ISO-9001-Lead-Auditor Authorized Certification | ISO-9001-Lead-Auditor Vce File

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

Topic	Details
Topic 1	• Closing an ISO 9001 audit: The topic focuses on concluding a QMS audit and conducting audit follow-up activities.
Topic 2	• 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	• 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 (Q215-Q220):

NEW QUESTION # 215
In the context of a management system audit, identify the sequence of a typical process for collecting and verifying information. The first one has been done for you.
To complete the sequence 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.

Answer:

Explanation:

Explanation:
Identifying the source of information
Sampling available data
Gathering audit evidence
Verifying objective evidence
Evaluating evidence against the audit criteria
Making audit conclusions
Evaluating against the audit criteria
According to ISO 19011:2018, clause 6.4, the process of collecting and verifying information during an audit involves the following steps1:
Identifying the source of information: The audit team should identify the sources of information that are relevant to the audit objectives, scope and criteria. These sources may include documents, records, personnel, processes, activities, facilities, equipment, etc. The audit team should also determine the methods and tools for accessing and collecting the information, such as interviews, observations, document review, sampling, etc.
Sampling available data: The audit team should select a representative sample of the available data to verify the conformity and effectiveness of the management system. The sample size and selection method should be based on the audit objectives, scope and criteria, as well as the level of confidence and risk. The audit team should also consider the validity, reliability, relevance and sufficiency of the data.
Gathering audit evidence: The audit team should use the methods and tools identified in the previous step to collect audit evidence, which is the records, statements of fact or other information that are relevant to the audit criteria and verifiable. The audit team should record the audit evidence in a clear, concise and objective manner, using notes, checklists, photographs, audio or video recordings, etc.
Verifying objective evidence: The audit team should verify the accuracy, completeness and authenticity of the audit evidence collected. This may involve cross-checking different sources of information, confirming the identity and authority of the persons providing the information, examining the original documents or records, etc. The audit team should also identify any discrepancies, inconsistencies or gaps in the audit evidence.
Evaluating evidence against the audit criteria: The audit team should compare the audit evidence with the audit criteria to determine the extent of conformity and nonconformity. The audit team should also identify any opportunities for improvement, best practices, positive aspects or potential risks. The audit team should use professional judgement and apply the principles of auditing when evaluating the audit evidence.
Making audit conclusions: The audit team should consolidate the audit findings and evaluate the overall performance and effectiveness of the management system. The audit team should also consider the audit objectives, scope and criteria, as well as the context and expectations of the auditee and other interested parties. The audit team should provide a clear, concise and objective statement of the audit conclusions, which may include the degree of conformity, the achievement of the intended outcomes, the need for corrective actions, the suitability for certification, etc.
Evaluating against the audit criteria: The audit team should review the audit conclusions and ensure that they are consistent with the audit criteria and supported by sufficient and appropriate audit evidence. The audit team should also ensure that the audit conclusions are communicated to the auditee and other relevant parties in a timely and effective manner, using the agreed audit report format and distribution method.
References: ISO 19011:2018(en), Guidelines for auditing management systems

NEW QUESTION # 216
In the context of a management system audit, identify the sequence of a typical process for collecting and verifying information. The first one has been done for you.
To complete the sequence 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.

Answer:

Explanation:

Explanation:
Identifying the source of information
Sampling available data
Gathering audit evidence
Verifying objective evidence
Evaluating evidence against the audit criteria
Making audit conclusions
Evaluating against the audit criteria
According to ISO 19011:2018, clause 6.4, the process of collecting and verifying information during an audit involves the following steps1:
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References: ISO 19011:2018(en), Guidelines for auditing management systems

NEW QUESTION # 217
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:
Scenario 1 indicates that AL-TAX did not ensure clear and open communication channels with interested parties. Which quality management principle did the organization not follow in this case?

- A. Relationship management
- B. Leadership
- C. Evidence-based decision making

Answer: A

Explanation:
Comprehensive and Detailed In-Depth Explanation:
ISO 9001:2015 is based on seven quality management principles, one of which is Relationship Management. This principle emphasizes the importance of maintaining open communication and collaboration with interested parties, including suppliers and customers.
Clause 7.4 (Communication) requires organizations to determine what, when, with whom, and how communication should take place. Since AL-TAX failed to ensure clear communication channels, it did not adhere to this principle. Effective relationship management helps improve supply chain performance, customer satisfaction, and overall QMS effectiveness.
Reference:
ISO 9001:2015, Clause 7.4 - Communication
ISO 9001:2015, Quality Management Principles - Relationship Management

NEW QUESTION # 218
During a third-party audit of a pharmaceutical organisation (CD9000) site of seven COVID-19 testing laboratories in various terminals at a major international airport, you interview the CD 9000's General Manager (GM), who was accompanied by Jack, the legal compliance expert. Jack is acting as the guide in the absence of the Technical Manager due to him contracting COVID-19.
You: "What external and internal issues have been identified that could affect CD9000 and its quality management system?" GM: "Jack guided us on this. We identified issues like probable competition of another laboratory organisation in the airport, legal requirements on COVID-19 continuously changing, the shortage of competent laboratory analysists, the epidemic declining soon, shortage of chemicals for the analysis. It was quite a good experience." You: "Did you document these issues?" GM: "No. Jack said that ISO 9001 does not require us to document these issues." You: "How did you determine the risks associated with the issues and did you plan actions to address them?" GM: "I am not sure. The Technical Manager is responsible for this process. Jack may be able to answer this question in his absence." Select two options for how you would respond to the General Manager's suggestion:

- A. I would look for evidence that the actions resulting from the risk assessment had been taken.
- B. I would not accept the legal compliance expert answering the question.
- C. I would ask the consultant to leave the meeting since he is not an employee of the organisation.
- D. I would ask for a different guide instead of the legal compliance expert.
- E. I would delay the audit until the return of the technical manager
- F. I would ask to audit the Technical Manager by phone.

Answer: A,B

Explanation:
According to clause 4.1 of ISO 9001:2015, the organization should determine external and internal issues that are relevant to its purpose and its strategic direction and that affect its ability to achieve the intended results of its quality management system. The organization should monitor and review these issues and update them as necessary. Although the standard does not explicitly require documented information of these issues, it does require documented information as evidence of the implementation of the actions taken to address risks and opportunities, as per clause 6.1. The organization should also retain documented information as evidence of the results of the monitoring, measurement, analysis and evaluation of its QMS, as per clause 9.1. Therefore, the auditor should not accept the legal compliance expert answering the question, as he is not the person responsible for the process and may not have the necessary competence or knowledge of the QMS. The auditor should also look for evidence that the actions resulting from the risk assessment had been taken, as this is a requirement of the standard and a way to verify the effectiveness of the QMS. The other options are not appropriate courses of action for the auditor, because they do not address the audit objective or criteria, or they may

compromise the audit integrity or impartiality. For example, option B may not be feasible or reliable, as the Technical Manager may not be available or able to provide the necessary evidence by phone. Option C may cause unnecessary delay and inconvenience for the audit process and the auditee. Option E may not solve the problem, as the guide is not the main source of evidence or information for the audit. Option F may be disrespectful or unprofessional, as the consultant may have a legitimate role or interest in the audit.
References: ISO 9001:2015, ISO 9001 Auditing Practices Group Guidance on Context of the Organization, ISO 9001 Auditing Practices Group Guidance on Audit Evidence

NEW QUESTION # 219
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 system345.
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 # 220
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