

PECB ISO-9001-Lead-Auditor問題例 & ISO-9001-Lead-Auditor無料問題

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ISO 9001 Lead Auditor

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>> PECB ISO-9001-Lead-Auditor問題例 <<

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PECB ISO-9001-Lead-Auditor 認定試験の出題範囲:

トピック	出題範囲
トピック 1	Conducting an ISO 9001 audit: It evaluates your skills to conduct a QMS audit.
トピック 2	Managing an ISO 9001 audit program: This topic evaluates your abilities to establish and managing a QMS audit program.

- Preparing an ISO 9001 audit: This topic covers sub-topics related to preparing a quality management system audit.

PECB QMS ISO 9001:2015 Lead Auditor Exam 認定 ISO-9001-Lead-Auditor 試験問題 (Q242-Q247):

質問 # 242

Whistlekleen is a national dry cleaning and laundry company with 50 shops. You are conducting a surveillance audit of the Head Office and are sampling customer complaints. You find that 80% of complaints originate from five shops in the same region. Most of these complaints relate to damage to customer laundry. The Quality Manager tells you that these are the oldest shops in the company. The cleaning equipment needs replacing but the company cannot afford it at the moment. You learn that the shop managers were told to dismiss most of the claims on the basis of the poor quality of the laundered materials.

On raising the matter with senior management, you are told that there are plans to replace the equipment in these shops over the next five years.

正解:

解説:

□ Explanation:

The quality system failed to control the laundry services provided for customers in five shops.

The equipment used was not capable of consistently producing the required service.

質問 # 243

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 dosed 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 leader**
- C. The auditee organisation
- D. The audit team member

正解: B

解説:

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.

質問 # 244

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

The organisation offers warehousing and export services to customers. Customers are invoiced for the time stock items are stored in the warehouse. Transport to and from the warehouse is controlled by the organisation and approved subcontract transport services are used. The organization does not have its own transport vehicles. Stock items are not purchased by the organisation.

You have gathered audit evidence as outlined in the table. Match the ISO 9001 Clause 8 extract to the audit evidence.

正解:

解説:

Explanation:

The table below shows the possible matching of the ISO 9001 Clause 8 extract to the audit evidence.

Table

Audit evidence

ISO 9001 Clause 8 extract

Four of the 10 pallets of stock sampled in the warehouse were not labelled.

"8.5.2 ... shall use suitable means to identify outputs ..."

A damaged pallet of stock seen in the quarantine area was leaking liquid onto the floor.

"8.7.1 ... shall ensure that outputs that do not conform to their requirements are identified and controlled ..." One of the fork-lift truck drivers had no fork-lift truck driving licence.

"8.5.1 e ... shall include, as applicable ... the appointment of competent persons ..." There was no pest control provision in the warehouse.

"8.5.4 ... shall preserve the outputs during production and service provision ..." Two pallets of temperature-sensitive stock items were being stored at ambient as the chilled storage facility was full.

"8.1 ... shall plan, implement and control the processes ..."

質問 # 245

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.

In scenario 2, the team determined the QMS scope by taking into account only the requirements of top management. Is this compliant with ISO 9001?

- A. No, the QMS scope must be determined by considering the needs and expectations of relevant interested parties.
- B. No, the QMS scope must take into account only those directly involved in QMS implementation.
- C. Yes, as long as the top management defines the scope, it meets ISO 9001 requirements.
- D. Yes, ISO 9001 does not specify whether any interested party should be considered when determining QMS scope.

正解: A

解説:

Comprehensive and Detailed In-Depth Explanation: ISO 9001:2015, Clause 4.3 (Determining the Scope of the Quality Management System) states that when determining the QMS scope, an organization must consider:

* External and internal issues (Clause 4.1)

* The needs and expectations of interested parties (Clause 4.2)

* The products and services provided by the organization

In the scenario, Bell only considered top management's input, which fails to address Clause 4.2 (interested parties' expectations)- such as customers, suppliers, and regulatory authorities.

質問 # 246

XYZ Corporation employs 100 people, and during a Stage 1 certification audit, certain issues are identified with the Quality Management System (QMS). Which two options describe the circumstances in which you could raise a nonconformity against Clause 6.2 of ISO 9001:2015?

- A. The organisation cannot afford to undertake quality objectives all at once.
- B. Quality objectives are not maintained as documented information.
- C. Quality objectives are not being implemented by the organisation's personnel.
- D. Quality objectives were not established in alignment with the organisation's quality policy.
- E. Establishing quality objectives did not include top management.
- F. The consultant has not interpreted ISO 9001 correctly.

正解: B、D

解説:

Understanding Clause 6.2 of ISO 9001:2015: Clause 6.2 (Quality Objectives and Planning to Achieve Them) specifies that organizations must:

Establish measurable and relevant quality objectives consistent with the quality policy (Clause 6.2.1).

Include objectives applicable to product/service conformity and customer satisfaction.

Document these objectives and their planning as documented information (Clause 6.2.1 & 6.2.2).

Plan how to achieve the objectives, including defining actions, resources, responsibilities, timelines, and methods for evaluation.

Analysis of Options:

A). Quality objectives are not being implemented by the organisation's personnel: Incorrect. While implementation is critical, this relates more to operational aspects rather than the direct requirements of Clause 6.2. Implementation issues would typically raise concerns under Clause 9.1 (Performance Evaluation).

B). The consultant has not interpreted ISO 9001 correctly: Incorrect. The consultant's interpretation of ISO 9001 is irrelevant in terms of Clause 6.2 compliance. The focus is on whether the organization aligns with the requirements, not the consultant's role.

C). Establishing quality objectives did not include top management: Incorrect. While top management involvement is vital for QMS effectiveness (Clause 5.1), this is not a direct requirement of Clause 6.2. Top management alignment is implied but not explicitly mandated for establishing quality objectives.

D). Quality objectives were not established in alignment with the organisation's quality policy: Correct. Clause 6.2.1 requires that quality objectives be consistent with the organization's quality policy, ensuring they reflect its purpose, strategic direction, and commitment to continual improvement. Misalignment would constitute a nonconformity.

E). The organisation cannot afford to undertake quality objectives all at once: Incorrect. Financial constraints are not directly addressed in Clause 6.2. The clause focuses on planning to achieve objectives, which includes defining the necessary resources but does not demand achieving all objectives simultaneously.

F). Quality objectives are not maintained as documented information: Correct. Clause 6.2.1 specifically requires that quality objectives be maintained as documented information. Failure to document the objectives is a direct violation of this clause.

Why Options D and F Are Correct:

D: Misalignment between the quality objectives and the quality policy directly violates Clause 6.2.1, which mandates that objectives support the strategic direction of the organization.

F: Lack of documentation for quality objectives breaches the requirement to maintain them as documented information under Clause 6.2.1.

Relevant References:

Clause 6.2.1: Establishing quality objectives aligned with the quality policy.

Clause 6.2.2: Maintaining documented information for quality objectives and planning to achieve them.

Clause 5.1.1: Top management's responsibility to ensure alignment between the QMS and strategic direction.

質問 # 247

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- 試験の準備方法-ハイパスレートのISO-9001-Lead-Auditor問題例試験-検証するISO-9001-Lead-Auditor無料問

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