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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">Conducting an ISO 9001 audit: It evaluates your skills to conduct a QMS audit.
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 (Q64-Q69):

NEW QUESTION # 64

Scenario 4:

TD Advertising is a print management company based in Chicago. The company offers design services, digital printing, storage, and distribution. As TD expanded, its management recognized that success depended on adopting new technologies and improving quality.

To ensure customer satisfaction and quality improvement, the company decided to pursue ISO 9001 certification.

After implementing the QMS, TD hired a well-known certification body for an audit. Anne Key was appointed as the audit team leader. She received a document listing the audit team members, audit scope, criteria, duration, and audit engagement limits. Anne reviewed the document and approved the audit mandate. The certification body and TD's top management signed the certification agreement.

Before contacting TD, Anne reviewed the audit scope and noticed that TD made changes to it due to the adoption of new printing equipment. However, Anne disagreed with the changes, stating they would affect the audit timeline. She considered withdrawing from the audit.

In scenario 4, the audit team determined the audit feasibility by considering only the resources available for the audit. Is this acceptable?

- A. Yes, considering only the resources available for the audit is sufficient for determining the audit feasibility.
- B. Yes, because the audit team leader has final authority over audit feasibility.
- C. No, the audit feasibility should be determined by TD's top management.
- D. No, because other factors should be considered when determining the audit feasibility, such as information needed to plan the audit, the cooperation of the auditee, duration of the audit, etc.

Answer: D

Explanation:

Comprehensive and Detailed In-Depth Explanation:

An audit's feasibility must be assessed using multiple factors, not just resource availability.

Clause References:

* ISO 19011:2018, Clause 5.3 - Establishing the Audit Program: Requires consideration of logistical, technical, and cooperation factors when assessing audit feasibility.

* ISO/IEC 17021-1:2015, Clause 9.1.3 - Determining Feasibility of the Audit: Requires evaluating more than just resources to ensure a successful audit.

Why is the Correct Answer B?

* Audit feasibility should consider:

* Availability of information (documents, records).

* Cooperation from the auditee.

* Operational conditions that might affect the audit.

* Scope and complexity of the QMS being audited.

* Resource availability alone is not enough to determine feasibility.

Why are the Other Options Incorrect?

- * A (Top management determines feasibility) # Incorrect because feasibility is determined by the certification body, not the auditee.
- * C (Resources alone are sufficient) # Incorrect because other key factors must be evaluated.
- * D (Final authority lies with the audit leader) # Incorrect because ISO requires multiple factors to be considered, not just an auditor's decision.

NEW QUESTION # 65

Noitol is an organisation specialising in the design and production of e-learning training materials for the insurance market. During an ISO 9001 audit of the development department, the auditor asks the Head of Development about the process used for validation of the final course design. She states that they usually ask customers to validate the product with volunteers. She says that the feedback received often leads to key improvements.

The auditor samples the design records for a recently completed course for the 247 Insurance organisation.

Design verification was carried out but there was no validation report. The Head of Development advises that this customer required the product on an urgent basis, so the validation stage was omitted. When asked, the Head estimates that this occurs about 50% of the time. She confirms that they always ask for feedback and often make changes. There is no record of feedback in the design file for the course.

The auditor decides to review the training course design process in more depth.

Select three options that provide a meaningful audit trail for this process.

- A. What risks and opportunities have been notified to interested parties?
- B. How is the cost of the course calculated?
- C. What are the qualifications of the administrative staff?
- **D. How is design documentation controlled and managed?**
- E. How is the tutor trained to deliver the completed course?
- F. How are students advised about prior learning requirements?
- **G. How is technical content of courses verified as correct?**
- **H. How is customer feedback integrated into the course?**

Answer: D,G,H

Explanation:

According to clause 8.3 of ISO 9001:2015, the organization should establish, implement, and maintain a design and development process that is appropriate to ensure the subsequent provision of products and services. The design and development process should include the following activities:

*Determining the requirements for the products and services to be designed and developed, considering the intended use, the statutory and regulatory requirements, the customer and other relevant interested parties' needs and expectations, and the potential risks and opportunities.

*Defining the design and development objectives, stages, responsibilities, and authorities, and ensuring the availability of adequate resources and competence.

*Implementing design and development controls, such as reviews, verification, and validation, to ensure that the design and development outputs meet the design and development inputs, and to identify and resolve any problems or errors.

*Maintaining documented information on the design and development inputs, outputs, reviews, verification, validation, and changes, and ensuring the traceability and conformity of the products and services to the requirements.

*Managing the design and development changes, by identifying, reviewing, and controlling them, and evaluating their effects on the products and services and the QMS.

In this case, the evidence statements that provide a meaningful audit trail for the design and development process are B, E, and F, because they relate to the design and development controls, the documented information, and the verification activities that are required by the standard. These options can help the auditor to assess the effectiveness and conformity of the design and development process, and to identify any nonconformities or opportunities for improvement. The other options are not directly related to clause 8.3, although they may be relevant for other aspects of the QMS, such as clause 7.2 on competence, clause 7.3 on awareness, clause 7.4 on communication, clause 8.2 on requirements for products and services, clause 8.4 on externally provided processes, products, and services, and clause 8.7 on control of nonconforming outputs.

References: ISO 9001:2015, ISO 9001 Auditing Practices Group Guidance on Design and Development, ISO 9001 Clause 8.3 Design and development of products and services

NEW QUESTION # 66

Scenario 2:

Bell is a Canadian food manufacturing company that operates globally. Their main products include nuts, dried fruits, and

confections. Bell has always prioritized product quality and has maintained a good reputation for many years. However, the company's production error rate increased significantly, leading to more customer complaints.

To increase efficiency and customer satisfaction, Bell implemented a Quality Management System (QMS) based on ISO 9001. The top management established a QMS implementation team comprising five middle managers from various departments, including Leslie, the quality manager.

Leslie was responsible for assigning responsibilities and authorities for QMS-related roles. He also suggested including a top management representative in the QMS team, but top management declined due to other priorities.

The team defined the QMS scope as:

"The scope of the QMS includes all activities related to food processing." Leslie established a quality policy and presented it to the team for review before top management approval

. Top management also proposed a new strategy for handling customer complaints, requiring biweekly customer surveys to monitor customer perceptions.

Which of the following indicates that Bell has defined its quality objectives?

- A. Establishing a new strategy for handling customer complaints and requests
- B. Implementing a QMS to increase efficiency in the manufacturing process and customer satisfaction
- C. Establishing a QMS implementation team of middle managers from various departments
- D. Assigning responsibilities for QMS roles

Answer: A

Explanation:

Comprehensive and Detailed In-Depth Explanation: ISO 9001:2015, Clause 6.2 (Quality Objectives and Planning to Achieve Them) states that an organization must establish measurable and relevant quality objectives to improve QMS effectiveness.

Bell's strategy for handling customer complaints aligns with this requirement because it includes specific, measurable goals (biweekly customer surveys) to enhance customer satisfaction and service quality.

Other options are not directly related to defining quality objectives:

* Option B (Implementing a QMS) refers to the overall system, not specific objectives.

* Option C (Creating a QMS team) is an implementation step, not an objective.

* Option D (Assigning responsibilities) is necessary for QMS but does not define objectives.

NEW QUESTION # 67

What must the auditor consider in order to mitigate audit risks and obtain reasonable assurance?

- A. The needs and expectations of internal interested parties.
- B. The processes deemed material to the auditee.
- C. The previous audit results.
- D. The financial risks associated with QMS implementation.

Answer: B

Explanation:

Comprehensive and Detailed In-Depth Explanation:

Auditors must focus on key processes that impact QMS effectiveness to ensure audit risks are minimized.

Clause References:

ISO 19011:2018, Clause 6.3 - Managing Audit Risk: Auditors should prioritize critical processes to obtain reasonable assurance.

Why is the Correct Answer A?

Some processes are critical (e.g., production quality, customer complaints handling).

If these material processes fail, the QMS could collapse.

Why are the Other Options Incorrect?

B (Needs of internal parties) # Important, but not the primary focus for reducing audit risk.

C (Previous audit results) # Useful for improvement but does not directly reduce current audit risks.

D (Financial risks) # ISO 9001 focuses on quality risks, not financial risks.

Reference:

ISO 19011:2018, Clause 6.3 - Managing Audit Risk

NEW QUESTION # 68

How can an organization ensure the objectivity and impartiality of the internal audit function?

- A. By always outsourcing the internal audit function to a third party
- **B. By assigning internal auditors that do not have operational roles related to the QMS**
- C. By having a representative of top management involved during the internal audit process

Answer: B

Explanation:

Comprehensive and Detailed In-Depth Explanation:

According to ISO 19011:2018, Clause 5.1 (Impartiality):

* Internal auditors must not audit areas where they have direct responsibilities to avoid conflicts of interest.

* Outsourcing (C) is not required, as long as impartiality is maintained internally.

Thus, B is the correct answer.

Reference:

ISO 19011:2018, Clause 5.1 (Impartiality)

NEW QUESTION # 69

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