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PECB QMS ISO 9001:2015 Lead Auditor Exam Sample Questions (Q211-Q216):

NEW QUESTION # 211

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. What type of evidence has been collected by the ACB's audit team, as presented in scenario 3?

- A. Observational, secondary, qualitative.
- B. Documentary, confirmative, verbal.
- C. Physical, verbal, analytical.
- **D. Verbal, documentary, physical.**

Answer: D

Explanation:

Comprehensive and Detailed In-Depth Explanation:

Audit evidence includes information collected through different methods to assess compliance with ISO 9001:2015 requirements.

Clause References:

ISO 19011:2018, Clause 6.4.6 - Audit Evidence: Audit evidence must be objective, verifiable, and based on facts.

ISO 9001:2015, Clause 9.1.1 - Monitoring, Measurement, Analysis, and Evaluation: Requires organizations to collect and analyze data from multiple sources to verify effectiveness.

Types of Audit Evidence Collected in Scenario 3:

Verbal Evidence - Employee interviews regarding training and awareness sessions.

Documentary Evidence - Organizational charts, job descriptions, training records.

Physical Evidence - Workplace observations to assess working conditions.

Why is the Correct Answer B?

The audit team used a combination of verbal (interviews), documentary (records), and physical (site observations) evidence.

This triangulation approach enhances audit reliability and ensures compliance verification.

Why are the Other Options Incorrect?

A (Confirmative evidence) # Not a formal audit term in ISO 9001 or ISO 19011.

C (Analytical evidence) # Incorrect, as analysis was not a primary method used.

D (Qualitative evidence only) # Incorrect because the audit involved both qualitative (interviews) and quantitative (documents, physical) evidence.

Reference:

ISO 19011:2018, Clause 6.4.6 - Audit Evidence

ISO 9001:2015, Clause 9.1.1 - Monitoring, Measurement, Analysis, and Evaluation

NEW QUESTION # 212

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

- A. The expectations of suppliers
- B. The competitive environment
- C. The social and economic environments
- **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 # 213

XYZ Corporation is an organisation that employs 100 people. As audit team leader, you are conducting a certification audit at Stage 1. When reviewing the quality management system (QMS) documentation, you find that quality objectives have been set for every employee in the organisation except top management.

The Quality Manager complains that this has created a lot of resistance to the QMS, and the Chief Executive is asking questions about how much it will cost. He asks for your opinion on whether this is the correct method of setting objectives.

Three months after Stage 1, you return to XYZ Corporation to conduct a Stage 2 certification audit as Audit Team Leader with one other auditor. You find that the Quality Manager has cancelled the previous quality objectives for all employees and replaced them with a single objective for himself. This states that "The Quality Manager will drive multiple improvements in the QMS in the next year". The Quality Manager indicates that this gives him the authority to issue instructions to department managers when quality improvement is needed. He says that this approach has the full backing of senior management. He shows you the latest Quality Improvement Request that was included in the last management review.

After further auditing, the issues below were found. Select two statements that apply to the term 'nonconformity'.

- A. No quality objectives planned for the top management team
- B. Top management claim not to be aware of the improvement request (QI/12/20/HR-3) initiated by the Quality Manager.
- C. Quality improvements not aligning with the quality policy.
- D. Decisions on improvement action timescales not involving departmental managers.
- E. Evaluation of the results of the improvement action not always documented by the Quality Manager.
- F. Limited knowledge of the content of Quality Improvement Requests by departmental staff.

Answer: A,C

Explanation:

According to the ISO 9001:2015 standard, clause 10.2.1 defines nonconformity as the non-fulfilment of a requirement. A requirement can be related to the quality management system, the products and services, the customer expectations, or the applicable statutory and regulatory requirements. Nonconformities can be detected through various sources, such as audits, inspections, tests, customer complaints, or internal reviews.

Nonconformities must be addressed by taking appropriate actions to correct them and prevent their recurrence.

In this scenario, the auditee has shown several issues that indicate nonconformities in their quality management system. Two statements that apply to the term nonconformity are:

A). No quality objectives planned for the top management team: According to ISO 9001, clause 6.2.1, the organization must establish quality objectives at relevant functions, levels, and processes. The quality objectives must be consistent with the quality policy and the strategic direction of the organization. The top management team is responsible for providing leadership and direction for the quality management system and ensuring its alignment with the organization's purpose and context. Therefore, the absence of quality objectives for the top management team is a nonconformity as it violates the requirement of clause 6.2.1.

E). Quality improvements not aligning with the quality policy: According to ISO 9001, clause 5.2.1, the quality policy is a statement of the organization's intentions and direction regarding quality, as formally expressed by top management. The quality policy must provide a framework for setting quality objectives and be compatible with the context and strategic direction of the organization. The quality policy must also be communicated, understood, and applied within the organization. Therefore, if the quality improvements are not aligned with the quality policy, it is a nonconformity as it violates the requirement of clause 5.2.1.

NEW QUESTION # 214

What is a list of actions that should be performed during the audit with their respective timeline?

- A. The audit schedule.
- B. The audit objectives.
- C. The audit criteria.
- D. The audit offer.

Answer: A

Explanation:

Comprehensive and Detailed In-Depth Explanation:

The audit schedule provides a structured timeline of activities to be conducted during the audit.

Clause References:

* ISO 19011:2018, Clause 6.4.2 - Preparing the Audit Plan:

* Requires the development of an audit schedule, including the sequence and timing of activities

.

* ISO/IEC 17021-1:2015, Clause 9.1.3 - Audit Program:

* Certification bodies must establish a schedule for conducting audits.

Why is the Correct Answer C?

* The audit schedule ensures systematic execution of the audit by defining activities, responsible auditors, and timeframes.

* A well-planned schedule improves efficiency and helps auditors cover all necessary areas within the given time.

Why are the Other Options Incorrect?

* A (Audit objectives) # Define why the audit is conducted, not the schedule.

* B (Audit criteria) # Define the standards and requirements to be evaluated, not the timeline.

* D (Audit offer) # Refers to the initial proposal sent to the auditee, not the activity timeline.

Reference:

ISO 19011:2018, Clause 6.4.2 - Preparing the Audit Plan

ISO/IEC 17021-1:2015, Clause 9.1.3 - Audit Program

NEW QUESTION # 215

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

According to ISO 19011:2018, clause 5, the audit programme is a set of one or more audits planned for a specific time frame and directed towards a specific purpose. The audit programme includes all activities necessary to plan, organize, and conduct the audits.

The audit programme management involves the following steps1:

Establishing the audit programme objectives: The audit programme objectives define the intended outcomes of the audit programme, such as verifying conformity, evaluating performance, identifying improvement opportunities, etc. The audit programme objectives should be aligned with the strategic direction and policies of the organization and the needs and expectations of the interested parties.

Determining and evaluating the audit programme risks and opportunities: The audit programme risks and opportunities are the factors that can affect the achievement of the audit programme objectives, such as changes in the internal or external context, availability of resources, competence of auditors, etc. The audit programme risks and opportunities should be identified, analyzed, and evaluated to determine the appropriate actions to address them.

Establishing the audit programme: The audit programme is established by defining the audit programme scope, criteria, methods, and resources. The audit programme scope defines the extent and boundaries of the audit programme, such as the processes, functions, sites, activities, etc. that will be audited. The audit programme criteria are the set of policies, procedures, or requirements used as a reference for the audits. The audit programme methods are the techniques used to conduct the audits, such as interviews, observations, document review, sampling, etc. The audit programme resources are the human, technical, and financial resources needed to implement the audit programme.

Initiating the audit: The audit initiation is the process of formally establishing the arrangements for an individual audit within the audit

programme. The audit initiation involves contacting the auditee and the audit client, confirming the audit objectives, scope, and criteria, and obtaining the necessary information and access for the audit.

Preparing all audit activity: The audit preparation is the process of developing the audit plan and the audit work documents for an individual audit. The audit plan is a document that provides the basis for agreement regarding the conduct of the audit, such as the audit schedule, the audit team, the audit methods, the audit language, the audit report, etc. The audit work documents are the records that provide evidence of the audit activities, such as the audit checklist, the audit notes, the audit findings, etc.

Conducting the audit activities: The audit activities are the processes of collecting and verifying audit evidence and evaluating it against the audit criteria to make the audit conclusions. The audit activities include the opening meeting, the communication during the audit, the roles and responsibilities of the audit team and the auditee, the audit evidence collection and verification, the audit findings generation and recording, the closing meeting, and the audit report preparation and distribution.

References: ISO 19011:2018(en), Guidelines for auditing management systems

NEW QUESTION # 216

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