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

Topic	Details

Topic 1	<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 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"> 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 4	<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 5	<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 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.

PECB QMS ISO 9001:2015 Lead Auditor Exam Sample Questions (Q148-Q153):

NEW QUESTION # 148

Select the words that best complete the sentence:

Answer:

Explanation:

Explanation:

According to the ISO 19011:2018 document, the audit plan should provide the basis for agreement regarding the conduct and scheduling of the audit activities. The amount of detail provided in the audit plan should reflect the scope and complexity of the audit, as well as the risk of not achieving the audit objectives¹. The scope of the audit refers to the extent and boundaries of the audit, such as the audit criteria, the audit objectives, the organizational and functional units, and the processes to be audited¹. The complexity of the audit refers to the degree of difficulty or intricacy of the audit, such as the number and diversity of the auditees, the audit criteria, the audit methods, and the audit team composition². The risk of not achieving the audit objectives refers to the possibility that the audit may fail to provide reliable and sufficient audit evidence to support the audit conclusions and report¹.

Therefore, the complete sentence is:

In the context of a third-party audit, the amount of detail provided in the audit plan should reflect the scope and complexity of the audit, as well as the risk of not achieving the audit objectives.

References: 1: ISO 19011:2018 - Guidelines for auditing management systems 2: Audit Complexity - an overview | ScienceDirect Topics

NEW QUESTION # 149

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 # 150

You are conducting an ISO 9001 audit of a Materials Recycling Facility (MRF). The organisation processes waste plastics into raw materials for plastic bottle manufacturers. You reach the manual picking line where operators are removing contaminant materials from incoming products, such as plastic bags, plastic film and badly contaminated items that would compromise the recycling process. You interview the line supervisor.

You: "Why are these plastic items being rejected at this stage?"

Auditee: "They do not meet our processing standards."

You: "What is the reason for that?"

Auditee: "These items are likely to damage the machinery down the line. They can also compromise our quality standards. We need to protect our reputation for good quality output materials." You: "What happens to the rejected items?" Auditee: "Some get melted down in another process later on and some are disposed of as waste products that cannot be recycled." You: "What happens to the waste products?" Auditee: "I'm not sure. I suppose they go to landfill." Which two of the following actions would you take to investigate further?

- A. Ask to review the percentage of waste materials.
- B. Ask about operator PPE (Personal Protective Equipment).
- C. Determine what happens to the waste products.
- D. Find out if operators have regular hearing tests.
- E. Check the process for handling nonconforming items.
- F. Determine whether there are quality objectives for reducing rejected material.

Answer: C,E

Explanation:

According to the ISO 9001:2015 standard, clause 8.7 requires that an organization identify and control any nonconforming outputs that do not conform to the requirements of the customer or other relevant requirements. Nonconforming outputs are any outputs from the process, product or service that do not meet the specified quality criteria. Nonconforming outputs must be dealt with in one or more of the following ways:

Correction of the nonconformity

Segregation, containment, return or suspension of provision of products and services Informing the customer Authorisation for acceptance under concession The organization must also retain documented information on the description of the nonconformity, the actions taken, any concessions obtained, and the identification of the authority deciding the action to resolve the nonconformity.

In this scenario, you have interviewed a line supervisor who is responsible for managing a manual picking line where operators are removing contaminant materials from incoming products. The supervisor has explained that these plastic items are rejected at this

stage because they do not meet their processing standards and they can damage their machinery and compromise their quality standards. The supervisor has also mentioned that some of these rejected items are melted down in another process later on and some are disposed of as waste products that cannot be recycled.

Based on this information, you can investigate further by taking two actions:

A: Check the process for handling nonconforming items: You can verify whether there is a documented procedure for identifying, segregating, containing, returning or suspending provision of nonconforming items at this stage. You can also check whether there is a system for informing customers about any nonconforming items that may affect their satisfaction or expectations.

D: Determine what happens to the waste products: You can verify whether there is a documented procedure for disposing of waste products that cannot be recycled as per environmental regulations and customer requirements.

These two actions would help you to determine whether there are any nonconforming outputs at this stage and how they are controlled by the organization.

NEW QUESTION # 151

Consultancy ABC, which is a subsidiary of a certification body called ABC-CERT, provided consultancy services regarding the implementation of a QMS based on ISO 9001 to an organization.

Considering this, can ABC-CERT provide certification services to the organization which obtained consultancy services from Consultancy ABC?

- A. Yes, if both parties sign an agreement which states that previous services by Consultancy ABC will not impact the judgment of auditors.
- **B. No, ABC-CERT is not allowed to provide certification services to that organization ever, as this would be a conflict of interest.**
- C. Yes, after a minimum period of two years has passed.

Answer: B

Explanation:

Comprehensive and Detailed In-Depth Explanation:

Certification bodies must remain independent and impartial. If a certification body (ABC-CERT) provides consulting services to an organization through its subsidiary (Consultancy ABC), it cannot later certify the same organization.

Clause References:

* ISO/IEC 17021-1:2015, Clause 5.2.5 - Impartiality Requirements:

* A certification body must not certify an organization to which it has provided consultancy services.

* ISO/IEC 17021-1:2015, Clause 5.2.6:

* Subsidiaries of certification bodies must not provide consulting services to prevent conflicts of interest.

Why is the Correct Answer C?

* Certifying a client after providing consultancy creates a conflict of interest and violates ISO/IEC 17021-1:2015 impartiality rules.

* The certification body (ABC-CERT) and consultancy firm (Consultancy ABC) are related entities, making it impossible to remain objective and independent.

Why are the Other Options Incorrect?

* A (Waiting two years) # ISO does not specify a time frame; the issue is impartiality, not just time.

* B (Signing an agreement to ensure objectivity) # Conflicts of interest cannot be resolved through an agreement; independence is required.

NEW QUESTION # 152

Confidence in the audit process and its ability to achieve its objectives depends on the competence of those involved in performing audits:

According to ISO 19011, select the two participants who need to be competent in performing audits.

- **A. Audit team leaders**
- B. Guides
- C. Observers
- **D. Auditor(s)**
- E. Auditee
- F. Translators

Answer: A,D

NEW QUESTION # 153

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