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

Topic	Details
Topic 1	• 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 2	• Preparing an ISO 9001 audit: This topic covers sub-topics related to preparing a quality management system audit.
Topic 3	• Managing an ISO 9001 audit program: This topic evaluates your abilities to establish and managing a QMS audit program.
Topic 4	• Conducting an ISO 9001 audit: It evaluates your skills to conduct a QMS audit.
Topic 5	• 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.

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PECB QMS ISO 9001:2015 Lead Auditor Exam Sample Questions (Q211-Q216):

NEW QUESTION # 211

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:

Ask the audit Programme Manager for direction.

Complete the audit on day 3 and report back to the certification body for a certification decision.

Continue the audit on days 2 and 3 and return later to audit the Site 2 laboratory.

Immediately cancel the audit since the audit plan cannot be completed.

Who has the responsibility for assigning work to the audit team?

- A. The certification body
- B. The audit team member
- C. The auditee organisation
- D. The audit team leader

Answer: D

Explanation:

In the context of ISO 9001:2015 audits, it is the audit team leader who holds the responsibility for assigning work to the audit team. According to ISO 19011:2018 (Guidelines for auditing management systems, which complements ISO 9001:2015), the audit team leader is responsible for the organization and direction of the audit, including assigning specific roles and responsibilities to audit team members. This includes preparation of the audit plan, leading the audit, and ensuring that each team member understands their tasks.

NEW QUESTION # 212

You are auditing a manufacturer of specialty tea products during a Stage 2 certification audit. In the quality laboratory, you interview one of three operatives conducting sensory testing of a batch from the production line.

Select three options of evidence which could demonstrate conformance with clause 9.1.1 of ISO 9001:2015.

- A. The Hedonic Method is used to monitor the quality of the product
- B. Laboratory staff routinely tested for respiratory ailments
- C. Independent experts were brought in to review test processes
- D. Operatives having a university degree in food science
- E. Safe disposal of the tested product
- F. Outsourcing the sensory testing to an accredited laboratory
- G. Sensory testing results are recorded
- H. Analysis of the results of sensory tests

Answer: A,G,H

Explanation:
Comprehensive and Detailed Explanation From Exact Extract:
Clause 9.1.1 - Monitoring, measurement, analysis and evaluation (General) requires the organization to:
"Determine what needs to be monitored and measured, the methods for monitoring, measurement, analysis and evaluation needed to ensure valid results, and when results shall be analyzed and evaluated." The goal is to ensure valid, reliable, and consistent measurement of process and product performance. Here's how each correct option supports compliance:
B. Analysis of the results of sensory tests
This directly aligns with the requirement for analysis and evaluation of monitoring results. Clause 9.1.3 also supports the use of such data for evaluating product conformity and process effectiveness.
G. Sensory testing results are recorded
This supports documented evidence of monitoring results, as required under 9.1.1(e), to verify that quality checks (such as flavor and aroma assessments) are being done consistently.
H. The Hedonic Method is used to monitor the quality of the product
Use of a standardized measurement method like the Hedonic Scale aligns with 9.1.1(b), which requires defined methods to ensure valid and reproducible results.
Why the Other Options Are Incorrect or Less Relevant:
A). University degrees # Related to competence (Clause 7.2), not monitoring and measurement (Clause 9.1.1).
C). Independent expert review # Not part of regular monitoring unless it's built into the process.

D). Respiratory testing # Irrelevant to product quality monitoring.

E). Outsourcing # Would shift responsibility but doesn't demonstrate internal conformance.

F). Safe disposal # Pertains to Clause 8.5.4 (Preservation), not Clause 9.1.1.

References:

ISO 9001:2015 Clause 9.1.1 - Monitoring, measurement, analysis and evaluation ISO 9001:2015 Clause 9.1.3 - Analysis and evaluation ISO 9001:2015 Clause 7.2 - Competence (for contrast)

NEW QUESTION # 213

ISO 9001 requires that the organisation shall continually improve the quality management system.

Select the two options for how this can best be achieved.

- A. Communicate a policy commitment to continual improvement
- B. Appoint external consultants to train quality control staff
- C. Use the management review process to identify improvements
- D. Require that all employees make fewer mistakes
- E. Require higher standards for the work being done
- F. Send the Chief Executive on an ISO 9001 course

Answer: A,C

Explanation:

Comprehensive and Detailed Explanation From Exact Extract:

Correct Option B - "Communicate a policy commitment to continual improvement" This aligns directly with Clause 5.2.1(d) of ISO 9001:2015, which states that the quality policy shall include a commitment to continual improvement of the QMS:

"Top management shall establish, implement and maintain a quality policy that... includes a commitment to continual improvement of the quality management system." A clearly communicated policy sets expectations and a strategic direction that cascades throughout the organization, promoting a culture that values ongoing enhancement.

Correct Option F - "Use the management review process to identify improvements" This is based on Clause 9.3.3 of ISO 9001:2015, which specifies that outputs of management reviews must include decisions and actions related to:

"a) opportunities for improvement;

b) any need for changes to the quality management system;

c) resource needs."

The management review process is a structured mechanism to analyze data, monitor performance, assess risks and opportunities, and drive continual improvement initiatives.

Why the Other Options Are Incorrect:

A (Appoint external consultants to train staff): While training may help improve competence, ISO 9001 emphasizes internal process evaluation and strategic improvement. This option is not directly aligned with the systematic improvement of the QMS.

C (Require higher standards): Higher standards alone don't ensure continual improvement unless supported by a structured QMS approach involving evaluation, planning, and measurement.

D (Require fewer mistakes): Unrealistic or unqualified demands like "make fewer mistakes" don't support structured process-based improvement and may conflict with ISO's emphasis on risk-based thinking and root cause analysis.

E (Send Chief Executive on a course): While leadership involvement is vital (Clause 5), this action by itself does not constitute a continual improvement mechanism for the QMS.

References:

ISO 9001:2015 Clause 5.2.1(d) - Establishing the Quality Policy

ISO 9001:2015 Clause 9.3.3 - Management Review Outputs

ISO 9001:2015 Clause 10.3 - Continual Improvement

NEW QUESTION # 214

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:

| Calibration | Evaluation | Sampling | Monitoring | Analysis | Measurement |

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.
[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]

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:

| Calibration | Evaluation | Sampling | Monitoring | Analysis | Measurement |

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 # 215

Scenario 3:

Fin-Pro is a financial institution in Austria offering commercial banking, wealth management, and investment services. The company faced a significant loss of customers due to failing to improve service quality as they expanded.

To regain customer confidence, top management implemented a QMS based on ISO 9001. After a year, they contacted ACB, a local certification body, to pursue ISO 9001 certification.

The audit team was led by Emilia, an experienced lead auditor, and included three auditors. After an agreement was reached, ACB sent the audit objectives to the audit team.

The audit team began by gathering information about Fin-Pro's understanding of ISO 9001 requirements.

While reviewing documented information, they noticed missing records of training and awareness sessions.

They conducted employee interviews to verify attendance.

The team also reviewed the organizational chart and job descriptions to confirm employee competence. They observed the company's working environment (social, psychological, and physical conditions).

The audit team analyzed the evidence and prepared an audit report with findings and conclusions.

What type of evidence has been collected by the ACB's audit team, as presented in scenario 3?

- A. Documentary, confirmative, verbal.
- B. Physical, verbal, analytical.
- C. Observational, secondary, qualitative.
- D. Verbal, documentary, physical.

Answer: D

Explanation:
Comprehensive and Detailed In-Depth Explanation:
Audit evidence includes information collected through different methods to assess compliance with ISO 9001:
2015 requirements.
Clause References:
ISO 19011:2018, Clause 6.4.6 - Audit Evidence: Audit evidence must be objective, verifiable, and based on facts.
ISO 9001:2015, Clause 9.1.1 - Monitoring, Measurement, Analysis, and Evaluation: Requires organizations to collect and analyze data from multiple sources to verify effectiveness.
Types of Audit Evidence Collected in Scenario 3:
Verbal Evidence - Employee interviews regarding training and awareness sessions.
Documentary Evidence - Organizational charts, job descriptions, training records.
Physical Evidence - Workplace observations to assess working conditions.
Why is the Correct Answer B?
The audit team used a combination of verbal (interviews), documentary (records), and physical (site observations) evidence.
This triangulation approach enhances audit reliability and ensures compliance verification.
Why are the Other Options Incorrect?
A (Confirmative evidence) # Not a formal audit term in ISO 9001 or ISO 19011.
C (Analytical evidence) # Incorrect, as analysis was not a primary method used.
D (Qualitative evidence only) # Incorrect because the audit involved both qualitative (interviews) and quantitative (documents, physical) evidence.
Reference:
ISO 19011:2018, Clause 6.4.6 - Audit Evidence
ISO 9001:2015, Clause 9.1.1 - Monitoring, Measurement, Analysis, and Evaluation

NEW QUESTION # 216

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