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PECB ISO-9001-Lead-Auditor Prüfungsplan:

Thema	Einzelheiten
Thema 1	<ul style="list-style-type: none"> Closing an ISO 9001 audit: The topic focuses on concluding a QMS audit and conducting audit follow-up activities.
Thema 2	<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.
Thema 3	<ul style="list-style-type: none"> Managing an ISO 9001 audit program: This topic evaluates your abilities to establish and managing a QMS audit program.
Thema 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.
Thema 5	<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.

>> ISO-9001-Lead-Auditor Probesfragen <<

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PECB QMS ISO 9001:2015 Lead Auditor Exam ISO-9001-Lead-Auditor Prüfungsfragen mit Lösungen (Q78-Q83):

78. Frage

Which two of the following aspects of a quality management system must the organisation continually improve?

- A. Applicability
- B. Effectiveness
- C. Efficiency
- D. Suitability
- E. Responsiveness
- F. Adaptability

Antwort: B,C

Begründung:

According to the ISO 9001:2015 document, the organisation must continually improve the suitability, adequacy, and effectiveness of the quality management system¹. However, among the six options given, only effectiveness is directly mentioned as an aspect of the quality management system that must be continually improved. Therefore, C is one of the correct answers.

Efficiency, on the other hand, is not explicitly stated as an aspect of the quality management system that must be continually improved, but it is implied by the quality management principle of improvement, which states that successful organisations have an ongoing focus on improvement². One of the key benefits of applying this principle is improving operational effectiveness and efficiency². Therefore, E is another correct answer.

Suitability, adaptability, responsiveness, and applicability are not aspects of the quality management system that must be continually improved, according to the ISO 9001:2015 document. They may be related to the quality management system, but they are not the focus of continual improvement.

Therefore, the correct answer is C and E.

References: 1: ISO 9001:2015 - Quality management systems - Requirements 2: ISO - Quality management principles

79. Frage

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

The organisation manufactures cosmetics for major retailers and the name of the retailer supplied appears on the product packaging.

Sales turnover has increased significantly over the past five years.

You are interviewing the new Product Development Manager. You note that a software application called SWIFT is used to help control the product development process.

You have gathered audit evidence as outlined in the table. Match the ISO 9001 clause 8.3 extracts to the audit evidence.

Antwort:

Begründung:

A screenshot of a computer AI-generated content may be incorrect.

Audit Evidence	Correct ISO 9001 Clause Extract
1. Half of all new products launched in the past 12 months were late. The Product Development Manager explains he lacks people to cope with demand.	8.3.2 e) ... internal ... resource needs for the design and development of products ...
2. Many changes are made to cosmetic formulations during product development due to retailer feedback. Final formulations are documented in SWIFT.	8.3.6 ... retain documented information ...
3. Customer confirms approval to proceed with a new formulation via email. These emails are stored in SWIFT.	8.3.5 ... retain documented information ...
4. Consumer trials are carried out before full-scale launch.	8.3.4 d) ... conducted to ensure that the resulting products and services meet the requirements ...
5. Shelf-life stability testing is done by an approved external lab during product development.	8.3.2 e) ... external ... resource needs for the design and development of products ...

Comprehensive and Detailed In-Depth Explanation:

- * Clause 8.3.2 e) - Internal Resource Needs: Delays due to staff shortages highlight a lack of internal resources, directly relating to this clause that requires internal resource planning for design and development.
- * Clause 8.3.6 - Design and Development Changes: Ongoing formulation changes due to feedback need to be documented and reviewed. This clause requires retention of documented information on changes.
- * Clause 8.3.5 - Design and Development Outputs: Customer approvals for formulations are outputs of the design process and must be retained as documented information, as per this clause.
- * Clause 8.3.4 d) - Design and Development Controls: Consumer trials are a validation activity. This clause ensures such trials are conducted to confirm that resulting products meet defined requirements.
- * Clause 8.3.2 e) - External Resource Needs: Shelf-life tests done by an external lab are part of the external resources needed for development and are referenced here.

80. Frage

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 and the name of the retailer supplied appears on the product packaging. Sales turnover has increased significantly over the past five years. The organisation uses a software programme called SWIFT, which is used to record sales, plan production, purchase supplies, print despatch notes, track new product development, perform traceability exercises, carry out mass balance checks, raise invoices, create budgets, and support financial control.

You are nearing the end of the audit and you are reviewing your audit notes. You notice a recurring trend concerning the SWIFT database as shown below:

Your audit notes	Status
Production Planner: SWIFT database version 202	Requires audit trail
Manufacturing Manager: SWIFT database version 169	Requires audit trail
Manufacturing Supervisor: SWIFT database version 169	Requires audit trail
Product Development Manager: SWIFT database version 169	Requires audit trail
Logistics Supervisor: SWIFT database version 182	Requires audit trail
Quality Manager: SWIFT database version 205	Requires audit trail

You ask the Quality Manager to explain how the SWIFT database is controlled. You learn that the Operations Director is responsible for determining and progressing SWIFT software updates. You decide to meet the Operations Director (OD).

You: "Good afternoon."

OD: "Good afternoon."

You: "What responsibility do you have concerning the SWIFT database?"

OD: "I maintain it. If anyone wishes to propose an update to the database, they send me an email with details of their proposal. I then either process the database update myself, or I send the request to the consultant who designed the database 20 years ago. The necessary software changes are made, and the amended software is immediately released to users." You: "Would you explain how the software amendments are controlled?" OD: "Of course. I personally update every computer myself." You: "Do you inform the database users of the changes?" OD: "No I don't. They find out for themselves by using the software, or they come to see me if they have any questions." You: "How do you ensure that the database users use the latest version?" OD: "That's easy, I update every computer myself." You: "During the audit, I noted there were several versions of SWIFT in use (you refer to your audit notes)." OD: "I know. That's because some versions work better than others, and depending on user needs and experiences, we allow users to revert to using an earlier version if they find it works better for them." Based on the scenario, which two of the following statements are true? There is evidence of nonconformity with a requirement defined in ...

- A. ... clause 7.5.3 Control of documented information
- B. clause 7.1.3 Infrastructure
- C. clause 7.5.1 Documented information - General
- D. ... clause 7.5.2 Documented information - Creating and updating
- E. ... clause 7.1.4 Environment for the operation of processes

Antwort: A,C

Begründung:

Based on the scenario provided, there is evidence of nonconformity with the requirements defined in:

C: Clause 7.5.1 Documented information - General: The scenario indicates that there is no formal process for informing users about

updates to the SWIFT database, which suggests a lack of control over documented information. This could lead to users being unaware of important changes and not using the latest version of the software, which is required by the quality management system1. E: Clause 7.5.3 Control of documented information: The Operations Director's approach to updating the SWIFT database and the lack of communication to users about these updates indicate that the documented information is not adequately controlled. Allowing users to revert to earlier versions of the software at their discretion further suggests that the organization does not have a proper mechanism in place to ensure the integrity and suitability of documented information2.

These clauses are part of the ISO 9001:2015 standard, which requires organizations to have a systematic approach to controlling and managing documented information as part of their quality management system.

The scenario described shows a casual approach to managing critical software updates, which could affect the organization's ability to consistently meet customer and regulatory requirements.

81. Frage

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.

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Nonconformity report	
ISO 9001 Clause Number:	<input type="text"/>
Nature of problem:	<input type="text"/>
ISO 9001 requirement that has not been fulfilled:	<input type="text"/>
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.

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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	

Antwort:

Begründung:

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."

8.7

8.5.4

Cleaning and sanitising records are not available for every batch.

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

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

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.

82. Frage

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.

According to scenario 5, Li Na conducted group interviews with departmental managers and top management by herself. Is this in accordance with audit best practices?

- A. Yes, the auditee's top management is always interviewed by the audit team leader only.
- B. Yes, only the audit team leader should conduct group interviews.
- C. No, two auditors should be present in case of group interviews.

Antwort: C

Begründung:

Comprehensive and Detailed In-Depth Explanation:

According to ISO 19011:2018, Clause 6.4.6 (Conducting Interviews), group interviews should be conducted with at least two auditors to ensure objectivity and accuracy.

This prevents bias or misinterpretation of responses.

It allows for cross-validation of information.

It ensures that the audit results remain objective and impartial.

Since Li Na conducted the group interviews alone, she did not follow audit best practices. The correct approach would have been to have another auditor present during the interviews.

Reference:

ISO 19011:2018, Clause 6.4.6 (Conducting Interviews)

83. Frage

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