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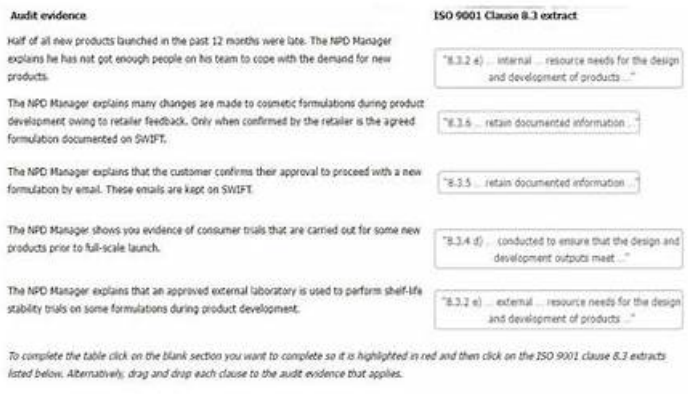

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PECB ISO-9001-Lead-Auditor Exam Syllabus Topics:

Topic	Details
Topic 1	• Closing an ISO 9001 audit: The topic focuses on concluding a QMS audit and conducting audit follow-up activities.
Topic 2	• 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	• Conducting an ISO 9001 audit: It evaluates your skills to conduct a QMS audit.
Topic 4	• Managing an ISO 9001 audit program: This topic evaluates your abilities to establish and managing a QMS audit program.

PECB QMS ISO 9001:2015 Lead Auditor Exam Sample Questions (Q106-Q111):

NEW QUESTION # 106
Which of the following three options could be considered potential threats to impartiality in an audit context?

- A. Experience
- B. Self-audit
- C. Familiarity
- D. Competence
- E. Intimidation

Answer: B,C,E

Explanation:
Questions no: 1 Verified answer: = C, D, E Comprehensive But Short Explanation: = Potential threats to impartiality in an audit context include familiarity (having a close relationship with the auditee), intimidation (being coerced or feeling pressured), and self-audit (auditing one's own work). These factors can compromise the auditor's objectivity and the audit's integrity. References: = The information is based on the ISO 9001 Auditing Practices Group documents which discuss threats to auditor impartiality and how they may compromise an auditor's objectivity123.

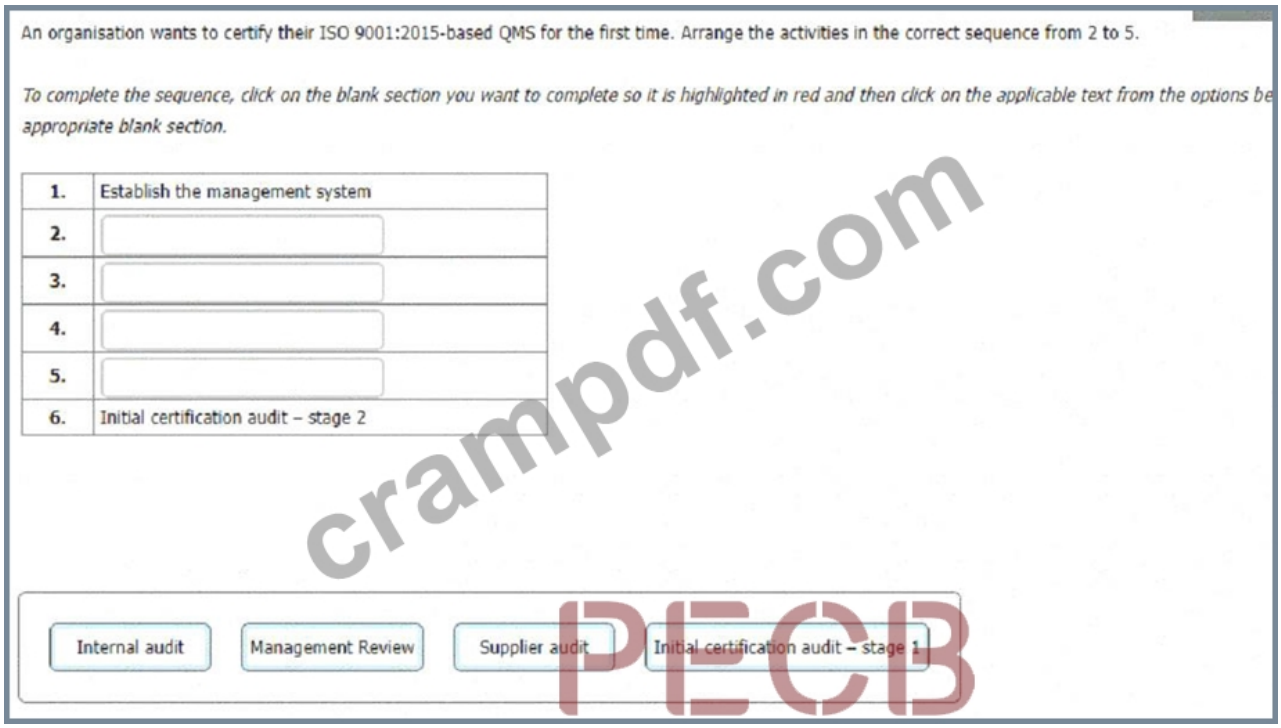
NEW QUESTION # 107
Knowledge and skills are requirements of the auditor's competence. Select two from the following topics of knowledge that apply to every member of an audit team auditing an ISO 9001 quality management system.

- A. ISO 19011 Audit principles
- B. Organisation's market sector
- C. Organisation's invoicing and profits of the last 5 years
- D. Requirements of ISO 9001
- E. Requirements of auditee's interested parties other than customers
- F. Organisation's processes

Answer: A,D

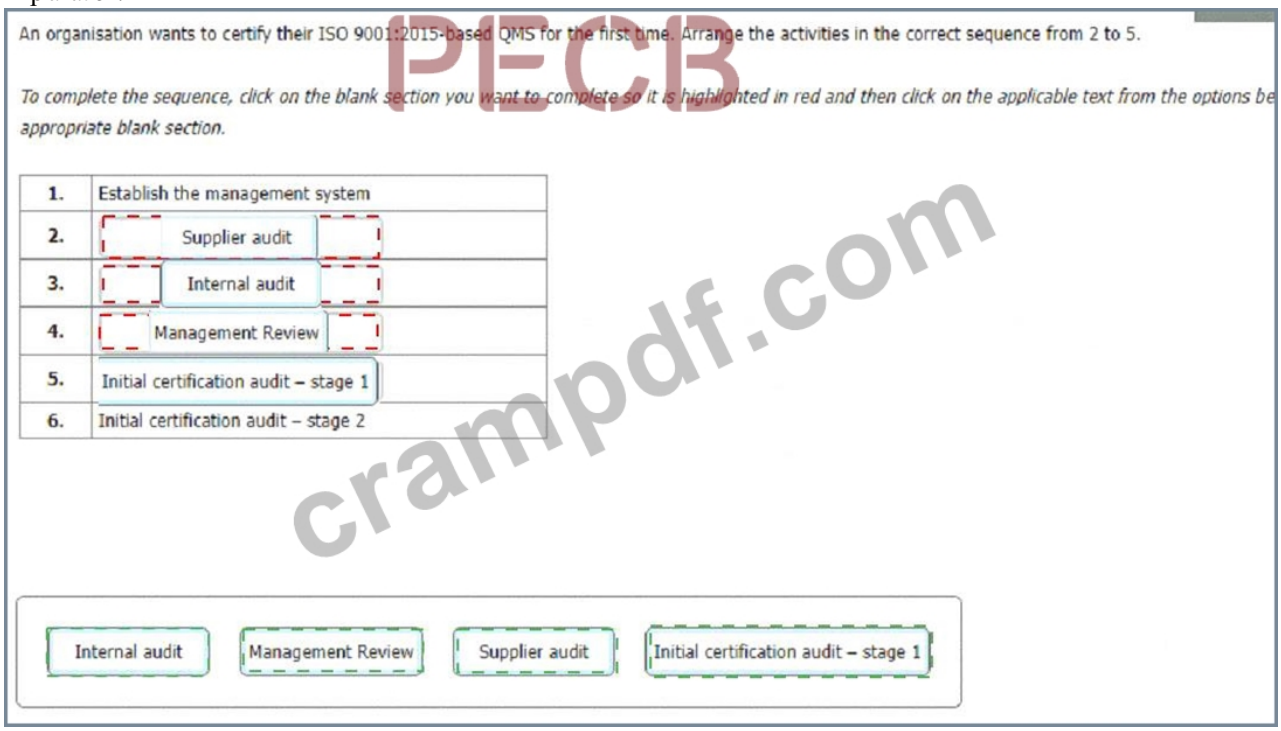
Explanation:
According to ISO 9001:2015, clause 7.2, an auditor shall have the competence to:
Understand the requirements of ISO 9001 and how they relate to the audit Understand the organization's quality management system and its processes Understand the applicable legal, regulatory, contractual and other requirements that affect the audit Understand the needs and expectations of interested parties other than customers Plan and conduct audits in accordance with ISO 19011 Evaluate audit evidence and draw appropriate conclusions Communicate audit findings effectively1 Therefore, knowledge of ISO 9001 requirements and ISO 19011 audit principles are essential for every member of an audit team auditing an ISO 9001 quality management system.
References:
ISO 9001:2015 - Quality management systems - Requirements
ISO 19011:2018 - Guidelines for auditing management systems

NEW QUESTION # 108
An organisation wants to certify their ISO 9001:2015-based QMS for the first time. Arrange the activities in the correct sequence from 2 to 5.
To complete the sequence, click on the blank section you want to complete so it is highlighted in red and then click on the applicable text from the options below. Alternatively, drag and drop the options to the appropriate blank section.



Answer:

Explanation:



Explanation:

To certify an organization's ISO 9001:2015-based Quality Management System (QMS) for the first time, the correct sequence of activities would be:

* Establish the management system (already in place).
* Supplier audit
* Internal audit
* Management review
* Initial certification audit - stage 1
* Initial certification audit - stage 2 (already in place).

This sequence follows the typical path for preparing and ensuring that a QMS is functioning as required, leading up to certification.

NEW QUESTION # 109
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.
You are interviewing the Manufacturing Manager (MM).
You: "I would like to begin by looking at the cleaning controls."
MM: "We record the cleaning of the equipment at the end of every batch. This document details the minimum cleaning frequency and the procedures to follow for all areas and each item of equipment. The person who carries out the cleaning puts their initial on the document and records the time and date alongside." Narrative: You sample production records over 3-days and note down evidence of nonconformity as per the table below.

Date	Batches of product made	Production line to be cleaned	Cleaned by	Number of cleaning records
10/XX	10	Line 1	DS	6
	14	Line 2	HM	8
11/XX	12	Line 1	WR	7
	12	Line 2	DD	9
12/XX	15	Line 1	DS	10

You decide to raise a nonconformity.

Nonconformity report	
ISO 9001 Clause Number:	
Nature of problem:	
ISO 9001 requirement that has not been fulfilled:	
Evidence:	40 cleaning records are available for 63 batches.

To complete the nonconformity report click on the blank section you want to complete so it is highlighted in red and then click on the applicable text from the options below. Alternatively, you may drag and drop the options to the appropriate blank section.

Cleaning and sanitising not always completed.

ISO 9001 - "The organization shall implement planned arrangements, at appropriate stages, to verify that the product requirements have been met."

Cleaning and sanitising records are not available for every batch.

8.7

8.5.4

ISO 9001 - "The organization shall preserve the outputs during production provision to the extent necessary to ensure conformity to requirements."

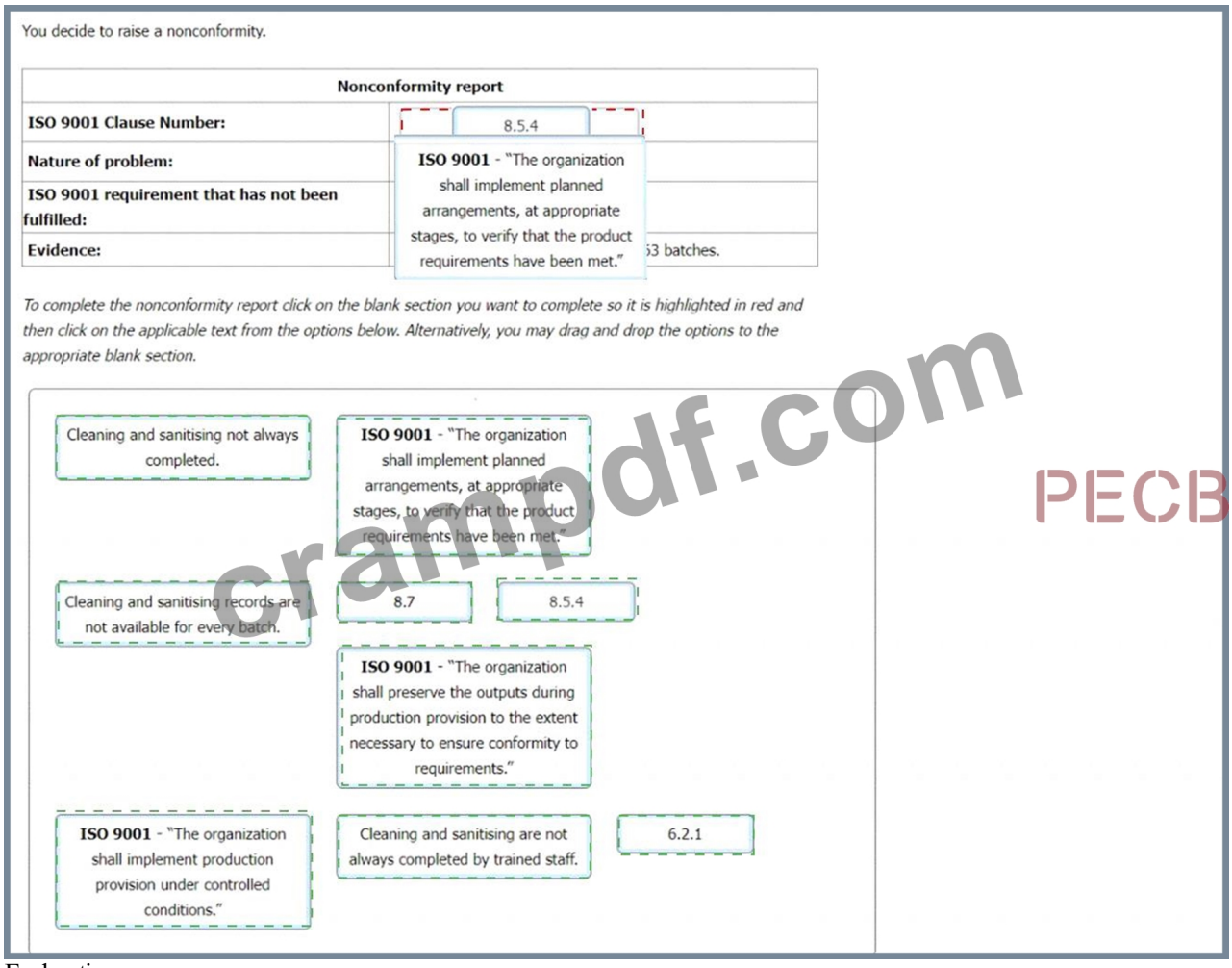
ISO 9001 - "The organization shall implement production provision under controlled conditions."

Cleaning and sanitising are not always completed by trained staff.

6.2.1

Answer:

Explanation:



Explanation:
Nonconformity report
ISO 9001 Clause Number: 8.5.4 Nature of problem: Cleaning and sanitising records are not available for every batch. ISO 9001 requirement that has not been fulfilled: ISO 9001 - "The organization shall implement planned arrangements, at appropriate stages, to verify that the product requirements have been met." Evidence: 40 cleaning records are available for 63 batches.

NEW QUESTION # 110
What should the auditor document during the Stage 1 audit?

- A. The main processes of the auditee
- B. The observations that could result in nonconformities during the on-site audit
- C. The interviews with the auditee's employees

Answer: B

Explanation:
Comprehensive and Detailed In-Depth Explanation:
Stage 1 Audit (ISO 9001:2015, Clause 9.2.2) is a documentation review to assess the readiness for a Stage 2 Audit. The auditor must document:
Observations that could lead to nonconformities, ensuring they are addressed before Stage 2.
Areas needing improvement, such as missing documented information or unclear process definitions.
While understanding the auditee's main processes is important, documenting interviews is not a requirement at Stage 1.
Reference:
ISO 9001:2015, Clause 9.2.2 (Internal Audit Reporting)

NEW QUESTION # 111
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