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

Topic	Details
Topic 1	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	Preparing an ISO 9001 audit: This topic covers sub-topics related to preparing a quality management system audit.

Topic 3

 Closing an ISO 9001 audit: The topic focuses on concluding a QMS audit and conducting audit follow-up activities.

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PECB QMS ISO 9001:2015 Lead Auditor Exam Sample Questions (Q198-Q203):

NEW QUESTION # 198

Which of the following is a responsibility of a guide in an audit?

- A. Maintaining logistics
- B. Witnessing the audit process on behalf of the certification body
- C. Filling any potential gaps in the auditor's knowledge

Answer: A

Explanation:

Comprehensive and Detailed In-Depth Explanation: A guide is assigned by the auditee to assist the audit team by:

- * Managing logistics, such as ensuring that relevant documents are available and arranging interviews.
- * Assisting in the coordination of meetings and access to facilities.
- * Helping the auditors navigate the organization during the audit.

However, the guide does not fill gaps in the auditor's knowledge or witness the audit for the certification body. Their primary function is logistical support, not providing interpretations or assessments.

NEW QUESTION # 199

Select the word that best completes the sentence:

Select the word that best completes the sentence:	
"The purpose of a management system standard is to	the performance of an organisation."
To complete the sentence with the best word, click on the blank section you want to composition(s) to the appropriate blank section.	plete so it is highlighted in red and then click on the applicable text from the option(s) below. Alternatively, drag and drop the
manage monitor improve dictate	

Answer:

Explanation:



Explanation:

"The purpose of a management system standard is to improve the performance of an organisation."

According to the ISO - Management system standards page, the key benefits of an effective management system include improved operational effectiveness and efficiency, improved risk management and protection of people and the environment, and enhanced drive for innovation. The Integrated Use of Management System Standards (IUMSS) handbook also states that the purpose and objectives of management system standards are to help organizations improve their performance by specifying repeatable steps that organizations consciously implement to achieve their goals and objectives.

Therefore, the complete sentence is:

"The purpose of a management system standard is to improve the performance of an organisation."

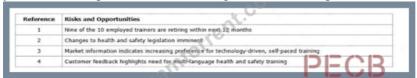
NEW QUESTION #200

You are carrying out an audit at an organisation seeking certification to ISO 9001 for the first time. The organisation offers health and safety training to customers.

You are interviewing the Quality Systems Manager (QSM).

You: "What risks and opportunities have the business identified?"

QSM: "I'11 show you. This was discussed with the Managing Director at the latest management review." Narrative: The QSM shows you the latest management review record and points to the following table:



You: "How is the business planning to address these risks and opportunities?" QSM: "The MD said that they already knew about them so it was not necessary."

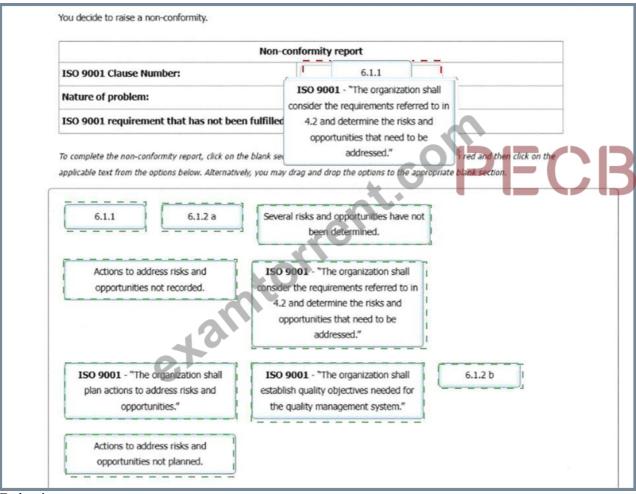


To complete the non-conformity report, click on the blank section you want to complete so it is highlighted in red and then click on the applicable text from the options below. Alternatively, you may drag and drop the options to the appropriate blank section.

6.1.1	6.1.2 a	Several risks and opportunities have not been determined.		
Actions to addi opportunities r		ISO 9001 - "The organization shall consider the requirements referred to in 4.2 and determine the risks and opportunities that need to be addressed."		
ISO 9001 - "The organization shall plan actions to address risks and opportunities."		ISO 9001 - "The organization shall establish quality objectives needed for the quality management system."	6.1.2 b	

Answer:

Explanation:



Explanation:

Non-Conformity Report:

ISO 9001 Clause Number

Nature of Problem

ISO 9001 Requirement That Has Not Been Fulfilled

6.1.1

Several risks and opportunities have not been determined.

"The organization shall consider the requirements referred to in 4.2 and determine the risks and opportunities that need to be addressed."

6.1.2 (a)

Actions to address risks and opportunities not planned.

"The organization shall plan actions to address risks and opportunities." Step-by-Step Reasoning:

- * Clause 6.1.1 Determining Risks and Opportunities:
- * Requirement: The organization must determine risks and opportunities that are relevant to its Quality Management System (QMS). This ensures that the QMS achieves intended results and prevents undesired effects.
- * Problem Identified: While some risks and opportunities were discussed, the organization did not perform a systematic evaluation of all risks (e.g., health and safety legislation changes, retiring trainers).
- * Clause 6.1.2 (a) Planning Actions for Risks and Opportunities:
- * Requirement: The organization must plan actions to address identified risks and opportunities.

These actions should be integrated into the QMS processes to ensure continuous improvement.

- * Problem Identified: The Quality Systems Manager confirmed that no plans were made to address the risks and opportunities because the Managing Director deemed it unnecessary. This violates the requirement to plan actions.
- * Correct Options Selected:
- * Clause 6.1.1 with the nature of the problem as: "Several risks and opportunities have not been determined."
- * Clause 6.1.2 (a) with the nature of the problem as: "Actions to address risks and opportunities not planned."
- * ISO 9001 Requirements Not Fulfilled:
- * For 6.1.1: The organization shall consider the requirements referred to in 4.2 and determine the risks and opportunities that need to be addressed."
- * For 6.1.2 (a): The organization shall plan actions to address risks and opportunities."

NEW QUESTION # 201

ISO 9001 addresses changes through several requirements, two examples of which are Clause 6.3 (Planning of Changes) and Clause 8.5.6 (Control of Changes). How do the requirements of Clause 8.5.6 differ from those of Clause 6.3?

- A. Clause 8.5.6 refers to leadership and management system responsibilities.
- B. Clause 8.5.6 refers to changes to legal and regulatory requirements.
- C. Clause 8.5.6 refers to changes during the design and development of products and services.
- D. Clause 8.5.6 refers to changes during the production and service provision.

Answer: D

Explanation:

Comprehensive and Detailed In-Depth Explanation:

ISO 9001:2015 recognizes change management as essential for maintaining process integrity and preventing nonconformities. Clause References:

- * Clause 6.3 (Planning of Changes) # Focuses on long-term changes that may impact QMS integrity.
- * Clause 8.5.6 (Control of Changes) # Focuses on changes occurring during production and service provision to ensure conformity. Why is the Correct Answer A?
- * Clause 8.5.6 applies specifically to operational changes, ensuring that modifications in production or service processes do not compromise quality.
- * Organizations must document who approves changes, how they are controlled, and how they affect product/service conformity. Why are the Other Options Incorrect?
- * B (Changes during design and development) # Covered under Clause 8.3 (Design and Development), not 8.5.6.
- * C (Changes to legal and regulatory requirements) # Addressed under Clause 4.2 (Interested Parties
- ' Requirements).
- \ast D (Leadership responsibilities) # Covered under Clause 5.1 (Leadership and Commitment), not 8.5.6.

NEW QUESTION # 202

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

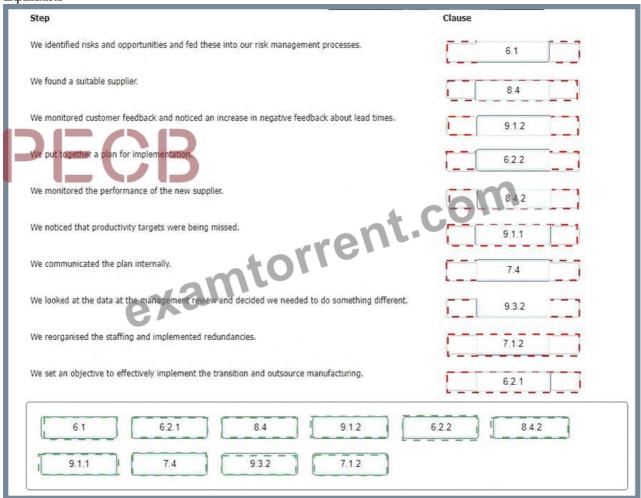
You: "I'd like to look at how you manage change in the organisation. What changes have you made as a business, say, over the last 12 months?" Auditee: "We have made some strategic changes, the main one being that we no longer manufacture our own products in house." You: "That sounds like quite a significant 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?" In relation to the auditor's question about how the change was managed, the auditee mentions the steps listed below. Match the ISO 9001 clauses to the steps.

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 clauses listed below. Alternatively, drag and drop each clause to show which step the requirement applies to.

				Clause	
We identified risks and or	pportunities and fed thes	e into our risk manager	ment processes.		
We found a suitable supp	lier.				
We monitored customer I	reedback and noticed an	increase in negative fe	edback about lead times	i.	
We put together a plan fo	or implementation.				
We monitored the perfor	mance of the new supplie	er.			
We noticed that producti	rity targets were being m	nissed.		+ 00	m
		4 - 10	croll	1.0	
We communicated the ol	an internally.	-a+01	0.		
	IBXC	-	rren		
	IBXC	-			
We communicated the pl We looked at the data at We reorganised the staffi	the management review	and decided we neede			
We looked at the data at	the management review	and decided we neede	ed to do something diffe		
We looked at the data at	the management review	and decided we neede	ed to do something diffe		
We looked at the data at	the management review	and decided we neede	ed to do something diffe		8.4.2

Answer:

Explanation:



Explanation:

Step	lause
We identified risks and opportunities and fed these into our risk management processes.	6.1
V found a suitable supplier.	8.4
We monitored customer feedback and noticed an increase in negative feedback about lead	
imes.	9.1.2
We put together a plan for implementation.	6.2.2
We monitored the performance of the new supplier.	8.4.2
We noticed that productivity targets were being missed.	9.1.1
We communicated the plan internally.	7.4
We looked at the data at the management review and decided we needed to do something	9.3.2
different.	7.3.2
We reorganised the staffing and implemented redundancies.	7.1.2
We set an objective to effectively implement the transition and outsource manufacturing.	6.2.1

Here is the correct matching of ISO 9001:2015 clauses to the steps mentioned in the change management process:

- * We identified risks and opportunities and fed these into our risk management processes.
- * Clause 6.1 (Actions to address risks and opportunities)
- * We found a suitable supplier.
- * Clause 8.4 (Control of externally provided processes, products, and services)
- * We monitored customer feedback and noticed an increase in negative feedback about lead times.
- * Clause 9.1.2 (Customer satisfaction)
- * We put together a plan for implementation.
- * Clause 6.2.2 (Planning to achieve quality objectives)
- * We monitored the performance of the new supplier.
- * Clause 8.4.2 (Type and extent of control of external providers)
- * We noticed that productivity targets were being missed.
- * Clause 9.1.1 (Monitoring, measurement, analysis, and evaluation)
- * We communicated the plan internally.
- * Clause 7.4 (Communication)
- * We looked at the data at the management review and decided we needed to do something different.
- * Clause 9.3.2 (Management review inputs)
- * We reorganised the staffing and implemented redundancies.
- * Clause 7.1.2 (People)
- * We set an objective to effectively implement the transition and outsource manufacturing.
- * Clause 6.2.1 (Quality objectives and planning to achieve them)

This aligns the steps of the change process with relevant ISO 9001:2015 clauses related to risk, planning, communication, and monitoring.

NEW QUESTION # 203

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