

ISO-9001-Lead-Auditor Valid Test Duration & Study

ISO-9001-Lead-Auditor Tool



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

Topic	Details
Topic 1	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	Conducting an ISO 9001 audit: It evaluates your skills to conduct a QMS audit.
Topic 3	Managing an ISO 9001 audit program: This topic evaluates your abilities to establish and managing a QMS audit program.
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.
Topic 5	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	Preparing an ISO 9001 audit: This topic covers sub-topics related to preparing a quality management system audit.

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PECB QMS ISO 9001:2015 Lead Auditor Exam Sample Questions (Q226-Q231):

NEW QUESTION # 226

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 ...
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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 # 227

A Health Trust has contracted with Servitup, a catering services organisation which has been certified to ISO 9001 for 1 year. It provides services to ten, small rural hospitals in remote locations involving purchase and storage of dry goods and fresh produce, preparing meals and loading heated trolleys for ward service by hospital staff. An auditor is conducting the first sole surveillance audit at one site with the Deputy Catering Manager (DCM).

At the closing meeting attended solely by the DCM, the auditor informs him that he has found numerous gaps in the QMS processes which lead him to consider recommending suspension of the organisation's certification. He is particularly concerned with the evidence that patient health is being adversely affected by produce stored beyond its safe consumption date, poor kitchen hygiene and undercooked meals. The DCM says that he cannot make any decisions about these issues in the absence of the Catering Manager due to illness but will write everything down and report to the Catering Manager.

Which two actions should you take in the context of the audit?

- A. Close the meeting immediately after the DCM's response and advise that the issues will be addressed at the next surveillance visit.
- B. Conclude the meeting early and advise that it will be rescheduled once the Catering Manager has returned to work.
- C. Continue with the meeting, present the audit conclusions and inform the DCM that the organisation will receive the audit report in due course.
- D. Recommend that all personnel should be given urgent in-depth training in the QMS.
- E. Call the individual(s) managing the audit programme to explain the situation and recommend immediate suspension of certification to protect the integrity of the Certification Body.
- F. Thank the DCM for his time and express an expectation that improvements will be made in the QMS.

Answer: C,E

Explanation:

The actions that should be taken in the context of the audit are:

*Option B: Call the individual(s) managing the audit programme to explain the situation and recommend immediate suspension of certification to protect the integrity of the Certification Body. This option is correct because the auditor has found serious and significant gaps in the QMS processes that affect the health and safety of the patients, which is a major nonconformity that may warrant suspension of certification. The auditor should inform the individual(s) managing the audit programme of the situation and the audit findings, and recommend immediate suspension of certification to protect the integrity of the Certification Body and the credibility of the certification scheme. The auditor should also follow the Certification Body's procedures and rules for suspension of certification and communicate the decision and the consequences to the auditee.

*Option C: Continue with the meeting, present the audit conclusions and inform the DCM that the organisation will receive the audit report in due course. This option is correct because the auditor should not terminate or postpone the closing meeting due to the absence of the Catering Manager, as the DCM is the auditee's nominated representative for the audit. The auditor should continue with the meeting, present the audit conclusions and the audit findings, and inform the DCM that the organisation will receive the audit report in due course. The auditor should also explain the audit outcome recommendation and the suspension of certification, and request the DCM to acknowledge the receipt and understanding of the audit results.

The following options are not correct:

*Option A: Close the meeting immediately after the DCM's response and advise that the issues will be addressed at the next surveillance visit. This option is not correct because the auditor should not close the meeting without presenting the audit conclusions and the audit findings, as this would violate the audit principles of fairness and transparency. The auditor should also not advise that the issues will be addressed at the next surveillance visit, as this would imply that the auditor is accepting the auditee's delay and inaction, and that the auditor is not taking the major nonconformity seriously.

*Option D: Conclude the meeting early and advise that it will be rescheduled once the Catering Manager has returned to work. This option is not correct because the auditor should not conclude the meeting early or reschedule it due to the absence of the Catering Manager, as this would disrupt the audit process and the audit schedule. The auditor should also not wait for the Catering Manager to return to work, as this would delay the communication and resolution of the major nonconformity, and potentially compromise the health and safety of the patients.

*Option E: Recommend that all personnel should be given urgent in-depth training in the QMS. This option is not correct because the auditor should not recommend or prescribe specific corrective actions to the auditee, as this would violate the audit principles of independence and objectivity. The auditor should only report the audit findings and the audit outcome recommendation, and leave the responsibility and authority for determining and implementing the corrective actions to the auditee.

*Option F: Thank the DCM for his time and express an expectation that improvements will be made in the QMS. This option is not correct because the auditor should not thank the DCM for his time and express an expectation that improvements will be made in the QMS, as this would imply that the auditor is satisfied and optimistic with the auditee's performance and response, and that the auditor is not taking the major nonconformity seriously. The auditor should instead express the concern and dissatisfaction with the auditee's QMS processes and the impact on the health and safety of the patients, and communicate the suspension of certification

and the need for urgent and effective corrective actions.

References:

*ISO 19011:2018 Guidelines for auditing management systems, Clause 6.4.2: Conducting audit activities, Subclause k) and l)

*ISO 9001 Lead Auditor Course Material, Module 5: Conducting an Audit, Slide 20: Closing Meeting

*ISO 9001 Lead Auditor Training Course - IRCA Certified, Section 5.5: Closing Meeting

*Lead Auditor Exam Preparation Guide (EPG) Template - PECB, Section 3.2: Exam Content Outline, Subsection 3.2.1: Section 1

- Audit Fundamentals, Subsection 3.2.2: Section 2 - Audit Principles, Subsection

3.2.3: Section 3 - Audit Process, Subsection 3.2.4: Section 4 - Audit Competencies

NEW QUESTION # 228

Which of the options below is an example of minor nonconformity?

- A. Some of the nonconformities were not closed as planned (on time) and no justification was provided or documented
- B. Lack of corrective actions to address recurrent incidents
- C. Lack of commitment from the top management

Answer: A

Explanation:

Comprehensive and Detailed In-Depth Explanation: Minor nonconformities are isolated issues that do not significantly impact the QMS but still require correction.

* Failure to close nonconformities on time (Answer A) is a procedural issue and is considered minor unless it leads to repeated failures.

Major nonconformities include:

* Lack of top management commitment (Answer B), which affects leadership and strategic direction.

* Failure to take corrective actions for recurrent issues (Answer C), which indicates systemic failure.

NEW QUESTION # 229

For a third-party, match the Activity with the Responsibility for conducting it.

For a third-party audit, match the Activity with the Responsibility for conducting it.

Activity	Responsibility
Approve Certification Body	
Award certification	
Recommend certification	
Maintain certification	

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 text from the option(s) below. Alternatively, drag and drop the option(s) to the appropriate blank section.

Accreditation Body	Certification Body	Audit Team Leader	Auditee organisation
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Answer:

Explanation:

For a third-party audit, match the Activity with the Responsibility for conducting it.

Activity	Responsibility
Approve Certification Body	Accreditation Body
Award certification	Certification Body
Recommend certification	Audit Team Leader
Maintain certification	Auditee organisation

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 text from the option(s) below. Alternatively, drag and drop the option(s) to the appropriate blank section.

Accreditation Body	Certification Body	Audit Team Leader	Auditee organisation
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Explanation:

Activity	Responsibility
Approve Certification Body	Accreditation Body
Award certification	Certification Body
Recommend certification	Audit Team Leader
Maintain certification	Auditee organisation

* Approve Certification Body: Accreditation Body

* Award certification: Certification Body

* Recommend certification: Audit Team Leader

* Maintain certification:

Comprehensive Detailed ExplanationIn the context of a third-party ISO 9001 audit, different entities play specific roles in the certification process. Here's a detailed explanation of the responsibilities:

* Approve Certification Body: Accreditation BodyThe Accreditation Body is responsible for approving Certification Bodies.

Accreditation Bodies are independent entities that evaluate the competence of Certification Bodies, ensuring they meet international standards like ISO/IEC 17021, which sets out the criteria for bodies providing audit and certification of management systems. In this role, they confirm that the Certification Body is capable of conducting ISO 9001 audits and granting certifications in accordance with international guidelines.

* Award Certification: Certification BodyThe Certification Body is the entity that ultimately awards the certification to an organization after verifying that it meets the ISO 9001 standards. Certification Bodies conduct audits, either directly or through a team of auditors, and based on the audit outcomes, they issue the certification, indicating that the organization complies with ISO 9001.

* Recommend Certification: Audit Team LeaderThe Audit Team Leader is responsible for leading the audit and making a recommendation to the Certification Body. This recommendation is based on the audit findings-whether the organization meets the ISO 9001 requirements or if there are areas of non- compliance that need corrective action. The final decision on certification is not made by the Audit Team Leader but by the Certification Body.

* Maintain Certification: Certification BodyMaintaining certification refers to the ongoing process of ensuring that an organization continues to comply with ISO 9001 requirements. The Certification Body conducts regular surveillance audits (e.g., annually) and may also perform recertification audits (typically every three years). This ongoing monitoring ensures that the certified organization continues to adhere to the quality management standards over time.

This breakdown clearly assigns responsibility based on the defined roles of Accreditation Bodies, Certification Bodies, and Audit Teams in the ISO 9001 certification process.

NEW QUESTION # 230

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 and the name of the retailer supplied appears on the product packaging.

Sales turnover has increased significantly over the past five years. The organisation uses a software programme called SWIFT, which is used to record sales, plan production, purchase supplies, print despatch notes, track new product development, perform traceability exercises, carry out mass balance checks, raise invoices, create budgets, and support financial control.

You are nearing the end of the audit and you are reviewing your audit notes. You notice a recurring trend concerning the SWIFT database as shown below:

Your audit notes	Status
Production Planner: SWIFT database version 202	Requires audit trail
Manufacturing Manager: SWIFT database version 169	Requires audit trail
Manufacturing Supervisor: SWIFT database version 169	Requires audit trail
Product Development Manager: SWIFT database version 169	Requires audit trail
Logistics Supervisor: SWIFT database version 182	Requires audit trail
Quality Manager: SWIFT database version 205	Requires audit trail

You ask the Quality Manager to explain how the SWIFT database is controlled. You learn that the Operations Director is responsible for determining and progressing SWIFT software updates. You decide to meet the Operations Director (OD).

You: "Good afternoon."

OD: "Good afternoon."

You: "What responsibility do you have concerning the SWIFT database?"

OD: "I maintain it. If anyone wishes to propose an update to the database, they send me an email with details of their proposal. I then either process the database update myself, or I send the request to the consultant who designed the database 20 years ago. The necessary software changes are made, and the amended software is immediately released to users." You: "Would you explain how the software amendments are controlled?" OD: "Of course. I personally update every computer myself." You: "Do you inform the database users of the changes?" OD: "No I don't. They find out for themselves by using the software, or they come to see me if they have any questions." You: "How do you ensure that the database users use the latest version?" OD: "That's easy, I update every computer myself." You: "During the audit, I noted there were several versions of SWIFT in use (you refer to your audit notes)." OD: "I know. That's because some versions work better than others, and depending on user needs and experiences, we allow users to revert to using an earlier version if they find it works better for them." Based on the scenario, which two of the following statements are true? There is evidence of nonconformity with a requirement defined in ...

- A. clause 7.5.1 Documented information - General
- B. ... clause 7.5.2 Documented information - Creating and updating
- C. ... clause 7.1.4 Environment for the operation of processes
- D. ... clause 7.5.3 Control of documented information
- E. clause 7.1.3 Infrastructure

Answer: A,D

Explanation:

Based on the scenario provided, there is evidence of nonconformity with the requirements defined in:

C: Clause 7.5.1 Documented information - General: The scenario indicates that there is no formal process for informing users about updates to the SWIFT database, which suggests a lack of control over documented information. This could lead to users being unaware of important changes and not using the latest version of the software, which is required by the quality management system¹.

E: Clause 7.5.3 Control of documented information: The Operations Director's approach to updating the SWIFT database and the lack of communication to users about these updates indicate that the documented information is not adequately controlled. Allowing users to revert to earlier versions of the software at their discretion further suggests that the organization does not have a proper mechanism in place to ensure the integrity and suitability of documented information².

These clauses are part of the ISO 9001:2015 standard, which requires organizations to have a systematic approach to controlling and managing documented information as part of their quality management system.

The scenario described shows a casual approach to managing critical software updates, which could affect the organization's ability to consistently meet customer and regulatory requirements.

NEW QUESTION # 231

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