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

Topic	Details
Topic 1	<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 2	<ul style="list-style-type: none">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 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.

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PECB QMS ISO 9001:2015 Lead Auditor Exam Sample Questions (Q35-Q40):

NEW QUESTION # 35

What are the criteria for reviewing documented information?

- A. Language of documented information, internal audit reports, client feedback
- B. Archive, volume, and confidentiality of documented information
- C. Content, format, and the procedure for managing documented information

Answer: C

Explanation:

Comprehensive and Detailed In-Depth Explanation: According to ISO 9001:2015, Clause 7.5.2 (Creating and Updating Documented Information), the criteria for reviewing documented information include:

- * Content - The accuracy and relevance of the information.
- * Format - Ensuring readability and proper structuring (e.g., language, versioning).
- * Procedure for managing documented information - Ensuring control, access, and updates.

Other options, such as internal audit reports and client feedback, are important for overall QMS evaluation but are not the main criteria for reviewing documented information.

NEW QUESTION # 36

Below are four of the seven principles on which ISO 9000 series are based. Match a potential benefit to each of the quality management principles (QMP).

□

Answer:

Explanation:

□ Explanation:

Quality management principles:

Customer focus = Increased revenue and market share

Engagement of people = Enhanced trust and collaboration throughout the organisation

Improvement = Enhanced drive for innovation

Evidence-based decision-making = Increased ability to demonstrate effectiveness of past actions According to the Quality management principles document published by ISO, each quality management principle has a statement, a rationale, key benefits, and actions you can take to apply it. Based on these descriptions, the potential benefits can be matched to the corresponding principles as follows:

Customer focus: The primary focus of quality management is to meet customer requirements and to strive to exceed customer expectations. The key benefits of this principle include increased customer value, customer satisfaction, customer loyalty, repeat business, reputation, customer base, revenue and market share.

Engagement of people: Competent, empowered and engaged people at all levels throughout the organization are essential to enhance its capability to create and deliver value. The key benefits of this principle include improved understanding of the organization's objectives and values, increased involvement in improvement activities, enhanced personal development, increased motivation and empowerment, enhanced trust and collaboration, and increased recognition and rewards.

Improvement: Successful organizations have an ongoing focus on improvement. The key benefits of this principle include improved organizational capabilities, alignment of improvement activities at all levels, increased ability to anticipate and react to opportunities and threats, enhanced drive for innovation, and increased levels of satisfaction.

Evidence-based decision-making: Decisions based on the analysis and evaluation of data and information are more likely to produce desired results. The key benefits of this principle include improved decision-making processes, increased ability to demonstrate the effectiveness of past decisions, increased ability to review, challenge and change opinions and decisions, and increased ability to improve performance.

NEW QUESTION # 37

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.

Answer:

Explanation:

Explanation:

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 # 38

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. Training courses are offered either as open courses, delivered at a public venue, or online, or as courses that are tailored to meet specific requirements.

The business operates from a single office and those who deliver the training are either full-time employees or subcontractors.

You have just completed the opening meeting. You are interviewing the Managing Director (MD).

You: "Good morning. I would like to gain an understanding of your business and its strategic direction." MD: "Of course. We are facing challenging times. The market is extremely competitive, and customers typically look for the least expensive option when arranging health and safety training. Our annual sales revenue has struggled to grow over the past two years. Most of our employed trainers are planning to retire over the next 12 months, and we are looking for more subcontract trainers. Achieving ISO 9001 certification will, I hope, give us the capability to improve our operational performance. Also, many of our competitors do not have any form of management system certification, so I hope it will give us that competitive edge needed to secure orders. We intend to promote our ISO 9001 certification on our website and across all other customer-facing media." Which three of the following audit trails would you take to explore the extent to which external and internal issues have been determined and used to enable the business to achieve the intended result(s) of its quality management system?

- A. Establish how the organisation specifies the structure for the training rooms.
- B. Establish how the organisation determines its relevant interested parties.
- C. Establish how the organisation determines subcontractor trainer competence.
- D. Establish how the organisation determined the scope of its quality management system.

- E. Establish how the organisation reviews information about external and internal issues.
- F. Establish how the organisation documents its external and internal issues.
- G. Establish how the organisation maintains its training products up to date.
- H. Establish how the organisation determines employed trainer competence.

Answer: B,E,F

Explanation:

ISO 9001:2015 requires organisations to determine external and internal issues relevant to their purpose and strategic direction and to use this understanding to support planning and achievement of intended QMS results.

The key requirement is Clause 4.1 - Understanding the organisation and its context, supported by Clause 4.2 - Understanding the needs and expectations of interested parties.

Explanation of the correct audit trails:

- A). Establish how the organisation determines its relevant interested parties Clause 4.2 requires the organisation to determine interested parties that are relevant to the QMS and their requirements. Understanding interested parties is essential to identifying external and internal issues that influence strategic direction and QMS outcomes.
- C). Establish how the organisation documents its external and internal issues Clause 4.1 requires the organisation to determine relevant external and internal issues. While documented information is not explicitly mandated, auditors must verify how these issues are identified and captured to demonstrate systematic application and use in planning.
- D). Establish how the organisation reviews information about external and internal issues Clause 4.1 also requires the organisation to monitor and review information relating to external and internal issues. This audit trail confirms that context analysis is not static and is actively used to support QMS planning and intended results.

Explanation of why the other options are not selected:

- * B: Determining scope (Clause 4.3) uses context as an input, but does not itself demonstrate how issues are determined and used.
- * E and G: Trainer competence relates to Clause 7.2, not to determination and use of organisational context.
- * F: Maintaining training products relates to operational control, not context analysis.
- * H: Training room structure is an operational detail unrelated to external and internal issues.

ISO-aligned conclusion:

To explore how external and internal issues are determined and used to achieve intended QMS results, the auditor must follow audit trails that confirm:

- * Identification of relevant interested parties,
- * Determination and capture of issues affecting the organisation, and
- * Ongoing review of those issues to support planning and performance.

NEW QUESTION # 39

Select the words that best complete the sentence:

Answer:

Explanation:

Explanation:

According to the ISO 19011:2018 document, the audit plan should provide the basis for agreement regarding the conduct and scheduling of the audit activities. The amount of detail provided in the audit plan should reflect the scope and complexity of the audit, as well as the risk of not achieving the audit objectives¹. The scope of the audit refers to the extent and boundaries of the audit, such as the audit criteria, the audit objectives, the organizational and functional units, and the processes to be audited¹. The complexity of the audit refers to the degree of difficulty or intricacy of the audit, such as the number and diversity of the auditees, the audit criteria, the audit methods, and the audit team composition². The risk of not achieving the audit objectives refers to the possibility that the audit may fail to provide reliable and sufficient audit evidence to support the audit conclusions and report¹.

Therefore, the complete sentence is:

In the context of a third-party audit, the amount of detail provided in the audit plan should reflect the scope and complexity of the audit, as well as the risk of not achieving the audit objectives.

References: 1: ISO 19011:2018 - Guidelines for auditing management systems 2: Audit Complexity - an overview | ScienceDirect Topics

NEW QUESTION # 40

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