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

Topic	Details
Topic 1	<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 2	<ul style="list-style-type: none">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 3	<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.

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PECB QMS ISO 9001:2015 Lead Auditor Exam Sample Questions (Q41-Q46):

NEW QUESTION # 41

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 # 42

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 team's 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:

Ten employees of POLKA were part of the audit team that conducted the internal audit. Is this acceptable?

- A. Yes, it is a requirement of ISO 9001 to include employees of the company in the internal audit
- B. No, ISO 9001 requires hiring a professional team of auditors who are not part of the company to conduct the internal audit
- C. Yes, members of the company can join the internal audit team

Answer: C

Explanation:

Comprehensive and Detailed In-Depth Explanation:

According to ISO 9001:2015, Clause 9.2 (Internal Audit):
Internal audits are conducted by employees of the company who are trained as auditors.
External auditors are not mandatory unless required by the organization.
Thus, A is the correct answer.
Reference:
ISO 9001:2015, Clause 9.2 (Internal Audit)

NEW QUESTION # 43

The following list gives examples of records that may be evidence of how an organisation has fulfilled the requirements of clause 8.4 of ISO 9001. Match the records to the appropriate requirement of clause 8.4.

Answer:

Explanation:

Explanation:

The following table shows the possible matching of the records to the requirements of clause 8.4:

Table

Requirements

Records

Define product requirements

Product specification

Criteria for selection

List of requirements to be met by the external provider

Evaluation of potential external provider

External provider questionnaire

External provider selection

Approved external provider list

Communicate requirements

Purchase order

Monitoring of performance

External provider delivery times and quality issues

Comprehensive and Detailed Explanation: = According to clause 8.4 of ISO 9001:2015, the organization should ensure that externally provided processes, products, and services conform to the specified requirements. To do so, the organization should:
Define the product requirements that are relevant for the external provision, such as specifications, drawings, standards, codes, etc. These should be documented and communicated to the external provider. A record of the product specification can be used as evidence of this requirement.

Establish the criteria for the selection, evaluation, and re-evaluation of external providers, based on their ability to provide processes, products, and services in accordance with the requirements. The criteria should be documented and applied consistently. A record of the list of requirements to be met by the external provider can be used as evidence of this requirement.

Evaluate the potential external providers before selecting them, using the established criteria. The evaluation methods may include questionnaires, audits, references, samples, etc. The results of the evaluation should be documented and reviewed. A record of the external provider questionnaire can be used as evidence of this requirement.

Select the external providers that have demonstrated their competence and conformity to the requirements.

The selection should be based on the evaluation results and the organization's needs. The selection should be documented and approved. A record of the approved external provider list can be used as evidence of this requirement.

Communicate the requirements for the processes, products, and services to be provided by the external provider, including the verification and validation activities, the acceptance criteria, the documentation requirements, the changes control, etc. The communication methods may include purchase orders, contracts, agreements, etc. The communication should be clear, complete, and timely. A record of the purchase order can be used as evidence of this requirement.

Monitor the performance and conformity of the external provider, using the established criteria and methods.

The monitoring methods may include inspections, tests, audits, feedback, complaints, etc. The monitoring results should be documented and analyzed. A record of the external provider delivery times and quality issues can be used as evidence of this requirement.

References: ISO 9001:2015, [ISO 9001 Auditing Practices Group Guidance on Scope], Mastering the Scope of ISO 9001 Quality Management Systems

NEW QUESTION # 44

In a third-party audit to ISO 9001, select two options of when the organisation is required to act in response to reported findings.

- A. A recommendation is given in the report.
- B. An opportunity for improvement is raised.
- C. A minor non-conformity is raised.
- D. A major non-conformity is raised.
- E. A finding of good practice is reported.
- F. A finding of conformity is reported.

Answer: C,D

Explanation:

According to ISO 19011:2018, clause 6.6.2, a nonconformity is the non-fulfilment of a requirement. A nonconformity can be classified as either major or minor, depending on the nature and extent of the deviation from the audit criteria. A major nonconformity is a nonconformity that affects the ability or the integrity of the organization's management system to achieve the intended results. A minor nonconformity is a nonconformity that does not affect the ability or the integrity of the organization's management system to achieve the intended results, but is a deviation from the audit criteria.

According to ISO/IEC 17021-1:2015, clause 9.4.9, the organization is required to analyze the cause and describe the specific correction and corrective actions taken, or planned to be taken, to eliminate detected nonconformities, within a defined time. The organization is also required to provide the certification body with records and evidence of the implementation and effectiveness of the correction and corrective actions taken.

The certification body will then verify the correction and corrective actions taken by the organization and decide on the certification status.

Therefore, the two options of when the organization is required to act in response to reported findings are D and F, as they indicate the presence of nonconformities that need to be corrected and prevented from recurring.

The other options are not correct, as they do not require the organization to act in response to reported findings:

*A. A recommendation is given in the report: A recommendation is a suggestion for improvement that is not related to a nonconformity. A recommendation is not binding for the organization and does not affect the certification status. The organization may choose to accept or reject the recommendation, but it is not required to act on it.

*B. A finding of good practice is reported: A finding of good practice is a positive observation that indicates a strength or a best practice of the organization's management system. A finding of good practice is not related to a nonconformity and does not affect the certification status. The organization may choose to acknowledge or share the finding of good practice, but it is not required to act on it.

*C. An opportunity for improvement is raised: An opportunity for improvement is a potential area where the organization's management system can be enhanced or optimized. An opportunity for improvement is not related to a nonconformity and does not affect the certification status. The organization may choose to pursue or ignore the opportunity for improvement, but it is not required to act on it.

*E. A finding of conformity is reported: A finding of conformity is a confirmation that the organization's management system fulfils the audit criteria. A finding of conformity is not related to a nonconformity and does not affect the certification status. The organization may choose to celebrate or communicate the finding of conformity, but it is not required to act on it.

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 # 45

Knowledge and skills are requirements of the auditor's competence. Select two from the following topics of knowledge that apply to every member of an audit team auditing an ISO 9001 quality management system.

- A. Organisation's invoicing and profits of the last 5 years
- B. Organisation's market sector
- C. Requirements of ISO 9001
- D. Requirements of auditee's interested parties other than customers
- E. Organisation's processes
- F. ISO 19011 Audit principles

Answer: C,F

Explanation:

According to ISO 9001:2015, clause 7.2, an auditor shall have the competence to:

Understand the requirements of ISO 9001 and how they relate to the audit Understand the organization's quality management

system and its processes Understand the applicable legal, regulatory, contractual and other requirements that affect the audit Understand the needs and expectations of interested parties other than customers Plan and conduct audits in accordance with ISO 19011 Evaluate audit evidence and draw appropriate conclusions Communicate audit findings effectively¹ Therefore, knowledge of ISO 9001 requirements and ISO 19011 audit principles are essential for every member of an audit team auditing an ISO 9001 quality management system.

NEW QUESTION # 46

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