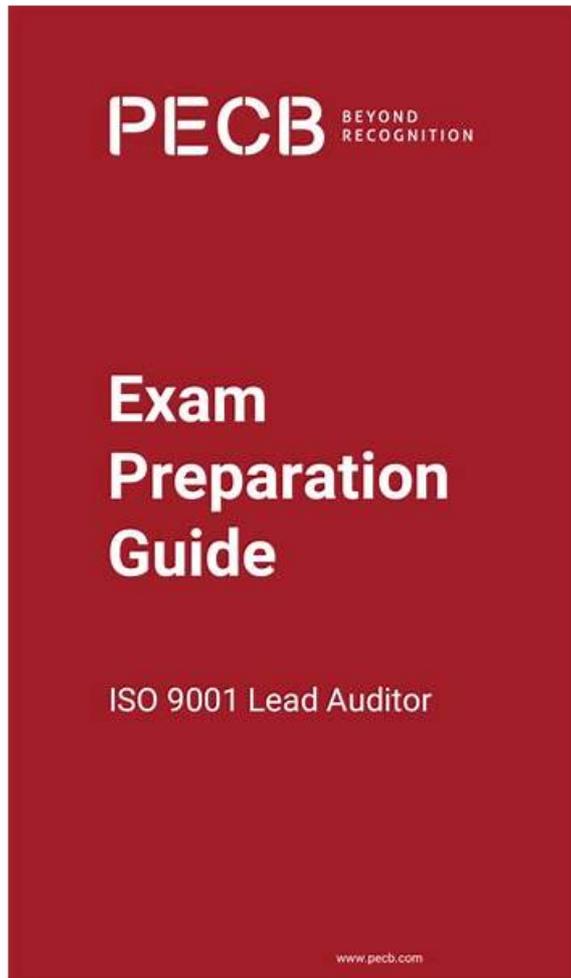


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PECB ISO-9001-Lead-Auditor Exam Syllabus Topics:

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">Conducting an ISO 9001 audit: It evaluates your skills to conduct a QMS audit.
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"> • Closing an ISO 9001 audit: The topic focuses on concluding a QMS audit and conducting audit follow-up activities.
Topic 5	<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 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.

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PECB QMS ISO 9001:2015 Lead Auditor Exam Sample Questions (Q57-Q62):

NEW QUESTION # 57

The following actions need to be carried out during a third-party audit planning stage. Which two actions correspond to the individual(s) managing the audit program before the involvement of the audit team leader'

- A. Select the audit team members
- B. Prepare the audit plan
- C. Review the reports of previous audits
- D. Assign responsibilities within the audit team
- E. Prepare the checklists
- F. Provide the resources needed

Answer: C,F

Explanation:

In ISO 9001:2015, the responsibility for managing the audit program lies with those overseeing the entire audit process rather than the Audit Team Leader. During the planning stage, before involving the Audit Team Leader, key actions for managing the audit program include:

1. Providing the Resources Needed: According to clause 7.1 (Resources), the audit program manager must ensure that the necessary resources are in place to conduct the audit effectively. This encompasses logistical support, personnel, and other required resources for the audit to proceed smoothly.
2. Reviewing Reports of Previous Audits: As per clause 9.2.2 (Internal Audit), it is essential to consider the results of previous audits to plan effectively for the upcoming audit. This helps identify areas that require particular attention, ensuring continuity and focusing on recurring issues or improvements since the last audit.

These actions ensure that the audit is thoroughly prepared and that there is continuity and focus on any areas that might need closer inspection. The other options, such as preparing the audit plan, assigning responsibilities, preparing checklists, and selecting the audit team members, generally fall under the duties of the Audit Team Leader once they are appointed and engaged in the planning process.

NEW QUESTION # 58

You are carrying out an audit to ISO 9001 at an organisation which offers regulatory consultancy services to manufacturers of cosmetics.

You are interviewing the Technical Director (TD), who manages a team of regulatory experts responsible for providing regulatory services to customers.

You: "How do you ensure your regulatory team's competence concerning regulatory requirements is maintained?" TD: "The two Regulatory Experts we employ full-time have years of experience of working in the cosmetics industry." You: "How is their regulatory competence maintained?" TD: "They are dedicated individuals with lots of contacts in the sector." You: "How does the business enable them to maintain their understanding of current regulatory requirements?" TD: "We leave that up to them."

You decide to raise a nonconformity.

Nonconformity report

ISO 9001 Clause Number:	
Nature of problem:	
ISO 9001 requirement that has not been fulfilled:	

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, drag and drop the options to the appropriate blank section.

The organisation has not determined the necessary competence of the Regulatory Experts with respect to relevant regulatory requirements.

The organisation has not ensured that persons doing work under the organisation's control are aware of relevant quality objectives.

7.1.2

ISO 9001 - "The organization shall ensure that persons are competent on the basis of appropriate education, training, or experience."

The business has not maintained its organisational knowledge.

7.1.6

ISO 9001 - "The organization shall determine and provide the persons necessary for the effective implementation of its quality management system."

ISO 9001 - "The organization shall determine the knowledge necessary for the operation of its processes and to achieve conformity of products and services."

7.2

Answer:

Explanation:

You decide to raise a nonconformity.

Nonconformity report

ISO 9001 Clause Number:	
Nature of problem:	The organisation has not determined the necessary competence of the Regulatory Experts with respect to relevant regulatory requirements.
ISO 9001 requirement that has not been fulfilled:	ISO 9001 - "The organization shall determine and provide the persons necessary for the effective implementation of its quality management system."

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, drag and drop the options to the appropriate blank section.

The organisation has not determined the necessary competence of the Regulatory Experts with respect to relevant regulatory requirements.

The organisation has not ensured that persons doing work under the organisation's control are aware of relevant quality objectives.

7.1.2

ISO 9001 - "The organization shall ensure that persons are competent on the basis of appropriate education, training, or experience."

The business has not maintained its organisational knowledge.

7.1.6

ISO 9001 - "The organization shall determine and provide the persons necessary for the effective implementation of its quality management system."

ISO 9001 - "The organization shall determine the knowledge necessary for the operation of its processes and to achieve conformity of products and services."

7.2

Explanation:

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Nonconformity report	
ISO 9001 Clause Number:	7.2
Nature of problem:	The organisation has not determined the necessary competence of the Regulatory Experts with respect to relevant regulatory requirements.
ISO 9001 requirement that has not been fulfilled:	ISO 9001 - "The organization shall determine and provide the persons necessary for the effective implementation of its quality management system."

NEW QUESTION # 59

You are the supervisor in Production of a medium size manufacturing organisation. You are qualified as an internal auditor. The Quality Manager asks you to lead the next internal audit of Production and Logistics Dispatch. The audit team includes two other internal auditors.

You are the supervisor in Production of a medium size manufacturing organisation. You are qualified as an internal auditor. The Quality Manager asks you to lead the next internal audit of Production and Logistics / Dispatch. The audit team includes two other internal auditors.

*if practicable
*You should not ...
You need not ...
You must ...
You must not ...
You should ...

To complete the sentences 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.

Answer:

Explanation:

You are the supervisor in Production of a medium size manufacturing organisation. You are qualified as an internal auditor. The Quality Manager asks you to lead the next internal audit of Production and Logistics / Dispatch. The audit team includes two other internal auditors.

*if practicable
*You should not ...
You need not ...
You must ...
You must not ...
You should ...

To complete the sentences 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.

Explanation:

Here is the correct matching of actions to the statements in the context of leading the internal audit:

- * If practicable carry out a formal opening meeting
- * You should not audit production (as you are a supervisor in that area, and this would compromise audit objectivity)
- * You need not change the audit team (unless there is a specific reason, such as conflict of interest)
- * You must raise audit findings if necessary (this is a key responsibility of an auditor when nonconformities are found)
- * You must not send the audit report to the Quality Manager (the audit report must be reviewed first; it is typically part of the internal audit process to go through necessary channels before final submission)
- * You should send the audit report to the Quality Manager (after appropriate reviews and approvals) This reflects key principles of conducting an internal audit according to ISO 9001:2015, ensuring objectivity, proper documentation, and clear reporting procedures.

NEW QUESTION # 60

In the context of a third-party audit, match the event with the responsibility for conducting it.

Event	Responsibility
Selecting audit team	
Conducting the audit	
Preparing the audit plan	
Requesting the audit	

To complete the table, 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 each option to the appropriate blank section.

Individual(s) managing the audit programme

Audit team

Audit team leader

Audit client

Answer:

Explanation:

Event	Responsibility
Selecting audit team	Individual(s) managing the audit programme
Conducting the audit	Audit team
Preparing the audit plan	Audit team leader
Requesting the audit	Audit client

To complete the table, 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 each option to the appropriate blank section.

Individual(s) managing the audit programme

Audit team

Audit team leader

Audit client

Explanation:

The correct answer is:

Event

Selecting audit team = Individual(s) managing the audit programme

Conducting the audit = Audit team

Preparing the audit plan = Audit team leader

Requesting the audit = Audit client

To complete the table, 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 each option to the appropriate blank section. Responsibility:- Individual(s) managing the audit programme Audit team Audit team leader Audit client According to ISO 19011:2018, clause 5.3, the individual(s) managing the audit programme are responsible for selecting the audit team, taking into account the competence and availability of the auditors and any experts needed. 1 According to clause 6.2, the audit team is responsible for conducting the audit, which includes collecting and verifying audit evidence, evaluating audit findings, and preparing the audit report. 1 According to clause 6.1, the audit team leader is responsible for preparing the audit plan, which includes defining the audit objectives, scope, criteria, and duration, as well as assigning roles and responsibilities to the audit team members. 1 According to clause 5.2, the audit client is the

person or organization that requests the audit, which can be the auditee (the person or organization being audited) or any other person or organization that has an interest in the audit results. 1 References:

* 1: ISO 19011:2018 - Guidelines for auditing management systems

NEW QUESTION # 61

Whistiekleen is a national dry cleaning and laundry organisation with 50 shops. You are conducting a surveillance audit of the Head Office and are sampling customer complaints. You find that 80% of complaints originate from five shops in the same region. Most of these complaints relate to damage to customer laundry.

The Quality Manager tells you that these are the oldest shops in the organisation. The cleaning equipment needs replacing but the organisation cannot afford it now. You learn that the shop managers were told to dismiss most of the claims based on the poor quality of the laundered materials.

On raising the matter with senior management, you are told that there are plans to replace the equipment in these shops over the next five years.

Match the ISO 9001 Clauses to the statements.

The organisation informing customers of the reason for the damage to their laundry.

Management allocating sufficient resources to replace outdated equipment.

Corrective action to deal with customer complaints.

Top management addressing the risk of damage to customer property.

Management setting a quality objective for the level of customer complaints.

To complete the table click on the blank section you want to complete so it is highlighted in red and then click on the applicable clause of ISO 9001 below. Alternatively, you may drag and drop each of the following clause's ISO 9001 shown to the appropriate statement:

8.5.3 7.1.3 b 5.1.2 b 6.2 10.2.1 b

Answer:

Explanation:

The organisation informing customers of the reason for the damage to their laundry.

Management allocating sufficient resources to replace outdated equipment.

Corrective action to deal with customer complaints.

Top management addressing the risk of damage to customer property.

Management setting a quality objective for the level of customer complaints.

To complete the table click on the blank section you want to complete so it is highlighted in red and then click on the applicable clause of ISO 9001 below. Alternatively, you may drag and drop each of the following clause's ISO 9001 shown to the appropriate statement:

8.5.3 7.1.3 b 5.1.2 b 6.2 10.2.1 b

Explanation:

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Statement	Clause
The organisation informing customers of the reason for the damage	8.5.3
Management allocating sufficient resources to replace outdated equipment	7.1.3 b
Corrective action to deal with customer complaints	10.2.1 b
Top management addressing the risk of damage to customer property	5.1.2 b
Management setting a quality objective for the level of complaints	6.2

Clause 8.5.3 - Property Belonging to Customers or External Providers: This clause requires the organization to care for customer property while it is under their control. If there is damage, they must inform the customer and retain documented information. Thus, informing customers of the reason for laundry damage relates directly to this clause. # Reference: ISO 9001:2015 Clause 8.5.3

Clause 7.1.3 b - Infrastructure: It refers to the provision and maintenance of infrastructure necessary for the operation of processes. This includes equipment. If resources are not allocated for outdated equipment, it directly breaches this clause. # Reference: ISO 9001:2015 Clause 7.1.3 b

Clause 10.2.1 b - Corrective Action: This clause covers actions to eliminate the causes of nonconformities to prevent recurrence, including evaluating and correcting customer complaints. # Reference: ISO 9001:2015 Clause 10.2.1 b

Clause 5.1.2 b - Customer Focus (Top Management): Top management must ensure risks to customer satisfaction, including property damage, are addressed. This aligns with addressing the risk of damaging customer laundry. # Reference: ISO 9001:2015 Clause 5.1.2 b

Clause 6.2 - Quality Objectives and Planning to Achieve Them: Setting objectives for reducing customer complaints (like those about laundry damage) falls under this clause. # Reference: ISO 9001:2015 Clause 6.2

NEW QUESTION # 62

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