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

Topic	Details
Topic 1	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	Closing an ISO 9001 audit: The topic focuses on concluding a QMS audit and conducting audit follow-up activities.
Topic 3	Managing an ISO 9001 audit program: This topic evaluates your abilities to establish and managing a QMS audit program.
Topic 4	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.

PECB QMS ISO 9001:2015 Lead Auditor Exam Sample Questions (Q75-Q80):

NEW QUESTION # 75

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.

We found a suitable supplier.

We monitored customer feedback and noticed an increase in negative feedback about lead times.

We put together a plan for implementation.

We monitored the performance of the new supplier.

We noticed that productivity targets were being missed.

We communicated the plan internally.

We looked at the data at the management review and decided we needed to do something different.

We reorganised the staffing and implemented redundancies.

We set an objective to effectively implement the transition and outsource manufacturing.

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 # 76

Which of the following subjects should an auditor discuss when communicating with the auditee's top management?

- A. The quality policy
- B. Internal audit
- C. Both A and B

Answer: C

Explanation:

Comprehensive and Detailed In-Depth Explanation: During communication with top management, the auditor should discuss:

- * The quality policy (ISO 9001:2015, Clause 5.2.1), ensuring that it is established, communicated, and understood.
- * Internal audits (ISO 9001:2015, Clause 9.2), verifying that they are planned and effectively implemented.

These discussions help assess leadership commitment and the effectiveness of the QMS.

NEW QUESTION # 77

According to ISO 9000, what is quality?

- A. A set of conditions under which work is performed
- B. The efficiency with which resources are utilized in achieving objectives
- C. The ability of an object to realize an output that will fulfill the requirements for that output
- D. The degree to which a set of inherent characteristics of an object fulfills requirements

Answer: D

Explanation:

Comprehensive and Detailed In-Depth Explanation:

ISO 9000:2015 defines quality as "the degree to which a set of inherent characteristics of an object fulfills requirements." Clause 3.6.2 (Quality) confirms this definition.

Quality is determined by how well an object (product, service, or process) meets defined requirements (customer, regulatory, or internal).

The other options do not align with the official ISO definition:

Option A refers to performance capability but does not define quality.

Option C describes work conditions, not quality.

Option D focuses on efficiency rather than fulfilling requirements.

Reference:

ISO 9000:2015, Clause 3.6.2 - Quality

NEW QUESTION # 78

You are a member of the audit team of a second-party audit of an organisation with 625 employees. The audit procedure recommends using sampling criteria which requires the review of the documented competence for 25 personnel. The audit team leader developed an audit plan allocating one hour to audit the Human Resources department (from 11:30 am to 12:30 pm). She told you that she could not allocate any additional time.

What would you do?

- A. Plan to review less than 25 cases.
- B. Plan to review as many as possible and see if you can extend the audit duration by one day.

- C. Extend the audit until 1.00pm and ask for a quick lunch later.
- D. Plan to miss lunch and review as many as possible.

Answer: A

Explanation:

In this scenario, the time allocated by the audit team leader for the Human Resources audit is fixed, and as an auditor, you must work within that constraint. Although the sampling criteria suggests reviewing 25 personnel files, it is acceptable to adjust the sample size based on time and resource limitations. ISO 9001:2015 emphasizes risk-based thinking and practical resource management (Clause 7.1), so it is reasonable to review a smaller sample if the time is insufficient.

Option B is a pragmatic approach, allowing you to focus on quality over quantity by reviewing as many cases as time allows without compromising the audit schedule.

Options like extending the audit (A, C, D) are impractical in a structured audit environment, especially for second-party audits where maintaining the agreed schedule is important.

NEW QUESTION # 79

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.

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Answer:

Explanation:

Step	Clause
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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
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Explanation:

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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:

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- * We found a suitable supplier.
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- * 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 # 80

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