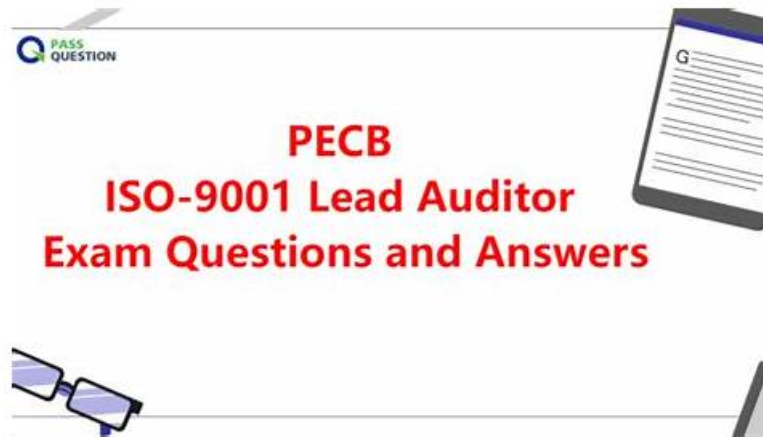


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PECB QMS ISO 9001:2015 Lead Auditor Exam Sample Questions (Q39-Q44):

NEW QUESTION # 39

The following list gives examples of records that may be evidence of how an organisation has fulfilled the requirements of clause 8.4 of ISO 9001. Match the records to the appropriate requirement of clause 8.4.

Answer:

Explanation:

Explanation:

The following table shows the possible matching of the records to the requirements of clause 8.4:

Table
Requirements
Records
Define product requirements
Product specification
Criteria for selection
List of requirements to be met by the external provider
Evaluation of potential external provider
External provider questionnaire
External provider selection
Approved external provider list
Communicate requirements
Purchase order
Monitoring of performance
External provider delivery times and quality issues

Comprehensive and Detailed Explanation: = According to clause 8.4 of ISO 9001:2015, the organization should ensure that externally provided processes, products, and services conform to the specified requirements. To do so, the organization should: Define the product requirements that are relevant for the external provision, such as specifications, drawings, standards, codes, etc. These should be documented and communicated to the external provider. A record of the product specification can be used as evidence of this requirement.

Establish the criteria for the selection, evaluation, and re-evaluation of external providers, based on their ability to provide processes, products, and services in accordance with the requirements. The criteria should be documented and applied consistently. A record of the list of requirements to be met by the external provider can be used as evidence of this requirement.

Evaluate the potential external providers before selecting them, using the established criteria. The evaluation methods may include questionnaires, audits, references, samples, etc. The results of the evaluation should be documented and reviewed. A record of the external provider questionnaire can be used as evidence of this requirement.

Select the external providers that have demonstrated their competence and conformity to the requirements. The selection should be based on the evaluation results and the organization's needs. The selection should be documented and approved. A record of the approved external provider list can be used as evidence of this requirement.

Communicate the requirements for the processes, products, and services to be provided by the external provider, including the verification and validation activities, the acceptance criteria, the documentation requirements, the changes control, etc. The communication methods may include purchase orders, contracts, agreements, etc. The communication should be clear, complete, and timely. A record of the purchase order can be used as evidence of this requirement.

Monitor the performance and conformity of the external provider, using the established criteria and methods. The monitoring methods may include inspections, tests, audits, feedback, complaints, etc. The monitoring results should be documented and analyzed. A record of the external provider delivery times and quality issues can be used as evidence of this requirement.

References: ISO 9001:2015, [ISO 9001 Auditing Practices Group Guidance on Scope], Mastering the Scope of ISO 9001 Quality Management Systems

NEW QUESTION # 40

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

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

Answer: A,D

Explanation:

According to the ISO 9001:2015 document, the organisation must continually improve the suitability, adequacy, and effectiveness of the quality management system. 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. One of the key benefits of applying this principle is improving operational effectiveness and efficiency. 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 # 41

You are carrying out an annual audit at an organisation that offers home security services. You are interviewing the Quality Manager (QM) You: "Would you tell me about your management review process?" QM: "The senior management team plans to review the management system every six months. The review follows a set agenda and records are maintained." You: "May I see the records from the last two management reviews?" Narrative: The Quality Manager gives you the latest record, which shows the last management review took place nine months ago.

The Quality Manager then gives you the previous management review record, which took place one year before the latest review.

You: "Are there any other review reports in the last two years?"

QM: "No, these are the only ones."

Answer:

Explanation:

Explanation:

Nonconformity report

ISO 9001 Clause Number: 9.3.1 Nature of problem: Management review has not been conducted at the defined frequency. ISO 9001 requirement that has not been fulfilled: ISO 9001 - "Top management shall review the organization's quality management system at planned intervals." Evidence: The last management review took place nine months ago, and the previous one took place one year before the latest review. The planned interval is six months.

NEW QUESTION # 42

You are carrying out an audit at a single-site organisation seeking certification to ISO 9001 for the first time.

The organization manufactures cosmetics for major retailers and the name of the retailer supplied appears on the product packaging. Sales turnover has increased significantly over the past five years.

You are interviewing the new Product Development Manager. You note that a software application called SWIFT is used to help control the product development process.

You have gathered audit evidence as outlined in the table. Match the ISO 9001 clause 8.3 extracts to the audit evidence.

Answer:

Explanation:

□

NEW QUESTION # 43

The ISO 9001 clause 5.1.1 states top management shall demonstrate leadership and commitment with respect to the quality management system.

In the context of the ISO 9001 management system certification, select the one correct description of top management's responsibilities.

- A. Top management needs only to comply with 50% of the 5.1.1 requirements.
- B. Depending on the organization's available resources, top management can comply with one or more of the 5.1.1 requirements.
- C. Depending on the size, complexity and business context, some of the 5.1.1 requirements can be excluded.
- **D. Top management shall ensure that all requirements are fulfilled.**

Answer: D

NEW QUESTION # 44

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