

Free PDF PECB - Professional ISO-9001-Lead-Auditor - Exam QMS ISO 9001:2015 Lead Auditor Exam Labs

Audit evidence	ISO 9001 Clause 8.3 extract
Half of all new products launched in the past 12 months were late. The NPD Manager explains he has not got enough people on his team to cope with the demand for new products.	"8.3.2 e) ... internal ... resource needs for the design and development of products ..."
The NPD Manager explains many changes are made to cosmetic formulations during product development owing to retailer feedback. Only when confirmed by the retailer is the agreed formulation documented on SWIFT.	"8.3.6 ... retain documented information ..."
The NPD Manager explains that the customer confirms their approval to proceed with a new formulation by email. These emails are kept on SWIFT.	"8.3.5 ... retain documented information ..."
The NPD Manager shows you evidence of consumer trials that are carried out for some new products prior to full-scale launch.	"8.3.4 d) ... conducted to ensure that the design and development outputs meet ..."
The NPD Manager explains that an approved external laboratory is used to perform shelf-life stability trials on some formulations during product development.	"8.3.2 e) ... external ... resource needs for the design and development of products ..."

To complete the table click on the blank section you want to complete so it is highlighted in red and then click on the ISO 9001 clause 8.3 extracts listed below. Alternatively, drag and drop each clause to the audit evidence that applies.

"8.3.2 e) ... internal ... resource needs for the design and development of products ..."

"8.3.2 e) ... external ... resource needs for the design and development of products ..."

"8.3.4 d) ... conducted to ensure that the design and development outputs meet ..."

"8.3.5 ... retain documented information ..."

"8.3.6 ... retain documented information ..."

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

Topic	Details
Topic 1	<ul style="list-style-type: none"> Conducting an ISO 9001 audit: It evaluates your skills to conduct a QMS audit.
Topic 2	<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 3	<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 4	<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 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.

Quiz PECB - Efficient ISO-9001-Lead-Auditor - Exam QMS ISO 9001:2015 Lead Auditor Exam Labs

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PECB QMS ISO 9001:2015 Lead Auditor Exam Sample Questions (Q13-Q18):

NEW QUESTION # 13

For each of the following scenarios, select four that are corrective actions.

- A. After the loss of an important football match 4-0, the manager is sacked
- B. The organization improves product identification to prevent customer complaints
- C. The organization uses fertilizers to prevent plants dying in a section of a garden centre
- D. The government develops a vaccine against a virulent virus
- E. The government increases payments to dentists for dental checks for children
- F. The government enforces a lockdown against a virulent virus
- G. Call out roadside assistance to a broken-down car
- H. A complaint about cold food was resolved by reheating food in the restaurant kitchen

Answer: A,B,C,D

NEW QUESTION # 14

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.

Which statement below represents the level of responsibility demonstrated by the audit team in scenario 3?

- A. Willful misconduct, the audit team intentionally disregarded audit procedures.
- B. Ordinary negligence, the audit team has demonstrated lack of diligence.
- C. No negligence, the audit team has demonstrated diligence during the audit and followed the best practices.
- D. Gross negligence, the audit team has demonstrated a total lack of diligence.

Answer: C

Explanation:

Comprehensive and Detailed In-Depth Explanation:

ISO 19011:2018 requires auditors to conduct audits professionally and diligently.

Clause References:

* ISO 19011:2018, Clause 4.4 - Professional Care: Auditors must exercise due diligence in conducting audits.

* ISO 9001:2015, Clause 9.2 - Internal Audit: Requires objective and systematic audits to evaluate QMS effectiveness.

Why is the Correct Answer A?

- * The audit team followed best practices by gathering verifiable audit evidence through interviews, document reviews, and observations.
- * They ensured fair presentation of findings in the final audit report.
- * They complied with ISO 9001 and ISO 19011 guidelines for audit procedures.

Why are the Other Options Incorrect?

- * B (Ordinary negligence) # No evidence of negligence; the team followed structured audit processes.
- * C (Gross negligence) # No indication that the auditors ignored important responsibilities.
- * D (Willful misconduct) # The auditors acted professionally and did not intentionally disregard rules.

Reference:

ISO 19011:2018, Clause 4.4 - Professional Care

ISO 9001:2015, Clause 9.2 - Internal Audit

NEW QUESTION # 15

Select six of the activities that are specifically required by ISO 17021-1 as part third-party (Certification Body) surveillance audit processes.

- A. Conduct a minimum number of annual surveillance audits during the certification period.
- **B. Handling of customer complaints since last visit.**
- **C. Verify legal compliance.**
- D. Complete a full document review of the quality management system.
- E. Failing to meet financial responsibilities.
- **F. Confirm effectiveness of internal audit and management review.**
- **G. Review changes to the QMS since last visit.**
- **H. Audit use of certification marks on marketing materials.**
- I. Review the calibration status of the instrumentation.
- **J. Review the status of previously raised findings and audit effectiveness of any outstanding findings.**

Answer: B,C,F,G,H,J

Explanation:

The activities that are specifically required by ISO 17021-1 as part of third-party (Certification Body) surveillance audit processes are:

*Option A: Audit use of certification marks on marketing materials. This option is correct because ISO

17021-1:2015 clause 9.6.2.2 requires the certification body to audit the client's use of marks and/or any other reference to certification, as applicable, to ensure conformity with the certification requirements.

*Option B: Review changes to the QMS since last visit. This option is correct because ISO 17021-1:2015 clause 9.6.2.2 requires the certification body to review any changes affecting the client's quality management system and its ability to continue to fulfil the requirements of the standard used for certification.

*Option C: Confirm effectiveness of internal audit and management review. This option is correct because ISO

17021-1:2015 clause 9.6.2.2 requires the certification body to confirm the continuing effectiveness of the client's quality management system, including the effectiveness of the internal audit and management review processes.

*Option F: Review the status of previously raised findings and audit effectiveness of any outstanding findings.

This option is correct because ISO 17021-1:2015 clause 9.6.2.2 requires the certification body to review the status of findings and any corrective actions taken by the client in response to previous audits, and to verify the effectiveness of the implemented corrective actions.

*Option H: Verify legal compliance. This option is correct because ISO 17021-1:2015 clause 9.6.2.2 requires the certification body to verify the client's compliance with applicable statutory and regulatory requirements related to the scope of certification.

*Option I: Handling of customer complaints since last visit. This option is correct because ISO 17021-1:2015 clause 9.6.2.2 requires the certification body to review the client's handling of customer complaints related to the certified activities since the last audit.

The following options are not correct:

*Option D: Complete a full document review of the quality management system. This option is not correct because ISO 17021-1:2015 clause 9.6.2.2 does not require the certification body to complete a full document review of the quality management system during surveillance audits. A full document review is only required during the initial certification audit or when there are significant changes to the quality management system or the certification requirements.

*Option E: Failing to meet financial responsibilities. This option is not correct because ISO 17021-1:2015 clause 9.6.2.2 does not require the certification body to audit the client's financial responsibilities during surveillance audits. The certification body may have contractual arrangements with the client regarding the payment of fees, but this is not part of the surveillance audit process.

*Option G: Review the calibration status of the instrumentation. This option is not correct because ISO

17021-1:2015 clause 9.6.2.2 does not require the certification body to review the calibration status of the instrumentation during surveillance audits. The certification body may audit the client's monitoring and measuring resources as part of the quality management system requirements, but this is not a specific activity required by ISO 17021-1.

*Option J: Conduct a minimum number of annual surveillance audits during the certification period. This option is not correct because ISO 17021-1:2015 clause 9.6.2.2 does not require the certification body to conduct a minimum number of annual surveillance audits during the certification period. The certification body may determine the frequency and duration of surveillance audits based on the risk and performance of the client, but this is not a specific activity required by ISO 17021-1.

References:

*ISO 17021-1:2015 Conformity assessment - Requirements for bodies providing audit and certification of management systems - Part 1: Requirements

*ISO 9001 Lead Auditor Course Material, Module 7: Audit Follow-up and Surveillance, Slide 8: Surveillance Audit

*ISO 9001 Lead Auditor Training Course - IRCA Certified, Section 7.2: Audit Follow-up and Surveillance

*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 # 16

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

The organisation offers warehousing and export services to customers. Customers are invoiced for the time stock items are stored in the warehouse. Transport to and from the warehouse is controlled by the organisation and approved subcontract transport services are used. The organization does not have its own transport vehicles. Stock items are not purchased by the organisation.

You have gathered audit evidence as outlined in the table. Match the ISO 9001 Clause 8 extract to the audit evidence.

Audit evidence	ISO 9001 Clause 8 extract
Four of the 10 pallets of stock sampled in the warehouse were not labelled.	<input type="text"/>
A damaged pallet of stock seen in the quarantine area was leaking liquid onto the floor.	<input type="text"/>
One of the fork-lift truck drivers had no fork-lift truck driving licence.	<input type="text"/>
There was no pest control provision in the warehouse.	<input type="text"/>
Two pallets of temperature-sensitive stock items were being stored at ambient as the chilled storage facility was full.	<input type="text"/>

To complete the table, click on the blank section you want to complete so it is highlighted in red and then click on the ISO 9001 Clause 8 extracts listed below. Alternatively, drag and drop each clause to the audit evidence that applies.

"8.5.2...shall use suitable means to identify outputs..."

"8.5.1 e ...shall include, as applicable...the appointment of competent persons..."

"8.1...shall plan, implement and control the processes..."

"8.7.1...shall ensure that outputs that do not conform to their requirements are identified and controlled..."

"8.5.4...shall preserve the outputs during production and service provision..."

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Answer:

Explanation:

Audit evidence	ISO 9001 Clause 8 extract
Four of the 10 pallets of stock sampled in the warehouse were not labelled.	"8.5.2...shall use suitable means to identify outputs..."
A damaged pallet of stock seen in the quarantine area was leaking liquid onto the floor.	"8.7.1...shall ensure that outputs that do not conform to their requirements are identified and controlled..."
One of the fork-lift truck drivers had no fork-lift truck driving licence.	"8.5.1 e ...shall include, as applicable...the appointment of competent persons..."
There was no pest control provision in the warehouse.	"8.5.4...shall preserve the outputs during production and service provision..."
Two pallets of temperature-sensitive stock items were being stored at ambient as the chilled storage facility was full.	"8.1...shall plan, implement and control the processes..."

To complete the table, click on the blank section you want to complete so it is highlighted in red and then click on the ISO 9001 Clause 8 extracts listed below. Alternatively, drag and drop each clause to the audit evidence that applies.

"8.5.2...shall use suitable means to identify outputs..."

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"8.1...shall plan, implement and control the processes..."

"8.7.1...shall ensure that outputs that do not conform to their requirements are identified and controlled..."

"8.5.4...shall preserve the outputs during production and service provision..."

Explanation:

The table below shows the possible matching of the ISO 9001 Clause 8 extract to the audit evidence.

Table

Audit evidence

ISO 9001 Clause 8 extract

Four of the 10 pallets of stock sampled in the warehouse were not labelled.

"8.5.2 ... shall use suitable means to identify outputs ..."

A damaged pallet of stock seen in the quarantine area was leaking liquid onto the floor.

"8.7.1 ... shall ensure that outputs that do not conform to their requirements are identified and controlled ..." One of the fork-lift truck drivers had no fork-lift truck driving licence.

"8.5.1 e ... shall include, as applicable ... the appointment of competent persons ..." There was no pest control provision in the warehouse.

"8.5.4 ... shall preserve the outputs during production and service provision ..." Two pallets of temperature-sensitive stock items were being stored at ambient as the chilled storage facility was full.

"8.1 ... shall plan, implement and control the processes ..."

NEW QUESTION # 17

Scenario 1: AL-TAX is a company located in California which provides financial and accounting services. The company manages the finances of 17 companies and now is seeking to expand their business even more. The CEO of AL-TAX, Liam Durham, claims that the company seeks to provide top-notch services to their clients. Recently, there were a number of new companies interested in the services provided by AL-TAX.

In order to fulfill the requirements of new clients and further improve quality, Liam discussed with other top management members

the idea of implementing a quality management system (QMS) based on ISO 9001. During the discussion, one of the members of the top management claimed that the size of the company was not large enough to implement a QMS. In addition, another member claimed that a QMS is not applicable for the industry in which AL TAX operates. However, as the majority of the members voted for implementing the QMS, Liam initiated the project.

Initially, Liam hired an experienced consultant to help AL-TAX with the implementation of the QMS.

They started by planning and developing processes and methods for the establishment of a QMS based on ISO 9001. Furthermore, they ensured that the quality policy is appropriate to the purpose and context of AL TAX and communicated to all employees. In addition, they also tried to follow a process that enables the company to ensure that its processes are adequately resourced and managed, and that improvement opportunities are determined.

During the implementation process, Liam and the consultant focused on determining the factors that could hinder their processes from achieving the planned results and implemented some preventive actions in order to avoid potential nonconformities. Six months after the implementation of the QMS.

AL-TAX conducted an internal audit. The results of the internal audit revealed that the QMS was not fulfilling all requirements of ISO 9001. A serious issue was that the QMS was not fulfilling the requirements of clause 5.1.2 Customer focus and had also not ensured clear and open communication channels with suppliers.

Throughout the next three years, the company worked on improving its QMS through the PDCA cycle in the respective areas. To assess the effectiveness of the intended actions while causing minimal disruptions, they tested changes that need to be made on a smaller scale. After taking necessary actions, AL-TAX decided to apply for certification against ISO 9001.

Based on the scenario above, answer the following question:

Scenario 1 indicates that AL-TAX did not ensure clear and open communication channels with interested parties. Which quality management principle did the organization not follow in this case?

- A. Relationship management
- B. Leadership
- C. Evidence-based decision making

Answer: A

Explanation:

Comprehensive and Detailed In-Depth Explanation:

ISO 9001:2015 is based on seven quality management principles, one of which is Relationship Management. This principle emphasizes the importance of maintaining open communication and collaboration with interested parties, including suppliers and customers.

Clause 7.4 (Communication) requires organizations to determine what, when, with whom, and how communication should take place. Since AL-TAX failed to ensure clear communication channels, it did not adhere to this principle. Effective relationship management helps improve supply chain performance, customer satisfaction, and overall QMS effectiveness.

Reference:

ISO 9001:2015, Clause 7.4 - Communication

ISO 9001:2015, Quality Management Principles - Relationship Management

NEW QUESTION # 18

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There are many certificates for you to get but which kind of certificate is most authorized, efficient and useful? We recommend you the ISO-9001-Lead-Auditor certificate because it can prove that you are competent in some area and boost outstanding abilities. If you buy our ISO-9001-Lead-Auditor Study Materials you will pass the test smoothly and easily. On one hand, you can study the most professional and specialized knowledge in this field. On the other hand, you can gain the ISO-9001-Lead-Auditor certification.

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