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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"> 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"> Preparing an ISO 9001 audit: This topic covers sub-topics related to preparing a quality management system audit.
Topic 4	<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 5	<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 (Q97-Q102):

NEW QUESTION # 97

You are carrying out an audit to ISO 9001 at an organisation which offers regulatory consultancy services to manufacturers of cosmetics.

You are interviewing the Technical Director (TD), who manages a team of regulatory experts responsible for providing regulatory services to customers.

You: "How do you ensure your regulatory team's competence concerning regulatory requirements is maintained?" TD: "The two Regulatory Experts we employ full-time have years of experience of working in the cosmetics industry." You: "How is their regulatory competence maintained?" TD: "They are dedicated individuals with lots of contacts in the sector." You: "How does the business enable them to maintain their understanding of current regulatory requirements?" TD: "We leave that up to them."

Answer:

Explanation:

□

NEW QUESTION # 98

In the context of a second-party audit, match the activity with the party responsible for conducting it.

Answer:

Explanation:

□ Explanation:

Here is the correct matching of the activities with the responsible parties in the context of a second-party audit:

- * Define the audit scope: Customer
- * Develop the audit plan: Audit team leader
- * Respond to the audit findings: External provider
- * Conduct the audit: Audit team

This reflects the typical division of responsibilities in a second-party audit, where the customer (the party commissioning the audit) sets the scope, the audit team leader manages the planning, the external provider responds to findings, and the audit team carries out the audit.

NEW QUESTION # 99

What should the auditor document during the Stage 1 audit?

- A. The observations that could result in nonconformities during the on-site audit
- B. The interviews with the auditee's employees
- C. The main processes of the auditee

Answer: A

Explanation:

Comprehensive and Detailed In-Depth Explanation: Stage 1 Audit (ISO 9001:2015, Clause 9.2.2) is a documentation review to assess the readiness for a Stage 2 Audit. The auditor must document:

- * Observations that could lead to nonconformities, ensuring they are addressed before Stage 2.
- * Areas needing improvement, such as missing documented information or unclear process definitions

While understanding the auditee's main processes is important, documenting interviews is not a requirement at Stage 1.

NEW QUESTION # 100

The following are stages of an audit, put them in the order they would be conducted.

Answer:

Explanation:

□ Explanation:

- Establishing the audit programme objectives
- Determining and evaluating the audit programme risks and opportunities
- Establishing the audit programme
- Initiating the audit
- Preparing all audit activity
- Conducting the audit activities

To complete the sequence, you can drag and drop the options to the appropriate blank section.

Here is a brief explanation of each stage:

Establishing the audit programme objectives: This is the first stage of the audit process, where the purpose, scope, and criteria of the audit programme are defined. The audit programme objectives should be aligned with the strategic direction and policies of the organization, and should address the needs and expectations of the interested parties¹².

Determining and evaluating the audit programme risks and opportunities: This is the second stage of the audit process, where the factors that can affect the achievement of the audit programme objectives are identified and assessed. The audit programme risks and opportunities should consider the internal and external issues, the requirements and changes of the interested parties, and the results and feedback from previous audits¹².

Establishing the audit programme: This is the third stage of the audit process, where the audit programme is designed and implemented. The audit programme should include the audit programme procedures, the audit programme resources, the audit methods and techniques, the audit frequency and schedule, and the audit programme performance indicators¹².

Initiating the audit: This is the fourth stage of the audit process, where the audit is prepared and planned. The audit initiation involves selecting the audit team, establishing the contact with the auditee, defining the audit objectives, scope, and criteria, developing the audit plan, and conducting the document review¹²³.

Preparing all audit activity: This is the fifth stage of the audit process, where the audit activities are organized and coordinated. The audit preparation involves assigning the audit tasks, communicating with the auditee and the audit team, arranging the logistics, preparing the working documents, and conducting the opening meeting¹²³.

Conducting the audit activities: This is the sixth and final stage of the audit process, where the audit evidence is collected and evaluated. The audit conduct involves performing the audit activities, such as interviews, observations, document reviews, and tests, documenting the audit findings, preparing the audit conclusions, and conducting the closing meeting¹²³.

I hope this helps you with your ISO 9001 Lead Auditor objectives and content. If you have any further questions, please feel free to ask. # References: 1: ISO 19011:2018 - Guidelines for auditing management systems 2: Audit Process | Flowchart | Summary - Accountingguide 3: What are the Stages of the Auditing Process & Why it is Important ...

NEW QUESTION # 101

What competence, among others, should each audit team member have?

- A. Expertise in each domain to be audited.
- B. Knowledge of the industry in which the auditee operates.
- C. A formal degree in quality management.
- **D. Knowledge of the risk-based approach to auditing.**

Answer: D

Explanation:

Comprehensive and Detailed In-Depth Explanation:

Auditors must have competence in risk-based auditing to effectively assess an organization's QMS performance and compliance.

Clause References:

- * ISO 19011:2018, Clause 7.2.3 - Determining Auditor Competence:
- * Auditors must have knowledge of risk-based thinking to assess risk impact on processes.
- * ISO 9001:2015, Clause 0.3.3 - Risk-Based Thinking:
- * The standard emphasizes proactive risk management, which auditors must understand.

Why is the Correct Answer B?

- * Risk-based auditing ensures audits focus on high-risk areas, improving audit effectiveness.
- * Auditors must assess how organizations apply risk-based thinking in decision-making, process control, and improvement.

Why are the Other Options Incorrect?

- * A (Industry knowledge) # While helpful, it is not mandatory for all auditors.
- * C (Expertise in all domains) # Auditors are not required to be experts in all areas, just in audit methodology.
- * D (Formal degree in quality management) # ISO does not require a formal degree, just competence in audit principles and methods.

Reference:

ISO 19011:2018, Clause 7.2.3 - Determining Auditor Competence

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

NEW QUESTION # 102

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