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

Topic	Details
Topic 1	<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.
Topic 2	<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 3	<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 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.

PECB QMS ISO 9001:2015 Lead Auditor Exam Sample Questions (Q21-Q26):

NEW QUESTION # 21

Which of the following is a responsibility of a guide in an audit?

- A. Filling any potential gaps in the auditor's knowledge
- B. Witnessing the audit process on behalf of the certification body
- C. Maintaining logistics

Answer: C

Explanation:

Comprehensive and Detailed In-Depth Explanation: A guide is assigned by the auditee to assist the audit team by:

- * Managing logistics, such as ensuring that relevant documents are available and arranging interviews.
- * Assisting in the coordination of meetings and access to facilities.
- * Helping the auditors navigate the organization during the audit.

However, the guide does not fill gaps in the auditor's knowledge or witness the audit for the certification body. Their primary function is logistical support, not providing interpretations or assessments.

NEW QUESTION # 22

Audit criteria are a set of requirements used as a reference against which objective evidence is compared.

Which two of the following are not potential audit criteria?

- A. Written agreements with interested parties
- B. ISO management system standards
- C. Commercial advertisements
- D. Organisation's documented information
- E. Health and safety notices
- F. Verbal agreements with interested parties
- G. Environmental aspects register
- H. Claims made on the organisation's website

- I. Verbal statements by the general manager
- J. Commitment to follow principles issued by an NGO

Answer: C,H

Explanation:

According to ISO 19011:2018, clause 3.2, audit criteria are a set of policies, procedures or requirements used as a reference against which objective evidence is compared. Audit criteria are usually selected by the audit client or by agreement between the audit client and the auditee, and they should be appropriate for the audit scope and objectives¹. Audit criteria may include, but are not limited to, the following sources²:

*ISO management system standards, such as ISO 9001, ISO 14001, ISO 45001, etc.

*Verbal statements by the general manager or other top management, as long as they are consistent with the documented policies and objectives of the organisation

*Verbal agreements with interested parties, such as customers, suppliers, regulators, etc., as long as they are documented and approved by the relevant authorities

*Health and safety notices, such as posters, signs, labels, etc., that communicate the organisation's legal obligations, policies, or procedures

*Written agreements with interested parties, such as contracts, orders, specifications, etc., that define the requirements and expectations of the parties involved

*Organisation's documented information, such as policies, procedures, manuals, records, etc., that describe the organisation's management system and its processes

*Commitment to follow principles issued by an NGO, such as the United Nations Global Compact, the International Labour Organization, etc., as long as they are relevant to the organisation's context and objectives

*Environmental aspects register, such as a list of the environmental impacts and risks associated with the organisation's activities, products, and services Therefore, the two options that are not potential audit criteria are F and H, as they are not reliable or verifiable sources of information, and they may not reflect the actual performance or conformity of the organisation's management system. Commercial advertisements and claims made on the organisation's website are forms of marketing communication that may be exaggerated, misleading, or inaccurate, and they are not subject to the same level of scrutiny or approval as the other sources of audit criteria.

References: ISO 19011:2018(en), Guidelines for auditing management systems, What are audit criteria? - ISO Update

NEW QUESTION # 23

An organization has decided to implement a QMS based on ISO 9001. What should they consider when determining internal issues?

- A. The competitive environment
- B. The social and economic environments
- C. The expectations of suppliers
- **D. Knowledge**

Answer: D

Explanation:

Comprehensive and Detailed In-Depth Explanation:

ISO 9001:2015 requires organizations to assess both internal and external issues that could impact the effectiveness of their Quality Management System (QMS).

Clause Reference:

* Clause 4.1 - Understanding the Organization and Its Context states that organizations must determine external and internal issues that affect their ability to achieve intended results.

* Internal issues include:

* Knowledge within the organization (documented or undocumented)

* Organizational culture

* Resource availability

* Technological advancements

* Infrastructure and capabilities

Why is the Correct Answer C?

* Knowledge (Clause 7.1.6) is a critical internal factor that directly affects the implementation and maintenance of a QMS.

* Organizations must identify, maintain, and make available the necessary knowledge to achieve quality objectives and meet customer requirements.

Why are the Other Options Incorrect?

- * A (Social and economic environments) # These are considered external issues rather than internal.
- * B (Competitive environment) # Competition is external, not an internal issue affecting the QMS.
- * D (Expectations of suppliers) # Supplier expectations relate to external interested parties, covered under Clause 4.2 (Understanding the Needs and Expectations of Interested Parties).

Reference:

ISO 9001:2015, Clause 4.1 - Understanding the Organization and Its Context ISO 9001:2015, Clause 7.1.6 - Organizational Knowledge

NEW QUESTION # 24

XYZ Corporation employs 100 people, and during a Stage 1 certification audit, certain issues are identified with the Quality Management System (QMS). Which two options describe the circumstances in which you could raise a nonconformity against Clause 6.2 of ISO 9001:2015?

- A. Establishing quality objectives did not include top management.
- B. Quality objectives are not being implemented by the organisation's personnel.
- C. The consultant has not interpreted ISO 9001 correctly.
- D. The organisation cannot afford to undertake quality objectives all at once.
- E. Quality objectives were not established in alignment with the organisation's quality policy.
- F. Quality objectives are not maintained as documented information.

Answer: E,F

Explanation:

* Understanding Clause 6.2 of ISO 9001:2015: Clause 6.2 (Quality Objectives and Planning to Achieve Them) specifies that organizations must:

* Establish measurable and relevant quality objectives consistent with the quality policy (Clause 6.2.1).

* Include objectives applicable to product/service conformity and customer satisfaction.

* Document these objectives and their planning as documented information (Clause 6.2.1 & 6.2.2).

* Plan how to achieve the objectives, including defining actions, resources, responsibilities, timelines, and methods for evaluation.

* Analysis of Options:

* A. Quality objectives are not being implemented by the organisation's personnel: Incorrect.

While implementation is critical, this relates more to operational aspects rather than the direct requirements of Clause 6.2.

Implementation issues would typically raise concerns under Clause

9.1 (Performance Evaluation).

* B. The consultant has not interpreted ISO 9001 correctly: Incorrect. The consultant's interpretation of ISO 9001 is irrelevant in terms of Clause 6.2 compliance. The focus is on whether the organization aligns with the requirements, not the consultant's role.

* C. Establishing quality objectives did not include top management: Incorrect. While top management involvement is vital for QMS effectiveness (Clause 5.1), this is not a direct requirement of Clause 6.2. Top management alignment is implied but not explicitly mandated for establishing quality objectives.

* D. Quality objectives were not established in alignment with the organisation's quality policy: Correct. Clause 6.2.1 requires that quality objectives be consistent with the organization's quality policy, ensuring they reflect its purpose, strategic direction, and commitment to continual improvement. Misalignment would constitute a nonconformity.

* E. The organisation cannot afford to undertake quality objectives all at once: Incorrect.

Financial constraints are not directly addressed in Clause 6.2. The clause focuses on planning to achieve objectives, which includes defining the necessary resources but does not demand achieving all objectives simultaneously.

* F. Quality objectives are not maintained as documented information: Correct. Clause 6.2.1 specifically requires that quality objectives be maintained as documented information. Failure to document the objectives is a direct violation of this clause.

* Why Options D and F Are Correct:

* D: Misalignment between the quality objectives and the quality policy directly violates Clause 6.2.1, which mandates that objectives support the strategic direction of the organization.

* F: Lack of documentation for quality objectives breaches the requirement to maintain them as documented information under Clause 6.2.1.

* Relevant References:

* Clause 6.2.1: Establishing quality objectives aligned with the quality policy.

* Clause 6.2.2: Maintaining documented information for quality objectives and planning to achieve them.

* Clause 5.1.1: Top management's responsibility to ensure alignment between the QMS and strategic direction.

NEW QUESTION # 25

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

The organization 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.

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.

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.

The NPD Manager explains that the customer confirms their approval to proceed with a new formulation by email. These emails are kept on SWIFT.

The NPD Manager shows you evidence of consumer trials that are carried out for some new products prior to full-scale launch.

The NPD Manager explains that an approved external laboratory is used to perform shelf-life stability trials on some formulations during product development.

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 ..."

Answer:

Explanation:

Audit evidence

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.

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ISO 9001 Clause 8.3 extract

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

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NEW QUESTION # 26

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