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## PECB QMS ISO 9001:2015 Lead Auditor Exam Sample Questions (Q222-Q227):

### NEW QUESTION # 222

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

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

**Answer: C,D**

Explanation:

According to the ISO 9001:2015 document, the organisation must continually improve the suitability, adequacy, and effectiveness of the quality management system<sup>1</sup>. 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 improvement<sup>2</sup>. One of the key benefits of applying this principle is improving operational effectiveness and efficiency<sup>2</sup>. 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

### NEW QUESTION # 223

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.

□

**Answer:**

Explanation:

□ 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 ..."

### NEW QUESTION # 224

Who assigns a guide to assist the audit team?

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

**Answer: C**

Explanation:

Comprehensive and Detailed In-Depth Explanation: According to ISO 19011:2018, Clause 6.4.3 (Roles and Responsibilities of Guides and Observers):

- \* The auditee assigns a guide to assist the audit team.
- \* The guide provides logistical support, helps with navigation, and arranges access to necessary personnel and records.
- \* The audit team leader does not assign the guide, but they may request one.

#### **NEW QUESTION # 225**

What does an auditor evaluate during an audit follow-up?

- **A. The effectiveness of all corrections and corrective actions taken**
- B. The auditee's site-specific conditions
- C. If internal audits and management reviews are being planned and performed

**Answer: A**

Explanation:

Comprehensive and Detailed In-Depth Explanation: According to ISO 19011:2018, Clause 6.6 (Audit Follow-Up):

- \* The primary focus of an audit follow-up is verifying that corrective actions were effectively implemented.
- \* Internal audits and management reviews (B) are part of routine QMS operations, not the main objective of follow-ups.
- \* Site conditions (C) are relevant but secondary to verifying corrective action effectiveness.

Thus, A is the correct answer.

#### **NEW QUESTION # 226**

You, as auditor, are in dialogue with the quality lead and managing director of a small business that supplies specialist laboratory equipment and furniture.

You: "I'd like to look at how you manage change in the organisation. What changes have you made as a business, say, over the last 12 months?" Auditee: "We have made some strategic changes, the main one being that we no longer manufacture our own products in house." You: "That sounds like quite a significant change. What has been the impact of that?" Auditee: "We now mainly sell other manufacturers' products, under their brand names, and have outsourced manufacture of our own brand products to one of our suppliers. Unfortunately, we had to make six members of our staff redundant. This represents about 20% of our workforce, so this has been quite a challenging time." You: "I'm sure. What were the reasons for making the change?" Auditee: "Our manufacturing section was a small operation, and we struggled to cope with fluctuations in demand. During busy periods, we found it hard to meet lead times, and in quiet periods we had staff with little to do. This was having an impact on customer satisfaction and meant we had to charge premium prices that made our product uncompetitive." You: "How did you go about the change?" The auditor asks to speak to the purchasing manager about the selection of the subcontractor to manufacture the company's own brand products. You: "How did you choose a supplier to manufacture your products?"

Auditee: "We have had a long-term relationship with a supplier ABC Ltd - we gave them our design drawings, got them to complete a supplier questionnaire and run a couple of trial batches for us. We were happy with the result and we have used them ever since."

ISO 9001:2015, clause 8.4.1 outlines situations when controls need to be applied to externally provided processes, products and services. Which one of the following situations is applicable to this scenario?

- A. Products and services for which the customer(s) supplies materials
- B. Raw materials from external providers are intended for incorporation into the organisation's own products.
- C. Products and services are provided directly to the customer(s) by external providers on behalf of the organisation.
- **D. A process or part of a process is provided by an external provider as a result of a decision by the organisation.**

**Answer: D**

Explanation:

According to the ISO 9001:2015 standard, clause 8.4.1 requires organizations to ensure that externally provided processes,

products and services conform to requirements. Controls must be applied to externally provided processes, products and services when:

The products and services are intended for incorporation into the organization's own products and services.

They are provided directly to customers by the external provider on behalf of the organization.

A process, or part of a process, is provided by an external provider as a result of a decision by the organization.

In this scenario, the auditee has chosen a supplier to manufacture their own brand products based on their design drawings, supplier questionnaire and trial batches. This means that the supplier is providing a process (manufacturing) as a result of a decision by the organization (the auditee). Therefore, clause 8.4.1 applies to this situation.

## NEW QUESTION # 227

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