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

Topic	Details
Topic 1	Fundamental audit concepts and principles: Questions about interpreting and applying the main concepts and principles related to a QMS audit appear in this topic.
Topic 2	Closing an ISO 9001 audit: The topic focuses on concluding a QMS audit and conducting audit follow-up activities.
Topic 3	Preparing an ISO 9001 audit: This topic covers sub-topics related to preparing a quality management system audit.

PECB QMS ISO 9001:2015 Lead Auditor Exam Sample Questions (Q206-Q211):

NEW QUESTION # 206

Scenario 7: POLKA is a car manufacturing company based in Stockholm, Sweden. The company has around 14,000 employees working in different sectors which help with the design, painting, assembling, and test drives of the final product. The company is widely known for its qualitative products and affordable prices. In order to retain their reputation, POLKA implemented a quality management system (QMS) based on ISO 9001.

Before applying for certification, the company decided to conduct an internal audit to check whether there are any nonconformities in their QMS and if the requirements of ISO 9001 are being fulfilled.

The top management appointed Sean, the internal auditor, as the team leader of the internal audit team. Sean required from the top management to have unrestricted access to the employees and executives of POLKA and to the documented information.

Furthermore, Sean required to establish a team with a large number of auditors, considering the size and the complexity of the organization. The top management of POLKA agreed with Sean's requirements.

The top management, in cooperation with Sean, assigned 10 more employees to the audit team.

Following that, Sean planned the audit activities and assigned the roles and responsibilities to each auditor. They began by interviewing employees of different manufacturing departments to check whether they are aware of the process of the QMS implementation. While conducting these activities, one of the auditors asked Sean for permission to audit the department in which he worked on a daily basis, as he was very familiar with the processes of the department.

Along the way, the teams findings showed that the staff were trained, documented information was updated, and the QMS fulfilled the requirements of ISO 9001. The internal audit took three weeks to complete, and on the last week the audit team held a final meeting. The team shared their results and together drafted the audit report. This report was submitted to the top management of the company. The report was maintained as documented information, and was available to the relevant interested parties.

Based on the scenario above, answer the following question:

Scenario 7 states that Sean planned audit activities on his own. Is this acceptable?

- A. No, audit activities should be planned by top management
- B. No, the audit team leader should always cooperate with the other members of the team to plan audit activities
- C. Yes, it is the responsibility of the audit team leader to plan audit activities

Answer: C

Explanation:

Comprehensive and Detailed In-Depth Explanation:

According to ISO 19011:2018, Clause 6.2.2 (Audit Planning):

- * The audit team leader is responsible for planning the audit and assigning roles.
- * Top management (A) does not plan the audit, but they provide resources.
- * While team members may provide input, the leader has the final authority.

Thus, B is the correct answer.

Reference:
ISO 19011:2018, Clause 6.2.2 (Audit Planning)

NEW QUESTION # 207

You will lead a third-party audit next Monday on ABC, an organisation that provides services for cleaning windows from the outside of tall buildings. They work on demand, and usually have 4-5 orders per week. All documented information on these activities is kept at the central office.

On Friday evening, before the audit, you are informed by mail that customers cancelled all orders for the next week; therefore, the auditors will not have the chance to see them working at the customer's premises, but the field supervisors will be available at the ABC offices.

You have prepared the audit plan and the checklist. Choose the best action you would take:

- A. Start the audit on Monday as planned, interviewing the functions that regularly work at the central office, and visit another customer's premises they cleaned the week before.
- B. Complete the audit but ask the quality manager to clean some windows at the ABC's office, simulating the process they carry out at customers' premises.
- C. Start the audit on Monday at ABC's as planned, interviewing the functions that regularly work at the central office, and plan visits to ABC customers wherever they may be working during the following week.
- **D. Ask the Certification Body you work for how to proceed with the audit.**

Answer: D

Explanation:

According to ISO 19011:2018, clause 6.3.3, the audit plan should be reviewed and revised as necessary to address changes that occur during the audit planning. The audit plan should be agreed upon, preferably in writing, by the audit team leader, the audit client and the auditee¹. Therefore, if there is a significant change in the auditee's situation, such as the cancellation of all orders for the next week, the audit plan should be reviewed and revised accordingly, with the agreement of all parties involved.

According to ISO/IEC 17021-1:2015, clause 9.1.4, the certification body should have a process to ensure that the audit team has the competence to achieve the audit objectives, and that the audit methods are appropriate for the scope and complexity of the audit. The certification body should also have a process to ensure that the audit is conducted under reasonable conditions and within a reasonable time frame². Therefore, if there is a risk that the audit objectives cannot be achieved, or that the audit methods are not suitable, due to the change in the auditee's situation, the certification body should be consulted and informed on how to proceed with the audit.

Therefore, the best action to take is B, ask the certification body you work for how to proceed with the audit.

This action will ensure that the audit plan is revised and agreed upon by all parties, and that the audit team has the competence and the methods to conduct the audit effectively and efficiently. The other options are not correct, as they may compromise the quality and validity of the audit:

*A. Start the audit on Monday at ABC's as planned, interviewing the functions that regularly work at the central office, and plan visits to ABC customers wherever they may be working during the following week:

This action may not be feasible or acceptable, as it may extend the audit duration and cost beyond the agreed terms, and it may not provide sufficient and appropriate audit evidence to verify the conformity and effectiveness of the auditee's processes. Moreover, this action may not be agreed upon by the audit client and the auditee, and it may not be approved by the certification body.

*C. Start the audit on Monday as planned, interviewing the functions that regularly work at the central office, and visit another customer's premises they cleaned the week before: This action may not be relevant or reliable, as it may not reflect the current performance and condition of the auditee's processes. The audit evidence collected from the previous customer may not be valid or representative of the audit criteria, and it may not address the risks and opportunities associated with the auditee's context and objectives. Moreover, this action may not be agreed upon by the audit client and the auditee, and it may not be approved by the certification body.

*D. Complete the audit but ask the quality manager to clean some windows at the ABC's office, simulating the process they carry out at customers' premises: This action may not be objective or impartial, as it may introduce bias and influence in the audit process. The audit evidence collected from the simulated process may not be accurate or authentic, and it may not demonstrate the actual capability and effectiveness of the auditee's processes. Moreover, this action may not be ethical or professional, as it may compromise the integrity and credibility of the audit and the certification.

References: ISO 19011:2018(en), Guidelines for auditing management systems, ISO/IEC 17021-1:2015(en), Conformity assessment - Requirements for bodies providing audit and certification of management systems
- Part 1: Requirements

NEW QUESTION # 208

You are carrying out an audit to ISO 9001 at an organisation which offers regulatory consultancy services to manufacturers of cosmetics.

You are interviewing the Technical Director (TD), who manages a team of regulatory experts responsible for providing regulatory services to customers.

You: "How do you ensure your regulatory team's competence concerning regulatory requirements is maintained?" TD: "The two Regulatory Experts we employ full-time have years of experience of working in the cosmetics industry." You: "How is their regulatory competence maintained?" TD: "They are dedicated individuals with lots of contacts in the sector." You: "How does the business enable them to maintain their understanding of current regulatory requirements?" TD: "We leave that up to them."

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.

The organisation has not determined the necessary competence of the Regulatory Experts with respect to relevant regulatory requirements.

The organisation has not ensured that persons doing work under the organisation's control are aware of relevant quality objectives.

ISO 9001 - "The organization shall ensure that persons are competent on the basis of appropriate education, training, or experience."

7.1.2

The business has not maintained its organisational knowledge.

7.1.6

ISO 9001 - "The organization shall determine and provide the persons necessary for the effective implementation of its quality management system."

ISO 9001 - "The organization shall determine the knowledge necessary for the operation of its processes and to achieve conformity of products and services."

7.2

Answer:

Explanation:

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.

The organisation has not determined the necessary competence of the Regulatory Experts with respect to relevant regulatory requirements.

The organisation has not ensured that persons doing work under the organisation's control are aware of relevant quality objectives.

ISO 9001 - "The organization shall ensure that persons are competent on the basis of appropriate education, training, or experience."

7.1.2

The business has not maintained its organisational knowledge.

7.1.6

ISO 9001 - "The organization shall determine and provide the persons necessary for the effective implementation of its quality management system."

ISO 9001 - "The organization shall determine the knowledge necessary for the operation of its processes and to achieve conformity of products and services."

7.2

Explanation:

A screenshot of a computer Description automatically generated

Nonconformity report	
ISO 9001 Clause Number:	7.2
Nature of problem:	The organisation has not determined the necessary competence of the Regulatory Experts with respect to relevant regulatory requirements.
ISO 9001 requirement that has not been fulfilled:	ISO 9001 - "The organization shall determine and provide the persons necessary for the effective implementation of its quality management system."

NEW QUESTION # 209

Scenario 1: AL-TAX is a company located in California which provides financial and accounting services.

The company manages the finances of 17 companies and now is seeking to expand their business even more. The CEO of AL-TAX, Liam Durham, claims that the company seeks to provide top-notch services to their clients. Recently, there were a number of new companies interested in the services provided by AL-TAX.

In order to fulfill the requirements of new clients and further improve quality, Liam discussed with other top management members the idea of implementing a quality management system (QMS) based on ISO 9001.

During the discussion, one of the members of the top management claimed that the size of the company was not large enough to implement a QMS. In addition, another member claimed that a QMS is not applicable for the industry in which AL TAX operates. However, as the majority of the members voted for implementing the QMS, Liam initiated the project.

Initially, Liam hired an experienced consultant to help AL-TAX with the implementation of the QMS. They started by planning and developing processes and methods for the establishment of a QMS based on ISO

9001. Furthermore, they ensured that the quality policy is appropriate to the purpose and context of AL TAX and communicated to all employees. In addition, they also tried to follow a process that enables the company to ensure that its processes are adequately resourced and managed, and that improvement opportunities are determined.

During the implementation process, Liam and the consultant focused on determining the factors that could hinder their processes from achieving the planned results and implemented some preventive actions in order to avoid potential nonconformities. Six months after the implementation of the QMS, AL-TAX conducted an internal audit. The results of the internal audit revealed that the QMS was not fulfilling all requirements of ISO 9001. A serious issue was that the QMS was not fulfilling the requirements of clause 5.1.2 Customer focus and had also not ensured clear and open communication channels with suppliers.

Throughout the next three years, the company worked on improving its QMS through the PDCA cycle in the respective areas. To assess the effectiveness of the intended actions while causing minimal disruptions, they tested changes that need to be made on a smaller scale. After taking necessary actions, AL-TAX decided to apply for certification against ISO 9001.

Based on the scenario above, answer the following question:

According to scenario 1, AL-TAX determined the factors that could hinder their processes from achieving the planned results and implemented preventive actions. This means they employed:

- A. Compliance requirements and regulations
- B. The process approach
- C. Risk-based thinking

Answer: C

Explanation:

Comprehensive and Detailed In-Depth Explanation:

ISO 9001:2015 emphasizes risk-based thinking, which helps organizations identify factors that could prevent achieving planned results and take preventive action. Clause 6.1 (Actions to Address Risks and Opportunities) requires organizations to determine risks and opportunities and implement actions to mitigate potential negative impacts.

In the scenario, AL-TAX identified potential risks and implemented preventive actions, aligning with risk-based thinking. ISO 9001:2015 integrates risk management throughout the standard, ensuring processes are designed to minimize uncertainties.

Reference:

ISO 9001:2015, Clause 6.1 - Actions to Address Risks and Opportunities

ISO 9001:2015, Clause 0.3.3 - Risk-Based Thinking

NEW QUESTION # 210

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.

Quality Improvement Request			QI/12/20/HR-3
To: HR Manager	QMS awareness training is to be included as part of the induction training for new employees.		Date: 12/12/20XX
Update by: 01/20XX	Update by: 02/20XX	Update by: 03/20XX	Action by: 31/03/20XX
☐	☐	☐	Signed: (QM)
Notes: Use of external resources for this action must be approved by senior management.			Action Completed: (Signature)
			Date:

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

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

Answer: C,D

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 # 211

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