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

Topic	Details

Topic 1	• 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.
Topic 2	• Closing an ISO 9001 audit: The topic focuses on concluding a QMS audit and conducting audit follow-up activities.
Topic 3	• Conducting an ISO 9001 audit: It evaluates your skills to conduct a QMS audit.
Topic 4	• Preparing an ISO 9001 audit: This topic covers sub-topics related to preparing a quality management system audit.

PECB QMS ISO 9001:2015 Lead Auditor Exam Sample Questions (Q110-Q115):

NEW QUESTION # 110
Who maintains ownership of the audit report?

- A. The auditee
- B. The certification body
- C. The audit team leader

Answer: B

Explanation:
Comprehensive and Detailed In-Depth Explanation:
According to ISO 17021-1:2015, Clause 9.4.8 (Audit Reporting):
* The certification body retains ownership of the audit report as it is responsible for the certification decision.
* The auditee may receive a copy, but it does not own the report.
* The audit team leader compiles the report but does not own it.
Thus, C is the correct answer.
Reference:
ISO 17021-1:2015, Clause 9.4.8 (Audit Reporting)

NEW QUESTION # 111
You are carrying out an audit at a single-site organisation seeking certification to ISO 9001 for the first time.
The organisation offers warehousing and export services to customers. Customers are invoiced for the time stock items are stored in the warehouse. Transport to and from the warehouse is controlled by the organisation and approved subcontract transport services are used. The organization does not have its own transport vehicles. Stock items are not purchased by the organisation.
You have gathered audit evidence as outlined in the table. Match the ISO 9001 Clause 8 extract to the audit evidence.

Audit evidence	ISO 9001 Clause 8 extract
Four of the 10 pallets of stock sampled in the warehouse were not labelled.	
A damaged pallet of stock seen in the quarantine area was leaking liquid onto the floor.	
One of the fork-lift truck drivers had no fork-lift truck driving licence.	
There was no pest control provision in the warehouse.	
Two pallets of temperature-sensitive stock items were being stored at ambient as the chilled storage facility was full.	

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 Clause 8 extracts listed below. Alternatively, drag and drop each clause to the audit evidence that applies.

"8.5.2...shall use suitable means to identify outputs..."

"8.5.1 e ...shall include, as applicable...the appointment of competent persons..."

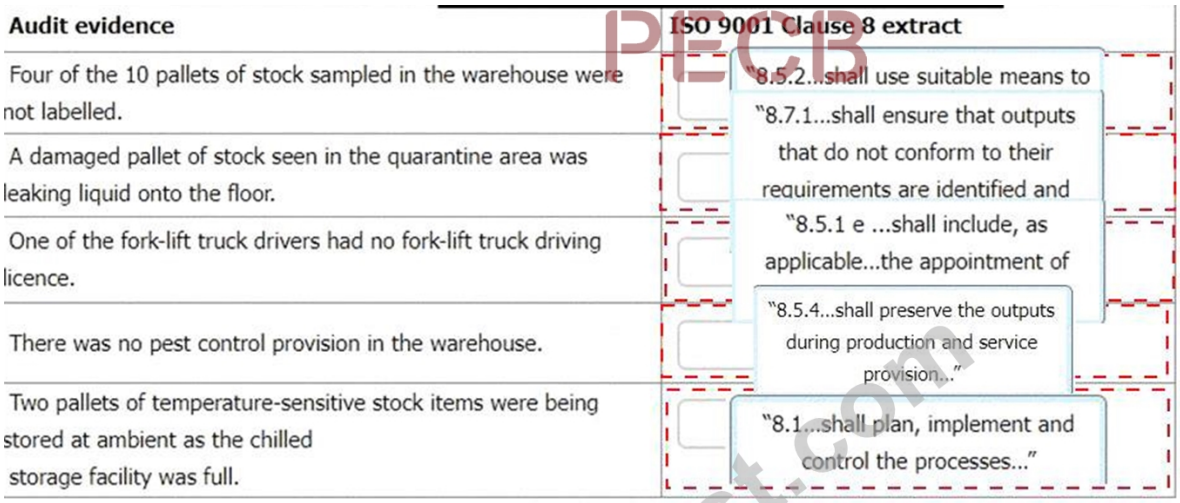
"8.1...shall plan, implement and control the processes..."

"8.7.1...shall ensure that outputs that do not conform to their requirements are identified and controlled..."

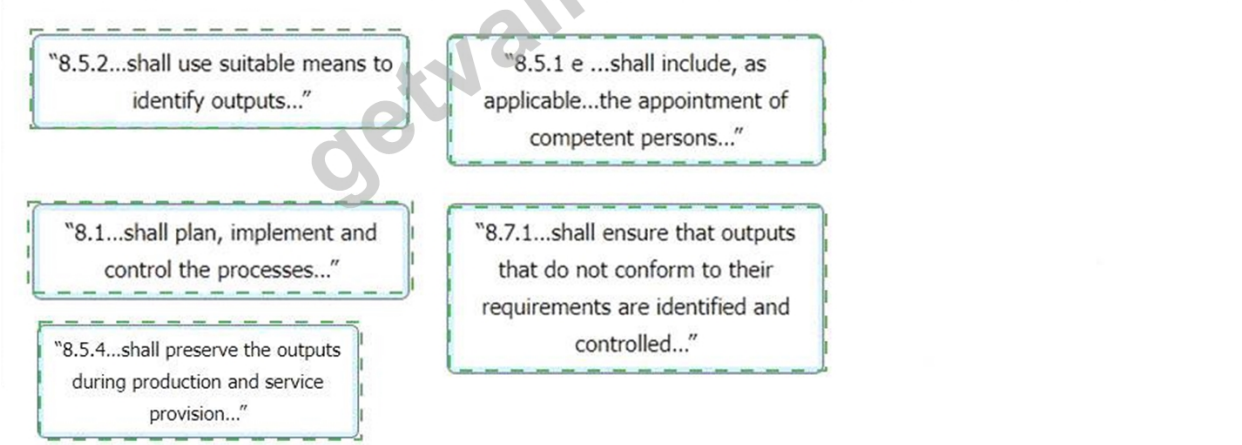
"8.5.4...shall preserve the outputs during production and service provision..."

Answer:

Explanation:



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 Clause 8 extracts listed below. Alternatively, drag and drop each clause to the audit evidence that applies.

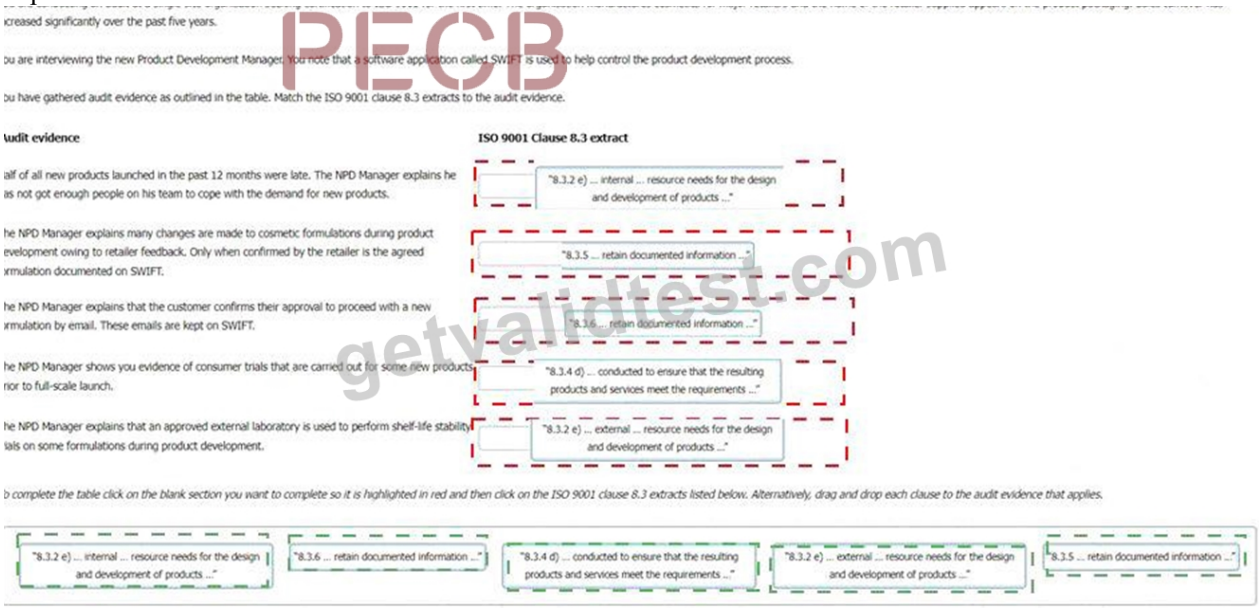


Explanation:
The table below shows the possible matching of the ISO 9001 Clause 8 extract to the audit evidence.
Table
Audit evidence
ISO 9001 Clause 8 extract
Four of the 10 pallets of stock sampled in the warehouse were not labelled.
"8.5.2 ... shall use suitable means to identify outputs ..."
A damaged pallet of stock seen in the quarantine area was leaking liquid onto the floor.
"8.7.1 ... shall ensure that outputs that do not conform to their requirements are identified and controlled ..." One of the fork-lift truck drivers had no fork-lift truck driving licence.
"8.5.1 e ... shall include, as applicable ... the appointment of competent persons ..." There was no pest control provision in the warehouse.
"8.5.4 ... shall preserve the outputs during production and service provision ..." Two pallets of temperature-sensitive stock items were being stored at ambient as the chilled storage facility was full.
"8.1 ... shall plan, implement and control the processes ..."

NEW QUESTION # 112
You are conducting an audit at a single-site organisation seeking certification to ISO 9001 for the first time.
The organisation 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:



Explanation:

Audit evidence	ISO 9001 Clause 8.3 extract
Half of all new products launched in the past 12 months were late. The NPD Manager explains he has not got enough people on his team to cope with the demand for new products.	"8.3.2 e) ... internal ... resource needs for the design and development of products ..."
The NPD Manager explains many changes are made to cosmetic formulations during product development owing to retailer feedback. Only when confirmed by the retailer is the agreed formulation documented on SWIFT.	"8.3.5 ... retain documented information ..."
The NPD Manager explains that the customer confirms their approval to proceed with a new formulation by email. These emails are kept on SWIFT.	"8.3.6 ... retain documented information ..."
The NPD Manager shows you evidence of consumer trials that are carried out for some new products prior to full-scale launch.	"8.3.4 d) ... conducted to ensure that the resulting products and services meet the requirements ..."
The NPD Manager explains that an approved external laboratory is used to perform shelf-life stability trials on some formulations during product development.	"8.3.2 e) ... external ... resource needs for the design and development of products ..."

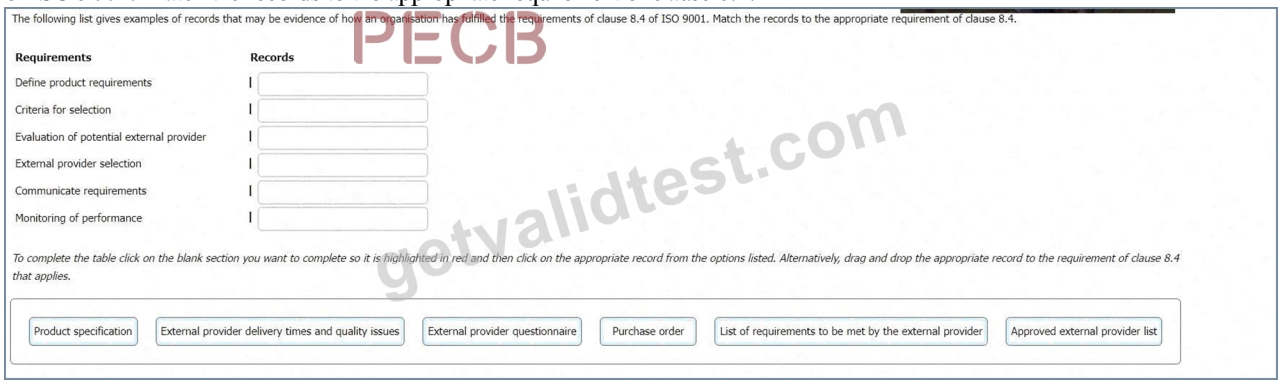
The table below shows the possible matching of the ISO 9001 Clause 8.3 extract to the audit evidence.

Table

Audit evidence

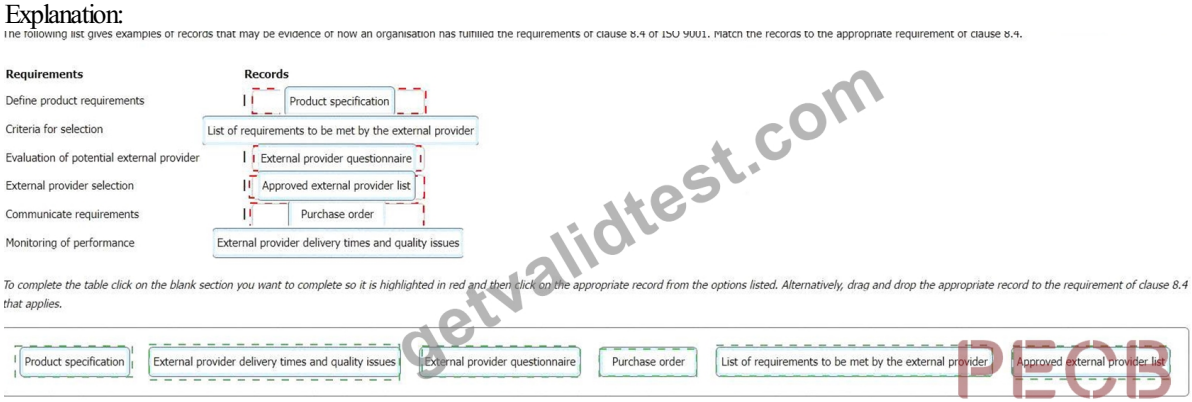
ISO 9001 Clause 8.3 extract
Half of all new products launched in the past 12 months were late. The NPD Manager explains he has not got enough people on his team to cope with the demand for new products.
"8.3.2 e) ... internal ... resource needs for the design and development of products ..." The NPD Manager explains many changes are made to cosmetic formulations during product development owing to retailer feedback. Only when confirmed by the retailer is the agreed formulation documented on SWIFT.
"8.3.5 ... retain documented information ..."
The NPD Manager explains that the customer confirms their approval to proceed with a new formulation by email. These emails are kept on SWIFT.
"8.3.6 ... retain documented information ..."
The NPD Manager shows you evidence of consumer trials that are carried out for some new products prior to full-scale launch.
"8.3.4 d) ... conducted to ensure that the resulting products and services meet the requirements ..." The NPD Manager explains that an approved external laboratory is used to perform shelf-life stability trials on some formulations during product development.
"8.3.2 e) ... external ... resource needs for the design and development of products ..."

NEW QUESTION # 113
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 # 114

You are conducting an ISO 9001 audit of a Materials Recycling Facility (MRF). The organisation processes waste plastics into raw materials for plastic bottle manufacturers. You reach the manual picking line where operators are removing contaminant materials from incoming products, such as plastic bags, plastic film and badly contaminated items that would compromise the recycling process. You interview the line supervisor.
You: "Why are these plastic items being rejected at this stage?"
Auditee: "They do not meet our processing standards."
You: "What is the reason for that?"
Auditee: "These items are likely to damage the machinery down the line. They can also compromise our quality standards. We need to protect our reputation for good quality output materials." You: "What happens to the rejected items?" Auditee: "Some get melted down in another process later on and some are disposed of as waste products that cannot be recycled." You: "What happens to the waste products?" Auditee: "I'm not sure. I suppose they go to landfill." Which two. of the following actions would you take to investigate further?

- A. Check the process for handling nonconforming items.
- B. Determine whether there are quality objectives for reducing rejected material.
- C. Ask to review the percentage of waste materials.
- D. Determine what happens to the waste products.
- E. Ask about operator PPE (Personal Protective Equipment).
- F. Find out if operators have regular hearing tests.

Answer: A,D

Explanation:
According to the ISO 9001:2015 standard, clause 8.7 requires that an organization identify and control any nonconforming outputs that do not conform to the requirements of the customer or other relevant requirements. Nonconforming outputs are any outputs from the process, product or service that do not meet the specified quality criteria. Nonconforming outputs must be dealt with in one or more of the following ways:
Correction of the nonconformity
Segregation, containment, return or suspension of provision of products and services Informing the customer Authorisation for acceptance under concession The organization must also retain documented information on the description of the nonconformity, the actions taken, any concessions obtained, and the identification of the authority deciding the action to resolve the nonconformity.
In this scenario, you have interviewed a line supervisor who is responsible for managing a manual picking line where operators are removing contaminant materials from incoming products. The supervisor has explained that these plastic items are rejected at this stage because they do not meet their processing standards and they can damage their machinery and compromise their quality standards. The supervisor has also mentioned that some of these rejected items are melted down in another process later on and some are disposed of as waste products that cannot be recycled.
Based on this information, you can investigate further by taking two actions:
A: Check the process for handling nonconforming items: You can verify whether there is a documented procedure for identifying, segregating, containing, returning or suspending provision of nonconforming items at this stage. You can also check whether there is a system for informing customers about any nonconforming items that may affect their satisfaction or expectations.
D: Determine what happens to the waste products: You can verify whether there is a documented procedure for disposing of waste products that cannot be recycled as per environmental regulations and customer requirements.
These two actions would help you to determine whether there are any nonconforming outputs at this stage and how they are controlled by the organization.

NEW QUESTION # 115
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