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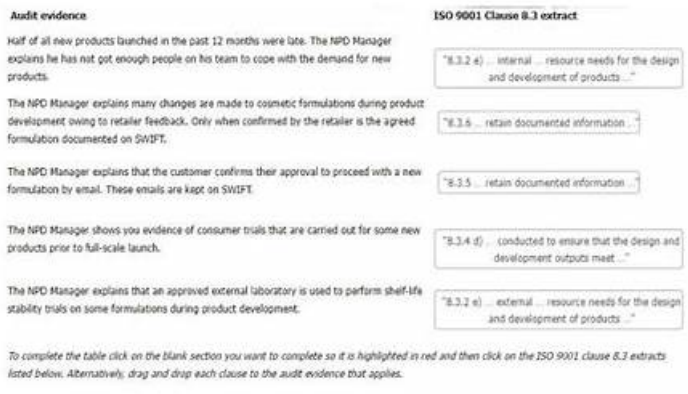

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PECB ISO-9001-Lead-Auditor Exam Syllabus Topics:

Topic	Details
Topic 1	• Preparing an ISO 9001 audit: This topic covers sub-topics related to preparing a quality management system audit.
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	• 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 4	• Closing an ISO 9001 audit: The topic focuses on concluding a QMS audit and conducting audit follow-up activities.
Topic 5	• Managing an ISO 9001 audit program: This topic evaluates your abilities to establish and managing a QMS audit program.
Topic 6	• Fundamental audit concepts and principles: Questions about interpreting and applying the main concepts and principles related to a QMS audit appear in this topic.

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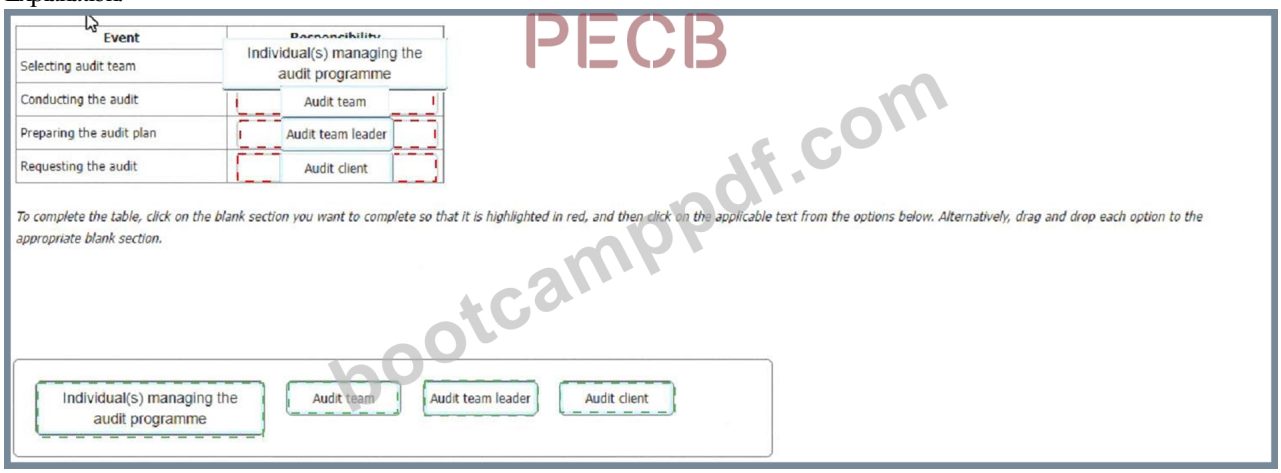
PECB QMS ISO 9001:2015 Lead Auditor Exam Sample Questions (Q53-Q58):

NEW QUESTION # 53
In the context of a third-party audit, match the event with the responsibility for conducting it.

Answer:

Explanation:



Explanation:
The correct answer is:
Event
Selecting audit team = Individual(s) managing the audit programme
Conducting the audit = Audit team
Preparing the audit plan = Audit team leader
Requesting the audit = Audit client
To complete the table, click on the blank section you want to complete so that it is highlighted in red, and then click on the applicable text from the options below. Alternatively, drag and drop each option to the appropriate blank section. Responsibility:- Individual(s) managing the audit programme Audit team Audit team leader Audit client According to ISO 19011:2018, clause 5.3, the individual(s) managing the audit programme are responsible for selecting the audit team, taking into account the competence and availability of the auditors and any experts needed. 1 According to clause 6.2, the audit team is responsible for conducting the audit, which includes collecting and verifying audit evidence, evaluating audit findings, and preparing the audit report. 1 According to clause 6.1, the audit team leader is responsible for preparing the audit plan, which includes defining the audit objectives, scope, criteria, and duration, as well as assigning roles and responsibilities to the audit team members. 1 According to clause 5.2, the audit client is the person or organization that requests the audit, which can be the auditee (the person or organization being audited) or any other person or organization that has an interest in the audit results. 1 References:
1: ISO 19011:2018 - Guidelines for auditing management systems

NEW QUESTION # 54
Scenario 4:
TD Advertising is a print management company based in Chicago. The company offers design services, digital printing, storage, and distribution. As TD expanded, its management recognized that success depended on adopting new technologies and improving quality.
To ensure customer satisfaction and quality improvement, the company decided to pursue ISO 9001 certification.
After implementing the QMS, TD hired a well-known certification body for an audit. Anne Key was appointed as the audit team leader. She received a document listing the audit team members, audit scope, criteria, duration, and audit engagement limits. Anne reviewed the document and approved the audit mandate. The certification body and TD's top management signed the certification agreement.
Before contacting TD, Anne reviewed the audit scope and noticed that TD made changes to it due to the adoption of new printing equipment. However, Anne disagreed with the changes, stating they would affect the audit timeline. She considered withdrawing from the audit.
Based on scenario 4, conducting which of the activities below is NOT the responsibility of Anne?

- A. Signing the certification agreement.
- B. Determining the audit feasibility.
- C. Establishing audit criteria and objectives.
- D. Assigning responsibilities for the audit team members.

Answer: A

Explanation:
Comprehensive and Detailed In-Depth Explanation:
ISO 9001:2015 requires specific roles and responsibilities for audit leaders and certification bodies.
Clause References:
* ISO 19011:2018, Clause 5.5 - Conducting the Audit: Defines audit team leader responsibilities.
* ISO/IEC 17021-1:2015, Clause 9.1.2 - Audit Planning: Defines certification body responsibilities, including the certification agreement.
Why is the Correct Answer D?
* The certification agreement is signed between the certification body and the auditee (TD Advertising).
* Anne (audit team leader) does NOT have authority to sign the agreement-that is the responsibility of the certification body's management.
Why are the Other Options Incorrect?
* A (Establishing audit criteria and objectives) # Correct responsibility of the audit leader as per ISO 19011.
* B (Determining audit feasibility) # Audit leaders assess feasibility but do not sign agreements.
* C (Assigning responsibilities for the audit team) # This is part of the audit leader's role in planning audits.

NEW QUESTION # 55
XYZ Corporation employs 100 people, and during a Stage 1 certification audit, certain issues are identified with the Quality Management System (QMS). Which two options describe the circumstances in which you could raise a nonconformity against Clause 6.2 of ISO 9001:2015?

- A. The organisation cannot afford to undertake quality objectives all at once.
- B. The consultant has not interpreted ISO 9001 correctly.
- C. Quality objectives were not established in alignment with the organisation's quality policy.
- D. Quality objectives are not maintained as documented information.
- E. Quality objectives are not being implemented by the organisation's personnel.
- F. Establishing quality objectives did not include top management.

Answer: C,D

Explanation:
* Understanding Clause 6.2 of ISO 9001:2015:Clause 6.2 (Quality Objectives and Planning to Achieve Them) specifies that organizations must:
* Establish measurable and relevant quality objectives consistent with the quality policy (Clause 6.2.1).
* Include objectives applicable to product/service conformity and customer satisfaction.
* Document these objectives and their planning as documented information (Clause 6.2.1 &

6.2.2).
* Plan how to achieve the objectives, including defining actions, resources, responsibilities, timelines, and methods for evaluation.
* Analysis of Options:
* A. Quality objectives are not being implemented by the organisation's personnel:Incorrect.
While implementation is critical, this relates more to operational aspects rather than the direct requirements of Clause 6.2. Implementation issues would typically raise concerns under Clause
9.1 (Performance Evaluation).
* B. The consultant has not interpreted ISO 9001 correctly:Incorrect. The consultant's interpretation of ISO 9001 is irrelevant in terms of Clause 6.2 compliance. The focus is on whether the organization aligns with the requirements, not the consultant's role.
* C. Establishing quality objectives did not include top management:Incorrect. While top management involvement is vital for QMS effectiveness (Clause 5.1), this is not a direct requirement of Clause 6.2. Top management alignment is implied but not explicitly mandated for establishing quality objectives.
* D. Quality objectives were not established in alignment with the organisation's quality policy:Correct. Clause 6.2.1 requires that quality objectives be consistent with the organization's quality policy, ensuring they reflect its purpose, strategic direction, and commitment to continual improvement. Misalignment would constitute a nonconformity.
* E. The organisation cannot afford to undertake quality objectives all at once:Incorrect.
Financial constraints are not directly addressed in Clause 6.2. The clause focuses on planning to achieve objectives, which includes defining the necessary resources but does not demand achieving all objectives simultaneously.
* F. Quality objectives are not maintained as documented information:Correct. Clause 6.2.1 specifically requires that quality objectives be maintained as documented information. Failure to document the objectives is a direct violation of this clause.
* Why Options D and F Are Correct:
* D: Misalignment between the quality objectives and the quality policy directly violates Clause
6.2.1, which mandates that objectives support the strategic direction of the organization.
* F: Lack of documentation for quality objectives breaches the requirement to maintain them as documented information under Clause 6.2.1.
* Relevant References:
* Clause 6.2.1: Establishing quality objectives aligned with the quality policy.
* Clause 6.2.2: Maintaining documented information for quality objectives and planning to achieve them.
* Clause 5.1.1: Top management's responsibility to ensure alignment between the QMS and strategic direction.

NEW QUESTION # 56
What is a horizontal audit?

- A. In-depth investigation of one process across various departments in the organization
- B. In-depth investigation of all the processes in a specific department or organizational unit
- C. In-depth investigation of all the processes in major functional areas of the organization

Answer: A

Explanation:
Comprehensive and Detailed In-Depth Explanation:
A horizontal audit examines one process across multiple departments to assess consistency.
Thus, A is the correct answer.
Reference:
ISO 19011:2018, Clause 6.2 (Audit Types & Scope)

NEW QUESTION # 57
You are carrying out an audit at a single-site organisation seeking certification to ISO 9001 for the first time.
The organisation 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.

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

8.5.4

Cleaning and sanitising not always completed.

Cleaning and sanitising are not always completed by trained staff.

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 planned arrangements, at appropriate stages, to verify that the product requirements have been met."

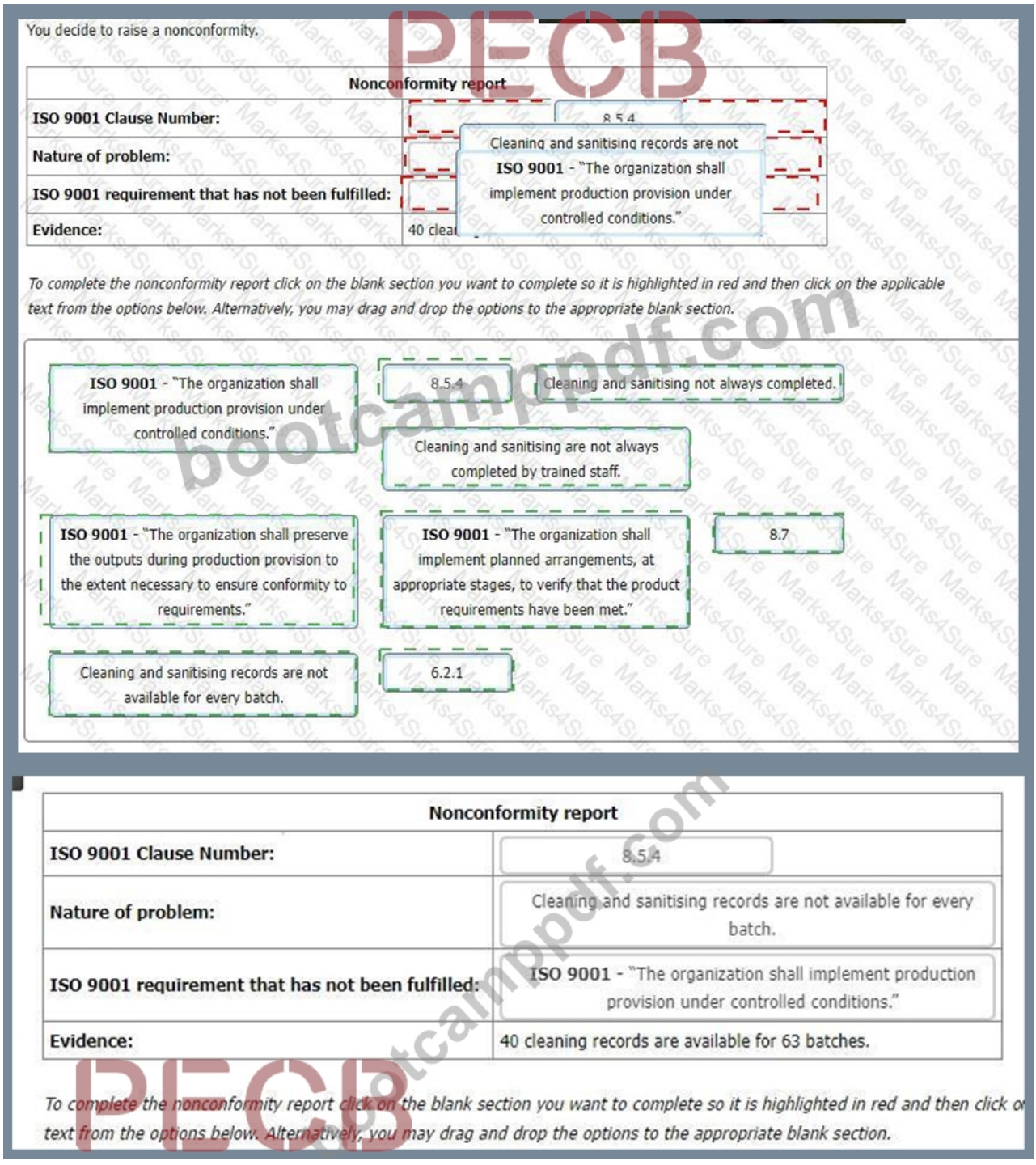
8.7

Cleaning and sanitising records are not available for every batch.

6.2.1

Answer:

Explanation:



NEW QUESTION # 58

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