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PECB QMS ISO 9001:2015 Lead Auditor Exam Sample Questions (Q159-

Q164):

NEW QUESTION # 159

Scenario 6: Davis Clinic (DC) is an American medical center focused on integrated health care. Since its establishment DC was committed to providing qualitative services for its clients, which is the reason why the company decided to implement a quality management system (QMS) based on ISO 9001. After a year of having an active QMS in place, DC applied for a certification audit.

A team of five auditors, from a well-known certification body, was selected to conduct the audit. Eva was appointed as the audit team leader. After three days of auditing, the team gathered to review and examine their findings. They also discussed the audit findings with DC's top management and then drafted the audit conclusions.

In the closing meeting, which was held between the audit team and the top management of DC. Eva presented two nonconformities that were detected during the audit. Eva stated that the company did not retain documented information regarding its outsourced services for an analysis laboratory and regarding the conducted management reviews. During the closing meeting, the audit team required from DC's top management to come up with corrective action plans within two weeks. Although the top management did not agree with the audit findings, the audit team insisted that the auditee must submit corrective actions within the given time frame in order for the audit activities to continue.

Once the action plans were evaluated, the audit team began preparing the audit report. Eva required from the team to provide accurate descriptions of the audit findings and the audit conclusions. The report was then distributed to all the interested parties involved in the audit, including the certification body. Based on the report, the certification body together with Eva, as the audit team leader, made the certification decision.

Based on the scenario above, answer the following question:

Why is it important to discuss the audit findings with DC's top management prior to the closing meeting and the submission of the final audit report?

- A. To encourage the implementation of corrective actions as soon as possible
- **B. To verify whether the audit objectives have been met**
- C. To identify the persons responsible for the nonconformities

Answer: B

Explanation:

Comprehensive and Detailed In-Depth Explanation:

Discussing audit findings before the closing meeting ensures that:

- * The audit objectives have been met (ISO 19011:2018, Clause 6.4.10).
- * The auditee has an opportunity to clarify misunderstandings or provide additional evidence.
- * The audit team and the auditee agree on the accuracy of findings before finalizing the report.

While encouraging corrective actions (B) is beneficial, the primary purpose of discussing findings is to ensure that the audit was conducted effectively and aligned with objectives. Identifying responsible persons (C) is not the auditor's role.

Reference:

ISO 19011:2018, Clause 6.4.10 (Communicating Audit Findings Before the Closing Meeting)

NEW QUESTION # 160

Scenario 5: Mechanical-Electro (ME) Audit Stages

Mechanical-Electro, better known as ME, is an American company that provides mechanical and electrical services in China. Their services range from air-conditioning systems, ventilation systems, plumbing, to installation of electrical equipment in automobile plants, electronic manufacturing facilities, and food processing plants.

Due to the fierce competition from local Chinese companies and failing to meet customer requirements, ME's revenue dropped significantly. In addition, customers' trust and confidence in the company decreased, and the reputation of the company was damaged.

In light of these developments, the top management of ME decided to implement a quality management system (QMS) based on ISO 9001. After having an effective QMS in place for over a year, they applied for a certification audit.

A team of four auditors was appointed for the audit, including Li Na as the audit team leader. Initially, the audit team conducted a general review of ME's documents, including the quality policy, operational procedures, inventory lists, QMS scope, process documentation, training records, and previous audit reports.

Li Na stated that this would allow the team to maintain a systematic and structured approach to gathering documents for all audit stages. While reviewing the documented information, the team observed some minor issues but did not identify any major nonconformities. Therefore, Li Na claimed that it was not necessary to prepare a report or conduct a meeting with ME's representatives at that stage of the audit. She stated that all areas of concern would be discussed in the next phase of the audit.

Following the on-site activities and the opening meeting with ME's top management, the audit team structured an audit test plan to

verify whether ME's QMS conformed to Clause 8.2.1 (Customer Communication) of ISO 9001.

To do so, they gathered information through group interviews and sampling. Li Na conducted interviews with departmental managers in the first group and then with top management. In addition, she chose a sampling method that sufficiently represented customer complaints from both areas of ME's operations.

The team members were responsible for the sampling procedure. They selected a sample size of 4 out of 45 customer complaints received weekly for electrical services and 2 out of 10 complaints for mechanical services.

Afterward, the audit team evaluated the evidence against the audit criteria and generated the audit findings.

After reviewing the documented information, Li Na claimed that it was not necessary to report the minor nonconformities that were identified; instead, they would be discussed in the next audit phase. Is this acceptable?

- A. Yes, all identified nonconformities throughout the audit need to be documented and communicated at the end of the audit.
- B. Yes, during the review of documented information, only major nonconformities need to be documented if detected.
- C. No, identification of minor nonconformities or areas of concern that could become nonconformities need to be documented and communicated to the auditee before proceeding to the next audit phase.

Answer: C

Explanation:

Comprehensive and Detailed In-Depth Explanation: As per ISO 9001:2015, Clause 10.2 (Nonconformity and Corrective Action), all identified nonconformities, including minor ones, must be documented and communicated to the auditee.

Minor nonconformities can lead to major issues if left unaddressed. The auditor must inform the organization before moving to the next audit phase so that corrective actions can be taken. Clause 9.2.2 (Internal Audit) states that audit findings should be reported without undue delay.

Since Li Na did not report the minor nonconformities immediately, her decision was incorrect. Minor nonconformities should always be documented and communicated before proceeding to the next phase.

NEW QUESTION # 161

You are carrying out an audit at a single-site organisation seeking certification to ISO 9001 for the first time.

The organisation manufactures cosmetics for major retailers.

You are interviewing the Manufacturing Manager (MM).

You: "I would like to begin by looking at the cleaning controls."

MM: "We record the cleaning of the equipment at the end of every batch. This document details the minimum cleaning frequency and the procedures to follow for all areas and each item of equipment. The person who carries out the cleaning puts their initial on the document and records the time and date alongside." Narrative: You sample production records over 3-days and note down evidence of nonconformity as per the table below.

You decide to raise a non-conformity.

Answer:

Explanation:

Explanation:

Clause: 8.5.4

Nature of Problem: Cleaning and sanitising records are not available for every batch.

Unfulfilled Requirement: "The organization shall implement production provision under controlled conditions."

NEW QUESTION # 162

Scenario 6: Davis Clinic (DC) is an American medical center focused on integrated health care. Since its establishment DC was committed to providing qualitative services for its clients, which is the reason why the company decided to implement a quality management system (QMS) based on ISO 9001. After a year of having an active QMS in place, DC applied for a certification audit.

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In the closing meeting, which was held between the audit team and the top management of DC. Eva presented two nonconformities that were detected during the audit. Eva stated that the company did not retain documented information regarding its outsourced services for an analysis laboratory and regarding the conducted management reviews. During the closing meeting, the audit team required from DC's top management to come up with corrective action plans within two weeks. Although the top management did not agree with the audit findings, the audit team insisted that the auditee must submit corrective actions within the given time frame in

order for the audit activities to continue.

Once the action plans were evaluated, the audit team began preparing the audit report. Eva required from the team to provide accurate descriptions of the audit findings and the audit conclusions. The report was then distributed to all the interested parties involved in the audit, including the certification body. Based on the report, the certification body together with Eva, as the audit team leader, made the certification decision.

Based on the scenario above, answer the following question:

Is it acceptable for the certification body and Eva to make the certification decision together?

- A. No, auditors that take part in the audit should never take part in the certification decision
- B. No, only the audit team leader must make the certification decision
- C. Yes, because the audit team leader must be involved in the certification decision

Answer: A

Explanation:

Comprehensive and Detailed In-Depth Explanation: According to ISO 17021-1:2015, Clause 9.5.1 (Certification Decision):

- * Auditors who conduct the audit cannot be involved in the certification decision to ensure impartiality.
- * The certification body alone is responsible for making the certification decision based on the audit report and findings.
- * The audit team leader (Eva) must not take part in the certification decision.

Thus, C is the correct answer.

NEW QUESTION # 163

You are leading a Stage 2 certification audit of a multi-site organisation and have received the audit schedule below; Head Office and Site 1 - Day 1 Site 2 (150 km from HQ) - Days 2 and 3. During Day 1 of the audit, the client informs you that the laboratory at Site 2 has been closed for decontamination due to a serious outbreak of an infectious disease among workers. In Site 2, all other functions could be audited as planned.

As the audit team leader, what would you do?

Choose the best acceptable action you could take:

- A. Immediately cancel the audit since the audit plan cannot be completed.
- B. Ask the audit Programme Manager for direction.
- C. Continue the audit on days 2 and 3 and return later to audit the Site 2 laboratory.
- D. Complete the audit on day 3 and report back to the certification body for a certification decision.

Answer: B

Explanation:

ISO 9001:2015 requires that certification audits be planned, controlled, and conducted in a way that ensures valid and reliable audit conclusions. However, ISO 9001 does not give operational detail on how to manage disrupted audits. For this, ISO 9001 explicitly refers to ISO 19011 and certification schemes require escalation to the audit programme or certification management function. ISO 9001:2015, Clause 9.2.2 (NOTE) states that guidance on auditing management systems is provided in ISO 19011. In a Stage 2 certification audit, all applicable processes within the scope must be audited before a certification decision can be made. The laboratory at Site 2 is clearly part of the operational scope and cannot be audited due to circumstances outside the organisation's control (health and safety risk).

Why option C is correct:

- * Certification audits operate under a controlled certification programme, not solely at the discretion of the audit team leader.
- * ISO 19011 requires auditors to act responsibly when conditions prevent safe or complete auditing and to escalate significant changes or risks.

* Certification bodies require the Audit Programme Manager (or Certification Manager) to decide whether the audit should be paused, partially completed, rescheduled, or split to preserve certification integrity.

Therefore, seeking direction from the audit Programme Manager is the correct and compliant action.

NEW QUESTION # 164

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