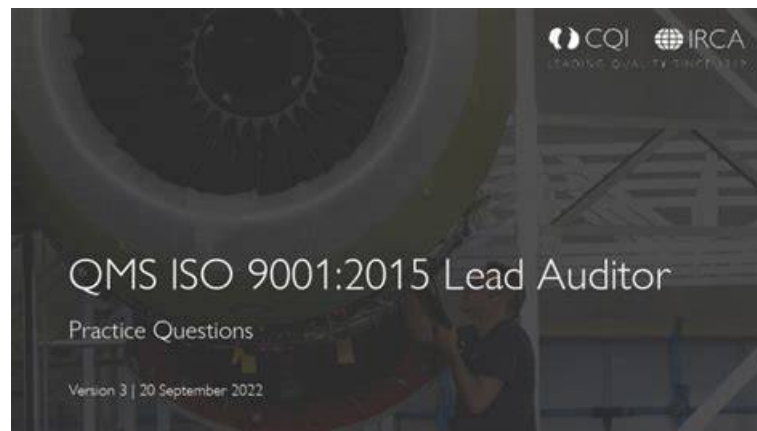


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Practice questions



Information for learners

This exam is open book

- All references to ISO 9001 refer to the latest issue (ISO 9001:2015).
- A copy of ISO 9001, ISO 19011, course materials, notes and a bilingual dictionary are permitted for reference.
- The practice paper is in five sections. Learners should attempt all sections and all 24 questions. All questions are partially marked.
- Learners may attempt the practice questions up to 99 times.
- These are questions for learners to use ahead of the actual exam. They will familiarise learners with the questions in each section and the layout and functionality of the online exam platform.
- Learners should read each question carefully before answering. Learners are advised to consider the context given in the question as well as the knowledge they have from the course.
- All the questions are based on the learning and enabling objectives detailed in the CQI and IRCA QMS ISO 9001:2015 Lead Auditor course specification (PR328).

Section 1 - Concepts and principles of Management Standards and Systems



1 Please match each of the following items to the appropriate audit term.

To complete the table click on the blank section you want to complete as it is highlighted in red and then click on the applicable text from the options below.
Alternatively you may drag and drop each option to the appropriate blank section.

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Certification Vendor:	PECB
Exam Name:	QMS ISO 9001:2015 Lead Auditor Exam
Exam Number:	ISO-9001-Lead-Auditor
Certificate Validity Period:	3 years
Exam Format:	Multiple choice, Multi-response, Scenario-based, Open-book
Exam Price:	\$1000 USD
Available Languages:	English, French, Spanish, German, Italian, Portuguese, Russian, Chinese, Arabic
Exam Duration:	180 (120 + 30 for non-native speakers)

Related Certifications:	ISO 9001 Foundation ISO 9001 Auditor ISO 9001 Provisional Auditor
Passing Score:	70% (minimum 28/40 or 56/80 correct answers)
Real Exam Qty:	40–80
Recommended Training:	PECB ISO 9001 Lead Auditor Training Course
Exam Registration:	PECB Official Registration
Sample Questions:	PECB ISO-9001-Lead-Auditor Sample Questions
Exam Way:	Online proctored via PECB Exams app or paper-based at authorized test centers
Pre Condition:	Recommended: ISO 9001 Foundation knowledge or certification; no mandatory prerequisites, but experience in quality management is advised
Official Syllabus URL:	https://pecb.com/en/education-and-certification-for-individuals/iso-9001/iso-9001-lead-auditor

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

Topic	Details
Topic 1	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 2	Conducting an ISO 9001 audit: It evaluates your skills to conduct a QMS audit.
Topic 3	Preparing an ISO 9001 audit: This topic covers sub-topics related to preparing a quality management system audit.

PECB QMS ISO 9001:2015 Lead Auditor Exam Sample Questions (Q38-Q43):

NEW QUESTION # 38

ISO 9001 addresses changes through several requirements, two examples of which are Clause 6.3 (Planning of Changes) and Clause 8.5.6 (Control of Changes). How do the requirements of Clause 8.5.6 differ from those of Clause 6.3?

- **A. Clause 8.5.6 refers to changes during the production and service provision.**
- B. Clause 8.5.6 refers to changes during the design and development of products and services.
- C. Clause 8.5.6 refers to leadership and management system responsibilities.
- D. Clause 8.5.6 refers to changes to legal and regulatory requirements.

Answer: A

Explanation:

Comprehensive and Detailed In-Depth Explanation:

ISO 9001:2015 recognizes change management as essential for maintaining process integrity and preventing nonconformities.

Clause References:

* Clause 6.3 (Planning of Changes) # Focuses on long-term changes that may impact QMS integrity.

* Clause 8.5.6 (Control of Changes) # Focuses on changes occurring during production and service provision to ensure conformity.

Why is the Correct Answer A?

- * Clause 8.5.6 applies specifically to operational changes, ensuring that modifications in production or service processes do not compromise quality.
- * Organizations must document who approves changes, how they are controlled, and how they affect product/service conformity. Why are the Other Options Incorrect?
- * B (Changes during design and development) # Covered under Clause 8.3 (Design and Development), not 8.5.6.
- * C (Changes to legal and regulatory requirements) # Addressed under Clause 4.2 (Interested Parties' Requirements).
- * D (Leadership responsibilities) # Covered under Clause 5.1 (Leadership and Commitment), not 8.5.6.

NEW QUESTION # 39

Scenario 3:

Fin-Pro is a financial institution in Austria offering commercial banking, wealth management, and investment services. The company faced a significant loss of customers due to failing to improve service quality as they expanded.

To regain customer confidence, top management implemented a QMS based on ISO 9001. After a year, they contacted ACB, a local certification body, to pursue ISO 9001 certification.

The audit team was led by Emilia, an experienced lead auditor, and included three auditors. After an agreement was reached, ACB sent the audit objectives to the audit team.

The audit team began by gathering information about Fin-Pro's understanding of ISO 9001 requirements.

While reviewing documented information, they noticed missing records of training and awareness sessions. They conducted employee interviews to verify attendance.

The team also reviewed the organizational chart and job descriptions to confirm employee competence.

They observed the company's working environment (social, psychological, and physical conditions).

The audit team analyzed the evidence and prepared an audit report with findings and conclusions.

In scenario 3, the audit team required access to see the organizational chart and job descriptions to verify the employees' competence. Based on audit best practices, is this acceptable?

- A. Yes, because auditors should see the organizational chart and job descriptions to verify competence.
- B. No, because the audit evidence would not be relevant.
- C. No, because competence should only be verified through direct observation.
- D. Yes, because that would be sufficient evidence to verify competence.

Answer: A

Explanation:

Comprehensive and Detailed In-Depth Explanation:

ISO 9001:2015 requires organizations to ensure competence of personnel whose work affects quality performance.

Clause References:

* Clause 7.2 - Competence: Organizations must determine, provide, and evaluate competence of employees performing work under the QMS.

* ISO 19011:2018, Clause 6.4.6 - Audit Evidence: Auditors should use a combination of document review, interviews, and observation to verify competence.

Why is the Correct Answer C?

* The organizational chart shows reporting structures and helps verify roles and responsibilities.

* Job descriptions outline required qualifications, skills, and competencies for each role.

* These documents provide objective audit evidence that personnel meet the required competencies for their positions.

Why are the Other Options Incorrect?

* A (Sufficient evidence) # Partially correct, but competence verification often requires multiple sources of evidence, including training records, certifications, and observations.

* B (Not relevant) # Incorrect because verifying competence is crucial for ensuring effective QMS implementation.

* D (Direct observation only) # Observation alone is insufficient; documentation and interviews are also required to confirm competence.

NEW QUESTION # 40

You work for organisation A. You are asked to lead an internal audit of A's quality management system. It has a head office in Plant A1 and a second Plant A2 nearby. Due to the COVID-19 pandemic, production in A2 was discontinued and it was rented to a logistics organisation B, not related to A. There are no A employees working in A2. Organisation A expects to reassume production in A2 as soon as possible.

Which of the following actions would you consider appropriate when planning the internal audit of A's quality management system?

- A. Visit Plant A2 to interview B's quality manager
- B. Visit Plant A2 to interview A's security personnel and B's maintenance department
- C. Visit Plant A2 to interview personnel of company B
- **D. Interview the A2 plant manager, now working in Plant A1**

Answer: D

Explanation:

In this scenario, the organisation A has two plants, A1 and A2, but the production in A2 was discontinued due to the COVID-19 pandemic and the plant was rented to another organisation B. There are no A employees working in A2, and the organisation A expects to reassume production in A2 as soon as possible. Therefore, the appropriate action to plan the internal audit of A's quality management system is:

*Interview the A2 plant manager, now working in Plant A1: This action involves interviewing the person who is responsible for the management and operation of the plant A2, and who is currently working in the plant A1. The interview should aim to gather information about the status and condition of the plant A2, the impact of the COVID-19 pandemic on the quality management system, the arrangements and agreements with the organisation B, and the plans and actions to resume production in the plant A25 . This action is relevant and necessary for the internal audit, as it can help to assess the readiness and effectiveness of the quality management system, and to identify any gaps or nonconformities that need to be addressed.

The other options are not appropriate actions to plan the internal audit of A's quality management system, according to the web search results from my internal tool. They are:

*Visit Plant A2 to interview personnel of company B: This action involves visiting the plant A2 and interviewing the personnel of the organisation B, who are not related to the organisation A and who are not part of the quality management system. This action is irrelevant and unnecessary for the internal audit, as it can not provide any evidence or information about the conformity and improvement of the quality management system of the organisation A5 .

*Visit Plant A2 to interview B's quality manager: This action involves visiting the plant A2 and interviewing the quality manager of the organisation B, who is not related to the organisation A and who is not part of the quality management system. This action is irrelevant and unnecessary for the internal audit, as it can not provide any evidence or information about the conformity and improvement of the quality management system of the organisation A5 .

*Visit Plant A2 to interview A's security personnel and B's maintenance department: This action involves visiting the plant A2 and interviewing the security personnel of the organisation A and the maintenance department of the organisation B, who are not directly involved in the quality management system. This action is irrelevant and unnecessary for the internal audit, as it can not provide any evidence or information about the conformity and improvement of the quality management system of the organisation A5 .

Therefore, the correct answer is D.

References: 1: Quality audit - Wikipedia 2: A step-by-step guide to internal quality audits 3: ISO 9001:2015 - Quality management systems - Requirements 4: ISO 19011:2018 - Guidelines for auditing management systems 5: Audit Process | Flowchart | Summary - Accountinguide : What are the Stages of the Auditing Process & Why it is Important ...

NEW QUESTION # 41

You are conducting a Stage 2 audit at an organisation that services refrigeration equipment for a large customer base. The scope of certification is "Provision of refrigeration equipment maintenance and repair services". You are interviewing the Managing Director to learn more about the organisation and to explore how the requirements for policy, objectives, and risks and opportunities in ISO 9001 are addressed.

The Managing Director explains that they only use sub-contract refrigeration engineers and do not have any full-time refrigeration engineers, which helps to optimise overhead costs.

The Managing Director adds that the ISO 9001 requirements for the competence of personnel extend to both sub-contract and full-time staff.

You then asked 2 of the sub-contract engineers what they could do to contribute to the effectiveness of the quality management system, they replied stating that "we are not really sure as we have not been told how we could contribute". The Managing Director added that this is not applicable as they only use sub-contractors who operate ISO 9001 certificated quality management systems. The documented information provided to the auditor confirms this.

Which clause in ISO 9001 has not been fulfilled in this instance?

- A. 7.4 Communication - because the sub-contract engineers claim they have not been told of their role in the QMS.
- **B. 7.3 Awareness - because the sub-contract engineers do not know of their role in the QMS.**
- C. 7.5 Documented information - because the sub-contract engineers did not have training records in QMS awareness.
- D. 7.2 Competence - because the sub-contract engineers are not competent to work in a QMS environment.

Answer: B

Explanation:

ISO 9001:2015 clause 7.3 requires persons doing work under the organisation's control to be aware of their contribution to the effectiveness of the quality management system, including the benefits of improved performance.

The subcontract refrigeration engineers are performing work under the organisation's control because they deliver the maintenance and repair services included in the certification scope. Their own ISO 9001 certification does not remove the organisation's responsibility to ensure they understand their contribution to the QMS.

The evidence shows that two subcontract engineers stated they were not sure how they could contribute because they had not been told. This directly indicates a failure of clause 7.3 Awareness.

A is less accurate because the issue is not simply communication method; it is the required awareness outcome. B is not supported because there is no evidence that the engineers lack technical competence. D is not the best answer because ISO 9001 does not specifically require "QMS awareness training records" in this scenario.

NEW QUESTION # 42

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 ...

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

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 # 43

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