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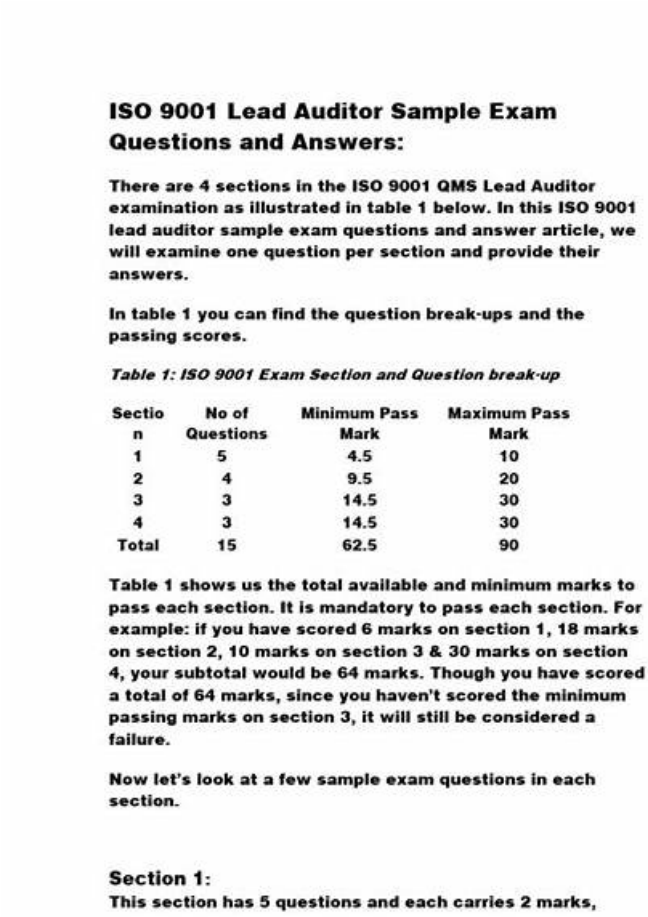

ISO 9001 Lead Auditor Sample Exam Questions and Answers:

There are 4 sections in the ISO 9001 QMS Lead Auditor examination as illustrated in table 1 below. In this ISO 9001 lead auditor sample exam questions and answer article, we will examine one question per section and provide their answers.

In table 1 you can find the question break-ups and the passing scores.

Table 1: ISO 9001 Exam Section and Question break-up

Section	No of Questions	Minimum Pass Mark	Maximum Pass Mark
1	5	4.5	10
2	4	9.5	20
3	3	14.5	30
4	3	14.5	30
Total	15	62.5	90

Table 1 shows us the total available and minimum marks to pass each section. It is mandatory to pass each section. For example: if you have scored 6 marks on section 1, 18 marks on section 2, 10 marks on section 3 & 30 marks on section 4, your subtotal would be 64 marks. Though you have scored a total of 64 marks, since you haven't scored the minimum passing marks on section 3, it will still be considered a failure.

Now let's look at a few sample exam questions in each section.

Section 1:
This section has 5 questions and each carries 2 marks,

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Auditor Answers

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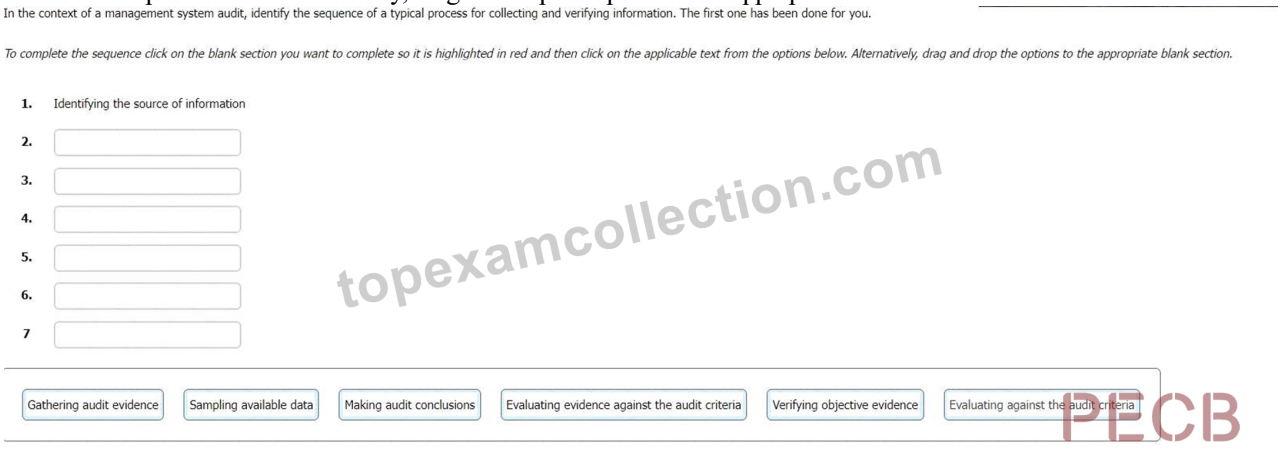
PECB ISO-9001-Lead-Auditor Exam Syllabus Topics:

Topic	Details
Topic 1	• Managing an ISO 9001 audit program: This topic evaluates your abilities to establish and managing a QMS audit program.
Topic 2	• 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 3	• 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 4	• Conducting an ISO 9001 audit: It evaluates your skills to conduct a QMS audit.
Topic 5	• Closing an ISO 9001 audit: The topic focuses on concluding a QMS audit and conducting audit follow-up activities.
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.

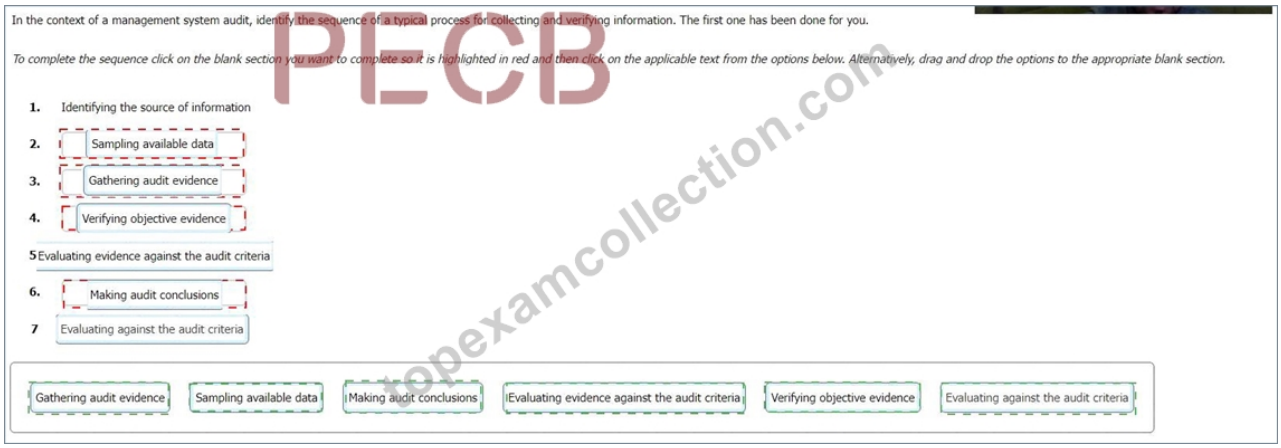
PECB QMS ISO 9001:2015 Lead Auditor Exam Sample Questions (Q119-Q124):

NEW QUESTION # 119
In the context of a management system audit, identify the sequence of a typical process for collecting and verifying information. The first one has been done for you.
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:
Identifying the source of information
Sampling available data
Gathering audit evidence
Verifying objective evidence
Evaluating evidence against the audit criteria
Making audit conclusions
Evaluating against the audit criteria
According to ISO 19011:2018, clause 6.4, the process of collecting and verifying information during an audit involves the following steps1:
Identifying the source of information: The audit team should identify the sources of information that are relevant to the audit objectives, scope and criteria. These sources may include documents, records, personnel, processes, activities, facilities, equipment, etc. The audit team should also determine the methods and tools for accessing and collecting the information, such as interviews, observations, document review, sampling, etc.
Sampling available data: The audit team should select a representative sample of the available data to verify the conformity and effectiveness of the management system. The sample size and selection method should be based on the audit objectives, scope and criteria, as well as the level of confidence and risk. The audit team should also consider the validity, reliability, relevance and sufficiency of the data.
Gathering audit evidence: The audit team should use the methods and tools identified in the previous step to collect audit evidence, which is the records, statements of fact or other information that are relevant to the audit criteria and verifiable. The audit team should record the audit evidence in a clear, concise and objective manner, using notes, checklists, photographs, audio or video recordings, etc.
Verifying objective evidence: The audit team should verify the accuracy, completeness and authenticity of the audit evidence collected. This may involve cross-checking different sources of information, confirming the identity and authority of the persons providing the information, examining the original documents or records, etc. The audit team should also identify any discrepancies, inconsistencies or gaps in the audit evidence.
Evaluating evidence against the audit criteria: The audit team should compare the audit evidence with the audit criteria to determine the extent of conformity and nonconformity. The audit team should also identify any opportunities for improvement, best practices, positive aspects or potential risks. The audit team should use professional judgement and apply the principles of auditing when evaluating the audit evidence.
Making audit conclusions: The audit team should consolidate the audit findings and evaluate the overall performance and effectiveness of the management system. The audit team should also consider the audit objectives, scope and criteria, as well as the context and expectations of the auditee and other interested parties. The audit team should provide a clear, concise and objective statement of the audit conclusions, which may include the degree of conformity, the achievement of the intended outcomes, the need for corrective actions, the suitability for certification, etc.
Evaluating against the audit criteria: The audit team should review the audit conclusions and ensure that they are consistent with the audit criteria and supported by sufficient and appropriate audit evidence.
The audit team should also ensure that the audit conclusions are communicated to the auditee and other relevant parties in a timely and effective manner, using the agreed audit report format and distribution method.
References: ISO 19011:2018(en), Guidelines for auditing management systems

NEW QUESTION # 120
ISO 9001 addresses changes through several requirements, two examples of which are Clause 6.3 (Planning of Changes) and Clause 8.5.6 (Control of Changes). How do the requirements of Clause 8.5.6 differ from those of Clause 6.3?

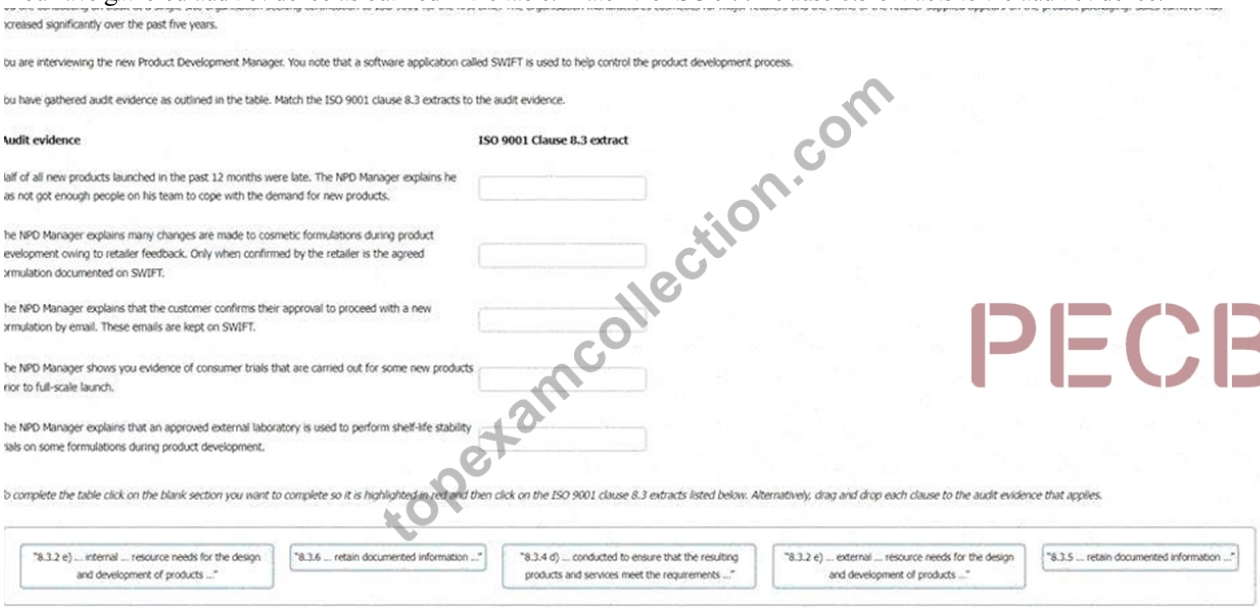
- A. Clause 8.5.6 refers to changes during the production and service provision.

- B. Clause 8.5.6 refers to changes during the design and development of products and services.
- C. Clause 8.5.6 refers to changes to legal and regulatory requirements.
- D. Clause 8.5.6 refers to leadership and management system responsibilities.

Answer: A

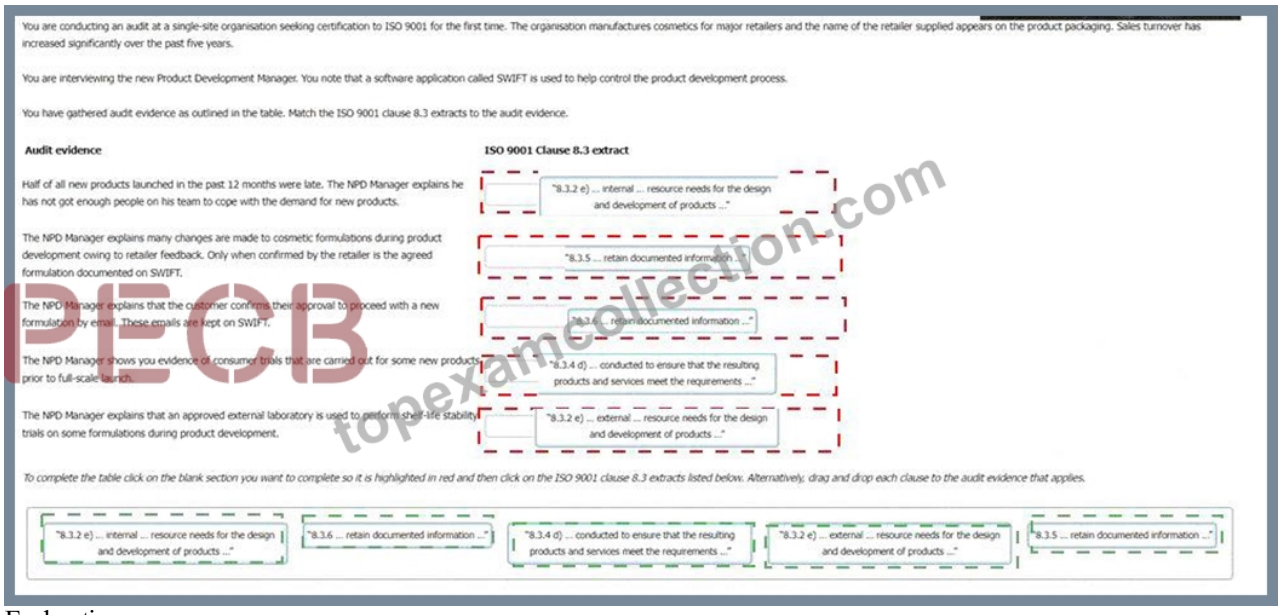
Explanation:
Comprehensive and Detailed In-Depth Explanation:
ISO 9001:2015 recognizes change management as essential for maintaining process integrity and preventing nonconformities.
Clause References:
Clause 6.3 (Planning of Changes) # Focuses on long-term changes that may impact QMS integrity.
Clause 8.5.6 (Control of Changes) # Focuses on changes occurring during production and service provision to ensure conformity.
Why is the Correct Answer A?
Clause 8.5.6 applies specifically to operational changes, ensuring that modifications in production or service processes do not compromise quality.
Organizations must document who approves changes, how they are controlled, and how they affect product /service conformity.
Why are the Other Options Incorrect?
B (Changes during design and development) # Covered under Clause 8.3 (Design and Development), not 8.5.6.
C (Changes to legal and regulatory requirements) # Addressed under Clause 4.2 (Interested Parties' Requirements).
D (Leadership responsibilities) # Covered under Clause 5.1 (Leadership and Commitment), not 8.5.6.
Reference:
ISO 9001:2015, Clause 6.3 - Planning of Changes
ISO 9001:2015, Clause 8.5.6 - Control of Changes

NEW QUESTION # 121
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.

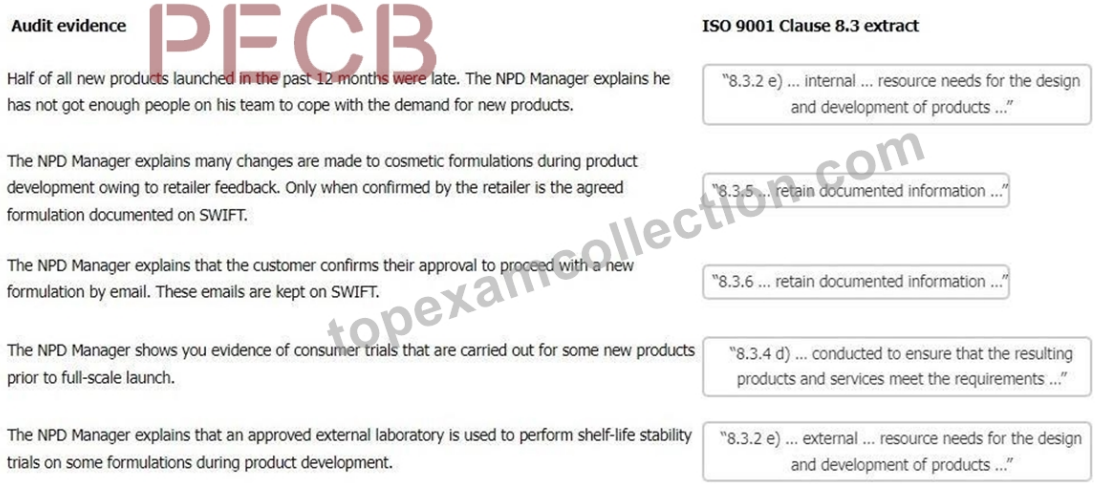


Answer:

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 # 122

Scenario 3:

Fin-Pro is a financial institution in Austria offering commercial banking, wealth management, and investment services. The company faced a significant loss of customers due to failing to improve service quality as they expanded.

To regain customer confidence, top management implemented a QMS based on ISO 9001. After a year, they contacted ACB, a local certification body, to pursue ISO 9001 certification.

The audit team was led by Emilia, an experienced lead auditor, and included three auditors. After an agreement was reached, ACB sent the audit objectives to the audit team.
The audit team began by gathering information about Fin-Pro's understanding of ISO 9001 requirements.
While reviewing documented information, they noticed missing records of training and awareness sessions.
They conducted employee interviews to verify attendance.
The team also reviewed the organizational chart and job descriptions to confirm employee competence. They observed the company's working environment (social, psychological, and physical conditions).
The audit team analyzed the evidence and prepared an audit report with findings and conclusions.
ACB sent the audit objectives to the audit team after an agreement was reached. Is this acceptable?

- A. No, only the auditee should know the audit objectives.
- B. Yes, the audit objectives should be known only after an agreement is reached.
- C. Yes, as long as the audit team leader approves.
- D. No, the audit objectives should be part of the audit offer.

Answer: D

Explanation:
Comprehensive and Detailed In-Depth Explanation:
Clause References:
ISO 19011:2018 (Guidelines for Auditing Management Systems), Clause 5.3 - Establishing the Audit Objectives ISO/IEC 17021-1:2015, Clause 9.1.2 - Audit Planning Why is the Correct Answer C?
Audit objectives must be clearly defined in the audit offer to ensure that the scope, criteria, and purpose are agreed upon in advance.
ISO/IEC 17021-1:2015 (which governs certification bodies) requires that audit objectives be established before the audit begins to ensure transparency and effectiveness.
Sending audit objectives after an agreement has been reached could lead to misalignment between the auditee' s expectations and the audit's purpose.
Why are the Other Options Incorrect?
A (Audit objectives should be known only after agreement) # Incorrect because objectives must be pre- defined in the audit offer.
B (Only the auditee should know the objectives) # Incorrect because both the auditor and auditee must align on objectives.
D (Approval from the lead auditor is sufficient) # Incorrect because audit planning follows formal procedures defined by ISO/IEC 17021-1.
Reference:
ISO/IEC 17021-1:2015, Clause 9.1.2 - Audit Planning
ISO 19011:2018, Clause 5.3 - Establishing the Audit Objectives

NEW QUESTION # 123
XYZ Corporation is an organisation that employs 100 people. As audit team leader, you are conducting a certification audit at Stage 1. When reviewing the quality management system (QMS) documentation, you find that quality objectives have been set for every employee in the organisation except top management.
The Quality Manager complains that this has created a lot of resistance to the QMS, and the Chief Executive is asking questions about how much it will cost. He asks for your opinion on whether this is the correct method of setting objectives.
Three months after Stage 1, you return to XYZ Corporation to conduct a Stage 2 certification audit as Audit Team Leader with one other auditor. You find that the Quality Manager has cancelled the previous quality objectives for all employees and replaced them with a single objective for himself. This states that "The Quality Manager will drive multiple improvements in the QMS in the next year". The Quality Manager indicates that this gives him the authority to issue instructions to department managers when quality improvement is needed. He says that this approach has the full backing of senior management. He shows you the latest Quality Improvement Request that was included in the last management review.

Quality Improvement Request			QI/12/20/HR-3
To: HR Manager	QMS awareness training is to be included as part of the induction training for new employees.		Date: 12/12/20XX Action by: 31/03/20XX
Update by: 01/20XX ☐	Update by: 02/20XX ☐	Update by: 03/20XX ☐	Signed: (QM)
Notes: Use of external resources for this action must be approved by senior management.			Action Completed: (Signature) Date:

After further auditing, the issues below were found. Select two statements that apply to the term `nonconformity'.

- A. Decisions on improvement action timescales not involving departmental managers.
- B. Limited knowledge of the content of Quality Improvement Requests by departmental staff.
- C. No quality objectives planned for the top management team
- D. Quality improvements not aligning with the quality policy.
- E. Evaluation of the results of the improvement action not always documented by the Quality Manager.
- F. Top management claim not to be aware of the improvement request (QI/12/20/HR-3) initiated by the Quality Manager.

Answer: C,D

Explanation:
According to the ISO 9001:2015 standard, clause 10.2.1 defines nonconformity as the non-fulfilment of a requirement. A requirement can be related to the quality management system, the products and services, the customer expectations, or the applicable statutory and regulatory requirements. Nonconformities can be detected through various sources, such as audits, inspections, tests, customer complaints, or internal reviews.
Nonconformities must be addressed by taking appropriate actions to correct them and prevent their recurrence.
In this scenario, the auditee has shown several issues that indicate nonconformities in their quality management system. Two statements that apply to the term nonconformity are:
A). No quality objectives planned for the top management team: According to ISO 9001, clause 6.2.1, the organization must establish quality objectives at relevant functions, levels, and processes. The quality objectives must be consistent with the quality policy and the strategic direction of the organization. The top management team is responsible for providing leadership and direction for the quality management system and ensuring its alignment with the organization's purpose and context. Therefore, the absence of quality objectives for the top management team is a nonconformity as it violates the requirement of clause 6.2.1.
E). Quality improvements not aligning with the quality policy: According to ISO 9001, clause 5.2.1, the quality policy is a statement of the organization's intentions and direction regarding quality, as formally expressed by top management. The quality policy must provide a framework for setting quality objectives and be compatible with the context and strategic direction of the organization. The quality policy must also be communicated, understood, and applied within the organization. Therefore, if the quality improvements are not aligned with the quality policy, it is a nonconformity as it violates the requirement of clause 5.2.1.

NEW QUESTION # 124
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