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>> **PECB ISO-9001-Lead-Auditor Latest Exam Camp** <<

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PECB QMS ISO 9001:2015 Lead Auditor Exam Sample Questions (Q29-

Q34):

NEW QUESTION # 29

A Health Trust has contracted with Servitup, a catering services organisation which has been certified to ISO 9001 for 1 year. It provides services to ten, small rural hospitals in remote locations involving purchase and storage of dry goods and fresh produce, preparing meals and loading heated trolleys for ward service by hospital staff. An auditor is conducting the first sole surveillance audit at one site with the Deputy Catering Manager (DCM).

At the closing meeting attended solely by the DCM, the auditor informs him that he has found numerous gaps in the QMS processes which lead him to consider recommending suspension of the organisation's certification. He is particularly concerned with the evidence that patient health is being adversely affected by produce stored beyond its safe consumption date, poor kitchen hygiene and undercooked meals. The DCM says that he cannot make any decisions about these issues in the absence of the Catering Manager due to illness but will write everything down and report to the Catering Manager.

Which two actions should you take in the context of the audit?

- A. Recommend that all personnel should be given urgent in-depth training in the QMS.
- B. Conclude the meeting early and advise that it will be rescheduled once the Catering Manager has returned to work.
- C. Continue with the meeting, present the audit conclusions and inform the DCM that the organisation will receive the audit report in due course.
- D. Close the meeting immediately after the DCM's response and advise that the issues will be addressed at the next surveillance visit.
- E. Thank the DCM for his time and express an expectation that improvements will be made in the QMS.
- F. Call the individual(s) managing the audit programme to explain the situation and recommend immediate suspension of certification to protect the integrity of the Certification Body.

Answer: C,F

Explanation:

The actions that should be taken in the context of the audit are:

*Option B: Call the individual(s) managing the audit programme to explain the situation and recommend immediate suspension of certification to protect the integrity of the Certification Body. This option is correct because the auditor has found serious and significant gaps in the QMS processes that affect the health and safety of the patients, which is a major nonconformity that may warrant suspension of certification. The auditor should inform the individual(s) managing the audit programme of the situation and the audit findings, and recommend immediate suspension of certification to protect the integrity of the Certification Body and the credibility of the certification scheme. The auditor should also follow the Certification Body's procedures and rules for suspension of certification and communicate the decision and the consequences to the auditee.

*Option C: Continue with the meeting, present the audit conclusions and inform the DCM that the organisation will receive the audit report in due course. This option is correct because the auditor should not terminate or postpone the closing meeting due to the absence of the Catering Manager, as the DCM is the auditee's nominated representative for the audit. The auditor should continue with the meeting, present the audit conclusions and the audit findings, and inform the DCM that the organisation will receive the audit report in due course. The auditor should also explain the audit outcome recommendation and the suspension of certification, and request the DCM to acknowledge the receipt and understanding of the audit results.

The following options are not correct:

*Option A: Close the meeting immediately after the DCM's response and advise that the issues will be addressed at the next surveillance visit. This option is not correct because the auditor should not close the meeting without presenting the audit conclusions and the audit findings, as this would violate the audit principles of fairness and transparency. The auditor should also not advise that the issues will be addressed at the next surveillance visit, as this would imply that the auditor is accepting the auditee's delay and inaction, and that the auditor is not taking the major nonconformity seriously.

*Option D: Conclude the meeting early and advise that it will be rescheduled once the Catering Manager has returned to work. This option is not correct because the auditor should not conclude the meeting early or reschedule it due to the absence of the Catering Manager, as this would disrupt the audit process and the audit schedule. The auditor should also not wait for the Catering Manager to return to work, as this would delay the communication and resolution of the major nonconformity, and potentially compromise the health and safety of the patients.

*Option E: Recommend that all personnel should be given urgent in-depth training in the QMS. This option is not correct because the auditor should not recommend or prescribe specific corrective actions to the auditee, as this would violate the audit principles of independence and objectivity. The auditor should only report the audit findings and the audit outcome recommendation, and leave the responsibility and authority for determining and implementing the corrective actions to the auditee.

*Option F: Thank the DCM for his time and express an expectation that improvements will be made in the QMS. This option is not correct because the auditor should not thank the DCM for his time and express an expectation that improvements will be made in the QMS, as this would imply that the auditor is satisfied and optimistic with the auditee's performance and response, and that the auditor is not taking the major nonconformity seriously. The auditor should instead express the concern and dissatisfaction with the

auditee's QMS processes and the impact on the health and safety of the patients, and communicate the suspension of certification and the need for urgent and effective corrective actions.

References:

*ISO 19011:2018 Guidelines for auditing management systems, Clause 6.4.2: Conducting audit activities, Subclause k) and l)

*ISO 9001 Lead Auditor Course Material, Module 5: Conducting an Audit, Slide 20: Closing Meeting

*ISO 9001 Lead Auditor Training Course - IRCA Certified, Section 5.5: Closing Meeting

*Lead Auditor Exam Preparation Guide (EPG) Template - PECB, Section 3.2: Exam Content Outline, Subsection 3.2.1: Section 1 - Audit Fundamentals, Subsection 3.2.2: Section 2 - Audit Principles, Subsection 3.2.3: Section 3 - Audit Process, Subsection 3.2.4: Section 4 - Audit Competencies

NEW QUESTION # 30

Which quality management principle does an organization fulfill when it assesses risks, consequences, and impacts before taking action?

- A. Leadership
- B. Process approach
- C. Relationship management
- **D. Improvement**

Answer: D

Explanation:

Comprehensive and Detailed In-Depth Explanation:

One of the seven quality management principles in ISO 9001:2015 is Improvement, which emphasizes continual enhancement of processes, products, and services.

Clause 10.3 (Continual Improvement) states that organizations must continuously assess risks, consequences, and impacts to improve their QMS.

* Risk-based thinking (Clause 0.3.3) supports improvement by identifying and mitigating risks before they affect performance.

* Clause 6.1 (Actions to Address Risks and Opportunities) requires organizations to take a proactive approach, ensuring long-term success.

Other options do not fully align with the question:

* Process approach (A) focuses on managing interrelated activities.

* Leadership (B) ensures commitment but does not directly address risk assessment.

* Relationship management (D) deals with interested parties, not risk mitigation.

Reference:

ISO 9001:2015, Clause 10.3 - Continual Improvement

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

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

NEW QUESTION # 31

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:

According to Scenario 7, one of the auditors requested permission from Sean to audit the department in which he worked on a daily basis. Should Sean grant the auditor permission?

- A. Yes, Sean should grant the auditor permission
- B. Yes, but Sean himself must be present in every audit activity
- C. No, internal auditors should be independent of the processes being audited

Answer: C

Explanation:

Comprehensive and Detailed In-Depth Explanation:

ISO 19011:2018, Clause 5.1 (Impartiality) states that:

* Internal auditors must be independent of the processes they audit to ensure objectivity.

* Auditing one's own department introduces bias and is not permitted.

Thus, Sean must not allow the auditor to audit their own department.

Reference:

ISO 19011:2018, Clause 5.1 (Impartiality)

NEW QUESTION # 32

Which statement regarding the drafting of the audit conclusions is correct?

- A. The audit conclusions must not include the revisions that resulted from the closing meeting
- B. The audit conclusions must be drafted based on observation
- C. The audit conclusions must be based on evidence that is examined and evaluated in terms of quantity and quality

Answer: C

Explanation:

Comprehensive and Detailed In-Depth Explanation: According to ISO 19011:2018, Clause 6.4.9 (Audit Conclusions):

* Audit conclusions must be based on verified evidence.

* The evidence must be evaluated both quantitatively and qualitatively to ensure accuracy.

* Observations alone (A) are insufficient; conclusions must be supported by objective evidence.

Thus, B is the correct answer.

NEW QUESTION # 33

The following are stages of an audit, put them in the order they would be conducted.

The following are stages of an audit, put them in the order they would be conducted.

The first and last stages have 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.

1. Establishing the audit programme objectives
2.
3.
4.
5.
6. Conducting the audit activities

Answer:

Explanation:

The following are stages of an audit, put them in the order they would be conducted.

The first and last stages have 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.

1. Establishing the audit programme objectives

Determining and evaluating the audit programme risks and opportunities

3. Establishing the audit programme

4. Initiating the audit

5. Preparing all audit activity

6. Conducting the audit activities

Determining and evaluating the audit programme risks and opportunities

Preparing all audit activity

Initiating the audit

Establishing the audit programme

Explanation:

Establishing the audit programme objectives

Determining and evaluating the audit programme risks and opportunities

Establishing the audit programme

Initiating the audit

Preparing all audit activity

Conducting the audit activities

According to ISO 19011:2018, clause 5, the audit programme is a set of one or more audits planned for a specific time frame and directed towards a specific purpose. The audit programme includes all activities necessary to plan, organize, and conduct the audits.

The audit programme management involves the following steps1:

Establishing the audit programme objectives: The audit programme objectives define the intended outcomes of the audit programme, such as verifying conformity, evaluating performance, identifying improvement opportunities, etc. The audit programme objectives should be aligned with the strategic direction and policies of the organization and the needs and expectations of the interested parties.

Determining and evaluating the audit programme risks and opportunities: The audit programme risks and opportunities are the factors that can affect the achievement of the audit programme objectives, such as changes in the internal or external context, availability of resources, competence of auditors, etc. The audit programme risks and opportunities should be identified, analyzed, and evaluated to determine the appropriate actions to address them.

Establishing the audit programme: The audit programme is established by defining the audit programme scope, criteria, methods, and resources. The audit programme scope defines the extent and boundaries of the audit programme, such as the processes, functions, sites, activities, etc. that will be audited. The audit programme criteria are the set of policies, procedures, or requirements used as a reference for the audits. The audit programme methods are the techniques used to conduct the audits, such as interviews, observations, document review, sampling, etc. The audit programme resources are the human, technical, and financial resources needed to implement the audit programme.

Initiating the audit: The audit initiation is the process of formally establishing the arrangements for an individual audit within the audit programme. The audit initiation involves contacting the auditee and the audit client, confirming the audit objectives, scope, and criteria, and obtaining the necessary information and access for the audit.

Preparing all audit activity: The audit preparation is the process of developing the audit plan and the audit work documents for an individual audit. The audit plan is a document that provides the basis for agreement regarding the conduct of the audit, such as the audit schedule, the audit team, the audit methods, the audit language, the audit report, etc. The audit work documents are the records that provide evidence of the audit activities, such as the audit checklist, the audit notes, the audit findings, etc.

Conducting the audit activities: The audit activities are the processes of collecting and verifying audit evidence and evaluating it against the audit criteria to make the audit conclusions. The audit activities include the opening meeting, the communication during the audit, the roles and responsibilities of the audit team and the auditee, the audit evidence collection and verification, the audit findings generation and recording, the closing meeting, and the audit report preparation and distribution.

References: ISO 19011:2018(en), Guidelines for auditing management systems

NEW QUESTION # 34

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