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PECB QMS ISO 9001:2015 Lead Auditor Exam Sample Questions (Q50-Q55):

NEW QUESTION # 50

Scenario 3:

Fin-Pro is a financial institution in Austria offering commercial banking, wealth management, and investment services. The company faced a significant loss of customers due to failing to improve service quality as they expanded.

To regain customer confidence, top management implemented a QMS based on ISO 9001. After a year, they contacted ACB, a local certification body, to pursue ISO 9001 certification.

The audit team was led by Emilia, an experienced lead auditor, and included three auditors. After an agreement was reached, ACB sent the audit objectives to the audit team.

The audit team began by gathering information about Fin-Pro's understanding of ISO 9001 requirements.

While reviewing documented information, they noticed missing records of training and awareness sessions. They conducted employee interviews to verify attendance.

The team also reviewed the organizational chart and job descriptions to confirm employee competence.

They observed the company's working environment (social, psychological, and physical conditions).

The audit team analyzed the evidence and prepared an audit report with findings and conclusions.

ACB sent the audit objectives to the audit team after an agreement was reached. Is this acceptable?

- A. Yes, as long as the audit team leader approves.
- **B. No, the audit objectives should be part of the audit offer.**
- C. Yes, the audit objectives should be known only after an agreement is reached.
- D. No, only the auditee should know the audit objectives.

Answer: B

Explanation:

Comprehensive and Detailed In-Depth Explanation:

Clause References:

* ISO 19011:2018 (Guidelines for Auditing Management Systems), Clause 5.3 - Establishing the Audit Objectives

* ISO/IEC 17021-1:2015, Clause 9.1.2 - Audit Planning

Why is the Correct Answer C?

* Audit objectives must be clearly defined in the audit offer to ensure that the scope, criteria, and purpose are agreed upon in advance.

* ISO/IEC 17021-1:2015 (which governs certification bodies) requires that audit objectives be established before the audit begins to ensure transparency and effectiveness.

* Sending audit objectives after an agreement has been reached could lead to misalignment between the auditee's expectations and the audit's purpose.

Why are the Other Options Incorrect?

* A (Audit objectives should be known only after agreement) # Incorrect because objectives must be pre-defined in the audit offer.

* B (Only the auditee should know the objectives) # Incorrect because both the auditor and auditee must align on objectives.

* D (Approval from the lead auditor is sufficient) # Incorrect because audit planning follows formal procedures defined by ISO/IEC 17021-1.

Reference:

ISO/IEC 17021-1:2015, Clause 9.1.2 - Audit Planning

ISO 19011:2018, Clause 5.3 - Establishing the Audit Objectives

NEW QUESTION # 51

Scenario 6: Davis Clinic (DC) is an American medical center focused on integrated health care. Since its establishment DC was committed to providing qualitative services for its clients, which is the reason why the company decided to implement a quality management system (QMS) based on ISO 9001. After a year of having an active QMS in place, DC applied for a certification audit.

A team of five auditors, from a well-known certification body, was selected to conduct the audit. Eva was appointed as the audit team leader. After three days of auditing, the team gathered to review and examine their findings. They also discussed the audit findings with DC's top management and then drafted the audit conclusions.

In the closing meeting, which was held between the audit team and the top management of DC, Eva presented two nonconformities that were detected during the audit. Eva stated that the company did not retain documented information regarding its outsourced services for an analysis laboratory and regarding the conducted management reviews. During the closing meeting, the audit team required from DC's top management to come up with corrective action plans within two weeks. Although the top management did not agree with the audit findings, the audit team insisted that the auditee must submit corrective actions within the given time frame in order for the audit activities to continue.

Once the action plans were evaluated, the audit team began preparing the audit report. Eva required from the team to provide accurate descriptions of the audit findings and the audit conclusions. The report was then distributed to all the interested parties involved in the audit, including the certification body. Based on the report, the certification body together with Eva, as the audit team leader, made the certification decision.

Based on the scenario above, answer the following question:

Why is it important to discuss the audit findings with DC's top management prior to the closing meeting and the submission of the final audit report?

- A. To verify whether the audit objectives have been met
- B. To identify the persons responsible for the nonconformities
- C. To encourage the implementation of corrective actions as soon as possible

Answer: A

Explanation:

Comprehensive and Detailed In-Depth Explanation: Discussing audit findings before the closing meeting ensures that:

- * The audit objectives have been met (ISO 19011:2018, Clause 6.4.10).
- * The auditee has an opportunity to clarify misunderstandings or provide additional evidence.
- * The audit team and the auditee agree on the accuracy of findings before finalizing the report.

While encouraging corrective actions (B) is beneficial, the primary purpose of discussing findings is to ensure that the audit was conducted effectively and aligned with objectives. Identifying responsible persons (C) is not the auditor's role.

NEW QUESTION # 52

You are carrying out an annual audit at an organisation that offers home security services. You are interviewing the Quality Manager (QM) You: "Would you tell me about your management review process?" QM: "The senior management team plans to review the management system every six months. The review follows a set agenda and records are maintained." You: "May I see the records from the last two management reviews?" Narrative: The Quality Manager gives you the latest record, which shows the last management review took place nine months ago.

The Quality Manager then gives you the previous management review record, which took place one year before the latest review.

You: "Are there any other review reports in the last two years?"

QM: "No, these are the only ones."

You decide to raise a nonconformity.

Nonconformity report	
ISO 9001 Clause Number:	
Nature of problem:	
ISO 9001 requirement that has not been fulfilled:	

To complete the nonconformity report 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 the options to the appropriate blank section.

9.3.1	Issues raised at management review are not being actioned.	9.3.3	ISO 9001 - "Top management shall review the organization's quality management system."
ISO 9001 - "Top management shall review the organization's quality management system at planned intervals."		Management review has not been conducted at the defined frequency.	
Management review records are not being retained.		ISO 9001 - "The organization shall retain documented information as evidence of the results of management review."	

Answer:

Explanation:

You decide to raise a nonconformity.

Nonconformity report	
ISO 9001 Clause Number:	9.3.1
Nature of problem:	Management review has not been conducted
ISO 9001 requirement that has not been fulfilled:	ISO 9001 - "Top management shall review the organization's quality management system at planned intervals."

To complete the nonconformity report 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 the options to the appropriate blank section.

9.3.1	Issues raised at management review are not being actioned.	9.3.3	ISO 9001 - "Top management shall review the organization's quality management system."
ISO 9001 - "Top management shall review the organization's quality management system at planned intervals."		Management review has not been conducted at the defined frequency.	
Management review records are not being retained.		ISO 9001 - "The organization shall retain documented information as evidence of the results of management review."	

Explanation:

Nonconformity report	
ISO 9001 Clause Number:	9.3.1
Nature of problem:	Management review has not been conducted at the defined frequency.
ISO 9001 requirement that has not been fulfilled:	ISO 9001 - "Top management shall review the organization's quality management system at planned intervals."

Nonconformity report

ISO 9001 Clause Number: 9.3.1 Nature of problem: Management review has not been conducted at the defined frequency. ISO 9001 requirement that has not been fulfilled: ISO 9001 - "Top management shall review the organization's quality management system at planned intervals." Evidence: The last management review took place nine months ago, and the previous one took place one year before the latest review. The planned interval is six months.

NEW QUESTION # 53

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).

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Quality management principles	
Customer focus	
Engagement of people	
Improvement	
Evidence-based decision-making	

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).

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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

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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 # 54

According to ISO 9000, what is quality?

- A. The efficiency with which resources are utilized in achieving objectives
- B. A set of conditions under which work is performed
- C. The degree to which a set of inherent characteristics of an object fulfills requirements
- D. The ability of an object to realize an output that will fulfill the requirements for that output

Answer: C

Explanation:

Comprehensive and Detailed In-Depth Explanation: ISO 9000:2015 defines quality as "the degree to which a set of inherent characteristics of an object fulfills requirements."

* Clause 3.6.2 (Quality) confirms this definition.

* Quality is determined by how well an object (product, service, or process) meets defined requirements (customer, regulatory, or internal).

The other options do not align with the official ISO definition:

* Option A refers to performance capability but does not define quality.

* Option C describes work conditions, not quality.

* Option D focuses on efficiency rather than fulfilling requirements.

NEW QUESTION # 55

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