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PECB ISO-9001-Lead-Auditor Exam Syllabus Topics:

Topic	Details
Topic 1	<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 2	<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.

Topic 3	<ul style="list-style-type: none"> Quality management system (QMS) requirements: It assesses your abilities to point out and explain different requirements for a quality management system based on ISO 9001.
Topic 4	<ul style="list-style-type: none"> Conducting an ISO 9001 audit: It evaluates your skills to conduct a QMS audit.

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PECB QMS ISO 9001:2015 Lead Auditor Exam Sample Questions (Q199-Q204):

NEW QUESTION # 199

Which of the options below is an example of minor nonconformity?

- A. Lack of commitment from the top management
- B. Lack of corrective actions to address recurrent incidents
- C. Some of the nonconformities were not closed as planned (on time) and no justification was provided or documented

Answer: C

Explanation:

Comprehensive and Detailed In-Depth Explanation: Minor nonconformities are isolated issues that do not significantly impact the QMS but still require correction.

* Failure to close nonconformities on time (Answer A) is a procedural issue and is considered minor unless it leads to repeated failures.

Major nonconformities include:

* Lack of top management commitment (Answer B), which affects leadership and strategic direction.

* Failure to take corrective actions for recurrent issues (Answer C), which indicates systemic failure.

NEW QUESTION # 200

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 statement related to the last paragraph of scenario 2 is correct?

- A. Customer surveys are the best method for obtaining and monitoring customer perceptions.
- B. Customer satisfaction is only measured through complaints, making surveys unnecessary.
- C. Customer surveys should be conducted every week to have a clear understanding of the needs and expectations of

customers.

- D. Top management demonstrated leadership and commitment with respect to customer satisfaction.

Answer: D

Explanation:

Comprehensive and Detailed In-Depth Explanation:

ISO 9001:2015, Clause 5.1.2 (Customer Focus) states that top management must ensure customer satisfaction by monitoring customer perceptions.

In scenario 2, top management initiated customer surveys, demonstrating their commitment to customer focus as required by Clause 5.1.2.

Reference:

ISO 9001:2015, Clause 5.1.2 - Customer Focus

NEW QUESTION # 201

Select the words that best complete the sentence:

Answer:

Explanation:

Explanation:

According to the ISO 19011:2018 document, the audit plan should provide the basis for agreement regarding the conduct and scheduling of the audit activities. The amount of detail provided in the audit plan should reflect the scope and complexity of the audit, as well as the risk of not achieving the audit objectives¹. The scope of the audit refers to the extent and boundaries of the audit, such as the audit criteria, the audit objectives, the organizational and functional units, and the processes to be audited¹. The complexity of the audit refers to the degree of difficulty or intricacy of the audit, such as the number and diversity of the auditees, the audit criteria, the audit methods, and the audit team composition². The risk of not achieving the audit objectives refers to the possibility that the audit may fail to provide reliable and sufficient audit evidence to support the audit conclusions and report¹.

Therefore, the complete sentence is:

In the context of a third-party audit, the amount of detail provided in the audit plan should reflect the scope and complexity of the audit, as well as the risk of not achieving the audit objectives.

References: 1: ISO 19011:2018 - Guidelines for auditing management systems 2: Audit Complexity - an overview | ScienceDirect Topics

NEW QUESTION # 202

The procedures of an organisation require that all purchase orders have to be signed by the Purchasing Manager, or, in her absence, by the Production Manager. During an audit carried out in November 2020, an auditor determined that during three weeks in February 2020, the purchase orders were not signed. You raise a nonconformance under Clause 8.4.3 of ISO 9001:2015.

Which one of the following answers would you accept as a 'correction' from the Purchasing Manager?

- A. All products related to those purchase orders have already been successfully used during the first quarter of 2020, therefore there is no need for correction. We will only take corrective action.
- B. I do not accept the nonconformity. Anything I may ask my employees to do will be seen as another piece of evidence that complying with ISO 9001 requirements is a bureaucratic valueless burden.
- C. I will sign all the purchase orders now. It will take some time to print them since they are on a backup disk, but I will get them done before the end of the audit.
- D. During those weeks, as I was on holiday, the production manager should have signed those purchase orders. As a correction to this particular nonconformity, I will ask him to sign them

Answer: C

Explanation:

Comprehensive and Detailed Explanation From Exact Extract:

Correct Option D - "I will sign all the purchase orders now."

This response represents an immediate correction in accordance with ISO 9001:2015 Clause 8.4.3 - Information for external providers, which requires control over procurement documentation. The absence of required authorisation (signature) is a nonconformity in executing the organization's purchasing procedure.

Clause 8.4.3 specifically mandates that the organization:

"Shall communicate to external providers its requirements for:

- a) the processes, products and services to be provided;
- b) the approval of:
 - * products and services;
 - * methods, processes, and equipment;
 - * the release of products and services."

The purchase order process includes documented approval, which in this case was defined internally as a signature by the Purchasing or Production Manager. Signing the documents retroactively, while not ideal, is a correction to bring the documentation back into compliance and resolve the immediate issue.

Why Other Options Are Incorrect:

- * A. "No correction needed": Dismissing the nonconformity based on product performance fails to address the lack of documented control, violating Clause 8.4.3 and internal procedures.
- * B. "I will ask the Production Manager to sign them now": This option shows intention but lacks immediacy and ownership. Also, backdating signatures without traceability can be ethically questionable.
- * C. "I do not accept the nonconformity": This reflects noncompliance and a poor quality culture, contradicting ISO 9001's Clause 5.1.1 (Leadership commitment).

References:

ISO 9001:2015 Clause 8.4.3 - Information for external providers

ISO 9001:2015 Clause 5.1.1 - Leadership and commitment

ISO 9001:2015 Clause 10.2.1 - Correction vs. corrective action

NEW QUESTION # 203

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 three statements that apply to the term 'audit trail'

- A. Quality improvements not aligning with the quality policy.
- B. The single quality objective set for the organisation by the Quality Manager.
- C. Evaluation of the results of the improvement action not always documented by the Quality Manager.
- D. Decisions on improvement action timescales not involving departmental managers.
- E. Top management claim not to be aware of the improvement request (QI/12/20/HR-3) initiated by the Quality Manager.
- F. Limited knowledge of the content of Quality Improvement Requests by departmental staff.

Answer: C,D,F

Explanation:

Based on the scenario and the concept of an 'audit trail' within the context of ISO 9001, the three statements that apply would likely be:

A). Decisions on improvement action timescales not involving departmental managers. This indicates a lack of involvement and communication with those responsible for implementing the improvements, which is a key part of an effective audit trail.

B). Evaluation of the results of the improvement action not always documented by the Quality Manager.

Proper documentation is essential for an audit trail, as it provides evidence that actions have been evaluated and are effective.

C). Limited knowledge of the content of Quality Improvement Requests by departmental staff. An audit trail should ensure that all relevant parties are aware of and understand the actions being taken, which is not the case here.

These points suggest issues with the communication, documentation, and involvement of relevant personnel in the quality management system processes, which are crucial for maintaining an effective audit trail and, by extension, a robust quality management system.

NEW QUESTION # 204

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