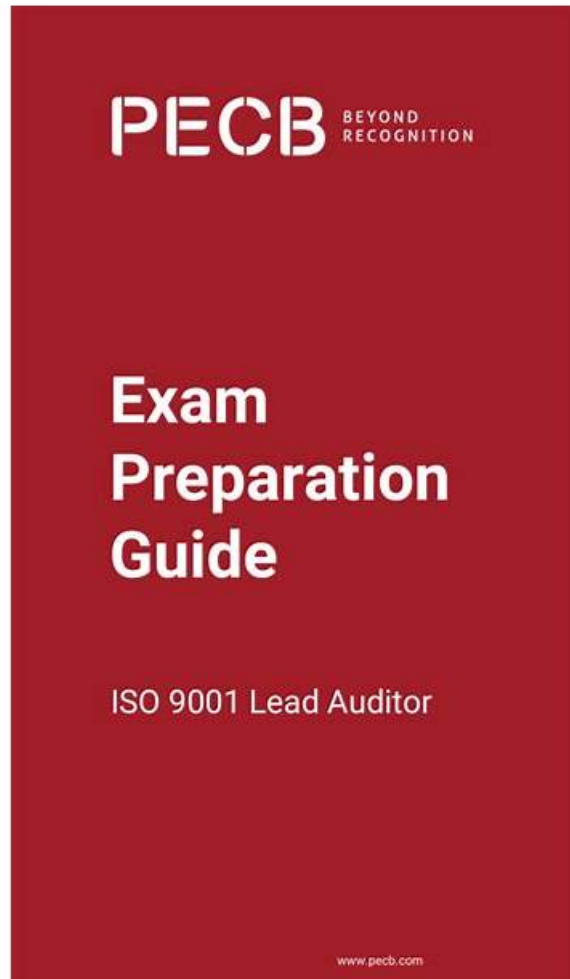


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PECB ISO-9001-Lead-Auditor Exam Syllabus Topics:

Topic	Details
Topic 1	Managing an ISO 9001 audit program: This topic evaluates your abilities to establish and managing a QMS audit program.
Topic 2	Preparing an ISO 9001 audit: This topic covers sub-topics related to preparing a quality management system audit.
Topic 3	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 4	Fundamental audit concepts and principles: Questions about interpreting and applying the main concepts and principles related to a QMS audit appear in this topic.

PECB QMS ISO 9001:2015 Lead Auditor Exam Sample Questions (Q134-Q139):

NEW QUESTION # 134

The Closing meeting of a second-party audit was planned for 6 pm with the general manager and the quality manager.

At 6 pm, when the audit team enters the meeting room, only the Quality Manager is present and waiting for them.

The dialogue among them is as follows:

Auditor team leader: "Good evening, could you please inform the general manager that we are ready to start with the closing meeting?" Quality manager: "Good evening, I am sorry to inform you that the general manager will not be able to attend the meeting. He will try to participate virtually to make some closing remarks." Auditor team leader: "OK. We identified seven nonconformities - these are the reports. Could you please review them and sign them?" Quality manager: "OK. As you know, I reviewed them after yesterday's meeting and accept of all them, where shall I sign?" General manager (from speakers in the room and addressing the quality manager): "Hold on! Do not sign the two nonconformities related to ABC Bank! I have just checked, and we did not provide any services to ABC Bank during September! You can sign the remaining five nonconformities." How would you proceed with the audit? Select one.

- A. I will discuss this issue with our corporate quality manager and will let you know what we will do
- B. I withdraw the two nonconformities related to service to ABC and will present the report with the remaining five nonconformities
- C. I will review this issue at length with the audit team tonight and will phone you tomorrow to let you know our decision
- D. I will include the seven nonconformities in the report, considering that we identified objective evidence on which all these nonconformities are based

Answer: C

NEW QUESTION # 135

You are conducting 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.

You are interviewing the new Product Development Manager. You note that a software application called SWIFT is used to help control the product development process.

You have gathered audit evidence as outlined in the table. Match the ISO 9001 clause 8.3 extracts to the audit evidence.

Answer:

Explanation:

A screenshot of a computer AI-generated content may be incorrect.

Audit Evidence	Correct ISO 9001 Clause Extract
1. Half of all new products launched in the past 12 months were late. The Product Development Manager explains he lacks people to cope with demand.	8.3.2 e) ... internal ... resource needs for the design and development of products ...
2. Many changes are made to cosmetic formulations during product development due to retailer feedback. Final formulations are documented in SWIFT.	8.3.6 ... retain documented information ...
3. Customer confirms approval to proceed with a new formulation via email. These emails are stored in SWIFT.	8.3.5 ... retain documented information ...
4. Consumer trials are carried out before full-scale launch.	8.3.4 d) ... conducted to ensure that the resulting products and services meet the requirements ...
5. Shelf-life stability testing is done by an approved external lab during product development.	8.3.2 e) ... external ... resource needs for the design and development of products ...

Comprehensive and Detailed In-Depth Explanation:

Clause 8.3.2 e) - Internal Resource Needs: Delays due to staff shortages highlight a lack of internal resources, directly relating to this clause that requires internal resource planning for design and development.

Clause 8.3.6 - Design and Development Changes: Ongoing formulation changes due to feedback need to be documented and reviewed. This clause requires retention of documented information on changes.

Clause 8.3.5 - Design and Development Outputs: Customer approvals for formulations are outputs of the design process and must be retained as documented information, as per this clause.

Clause 8.3.4 d) - Design and Development Controls: Consumer trials are a validation activity. This clause ensures such trials are conducted to confirm that resulting products meet defined requirements.

Clause 8.3.2 e) - External Resource Needs: Shelf-life tests done by an external lab are part of the external resources needed for development and are referenced here.

NEW QUESTION # 136

You are conducting an ISO 9001 audit of a Materials Recycling Facility (MRF). The company processes waste plastics into raw material for plastic bottle manufacturers. You reach the manual picking line where operators are removing contaminant materials from incoming products, such as plastic bags, plastic film and badly contaminated items that would compromise the recycling process.

You interview the line supervisor.

You: "Why are these plastic items being rejected at this stage?"

Auditee: "They do not meet our processing standards."

You: "What is the reason for that?"

Auditee: "These items are likely to damage the machinery down the line. They can also compromise our quality standards. We need to protect our reputation for good quality output materials." You: "What happens to the rejected items?" Auditee: "Some get melted down in another process later on and some are disposed of as waste products that cannot be recycled." You: "What happens to the waste products?" Auditee: "I'm not sure. I suppose they go to landfill." After further auditing, you have gathered additional evidence.

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 options below. Alternatively, drag and drop each of the following statements to the correct ISO 9001 standard clause shown:

There is no specification for incoming materials.

The picking operators have been trained.

The picked reject materials are not documented.

The rejected materials are segregated.

Management has set an objective for the level of rejects for incoming materials.

8.4.3 a

7.2.b

10.2.2

10.2.1

6.2

Answer:

Explanation:

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 options below. Alternatively, drag and drop each of the following statements to the correct ISO 9001 standard clause shown:

There is no specification for incoming materials.

The picking operators have been trained.

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8.4.3 a

7.2.b

10.2.2

10.2.1

6.2

8.4.3 a

7.2.b

10.2.2

10.2.1

6.2

Explanation:

A # 8.4.3.a

B # 7.2.b

C # 10.2.2

D # 10.2.1

E # 6.2

Comprehensive and Detailed Explanation From Exact Extract:

A. There is no specification for incoming materials # 8.4.3.a

Clause 8.4.3(a) relates to the control of externally provided processes, products, and services, specifically the requirement to communicate appropriate specifications and requirements to suppliers:

"The organization shall ensure the adequacy of requirements prior to their communication to the external provider." Failure to specify requirements for incoming materials (e.g., what is acceptable waste plastic) risks compromising product quality.

B. The picking operators have been trained # 7.2.b

Clause 7.2(b) relates to Competence and mandates:

"Ensure that these persons are competent on the basis of appropriate education, training, or experience." Training is a critical part of establishing and maintaining operator competence in quality-affecting tasks.

C. The picked reject materials are not documented # 10.2.2

This clause focuses on the retention of documented information regarding nonconformities and actions taken:

"The organization shall retain documented information as evidence of: the nature of the nonconformities and any subsequent actions taken..." If rejects are not recorded, traceability and root cause analysis for quality failures are weakened.

D. The rejected materials are segregated # 10.2.1

Clause 10.2.1 relates to nonconformity and corrective action, including containment activities such as:

"Deal with nonconforming outputs in one or more of the following ways: correction; segregation, containment..." Segregation ensures nonconforming material doesn't contaminate acceptable output.

E. Management has set an objective for the level of rejects # 6.2

Clause 6.2 is about quality objectives. It requires organizations to:

"Establish quality objectives at relevant functions... The quality objectives shall be measurable..." Setting a measurable reject-level target aligns with improving process control and reducing waste.

References:

ISO 9001:2015 Clause 8.4.3.a - Information for External Providers

ISO 9001:2015 Clause 7.2.b - Competence

ISO 9001:2015 Clause 10.2.2 - Documentation of Nonconformity

ISO 9001:2015 Clause 10.2.1 - Control of Nonconforming Outputs

ISO 9001:2015 Clause 6.2 - Quality Objectives

NEW QUESTION # 137

Scenario 7: POLKA is a car manufacturing company based in Stockholm, Sweden. The company has around 14,000 employees working in different sectors which help with the design, painting, assembling, and test drives of the final product. The company is widely known for its qualitative products and affordable prices. In order to retain their reputation, POLKA implemented a quality management system (QMS) based on ISO 9001.

Before applying for certification, the company decided to conduct an internal audit to check whether there are any nonconformities in their QMS and if the requirements of ISO 9001 are being fulfilled.

The top management appointed Sean, the internal auditor, as the team leader of the internal audit team. Sean required from the top management to have unrestricted access to the employees and executives of POLKA and to the documented information.

Furthermore, Sean required to establish a team with a large number of auditors, considering the size and the complexity of the organization. The top management of POLKA agreed with Sean's requirements.

The top management, in cooperation with Sean, assigned 10 more employees to the audit team.

Following that, Sean planned the audit activities and assigned the roles and responsibilities to each auditor. They began by interviewing employees of different manufacturing departments to check whether they are aware of the process of the QMS implementation. While conducting these activities, one of the auditors asked Sean for permission to audit the department in which he worked on a daily basis, as he was very familiar with the processes of the department.

Along the way, the teams findings showed that the staff were trained, documented information was updated, and the QMS fulfilled the requirements of ISO 9001. The internal audit took three weeks to complete, and on the last week the audit team held a final meeting. The team shared their results and together drafted the audit report. This report was submitted to the top management of the company. The report was maintained as documented information, and was available to the relevant interested parties.

Based on the scenario above, answer the following question:

Sean requested unrestricted access to the employees, executives, and documented information of POLKA. Is this in accordance with audit best practices?

- A. No, such requests are acceptable only if a third-party audit is being conducted
- **B. Yes, unrestricted access for the internal auditor should be provided by the company**
- C. Yes, but the internal auditor should make such a request to the CEO directly as only the CEO of the company can approve such a request

Answer: B

Explanation:

Comprehensive and Detailed In-Depth Explanation: According to ISO 19011:2018, Clause 5.3.2 (Access to Information), internal auditors must have unrestricted access to:

- * Employees and executives for interviews and observations.
- * Documented information to verify compliance with ISO 9001.

This ensures a transparent and objective audit process. The CEO's approval (B) is not required unless restricted information is involved.

NEW QUESTION # 138

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:

According to scenario 1, AL-TAX determined the factors that could hinder their processes from achieving the planned results and implemented preventive actions. This means they employed:

- A. The process approach
- **B. Risk-based thinking**
- C. Compliance requirements and regulations

Answer: B

Explanation:

Comprehensive and Detailed In-Depth Explanation:

ISO 9001:2015 emphasizes risk-based thinking, which helps organizations identify factors that could prevent achieving planned results and take preventive action. Clause 6.1 (Actions to Address Risks and Opportunities) requires organizations to determine risks and opportunities and implement actions to mitigate potential negative impacts.

In the scenario, AL-TAX identified potential risks and implemented preventive actions, aligning with risk-based thinking. ISO 9001:2015 integrates risk management throughout the standard, ensuring processes are designed to minimize uncertainties.

Reference:

ISO 9001:2015, Clause 6.1 - Actions to Address Risks and Opportunities

ISO 9001:2015, Clause 0.3.3 - Risk-Based Thinking

NEW QUESTION # 139

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