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

Topic	Details
Topic 1	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 2	Managing an ISO 9001 audit program: This topic evaluates your abilities to establish and managing a QMS audit program.

Topic 3	• Closing an ISO 9001 audit: The topic focuses on concluding a QMS audit and conducting audit follow-up activities.
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.

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PECB QMS ISO 9001:2015 Lead Auditor Exam Sample Questions (Q41-Q46):

NEW QUESTION # 41

Scenario 4:

TD Advertising is a print management company based in Chicago. The company offers design services, digital printing, storage, and distribution. As TD expanded, its management recognized that success depended on adopting new technologies and improving quality.

To ensure customer satisfaction and quality improvement, the company decided to pursue ISO 9001 certification.

After implementing the QMS, TD hired a well-known certification body for an audit. Anne Key was appointed as the audit team leader. She received a document listing the audit team members, audit scope, criteria, duration, and audit engagement limits. Anne reviewed the document and approved the audit mandate. The certification body and TD's top management signed the certification agreement.

Before contacting TD, Anne reviewed the audit scope and noticed that TD made changes to it due to the adoption of new printing equipment. However, Anne disagreed with the changes, stating they would affect the audit timeline. She considered withdrawing from the audit.

The audit team members were selected based on their knowledge of the legal and other regulations that TD is subject to. Is this acceptable?

- A. No, because there is no need to have knowledge of the legal and other requirements that TD is subject to.
- **B. Yes, to ensure effective conduct of the audit, each audit team member should have knowledge of legal and other requirements that TD is subject to.**
- C. Yes, but only the lead auditor needs to have knowledge of legal and other regulatory requirements.
- D. No, because only one audit team member is required to have knowledge of legal and other regulatory requirements that TD is subject to.

Answer: B

Explanation:

Comprehensive and Detailed In-Depth Explanation:

ISO 9001:2015 requires organizations to ensure that auditors have the necessary competence and knowledge to conduct audits effectively.

Clause References:

* ISO 19011:2018, Clause 7.2.1 - Determining Competence of Auditors: Auditors must have knowledge of applicable legal and regulatory requirements that affect the scope of the audit.

* ISO/IEC 17021-1:2015, Clause 7.1.2 - Competence Requirements: Certification bodies must ensure that auditors assigned to the audit team possess relevant knowledge in areas such as legal and regulatory compliance.

Why is the Correct Answer C?

- * Each audit team member should have sufficient knowledge of relevant legal and regulatory requirements to ensure compliance.
 - * This helps auditors identify gaps or nonconformities related to compliance obligations.
 - * Having multiple team members with knowledge reduces reliance on a single expert and ensures a comprehensive assessment.
- Why are the Other Options Incorrect?
- * A (Only one team member needs knowledge) # Incorrect because audits involve various aspects, and all auditors should have basic awareness of legal and regulatory requirements.
 - * B (Legal knowledge is not necessary) # Incorrect because compliance is essential for QMS effectiveness.
 - * D (Only the lead auditor needs legal knowledge) # Incorrect because ISO requires all auditors to be competent in applicable laws, not just the leader.

NEW QUESTION # 42

State the correct sequence of events in the certification process for an organisation to obtain third-party accredited certification to ISO 9001.

State the correct sequence of events in the certification process for an organisation to obtain third-party accredited certification to ISO 9001.

	Event
1	
2	
3	
4	

To complete the sequence, 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 the options to the appropriate blank section.

Conduct certification audit stages	Accredit Certification Body	Award ISO 9001 certificate	Programme initial certification audit
------------------------------------	-----------------------------	----------------------------	---------------------------------------

Answer:

Explanation:

State the correct sequence of events in the certification process for an organisation to obtain third-party accredited certification to ISO 9001.

	Event
1	Programme initial certification audit
2	Conduct certification audit stages
3	Award ISO 9001 certificate
4	Accredit Certification Body

To complete the sequence, 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 the options to the appropriate blank section.

Conduct certification audit stages	Accredit Certification Body	Award ISO 9001 certificate	Programme initial certification audit
------------------------------------	-----------------------------	----------------------------	---------------------------------------

NEW QUESTION # 43

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

The organization 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.

Date	Batches of product made	Production line to be cleaned	Cleaned by	Number of cleaning records
10/XX	10	Line 1	DS	6
	14	Line 2	HM	8
11/XX	12	Line 1	WR	7
	12	Line 2	DD	9
12/XX	15	Line 1	DS	10

You decide to raise a nonconformity.

Nonconformity report	
ISO 9001 Clause Number:	
Nature of problem:	
ISO 9001 requirement that has not been fulfilled:	
Evidence:	40 cleaning records are available for 63 batches.

To complete the nonconformity report click on the blank section you want to complete so it is highlighted in red and then click on the applicable text from the options below. Alternatively, you may drag and drop the options to the appropriate blank section.

Cleaning and sanitising not always completed.	ISO 9001 - "The organization shall implement planned arrangements, at appropriate stages, to verify that the product requirements have been met."
Cleaning and sanitising records are not available for every batch.	8.7 8.5.4
ISO 9001 - "The organization shall implement production provision under controlled conditions."	ISO 9001 - "The organization shall preserve the outputs during production provision to the extent necessary to ensure conformity to requirements."
Cleaning and sanitising are not always completed by trained staff.	6.2.1

Answer:

Explanation:

You decide to raise a nonconformity.

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Nonconformity report	
ISO 9001 Clause Number:	8.5.4
Nature of problem:	ISO 9001 - "The organization shall implement planned arrangements, at appropriate stages, to verify that the product requirements have been met."
ISO 9001 requirement that has not been fulfilled:	
Evidence:	

To complete the nonconformity report click on the blank section you want to complete so it is highlighted in red and then click on the applicable text from the options below. Alternatively, you may drag and drop the options to the appropriate blank section.

Cleaning and sanitising not always completed.

ISO 9001 - "The organization shall implement planned arrangements, at appropriate stages, to verify that the product requirements have been met."

Cleaning and sanitising records are not available for every batch.

8.7

8.5.4

ISO 9001 - "The organization shall preserve the outputs during production provision to the extent necessary to ensure conformity to requirements."

ISO 9001 - "The organization shall implement production provision under controlled conditions."

Cleaning and sanitising are not always completed by trained staff.

6.2.1

Explanation:

Nonconformity report

ISO 9001 Clause Number: 8.5.4 Nature of problem: Cleaning and sanitising records are not available for every batch. ISO 9001 requirement that has not been fulfilled: ISO 9001 - "The organization shall implement planned arrangements, at appropriate stages, to verify that the product requirements have been met." Evidence: 40 cleaning records are available for 63 batches.

NEW QUESTION # 44

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

Answer: A

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.

NEW QUESTION # 45

The following are stages of an audit, put them in the order they would be conducted.

The following are stages of an audit, put them in the order they would be conducted.

The first and last stages have been done for you.

To complete the sequence click on the blank section you want to complete so it is highlighted in red and then click on the applicable text from the options below. Alternatively, drag and drop the options to the appropriate blank section.

1. Establishing the audit programme objectives
2.
3.
4.
5.
6. Conducting the audit activities

Determining and evaluating the audit programme risks and opportunities

Initiating the audit

Establishing the audit programme

Preparing all audit activity

Answer:

Explanation:

The following are stages of an audit, put them in the order they would be conducted.

The first and last stages have been done for you.

To complete the sequence click on the blank section you want to complete so it is highlighted in red and then click on the applicable text from the options below. Alternatively, drag and drop the options to the appropriate blank section.

1. Establishing the audit programme objectives
- Determining and evaluating the audit programme risks and opportunities
3. Establishing the audit programme
4.

Initiating the audit
5.

Preparing all audit activity
6. Conducting the audit activities

Determining and evaluating the audit programme risks and opportunities

Initiating the audit

Establishing the audit programme

Preparing all audit activity

Explanation:

1. Establishing the audit programme objectives
2.

Determining and evaluating the audit programme risks and opportunities
3.

Establishing the audit programme
4.

Initiating the audit
5.

Preparing all audit activity
6. Conducting the audit activities

Establishing the audit programme objectives

Determining and evaluating the audit programme risks and opportunities

Establishing the audit programme

Initiating the audit

Preparing all audit activity

Conducting the audit activities

To complete the sequence, you can drag and drop the options to the appropriate blank section.

Here is a brief explanation of each stage:

Establishing the audit programme objectives: This is the first stage of the audit process, where the purpose, scope, and criteria of the audit programme are defined. The audit programme objectives should be aligned with the strategic direction and policies of the organization, and should address the needs and expectations of the interested parties¹².

Determining and evaluating the audit programme risks and opportunities: This is the second stage of the audit process, where the

factors that can affect the achievement of the audit programme objectives are identified and assessed. The audit programme risks and opportunities should consider the internal and external issues, the requirements and changes of the interested parties, and the results and feedback from previous audits¹².

Establishing the audit programme: This is the third stage of the audit process, where the audit programme is designed and implemented. The audit programme should include the audit programme procedures, the audit programme resources, the audit methods and techniques, the audit frequency and schedule, and the audit programme performance indicators¹².

Initiating the audit: This is the fourth stage of the audit process, where the audit is prepared and planned. The audit initiation involves selecting the audit team, establishing the contact with the auditee, defining the audit objectives, scope, and criteria, developing the audit plan, and conducting the document review¹²³.

Preparing all audit activity: This is the fifth stage of the audit process, where the audit activities are organized and coordinated. The audit preparation involves assigning the audit tasks, communicating with the auditee and the audit team, arranging the logistics, preparing the working documents, and conducting the opening meeting¹²³.

Conducting the audit activities: This is the sixth and final stage of the audit process, where the audit evidence is collected and evaluated. The audit conduct involves performing the audit activities, such as interviews, observations, document reviews, and tests, documenting the audit findings, preparing the audit conclusions, and conducting the closing meeting¹²³.

I hope this helps you with your ISO 9001 Lead Auditor objectives and content. If you have any further questions, please feel free to ask. # References: 1: ISO 19011:2018 - Guidelines for auditing management systems 2: Audit Process | Flowchart | Summary - Accountingdue 3: What are the Stages of the Auditing Process & Why it is Important ...

NEW QUESTION # 46

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