits, where the customer audits the supplier to ensure that they are meeting the requirements specified in the contract, such as service or product quality, delivery, or performance^{3,4}. The audit scope is usually focused on the specific aspects of the service or product that are of interest to the customer³. This statement does not apply to first-party audits or third-party audits, where the audit scope is broader and covers the entire quality management system or the relevant clauses of the standard^{1,4}.

NEW QUESTION # 169

You are carrying out an audit at a single-site organisation seeking certification to ISO 9001 for the first time.

The organisation manufactures

cosmetics for major retailers.

You are interviewing the Manufacturing Manager (MM).

You: "I would like to begin by looking at the cleaning controls."

MM: "We record the cleaning of the equipment at the end of every batch. This document details the minimum cleaning frequency and the procedures to follow for all areas and each item of equipment. The person who carries out the cleaning puts their initial on the document and records the time and date alongside." Narrative: You sample production records over 3-days and note down evidence of nonconformity as per the table below.

Answer:

Explanation:

NEW QUESTION # 170

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