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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	• 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 4	• Managing an ISO 9001 audit program: This topic evaluates your abilities to establish and managing a QMS audit program.
Topic 5	• Preparing an ISO 9001 audit: This topic covers sub-topics related to preparing a quality management system audit.
Topic 6	• 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.

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PECB QMS ISO 9001:2015 Lead Auditor Exam Sample Questions (Q109-Q114):

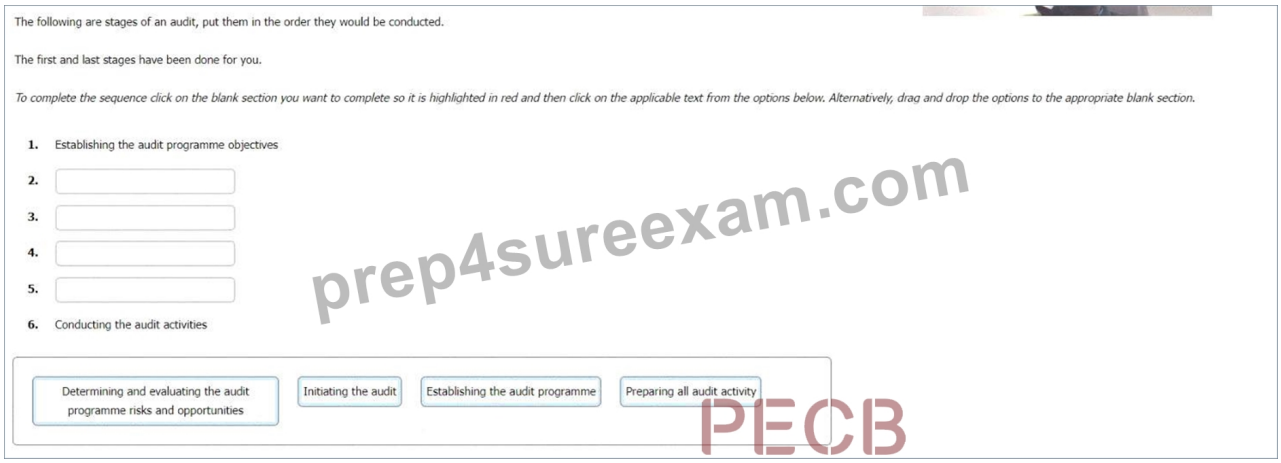
NEW QUESTION # 109
Select the term that best describes the purpose of retaining documented information in a quality management system to ISO 9001.

- 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 support the operation of the processes of the quality management system.
- D. To safeguard the integrity of the quality management system.

Answer: C

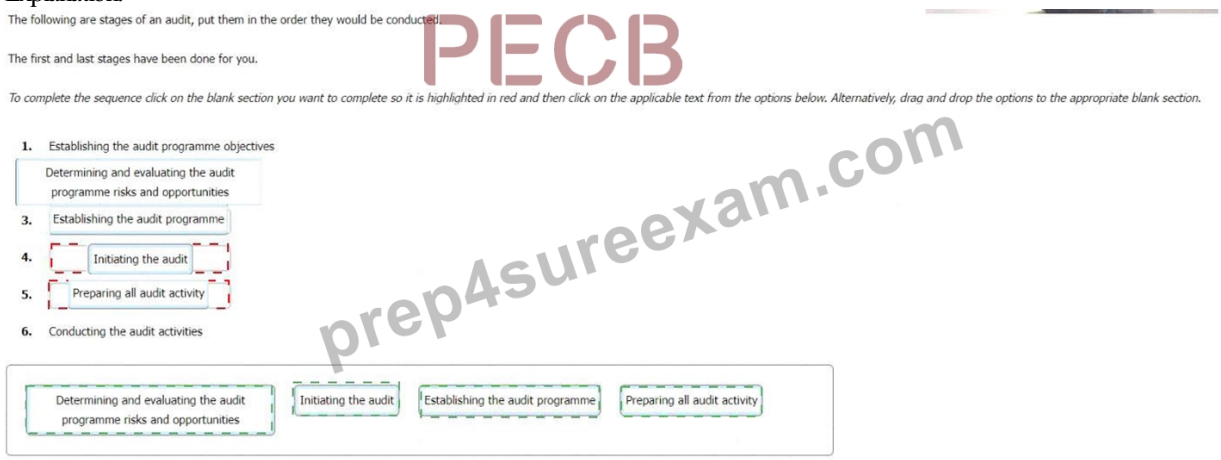
Explanation:
Documented information is a means by which an organization demonstrates compliance. It communicates what we do and how we do things, it communicates what happened and what results were achieved. It is, essentially, a tool for communication. ISO 9001:2015 allows an organization flexibility 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 # 110
The following are stages of an audit, put them in the order they would be conducted.

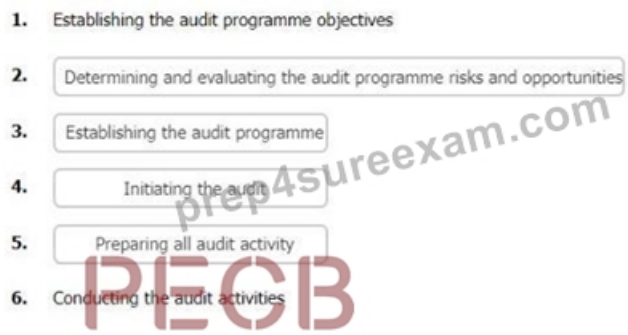


Answer:

Explanation:



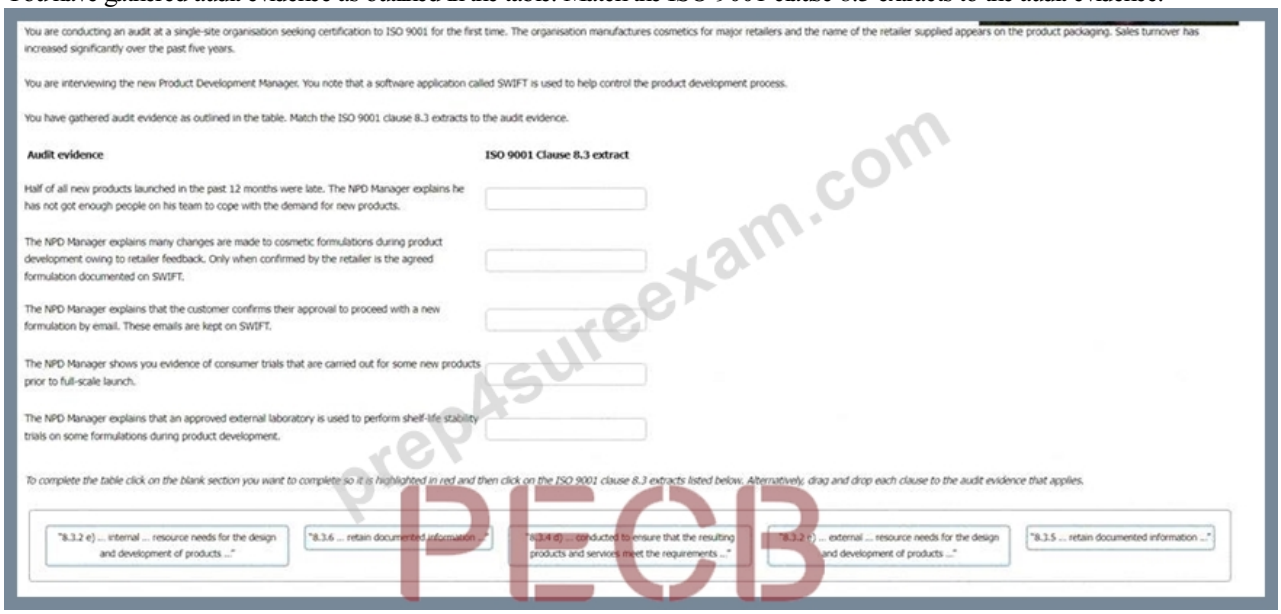
Explanation:



Establishing the audit programme objectives
Determining and evaluating the audit programme risks and opportunities
Establishing the audit programme
Initiating the audit
Preparing all audit activity
Conducting the audit activities
To complete the sequence, you can drag and drop the options to the appropriate blank section.
Here is a brief explanation of each stage:
Establishing the audit programme objectives: This is the first stage of the audit process, where the purpose, scope, and criteria of the audit programme are defined. The audit programme objectives should be aligned with the strategic direction and policies of the organization, and should address the needs and expectations of the interested parties12.
Determining and evaluating the audit programme risks and opportunities: This is the second stage of the audit process, where the factors that can affect the achievement of the audit programme objectives are identified and assessed. The audit programme risks and opportunities should consider the internal and external issues, the requirements and changes of the interested parties, and the results and feedback from previous audits12.
Establishing the audit programme: This is the third stage of the audit process, where the audit programme is designed and implemented. The audit programme should include the audit programme procedures, the audit programme resources, the audit

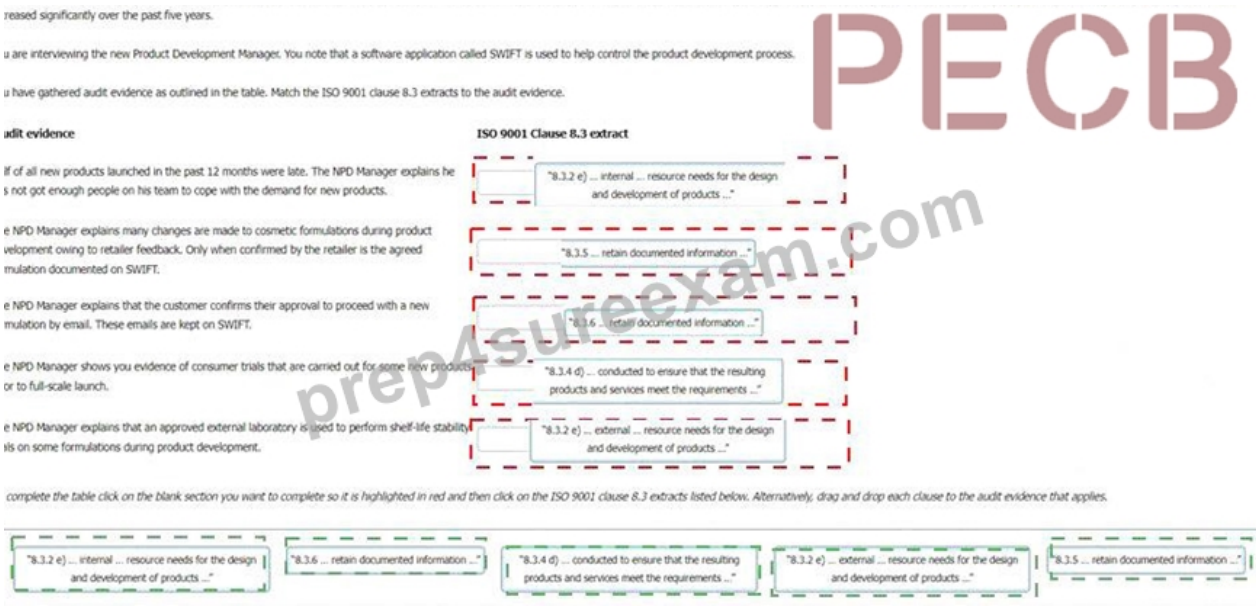
methods and techniques, the audit frequency and schedule, and the audit programme performance indicators12.
Initiating the audit: This is the fourth stage of the audit process, where the audit is prepared and planned. The audit initiation involves selecting the audit team, establishing the contact with the auditee, defining the audit objectives, scope, and criteria, developing the audit plan, and conducting the document review123.
Preparing all audit activity: This is the fifth stage of the audit process, where the audit activities are organized and coordinated. The audit preparation involves assigning the audit tasks, communicating with the auditee and the audit team, arranging the logistics, preparing the working documents, and conducting the opening meeting123.
Conducting the audit activities: This is the sixth and final stage of the audit process, where the audit evidence is collected and evaluated. The audit conduct involves performing the audit activities, such as interviews, observations, document reviews, and tests, documenting the audit findings, preparing the audit conclusions, and conducting the closing meeting123.
I hope this helps you with your ISO 9001 Lead Auditor objectives and content. If you have any further questions, please feel free to ask. # References: 1: ISO 19011:2018 - Guidelines for auditing management systems 2: Audit Process | Flowchart | Summary - Accountinguide 3: What are the Stages of the Auditing Process & Why it is Important ...

NEW QUESTION # 111
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.

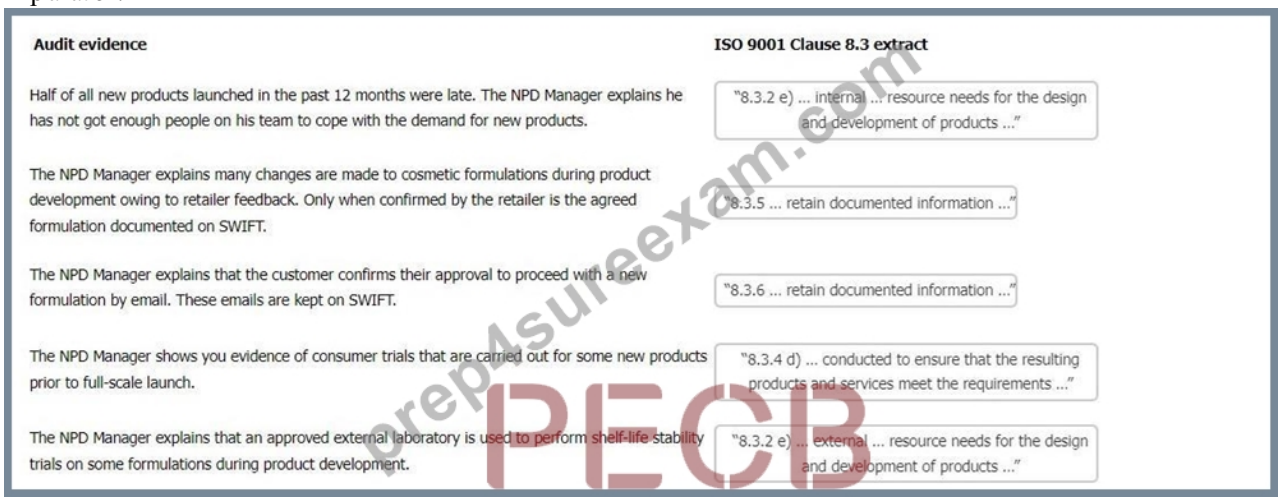


Answer:

Explanation:



Explanation:



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 # 112

Scenario 6: Davis Clinic (DC) is an American medical center focused on integrated health care. Since its establishment DC was committed to providing qualitative services for its clients, which is the reason why the company decided to implement a quality management system (QMS) based on ISO 9001. After a year of having an active QMS in place, DC applied for a certification audit.

A team of five auditors, from a well-known certification body, was selected to conduct the audit. Eva was appointed as the audit

team leader. After three days of auditing, the team gathered to review and examine their findings. They also discussed the audit findings with DC's top management and then drafted the audit conclusions.
In the closing meeting, which was held between the audit team and the top management of DC. Eva presented two nonconformities that were detected during the audit. Eva stated that the company did not retain documented information regarding its outsourced services for an analysis laboratory and regarding the conducted management reviews. During the closing meeting, the audit team required from DCs top management to come up with corrective action plans within two weeks. Although the top management did not agree with the audit findings, the audit team insisted that the auditee must submit corrective actions within the given time frame in order for the audit activities to continue.
Once the action plans were evaluated, the audit team began preparing the audit report. Eva required from the team to provide accurate descriptions of the audit findings and the audit conclusions. The report was then distributed to all the interested parties involved in the audit, including the certification body Based on the report, the certification body together with Eva, as the audit team leader, made the certification decision.
Based on the scenario above, answer the following question:
The audit team delayed audit activities until DC's top management submitted their action plans. Is this acceptable?

- A. Yes, DC's top management promised the submission of action plans within a short period of time
- B. Yes, the audit report can be prepared once the auditee submits the action plans in cases of minor nonconformities
- C. No, the audit report should be prepared and submitted to the certification body prior to the submission of action plans by the auditee

Answer: C

Explanation:
Comprehensive and Detailed In-Depth Explanation:
According to ISO 17021-1:2015, Clause 9.4.8 (Audit Reporting):
* The audit report must be submitted to the certification body regardless of corrective actions.
* Corrective actions are reviewed after the audit, but the audit process should not be delayed.
* Certification decisions should be made based on the audit findings and evidence, not pending corrective actions.
Thus, delaying audit activities until corrective actions are submitted is not acceptable.
Reference:
ISO 17021-1:2015, Clause 9.4.8 (Audit Reporting)

NEW QUESTION # 113
How can an organization ensure the objectivity and impartiality of the internal audit function?

- A. By always outsourcing the internal audit function to a third party
- B. By assigning internal auditors that do not have operational roles related to the QMS
- C. By having a representative of top management involved during the internal audit process

Answer: B

Explanation:
Comprehensive and Detailed In-Depth Explanation:
According to ISO 19011:2018, Clause 5.1 (Impartiality):
Internal auditors must not audit areas where they have direct responsibilities to avoid conflicts of interest.
Outsourcing (C) is not required, as long as impartiality is maintained internally.
Thus, B is the correct answer.
Reference:
ISO 19011:2018, Clause 5.1 (Impartiality)

NEW QUESTION # 114
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