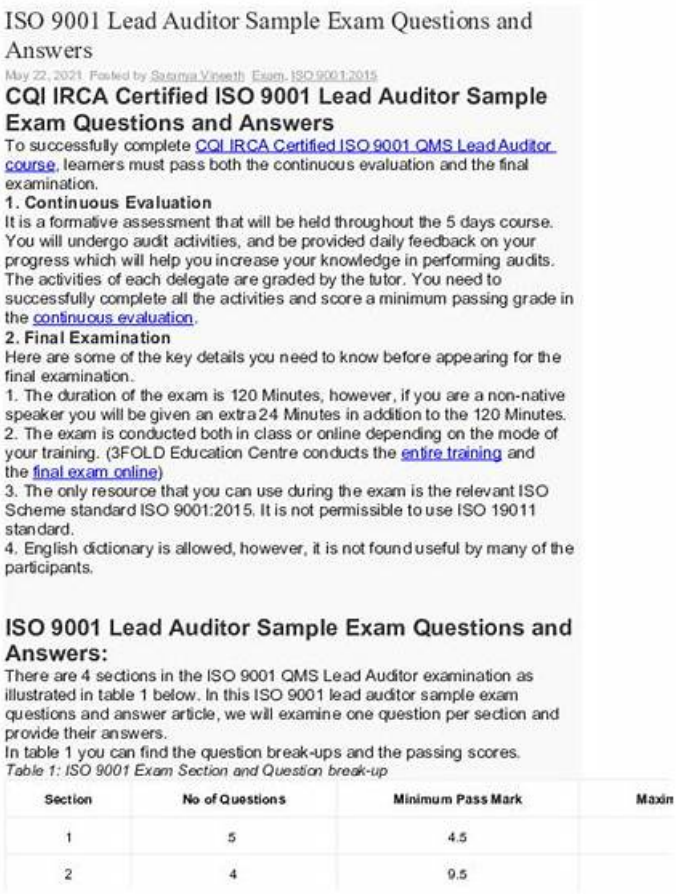
ISO-9001-Lead-Auditor Testking Exam Questions - Valid ISO-9001-Lead-Auditor Exam Cram



ISO 9001 Lead Auditor Sample Exam Questions and Answers

May 22, 2021 Posted by Saumya Vineeth Exam, ISO 9001:2015

CQI IRCA Certified ISO 9001 Lead Auditor Sample Exam Questions and Answers

To successfully complete CQI IRCA Certified ISO 9001 QMS Lead Auditor course, learners must pass both the continuous evaluation and the final examination.

1. Continuous Evaluation

It is a formative assessment that will be held throughout the 5 days course. You will undergo audit activities, and be provided daily feedback on your progress which will help you increase your knowledge in performing audits. The activities of each delegate are graded by the tutor. You need to successfully complete all the activities and score a minimum passing grade in the continuous evaluation.

2. Final Examination

Here are some of the key details you need to know before appearing for the final examination.

1. The duration of the exam is 120 Minutes, however, if you are a non-native speaker you will be given an extra 24 Minutes in addition to the 120 Minutes.
2. The exam is conducted both in class or online depending on the mode of your training. (3FOLD Education Centre conducts the entire training and the final exam online)
3. The only resource that you can use during the exam is the relevant ISO Scheme standard ISO 9001:2015. It is not permissible to use ISO 19011 standard.
4. English dictionary is allowed, however, it is not found useful by many of the participants.

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	Maxin
1	5	4.5	
2	4	9.5	

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

Topic	Details
Topic 1	• 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 2	• Managing an ISO 9001 audit program: This topic evaluates your abilities to establish and managing a QMS audit program.

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.

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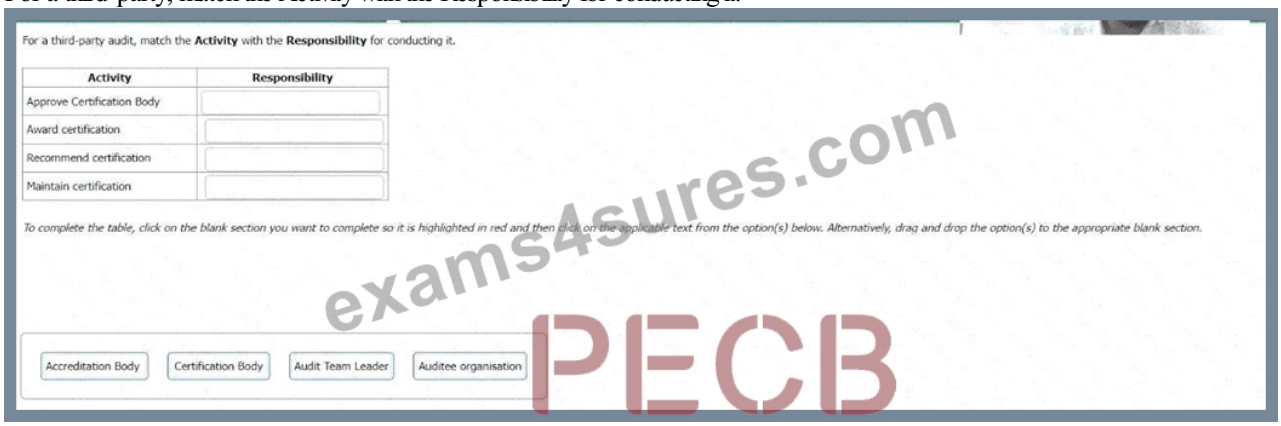
PECB QMS ISO 9001:2015 Lead Auditor Exam Sample Questions (Q98-Q103):

NEW QUESTION # 98
For a third-party, match the Activity with the Responsibility for conducting it.



Answer:

Explanation:

Explanation:

Activity	Responsibility
Approve Certification Body	Accreditation Body
Award certification	Certification Body
Recommend certification	Audit Team Leader
Maintain certification	Auditee organisation

* Approve Certification Body: Accreditation Body
* Award certification: Certification Body
* Recommend certification: Audit Team Leader
* Maintain certification:

Comprehensive Detailed Explanation
In the context of a third-party ISO 9001 audit, different entities play specific roles in the certification process.
Here's a detailed explanation of the responsibilities:
* Approve Certification Body: Accreditation BodyThe Accreditation Body is responsible for approving Certification Bodies. Accreditation Bodies are independent entities that evaluate the competence of Certification Bodies, ensuring they meet international standards like ISO/IEC 17021, which sets out the criteria for bodies providing audit and certification of management systems. In this role, they confirm that the Certification Body is capable of conducting ISO 9001 audits and granting certifications in accordance with international guidelines.
* Award Certification: Certification BodyThe Certification Body is the entity that ultimately awards the certification to an organization after verifying that it meets the ISO 9001 standards. Certification Bodies conduct audits, either directly or through a team of auditors, and based on the audit outcomes, they issue the certification, indicating that the organization complies with ISO 9001.
* Recommend Certification: Audit Team LeaderThe Audit Team Leader is responsible for leading the audit and making a recommendation to the Certification Body. This recommendation is based on the audit findings-whether the organization meets the ISO 9001 requirements or if there are areas of non- compliance that need corrective action. The final decision on certification is not made by the Audit Team Leader but by the Certification Body.
* Maintain Certification: Certification BodyMaintaining certification refers to the ongoing process of ensuring that an organization continues to comply with ISO 9001 requirements. The Certification Body conducts regular surveillance audits (e.g., annually) and may also perform recertification audits (typically every three years). This ongoing monitoring ensures that the certified organization continues to adhere to the quality management standards over time.

This breakdown clearly assigns responsibility based on the defined roles of Accreditation Bodies, Certification Bodies, and Audit Teams in the ISO 9001 certification process.

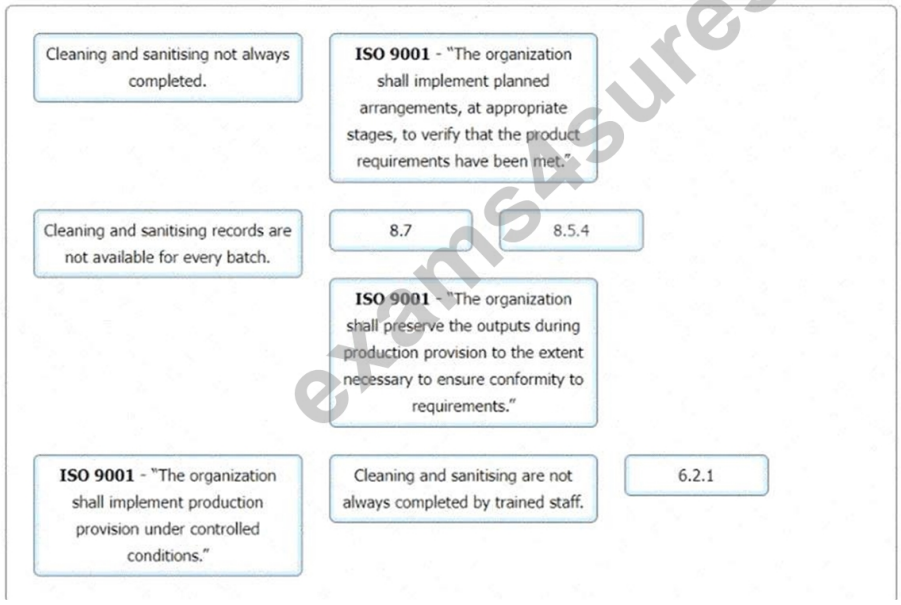
NEW QUESTION # 99
You are carrying out an audit at a single-site organisation seeking certification to ISO 9001 for the first time.
The organization manufactures cosmetics for major retailers.
You are interviewing the Manufacturing Manager (MM).
You: "I would like to begin by looking at the cleaning 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.

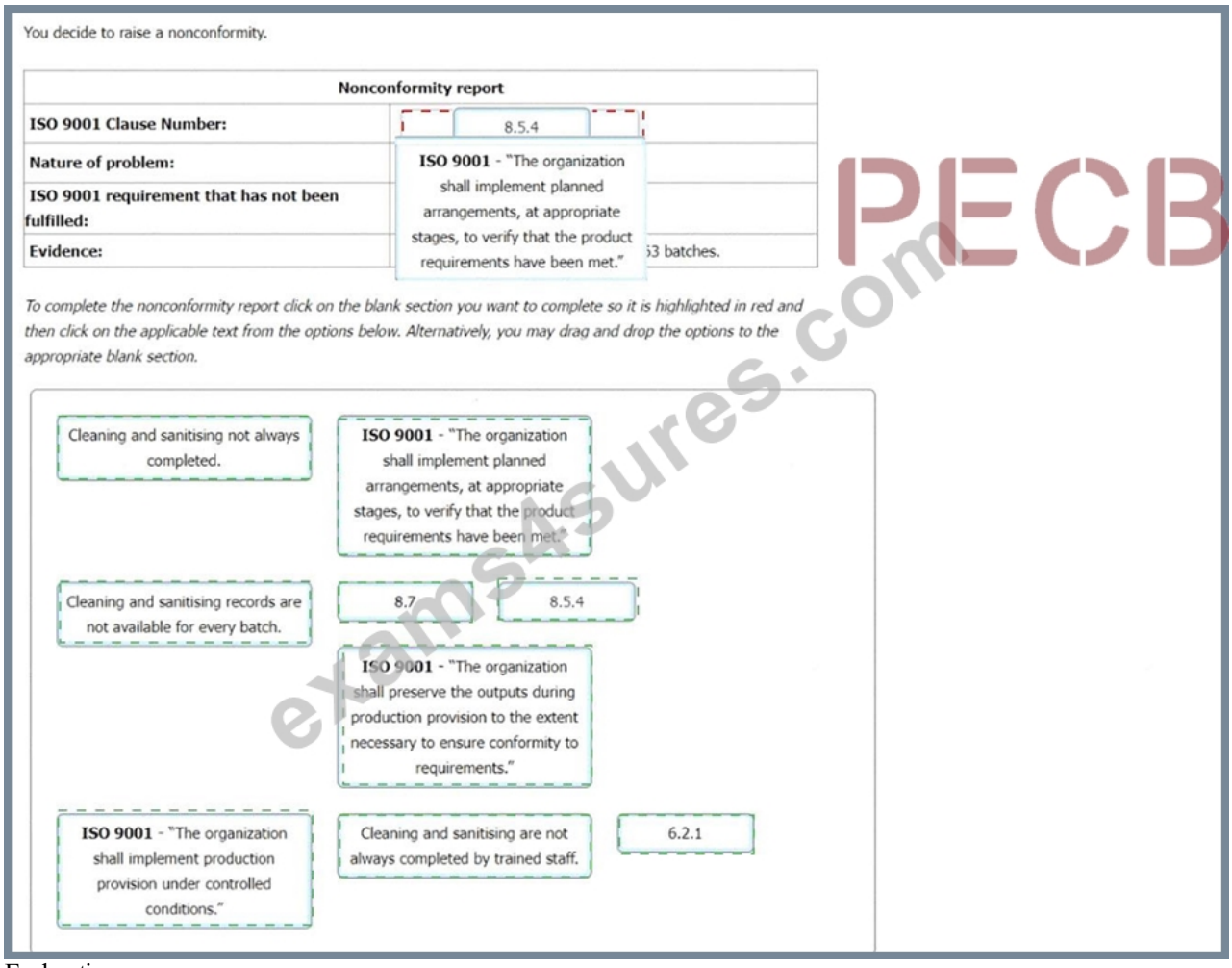
Nonconformity report	
ISO 9001 Clause Number:	
Nature of problem:	
ISO 9001 requirement that has not been fulfilled:	
Evidence:	40 cleaning records are available for 63 batches.

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.



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 # 100
Select six of the activities that are specifically required by ISO 17021-1 as part third-party (Certification Body) surveillance audit processes.

- A. Confirm effectiveness of internal audit and management review.
- B. Handling of customer complaints since last visit.
- C. Verify legal compliance.
- D. Audit use of certification marks on marketing materials.
- E. Review the status of previously raised findings and audit effectiveness of any outstanding findings.
- F. Complete a full document review of the quality management system.
- G. Review the calibration status of the instrumentation.
- H. Conduct a minimum number of annual surveillance audits during the certification period.
- I. Review changes to the QMS since last visit.
- J. Failing to meet financial responsibilities.

Answer: A,B,C,D,E,I

Explanation:
The activities that are specifically required by ISO 17021-1 as part of third-party (Certification Body) surveillance audit processes are:
*Option A: Audit use of certification marks on marketing materials. This option is correct because ISO 17021-1:2015 clause 9.6.2.2 requires the certification body to audit the client's use of marks and/or any other reference to certification, as applicable, to ensure conformity with the certification requirements.

*Option B: Review changes to the QMS since last visit. This option is correct because ISO 17021-1:2015 clause 9.6.2.2 requires the certification body to review any changes affecting the client's quality management system and its ability to continue to fulfil the requirements of the standard used for certification.
*Option C: Confirm effectiveness of internal audit and management review. This option is correct because ISO 17021-1:2015 clause 9.6.2.2 requires the certification body to confirm the continuing effectiveness of the client's quality management system, including the effectiveness of the internal audit and management review processes.
*Option F: Review the status of previously raised findings and audit effectiveness of any outstanding findings.
This option is correct because ISO 17021-1:2015 clause 9.6.2.2 requires the certification body to review the status of findings and any corrective actions taken by the client in response to previous audits, and to verify the effectiveness of the implemented corrective actions.
*Option H: Verify legal compliance. This option is correct because ISO 17021-1:2015 clause 9.6.2.2 requires the certification body to verify the client's compliance with applicable statutory and regulatory requirements related to the scope of certification.
*Option I: Handling of customer complaints since last visit. This option is correct because ISO 17021-1:2015 clause 9.6.2.2 requires the certification body to review the client's handling of customer complaints related to the certified activities since the last audit.
The following options are not correct:
*Option D: Complete a full document review of the quality management system. This option is not correct because ISO 17021-1:2015 clause 9.6.2.2 does not require the certification body to complete a full document review of the quality management system during surveillance audits. A full document review is only required during the initial certification audit or when there are significant changes to the quality management system or the certification requirements.
*Option E: Failing to meet financial responsibilities. This option is not correct because ISO 17021-1:2015 clause 9.6.2.2 does not require the certification body to audit the client's financial responsibilities during surveillance audits. The certification body may have contractual arrangements with the client regarding the payment of fees, but this is not part of the surveillance audit process.
*Option G: Review the calibration status of the instrumentation. This option is not correct because ISO 17021-1:2015 clause 9.6.2.2 does not require the certification body to review the calibration status of the instrumentation during surveillance audits. The certification body may audit the client's monitoring and measuring resources as part of the quality management system requirements, but this is not a specific activity required by ISO 17021-1.
*Option J: Conduct a minimum number of annual surveillance audits during the certification period. This option is not correct because ISO 17021-1:2015 clause 9.6.2.2 does not require the certification body to conduct a minimum number of annual surveillance audits during the certification period. The certification body may determine the frequency and duration of surveillance audits based on the risk and performance of the client, but this is not a specific activity required by ISO 17021-1.
References:
*ISO 17021-1:2015 Conformity assessment - Requirements for bodies providing audit and certification of management systems - Part 1: Requirements
*ISO 9001 Lead Auditor Course Material, Module 7: Audit Follow-up and Surveillance, Slide 8: Surveillance Audit
*ISO 9001 Lead Auditor Training Course - IRCA Certified, Section 7.2: Audit Follow-up and Surveillance
*Lead Auditor Exam Preparation Guide (EPG) Template - PECB, Section 3.2: Exam Content Outline, Subsection 3.2.1: Section 1 - Audit Fundamentals, Subsection 3.2.2: Section 2 - Audit Principles, Subsection 3.2.3: Section 3 - Audit Process, Subsection 3.2.4: Section 4 - Audit Competencies

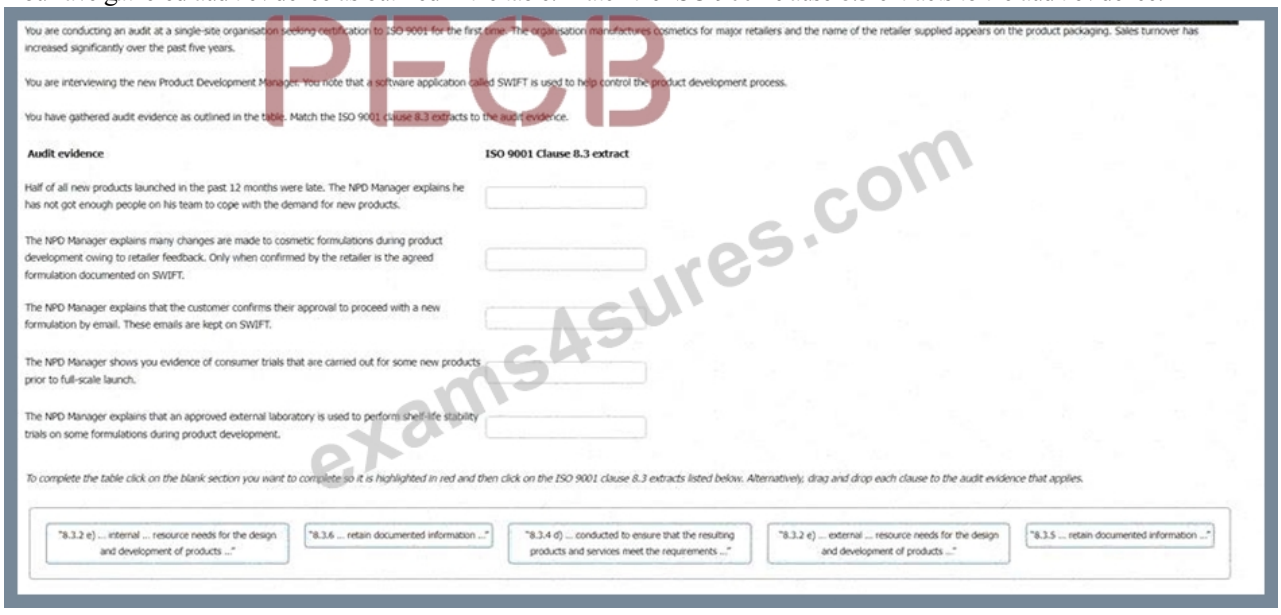
NEW QUESTION # 101
A small deaning services organisation is about to start work on a hospital dleaning contract for the local Health Trust. You, as auditor, are conducting a Stage 2 audit to ISO 9001 and review the contract with the Service Manager. The contract requires that a cleaning plan is produced. You: "How was the cleaning plan for the contract developed?" Service Manager: "We have a basic template that covers the materials, labour requirements and cleaning methods to be employed. Some of that is specified by the customer." You: "How does the plan deal with locations like the intensive care wards and the operating theatres, which are included in the contract?" Service Manager: "The basic plan covers general wards, but we will do more frequent cleaning in those areas if the hospital requests it." You: "Are you aware of the regulatory requirements for cleaning standards in hospitals?" Service Manager: "No. We depend on the hospital to look after that side of things in the contract." You decide to raise a non-conformity against section 8.2.2.a.1 of ISO 9001. You decide to raise another non-conformity against section 8.2.4 of ISO 9001 when finding that the cleaning plan was amended without the agreement of the Health Trust. A different cleaning chemical was substituted to that specified in the contract. At the follow- up audit, the corrective action proposed was to "obtain a concession from the Health Trust for use of the new chemical." Which one of the following options is the reason why you did not accept this action taken?

- A. The substitute chemical has not been used before in the Health Trust.
- B. The process for making changes to the contract has not been addressed.
- C. The action assumes that the Health Trust will agree to the change.
- D. Staff have not been trained in the use of the new chemical.
- E. The substitute chemical may not be as effective as the original.

Answer: B

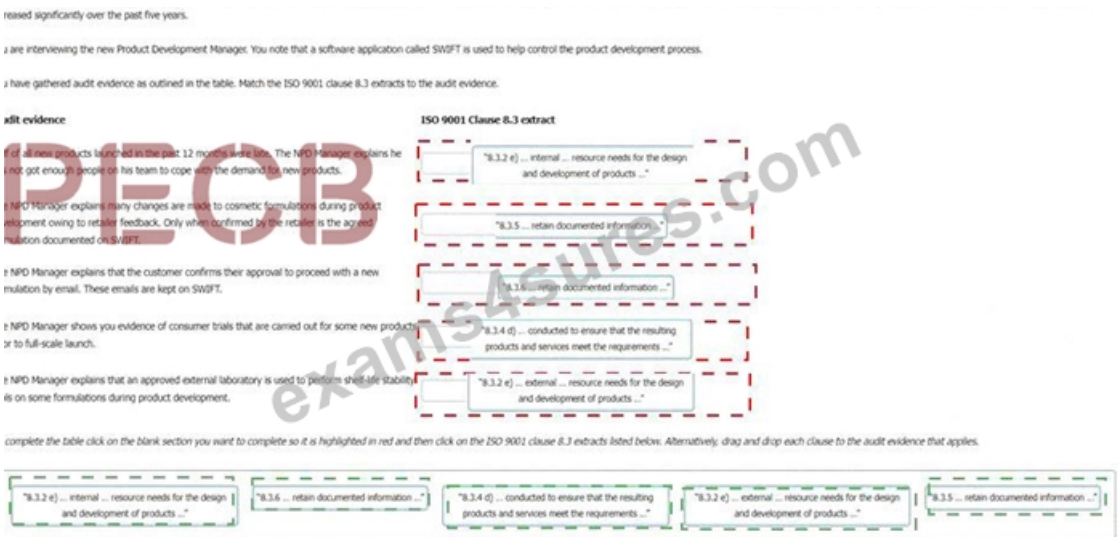
Explanation:
* Clause 8.2.4 of ISO 9001:2015 - Changes to Requirements for Products and Services:ISO 9001:
2015 Clause 8.2.4 states that when changes to requirements for products or services are made, they must be communicated and agreed upon with relevant interested parties (in this case, the Health Trust).
The lack of communication and agreement for substituting the cleaning chemical represents a clear violation of this clause.
* Analysis of the Corrective Action Proposed:The organization proposed "obtaining a concession from the Health Trust for the use of the new chemical." This action is reactive and assumes approval from the Health Trust without addressing the systemic issue: the lack of a defined change control process for managing contract changes.
* Option Analysis:
* A. The substitute chemical has not been used before in the Health Trust:Incorrect. While this may be a concern, it is not directly relevant to the root cause of the nonconformity, which is the absence of a process to handle contract changes.
* B. The action assumes that the Health Trust will agree to the change:Incorrect. Although this is true, it is not the primary issue. The nonconformity lies in the lack of a structured approach to obtain agreement, not whether the Health Trust agrees.
* C. Staff have not been trained in the use of the new chemical:Incorrect. This is a separate issue related to staff competence (Clause 7.2), but it is not the main reason why the corrective action is unacceptable under Clause 8.2.4.
* D. The process for making changes to the contract has not been addressed:Correct. The fundamental issue is the organization's failure to follow or establish a change control process for amending contracts, including gaining formal agreement from the Health Trust. The proposed corrective action does not ensure that such issues will be systematically prevented in the future.
* E. The substitute chemical may not be as effective as the original:Incorrect. The effectiveness of the substitute chemical is secondary to the primary issue, which is the lack of a change management process.
* ISO 9001 References Supporting the Correct answer:
* Clause 8.2.4: Requires that changes to product/service requirements be reviewed, communicated, and agreed upon with the customer.
* Clause 10.2 (Nonconformity and Corrective Action): Requires the organization to address the root cause of the nonconformity and take actions to ensure it does not recur. In this case, the root cause is the absence of a change control process.
* Why D is the Best answer:The core issue is that the organization did not have a formalized process for managing and agreeing upon changes to contract requirements. Addressing this process gap is essential to prevent recurrence of similar nonconformities. Merely seeking a concession from the Health Trust is a one-off solution that does not address the systemic issue.

NEW QUESTION # 102
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.

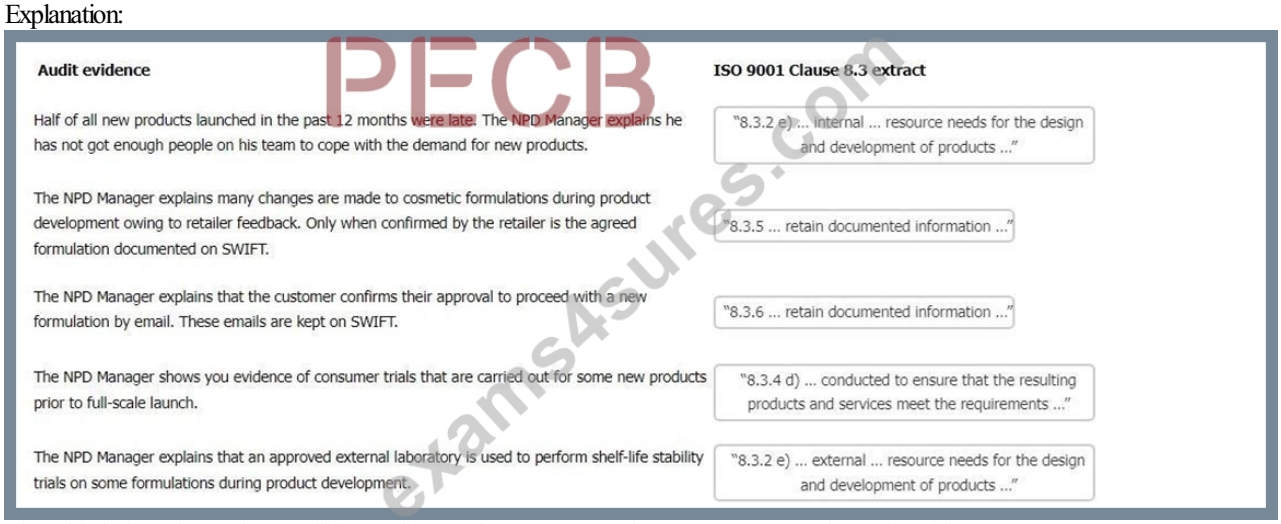


Answer:

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.
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.
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 # 103

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