

Reliable ISO-9001-Lead-Auditor Exam Practice, ISO-9001-Lead-Auditor Valid Test Vce

Audit evidence	ISO 9001 Clause 8.3 extract
Half of all new products launched in the past 12 months were late. The NPD Manager explains he has not got enough people on his team to cope with the demand for new products.	"8.3.2 e) ... internal ... resource needs for the design and development of products ..."
The NPD Manager explains many changes are made to cosmetic formulations during product development owing to retailer feedback. Only when confirmed by the retailer is the agreed formulation documented on SWIFT.	"8.3.6 ... retain documented information ..."
The NPD Manager explains that the customer confirms their approval to proceed with a new formulation by email. These emails are kept on SWIFT.	"8.3.5 ... retain documented information ..."
The NPD Manager shows you evidence of consumer trials that are carried out for some new products prior to full-scale launch.	"8.3.4 d) ... conducted to ensure that the design and development outputs meet ..."
The NPD Manager explains that an approved external laboratory is used to perform shelf-life stability trials on some formulations during product development.	"8.3.2 e) ... external ... resource needs for the design and development of products ..."

To complete the table click on the blank section you want to complete so it is highlighted in red and then click on the ISO 9001 clause 8.3 extracts listed below. Alternatively, drag and drop each clause to the audit evidence that applies.

"8.3.2 e) ... internal ... resource needs for the design and development of products ..."

"8.3.2 e) ... external ... resource needs for the design and development of products ..."

"8.3.4 d) ... conducted to ensure that the design and development outputs meet ..."

"8.3.5 ... retain documented information ..."

"8.3.6 ... retain documented information ..."

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

Topic	Details
Topic 1	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> Conducting an ISO 9001 audit: It evaluates your skills to conduct a QMS audit.
Topic 3	<ul style="list-style-type: none"> 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.
Topic 4	<ul style="list-style-type: none"> Preparing an ISO 9001 audit: This topic covers sub-topics related to preparing a quality management system audit.

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PECB QMS ISO 9001:2015 Lead Auditor Exam Sample Questions (Q122-Q127):

NEW QUESTION # 122

Select six of the activities that are specifically required by ISO 17021-1 as part third-party (Certification Body) surveillance audit processes.

- A. Review the status of previously raised findings and audit effectiveness of any outstanding findings.
- B. Failing to meet financial responsibilities.
- C. Confirm effectiveness of internal audit and management review.
- D. Complete a full document review of the quality management system.
- E. Audit use of certification marks on marketing materials.
- F. Review the calibration status of the instrumentation.
- G. Handling of customer complaints since last visit.
- H. Review changes to the QMS since last visit.
- I. Conduct a minimum number of annual surveillance audits during the certification period.
- J. Verify legal compliance.

Answer: A,C,E,G,H,J

Explanation:

The activities that are specifically required by ISO 17021-1 as part of third-party (Certification Body) surveillance audit processes are:

*Option A: Audit use of certification marks on marketing materials. This option is correct because ISO 17021-1:2015 clause 9.6.2.2 requires the certification body to audit the client's use of marks and/or any other reference to certification, as applicable, to ensure conformity with the certification requirements.

*Option B: Review changes to the QMS since last visit. This option is correct because ISO 17021-1:2015 clause 9.6.2.2 requires the certification body to review any changes affecting the client's quality management system and its ability to continue to fulfil the requirements of the standard used for certification.

*Option C: Confirm effectiveness of internal audit and management review. This option is correct because ISO 17021-1:2015 clause 9.6.2.2 requires the certification body to confirm the continuing effectiveness of the client's quality management system, including the effectiveness of the internal audit and management review processes.

*Option F: Review the status of previously raised findings and audit effectiveness of any outstanding findings.

This option is correct because ISO 17021-1:2015 clause 9.6.2.2 requires the certification body to review the status of findings and any corrective actions taken by the client in response to previous audits, and to verify the effectiveness of the implemented corrective actions.

*Option H: Verify legal compliance. This option is correct because ISO 17021-1:2015 clause 9.6.2.2 requires the certification body to verify the client's compliance with applicable statutory and regulatory requirements related to the scope of certification.

*Option I: Handling of customer complaints since last visit. This option is correct because ISO 17021-1:2015 clause 9.6.2.2 requires the certification body to review the client's handling of customer complaints related to the certified activities since the last audit.

The following options are not correct:

*Option D: Complete a full document review of the quality management system. This option is not correct because ISO 17021-1:2015 clause 9.6.2.2 does not require the certification body to complete a full document review of the quality management system during surveillance audits. A full document review is only required during the initial certification audit or when there are significant changes to the quality management system or the certification requirements.

*Option E: Failing to meet financial responsibilities. This option is not correct because ISO 17021-1:2015 clause 9.6.2.2 does not require the certification body to audit the client's financial responsibilities during surveillance audits. The certification body may have contractual arrangements with the client regarding the payment of fees, but this is not part of the surveillance audit process.

*Option G: Review the calibration status of the instrumentation. This option is not correct because ISO 17021-1:2015 clause 9.6.2.2 does not require the certification body to review the calibration status of the instrumentation during surveillance audits. The certification body may audit the client's monitoring and measuring resources as part of the quality

management system requirements, but this is not a specific activity required by ISO 17021-1.

*Option J: Conduct a minimum number of annual surveillance audits during the certification period. This option is not correct because ISO 17021-1:2015 clause 9.6.2.2 does not require the certification body to conduct a minimum number of annual surveillance audits during the certification period. The certification body may determine the frequency and duration of surveillance audits based on the risk and performance of the client, but this is not a specific activity required by ISO 17021-1.

References:

*ISO 17021-1:2015 Conformity assessment - Requirements for bodies providing audit and certification of management systems - Part 1: Requirements

*ISO 9001 Lead Auditor Course Material, Module 7: Audit Follow-up and Surveillance, Slide 8: Surveillance Audit

*ISO 9001 Lead Auditor Training Course - IRCA Certified, Section 7.2: Audit Follow-up and Surveillance

*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 # 123

Match the process descriptions below to the process names:

□

Answer:

Explanation:

□
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 # 124

Who maintains ownership of the audit report?

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

Answer: C

Explanation:

Comprehensive and Detailed In-Depth Explanation:

According to ISO 17021-1:2015, Clause 9.4.8 (Audit Reporting):

* The certification body retains ownership of the audit report as it is responsible for the certification decision.

* The auditee may receive a copy, but it does not own the report.

* The audit team leader compiles the report but does not own it.

Thus, C is the correct answer.

Reference:

ISO 17021-1:2015, Clause 9.4.8 (Audit Reporting)

NEW QUESTION # 125

The certification body has not been able to verify the implementation of corrective actions for any identified major nonconformity within six months after the last day of the Stage 2 audit. What must the certification body do in this case?

- A. It must conduct all audit activities from the beginning
- **B. It must issue an unfavorable recommendation of certification**
- C. It must conduct another Stage 2 audit before granting certification

Answer: B

Explanation:

Comprehensive and Detailed In-Depth Explanation: According to ISO 17021-1:2015, Clause 9.4.10 (Corrective Actions for Major Nonconformities):

* If a major nonconformity is not corrected within six months, the certification body must reject the certification request.

* Another Stage 2 audit (C) is not required unless the organization reapplies for certification.

* Restarting all audit activities (B) is unnecessary; instead, certification is denied.

Thus, A is the correct answer.

NEW QUESTION # 126

Scenario 2:

Bell is a Canadian food manufacturing company that operates globally. Their main products include nuts, dried fruits, and confections. Bell has always prioritized product quality and has maintained a good reputation for many years. However, the company's production error rate increased significantly, leading to more customer complaints.

To increase efficiency and customer satisfaction, Bell implemented a Quality Management System (QMS) based on ISO 9001. The top management established a QMS implementation team comprising five middle managers from various departments, including Leslie, the quality manager.

Leslie was responsible for assigning responsibilities and authorities for QMS-related roles. He also suggested including a top management representative in the QMS team, but top management declined due to other priorities.

The team defined the QMS scope as:

"The scope of the QMS includes all activities related to food processing." Leslie established a quality policy and presented it to the team for review before top management approval

. Top management also proposed a new strategy for handling customer complaints, requiring biweekly customer surveys to monitor customer perceptions.

Which of the following indicates that Bell has defined its quality objectives?

- A. Implementing a QMS to increase efficiency in the manufacturing process and customer satisfaction
- B. Establishing a QMS implementation team of middle managers from various departments
- C. Assigning responsibilities for QMS roles
- **D. Establishing a new strategy for handling customer complaints and requests**

Answer: D

Explanation:

Comprehensive and Detailed In-Depth Explanation: ISO 9001:2015, Clause 6.2 (Quality Objectives and Planning to Achieve Them) states that an organization must establish measurable and relevant quality objectives to improve QMS effectiveness.

Bell's strategy for handling customer complaints aligns with this requirement because it includes specific, measurable goals (biweekly customer surveys) to enhance customer satisfaction and service quality.

Other options are not directly related to defining quality objectives:

* Option B (Implementing a QMS) refers to the overall system, not specific objectives.

* Option C (Creating a QMS team) is an implementation step, not an objective.

* Option D (Assigning responsibilities) is necessary for QMS but does not define objectives.

NEW QUESTION # 127

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