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PECB QMS ISO 9001:2015 Lead Auditor Exam Sample Questions (Q201-Q206):

NEW QUESTION # 201

Put the following steps of a third-party audit into the correct sequence in which they happen.

☐

Answer:

Explanation:

☐

Explanation:

Sequence:

Stage 1 Audit

Stage 2 Opening Meeting

Interviews

Stage 2 Closing Meeting

Close-out of Stage 2 Audit Findings

Issue Certificate

Surveillance Audit

Follow-up Audit

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

Here is a brief explanation of each step:

Stage 1 Audit: This is the initial audit that aims to assess the readiness of the organization for the stage 2 audit. It involves reviewing the documentation of the quality management system, evaluating the scope and objectives of the audit, and identifying any major gaps or nonconformities³⁴.

Stage 2 Opening Meeting: This is the meeting that marks the start of the stage 2 audit. It involves confirming the audit plan, the audit criteria, the audit scope, and the audit team. It also provides an opportunity for the auditee to ask any questions or raise any concerns³⁴.

Interviews: This is the main activity of the stage 2 audit, where the audit team collects evidence by interviewing the personnel involved in the quality management system, observing the processes and activities, and examining the records and documents. The audit team uses various techniques, such as sampling, measurement, analysis, and evaluation, to verify the conformity and effectiveness of the quality management system^{34,5}.

Stage 2 Closing Meeting: This is the meeting that marks the end of the stage 2 audit. It involves presenting the audit findings, the audit conclusions, and the audit report to the auditee. It also provides an opportunity for the auditee to provide feedback, ask questions, or dispute any findings³⁴.

Close-out of Stage 2 Audit Findings: This is the process of verifying that the auditee has taken appropriate corrective actions to address any nonconformities or opportunities for improvement identified during the stage 2 audit. The audit team may request evidence or conduct a follow-up visit to confirm the effectiveness of the corrective actions³⁴.

Issue Certificate: This is the process of issuing a certificate of conformity to the auditee, if the audit team is satisfied that the quality management system meets the requirements of the standard and that there are no major nonconformities or unresolved issues. The certificate is valid for a specified period, usually three years, and is subject to periodic surveillance audits³⁴.

Surveillance Audit: This is the process of conducting periodic audits, usually once a year, to monitor the continued conformity and effectiveness of the quality management system. It involves reviewing the changes, improvements, and performance of the quality management system, and identifying any new nonconformities or opportunities for improvement³⁴.

Follow-up Audit: This is the process of conducting an additional audit, usually in response to a significant change, a complaint, or a major nonconformity, to verify the impact and the corrective actions taken by the auditee. It may result in the suspension, withdrawal, or renewal of the certificate, depending on the outcome of the audit³⁴.

NEW QUESTION # 202

"A set of interrelated or interlacing elements of an organization to establish policies and objectives, and processes to achieve those objectives" is the definition of a/an:

- A. Organization scope
- B. Standard
- C. Quality manual
- **D. Management system**

Answer: D

Explanation:

Comprehensive and Detailed In-Depth Explanation:

According to ISO 9000:2015, which provides definitions for terms used in ISO 9001:2015, a management system is defined as a set of interrelated or interacting elements of an organization to establish policies, objectives, and processes to achieve those objectives.

A Quality Management System (QMS) is a type of management system that ensures organizations meet customer and regulatory requirements while improving performance.

Clause 3.5.3 of ISO 9000:2015 clearly defines "management system" and aligns with this question. The other options do not fit the definition:

* Standard refers to an established norm or requirement.

* Organization scope defines the boundaries of a QMS but is not a system itself.

* Quality manual is a document (optional under ISO 9001:2015) that describes a QMS but is not the system itself.

Reference:

ISO 9000:2015, Clause 3.5.3 - Management System

NEW QUESTION # 203

You are carrying out an annual surveillance audit at an organisation that has been certificated to ISO 9001 for two years. The organisation offers home cleaning services. The scope of the quality management system covers planning the weekly activities, providing cleaning materials, cleaning the whole property (including outdoor space) alarm installation, alarm servicing, alarm monitoring and response. The business operates from a single office and employs subcontract cleaners across the whole city. You have just completed the opening meeting. You are interviewing the Managing Director (MD).

You: I would like to gain an understanding of how the quality management system has been supporting your business and its strategic direction.

MD: We are continuing to face difficult times. The market is extremely competitive, and customers typically look for the least expensive option when choosing home cleaning services. We have not yet seen any business benefit from our quality management system.

You: Tell me how you determine external and internal issues.

MD: We use PESTLE analysis (Political, economic, social, technological, legal, environmental).

You: Why did you not use the SWOT model (Strengths, Weaknesses, Opportunities, Threats)?

MD: I had used PESTLE in my previous job.

You: How have the outputs from your PESTLE been used?

Select two audit trails which would lead to a determination of how the PESTLE analysis would affect the planning of a QMS to ISO 9001.

- A. How many external interested parties were consulted?
- **B. How has the PESTLE analysis contributed to the improvement of the QMS?**
- C. Has the PESTLE analysis been reviewed by the operations manager?
- D. What, if any, training has been given in SWOT analysis?
- E. How does the organisation share information with external interested parties?
- **F. What actions have been taken to address the risks and opportunities from the PESTLE analysis?**

Answer: B,F

Explanation:

ISO 9001:2015 requires organisations to understand their context and to use this understanding as an input to planning the quality management system. Tools such as PESTLE are acceptable methods, but auditors must verify how the outputs are used, not simply that the analysis exists.

Relevant ISO 9001 requirements:

* Clause 4.1 - Understanding the organisation and its context The organisation shall determine external and internal issues that are relevant to its purpose and strategic direction and that affect its ability to achieve the intended results of the QMS.

* Clause 6.1 - Actions to address risks and opportunities The organisation shall plan actions to address risks and opportunities identified from context analysis and integrate these actions into the QMS processes.

Explanation of the correct audit trails:

C). What actions have been taken to address the risks and opportunities from the PESTLE analysis?

This audit trail directly links PESTLE outputs to Clause 6.1. It allows the auditor to determine whether the organisation has translated identified political, economic, social, technological, legal, and environmental issues into concrete actions within planning, operational control, or resource allocation. Without actions, the PESTLE analysis has no impact on QMS planning.

E). How has the PESTLE analysis contributed to the improvement of the QMS?

ISO 9001 requires context analysis to support improvement and strategic alignment of the QMS. This audit trail confirms whether PESTLE outputs are used as inputs to improvement activities, management review, or changes to processes, supporting Clauses 4.1, 6.1, and 10.3.

Explanation of why the other options are not selected:

* A: Review by a specific manager is not a requirement of ISO 9001 and does not demonstrate impact on QMS planning.

* B: PESTLE does not require consultation with external interested parties; that relates to Clause 4.2, not planning impact.

* D: Training in SWOT is irrelevant, as ISO 9001 does not mandate any specific analysis tool.

* F: Sharing information with external interested parties relates to communication, not to how PESTLE affects QMS planning.

ISO-aligned conclusion:

To determine how PESTLE analysis affects planning of a QMS, the auditor must follow audit trails that demonstrate:

* Conversion of identified issues into risk-based actions, and

* Use of those outputs to improve and adapt the QMS.

Therefore, the correct answers are C and E.

NEW QUESTION # 204

Select the word that best completes the sentence:

Answer:

Explanation:

Explanation:

According to the ISO - Management system standards page, the key benefits of an effective management system include improved operational effectiveness and efficiency, improved risk management and protection of people and the environment, and enhanced drive for innovation. The Integrated Use of Management System Standards (IUMSS) handbook also states that the purpose and objectives of management system standards are to help organizations improve their performance by specifying repeatable steps that organizations consciously implement to achieve their goals and objectives.

Therefore, the complete sentence is:

"The purpose of a management system standard is to improve the performance of an organisation."

NEW QUESTION # 205

Match each of the following statements into the table below to show whether they apply to first-party audits, second-party audits or third-party audits:

Answer:

Explanation:

Explanation:

Table

Statement

First-party audits

Second-party audits

Third-party audits

The audit scope is typically determined by the organisation being audited.

Yes

No

No

The outcome of the audit is typically certification to a recognised standard.

No

No

Yes

The audit scope is typically confined to service/product provision capability.

No

Yes

No

Here is a brief explanation of each statement:

The audit scope is typically determined by the organisation being audited: This statement applies to first-party audits, also known as internal audits, where the organisation audits its own processes and activities to ensure conformity and improvement¹. The organisation can decide the scope of the audit based on its own needs and objectives². This statement does not apply to second-party audits, where the customer audits the supplier, or third-party audits, where an independent body audits the organisation. In these cases, the audit scope is determined by the customer or the certification body, respectively^{3,4}.

The outcome of the audit is typically certification to a recognised standard: This statement applies to third-party audits, where an independent body audits the organisation to verify that it meets the requirements of a specific standard, such as ISO 9001, and issues a certificate of conformity if the audit is successful⁴. This statement does not apply to first-party audits or second-party audits, where the outcome of the audit is not certification, but rather self-improvement or supplier qualification^{1,3}.

The audit scope is typically confined to service/product provision capability: This statement applies to second-party audits, where the customer audits the supplier to ensure that they are meeting the requirements specified in the contract, such as service or product quality, delivery, or performance^{3,4}. The audit scope is usually focused on the specific aspects of the service or product that are of interest to the customer³. This statement does not apply to first-party audits or third-party audits, where the audit scope is broader and covers the entire quality management system or the relevant clauses of the standard^{1,4}.

NEW QUESTION # 206

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