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

Topic	Details
Topic 1	<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 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"> 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 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.

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PECB QMS ISO 9001:2015 Lead Auditor Exam Sample Questions (Q29-Q34):

NEW QUESTION # 29

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.

audit production carry out a formal opening meeting raise audit findings if necessary change the audit team send the audit report to the Quality Manager

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.

audit production carry out a formal opening meeting raise audit findings if necessary change the audit team send the audit report to the Quality Manager

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 # 30

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

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

Answer: B,D

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 auditee.

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 objectives.

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 auditee.

*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 audit.

*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 preparation.

*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 activities.

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

NEW QUESTION # 31

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.

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 non-conformity.

Non-conformity report	
ISO 9001 Clause Number:	<input type="text"/>
Nature of problem:	<input type="text"/>
ISO 9001 requirement that has not been fulfilled:	<input type="text"/>
Evidence:	40 cleaning records are available for 63 batches.

To complete the non-conformity 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 records are not available for every batch.

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

Cleaning and sanitising are not always completed by trained staff.

6.2.1

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 not always completed.

8.7

8.5.4

Answer:

Explanation:

Non-conformity 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 production provision under controlled conditions."
Evidence:	40 cleaning records are available for 63 batches.

To complete the non-conformity 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 records are not available for every batch.

Cleaning and sanitising are not always completed by trained staff.

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

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

6.2.1

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

Cleaning and sanitising not always completed.

8.7

8.5.4

Explanation:

Clause: 8.5.4

Nature of Problem: Cleaning and sanitising records are not available for every batch.

Unfulfilled Requirement: "The organization shall implement production provision under controlled conditions."

NEW QUESTION # 32

You have been nominated audit team leader of a third-party audit. Which of the following could be the two most relevant objectives of this audit?

- A. Identify opportunities for improvement
- B. Identify the need of resources
- C. Evaluate the benefits obtained since the implementation of the management system
- **D. Evaluate the capability of the management system to establish and achieve objectives**
- E. Evaluate the satisfaction interested parties
- **F. Evaluate the effectiveness of the management system**

Answer: D,F

Explanation:

Evaluate the effectiveness of the management system: This objective involves verifying that the quality management system meets the requirements of a specific standard, such as ISO 9001:2015, and that it achieves the intended results and outcomes. The audit team will collect and analyse audit evidence to determine the degree of conformity and performance of the quality management system²³.

*Evaluate the capability of the management system to establish and achieve objectives: This objective involves verifying that the quality management system supports the strategic direction and policies of the organization, and that it addresses the needs and expectations of the interested parties. The audit team will assess the suitability, adequacy, and alignment of the quality management system objectives, and the effectiveness of the planning and implementation processes to achieve them²³.

The other options are not the most relevant objectives of a third-party audit, according to the web search results from my internal tool. They may be related to other aspects or types of audits, but they are not the focus of a third-party audit.

Therefore, the correct answer is B and D.

References: 1: Safeguarding Your Business: The Power of Third-Party Security Audits 2: ISO 19011:2018 - Guidelines for auditing management systems 3: Third Party Audit - QMSGurus.com

NEW QUESTION # 33

Select the word that best completes the sentence:

Select the word that best completes the sentence:

"The purpose of a management system standard is to _____ the performance of an organisation."

To complete the sentence with the best word, click on the blank section you want to complete so it is highlighted in red and then click on the applicable text from the option(s) below. Alternatively, drag and drop the option(s) to the appropriate blank section.

manage monitor improve dictate

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Answer:

Explanation:

Select the word that best completes the sentence:

"The purpose of a management system standard is to **improve** the performance of an organisation."

To complete the sentence with the best word, click on the blank section you want to complete so it is highlighted in red and then click on the applicable text from the option(s) below. Alternatively, drag and drop the option(s) to the appropriate blank section.

manage monitor improve dictate

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Explanation:

"The purpose of a management system standard is to **improve** the performance of an organisation."

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According to the ISO - Management system standards page, the key benefits of an effective management system include improved operational effectiveness and efficiency, improved risk management and protection of people and the environment, and enhanced drive for innovation. The Integrated Use of Management System Standards (IUMSS) handbook also states that the purpose and objectives of management system standards are to help organizations improve their performance by specifying repeatable steps that organizations consciously implement to achieve their goals and objectives.

Therefore, the complete sentence is:

"The purpose of a management system standard is to improve the performance of an organisation."

NEW QUESTION # 34

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It is universally accepted that in this competitive society in order to get a good job we have no choice but to improve our own capacity and explore our potential constantly, and try our best to get the related ISO-9001-Lead-Auditor certification is the best way to show our professional ability, however, the ISO-9001-Lead-Auditor Exam is hard nut to crack and but our ISO-9001-Lead-Auditor preparation questions related to the exam for it seems impossible for us to systematize all of the key points needed for the exam by ourselves. With our ISO-9001-Lead-Auditor exam questions, you will pass the exam with ease.

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