

Latest ISO-9001-Lead-Auditor Exam Practice, Valid ISO-9001-Lead-Auditor Test Book

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.	<input type="text"/>
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.	<input type="text"/>
The NPD Manager explains that the customer confirms their approval to proceed with a new formulation by email. These emails are kept on SWIFT.	<input type="text"/>
The NPD Manager shows you evidence of consumer trials that are carried out for some new products prior to full-scale launch.	<input type="text"/>
The NPD Manager explains that an approved external laboratory is used to perform shelf-life stability trials on some formulations during product development.	<input type="text"/>

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"> 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	<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 3	<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.
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.
Topic 5	<ul style="list-style-type: none"> Conducting an ISO 9001 audit: It evaluates your skills to conduct a QMS audit.

PECB QMS ISO 9001:2015 Lead Auditor Exam Sample Questions (Q139-Q144):

NEW QUESTION # 139

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.

□

Answer:

Explanation:

□

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 # 140

A small cleaning services organisation is about to start work on a hospital cleaning contract for the local Health Trust. You, as auditor, are conducting a Stage 2 audit to ISO 9001 and review the contract with the Service Manager. The contract requires that a cleaning plan is produced. You: "How was the cleaning plan for the contract developed?" Service Manager: "We have a basic template that covers the materials, labour requirements and cleaning methods to be employed. Some of that is specified by the customer." You: "How does the plan deal with locations like the intensive care wards and the operating theatres, which are included in the contract?" Service Manager: "The basic plan covers general wards, but we will do more frequent cleaning in those areas if the hospital requests it." You: "Are you aware of the regulatory requirements for cleaning standards in hospitals?" Service Manager: "No. We depend on the hospital to look after that side of things in the contract." You decide to raise a non-conformity against section 8.2.2.a.1 of ISO 9001. You decide to raise another non-conformity against section 8.2.4 of ISO 9001 when finding that the cleaning plan was amended without the agreement of the Health Trust. A different cleaning chemical was substituted to that specified in the contract. At the follow-up audit, the corrective action proposed was to "obtain a concession from the Health Trust for use of the new chemical." Which one of the following options is the reason why you did not accept this action taken?

- A. The substitute chemical may not be as effective as the original.
- B. The process for making changes to the contract has not been addressed.
- C. Staff have not been trained in the use of the new chemical.
- D. The action assumes that the Health Trust will agree to the change.

- E. The substitute chemical has not been used before in the Health Trust.

Answer: B

Explanation:

* Clause 8.2.4 of ISO 9001:2015 - Changes to Requirements for Products and Services:ISO 9001:

2015 Clause 8.2.4 states that when changes to requirements for products or services are made, they must be communicated and agreed upon with relevant interested parties (in this case, the Health Trust).

The lack of communication and agreement for substituting the cleaning chemical represents a clear violation of this clause.

* Analysis of the Corrective Action Proposed:The organization proposed "obtaining a concession from the Health Trust for the use of the new chemical." This action is reactive and assumes approval from the Health Trust without addressing the systemic issue: the lack of a defined change control process for managing contract changes.

* Option Analysis:

* A. The substitute chemical has not been used before in the Health Trust:Incorrect. While this may be a concern, it is not directly relevant to the root cause of the nonconformity, which is the absence of a process to handle contract changes.

* B. The action assumes that the Health Trust will agree to the change:Incorrect. Although this is true, it is not the primary issue. The nonconformity lies in the lack of a structured approach to obtain agreement, not whether the Health Trust agrees.

* C. Staff have not been trained in the use of the new chemical:Incorrect. This is a separate issue related to staff competence (Clause 7.2), but it is not the main reason why the corrective action is unacceptable under Clause 8.2.4.

* D. The process for making changes to the contract has not been addressed:Correct. The fundamental issue is the organization's failure to follow or establish a change control process for amending contracts, including gaining formal agreement from the Health Trust. The proposed corrective action does not ensure that such issues will be systematically prevented in the future.

* E. The substitute chemical may not be as effective as the original:Incorrect. The effectiveness of the substitute chemical is secondary to the primary issue, which is the lack of a change management process.

* ISO 9001 References Supporting the Correct answer:

* Clause 8.2.4: Requires that changes to product/service requirements be reviewed, communicated, and agreed upon with the customer.

* Clause 10.2 (Nonconformity and Corrective Action): Requires the organization to address the root cause of the nonconformity and take actions to ensure it does not recur. In this case, the root cause is the absence of a change control process.

* Why D is the Best answer:The core issue is that the organization did not have a formalized process for managing and agreeing upon changes to contract requirements. Addressing this process gap is essential to prevent recurrence of similar nonconformities. Merely seeking a concession from the Health Trust is a one-off solution that does not address the systemic issue.

NEW QUESTION # 141

You have been nominated audit team leader of a third-party audit. Which of the following could be the two most relevant objectives of this audit?

- A. Evaluate the effectiveness of the management system
- B. Evaluate the benefits obtained since the implementation of the management system
- C. Evaluate the capability of the management system to establish and achieve objectives
- D. Identify the need of resources
- E. Evaluate the satisfaction interested parties
- F. Identify opportunities for improvement

Answer: A,C

Explanation:

Evaluate the effectiveness of the management system: This objective involves verifying that the quality management system meets the requirements of a specific standard, such as ISO 9001:2015, and that it achieves the intended results and outcomes. The audit team will collect and analyse audit evidence to determine the degree of conformity and performance of the quality management system²³.

*Evaluate the capability of the management system to establish and achieve objectives: This objective involves verifying that the quality management system supports the strategic direction and policies of the organization, and that it addresses the needs and expectations of the interested parties. The audit team will assess the suitability, adequacy, and alignment of the quality management system objectives, and the effectiveness of the planning and implementation processes to achieve them²³.

The other options are not the most relevant objectives of a third-party audit, according to the web search results from my internal tool. They may be related to other aspects or types of audits, but they are not the focus of a third-party audit.

Therefore, the correct answer is B and D.

References: 1: Safeguarding Your Business: The Power of Third-Party Security Audits 2: ISO 19011:2018 - Guidelines for auditing management systems 3: Third Party Audit - QMSGurus.com

NEW QUESTION # 142

You are carrying out an audit to ISO 9001 at an organisation which offers regulatory consultancy services to manufacturers of cosmetics.

You are interviewing the Technical Director (TD), who manages a team of regulatory experts responsible for providing regulatory services to customers.

You: "How do you ensure your regulatory team's competence concerning regulatory requirements is maintained?" TD: "The two Regulatory Experts we employ full-time have years of experience of working in the cosmetics industry." You: "How is their regulatory competence maintained?" TD: "They are dedicated individuals with lots of contacts in the sector." You: "How does the business enable them to maintain their understanding of current regulatory requirements?" TD: "We leave that up to them."

Answer:

Explanation:

Explanation:

A screenshot of a computer Description automatically generated

NEW QUESTION # 143

Put the following steps of a third-party audit into the correct sequence in which they happen.

Answer:

Explanation:

Explanation:

Sequence:

Stage 1 Audit

Stage 2 Opening Meeting

Interviews

Stage 2 Closing Meeting

Close-out of Stage 2 Audit Findings

Issue Certificate

Surveillance Audit

Follow-up Audit

To complete the sequence, you can drag and drop the options to the appropriate blank section.

Here is a brief explanation of each step:

Stage 1 Audit: This is the initial audit that aims to assess the readiness of the organization for the stage 2 audit. It involves reviewing the documentation of the quality management system, evaluating the scope and objectives of the audit, and identifying any major gaps or nonconformities³⁴.

Stage 2 Opening Meeting: This is the meeting that marks the start of the stage 2 audit. It involves confirming the audit plan, the audit criteria, the audit scope, and the audit team. It also provides an opportunity for the auditee to ask any questions or raise any concerns³⁴.

Interviews: This is the main activity of the stage 2 audit, where the audit team collects evidence by interviewing the personnel involved in the quality management system, observing the processes and activities, and examining the records and documents. The audit team uses various techniques, such as sampling, measurement, analysis, and evaluation, to verify the conformity and effectiveness of the quality management system^{34,5}.

Stage 2 Closing Meeting: This is the meeting that marks the end of the stage 2 audit. It involves presenting the audit findings, the audit conclusions, and the audit report to the auditee. It also provides an opportunity for the auditee to provide feedback, ask questions, or dispute any findings³⁴.

Close-out of Stage 2 Audit Findings: This is the process of verifying that the auditee has taken appropriate corrective actions to address any nonconformities or opportunities for improvement identified during the stage 2 audit. The audit team may request evidence or conduct a follow-up visit to confirm the effectiveness of the corrective actions³⁴.

Issue Certificate: This is the process of issuing a certificate of conformity to the auditee, if the audit team is satisfied that the quality management system meets the requirements of the standard and that there are no major nonconformities or unresolved issues. The certificate is valid for a specified period, usually three years, and is subject to periodic surveillance audits³⁴.

Surveillance Audit: This is the process of conducting periodic audits, usually once a year, to monitor the continued conformity and effectiveness of the quality management system. It involves reviewing the changes, improvements, and performance of the quality management system, and identifying any new nonconformities or opportunities for improvement³⁴.

Follow-up Audit: This is the process of conducting an additional audit, usually in response to a significant change, a complaint, or a

