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

Topic	Details
Topic 1	<ul style="list-style-type: none">• Conducting an ISO 9001 audit: It evaluates your skills to conduct a QMS audit.
Topic 2	<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 3	<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 4	<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 5	<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.

PECB QMS ISO 9001:2015 Lead Auditor Exam Sample Questions (Q211-Q216):

NEW QUESTION # 211

Select the term that best describes the purpose of retaining documented information in a quality management system to ISO 9001.

- A. To provide confidence in the effectiveness of the quality management system.
- B. To facilitate auditing for proof of conformity to the standard.
- C. To safeguard the integrity of the quality management system.
- **D. To support the operation of the processes of the quality management system.**

Answer: D

Explanation:

Documented information is a means by which an organization demonstrates compliance. It communicates what we do and how we do things, it communicates what happened and what results were achieved. It is, essentially, a tool for communication. ISO 9001:2015 allows an organization flexibility in the way it chooses to document its quality management system (QMS). This enables each individual organization to determine the correct amount of documented information needed in order to demonstrate the effective planning, operation and control of its processes and the implementation and continual improvement of the effectiveness of its QMS. The standard states that the organization shall maintain documented information to the extent necessary to support the operation of processes and retain documented information to the extent necessary to have confidence that the processes are being carried out as planned. Therefore, the purpose of retaining documented information is to support the operation of the processes of the QMS, not to facilitate auditing, provide confidence or safeguard integrity, which are secondary benefits of documented information.

References: Guidance on the requirements for Documented Information of ISO 9001:2015, ISO 9001:2015 documented information | CQI | IRCA, Documented Information Required by ISO 9001:2015 - 9000 Store

NEW QUESTION # 212

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'll 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:

Reference	Risks and Opportunities
1	Nine of the 10 employed trainers are retiring within next 12 months
2	Changes to health and safety legislation imminent
3	Market information indicates increasing preference for technology-driven, self-paced training
4	Customer feedback highlights need for multi-language health and safety training

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."

You decide to raise a non-conformity.

Non-conformity report	
ISO 9001 Clause Number:	
Nature of problem:	
ISO 9001 requirement that has not been fulfilled:	

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 address risks and opportunities not recorded.

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

Actions to address risks and opportunities not planned.

Answer:

Explanation:

You decide to raise a non-conformity.

Non-conformity report	
ISO 9001 Clause Number:	6.1.1
Nature of problem:	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 requirement that has not been fulfilled	

To complete the non-conformity report, click on the blank section, type the problem, click on the 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 address risks and opportunities not recorded.

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

Actions to address risks and opportunities not planned.

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."

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.

Step	Clause
We identified risks and opportunities and fed these into our risk management processes.	<input type="text"/>
We found a suitable supplier.	<input type="text"/>
We monitored customer feedback and noticed an increase in negative feedback about lead times.	<input type="text"/>
We put together a plan for implementation.	<input type="text"/>
We monitored the performance of the new supplier.	<input type="text"/>
We noticed that productivity targets were being missed.	<input type="text"/>
We communicated the plan internally.	<input type="text"/>
We looked at the data at the management review and decided we needed to do something different.	<input type="text"/>
We reorganised the staffing and implemented redundancies.	<input type="text"/>
We set an objective to effectively implement the transition and outsource manufacturing.	<input type="text"/>

6.1	6.2.1	8.4	9.1.2	6.2.2	8.4.2
9.1.1	7.4	9.3.2	7.1.2		

Answer:

Explanation:

Step	Clause
We identified risks and opportunities and fed these into our risk management processes.	6.1
We found a suitable supplier.	8.4
We monitored customer feedback and noticed an increase in negative feedback about lead times.	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 different.	9.3.2
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

6.1

6.2.1

8.4

9.1.2

6.2.2

8.4.2

9.1.1

7.4

9.3.2

7.1.2

Explanation:

Step	Clause
We identified risks and opportunities and fed these into our risk management processes.	6.1
We found a suitable supplier.	8.4
We monitored customer feedback and noticed an increase in negative feedback about lead times.	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 different.	9.3.2
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 # 214

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.

After reviewing the documented information, Li Na claimed that it was not necessary to report the minor nonconformities that were identified; instead, they would be discussed in the next audit phase. Is this acceptable?

- A. Yes, during the review of documented information, only major nonconformities need to be documented if detected.
- B. Yes, all identified nonconformities throughout the audit need to be documented and communicated at the end of the audit.
- **C. No, identification of minor nonconformities or areas of concern that could become nonconformities need to be documented and communicated to the auditee before proceeding to the next audit phase.**

Answer: C

Explanation:

Comprehensive and Detailed In-Depth Explanation: As per ISO 9001:2015, Clause 10.2 (Nonconformity and Corrective Action), all identified nonconformities, including minor ones, must be documented and communicated to the auditee.

Minor nonconformities can lead to major issues if left unaddressed. The auditor must inform the organization before moving to the next audit phase so that corrective actions can be taken. Clause 9.2.2 (Internal Audit) states that audit findings should be reported without undue delay.

Since Li Na did not report the minor nonconformities immediately, her decision was incorrect. Minor nonconformities should always be documented and communicated before proceeding to the next phase.

NEW QUESTION # 215

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

Answer: B,F

NEW QUESTION # 216

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