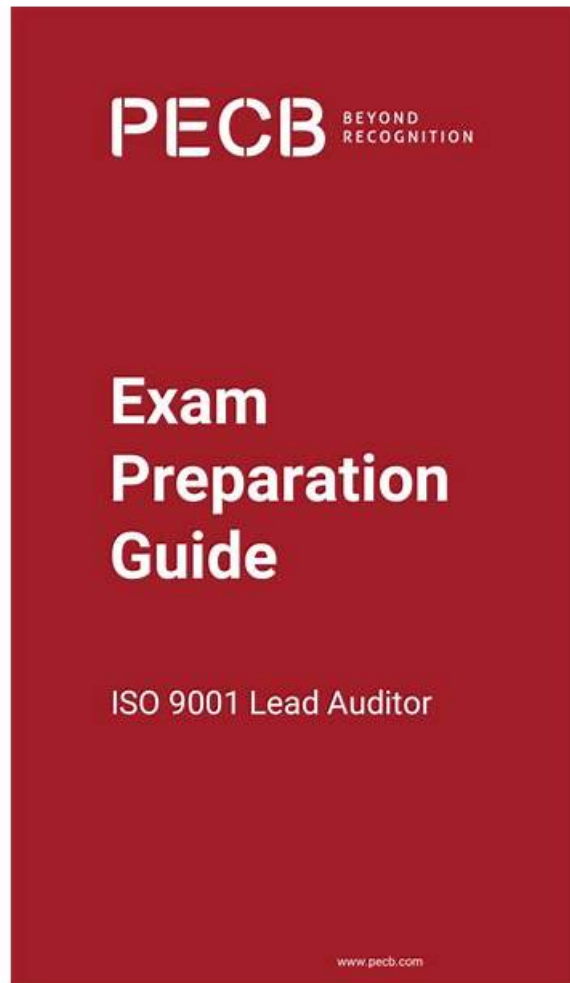


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PECB ISO-9001-Lead-Auditor Exam Syllabus Topics:

Topic	Details
Topic 1	<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 2	<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 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"> 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 5	<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 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.

PECB QMS ISO 9001:2015 Lead Auditor Exam Sample Questions (Q138-Q143):

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:

As stated in scenario 1, AL-TAX tested the effectiveness of the intended actions as part of the QMS improvement through the PDCA cycle. Which stage did it perform in this case?

- A. Do
- **B. Check**
- C. Act

Answer: B

Explanation:

Comprehensive and Detailed In-Depth Explanation:

The PDCA (Plan-Do-Check-Act) cycle is a continuous improvement model used in ISO 9001:2015. The

"Check" phase involves monitoring, measuring, and analyzing the results to assess if the planned actions have been effective.

In scenario 1, AL-TAX tested the effectiveness of the intended actions, which aligns with the Check stage of the PDCA cycle.

Clause 9.1.1 (Monitoring, Measurement, Analysis, and Evaluation) requires organizations to evaluate their QMS and determine whether improvements are necessary.

Reference:

ISO 9001:2015, Clause 0.3.2 - PDCA Cycle

ISO 9001:2015, Clause 9.1.1 - General (Performance Evaluation)

NEW QUESTION # 139

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 # 140

Below are four of the seven principles on which ISO 9000 series are based. Match a potential benefit to each of the quality management principles (QMP).

Below are four of the seven principles on which ISO 9000 series are based. Match a potential benefit to each of the quality management principles (QMP).

Quality management principles	
Customer focus	<input type="text"/>
Engagement of people	<input type="text"/>
Improvement	<input type="text"/>
Evidence-based decision-making	<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 applicable text from the options below. Alternatively, drag and drop each of the following potential benefits to a QMP.

Increased revenue and market share	Common understanding of objectives and values among interested parties	Better communication between levels and functions of the organisation	Improved operational effectiveness and efficiency	Enhanced trust and collaboration throughout the organisation	Enhanced drive for innovation
Increased ability to demonstrate effectiveness of past actions					

Answer:

Explanation:

Below are four of the seven principles on which ISO 9000 series are based. Match a potential benefit to each of the quality management principles (QMP).

Quality management principles	
Customer focus	Increased revenue and market share
Engagement of people	Enhanced trust and collaboration throughout the organisation
Improvement	Enhanced drive for innovation
Evidence-based decision-making	Increased ability to demonstrate effectiveness of past actions

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 potential benefits to a QMP.

Increased revenue and market share	Common understanding of objectives and values among interested parties	Better communication between levels and functions of the organisation	Improved operational effectiveness and efficiency	Enhanced trust and collaboration throughout the organisation	Enhanced drive for innovation
Increased ability to demonstrate effectiveness of past actions					

Explanation:

Quality management principles:

Customer focus = Increased revenue and market share

Engagement of people = Enhanced trust and collaboration throughout the organisation

Improvement = Enhanced drive for innovation

Evidence-based decision-making = Increased ability to demonstrate effectiveness of past actions

According to the Quality management principles document published by ISO, each quality management principle has a statement, a rationale, key benefits, and actions you can take to apply it. Based on these descriptions, the potential benefits can be matched to the corresponding principles as follows:

Customer focus: The primary focus of quality management is to meet customer requirements and to strive to exceed customer expectations. The key benefits of this principle include increased customer value, customer satisfaction, customer loyalty, repeat business, reputation, customer base, revenue and market share.

Engagement of people: Competent, empowered and engaged people at all levels throughout the organization are essential to enhance its capability to create and deliver value. The key benefits of this principle include improved understanding of the organization's objectives and values, increased involvement in improvement activities, enhanced personal development, increased motivation and empowerment, enhanced trust and collaboration, and increased recognition and rewards.

Improvement: Successful organizations have an ongoing focus on improvement. The key benefits of this principle include improved organizational capabilities, alignment of improvement activities at all levels, increased ability to anticipate and react to opportunities and threats, enhanced drive for innovation, and increased levels of satisfaction.

Evidence-based decision-making: Decisions based on the analysis and evaluation of data and information are more likely to produce desired results. The key benefits of this principle include improved decision-making processes, increased ability to demonstrate the effectiveness of past decisions, increased ability to review, challenge and change opinions and decisions, and increased ability to improve performance.

NEW QUESTION # 141

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

Answer: B

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.

Reference:

ISO 9001:2015, Clause 6.3 - Planning of Changes

ISO 9001:2015, Clause 8.5.6 - Control of Changes

NEW QUESTION # 142

What are the criteria for reviewing documented information?

- A. Archive, volume, and confidentiality of documented information
- B. Language of documented information, internal audit reports, client feedback
- **C. Content, format, and the procedure for managing documented information**

Answer: C

Explanation:

Comprehensive and Detailed In-Depth Explanation: According to ISO 9001:2015, Clause 7.5.2 (Creating and Updating Documented Information), the criteria for reviewing documented information include:

* Content - The accuracy and relevance of the information.

* Format - Ensuring readability and proper structuring (e.g., language, versioning).

* Procedure for managing documented information - Ensuring control, access, and updates.

Other options, such as internal audit reports and client feedback, are important for overall QMS evaluation but are not the main criteria for reviewing documented information.

NEW QUESTION # 143

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