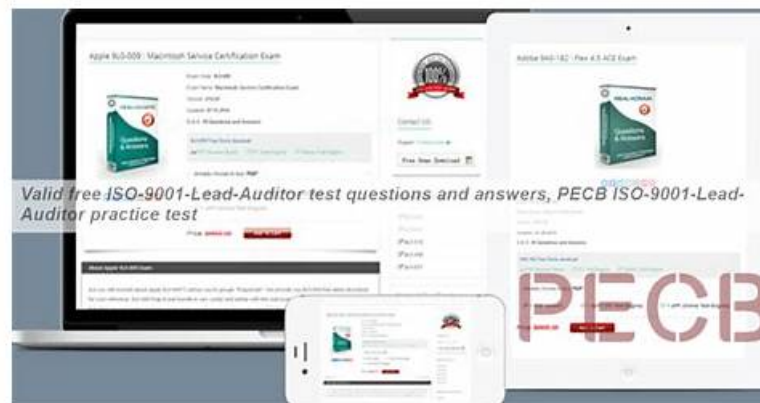


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PECB ISO-9001-Lead-Auditor Exam Syllabus Topics:

Topic	Details
Topic 1	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	Closing an ISO 9001 audit: The topic focuses on concluding a QMS audit and conducting audit follow-up activities.
Topic 3	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 4	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 (Q200-Q205):

NEW QUESTION # 200

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:

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

Answer: A

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 # 201

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

The organization 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.

Date	Batches of product made	Production line to be cleaned	Cleaned by	Number of cleaning records
10/XX	10	Line 1	DS	6
	14	Line 2	HM	8
11/XX	12	Line 1	WR	7
	12	Line 2	DD	9
12/XX	15	Line 1	DS	10

You decide to raise a nonconformity.

Nonconformity report	
ISO 9001 Clause Number:	
Nature of problem:	
ISO 9001 requirement that has not been fulfilled:	
Evidence:	40 cleaning records are available for 63 batches.

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, you may drag and drop the options to the appropriate blank section.

Cleaning and sanitising not always completed.	ISO 9001 - "The organization shall implement planned arrangements, at appropriate stages, to verify that the product requirements have been met."
Cleaning and sanitising records are not available for every batch.	8.7 8.5.4
ISO 9001 - "The organization shall implement production provision under controlled conditions."	ISO 9001 - "The organization shall preserve the outputs during production provision to the extent necessary to ensure conformity to requirements."
	Cleaning and sanitising are not always completed by trained staff. 6.2.1

Answer:

Explanation:

You decide to raise a nonconformity.

Nonconformity report	
ISO 9001 Clause Number:	8.5.4
Nature of problem:	ISO 9001 - "The organization shall implement planned arrangements, at appropriate stages, to verify that the product requirements have been met."
ISO 9001 requirement that has not been fulfilled:	
Evidence:	
	63 batches.

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, you may drag and drop the options to the appropriate blank section.

Cleaning and sanitising not always completed.

ISO 9001 - "The organization shall implement planned arrangements, at appropriate stages, to verify that the product requirements have been met."

Cleaning and sanitising records are not available for every batch.

8.7

8.5.4

ISO 9001 - "The organization shall implement production provision under controlled conditions."

ISO 9001 - "The organization shall preserve the outputs during production provision to the extent necessary to ensure conformity to requirements."

Cleaning and sanitising are not always completed by trained staff.

6.2.1

Explanation:

Nonconformity report

ISO 9001 Clause Number: 8.5.4 Nature of problem: Cleaning and sanitising records are not available for every batch. ISO 9001 requirement that has not been fulfilled: ISO 9001 - "The organization shall implement planned arrangements, at appropriate stages, to verify that the product requirements have been met." Evidence: 40 cleaning records are available for 63 batches.

NEW QUESTION # 202

Consultancy ABC, which is a subsidiary of a certification body called ABC-CERT, provided consultancy services regarding the implementation of a QMS based on ISO 9001 to an organization. Considering this, can ABC-CERT provide certification services to the organization which obtained consultancy services from Consultancy ABC?

- A. No, ABC-CERT is not allowed to provide certification services to that organization ever, as this would be a conflict of interest.
- B. Yes, after a minimum period of two years has passed.
- C. Yes, if both parties sign an agreement which states that previous services by Consultancy ABC will not impact the judgment of auditors.

Answer: A

Explanation:

Comprehensive and Detailed In-Depth Explanation:

Certification bodies must remain independent and impartial. If a certification body (ABC-CERT) provides consulting services to an organization through its subsidiary (Consultancy ABC), it cannot later certify the same organization.

Clause References:

ISO/IEC 17021-1:2015, Clause 5.2.5 - Impartiality Requirements:

A certification body must not certify an organization to which it has provided consultancy services.

ISO/IEC 17021-1:2015, Clause 5.2.6:

Subsidiaries of certification bodies must not provide consulting services to prevent conflicts of interest.

Why is the Correct Answer C?

Certifying a client after providing consultancy creates a conflict of interest and violates ISO/IEC 17021-1:2015 impartiality rules.

The certification body (ABC-CERT) and consultancy firm (Consultancy ABC) are related entities, making it impossible to remain objective and independent.

Why are the Other Options Incorrect?

A (Waiting two years) # ISO does not specify a time frame; the issue is impartiality, not just time.

B (Signing an agreement to ensure objectivity) # Conflicts of interest cannot be resolved through an agreement; independence is required.

Reference:

ISO/IEC 17021-1:2015, Clause 5.2.5 - Impartiality Requirements

NEW QUESTION # 203

Match the process descriptions below to the process names:

Match the process descriptions below to the process names:

The process by which the accuracy of test equipment is checked against a known standard. |

The process by which a product or service is visually examined to determine conformity to requirements. |

The process by which data is examined in detail to reach a specific answer or answers. |

The process by which a parameter of a product or service is examined to determine a specific value. |

To complete the table 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 you may drag and drop each of the following process names to the descriptions:

Answer:

Explanation:

Match the process descriptions below to the process names:

The process by which the accuracy of test equipment is checked against a known standard. |

The process by which a product or service is visually examined to determine conformity to requirements. |

The process by which data is examined in detail to reach a specific answer or answers. |

The process by which a parameter of a product or service is examined to determine a specific value. |

To complete the table 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 you may drag and drop each of the following process names to the descriptions:

Explanation:

Match the process descriptions below to the process names:

The process by which the accuracy of test equipment is checked against a known standard. = Calibration
The process by which a product or service is visually examined to determine conformity to requirements. = Evaluation
The process by which data is examined in detail to reach a specific answer or answers. = Analysis
The process by which a parameter of a product or service is examined to determine a specific value. = Measurement
According to the ISO 9000:2015 - Quality management systems - Fundamentals and vocabulary, the definitions of the process names are as follows:

Calibration: operation that, under specified conditions, in a first step, establishes a relation between the quantity values with measurement uncertainties provided by measurement standards and corresponding indications with associated measurement uncertainties and, in a second step, uses this information to establish a relation for obtaining a measurement result from an indication.

Evaluation: determination of the suitability, adequacy or effectiveness of an object to achieve established objectives.

Analysis: detailed examination of the elements or structure of something.

Measurement: process to experimentally obtain one or more quantity values that can reasonably be attributed to a quantity.

Therefore, the process descriptions can be matched to the process names based on these definitions.

References:

ISO 9000:2015 - Quality management systems - Fundamentals and vocabulary

NEW QUESTION # 204

What must the auditor consider in order to mitigate audit risks and obtain reasonable assurance?

- A. The previous audit results.
- B. The needs and expectations of internal interested parties.
- **C. The processes deemed material to the auditee.**
- D. The financial risks associated with QMS implementation.

Answer: C

Explanation:

Comprehensive and Detailed In-Depth Explanation:

Auditors must focus on key processes that impact QMS effectiveness to ensure audit risks are minimized.

Clause References:

ISO 19011:2018, Clause 6.3 - Managing Audit Risk: Auditors should prioritize critical processes to obtain reasonable assurance.

Why is the Correct Answer A?

Some processes are critical (e.g., production quality, customer complaints handling).

If these material processes fail, the QMS could collapse.

Why are the Other Options Incorrect?

B (Needs of internal parties) # Important, but not the primary focus for reducing audit risk.

C (Previous audit results) # Useful for improvement but does not directly reduce current audit risks.

D (Financial risks) # ISO 9001 focuses on quality risks, not financial risks.

Reference:

ISO 19011:2018, Clause 6.3 - Managing Audit Risk

NEW QUESTION # 205

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