PECB.ISO-9001-Lead-Auditor.v2026-03-30.q113

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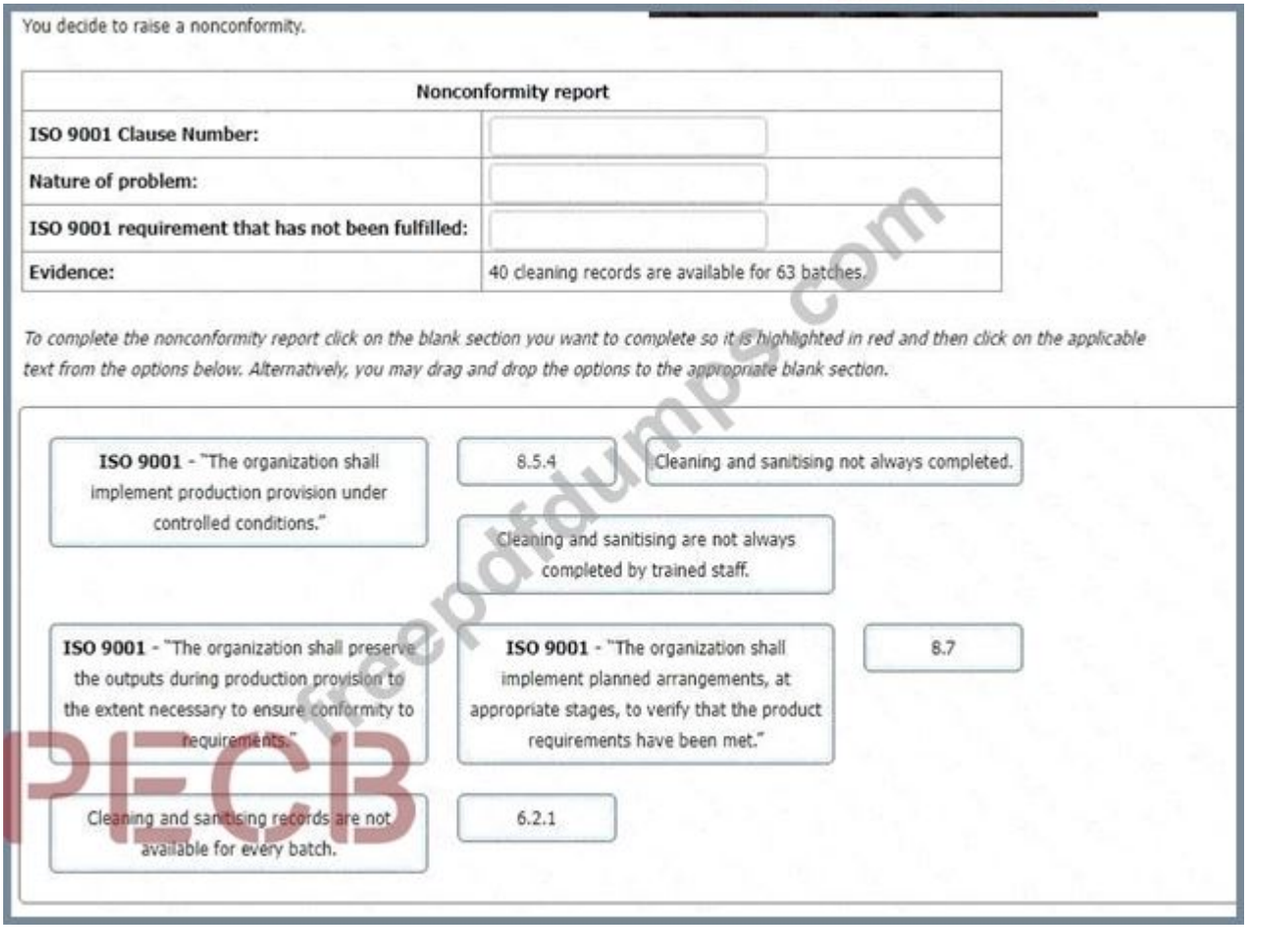
NEW QUESTION: 1
ABC is a service organisation that cleans and irons bed and table linen for four large hospitals in the city centre. It claims to meet ISO 9001:2015 requirements. During an internal audit, an auditor observes that machine No. 4 is being operated with the three variables outside the limits established in the applicable documented procedure SP-701. The auditor has decided to raise a nonconformity.
Which six elements should be included in the nonconformity report?
A. Condition of the table linens upon receipt from the hospital
B. Applicable procedure: SP-701
C. Competence record of the machine operator
D. Identification number of the washing machine
E. Manufacturer of the washing machine
F. Name of the Quality Manager
G. Number of the production order
H. The concentration of the cleaning liquid used vs the concentration fixed in SP-701
I. The planned duration of the process vs the minimum time required in SP-701
J. Weight of linen being washed vs the maximum weight required in SP-701
Answer: (SHOW ANSWER)
B: Applicable procedure: SP-701
D: Identification number of the washing machine
H: The concentration of the cleaning liquid used vs the concentration fixed in SP-701 I: The planned duration of the process vs the minimum time required in SP-701 J: Weight of linen being washed vs the maximum weight required in SP-701 C: Competence record of the machine operator

NEW QUESTION: 2

You work for an organisation, 'ABC', which provides packaged food to the public. You are asked to lead a team (you as the leader and two other auditors) to audit an external provider, 'XYZ', which provides packaging materials to your organisation. It is 4 pm, and the audit is dlose to an end; you are having an internal meeting with the team to decide what will be presented to the auditee during the Closing meeting. The Closing meeting was scheduled for 5 pm.
'XYZ' has two manufacturing lines: M1 is a clean room for primary packaging materials (i.e. will be in direct contact with the food), and M2 is for secondary materials (i.e. will not be in direct contact with food).
Auditor 1 audited the two manufacturing lines.
You: "What findings would you report?"
Auditor 1: "I have one issue. Earlier today in the morning I saw some secondary material stocked in the clean room. I would propose raising a nonconformity." You: "How would you write the nonconformity?" Auditor 1: "In the clean room, there was a pallet with secondary materials." What additional information would you add to this text to complete the nonconformity report? Select six.
A. Batch number of the secondary material
B. The signature of the clean room's supervisor accepting the nonconformity
C. Evidence that the secondary material was approved ready to be used
D. The date on which the evidence was identified
E. The type of nonconformity (major or minor)
F. Description of the secondary material
G. Name of the forklift driver that was moving the pallet
H. Description of any primary material close to this pallet
I. More information in the place within the clean room where secondary material was found
J. Description of the ISO 9001:2015 requirement not being complied with and the clause number
Answer: A,D,E,F,H,J (LEAVE A REPLY)

NEW QUESTION: 3
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:

You decide to raise a nonconformity.

Nonconformity report	
ISO 9001 Clause Number:	8.5.4
Nature of problem:	Cleaning and sanitising records are not
ISO 9001 requirement that has not been fulfilled:	**ISO 9001** - "The organization shall implement production provision under controlled conditions."
Evidence:	40 clea

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.

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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 production provision under controlled conditions."
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 o text from the options below. Alternatively, you may drag and drop the options to the appropriate blank section.

NEW QUESTION: 4

Whistlekleen is a national dry cleaning and laundry company with 50 shops. You are conducting a surveillance audit of the Head Office and are sampling customer complaints. You find that 80% of complaints originate from five shops in the same region. Most of these complaints relate to damage to customer laundry.

The Quality Manager tells you that these are the oldest shops in the company. The cleaning equipment needs replacing but the company cannot afford it at the moment. You learn that the

shop managers were told to dismiss most of the claims on the basis of the poor quality of the laundered materials.
On raising the matter with senior management, you are told that there are plans to replace the equipment in these shops over the next five years.
When reviewing the customer complaint file, you find that the organisation is facing a legal dispute with a customer over damage to an expensive cashmere coat.
Select the best option for how this should be handled by the Quality Management System.
A. Settle the court case by negotiation with the customer.
B. Report the situation to the customer with suggested remedial action.
C. Make an offer to replace the coat with a new one.
D. Give an explanation to the customer of what went wrong.
Answer: B (LEAVE A REPLY)
According to the ISO 9001:2015 standard, clause 10.2 requires organizations to review nonconformities, including any arising from customer complaints, and to take appropriate actions to determine the cause, implement corrections and preventive actions, and verify their effectiveness. The organization must also monitor the effectiveness of the actions taken and make changes if necessary.
In this scenario, the auditee is facing a legal dispute with a customer over damage to an expensive cashmere coat. This is a nonconformity that arises from customer complaint and has a significant impact on customer satisfaction and reputation. Therefore, clause 10.2 applies to this situation.
The best option for how this should be handled by the Quality Management System is B.
B means that the organization should report the situation to the customer with suggested remedial action. This option follows the principle of transparency and accountability, as well as respecting the customer's rights and expectations. The organization should also investigate the root cause of the damage and prevent it from happening again in other shops or products.
The other options are not appropriate because:
A means that the organization should settle the court case by negotiation with the customer. This option may not be feasible or satisfactory for both parties, especially if there is a large amount of compensation involved or if there are legal implications for other customers.
C means that the organization should make an offer to replace the coat with a new one. This option may not be sufficient or acceptable for both parties, especially if there is evidence of negligence or poor quality on behalf of the organization.
D means that the organization should give an explanation to the customer of what went wrong. This option may not be enough or convincing for both parties, especially if there is no evidence of negligence or poor quality on behalf of the organization.

NEW QUESTION: 5
What is reliability in the context of service quality?
A. Ability to offer safe services
B. Readiness and goodwill in providing services

C. Providing the promised services correctly and dependably
D. Ensuring service costs remain low
Answer: C (LEAVE A REPLY)
Comprehensive and Detailed In-Depth Explanation:
Reliability in service quality refers to the consistent and dependable delivery of promised services. ISO 9001:2015 emphasizes reliability through:
* Clause 8.2.1 (Customer Communication) - Ensuring clarity in service commitments.
* Clause 8.5.1 (Control of Service Provision) - Ensuring processes meet requirements consistently.
Other options do not fully define reliability:
* Option A (Safe services) relates to safety, not reliability.
* Option B (Readiness and goodwill) relates to responsiveness, not reliability.
* Option D (Low cost) focuses on pricing, not quality.
Reference:
ISO 9001:2015, Clause 8.2.1 - Customer Communication
ISO 9001:2015, Clause 8.5.1 - Control of Service Provision

NEW QUESTION: 6
Whistlekleen is a national dry cleaning and laundry company with 50 shops. You are conducting a surveillance audit of the Head Office and are sampling customer complaints. 80% of complaints originate from five shops in the same region. Most of these complaints relate to customer laundry not being cleaned as customers require. The Quality Manager tells you that these are the oldest shops in the company. The cleaning equipment needs replacing but the company cannot afford it now. You learn that the shop managers were told to dismiss most of the complaints because of the poor quality of the laundered materials.
On raising the matter with senior management, you are told that there are plans to replace the equipment in these shops over the next five years.
You raised a nonconformity against clause 8.5.1 of ISO 9001.
Based on the scenario, select the three options which best describe the evidence for raising such a nonconformity.
A. The management failed in planning to replace obsolete equipment.
B. The organisation failed to maintain all of its equipment to an adequate standard.
C. Some equipment used was not suitable for the laundry process.
D. The operators did not check the laundry before release to the customer.
E. Customer complaints are not taken seriously by the organisation.
F. The operators did not check the condition of the customer's product upon receipt.
G. The organisation failed to control the laundry operations in 5 shops adequately.
H. Shop managers were told to make excuses to customers with complaints.
Answer: E,G,H (LEAVE A REPLY)

NEW QUESTION: 7

You have been nominated audit team leader of a third-party audit. Which of the following could be the two most relevant objectives of this audit?

A. Evaluate the satisfaction interested parties

B. Evaluate the effectiveness of the management system

C. Identify the need of resources

D. Evaluate the capability of the management system to establish and achieve objectives

E. Identify opportunities for improvement

F. Evaluate the benefits obtained since the implementation of the management system

Answer: (SHOW ANSWER)

Evaluate the effectiveness of the management system: This objective involves verifying that the quality management system meets the requirements of a specific standard, such as ISO 9001:2015, and that it achieves the intended results and outcomes. The audit team will collect and analyse audit evidence to determine the degree of conformity and performance of the quality management system23.

*Evaluate the capability of the management system to establish and achieve objectives: This objective involves verifying that the quality management system supports the strategic direction and policies of the organization, and that it addresses the needs and expectations of the interested parties. The audit team will assess the suitability, adequacy, and alignment of the quality management system objectives, and the effectiveness of the planning and implementation processes to achieve them23.

The other options are not the most relevant objectives of a third-party audit, according to the web search results from my internal tool. They may be related to other aspects or types of audits, but they are not the focus of a third-party audit.

Therefore, the correct answer is B and D.

References: 1: Safeguarding Your Business: The Power of Third-Party Security Audits 2: ISO 19011:2018 - Guidelines for auditing management systems 3: Third Party Audit - QMSGurus.com

NEW QUESTION: 8

In the context of a third-party audit, select the issue which is not expected to be included in the audit plan.

A. Number of sites to be audited

B. Risk to achieving audit objectives

C. Expectations of the organisation's management

D. Scope of the audit

Answer: (SHOW ANSWER)

According to ISO 19011:2018, clause 6.3.2, the audit plan is a document that provides the basis for agreement regarding the conduct of the audit. The audit plan should include the following information1:

*the audit objectives, scope and criteria

*the audit team members and their roles and responsibilities

*the audit schedule, including the date, time and location of each audit activity

*the expected time and duration of meetings and interviews
*the allocation of appropriate resources to critical areas of the audit
*the identification of the audit client and the auditee
*the identification of the guides and observers, if any
*the documents and records to be reviewed before and during the audit
*the audit methods and tools to be used
*the audit language and terminology
*the audit report content, format, distribution and expected completion date
*the risk to achieving audit objectives and the contingency plan, if any Therefore, the issue which is not expected to be included in the audit plan is C, expectations of the organisation's management. This issue is not relevant to the conduct of the audit, as the audit is based on the audit criteria, not on the management's expectations. The management's expectations may be considered during the audit initiation or the audit programme management, but they are not part of the audit plan.
References: ISO 19011:2018(en), Guidelines for auditing management systems, How to create an ISO 9001 internal audit plan - Advisera

NEW QUESTION: 9
You are carrying out an annual audit at an organisation that has been certificated to ISO 9001 for two years.
The organisation offers home security
services. The scope of the quality management system covers alarm installation, alarm servicing, alarm monitoring and response. The business operates from a single office and employs subcontract installers and service technicians across the country.
You have just completed the opening meeting. You are interviewing the Managing Director (MD).
You: "I would like to gain an understanding of how the quality management system has been supporting your business and its strategic direction." MD: "We are continuing to face difficult times. The market is extremely competitive, and customers typically look for the least expensive option when choosing home security services. We have not yet seen any business benefit from our quality management system." You: "Tell me how you determine external and internal issues." MD: "We use SWOT analysis (Strengths Weaknesses, Opportunities, Threats)." You: "How have the outputs from your SWOT been used?" Select two of the following audit trails would you take to explore the extent to which the SWOT analysis and the outputs from this have been used to enable the business to achieve the intended results(s) of its quality management system according to ISO 9001.
A. Establish how many interested parties need to be consulted
B. Establish how the organisation reviews information about external and internal issues
C. Establish how the organisation shares information with external interested parties
D. Establish what actions were taken to improve the QMS
E. Establish whether the SWOT analysis has been reviewed by the procurement manager
F. Establish whether the SWOT analysis is focussed solely on the QMS

Answer: B,D (LEAVE A REPLY)

According to ISO 9001:2015, clause 4.1, the organisation must determine the external and internal issues that are relevant to its purpose and that affect its ability to achieve the intended results of its quality management system. The organisation must also monitor and review the information about these issues. SWOT analysis is a tool that can help the organisation to identify its strengths, weaknesses, opportunities, and threats. However, the SWOT analysis alone is not sufficient to comply with the requirement, as the organisation also needs to review the information periodically and update it as necessary. Therefore, one audit trail would be to establish how the organisation reviews information about external and internal issues, such as how often, by whom, using what criteria, and with what results. 123 According to ISO 9001:2015, clause 10.3, the organisation must continually improve the suitability, adequacy, and effectiveness of the quality management system. The organisation must also consider the results of analysis and evaluation, and the outputs from management review, to determine if there are any needs or opportunities for improvement. SWOT analysis can help the organisation to identify the areas where improvement is needed or possible, such as addressing the weaknesses and threats, or exploiting the strengths and opportunities. However, the SWOT analysis alone is not sufficient to comply with the requirement, as the organisation also needs to take actions to implement the improvement, such as setting objectives, allocating resources, assigning responsibilities, and evaluating the effectiveness. Therefore, another audit trail would be to establish what actions were taken to improve the QMS, such as what, when, by whom, how, and with what results. 124 References:

1: ISO 9001:2015 - Quality management systems - Requirements
2: Advisera, "Context of the organization in ISO 9001:2015 explained", https://advisera.com/9001academy /knowledgebase/how-to-identify-the-context-of-the-organization-in-iso-90012015/
3: ISO Templates, "ISO 9001 - Clause 4: Context of the organisation explained", https://resources.iso- templates.com/blog/iso-9001-clause-4-context-of-the-organisation-explained
4: Advisera, "How to implement continual improvement in ISO 9001", https://advisera.com/9001academy /knowledgebase/how-to-implement-continual-improvement-in-iso-9001/

NEW QUESTION: 10

For each of the following scenarios, select four that are corrective actions.

A. The organization improves product identification to prevent customer complaints
B. The government develops a vaccine against a virulent virus
C. The organization uses fertilizers to prevent plants dying in a section of a garden centre
D. Call out roadside assistance to a broken-down car
E. A complaint about cold food was resolved by reheating food in the restaurant kitchen
F. After the loss of an important football match 4-0, the manager is sacked
G. The government increases payments to dentists for dental checks for children
H. The government enforces a lockdown against a virulent virus

Answer: A,B,C,F (LEAVE A REPLY)

NEW QUESTION: 11
TIX provides services to the informatic equipment of large organisations. They operate an ISO 9001:2015 QMS that is being audited by an important customer (second-party audit). During the audit, the audit team has identified two nonconformities. When preparing the Closing meeting, the audit team discussed and agreed both nonconformities with TIX's quality manager. The Closing meeting was planned for 6pm with the general manager, quality manager and service manager at the meeting room.
At 6pm, when the audit team enters the meeting room, only two people are present and waiting for them: the Health and Safety supervisor and the warehouse supervisor. Neither have participated in the audit.
The dialogue among them is as follows:
Audit team leader: "Good evening, could you please inform the three managers that we are ready to start with the Closing meeting?" Health and Safety supervisor: "Good evening. We are sorry to inform you that the general manager was involved in a serious car accident, and the other two managers have had to leave urgently to attend the emergency." Warehouse supervisor: "They have asked us to listen to what you need to say and to sign whatever we need to sign. We also have a message from them about the two nonconformities. They wanted us to ask you if you could contact them in a couple of days to determine how to proceed." Which one of the following options would be your preferred response to the final comment made by the warehouse manager?
A. Sorry, but we cannot proceed with the Closing meeting. So, we are leaving now, and please tell the quality manager that I will phone him tomorrow early in the morning.
B. We will hear what you were asked to tell us and will then leave. Please ask the managers to contact us as soon as the emergency is over to agree on a new date to carry out the Closing meeting.
C. We will hear what you were asked to tell us and will ask you to sign the nonconformity reports as evidence that you have accepted them. Please ask the managers to contact us as soon as the emergency is over to agree on a new date to complete the Closing meeting.
D. We will hear what you were asked to tell us and will leave copies of the nonconformity reports that have been agreed with the quality manager. Please tell the managers that we will consider this as the Closing meeting and that the individual(s) managing the audit programme will send the full report in five days.
Answer: B (LEAVE A REPLY)

NEW QUESTION: 12
You are conducting a third-party Stage 1 audit at ABC Ltd, a single-site organisation that manufactures wooden furniture. You interview the Technical Director to learn more about the organisation. The Technical Director explains that they have had a successful year and that

obtaining ISO 9001 certification will support the further growth of the business. You ask for an overview of the organisation's structure and its interrelationships with external interested parties. The Technical Director shows you a document detailing all business processes and interrelationships. You notice in this document that another organisation called Teak Ltd manufactures wooden furniture on behalf of ABC Ltd. The Technical Director confirms this capability has been accounted for in the scope of the quality management system. You learn that the furniture manufactured by Teak Ltd has accounted for 40% of the sales revenue over the previous 12 months.

Which two of the following options best describe how you would plan the audit of the interrelationship with Teak Ltd during the Stage 2 audit at ABC Ltd?

A. Verify Teak Ltd supply arrangements as described in the ABC Ltd quality management system

B. Verify if Teak Ltd are certified to ISO 9001

C. Verify the controls concerning customer property implemented by Teak Ltd

D. Verify how ABC Ltd evaluates the performance of Teak Ltd

E. Verify the quality management system at Teak Ltd by conducting an audit at their site

F. Verify whether the design processes of Teak Ltd comply with ISO 9001

Answer: A,D (LEAVE A REPLY)

According to ISO 9001:2015, clause 8.4, an organization is required to control the processes, products and services provided by external providers, including those that affect the quality of the organization's own products and services. This includes determining the controls to be applied to the external provision of processes, products and services, as well as the information to be communicated to the external providers. The organization is also required to monitor, measure, and evaluate the performance of the external providers and retain documented information of these activities.

Therefore, in the scenario given, ABC Ltd is responsible for controlling the processes, products and services provided by Teak Ltd, as they affect the quality of ABC Ltd's own products and services. This means that ABC Ltd should have established criteria and methods for evaluating the performance of Teak Ltd, as well as documented information of the results of such evaluation. ABC Ltd should also have defined the supply arrangements with Teak Ltd, including the specifications, requirements, and verification activities related to the products and services provided by Teak Ltd.

Hence, the best options to describe how to plan the audit of the interrelationship with Teak Ltd during the Stage 2 audit at ABC Ltd are A and D, as they are aligned with the requirements of ISO 9001:2015, clause

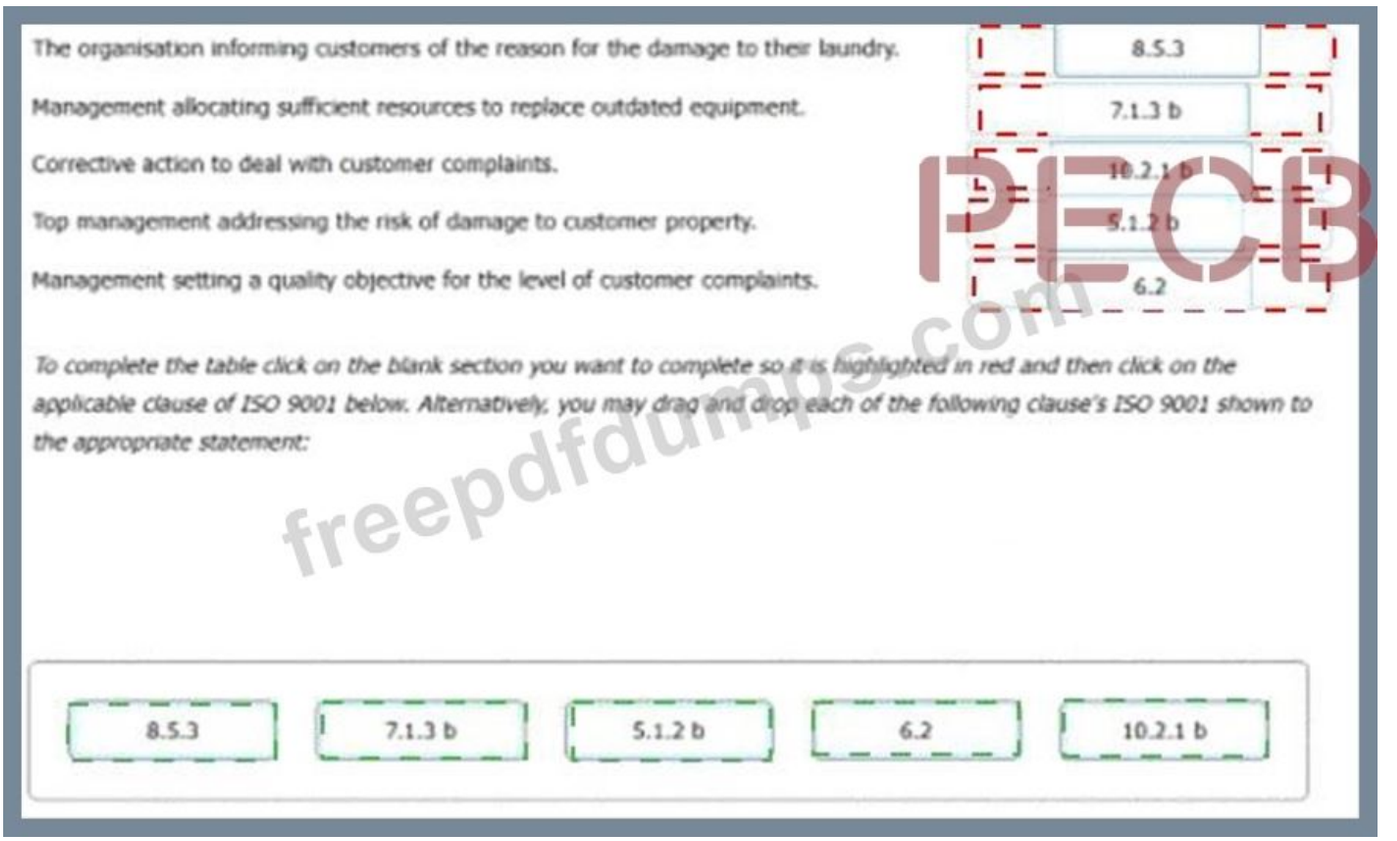
8.4. The other options are either irrelevant or beyond the scope of the audit, as they do not pertain to the control of external provision by ABC Ltd.

References:

ISO 9001:2015(en), Quality management systems - Requirements, clause 8.4 ISO 19011:2018(en), Guidelines for auditing management systems, clause 6.3.1 and 6.4.2 ISO 9001 Lead Auditor Training Course | IRCA Certified | BSI, section "Learning objectives" ISO 9001 Lead Auditor Course Material | 3FOLD Education Centre, module 5 and 6

NEW QUESTION: 13
Whistiekleen is a national dry cleaning and laundry organisation with 50 shops. You are conducting a surveillance audit of the Head Office and are sampling customer complaints. You find that 80% of complaints originate from five shops in the same region. Most of these complaints relate to damage to customer laundry.
The Quality Manager tells you that these are the oldest shops in the organisation. The deaning equipment needs replacing but the organisation cannot afford it now. You learn that the shop managers were told to dismiss most of the claims based on the poor quality of the laundered materials.
On raising the matter with senior management, you are told that there are plans to replace the equipment in these shops over the next five years.
Match the ISO 9001 Clauses to the statements.

Answer:



Explanation:

A screenshot of a computer AI-generated content may be incorrect.

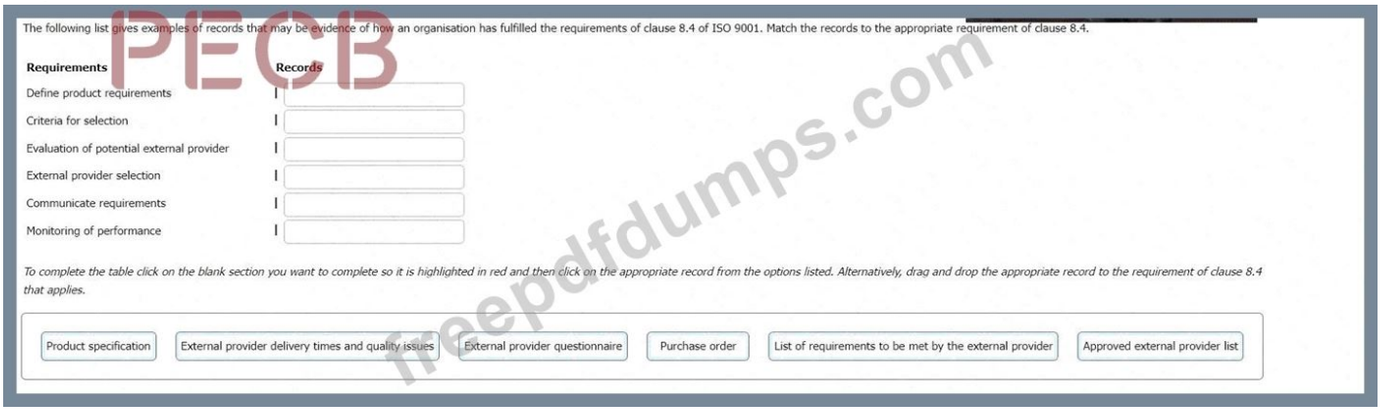
Statement	Clause
The organisation informing customers of the reason for the damage	8.5.3
Management allocating sufficient resources to replace outdated equipment	7.1.3 b
Corrective action to deal with customer complaints	10.2.1 b
Top management addressing the risk of damage to customer property	5.1.2 b
Management setting a quality objective for the level of complaints	6.2

Clause 8.5.3 - Property Belonging to Customers or External Providers:This clause requires the organization to care for customer property while it is under their control. If there is damage, they must inform the customer and retain documented information. Thus, informing customers of the reason for laundry damage relates directly to this clause.# Reference: ISO 9001:2015 Clause 8.5.3 Clause 7.1.3 b - Infrastructure:It refers to the provision and maintenance of infrastructure necessary for the operation of processes. This includes equipment. If resources are not allocated for outdated equipment, it directly breaches this clause.# Reference: ISO 9001:2015 Clause 7.1.3 b Clause 10.2.1 b - Corrective Action:This clause covers actions to eliminate the causes of nonconformities to prevent recurrence, including evaluating and correcting customer complaints.# Reference: ISO 9001:2015 Clause 10.2.1 b Clause 5.1.2 b - Customer Focus (Top Management):Top management must ensure risks to customer satisfaction, including property damage, are addressed. This aligns with addressing the risk of damaging customer laundry.# Reference: ISO 9001:2015 Clause 5.1.2 b Clause 6.2 - Quality Objectives and Planning to

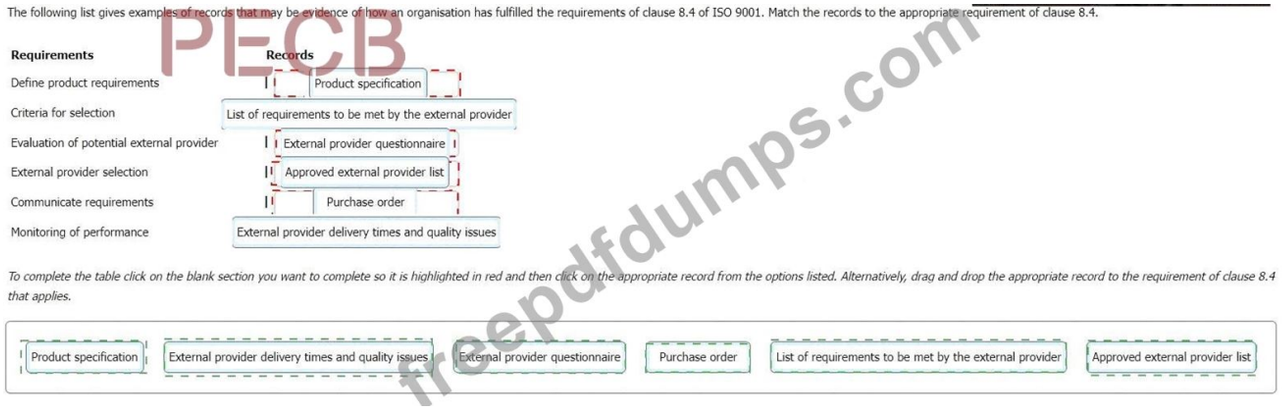
Achieve Them:Setting objectives for reducing customer complaints (like those about laundry damage) falls under this clause.# Reference: ISO 9001:2015 Clause 6.2

NEW QUESTION: 14

The following list gives examples of records that may be evidence of how an organisation has fulfilled the requirements of clause 8.4 of ISO 9001. Match the records to the appropriate requirement of clause 8.4.



Answer:



Explanation:

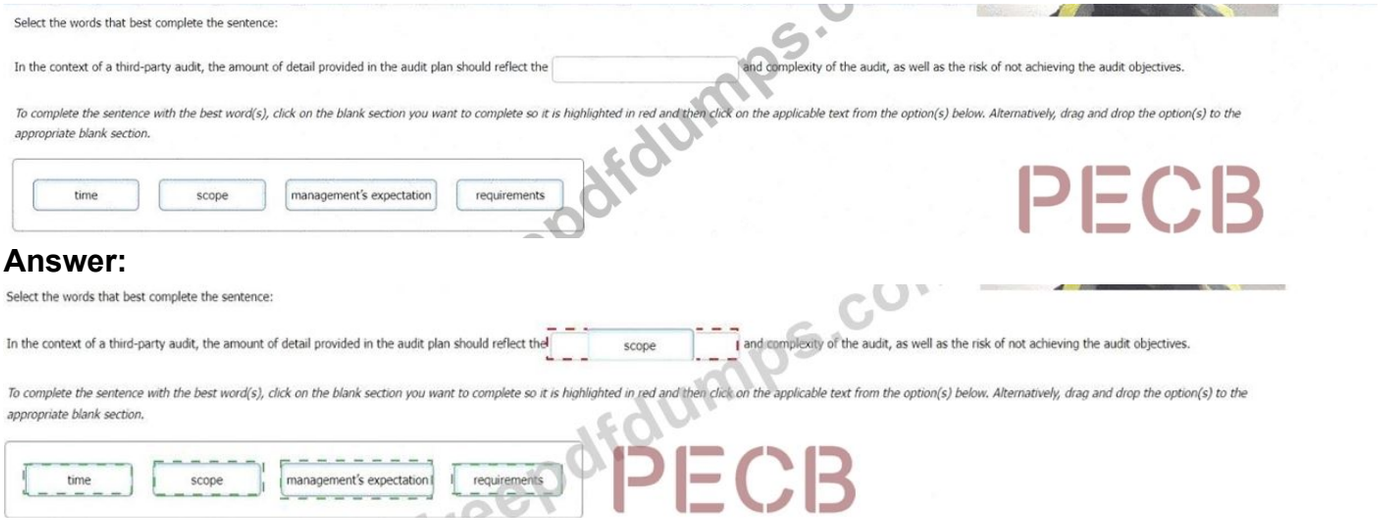
The following table shows the possible matching of the records to the requirements of clause 8.4:

Table

Requirements
Records
Define product requirements
Product specification
Criteria for selection
List of requirements to be met by the external provider
Evaluation of potential external provider
External provider questionnaire
External provider selection
Approved external provider list
Communicate requirements
Purchase order
Monitoring of performance
External provider delivery times and quality issues
Comprehensive and Detailed Explanation: = According to clause 8.4 of ISO 9001:2015, the organization should ensure that externally provided processes, products, and services conform to the specified requirements. To do so, the organization should:
Define the product requirements that are relevant for the external provision, such as specifications, drawings, standards, codes, etc. These should be documented and communicated to the external provider. A record of the product specification can be used as evidence of this requirement.
Establish the criteria for the selection, evaluation, and re-evaluation of external providers, based on their ability to provide processes, products, and services in accordance with the requirements. The criteria should be documented and applied consistently. A record of the list of requirements to be met by the external provider can be used as evidence of this requirement.
Evaluate the potential external providers before selecting them, using the established criteria. The evaluation methods may include questionnaires, audits, references, samples, etc. The results of the evaluation should be documented and reviewed. A record of the external provider questionnaire can be used as evidence of this requirement.
Select the external providers that have demonstrated their competence and conformity to the requirements.
The selection should be based on the evaluation results and the organization's needs. The selection should be documented and approved. A record of the approved external provider list can be used as evidence of this requirement.
Communicate the requirements for the processes, products, and services to be provided by the external provider, including the verification and validation activities, the acceptance criteria, the documentation requirements, the changes control, etc. The communication methods may include purchase orders, contracts, agreements, etc. The communication should be clear, complete, and timely. A record of the purchase order can be used as evidence of this requirement.
Monitor the performance and conformity of the external provider, using the established criteria and methods.

The monitoring methods may include inspections, tests, audits, feedback, complaints, etc. The monitoring results should be documented and analyzed. A record of the external provider delivery times and quality issues can be used as evidence of this requirement.
References: ISO 9001:2015, [ISO 9001 Auditing Practices Group Guidance on Scope], Mastering the Scope of ISO 9001 Quality Management Systems

NEW QUESTION: 15
Select the words that best complete the sentence:



Answer:

Explanation:
According to the ISO 19011:2018 document, the audit plan should provide the basis for agreement regarding the conduct and scheduling of the audit activities. The amount of detail provided in the audit plan should reflect the scope and complexity of the audit, as well as the risk of not achieving the audit objectives1. The scope of the audit refers to the extent and boundaries of the audit, such as the audit criteria, the audit objectives, the organizational and functional units, and the processes to be audited1. The complexity of the audit refers to the degree of difficulty or intricacy of the audit, such as the number and diversity of the auditees, the audit criteria, the audit methods, and the audit team composition2. The risk of not achieving the audit objectives refers to the possibility that the audit may fail to provide reliable and sufficient audit evidence to support the audit conclusions and report1.
Therefore, the complete sentence is:
In the context of a third-party audit, the amount of detail provided in the audit plan should reflect the scope and complexity of the audit, as well as the risk of not achieving the audit objectives.
References: 1: ISO 19011:2018 - Guidelines for auditing management systems 2: Audit Complexity - an overview | ScienceDirect Topics

NEW QUESTION: 16
Who is responsible for the development of surveillance activities?
A. A representative of the auditee's top management
B. The certification body
C. The audit team leader

Answer: B (LEAVE A REPLY)
Comprehensive and Detailed In-Depth Explanation:
According to ISO 17021-1:2015, Clause 9.6.2 (Surveillance Activities):
The certification body is responsible for planning and conducting surveillance audits to ensure continued compliance.
The auditee's top management (A) does not develop surveillance activities, but they must participate.
The audit team leader (C) conducts the surveillance audit, but they do not develop the program.
Thus, B is the correct answer.
Reference:
ISO 17021-1:2015, Clause 9.6.2 (Surveillance Activities)

NEW QUESTION: 17
What does the application of the process approach in a QMS enable?
A. The improvement of processes based on the needs and expectations of interested parties
B. The consideration of processes in terms of financial value
C. The achievement of effective process performance
D. The reduction of resource consumption
Answer: (SHOW ANSWER)
Comprehensive and Detailed In-Depth Explanation:
ISO 9001:2015 promotes the process approach, which allows organizations to structure their activities into interrelated processes. This approach helps ensure that processes effectively achieve intended results.
Clause 0.3.1 (Process Approach) states that "The application of the process approach in a quality management system enables understanding and consistency in meeting requirements, considering processes in terms of added value, and achieving effective process performance."
This aligns directly with option C, making it the correct answer. The other options are either partially correct or do not fully capture the purpose of the process approach:
* Option A (Improvement based on interested parties) is a benefit but does not define the main goal.
* Option B (Financial value) is not the primary focus of the process approach.

* Option D (Reduction of resource consumption) may be an indirect benefit but is not a core objective.
Reference:
ISO 9001:2015, Clause 0.3.1 - Process Approach
ISO 9001:2015, Clause 4.4 - QMS and its Processes

NEW QUESTION: 18
What are the objectives of the Stage 2 audit?
A. To evaluate whether the QMS is effectively implemented
B. To review the auditee's management system documented information
C. To gather information regarding the scope of the QMS
Answer: A (LEAVE A REPLY)
Comprehensive and Detailed In-Depth Explanation:
The Stage 2 audit (ISO 17021-1:2015, Clause 9.3.1.3) is conducted to:
* Verify whether the QMS is effectively implemented and operational.
* Ensure compliance with ISO 9001 requirements in actual practice.
* Identify nonconformities that may impact certification.
Reviewing documented information (Answer B) is part of Stage 1, and gathering scope information (Answer C) is done before the certification audit.
Reference:
ISO 17021-1:2015, Clause 9.3.1.3 (Stage 2 Audit)

NEW QUESTION: 19
A Health Trust has contracted with Servitup, a catering services organisation which has been certified to ISO
9001 for 1 year. It provides services to ten, small rural
hospitals in remote locations involving purchase and storage of dry goods and fresh produce, preparing meals and loading heated trolleys for ward service by hospital staff. An auditor is conducting the first sole surveillance audit at one site with the Deputy Catering Manager (DCM). At the closing meeting attended solely by the DCM, the auditor informs him that he has found numerous gaps in the QMS processes which lead him to consider recommending suspension of the organisation's certification. He is particularly concerned with the evidence that patient health is being adversely affected by produce stored beyond its safe consumption date, poor kitchen hygiene and undercooked meals. The DCM says that he cannot make any decisions about these issues in the absence of the Catering Manager due to illness but will write everything down and report to the Catering Manager.
Which two actions should you take in the context of the audit?
A. Close the meeting immediately after the DCM's response and advise that the issues will be addressed at the next surveillance visit.
B. Call the individual(s) managing the audit programme to explain the situation and recommend immediate suspension of certification to protect the integrity of the Certification Body.

C. Continue with the meeting, present the audit conclusions and inform the DCM that the organisation will receive the audit report in due course.
D. Conclude the meeting early and advise that it will be rescheduled once the Catering Manager has returned to work.
E. Recommend that all personnel should be given urgent in-depth training in the QMS.
F. Thank the DCM for his time and express an expectation that improvements will be made in the QMS.
Answer: B,C (LEAVE A REPLY)
The actions that should be taken in the context of the audit are:
*Option B: Call the individual(s) managing the audit programme to explain the situation and recommend immediate suspension of certification to protect the integrity of the Certification Body. This option is correct because the auditor has found serious and significant gaps in the QMS processes that affect the health and safety of the patients, which is a major nonconformity that may warrant suspension of certification. The auditor should inform the individual(s) managing the audit programme of the situation and the audit findings, and recommend immediate suspension of certification to protect the integrity of the Certification Body and the credibility of the certification scheme. The auditor should also follow the Certification Body's procedures and rules for suspension of certification and communicate the decision and the consequences to the auditee.
*Option C: Continue with the meeting, present the audit conclusions and inform the DCM that the organisation will receive the audit report in due course. This option is correct because the auditor should not terminate or postpone the closing meeting due to the absence of the Catering Manager, as the DCM is the auditee's nominated representative for the audit. The auditor should continue with the meeting, present the audit conclusions and the audit findings, and inform the DCM that the organisation will receive the audit report in due course. The auditor should also explain the audit outcome recommendation and the suspension of certification, and request the DCM to acknowledge the receipt and understanding of the audit results.
The following options are not correct:
*Option A: Close the meeting immediately after the DCM's response and advise that the issues will be addressed at the next surveillance visit. This option is not correct because the auditor should not close the meeting without presenting the audit conclusions and the audit findings, as this would violate the audit principles of fairness and transparency. The auditor should also not advise that the issues will be addressed at the next surveillance visit, as this would imply that the auditor is accepting the auditee's delay and inaction, and that the auditor is not taking the major nonconformity seriously.
*Option D: Conclude the meeting early and advise that it will be rescheduled once the Catering Manager has returned to work. This option is not correct because the auditor should not conclude the meeting early or reschedule it due to the absence of the Catering Manager, as this would disrupt the audit process and the audit schedule. The auditor should also not wait for the Catering Manager to return to work, as this would delay the communication and resolution of the major nonconformity, and potentially compromise the health and safety of the patients.

*Option E: Recommend that all personnel should be given urgent in-depth training in the QMS. This option is not correct because the auditor should not recommend or prescribe specific corrective actions to the auditee, as this would violate the audit principles of independence and objectivity. The auditor should only report the audit findings and the audit outcome recommendation, and leave the responsibility and authority for determining and implementing the corrective actions to the auditee.
*Option F: Thank the DCM for his time and express an expectation that improvements will be made in the QMS. This option is not correct because the auditor should not thank the DCM for his time and express an expectation that improvements will be made in the QMS, as this would imply that the auditor is satisfied and optimistic with the auditee's performance and response, and that the auditor is not taking the major nonconformity seriously. The auditor should instead express the concern and dissatisfaction with the auditee's QMS processes and the impact on the health and safety of the patients, and communicate the suspension of certification and the need for urgent and effective corrective actions.
References:
*ISO 19011:2018 Guidelines for auditing management systems, Clause 6.4.2: Conducting audit activities, Subclause k) and l)
*ISO 9001 Lead Auditor Course Material, Module 5: Conducting an Audit, Slide 20: Closing Meeting
*ISO 9001 Lead Auditor Training Course - IRCA Certified, Section 5.5: Closing Meeting
*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: 20
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.
How do you assess the situation presented in the last paragraph of scenario 4?

A. Anne cannot withdraw from the audit once the audit mandate is accepted.
B. TD cannot make any change to the audit scope once it has been defined.
C. TD should have agreed with the certification body and Anne about any change in the audit scope.
D. Anne has full authority to reject any scope changes, even if TD and the certification body agree.
Answer: C (LEAVE A REPLY)
Comprehensive and Detailed In-Depth Explanation:
ISO 9001:2015 requires collaboration between the auditee (TD Advertising), the certification body, and the audit leader when making changes to audit scope.
Clause References:
* ISO/IEC 17021-1:2015, Clause 9.2.3 - Conducting the Audit: Any change in audit scope must be agreed upon by all parties before proceeding.
Why is the Correct Answer C?
* TD cannot unilaterally change the scope without agreement from the certification body and audit leader.
* The certification body must ensure the scope remains relevant and that resources are allocated properly.
Why are the Other Options Incorrect?
* A (Anne cannot withdraw) # Incorrect, Anne CAN withdraw if the changes make the audit unfeasible, but she must consult with the certification body first.
* B (TD cannot change the scope) # Incorrect, scope changes are allowed but must be formally approved.
* D (Anne has full authority to reject scope changes) # Incorrect, scope changes require mutual agreement among all parties.
Reference:
ISO/IEC 17021-1:2015, Clause 9.2.3 - Conducting the Audit

NEW QUESTION: 21
One of the conflict resolution techniques is toning down. How is the conflict managed in that case?
A. Following negotiations, each party makes concessions in order to reach a common agreement.
B. The audit team leader uses their authority to solve the conflict.
C. The points of agreement are emphasized and the points of disagreement are put into perspective.
Answer: C (LEAVE A REPLY)
Comprehensive and Detailed In-Depth Explanation:
Toning down (or de-escalation) is a conflict resolution technique where:
Common agreements are emphasized to reduce tension.
Disagreements are addressed with a rational and constructive approach.

Option A describes compromise, and Option B describes authoritative resolution, which are different conflict resolution techniques.
Reference:
ISO 19011:2018, Clause 7.1.3 (Managing Conflict During an Audit)

NEW QUESTION: 22
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.
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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. Establishing audit criteria and objectives.
B. Determining the audit feasibility.
C. Assigning responsibilities for the audit team members.
D. Signing the certification agreement.
Answer: D (LEAVE A REPLY)
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.
Reference:
ISO 19011:2018, Clause 5.5 - Conducting the Audit
ISO/IEC 17021-1:2015, Clause 9.1.2 - Audit Planning

NEW QUESTION: 23
An audit team of three people is conducting a Stage 2 audit to ISO 9001 of an engineering organisation which manufactures sacrificial anodes for the oil and gas industry in marine environments. These are aluminium products designed to prevent corrosion of submerged steel structures. As one of the auditors, you find that the organisation has shipped anodes for Project DK in the Gulf of Mexico before the galvanic efficiency test results for the anodes have been fully analysed and reported as required by the customer. The Quality Manager explains that the Managing Director authorised the release of the anodes to avoid late delivery as penalties would be imposed. The customer was not informed since the tests rarely fall below the required efficiency. You raise a nonconformity against clause 8.6 of ISO 9001.
During the audit team meeting in preparation for the Closing meeting, the second auditor disagreed with the clause of ISO 9001 selected for the above nonconformity. He thinks it should be clause 9.1.1.
Choose three options for how the audit team leader should best respond to the situation:
A. The audit team leader will refer to the quality manager to determine which clause they agree with.
B. Advise that he will think about the clause and announce his decision during the Closing meeting.
C. Immediately agree with the second auditor that clause 9.1.1 would be better.
D. Immediately overule the objection of the second auditor with no discussion of the clause.
E. Invite you and the second auditor to fully explain your point of view and then decide which clause to select.
F. Review the evidence with you and the second auditor, and then decide which clause of ISO 9001 would best apply.
G. Suggest that neither clause is accurate and instead propose clause 9.1.3 as the best one for the nonconformity.
H. Try to obtain a consensus between you and the second auditor after a discussion of the different opinions.
Answer: (SHOW ANSWER)
As the audit team leader, it is crucial to manage differing opinions constructively and ensure that the correct clause is selected for the nonconformity based on solid evidence. Here's how the situation should be handled:

E). Invite you and the second auditor to fully explain your point of view and then decide which clause to select: This promotes collaboration and transparency, allowing both auditors to present their rationale for choosing the specific clause.
F). Review the evidence with you and the second auditor, and then decide which clause of ISO 9001 would best apply: Reviewing the evidence in relation to the specific requirements of ISO 9001 is essential for determining which clause is most appropriate.
H). Try to obtain a consensus between you and the second auditor after a discussion of the different opinions:
Consensus-building is a crucial skill for an audit team leader. Achieving agreement ensures the nonconformity is addressed accurately and with full team support.
Options such as overruling immediately (D) or deferring the decision without full discussion (B) could undermine team dynamics and the audit process. Consulting the quality manager (A) or selecting an entirely different clause (G) is unnecessary, as the team should resolve the issue internally.

NEW QUESTION: 24
An audit team leader arrives at a printing organisation to carry out a Stage 2 audit for a certification body. At a meeting with the Quality Manager, she is told that they have won their biggest contract from a computer manufacturer to print and compile computer documentation packages. They have leased the unit next door for space reasons but have never worked in this sector before. The Quality Manager wants the ISO 9001 certificate to cover the new contract. During the audit, a team member finds that a number of print jobs have been rejected by several clients over a number of months due to spelling errors in the print run. The Print Manager blames the new employees they had to take on because of a big contract. The auditor raises a nonconformance against clause 10.2.1.b of ISO
9001.
Which one of the evidence statements would support this finding?
A. There was no record that the organisation evaluated the effectiveness of the training given to new employees.
B. There was no evidence that a check of spelling took place before the release of printing to the client.
C. The actions taken to deal with customer complaints did not prevent recurrence of the problem.
D. The organisation did not provide the correct resources to prevent nonconformity.
Answer: C (LEAVE A REPLY)
According to clause 10.2.1.b of ISO 9001:2015, the organization should evaluate the need for action to eliminate the causes of nonconformities, in order to prevent their recurrence. This means that the organization should identify and address the root causes and contributing factors of the nonconformities, and implement appropriate corrective actions that are effective and proportional to the impact of the nonconformities. In this case, the evidence statement that supports the finding of nonconformance is C, because it shows that the organization did not take effective actions to prevent the recurrence of the spelling errors in the print run, which resulted in

repeated customer rejections and dissatisfaction. The other options are not directly related to clause 10.2.1.b, although they may indicate other nonconformities or weaknesses in the organization's QMS.
For example, option A may relate to clause 7.2 on competence, option B may relate to clause 8.6 on release of products and services, and option D may relate to clause 7.1 on resources.
References: ISO 9001:2015, [ISO
9001 Auditing Practices Group Guidance on Nonconformity and Corrective Action], ISO 9001 Clause 10.
Improvement - ISO-templates.com

NEW QUESTION: 25
Scenario 2:
Bell is a Canadian food manufacturing company that operates globally. Their main products include nuts, dried fruits, and confections. Bell has always prioritized product quality and has maintained a good reputation for many years. However, the company's production error rate increased significantly, leading to more customer complaints.
To increase efficiency and customer satisfaction, Bell implemented a Quality Management System (QMS) based on ISO 9001. The top management established a QMS implementation team comprising five middle managers from various departments, including Leslie, the quality manager.
Leslie was responsible for assigning responsibilities and authorities for QMS-related roles. He also suggested including a top management representative in the QMS team, but top management declined due to other priorities.
The team defined the QMS scope as:
"The scope of the QMS includes all activities related to food processing." Leslie established a quality policy and presented it to the team for review before top management approval
. Top management also proposed a new strategy for handling customer complaints, requiring biweekly customer surveys to monitor customer perceptions.
Which situation presented in scenario 2 is NOT compliant with ISO 9001?
A. The QMS implementation team comprised five middle managers.
B. The QMS implementation team did not include a representative from top management.
C. The responsibilities and authorities for QMS roles were assigned by Leslie, the quality manager.
D. The quality policy was reviewed by the implementation team before top management approval.
Answer: B (LEAVE A REPLY)
Comprehensive and Detailed In-Depth Explanation:
ISO 9001:2015 Clause 5.1.1 (Leadership and Commitment) states that top management must demonstrate leadership and commitment to the QMS by actively participating in QMS implementation, integration, and effectiveness.

In scenario 2, top management refused to be directly involved in the QMS implementation team, which violates Clause 5.1.1 because leadership involvement is essential for the system's success.
Other options do not indicate nonconformance:
* Option A (Middle managers in the QMS team) is acceptable.
* Option C (Leslie assigning roles) is valid if competence is ensured (Clause 5.3 - Organizational Roles, Responsibilities, and Authorities).
* Option D (Team reviewing the policy before approval) aligns with best practices.
Reference:
ISO 9001:2015, Clause 5.1.1 - Leadership and Commitment
ISO 9001:2015, Clause 5.3 - Organizational Roles, Responsibilities, and Authorities

NEW QUESTION: 26
Which action indicates that an organization is meeting the requirements of ISO 9001 regarding nonconforming outputs?
A. Retaining documented information only on the actions taken.
B. Verifying conformity to the applicable requirements prior to correction of the nonconforming outputs.
C. Taking appropriate action to nonconforming products and services detected after the delivery of products, during or after the provision of services.
D. Allowing employees to handle nonconformities based on their own judgment without structured procedures.
Answer: C (LEAVE A REPLY)
Comprehensive and Detailed In-Depth Explanation:
ISO 9001:2015 requires organizations to identify and control nonconforming outputs to prevent unintended use or delivery.
Clause References:
* Clause 8.7 (Control of Nonconforming Outputs): Organizations must ensure that nonconforming outputs are identified and controlled to prevent unintended use or delivery.
* Clause 10.2 (Nonconformity and Corrective Action): Requires organizations to take appropriate actions when nonconformities are found, including during or after service provision.
Why is the Correct Answer C?
* If nonconforming products or services are identified after delivery or during service, organizations must take corrective actions to protect customers and stakeholders.
* Actions may include recalls, rework, customer notifications, compensation, or process improvements.
* This approach aligns with ISO 9001:2015, ensuring that products/services consistently meet requirements.
Why are the Other Options Incorrect?
* A (Retaining documentation only) # While documentation is required, it alone does not ensure proper handling of nonconforming outputs.

* B (Verifying conformity before correction) # While verification is good practice, ISO 9001 prioritizes corrective action over mere verification.
* D (Allowing employees to handle nonconformities without structure) # ISO 9001 requires documented procedures for handling nonconformities (Clause 8.7).
Reference:
ISO 9001:2015, Clause 8.7 - Control of Nonconforming Outputs
ISO 9001:2015, Clause 10.2 - Nonconformity and Corrective Action

NEW QUESTION: 27
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 (LEAVE A REPLY)
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: 28
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. No quality objectives planned for the top management team
B. Decisions on improvement action timescales not involving departmental managers.
C. Evaluation of the results of the improvement action not always documented by the Quality Manager.
D. Limited knowledge of the content of Quality Improvement Requests by departmental staff.
E. Quality improvements not aligning with the quality policy.
F. Top management claim not to be aware of the improvement request (QI/12/20/HR-3) initiated by the Quality Manager.
Answer: (SHOW ANSWER)

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: 29
A person who provides specific knowledge or expertise to the audit team during the audit is known as a/an:
A. Observer.
B. Technical expert.
C. Guide.
Answer: B (LEAVE A REPLY)
Comprehensive and Detailed In-Depth Explanation:
A technical expert is someone with specialized knowledge that helps the audit team understand specific technical aspects of the auditee's processes.
Clause References:
ISO 19011:2018, Clause 7.3.4 - Use of Technical Experts:
Technical experts support the audit team with specialized knowledge but do not perform the audit themselves.
Why is the Correct Answer B?
A technical expert is needed when auditors lack deep expertise in specific areas, such as engineering, software, or medical devices.

They assist in interpreting complex technical requirements but do not act as auditors.
Why are the Other Options Incorrect?
A (Observer) # Observers do not contribute expertise; they only watch the audit (e.g., trainees).
C (Guide) # Guides help with logistics but do not provide technical expertise.
Reference:
ISO 19011:2018, Clause 7.3.4 - Use of Technical Experts

NEW QUESTION: 30
At the end of a second-party audit, the audit team enters the meeting room to hold the closing meeting; only two people are present and waiting for them: the Health and Safety supervisor and the Administrative Officer.
Neither has participated in the audit. However, the team had previously agreed with the auditee Quality Manager on two nonconformities identified during the audit (NC1 and NC2).
They said:
Health and Safety Supervisor: "Good evening. We are sorry to inform you that the general manager was involved in a serious car accident, and the other two managers have had to leave urgently to attend to the emergency." The Administration Officer: "Concerning 'nonconformity 2', the General Manager left a message asking us to tell you that he does not accept it and requests you not to include it in the audit report. Here is a note in which he explains why." Which one of the following would be your preferred answer (as team leader) to the General Manager's request?
A. OK. Please, let me review the message. I will try to see if I can change the text of the nonconformity if necessary. Let's take a 10-minute break, as I would like to discuss this issue with the audit team.
B. OK. I will get in contact with my company tomorrow to ask for instructions on what to do with this non-conformity.
C. Please tell him that I will phone him in two days and will discuss the issue. Could you please give me his mobile phone number?
D. Please tell him that this nonconformity has been previously accepted by the quality manager during the audit and will stand. I will include it in the report, along with the concern of the General Manager about it.
Answer: A (LEAVE A REPLY)

NEW QUESTION: 31
Scenario 5: Mechanical-Electro (ME) Audit Stages
Mechanical-Electro, better known as ME, is an American company that provides mechanical and electrical services in China. Their services range from air-conditioning systems, ventilation systems, plumbing, to installation of electrical equipment in automobile plants, electronic manufacturing facilities, and food processing plants.
Due to the fierce competition from local Chinese companies and failing to meet customer requirements, ME's revenue dropped significantly. In addition, customers' trust and confidence in the company decreased, and the reputation of the company was damaged.

In light of these developments, the top management of ME decided to implement a quality management system (QMS) based on ISO 9001. After having an effective QMS in place for over a year, they applied for a certification audit.
A team of four auditors was appointed for the audit, including Li Na as the audit team leader. Initially, the audit team conducted a general review of ME's documents, including the quality policy, operational procedures, inventory lists, QMS scope, process documentation, training records, and previous audit reports.
Li Na stated that this would allow the team to maintain a systematic and structured approach to gathering documents for all audit stages. While reviewing the documented information, the team observed some minor issues but did not identify any major nonconformities. Therefore, Li Na claimed that it was not necessary to prepare a report or conduct a meeting with ME's representatives at that stage of the audit. She stated that all areas of concern would be discussed in the next phase of the audit.
Following the on-site activities and the opening meeting with ME's top management, the audit team structured an audit test plan to verify whether ME's QMS conformed to Clause 8.2.1 (Customer Communication) of ISO
9001.
To do so, they gathered information through group interviews and sampling. Li Na conducted interviews with departmental managers in the first group and then with top management. In addition, she chose a sampling method that sufficiently represented customer complaints from both areas of ME's operations.
The team members were responsible for the sampling procedure. They selected a sample size of 4 out of 45 customer complaints received weekly for electrical services and 2 out of 10 complaints for mechanical services.
Afterward, the audit team evaluated the evidence against the audit criteria and generated the audit findings.
According to scenario 5, Li Na conducted group interviews with departmental managers and top management by herself. Is this in accordance with audit best practices?
A. Yes, only the audit team leader should conduct group interviews.
B. Yes, the auditee's top management is always interviewed by the audit team leader only.
C. No, two auditors should be present in case of group interviews.
Answer: C (LEAVE A REPLY)
Comprehensive and Detailed In-Depth Explanation:
According to ISO 19011:2018, Clause 6.4.6 (Conducting Interviews), group interviews should be conducted with at least two auditors to ensure objectivity and accuracy.
This prevents bias or misinterpretation of responses.
It allows for cross-validation of information.
It ensures that the audit results remain objective and impartial.
Since Li Na conducted the group interviews alone, she did not follow audit best practices. The correct approach would have been to have another auditor present during the interviews.
Reference:

ISO 19011:2018, Clause 6.4.6 (Conducting Interviews)

NEW QUESTION: 32
During a third-party surveillance audit, the auditor finds that the management review meeting minutes record that the improvement actions set by the previous review have not been completed for a second year running. It states that a new Quality Manager has been brought in at the middle management level to rectify the situation.
You learn that top management is not involved in the QMS other than being copied into the minutes of the management review meeting.
The audit reveals that the new Quality Manager was given responsibility by top management to:
a) take accountability for the effectiveness of the QMS,
b) select, approve, and monitor improvement actions without involving and reporting to top management, c) promote the improvement of the QMS, and d) make efficient use of the limited financial and personnel resources allocated for the QMS by top management.
The auditor considers whether there is a nonconformity against clause 5.1.1 of ISO 9001:2015.
Select two options of the evidence required for such a nonconformity:
A. Top management is not accountable for the effectiveness of the QMS.
B. The Quality Manager avoids giving improvement actions to the Chief Executive.
C. The Chief Executive never attends the management review meetings in person.
D. The Quality Manager is on target to complete only half of the improvement actions.
E. The Quality Manager only reports to one designated senior manager.
F. The Quality Manager does not have access to the resources needed for the QMS.
Answer: A,F (LEAVE A REPLY)
Comprehensive and Detailed In-Depth Explanation:
Clause 5.1.1 of ISO 9001:2015 - Leadership and Commitment - specifically mandates that top management must take accountability for the effectiveness of the QMS. They are also responsible for ensuring:
Integration of the QMS into business processes (5.1.1 c)
Promotion of customer focus and continual improvement (5.1.1 d, i)
Availability of necessary resources (5.1.1 e)
That the QMS achieves its intended results (5.1.1 g)

Let's analyze the selected options:
A. Top management is not accountable for the effectiveness of the QMS.
This directly violates clause 5.1.1 a, which explicitly requires top management to take accountability for the effectiveness of the QMS. Delegating this to a middle-level Quality Manager, as described in the scenario, constitutes a nonconformity.
F. The Quality Manager does not have access to the resources needed for the QMS.
According to clause 5.1.1 e, top management must ensure the availability of required resources for maintaining and improving the QMS. If the Quality Manager is resource-constrained, it indicates top management has failed to meet this requirement.
Now, why the other options are incorrect in terms of direct clause 5.1.1 nonconformity:
B. Avoiding giving improvement actions to the Chief Executive - While this may reflect poor communication, it is not, by itself, a clear breach of 5.1.1 unless linked directly to top management's lack of accountability or commitment.
C. Chief Executive never attending meetings - ISO 9001 does not require physical attendance of the Chief Executive at management reviews. What matters is whether top management is fulfilling their roles, not how.
D. Completing only half of improvement actions - This indicates performance issues but does not necessarily indicate top management's lack of accountability, unless they failed to monitor progress entirely.
E. Reporting to one designated senior manager - This is not inherently nonconforming unless that senior manager does not fulfill top management's responsibilities under 5.1.1.
Relevant ISO 9001:2015 Reference:
Clause 5.1.1 a, e, g, h:
"Top management shall demonstrate leadership and commitment with respect to the quality management system by:
a) taking accountability for the effectiveness of the quality management system; e) ensuring that the resources needed for the quality management system are available..."

NEW QUESTION: 33
What is the responsibility of the audit committee during an internal audit?
A. To define the audit schedule
B. To supervise all audit functions and activities
C. To establish an internal audit program
Answer: C (LEAVE A REPLY)
Comprehensive and Detailed In-Depth Explanation:
According to ISO 19011:2018, Clause 5.2 (Audit Program Management):
* The audit committee is responsible for establishing the internal audit program.
* The audit schedule (A) is determined within the program, but it is not the main role of the committee.
Thus, C is the correct answer.
Reference:

ISO 19011:2018, Clause 5.2 (Audit Program Management)

NEW QUESTION: 34

Scenario 1: AL-TAX is a company located in California which provides financial and accounting services.

The company manages the finances of 17 companies and now is seeking to expand their business even more The CEO of AL-TAX, Liam Durham, claims that the company seeks to provide top-notch services to their clients Recently, there were a number of new companies interested in the services provided by AL-TAX.

In order to fulfill the requirements of new clients and further improve quality, Liam discussed with other top management members the idea of implementing a quality management system (QMS) based on ISO 9001.

During the discussion, one of the members of the top management claimed that the size of the company was not large enough to implement a QMS. In addition, another member claimed that a QMS is not applicable for the industry in which AL TAX operates. However, as the majority of the members voted for implementing the QMS. Liam initiated the project.

Initially, Liam hired an experienced consultant to help AL-TAX with the implementation of the QMS. They started by planning and developing processes and methods for the establishment of a QMS based on ISO

9001. Furthermore, they ensured that the quality policy is appropriate to the purpose and context of AL TAX and communicated to all employees. In addition, they also tried to follow a process that enables the company to ensure that its processes are adequately resourced and managed, and that improvement opportunities are determined.

During the implementation process, Liam and the consultant focused on determining the factors that could hinder their processes from achieving the planned results and implemented some preventive actions in order to avoid potential nonconformities Six months after the implementation of the QMS. AL-TAX conducted an internal audit. The results of the internal audit revealed that the QMS was not fulfilling all requirements of ISO 9001. A serious issue was that the QMS was not fulfilling the requirements of clause 5.1.2 Customer focus and had also not ensured clear and open communication channels with suppliers.

Throughout the next three years, the company worked on improving its QMS through the PDCA cycle in the respective areas. To assess the effectiveness of the intended actions while causing minimal disruptions, they tested changes that need to be made on a smaller scale. After taking necessary actions, AL-TAX decided to apply for certification against ISO 9001.

Based on the scenario above, answer the following question:

Which of the following misconceptions about ISO 9001 was present in scenario 1?

A. A QMS based on ISO 9001 requires many resources and is time-consuming.

B. A QMS based on ISO 9001 is only applicable to organizations producing tangible goods.

C. A QMS based on ISO 9001 is a complex task and requires a lot of documentation.

Answer: B (LEAVE A REPLY)

Comprehensive and Detailed In-Depth Explanation:

One of the common misconceptions about ISO 9001 is that it only applies to manufacturing companies producing tangible goods. However, ISO 9001:2015 is designed for all types of organizations, including service providers such as financial, healthcare, and IT companies. Clause 1 (Scope) clearly states that ISO 9001 is applicable to any organization, regardless of type, size, or the products and services it provides. AL-TAX, being a financial services company, is equally eligible for implementing a QMS under ISO 9001.
Reference:
ISO 9001:2015, Clause 1 - Scope

NEW QUESTION: 35
The Closing meeting of a second-party audit was planned for 6 pm with the general manager and the quality manager.
At 6 pm, when the audit team enters the meeting room, only the Quality Manager is present and walting for them.
The dialogue among them is as follows:
Auditor team leader: "Good evening, could you please inform the general manager that we are ready to start with the closing meeting?" Quality manager: "Good evening. I am sorry to inform you that the general manager will not be able to attend the meeting. He will try to participate virtually to make some closing remarks." Auditor team leader: "OK. We identified seven nonconformities - these are the reports. Could you please review them and sign them?" Quality manager: "OK. As you know, I reviewed them after yesterday's meeting and accept of all them, where shall I sign?" General manager (from speakers in the room and addressing the quality manager): "Hold on! Do not sign the two nonconformities related to ABC Bank! I have just checked, and we did not provide any services to ABC Bank during September! You can sign the remaining five nonconformities." How would you proceed with the audit? Select one.
A. I will discuss this issue with our corporate quality manager and will let you know what we will do
B. I will include the seven nonconformities in the report, considering that we identified objective evidence on which all these nonconformities are based
C. I withdraw the two nonconformities related to service to ABC and will present the report with the remaining five nonconformities
D. I will review this issue at length with the audit team tonight and will phone you tomorrow to let you know our decision
Answer: (SHOW ANSWER)

NEW QUESTION: 36
An audit team of three people is conducting a Stage 2 audit to ISO 9001 of an engineering organisation that manufactures sacrificial anodes for the oil and gas industry in marine environments. These are aluminium products designed to prevent corrosion of submerged steel structures. You, as one of the auditors, find that the organisation has shipped anodes for Project DK in the Gulf of Mexico before the galvanic efficiency test results for the anodes have been fully

analysed and reported as required by the customer. The Quality Manager explains that the Managing Director authorised the release of the anodes to avoid late delivery as penalties would be Imposed. The customer was not informed since the tests very rarely fall below the required efficiency. You raise a nonconformity against clause 8.6 of ISO 9001.
At the Closing meeting, the audit team leader presents the findings of the audit and comes to the above nonconformity. The Quality Manager produces the test report for Project DK, which shows an acceptable galvanic efficiency, and presents an email from the customer confirming acceptance of the anodes. He asks that the nonconformity be withdrawn.
Which two of the following responses by the audit team leader would be acceptable?
A. Thank the Quality Manager for his contribution but dismiss the information as irrelevant after a quick review.
B. Indicate that the nonconformity is evidence of a system failure that needs to be rectified.
C. Refuse to accept the documentation produced and maintain the nonconformity.
D. Accept the Quality Manager's request without reviewing the documentation.
E. Ask the auditor (you) who raised the issue, to state what you think should happen
F. Advise management that the information provided will be reviewed at the audit follow-up stage.
Answer: B,F (LEAVE A REPLY)

NEW QUESTION: 37
Which two of the following are the key expected results of a quality management system that conforms to the requirements of ISO 9001:2015?
A. Consistently provide products that meet customers' requirements
B. Decreased number of management system nonconformities
C. Decreased number of warranty claims
D. Decreased number of nonconforming products in all stages of the manufacturing cycle
E. Enhanced customer satisfaction
F. Increased profits
Answer: A,E (LEAVE A REPLY)
The key expected results of a quality management system that conforms to the requirements of ISO 9001:
2015 are stated in clause 0.1 of the standard, which says: "The adoption of a quality management system is a strategic decision for an organization that can help to improve its overall performance and provide a sound basis for sustainable development initiatives. The potential benefits to an organization of implementing a quality management system based on this International Standard are: a) the ability to consistently provide products and services that meet customer and applicable statutory and regulatory requirements; b) facilitating opportunities to enhance customer satisfaction; c) addressing risks and opportunities associated with its context and objectives; d) the ability to demonstrate conformity to specified quality management system requirements."
Therefore, the two options that best match these benefits are A and E, as they directly relate to providing products and services that meet customer requirements and enhancing customer satisfaction. The other options are not explicitly mentioned as key expected results, although they

may be possible outcomes of implementing a quality management system. References: ISO 9001:2015 - Quality management systems - Requirements, Key Elements of an ISO 9001:2015 Quality Management System, What is ISO 9001 2015 as a Quality Management Systems?

NEW QUESTION: 38
You work for organisation A. You are asked to lead an internal audit of A's quality management system. It has a head office in Plant A1 and a second Plant A2 nearby. Due to the COVID-19 pandemic, production in A2 was discontinued and it was rented to a logistics organisation B, not related to A. There are no A employees working in A2. Organisation A expects to reassume production in A2 as soon as possible.
Which of the following actions would you consider appropriate when planning the internal audit of A's quality management system?
A. Visit Plant A2 to interview personnel of company B
B. Visit Plant A2 to interview B's quality manager
C. Visit Plant A2 to interview A's security personnel and B's maintenance department
D. Interview the A2 plant manager, now working in Plant A1
Answer: (SHOW ANSWER)
In this scenario, the organisation A has two plants, A1 and A2, but the production in A2 was discontinued due to the COVID-19 pandemic and the plant was rented to another organisation B. There are no A employees working in A2, and the organisation A expects to reassume production in A2 as soon as possible. Therefore, the appropriate action to plan the internal audit of A's quality management system is:
*Interview the A2 plant manager, now working in Plant A1: This action involves interviewing the person who is responsible for the management and operation of the plant A2, and who is currently working in the plant A1. The interview should aim to gather information about the status and condition of the plant A2, the impact of the COVID-19 pandemic on the quality management system, the arrangements and agreements with the organisation B, and the plans and actions to resume production in the plant A25 . This action is relevant and necessary for the internal audit, as it can help to assess the readiness and effectiveness of the quality management system, and to identify any gaps or nonconformities that need to be addressed.
The other options are not appropriate actions to plan the internal audit of A's quality management system, according to the web search results from my internal tool. They are:
*Visit Plant A2 to interview personnel of company B: This action involves visiting the plant A2 and interviewing the personnel of the organisation B, who are not related to the organisation A and who are not part of the quality management system. This action is irrelevant and unnecessary for the internal audit, as it can not provide any evidence or information about the conformity and improvement of the quality management system of the organisation A5 .
*Visit Plant A2 to interview B's quality manager: This action involves visiting the plant A2 and interviewing the quality manager of the organisation B, who is not related to the organisation A and who is not part of the quality management system. This action is irrelevant and unnecessary

for the internal audit, as it can not provide any evidence or information about the conformity and improvement of the quality management system of the organisation A5 .
*Visit Plant A2 to interview A's security personnel and B's maintenance department: This action involves visiting the plant A2 and interviewing the security personnel of the organisation A and the maintenance department of the organisation B, who are not directly involved in the quality management system. This action is irrelevant and unnecessary for the internal audit, as it can not provide any evidence or information about the conformity and improvement of the quality management system of the organisation A5 .
Therefore, the correct answer is D.
References: 1: Quality audit - Wikipedia 2: A step-by-step guide to internal quality audits 3: ISO 9001:2015 - Quality management systems - Requirements 4: ISO 19011:2018 - Guidelines for auditing management systems 5: Audit Process | Flowchart | Summary - Accountinguide : What are the Stages of the Auditing Process & Why it is Important ...

NEW QUESTION: 39
What is an advantage of group interviews?
A. Less time-consuming
B. Auditors pay more attention to each interviewee
C. Equal duration of time for each interviewee to answer questions
Answer: A (LEAVE A REPLY)
Comprehensive and Detailed In-Depth Explanation:
Group interviews allow auditors to gather more information in less time by:
Obtaining input from multiple participants simultaneously.
Encouraging discussions that might highlight inconsistencies.
Reducing the number of individual interviews needed.
While auditors strive for fairness, equal time for each interviewee is not guaranteed, and paying attention to each individual is more difficult in a group setting.
Reference:
ISO 19011:2018, Clause 6.4.6 (Conducting Interviews)

NEW QUESTION: 40
You, as auditor, are in dialogue with the quality lead and managing director of a small business that supplies specialist laboratory equipment and furniture.
You: "I'd like to look at how you manage change in the organisation. What changes have you made as a business, say, over the last 12 months?" Auditee: "We have made some strategic changes, the main one being that we no longer manufacture our own products in house." You: "That sounds like quite a significant change. What has been the impact of that?" Auditee: "We now mainly sell other manufacturers' products, under their brand names, and have outsourced manufacture of our own brand products to one of our suppliers. Unfortunately, we had to make six members of our staff redundant. This represents about 20% of our workforce, so this has been

quite a challenging time." This scenario presents a number of audit trails to different ISO 9001 requirements.
Which three of the following requirements would be relevant audit trails for this scenario?
A. Organisational knowledge
B. Control of externally provided processes, products, and services
C. Design and development of products and services
D. Documented information
E. Measurement traceability
F. Organisation roles and responsibilities
G. Preservation of product
H. Property belonging to customers or external providers
Answer: B,C,F (LEAVE A REPLY)
B: Control of externally provided processes, products, and services: This is relevant because the organization has outsourced the manufacture of its own brand products to a supplier. According to ISO 9001, the organization must ensure that externally provided processes remain within the control of its quality management system.
C: Design and development of products and services: Even though the organization no longer manufactures in- house, it still needs to control the design and development of its products, especially since they are now being produced by an external provider.
F: Organisation roles and responsibilities: The change in strategy has led to a significant reduction in staff, which would have an impact on the roles and responsibilities within the organization. It is important to audit how these changes have been managed and communicated within the organization to ensure continued effectiveness of the quality management system.
These audit trails are aligned with the requirements of ISO 9001:2015, which emphasizes the importance of controlling externally provided processes and products, managing design and development, and clearly defining roles and responsibilities within the quality management system.

NEW QUESTION: 41
Scenario 2:
Bell is a Canadian food manufacturing company that operates globally. Their main products include nuts, dried fruits, and confections. Bell has always prioritized product quality and has maintained a good reputation for many years. However, the company's production error rate increased significantly, leading to more customer complaints.
To increase efficiency and customer satisfaction, Bell implemented a Quality Management System (QMS) based on ISO 9001. The top management established a QMS implementation team comprising five middle managers from various departments, including Leslie, the quality manager.
Leslie was responsible for assigning responsibilities and authorities for QMS-related roles. He also suggested including a top management representative in the QMS team, but top management declined due to other priorities.

The team defined the QMS scope as:
"The scope of the QMS includes all activities related to food processing." Leslie established a quality policy and presented it to the team for review before top management approval.
Top management also proposed a new strategy for handling customer complaints, requiring biweekly customer surveys to monitor customer perceptions.
Which of the following indicates that Bell has defined its quality objectives?
A. Establishing a new strategy for handling customer complaints and requests
B. Implementing a QMS to increase efficiency in the manufacturing process and customer satisfaction
C. Establishing a QMS implementation team of middle managers from various departments
D. Assigning responsibilities for QMS roles
Answer: (SHOW ANSWER)
Comprehensive and Detailed In-Depth Explanation:
ISO 9001:2015, Clause 6.2 (Quality Objectives and Planning to Achieve Them) states that an organization must establish measurable and relevant quality objectives to improve QMS effectiveness.
Bell's strategy for handling customer complaints aligns with this requirement because it includes specific, measurable goals (biweekly customer surveys) to enhance customer satisfaction and service quality.
Other options are not directly related to defining quality objectives:
Option B (Implementing a QMS) refers to the overall system, not specific objectives.
Option C (Creating a QMS team) is an implementation step, not an objective.
Option D (Assigning responsibilities) is necessary for QMS but does not define objectives.
Reference:
ISO 9001:2015, Clause 6.2 - Quality Objectives and Planning to Achieve Them

NEW QUESTION: 42
You are carrying out an audit at an organisation seeking certification to ISO 9001 for the first time.
The organisation offers health and safety training to customers.
You are interviewing the Quality Systems Manager (QSM).
You: "What risks and opportunities have the business identified?"
QSM: "I'1l show you. This was discussed with the Managing Director at the latest management review." Narrative: The QSM shows you the latest management review record and points to the following table:

Reference	Risks and Opportunities
1	Nine of the 10 employed trainers are retiring within next 12 months
2	Changes to health and safety legislation imminent
3	Market information indicates increasing preference for technology-driven, self-paced training
4	Customer feedback highlights need for multi-language health and safety training

You: "How is the business planning to address these risks and opportunities?" QSM: "The MD said that they already knew about them so it was not necessary."

You decide to raise a non-conformity.

Non-conformity report	
ISO 9001 Clause Number:	
Nature of problem:	
ISO 9001 requirement that has not been fulfilled:	

To complete the non-conformity 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.

6.1.1

6.1.2 a

Several risks and opportunities have not been determined.

Actions to address risks and opportunities not recorded.

ISO 9001 - "The organization shall consider the requirements referred to in 4.2 and determine the risks and opportunities that need to be addressed."

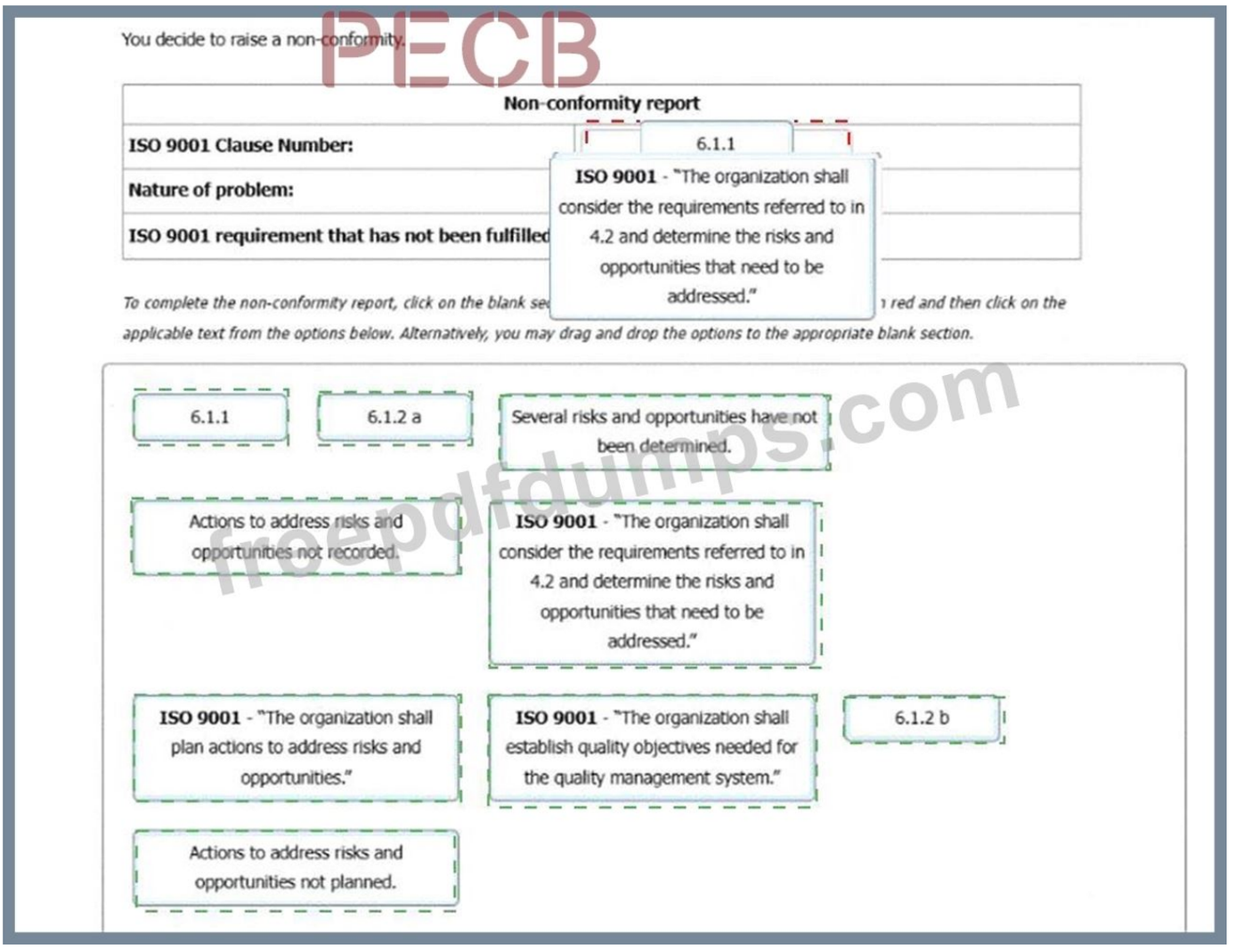
ISO 9001 - "The organization shall plan actions to address risks and opportunities."

ISO 9001 - "The organization shall establish quality objectives needed for the quality management system."

6.1.2 b

Actions to address risks and opportunities not planned.

Answer:



Explanation:

Non-Conformity Report:

ISO 9001 Clause Number

Nature of Problem

ISO 9001 Requirement That Has Not Been Fulfilled

6.1.1

Several risks and opportunities have not been determined.

"The organization shall consider the requirements referred to in 4.2 and determine the risks and opportunities that need to be addressed."

6.1.2 (a)

Actions to address risks and opportunities not planned.

"The organization shall plan actions to address risks and opportunities." Step-by-Step Reasoning:

Clause 6.1.1 - Determining Risks and Opportunities:

Requirement: The organization must determine risks and opportunities that are relevant to its Quality Management System (QMS). This ensures that the QMS achieves intended results and prevents undesired effects.

Problem Identified: While some risks and opportunities were discussed, the organization did not perform a systematic evaluation of all risks (e.g., health and safety legislation changes, retiring trainers).
Clause 6.1.2 (a) - Planning Actions for Risks and Opportunities:
Requirement: The organization must plan actions to address identified risks and opportunities. These actions should be integrated into the QMS processes to ensure continuous improvement.
Problem Identified: The Quality Systems Manager confirmed that no plans were made to address the risks and opportunities because the Managing Director deemed it unnecessary. This violates the requirement to plan actions.
Correct Options Selected:
Clause 6.1.1 with the nature of the problem as: "Several risks and opportunities have not been determined." Clause 6.1.2 (a) with the nature of the problem as: "Actions to address risks and opportunities not planned." ISO 9001 Requirements Not Fulfilled:
For 6.1.1:"The organization shall consider the requirements referred to in 4.2 and determine the risks and opportunities that need to be addressed." For 6.1.2 (a):"The organization shall plan actions to address risks and opportunities."

NEW QUESTION: 43
What is a combined audit?
A. Two or more management systems audited together at a single auditee.
B. Two or more auditing organizations cooperating to audit a single auditee.
C. Two or more management systems audited simultaneously at several auditees.
Answer: A (LEAVE A REPLY)
Comprehensive and Detailed In-Depth Explanation:
A combined audit is when multiple management systems (e.g., ISO 9001 for Quality, ISO 14001 for Environmental Management, and ISO 45001 for Occupational Health & Safety) are audited together in a single organization.
Clause References:
ISO 19011:2018, Clause 5.4 - Combined Audits:
A combined audit is performed when two or more management systems are assessed simultaneously at the same auditee.
Why is the Correct Answer A?
A combined audit reduces duplication of effort by auditing multiple standards together at a single organization.
Example: A company certified to both ISO 9001 and ISO 14001 can have one audit covering both standards.
Why are the Other Options Incorrect?
B (Two or more auditing organizations cooperating on a single auditee) # This is a joint audit, not a combined audit.
C (Two or more management systems audited at multiple auditees) # This is a multiple-site audit, not a combined audit.

Reference:
ISO 19011:2018, Clause 5.4 - Combined Audits

NEW QUESTION: 44
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.
In scenario 3, the audit team required access to see the organizational chart and job descriptions to verify the employees' competence. Based on audit best practices, is this acceptable?
A. Yes, because that would be sufficient evidence to verify competence.
B. No, because the audit evidence would not be relevant.
C. Yes, because auditors should see the organizational chart and job descriptions to verify competence.
D. No, because competence should only be verified through direct observation.
Answer: (SHOW ANSWER)
Comprehensive and Detailed In-Depth Explanation:
ISO 9001:2015 requires organizations to ensure competence of personnel whose work affects quality performance.
Clause References:
Clause 7.2 - Competence: Organizations must determine, provide, and evaluate competence of employees performing work under the QMS.
ISO 19011:2018, Clause 6.4.6 - Audit Evidence: Auditors should use a combination of document review, interviews, and observation to verify competence.
Why is the Correct Answer C?
The organizational chart shows reporting structures and helps verify roles and responsibilities.
Job descriptions outline required qualifications, skills, and competencies for each role.

These documents provide objective audit evidence that personnel meet the required competencies for their positions.
Why are the Other Options Incorrect?
A (Sufficient evidence) # Partially correct, but competence verification often requires multiple sources of evidence, including training records, certifications, and observations.
B (Not relevant) # Incorrect because verifying competence is crucial for ensuring effective QMS implementation.
D (Direct observation only) # Observation alone is insufficient; documentation and interviews are also required to confirm competence.
Reference:
ISO 9001:2015, Clause 7.2 - Competence
ISO 19011:2018, Clause 6.4.6 - Audit Evidence

NEW QUESTION: 45
You are carrying out an audit at a single-site organisation seeking certification to ISO 9001 for the first time.
The organisation offers warehousing and export services to customers. Customers are invoiced for the time stock items are stored in the warehouse. Transport to and from the warehouse is controlled by the organisation and approved subcontract transport services are used. The organization does not have its own transport vehicles. Stock items are not purchased by the organisation.
You have gathered audit evidence as outlined in the table. Match the ISO 9001 Clause 8 extract to the audit evidence.

Audit evidence	ISO 9001 Clause 8 extract
Four of the 10 pallets of stock sampled in the warehouse were not labelled.	
A damaged pallet of stock seen in the quarantine area was leaking liquid onto the floor.	
One of the fork-lift truck drivers had no fork-lift truck driving licence.	
There was no pest control provision in the warehouse.	
Two pallets of temperature-sensitive stock items were being stored at ambient as the chilled storage facility was full.	

To complete the table, click on the blank section you want to complete so it is highlighted in red and then click on the ISO 9001 Clause 8 extracts listed below. Alternatively, drag and drop each clause to the audit evidence that applies.

"8.5.2...shall use suitable means to identify outputs..."

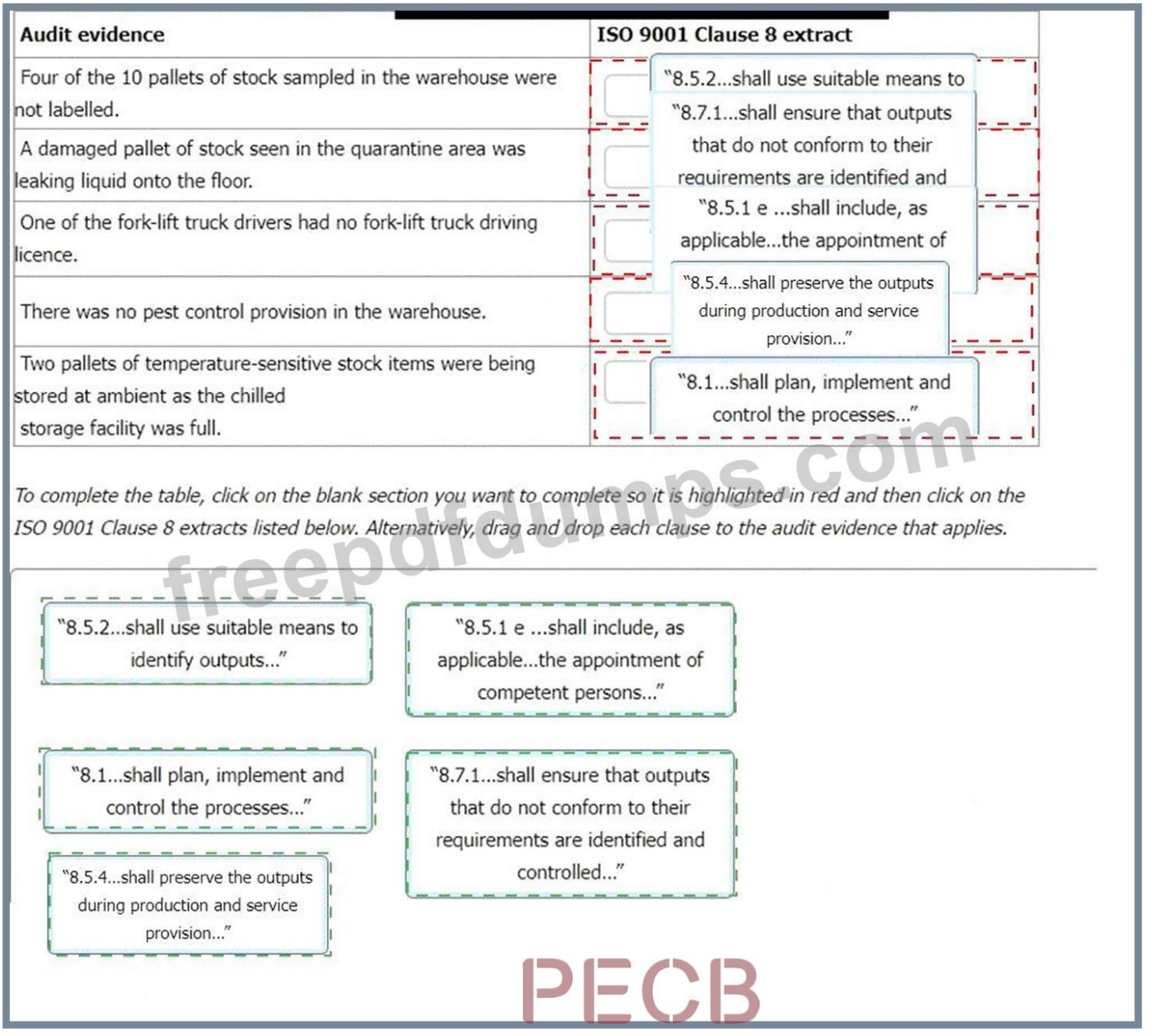
"8.5.1 e ...shall include, as applicable...the appointment of competent persons..."

"8.1...shall plan, implement and control the processes..."

"8.7.1...shall ensure that outputs that do not conform to their requirements are identified and controlled..."

"8.5.4...shall preserve the outputs during production and service provision..."

Answer:



Explanation:

The table below shows the possible matching of the ISO 9001 Clause 8 extract to the audit evidence.

Table

Audit evidence

ISO 9001 Clause 8 extract

Four of the 10 pallets of stock sampled in the warehouse were not labelled.

"8.5.2 ... shall use suitable means to identify outputs ..."

A damaged pallet of stock seen in the quarantine area was leaking liquid onto the floor.

"8.7.1 ... shall ensure that outputs that do not conform to their requirements are identified and controlled ..." One of the fork-lift truck drivers had no fork-lift truck driving licence.

"8.5.1 e ... shall include, as applicable ... the appointment of competent persons ..." There was no pest control provision in the warehouse.

"8.5.4 ... shall preserve the outputs during production and service provision ..." Two pallets of temperature-sensitive stock items were being stored at ambient as the chilled storage facility was full.
"8.1 ... shall plan, implement and control the processes ..."

NEW QUESTION: 46
The following actions need to be carried out during a third-party audit planning stage. Which two actions correspond to the individual(s) managing the audit program before the involvement of the audit team leader'
A. Prepare the audit plan
B. Assign responsibilities within the audit team
C. Prepare the checklists
D. Provide the resources needed
E. Review the reports of previous audits
F. Select the audit team members
Answer: (SHOW ANSWER)
In ISO 9001:2015, the responsibility for managing the audit program lies with those overseeing the entire audit process rather than the Audit Team Leader. During the planning stage, before involving the Audit Team Leader, key actions for managing the audit program include:
1. Providing the Resources Needed: According to clause 7.1 (Resources), the audit program manager must ensure that the necessary resources are in place to conduct the audit effectively. This encompasses logistical support, personnel, and other required resources for the audit to proceed smoothly.
2. Reviewing Reports of Previous Audits: As per clause 9.2.2 (Internal Audit), it is essential to consider the results of previous audits to plan effectively for the upcoming audit. This helps identify areas that require particular attention, ensuring continuity and focusing on recurring issues or improvements since the last audit.
These actions ensure that the audit is thoroughly prepared and that there is continuity and focus on any areas that might need closer inspection. The other options, such as preparing the audit plan, assigning responsibilities, preparing checklists, and selecting the audit team members, generally fall under the duties of the Audit Team Leader once they are appointed and engaged in the planning process.

NEW QUESTION: 47
What is a list of actions that should be performed during the audit with their respective timeline?
A. The audit objectives.
B. The audit criteria.
C. The audit schedule.
D. The audit offer.
Answer: C (LEAVE A REPLY)
Comprehensive and Detailed In-Depth Explanation:
The audit schedule provides a structured timeline of activities to be conducted during the audit.
Clause References:
ISO 19011:2018, Clause 6.4.2 - Preparing the Audit Plan:
Requires the development of an audit schedule, including the sequence and timing of activities.
ISO/IEC 17021-1:2015, Clause 9.1.3 - Audit Program:
Certification bodies must establish a schedule for conducting audits.
Why is the Correct Answer C?
The audit schedule ensures systematic execution of the audit by defining activities, responsible auditors, and timeframes.
A well-planned schedule improves efficiency and helps auditors cover all necessary areas within the given time.
Why are the Other Options Incorrect?
A (Audit objectives) # Define why the audit is conducted, not the schedule.
B (Audit criteria) # Define the standards and requirements to be evaluated, not the timeline.
D (Audit offer) # Refers to the initial proposal sent to the auditee, not the activity timeline.
Reference:
ISO 19011:2018, Clause 6.4.2 - Preparing the Audit Plan
ISO/IEC 17021-1:2015, Clause 9.1.3 - Audit Program

NEW QUESTION: 48
Scenario 7: POLKA is a car manufacturing company based in Stockholm, Sweden. The company has around
14,000 employees working in different sectors which help with the design, painting, assembling, and test drives of the final product. The company is widely known for its qualitative products and affordable prices. In order to retain their reputation, POLKA implemented a quality management system (QMS) based on ISO
9001.
Before applying for certification, the company decided to conduct an internal audit to check whether there are any nonconformities in their QMS and if the requirements of ISO 9001 are being fulfilled. The top management appointed Sean, the internal auditor, as the team leader of

the internal audit team. Sean required from the top management to have unrestricted access to the employees and executives of POLKA and to the documented information. Furthermore, Sean required to establish a team with a large number of auditors, considering the size and the complexity of the organization. The top management of POLKA agreed with Sean's requirements. The top management, in cooperation with Sean, assigned 10 more employees to the audit team. Following that. Sean planned the audit activities and assigned the roles and responsibilities to each auditor. They began by interviewing employees of different manufacturing departments to check whether they are aware of the process of the QMS implementation. While conducting these activities, one of the auditors asked Sean for permission to audit the department in which he worked on a daily basis, as he was very familiar with the processes of the department.
Along the way, the teams findings showed that the staff were trained, documented information was updated, and the QMS fulfilled the requirements of ISO 9001. The internal audit took three weeks to complete, and on the last week the audit team held a final meeting The team shared their results and together drafted the audit report This report was submitted to the top management of the company. The report was maintained as documented information, and was available to the relevant interested parties.
Based on the scenario above, answer the following question:
Sean requested unrestricted access to the employees, executives, and documented information of POLKA. Is this in accordance with audit best practices?
A. No, such requests are acceptable only if a third-party audit is being conducted
B. Yes, but the internal auditor should make such a request to the CEO directly as only the CEO of the company can approve such a request
C. Yes, unrestricted access for the internal auditor should be provided by the company
Answer: (SHOW ANSWER)
Comprehensive and Detailed In-Depth Explanation:
According to ISO 19011:2018, Clause 5.3.2 (Access to Information), internal auditors must have unrestricted access to:
Employees and executives for interviews and observations.
Documented information to verify compliance with ISO 9001.
This ensures a transparent and objective audit process. The CEO's approval (B) is not required unless restricted information is involved.
Reference:
ISO 19011:2018, Clause 5.3.2 (Access to Information)

NEW QUESTION: 49
An organization has decided to implement a QMS based on ISO 9001. What should they consider when determining internal issues?
A. The social and economic environments
B. The competitive environment
C. Knowledge
D. The expectations of suppliers

Answer: C (LEAVE A REPLY)
Comprehensive and Detailed In-Depth Explanation:
ISO 9001:2015 requires organizations to assess both internal and external issues that could impact the effectiveness of their Quality Management System (QMS).
Clause Reference:
* Clause 4.1 - Understanding the Organization and Its Context states that organizations must determine external and internal issues that affect their ability to achieve intended results.
* Internal issues include:
* Knowledge within the organization (documented or undocumented)
* Organizational culture
* Resource availability
* Technological advancements
* Infrastructure and capabilities
Why is the Correct Answer C?
* Knowledge (Clause 7.1.6) is a critical internal factor that directly affects the implementation and maintenance of a QMS.
* Organizations must identify, maintain, and make available the necessary knowledge to achieve quality objectives and meet customer requirements.
Why are the Other Options Incorrect?
* A (Social and economic environments) # These are considered external issues rather than internal.
* B (Competitive environment) # Competition is external, not an internal issue affecting the QMS.
* D (Expectations of suppliers) # Supplier expectations relate to external interested parties, covered under Clause 4.2 (Understanding the Needs and Expectations of Interested Parties).
Reference:
ISO 9001:2015, Clause 4.1 - Understanding the Organization and Its Context ISO 9001:2015, Clause 7.1.6 - Organizational Knowledge

NEW QUESTION: 50
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 non-conformity.

Non-conformity 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 non-conformity 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 records are not available for every batch.

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

Cleaning and sanitising are not always completed by trained staff.

6.2.1

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

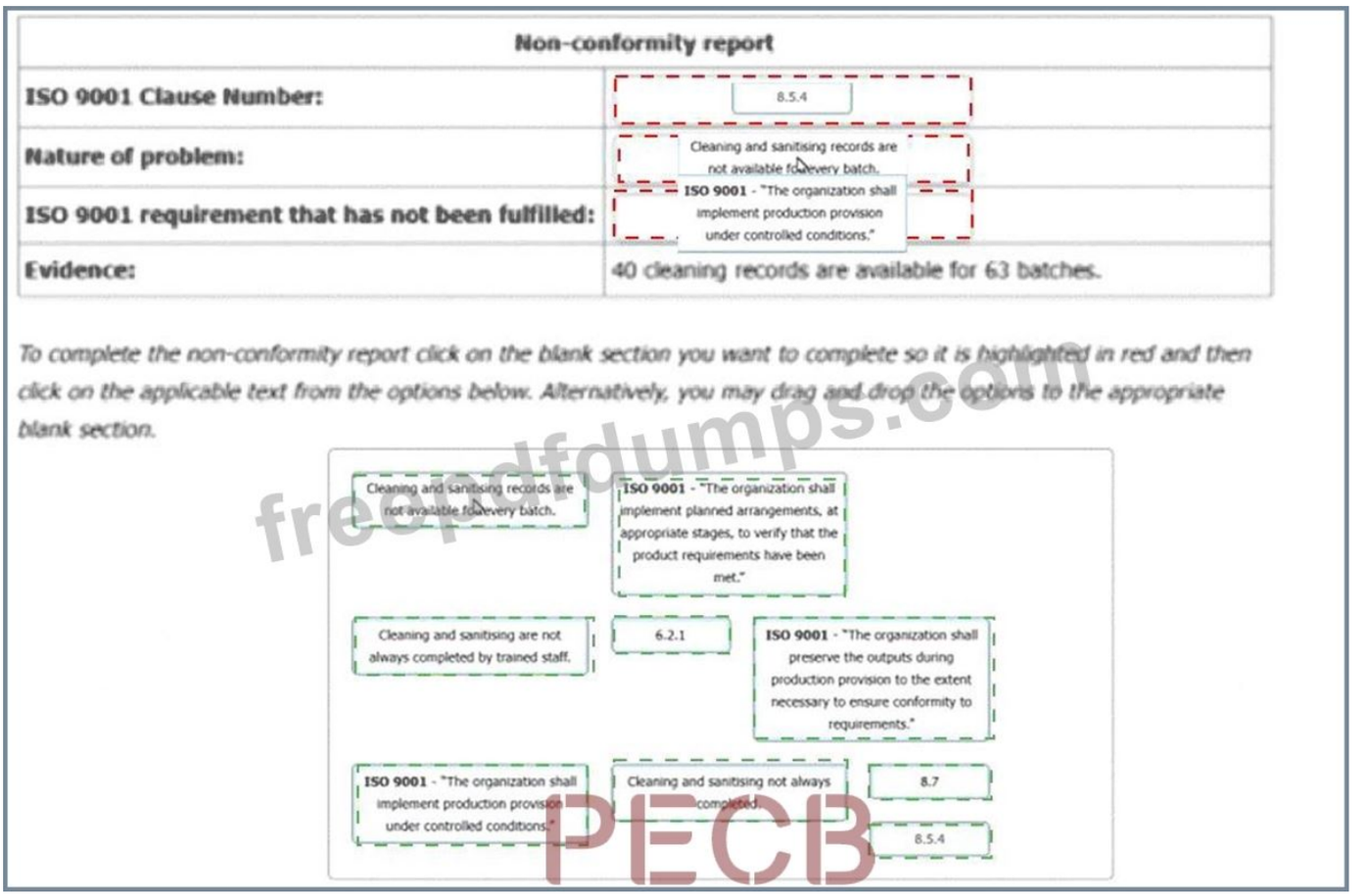
ISO 9001 - "The organization shall implement production provision under controlled conditions."

Cleaning and sanitising not always completed.

8.7

8.5.4

Answer:



Explanation:
Clause: 8.5.4
Nature of Problem: Cleaning and sanitising records are not available for every batch.
Unfulfilled Requirement: "The organization shall implement production provision under controlled conditions."

NEW QUESTION: 51
You are carrying out an audit to ISO 9001 at an organisation which offers regulatory consultancy services to manufacturers of cosmetics.
You are interviewing the Technical Director (TD), who manages a team of regulatory experts responsible for providing regulatory services to customers.
You: "How do you ensure your regulatory team's competence concerning regulatory requirements is maintained?" TD: "The two Regulatory Experts we employ full-time have years of experience of working in the cosmetics industry." You: "How is their regulatory competence maintained?" TD: "They are dedicated individuals with lots of contacts in the sector." You: "How does the business enable them to maintain their understanding of current regulatory requirements?" TD: "We leave that up to them."

You decide to raise a nonconformity.

Nonconformity report	
ISO 9001 Clause Number:	
Nature of problem:	
ISO 9001 requirement that has not been fulfilled:	

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, drag and drop the options to the appropriate blank section.

The organisation has not determined the necessary competence of the Regulatory Experts with respect to relevant regulatory requirements.

The organisation has not ensured that persons doing work under the organisation's control are aware of relevant quality objectives.

ISO 9001 - "The organization shall ensure that persons are competent on the basis of appropriate education, training, or experience."

7.1.2

The business has not maintained its organisational knowledge.

7.1.6

ISO 9001 - "The organization shall determine and provide the persons necessary for the effective implementation of its quality management system."

ISO 9001 - "The organization shall determine the knowledge necessary for the operation of its processes and to achieve conformity of products and services."

7.2

Answer:

ou decide to raise a nonconformity.

Nonconformity report	
SO 9001 Clause Number:	
Nature of problem:	
SO 9001 requirement that has not been fulfilled:	

o 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 om the options below. Alternatively, drag and drop the options to the appropriate blank section.

The organisation has not determined the necessary competence of the Regulatory Experts with respect to relevant regulatory requirements.

The organisation has not ensured that persons doing work under the organisation's control are aware of relevant quality objectives.

ISO 9001 - "The organization shall ensure that persons are competent on the basis of appropriate education, training, or experience."

7.1.2

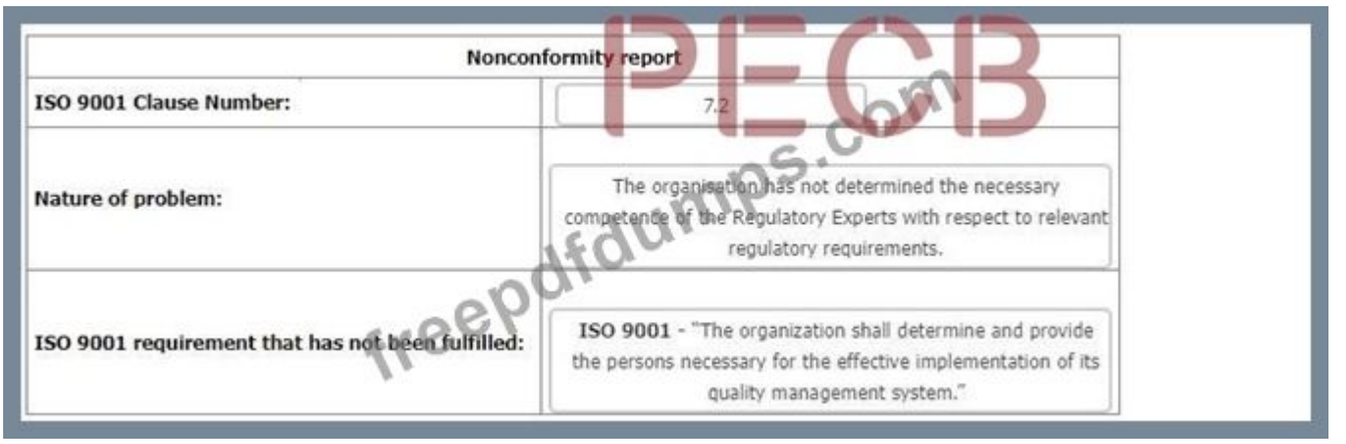
The business has not maintained its organisational knowledge.

7.1.6

ISO 9001 - "The organization shall determine and provide the persons necessary for the effective implementation of its quality management system."

ISO 9001 - "The organization shall determine the knowledge necessary for the operation of its processes and to achieve conformity of products and services."

7.2



Nonconformity report	
ISO 9001 Clause Number:	7.2
Nature of problem:	The organisation has not determined the necessary competence of the Regulatory Experts with respect to relevant regulatory requirements.
ISO 9001 requirement that has not been fulfilled:	ISO 9001 - "The organization shall determine and provide the persons necessary for the effective implementation of its quality management system."

NEW QUESTION: 52
Even though past audits have highlighted a consistently large number of nonconformities within an organisation's design team, the organisation has not varied the frequency or duration of audits on its audit plan.
The decision for whether this situation is acceptable or not should be governed by which of the following?
A. The organization's reasoning behind the lack of change to the audit plan
B. The authority of the audit team leader
C. The availability of competent internal auditors
D. A risk-based approach to the audit programme
Answer: D (LEAVE A REPLY)

NEW QUESTION: 53
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:
Is it acceptable for the certification body and Eva to make the certification decision together?
A. Yes, because the audit team leader must be involved in the certification decision
B. No, only the audit team leader must make the certification decision
C. No, auditors that take part in the audit should never take part in the certification decision
Answer: C (LEAVE A REPLY)
Comprehensive and Detailed In-Depth Explanation:
According to ISO 17021-1:2015, Clause 9.5.1 (Certification Decision):
* Auditors who conduct the audit cannot be involved in the certification decision to ensure impartiality.
* The certification body alone is responsible for making the certification decision based on the audit report and findings.
* The audit team leader (Eva) must not take part in the certification decision.
Thus, C is the correct answer.
Reference:
ISO 17021-1:2015, Clause 9.5.1 (Certification Decision)

NEW QUESTION: 54
An ISO 9001 certified organization sells packaged food. To maximize the benefits of third-party certification to the organization and stakeholders, the organization has labelled their product 'ISO 9001 certified product' and is selling it as 'quality food'.
Which TWO of the following describes this situation in the context of the purpose and benefits of third-party ISO 9001 certification?
A. The product from an ISO 9001 certified organization will taste better.
B. ISO 9001 certification can be used to identify opportunities for improvement of the management system.
C. ISO 9001 certified food can increase revenue.
D. ISO 9001 is not for product certification.
E. ISO 9001 certified food can increase customer confidence and satisfaction.
F. The organization will be able to increase its market share.
Answer: B,D (LEAVE A REPLY)

NEW QUESTION: 55
Scenario 5: Mechanical-Electro (ME) Audit Stages
Mechanical-Electro, better known as ME, is an American company that provides mechanical and electrical services in China. Their services range from air-conditioning systems, ventilation systems, plumbing, to installation of electrical equipment in automobile plants, electronic manufacturing facilities, and food processing plants.

Due to the fierce competition from local Chinese companies and failing to meet customer requirements, ME's revenue dropped significantly. In addition, customers' trust and confidence in the company decreased, and the reputation of the company was damaged.
In light of these developments, the top management of ME decided to implement a quality management system (QMS) based on ISO 9001. After having an effective QMS in place for over a year, they applied for a certification audit.
A team of four auditors was appointed for the audit, including Li Na as the audit team leader. Initially, the audit team conducted a general review of ME's documents, including the quality policy, operational procedures, inventory lists, QMS scope, process documentation, training records, and previous audit reports.
Li Na stated that this would allow the team to maintain a systematic and structured approach to gathering documents for all audit stages. While reviewing the documented information, the team observed some minor issues but did not identify any major nonconformities. Therefore, Li Na claimed that it was not necessary to prepare a report or conduct a meeting with ME's representatives at that stage of the audit. She stated that all areas of concern would be discussed in the next phase of the audit.
Following the on-site activities and the opening meeting with ME's top management, the audit team structured an audit test plan to verify whether ME's QMS conformed to Clause 8.2.1 (Customer Communication) of ISO
9001.
To do so, they gathered information through group interviews and sampling. Li Na conducted interviews with departmental managers in the first group and then with top management. In addition, she chose a sampling method that sufficiently represented customer complaints from both areas of ME's operations.
The team members were responsible for the sampling procedure. They selected a sample size of 4 out of 45 customer complaints received weekly for electrical services and 2 out of 10 complaints for mechanical services.
Afterward, the audit team evaluated the evidence against the audit criteria and generated the audit findings.
According to general principles of sampling procedure, did the audit team select a valid sample for electrical services?
A. No, the selected sample size is low compared to the population, as for a population from 13 to 52 the minimum sample size should be 5.
B. No, the selected sample size is high compared to the population, as for a population from 13 to 52 the minimum sample size should be 10.
C. Yes, the selected sample size is proportionate to the population.
Answer: (SHOW ANSWER)
Comprehensive and Detailed In-Depth Explanation:
The audit team selected 4 out of 45 customer complaints for electrical services, which is too low based on standard statistical sampling methods. According to ISO 19011:2018 (Guidelines for

Auditing Management Systems), for a population size between 13 and 52, a minimum sample size should be 5 to achieve a reasonable level of confidence.
This means the selected sample (4 complaints) was insufficient and did not align with standard sampling procedures. Therefore, the correct answer is A.
Reference:
ISO 19011:2018, Clause 6.4.5 (Sampling Methods in Auditing)

NEW QUESTION: 56
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. Requirements of ISO 9001
B. ISO 19011 Audit principles
C. Organisation's market sector
D. Organisation's invoicing and profits of the last 5 years
E. Organisation's processes
F. Requirements of auditee's interested parties other than customers
Answer: A,B (LEAVE A REPLY)
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: 57
What are the criteria for reviewing documented information?
A. Content, format, and the procedure for managing documented information
B. Language of documented information, internal audit reports, client feedback
C. Archive, volume, and confidentiality of documented information
Answer: A (LEAVE A REPLY)
Comprehensive and Detailed In-Depth Explanation:
According to ISO 9001:2015, Clause 7.5.2 (Creating and Updating Documented Information), the criteria for reviewing documented information include:
* Content - The accuracy and relevance of the information.

* Format - Ensuring readability and proper structuring (e.g., language, versioning).
* Procedure for managing documented information - Ensuring control, access, and updates.
Other options, such as internal audit reports and client feedback, are important for overall QMS evaluation but are not the main criteria for reviewing documented information.
Reference:
ISO 9001:2015, Clause 7.5.2 (Creating and Updating Documented Information)

NEW QUESTION: 58
An audit team leader arrives at a printing organisation to carry out a Stage 2 audit for a certification body. At a meeting with the Quality Manager, she is told that they have won their biggest contract from a computer manufacturer to print and compile computer documentation packages. They have leased the unit next door for space reasons but have never worked in this sector before. The Quality Manager wants the ISO 9001 certificate to cover the new contract.
Which one of the options is the correct response by the auditor?
A. Do you realise that this involves an extension to the scope of the audit and will require an application process?
B. How can we audit this area when we do not have an IT specialist in the team?
C. Would you like a separate certificate for the IT packages to show your new client?
D. Would you mind writing to my programme manager with this request?
Answer: A (LEAVE A REPLY)
When an organization wishes to extend the scope of their current certification to include new services or activities, such as the printing and compilation of computer documentation packages, it requires an extension to the scope of the audit. This involves a formal application process with the certification body to ensure that the new activities are included in the audit plan and that the organization's quality management system encompasses these new processes12. References: = The answer is based on the ISO 9001 Auditing Practices Group guidance on scope and applicability, which outlines the need for a formal application process when there is a change in the scope of the quality management system that affects the certification1. Additionally, the UKAS guide on the extension to scope (ETS) process provides information on how changes to the scope, including the addition of new services, require a formal application2.

NEW QUESTION: 59
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.
In scenario 4, the audit team determined the audit feasibility by considering only the resources available for the audit. Is this acceptable?
A. No, the audit feasibility should be determined by TD's top management.
B. No, because other factors should be considered when determining the audit feasibility, such as information needed to plan the audit, the cooperation of the auditee, duration of the audit, etc.
C. Yes, considering only the resources available for the audit is sufficient for determining the audit feasibility.
D. Yes, because the audit team leader has final authority over audit feasibility.
Answer: (SHOW ANSWER)
Comprehensive and Detailed In-Depth Explanation:
An audit's feasibility must be assessed using multiple factors, not just resource availability.
Clause References:
* ISO 19011:2018, Clause 5.3 - Establishing the Audit Program: Requires consideration of logistical, technical, and cooperation factors when assessing audit feasibility.
* ISO/IEC 17021-1:2015, Clause 9.1.3 - Determining Feasibility of the Audit: Requires evaluating more than just resources to ensure a successful audit.
Why is the Correct Answer B?
* Audit feasibility should consider:
* Availability of information (documents, records).
* Cooperation from the auditee.
* Operational conditions that might affect the audit.
* Scope and complexity of the QMS being audited.
* Resource availability alone is not enough to determine feasibility.
Why are the Other Options Incorrect?
* A (Top management determines feasibility) # Incorrect because feasibility is determined by the certification body, not the auditee.
* C (Resources alone are sufficient) # Incorrect because other key factors must be evaluated.
* D (Final authority lies with the audit leader) # Incorrect because ISO requires multiple factors to be considered, not just an auditor's decision.
Reference:
ISO 19011:2018, Clause 5.3 - Establishing the Audit Program
ISO/IEC 17021-1:2015, Clause 9.1.3 - Determining Feasibility of the Audit

NEW QUESTION: 60
During the opening meeting of a third-party audit of a pharmaceutical organisation (CD9000) with seven COVID-19 testing laboratories in various terminals at a major international airport, you are

asked if you could visit all laboratories. As audit team leader you say that, based on sampling criteria, you had planned to audit only three of them as CD9000 is a multisite organisation.
They tell you that they have worked so hard to get ready for the audit that the supervisors of those laboratories that would not be visited would be quite disappointed.
The following are possible responses to the request, select the two best responses:
A. I could audit the other laboratories virtually at the end of this audit.
B. I could decide to extend the audit for an extra day.
C. I could try to revise the audit programme to see if I can audit all laboratories.
D. Sorry, this is the plan, we cannot change it. However, they could attend the audit as observers.
E. The programme manager has selected the sample and we must follow it.
F. We could stay every day for one hour longer to see those supervisors and their laboratories.
Answer: (SHOW ANSWER)
In this scenario, the audit team leader must balance maintaining the integrity of the audit plan while considering the auditee's request. The two best responses allow for flexibility without compromising the audit's rigor:
A: I could audit the other laboratories virtually at the end of this audit: Virtual audits can be a valid option, especially in multi-site audits. ISO 9001:2015 does not prohibit virtual audits, and in certain situations, they are practical for reviewing documentation or observing operations remotely.
C: I could try to revise the audit programme to see if I can audit all laboratories: Revising the audit programme to accommodate additional site visits is a reasonable compromise. ISO 9001:2015 audits are based on risk and sampling, but the audit team leader has the flexibility to adjust the audit scope if it fits within the audit duration and resources.
The other options, such as extending the audit duration (B, F) or strictly adhering to the original plan (D, E), may not be practical or necessary. Revising the plan to audit all laboratories or using virtual auditing ensures that the audit remains efficient while addressing the organization's concerns.

NEW QUESTION: 61
Scenario 5: Mechanical-Electro (ME) Audit Stages
Mechanical-Electro, better known as ME, is an American company that provides mechanical and electrical services in China. Their services range from air-conditioning systems, ventilation systems, plumbing, to installation of electrical equipment in automobile plants, electronic manufacturing facilities, and food processing plants.
Due to the fierce competition from local Chinese companies and failing to meet customer requirements, ME's revenue dropped significantly. In addition, customers' trust and confidence in the company decreased, and the reputation of the company was damaged.
In light of these developments, the top management of ME decided to implement a quality management system (QMS) based on ISO 9001. After having an effective QMS in place for over a year, they applied for a certification audit.

A team of four auditors was appointed for the audit, including Li Na as the audit team leader. Initially, the audit team conducted a general review of ME's documents, including the quality policy, operational procedures, inventory lists, QMS scope, process documentation, training records, and previous audit reports.

Li Na stated that this would allow the team to maintain a systematic and structured approach to gathering documents for all audit stages. While reviewing the documented information, the team observed some minor issues but did not identify any major nonconformities. Therefore, Li Na claimed that it was not necessary to prepare a report or conduct a meeting with ME's representatives at that stage of the audit. She stated that all areas of concern would be discussed in the next phase of the audit.

Following the on-site activities and the opening meeting with ME's top management, the audit team structured an audit test plan to verify whether ME's QMS conformed to Clause 8.2.1 (Customer Communication) of ISO
9001.

To do so, they gathered information through group interviews and sampling. Li Na conducted interviews with departmental managers in the first group and then with top management. In addition, she chose a sampling method that sufficiently represented customer complaints from both areas of ME's operations.

The team members were responsible for the sampling procedure. They selected a sample size of 4 out of 45 customer complaints received weekly for electrical services and 2 out of 10 complaints for mechanical services.

Afterward, the audit team evaluated the evidence against the audit criteria and generated the audit findings.

After reviewing the documented information, Li Na claimed that it was not necessary to report the minor nonconformities that were identified; instead, they would be discussed in the next audit phase. Is this acceptable?

A. Yes, during the review of documented information, only major nonconformities need to be documented if detected.

B. Yes, all identified nonconformities throughout the audit need to be documented and communicated at the end of the audit.

C. No, identification of minor nonconformities or areas of concern that could become nonconformities need to be documented and communicated to the auditee before proceeding to the next audit phase.

Answer: (SHOW ANSWER)

Comprehensive and Detailed In-Depth Explanation:

As per ISO 9001:2015, Clause 10.2 (Nonconformity and Corrective Action), all identified nonconformities, including minor ones, must be documented and communicated to the auditee. Minor nonconformities can lead to major issues if left unaddressed. The auditor must inform the organization before moving to the next audit phase so that corrective actions can be taken.

Clause 9.2.2 (Internal Audit) states that audit findings should be reported without undue delay.

Since Li Na did not report the minor nonconformities immediately, her decision was incorrect. Minor nonconformities should always be documented and communicated before proceeding to the next phase.
Reference:
ISO 9001:2015, Clause 9.2.2 (Internal Audit Reporting)
ISO 9001:2015, Clause 10.2 (Nonconformity and Corrective Action)

NEW QUESTION: 62
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 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.

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.	
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.	
The NPD Manager shows you evidence of consumer trials that are carried out for some new products prior to full-scale launch.	
The NPD Manager explains that an approved external laboratory is used to perform shelf-life stability trials on some formulations during product development.	

To complete the table click on the blank section you want to complete so it is highlighted in red and then click on the ISO 9001 clause 8.3 extracts listed below. Alternatively, drag and drop each clause to the audit evidence that applies.

"8.3.2 e) ... internal ... resource needs for the design and development of products ..."

"8.3.2 e) ... external ... resource needs for the design and development of products ..."

"8.3.4 d) ... conducted to ensure that the design and development outputs meet ..."

"8.3.5 ... retain documented information ..."

"8.3.6 ... retain documented information ..."

Answer:

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.	"8.3.6 ... 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.	"8.3.5 ... 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 design and development outputs meet ..."
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 ..."

To complete the table click on the blank section you want to complete so it is highlighted in red and then click on the ISO 9001 clause 8.3 extracts listed below. Alternatively, drag and drop each clause to the audit evidence that applies.

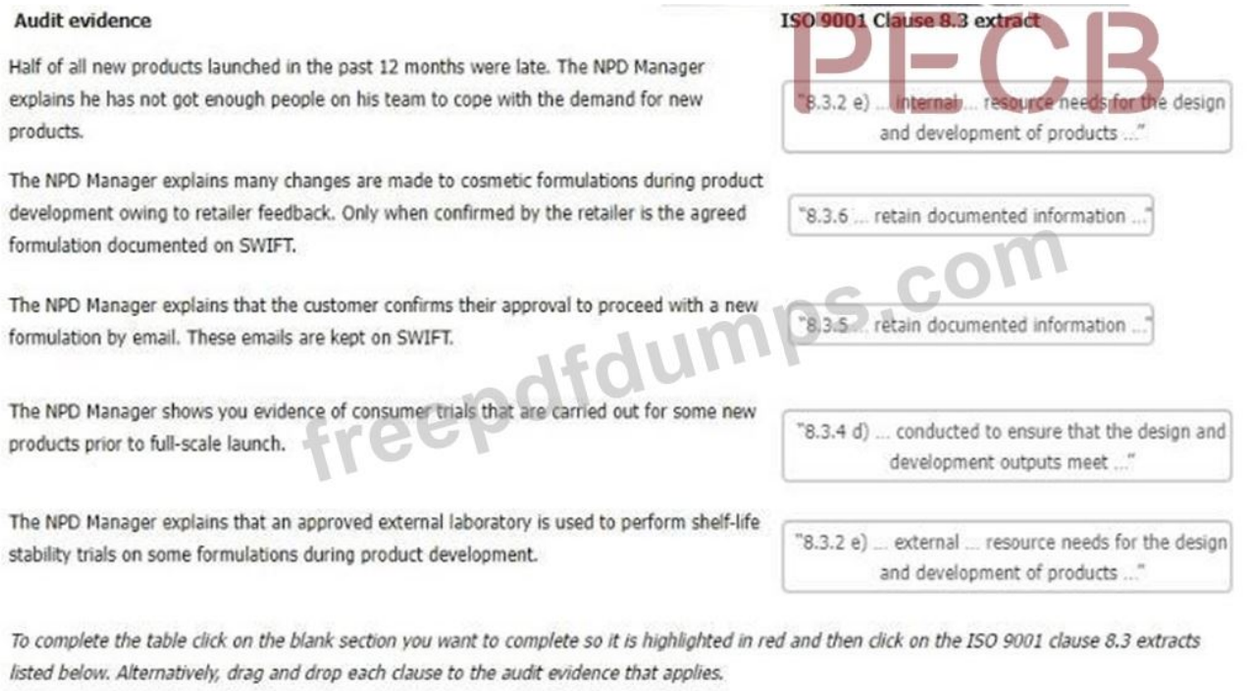
"8.3.2 e) ... internal ... resource needs for the design and development of products ..."

"8.3.2 e) ... external ... resource needs for the design and development of products ..."

"8.3.4 d) ... conducted to ensure that the design and development outputs meet ..."

"8.3.5 ... retain documented information ..."

"8.3.6 ... retain documented information ..."



NEW QUESTION: 63
Which one of the following options is the definition of the context of an organisation?
A. Combination of internal and external issues that can have an effect on an organisation's approach to developing and achieving its objectives.
B. Comparison of internal and external issues that can have an effect on an organisation's desire to achieve its objectives.
C. Complexity of internal and external issues that can have an effect on an organisation's approach to developing and achieving its purpose.
D. Coordination of internal and external issues that can have a positive or negative effect on an organisation's success.
Answer: (SHOW ANSWER)
Understanding "Context of the Organization":
The term "context of the organization" is defined in ISO 9001:2015 Clause 4.1, which states: "The organization shall determine external and internal issues that are relevant to its purpose and its strategic direction and that affect its ability to achieve the intended result(s) of its quality management system." The definition emphasizes identifying both internal and external issues that influence the organization's approach to developing and achieving its objectives.
Option Analysis:
Option A:Correct. This option aligns with the standard definition as it explicitly mentions the combination of internal and external issues that affect the organization's approach to achieving its objectives, which is the essence of Clause 4.1.
Option B:Incorrect. The term "comparison of internal and external issues" does not reflect the ISO 9001 requirements. The standard does not require a comparison but rather an understanding of these issues.

Option C:Incorrect. Although it mentions "complexity," the focus of ISO 9001:2015 is on identifying relevant issues rather than the complexity of those issues.
Option D:Incorrect. This option mentions "coordination" and focuses only on the positive or negative effects.
ISO 9001 requires identifying issues but does not emphasize coordination.
Clause Reference and Relevance:
ISO 9001:2015 requires organizations to understand their context because internal and external factors can influence the Quality Management System's effectiveness. Understanding this context helps in:
Addressing risks and opportunities (Clause 6.1).
Aligning the QMS with the organization's strategic direction.
Why A is Correct:
"Combination of internal and external issues" captures the essence of Clause 4.1, making it the accurate definition of the context of the organization.

NEW QUESTION: 64
Whistlekleen is a national dry cleaning and laundry organization with 50 shops. You are conducting a surveillance audit of the Head Office and are sampling customer complaints. You find that 80% of complaints originate from five shops in the same region. Most of these complaints relate to damage to customer laundry.
The Quality Manager tells you that those are the oldest shops in the organization. The cleaning equipment needs replacing, but the organization cannot afford it now. Complaining customers are offered a financial incentive to close the complaint.
On raising the matter with senior management, you are told that there are plans to replace the equipment in these shops over the next five years.
Select the one option which correctly describes the non-conformity to be raised against ISO 9001.
A. 7.2 - Staff were not competent to handle customers' laundry.
B. 8.5.3 - Customers were not advised of damage to their property.
C. 10.1 - The organization fails to enhance customer satisfaction.
D. 8.5.1.d - The organization does not have suitable infrastructure for five shops.
E. 8.5.5.d - The organization failed to advise its customers of the potential for damage.
F. 8.5.1.h - Laundry returned to customers with defects.
Answer: (SHOW ANSWER)

NEW QUESTION: 65
Consultancy ABC, which is a subsidiary of a certification body called ABC-CERT, provided consultancy services regarding the implementation of a QMS based on ISO 9001 to an organization. Considering this, can ABC-CERT provide certification services to the organization which obtained consultancy services from Consultancy ABC?
A. Yes, after a minimum period of two years has passed.

B. Yes, if both parties sign an agreement which states that previous services by Consultancy ABC will not impact the judgment of auditors.
C. No, ABC-CERT is not allowed to provide certification services to that organization ever, as this would be a conflict of interest.
Answer: C (LEAVE A REPLY)
Comprehensive and Detailed In-Depth Explanation:
Certification bodies must remain independent and impartial. If a certification body (ABC-CERT) provides consulting services to an organization through its subsidiary (Consultancy ABC), it cannot later certify the same organization.
Clause References:
ISO/IEC 17021-1:2015, Clause 5.2.5 - Impartiality Requirements:
A certification body must not certify an organization to which it has provided consultancy services.
ISO/IEC 17021-1:2015, Clause 5.2.6:
Subsidiaries of certification bodies must not provide consulting services to prevent conflicts of interest.
Why is the Correct Answer C?
Certifying a client after providing consultancy creates a conflict of interest and violates ISO/IEC 17021-1:
2015 impartiality rules.
The certification body (ABC-CERT) and consultancy firm (Consultancy ABC) are related entities, making it impossible to remain objective and independent.
Why are the Other Options Incorrect?
A (Waiting two years) # ISO does not specify a time frame; the issue is impartiality, not just time.
B (Signing an agreement to ensure objectivity) # Conflicts of interest cannot be resolved through an agreement; independence is required.
Reference:
ISO/IEC 17021-1:2015, Clause 5.2.5 - Impartiality Requirements

NEW QUESTION: 66
At the end of a second-party audit, the audit team enters the meeting room to hold the closing meeting; only two people are present and waiting for them: the Health and Safety supervisor and the administrative officer. Neither has participated in the audit. However, the team had previously agreed with the auditee Quality Manager on two nonconformities identified during the audit (NC1 and NC2).
They said:
Health and Safety supervisor: "Good evening. We are sorry to inform you that the general manager was involved in a serious car accident, and the other two managers have had to leave urgently to attend to the emergency." Administration officer: "Our quality manager, before leaving, left a written message about 'NC2'. He declares that the correction and corrective action have been already implemented and has attached some documents to the message as evidence of

these actions. Therefore, he expects that 'NC2' will not be included in the report." Which one of the following would be your preferred answer to the Quallty Manager's request?

A. OK. I will record in the audit report that 'nonconformity 2' was closed during the Closing meeting

B. OK. Let's all go to the workshop to see the supervisor. I hope he will be able to explain what they did to correct the nonconformity and prevent its recurrence

C. Let me review the message and documents, and I will give you my answer in a few minutes

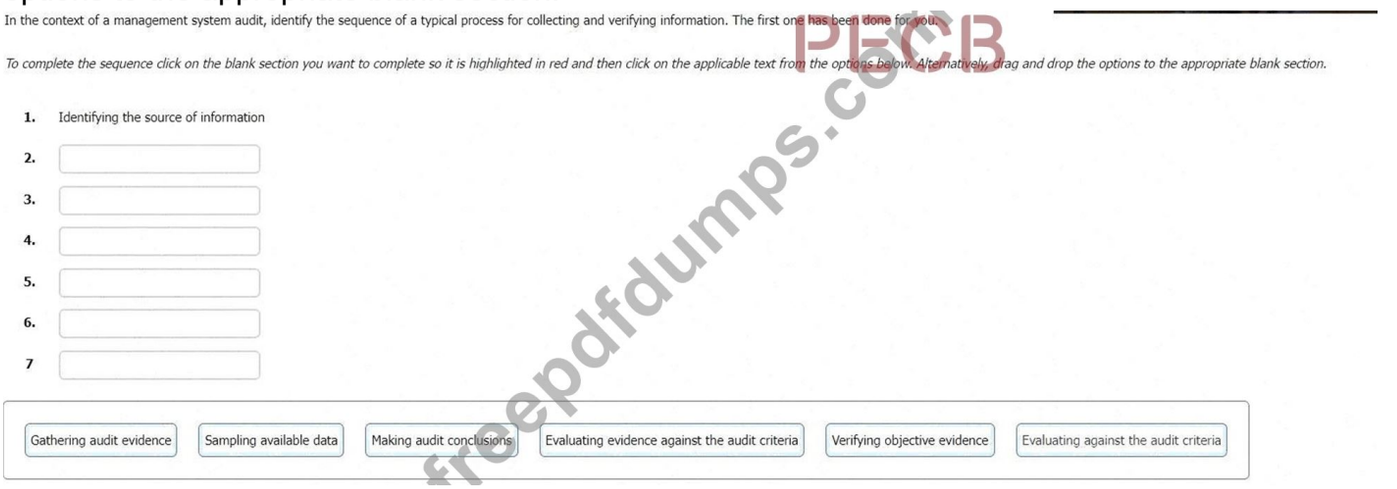
D. The scope of the audit does not allow auditors to review actions taken in response to the nonconformity.There would not be enough time for the full cycle of corrective action to take effect

Answer: C (LEAVE A REPLY)

NEW QUESTION: 67

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:

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: 68
You are carrying out an audit at an organisation seeking certification to ISO 9001 for the first time. The organisation offers health and safety training to customers. Training courses are offered either as open courses, delivered at a public venue, or online, or as courses that are tailored to meet specific requirements.
The business operates from a single office and those who deliver the training are either full-time employees or subcontractors.
You are interviewing the Training Manager (TM).
You: "What quality objectives apply to the training process?"
TM: "One of the quality objectives we aim for is a 90% minimum exam pass rate for all open training courses." You: "How do you measure this objective?" The Training Manager shows you a record on her computer and you see the following:

Month	Exam pass rates (%)					
	Course 1	Course 2	Course 3	Course 4	Course 5	Course 6
1	92	87	89	78	95	97
2	93	86	88	77	94	98
3	94	87	87	79	93	97
4	92	89	86	80	95	96
5	93	88	88	79	96	95
6	95	87	89	77	96	97

Which two of the following statements are true?
A. You would check the training of personnel.
B. You would determine how the exam pass rate figures were analysed.
C. You would determine the relative difficulty of each training course by reviewing them.
D. You would determine what corrective action was being taken to address the low pass rates.
E. You would raise a nonconformity as a requirement in clause 10.2 has not been fulfilled.
F. You would raise a nonconformity as a requirement in clause 8.7 has not been fulfilled.
Answer: (SHOW ANSWER)
In this scenario, the organization has set a quality objective of achieving a 90% minimum exam pass rate for all courses. The auditor's task is to assess whether this objective is being monitored effectively and if appropriate actions are taken when the objective is not met.
B). You would determine how the exam pass rate figures were analysed: ISO 9001:2015, particularly Clause

9.1 (Monitoring, measurement, analysis, and evaluation), requires organizations to evaluate performance data.
The auditor should verify how the organization analyses the pass rate data to ensure trends are identified, and corrective actions are planned based on this analysis.
D). You would determine what corrective action was being taken to address the low pass rates: When performance falls short of the objective, as seen with Course 4 (where the pass rate is below 90% in all months), Clause 10.2 (Nonconformity and corrective action) requires organizations to take corrective actions to address issues. The auditor would need to check if corrective actions have been initiated to address consistently low pass rates.
Statements A, C, E, and F do not directly address the monitoring and corrective action required under ISO
9001:2015 in this context.

NEW QUESTION: 69
Scenario 1: AL-TAX is a company located in California which provides financial and accounting services.
The company manages the finances of 17 companies and now is seeking to expand their business even more The CEO of AL-TAX, Liam Durham, claims that the company seeks to provide top-notch services to their clients Recently, there were a number of new companies interested in the services provided by AL-TAX.
In order to fulfill the requirements of new clients and further improve quality, Liam discussed with other top management members the idea of implementing a quality management system (QMS) based on ISO 9001.
During the discussion, one of the members of the top management claimed that the size of the company was not large enough to implement a QMS. In addition, another member claimed that a QMS is not applicable for the industry in which AL TAX operates. However, as the majority of the members voted for implementing the QMS. Liam initiated the project.
Initially, Liam hired an experienced consultant to help AL-TAX with the implementation of the QMS. They started by planning and developing processes and methods for the establishment of a QMS based on ISO
9001. Furthermore, they ensured that the quality policy is appropriate to the purpose and context of AL TAX and communicated to all employees. In addition, they also tried to follow a process that enables the company to ensure that its processes are adequately resourced and managed, and that improvement opportunities are determined.
During the implementation process, Liam and the consultant focused on determining the factors that could hinder their processes from achieving the planned results and implemented some preventive actions in order to avoid potential nonconformities Six months after the implementation of the QMS. AL-TAX conducted an internal audit. The results of the internal audit revealed that the QMS was not fulfilling all requirements of ISO 9001. A serious issue was that the QMS was not fulfilling the requirements of clause 5.1.2 Customer focus and had also not ensured clear and open communication channels with suppliers.

Throughout the next three years, the company worked on improving its QMS through the PDCA cycle in the respective areas. To assess the effectiveness of the intended actions while causing minimal disruptions, they tested changes that need to be made on a smaller scale. After taking necessary actions, AL-TAX decided to apply for certification against ISO 9001.
Based on the scenario above, answer the following question:
As stated in scenario 1, AL-TAX tested the effectiveness of the intended actions as part of the QMS improvement through the PDCA cycle. Which stage did it perform in this case?
A. Do
B. Check
C. Act
Answer: (SHOW ANSWER)
Comprehensive and Detailed In-Depth Explanation:
The PDCA (Plan-Do-Check-Act) cycle is a continuous improvement model used in ISO 9001:2015. The
"Check" phase involves monitoring, measuring, and analyzing the results to assess if the planned actions have been effective.
In scenario 1, AL-TAX tested the effectiveness of the intended actions, which aligns with the Check stage of the PDCA cycle. Clause 9.1.1 (Monitoring, Measurement, Analysis, and Evaluation) requires organizations to evaluate their QMS and determine whether improvements are necessary.
Reference:
ISO 9001:2015, Clause 0.3.2 - PDCA Cycle
ISO 9001:2015, Clause 9.1.1 - General (Performance Evaluation)

NEW QUESTION: 70
Select the term that best describes the purpose of retaining documented information in a quality management system to ISO 9001.
A. To facilitate auditing for proof of conformity to the standard.
B. To provide confidence in the effectiveness of the quality management system.
C. To safeguard the integrity of the quality management system.
D. To support the operation of the processes of the quality management system.
Answer: (SHOW ANSWER)
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: 71
The ISO 9001 clause 5.1.1 states top management shall demonstrate leadership and commitment with respect to the quality management system.
In the context of the ISO 9001 management system certification, select the one correct description of top management's responsibilities.
A. Top management shall ensure that all requirements are fulfilled.
B. Top management needs only to comply with 50% of the 5.1.1 requirements.
C. Depending on the organization's available resources, top management can comply with one or more of the 5.1.1 requirements.
D. Depending on the size, complexity and business context, some of the 5.1.1 requirements can be excluded.
Answer: A (LEAVE A REPLY)

NEW QUESTION: 72
What should the auditor document during the Stage 1 audit?
A. The main processes of the auditee
B. The interviews with the auditee's employees
C. The observations that could result in nonconformities during the on-site audit
Answer: C (LEAVE A REPLY)
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: 73
Scenario 7: POLKA is a car manufacturing company based in Stockholm, Sweden. The company has around

14,000 employees working in different sectors which help with the design, painting, assembling, and test drives of the final product. The company is widely known for its qualitative products and affordable prices. In order to retain their reputation, POLKA implemented a quality management system (QMS) based on ISO
9001.
Before applying for certification, the company decided to conduct an internal audit to check whether there are any nonconformities in their QMS and if the requirements of ISO 9001 are being fulfilled. The top management appointed Sean, the internal auditor, as the team leader of the internal audit team. Sean required from the top management to have unrestricted access to the employees and executives of POLKA and to the documented information. Furthermore, Sean required to establish a team with a large number of auditors, considering the size and the complexity of the organization. The top management of POLKA agreed with Sean's requirements. The top management, in cooperation with Sean, assigned 10 more employees to the audit team. Following that. Sean planned the audit activities and assigned the roles and responsibilities to each auditor. They began by interviewing employees of different manufacturing departments to check whether they are aware of the process of the QMS implementation. While conducting these activities, one of the auditors asked Sean for permission to audit the department in which he worked on a daily basis, as he was very familiar with the processes of the department.
Along the way, the teams findings showed that the staff were trained, documented information was updated, and the QMS fulfilled the requirements of ISO 9001. The internal audit took three weeks to complete, and on the last week the audit team held a final meeting The team shared their results and together drafted the audit report This report was submitted to the top management of the company. The report was maintained as documented information, and was available to the relevant interested parties.
Based on the scenario above, answer the following question:
Ten employees of POLKA were part of the audit team that conducted the internal audit. Is this acceptable?
A. Yes, members of the company can join the internal audit team
B. No, ISO 9001 requires hiring a professional team of auditors who are not part of the company to conduct the internal audit
C. Yes, it is a requirement of ISO 9001 to include employees of the company in the internal audit
Answer: (SHOW ANSWER)
Comprehensive and Detailed In-Depth Explanation:
According to ISO 9001:2015, Clause 9.2 (Internal Audit):
Internal audits are conducted by employees of the company who are trained as auditors.
External auditors are not mandatory unless required by the organization.
Thus, A is the correct answer.
Reference:
ISO 9001:2015, Clause 9.2 (Internal Audit)

NEW QUESTION: 74

Auditor competence is a combination of knowledge and skills. Which two of the following activities are predominately related to 'knowledge'?

A. Communicate with the auditee

B. Conduct audit meetings

C. Determine how to seek evidence from the auditee

D. Determining what evidence to gather

E. Evaluate proposals of corrective actions

F. Identify findings

Answer: D,E (LEAVE A REPLY)

Comprehensive and Detailed Explanation From Exact Extract:

According to ISO 19011:2018 - Guidelines for Auditing Management Systems, which is referenced in ISO

9001 Lead Auditor training and practice, auditor competence is defined by a combination of knowledge, skills, and personal attributes. Here's how each selected option aligns:

D). Determining what evidence to gather: This activity is rooted in knowledge of audit principles, criteria, and risk-based thinking. It requires an understanding of which types of evidence (documents, records, interviews, observations) are necessary to evaluate conformity to the audit criteria (Clause 7.2.3 of ISO 19011:2018).

E). Evaluate proposals of corrective actions: This task involves applying knowledge of ISO 9001 requirements, root cause analysis methods, and risk controls to assess whether proposed actions are suitable to prevent recurrence. It demands comprehension of quality management principles and corrective action methodologies, linking it firmly to knowledge.

Other options such as A (Communicate with auditee) and B (Conduct audit meetings) are predominantly skills-based, requiring interpersonal and communication abilities, not theoretical or regulatory knowledge.

C (Determine how to seek evidence) and F (Identify findings) involve both knowledge and skill but are more action-oriented and tied to situational judgment and auditor behavior.

References:

ISO 19011:2018, Clause 7.2.3 - Establishing Auditor Competence

ISO 9001:2015, Clause 9.2 - Internal Audit

ISO 19011:2018, Annex A.1 - Knowledge and skills of auditors

NEW QUESTION: 75

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. Quality objectives are not being implemented by the organisation's personnel.

B. The consultant has not interpreted ISO 9001 correctly.

C. Establishing quality objectives did not include top management.

D. Quality objectives were not established in alignment with the organisation's quality policy.

E. The organisation cannot afford to undertake quality objectives all at once.

F. Quality objectives are not maintained as documented information.

Answer: D,F (LEAVE A REPLY)

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: 76
Which two of the following aspects of a quality management system must the organisation continually improve?
A. Suitability
B. Adaptability
C. Effectiveness
D. Responsiveness
E. Efficiency
F. Applicability
Answer: (SHOW ANSWER)
According to the ISO 9001:2015 document, the organisation must continually improve the suitability, adequacy, and effectiveness of the quality management system1. However, among the six options given, only effectiveness is directly mentioned as an aspect of the quality management system that must be continually improved. Therefore, C is one of the correct answers.
Efficiency, on the other hand, is not explicitly stated as an aspect of the quality management system that must be continually improved, but it is implied by the quality management principle of improvement, which states that successful organisations have an ongoing focus on improvement2. One of the key benefits of applying this principle is improving operational effectiveness and efficiency2. Therefore, E is another correct answer.
Suitability, adaptability, responsiveness, and applicability are not aspects of the quality management system that must be continually improved, according to the ISO 9001:2015 document. They may be related to the quality management system, but they are not the focus of continual improvement.
Therefore, the correct answer is C and E.
References: 1: ISO 9001:2015 - Quality management systems - Requirements 2: ISO - Quality management principles

NEW QUESTION: 77
Noitol is an organisation specialising in the design and production of e-learning training materials for the insurance market. During an ISO 9001 audit of the development department, the auditor asks the Head of Development about the process used for validation of the final course design. She states that they usually ask customers to validate the product with volunteers. She says that the feedback received often leads to key improvements.
The auditor samples the design records for a recently completed course for the 247 Insurance organisation.
Design verification was carried out but there was no validation report. The Head of Development advises that this customer required the product on an urgent basis, so the validation stage was omitted. When asked, the Head estimates that this occurs about 50% of the time. She confirms that they always ask for feedback and often make changes. There is no record of feedback in the design file for the course.
The auditor raises a nonconformity against ISO 9001. Which one of the following options is the basis for the nonconformity?
A. 8.3.5 - The improvements made to course designs are not documented. Feedback from customers is not always actioned.
B. 8.3.2.c - Design planning does not include design validation. Design verification is part of the planning process.
C. 8.3.4.d - Design validation is not always conducted. It is omitted about half of the time.
D. 8.6 - Course materials are released without proper approval. A course for 247 Insurance was released on an urgent basis.
Answer: (SHOW ANSWER)
Clause 8.3.4.d of ISO 9001:2015 requires that design and development validation be performed to ensure that the resulting products or services meet the requirements for their specified application or intended use.
Validation is critical to confirm that the product works as intended in real-world conditions.
In this case, Noitol omitted the design validation step approximately 50% of the time, which is a direct violation of Clause 8.3.4.d. Although they collect feedback after the fact, this is not a substitute for formal validation before the product is released. The nonconformity arises because the process of validation was neglected, not the recording of improvements or feedback.
Other options, such as documenting improvements (A) or issues with planning verification (B), are important but do not directly address the primary concern: the lack of consistent design validation before product release. Option D (8.6) concerns product release, but this nonconformity focuses on the validation stage, not just approval for release.

NEW QUESTION: 78
According to ISO 19011, what two activities take place during the conduct of a audit follow-up?

A. Verify the effectiveness of the implemented corrective actions
B. Verify corrections taken to fix the reported non-conformities
C. Verify legal compliance
D. Plan the next audit
E. Determine feasibility of the audit
F. Assign roles and responsibilities of observers
Answer: (SHOW ANSWER)
According to ISO 19011:2018, clause 6.7, the audit follow-up is the process of verifying the completion and effectiveness of corrective actions taken by the auditee as a result of an audit. The audit follow-up can include two main activities:
Verifying the effectiveness of the implemented corrective actions: this means checking whether the actions taken by the auditee have addressed the root causes of the nonconformities and prevented their recurrence or occurrence in other areas. The verification can be done by reviewing documents, records, data, or other evidence provided by the auditee, or by conducting a follow-up audit on site or remotely.
Verifying corrections taken to fix the reported non-conformities: this means checking whether the auditee has corrected the nonconformities identified during the audit and eliminated their immediate effects. The verification can be done by reviewing documents, records, data, or other evidence provided by the auditee, or by conducting a follow-up audit on site or remotely.
The audit follow-up can be conducted as a separate audit or as part of a subsequent audit, depending on the audit programme, the audit objectives, the audit criteria, the audit scope, the audit risks, and the audit findings. The audit follow-up should be planned and conducted in accordance with the same principles and processes as the initial audit, and the results should be documented and reported accordingly. References:
ISO 19011:2018(en), Guidelines for auditing management systems, clause 6.7 ISO 19011 Management Systems Audit Checklist | Process Street, task 6.7.1 and 6.7.2 Conducting the Audit Follow-Up: When to Verify - The Auditor, section "Conducting the audit follow-up"

NEW QUESTION: 79
Who maintains ownership of the audit report?
A. The audit team leader
B. The auditee
C. The certification body
Answer: C (LEAVE A REPLY)
Comprehensive and Detailed In-Depth Explanation:
According to ISO 17021-1:2015, Clause 9.4.8 (Audit Reporting):
* The certification body retains ownership of the audit report as it is responsible for the certification decision.
* The auditee may receive a copy, but it does not own the report.
* The audit team leader compiles the report but does not own it.
Thus, C is the correct answer.

Reference:
ISO 17021-1:2015, Clause 9.4.8 (Audit Reporting)

NEW QUESTION: 80
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:
Why is it important to discuss the audit findings with DC's top management prior to the closing meeting and the submission of the final audit report?
A. To verify whether the audit objectives have been met
B. To encourage the implementation of corrective actions as soon as possible
C. To identify the persons responsible for the nonconformities
Answer: A (LEAVE A REPLY)
Comprehensive and Detailed In-Depth Explanation:
Discussing audit findings before the closing meeting ensures that:
* The audit objectives have been met (ISO 19011:2018, Clause 6.4.10).
* The auditee has an opportunity to clarify misunderstandings or provide additional evidence.
* The audit team and the auditee agree on the accuracy of findings before finalizing the report.
While encouraging corrective actions (B) is beneficial, the primary purpose of discussing findings is to ensure that the audit was conducted effectively and aligned with objectives. Identifying responsible persons (C) is not the auditor's role.
Reference:

ISO 19011:2018, Clause 6.4.10 (Communicating Audit Findings Before the Closing Meeting)

NEW QUESTION: 81

Which one of the following is not an ISO 9000:2015 quality management principle?

A. Evidence-based decision-making

B. Leadership

C. Process approach

D. Risk-based approach

Answer: D (LEAVE A REPLY)

According to the ISO 9000:2015 quality management principles document1, risk-based approach is not one of the seven quality management principles that ISO 9000, ISO 9001 and other related quality management standards are based on. The seven quality management principles are:

* Customer focus
* Leadership
* Engagement of people
* Process approach
* Improvement
* Evidence-based decision making
* Relationship management

Therefore, risk-based approach is not a quality management principle under ISO 9001:2015.

References: ISO - Quality management principles

NEW QUESTION: 82

The following are stages of an audit, put them in the order they would be conducted.

Answer:

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

According to ISO 19011:2018, clause 5, the audit programme is a set of one or more audits planned for a specific time frame and directed towards a specific purpose. The audit programme includes all activities necessary to plan, organize, and conduct the audits. The audit programme management involves the following steps1:

Establishing the audit programme objectives: The audit programme objectives define the intended outcomes of the audit programme, such as verifying conformity, evaluating performance, identifying improvement opportunities, etc. The audit programme objectives should be aligned with the strategic direction and policies of the organization and the needs and expectations of the interested parties.

Determining and evaluating the audit programme risks and opportunities: The audit programme risks and opportunities are the factors that can affect the achievement of the audit programme objectives, such as changes in the internal or external context, availability of resources, competence of auditors, etc. The audit programme risks and opportunities should be identified, analyzed, and evaluated to determine the appropriate actions to address them.

Establishing the audit programme: The audit programme is established by defining the audit programme scope, criteria, methods, and resources. The audit programme scope defines the extent and boundaries of the audit programme, such as the processes, functions, sites, activities, etc. that will be audited. The audit programme criteria are the set of policies, procedures, or requirements used as a reference for the audits. The audit programme methods are the techniques used to conduct the audits, such as interviews, observations, document review, sampling, etc. The audit programme resources are the human, technical, and financial resources needed to implement the audit programme.

Initiating the audit: The audit initiation is the process of formally establishing the arrangements for an individual audit within the audit programme. The audit initiation involves contacting the auditee

and the audit client, confirming the audit objectives, scope, and criteria, and obtaining the necessary information and access for the audit.
Preparing all audit activity: The audit preparation is the process of developing the audit plan and the audit work documents for an individual audit. The audit plan is a document that provides the basis for agreement regarding the conduct of the audit, such as the audit schedule, the audit team, the audit methods, the audit language, the audit report, etc. The audit work documents are the records that provide evidence of the audit activities, such as the audit checklist, the audit notes, the audit findings, etc.
Conducting the audit activities: The audit activities are the processes of collecting and verifying audit evidence and evaluating it against the audit criteria to make the audit conclusions. The audit activities include the opening meeting, the communication during the audit, the roles and responsibilities of the audit team and the auditee, the audit evidence collection and verification, the audit findings generation and recording, the closing meeting, and the audit report preparation and distribution.
References: ISO 19011:2018(en), Guidelines for auditing management systems

NEW QUESTION: 83
During a second-party audit of a dairy farm (by a potential customer) complying with ISO 9001:2015, the auditor verifies that there is large variability in the daily production of the milking yard. The current agreement with their only customer is to provide 2,000 litres per day. However, in the last two years, they have noticed an increasing variability in daily production.
If they produce less than 2,000 litres, they are penalised with a fine of 1.5 pesos for every litre that they do not provide. If they produce more than 2,000 litres, they use the extra milk to feed the pigs.
This process has been in operation for decades. The dairy farm was founded by the grandfather of the current owners, who did not want to alter the established practices.
The auditor raises a nonconformity on the basis that the process is not under control (Clause 8.1).
If you had been the auditor, which one of the following actions would you have accepted?
A. Modify the contract with the current customer to provide them with only 1,500 litres of milk per day and make an agreement with a second customer.
B. Apply the existing process of addressing the risks and opportunities of milk production.
C. Retain the current contract and try to sell the occasional surplus milk to a second customer.
D. Analyse the daily dispatch of milk for 7 days to determine its variability.
Answer: B (LEAVE A REPLY)
The action that the auditor would have accepted is:
*Option B: Apply the existing process of addressing the risks and opportunities of milk production. This option is correct because ISO 9001:2015 clause 8.1 requires the organization to plan, implement and control the processes needed to meet the requirements for the provision of products and services, and to implement actions determined in clause 6.1, which refers to the actions to address risks and opportunities. The organization should apply the existing process of addressing the risks and opportunities of milk production, which may include identifying the

sources of variability, assessing the potential impacts and consequences, determining and implementing appropriate actions to reduce or eliminate the variability, monitoring and measuring the effectiveness of the actions, and reviewing and updating the actions as necessary.
The following options are not correct:
*Option A: Modify the contract with the current customer to provide them with only 1,500 litres of milk per day and make an agreement with a second customer. This option is not correct because it does not address the root cause of the variability in the daily production of the milking yard, which may affect the quality and consistency of the products and services provided by the organization. It also does not demonstrate the organization's commitment to meet the customer and applicable statutory and regulatory requirements, as required by ISO 9001:2015 clause 8.2.2.
*Option C: Retain the current contract and try to sell the occasional surplus milk to a second customer. This option is not correct because it does not address the root cause of the variability in the daily production of the milking yard, which may affect the quality and consistency of the products and services provided by the organization. It also does not demonstrate the organization's commitment to meet the customer and applicable statutory and regulatory requirements, as required by ISO 9001:2015 clause 8.2.2.
*Option D: Analyse the daily dispatch of milk for 7 days to determine its variability. This option is not correct because it does not address the root cause of the variability in the daily production of the milking yard, which may affect the quality and consistency of the products and services provided by the organization. It also does not demonstrate the organization's commitment to implement actions to address risks and opportunities, as required by ISO 9001:2015 clause 8.1.
References:
*ISO 9001:2015 Quality management systems - Requirements, Clause 8: Operation, Subclause 8.1:
Operational planning and control, Subclause 8.2: Requirements for products and services
*ISO 9001 Lead Auditor Course Material, Module 4: ISO 9001:2015 Requirements, Slide 23: Clause 8 - Operation
*ISO 9001 Lead Auditor Training Course - IRCA Certified, Section 4.2: ISO 9001:2015 Requirements, Subsection 4.2.8: Clause 8 - Operation
*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: 84
You are a member of the audit team of a second-party audit of an organisation with 625 employees. The audit procedure recommends using sampling criteria which requires the review of the documented competence for
25 personnel. The audit team leader developed an audit plan allocating one hour to audit the Human Resources department (from 11:30 am to 12:30 pm). She told you that she could not allocate any additional time.

What would you do?
A. Extend the audit until 1.00pm and ask for a quick lunch later.
B. Plan to review less than 25 cases.
C. Plan to review as many as possible and see if you can extend the audit duration by one day.
D. Plan to miss lunch and review as many as possible.
Answer: B (LEAVE A REPLY)
In this scenario, the time allocated by the audit team leader for the Human Resources audit is fixed, and as an auditor, you must work within that constraint. Although the sampling criteria suggests reviewing 25 personnel files, it is acceptable to adjust the sample size based on time and resource limitations. ISO 9001:2015 emphasizes risk-based thinking and practical resource management (Clause 7.1), so it is reasonable to review a smaller sample if the time is insufficient. Option B is a pragmatic approach, allowing you to focus on quality over quantity by reviewing as many cases as time allows without compromising the audit schedule.
Options like extending the audit (A, C, D) are impractical in a structured audit environment, especially for second-party audits where maintaining the agreed schedule is important.

NEW QUESTION: 85
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.
Based on the last paragraph of scenario 3, which audit principle did the audit team follow?
A. Fair presentation.
B. Integrity.
C. Confidentiality.
D. Objectivity.
Answer: A (LEAVE A REPLY)

Comprehensive and Detailed In-Depth Explanation:
Auditors must report findings truthfully and accurately to ensure an unbiased assessment of the QMS.
Clause References:
ISO 19011:2018, Clause 4 - Principles of Auditing:
Fair Presentation # Requires auditors to report truthfully and accurately, without bias or omission.
Integrity # Ensures auditors adhere to ethical conduct.
Why is the Correct Answer A?
The audit team reported findings truthfully, based on collected evidence.
Fair presentation ensures that both positive and negative findings are included in the audit report.
Objective evidence was gathered through interviews, document reviews, and observations.
Why are the Other Options Incorrect?
B (Integrity) # Related to ethics and professional conduct, but not specifically about presenting findings.
C (Confidentiality) # Important, but does not apply to the principle of reporting findings accurately.
D (Objectivity) # Ensures impartiality, but "fair presentation" directly addresses accurate reporting of findings.
Reference:
ISO 19011:2018, Clause 4 - Principles of Auditing (Fair Presentation)

NEW QUESTION: 86
Which two of the following may be changed once a Stage 2 certification audit has commenced?
A. Agreed language of the audit
B. Audit scope
C. Audit plan
D. Agreed standard for the audit criteria
E. Audit checklist
F. Increase of audit duration
Answer: C,F (LEAVE A REPLY)
Comprehensive and Detailed In-Depth Explanation:
Once a Stage 2 certification audit has commenced, certain logistical or planning-related elements may still be adjusted, while others are fixed by prior agreement and cannot be changed.
C. Audit Plan:
The audit plan is a document that outlines the scope, objectives, criteria, and logistics of the audit.
According to ISO/IEC 17021-1:2015 (the standard for bodies providing audit and certification of management systems), clause 9.2.3.3 allows for modification of the audit plan based on real-time conditions during the audit - such as availability of auditees or changes in process access.
F. Increase of Audit Duration:
Audit duration is generally determined during audit planning based on factors like employee count, risk, complexity, etc. However, if during Stage 2 it is found that more time is needed (e.g., due to additional processes, scope not fully covered, or significant findings), auditors are

permitted to extend the audit. This ensures full coverage of all required areas as per ISO/IEC 17021-1 clause 9.1.4 and IAF MD 5.
A. Agreed Language of the Audit:
This is determined and agreed upon in the contract and audit planning stages. Changing it during Stage 2 would create communication and documentation issues, especially in multi-site or multi-national audits.
B. Audit Scope:
The audit scope is defined in the contract and certification agreement based on clause 4.3 of ISO 9001:2015.
Changing it mid-audit would invalidate planning, required competencies, and potentially even the certification basis.
D. Agreed Standard for the Audit Criteria:
Changing the standard (e.g., from ISO 9001 to ISO 13485) is fundamentally altering the purpose and contractual basis of the audit and is not permissible once Stage 2 has started.
E. Audit Checklist:
The checklist is a tool prepared by the auditor as part of audit preparation and is based on the audit plan and standard requirements. While it may be adapted during the audit (e.g., if new risks arise), it does not constitute a formal change like duration or scope.
Relevant References:
* ISO/IEC 17021-1:2015 Clause 9.2.3.3 (Audit Plan Modification)
* IAF MD 5:2019 (Duration of QMS Audits)
* ISO 9001:2015 Clause 4.3 (Scope of the QMS)
* ISO/IEC 17021-1:2015 Clause 9.1.4 (Audit Duration)

NEW QUESTION: 87
When should the certification body accept the audit?
A. After considering the integrity and reputation of the auditee.
B. After considering the nature of the operations of the auditee.
C. Both A and B.
D. Only if the auditee has no previous major nonconformities.
Answer: C (LEAVE A REPLY)
Comprehensive and Detailed In-Depth Explanation:
Before accepting an audit, the certification body must assess the integrity of the auditee and the nature of its operations to ensure compliance feasibility.
Clause References:
* ISO/IEC 17021-1:2015, Clause 9.1.2 - Audit Planning:
* The certification body must review the auditee's background, reputation, and operational complexity before accepting the audit.
Why is the Correct Answer C?
* The auditee's integrity and reputation impact the credibility of certification.
* The nature of operations determines audit complexity and resource allocation.

Why are the Other Options Incorrect?
* A (Integrity and reputation only) # Correct but incomplete; nature of operations is equally important.
* B (Nature of operations only) # Integrity is also a factor, not just operations.
* D (No previous major nonconformities required) # Auditees with past major nonconformities can still be audited if corrective actions are taken.
Reference:
ISO/IEC 17021-1:2015, Clause 9.1.2 - Audit Planning

NEW QUESTION: 88
You are conducting a third-party audit to ISO 9001 and interviewing the Training Manager. She explains that training is more important than ever because the organisation has had to reduce the number of staff employed. Many of the remaining staff are now required to be 'multi-skilled'. You ask to see plans for the multi-skilling training and are shown plans that look comprehensive, and include both 'on the job" training and internal and external training courses.
The records indicate that several staff required parts of their training to be repeated one month after the first training was provided. You ask why this was needed and are told that an investigation of customer complaints identified that several staff members did not complete certain tasks in the correct manner. The extra training was therefore recommended as a corrective action.
Based on this interview, which two of the tollowing audit trails would be the most appropriate to follow?
Select the two most appropriate audit trails from the following.
A. Ask if customer complaints had ceased since the multi-skilled training finished.
B. Ask the members of staff whether they found the training received useful.
C. Assess whether Quality objectives are being met.
D. Determine whether customers were consulted about the risks associated with the multi-skilling training.
E. Determine whether management has assessed the impact of staff reduction on the organisation's ability to meet its objectives.
F. Review records to assess if all planned training has been completed.
Answer: A,F (LEAVE A REPLY)
When conducting a third-party audit to ISO 9001, especially in the context of training and corrective actions taken due to customer complaints, the most appropriate audit trails to follow would be:
A: Ask if customer complaints had ceased since the multi-skilled training finished. This audit trail is relevant because it directly relates to the effectiveness of the corrective action taken. If customer complaints have decreased or ceased, it could indicate that the additional training was effective1.
F: Review records to assess if all planned training has been completed. This trail is important to ensure that the training plan has been fully implemented and to verify that all staff members have

received the necessary training. It also helps in assessing the adequacy of the training in terms of content, frequency, and outcomes1.
These two trails, A and F, are closely linked to the issue of customer complaints and the organization's response to them. They provide insight into whether the actions taken were suitable and whether they have led to improvements in staff performance and customer satisfaction1. The other options, while potentially useful, do not directly address the immediate concern of the effectiveness of the corrective actions taken in response to the customer complaints1.

NEW QUESTION: 89
Among others, what does Clause 4.4 (Quality Management System and Its Processes) of ISO 9001 require from organizations?
A. To change the QMS quarterly
B. To review the QMS annually
C. To continually improve the QMS
D. To conduct a QMS gap analysis every two years
Answer: C (LEAVE A REPLY)
Comprehensive and Detailed In-Depth Explanation:
ISO 9001:2015 emphasizes continual improvement as a fundamental requirement of an effective Quality Management System (QMS).
Clause Reference:
* Clause 4.4.1 (Quality Management System and Its Processes) states that organizations must:
* Determine processes needed for the QMS
* Establish criteria and methods for process effectiveness
* Ensure continual improvement of the system
Why is the Correct Answer C?
* Continual improvement is a core principle of ISO 9001.
* Organizations must regularly assess and enhance their QMS to adapt to new challenges and maintain effectiveness.
Why are the Other Options Incorrect?
* A (To change the QMS quarterly) # ISO 9001 does not mandate a specific frequency for system changes.
* B (To review the QMS annually) # QMS reviews must be conducted as needed, not strictly annually.
* D (To conduct a QMS gap analysis every two years) # Gap analysis is useful but is not a mandatory requirement under Clause 4.4.
Reference:
ISO 9001:2015, Clause 4.4 - Quality Management System and Its Processes

NEW QUESTION: 90
Scenario 2:

Bell is a Canadian food manufacturing company that operates globally. Their main products include nuts, dried fruits, and confections. Bell has always prioritized product quality and has maintained a good reputation for many years. However, the company's production error rate increased significantly, leading to more customer complaints.
To increase efficiency and customer satisfaction, Bell implemented a Quality Management System (QMS) based on ISO 9001. The top management established a QMS implementation team comprising five middle managers from various departments, including Leslie, the quality manager.
Leslie was responsible for assigning responsibilities and authorities for QMS-related roles. He also suggested including a top management representative in the QMS team, but top management declined due to other priorities.
The team defined the QMS scope as:
"The scope of the QMS includes all activities related to food processing." Leslie established a quality policy and presented it to the team for review before top management approval.
Top management also proposed a new strategy for handling customer complaints, requiring biweekly customer surveys to monitor customer perceptions.
The quality policy was established by Leslie and approved by top management. Is this acceptable? Please refer to scenario 2.
A. No, the quality policy must be established and approved by top management.
B. Yes, the quality policy can be established by the QMS implementation team and be approved by top management.
C. No, the quality policy must be established and approved only by the quality manager.
D. Yes, as long as top management is informed, the policy can be established by any responsible employee.
Answer: A (LEAVE A REPLY)
Comprehensive and Detailed In-Depth Explanation:
ISO 9001:2015, Clause 5.2.1 (Establishing the Quality Policy) states that top management must establish, implement, and maintain a quality policy.
In the scenario, the quality manager (Leslie) created the policy, but top management did not establish it themselves, which violates Clause 5.2.1. While the policy can be drafted by a team, top management must take full ownership of its development and approval.
Reference:
ISO 9001:2015, Clause 5.2.1 - Establishing the Quality Policy

NEW QUESTION: 91
Which two of the following should be included in an audit plan?
A. List of findings from the last audit
B. Name of the auditee general manager
C. Signature of Certification Body Technical Reviewer
D. Sequence and timings of audit activities
E. Date of next audit

F. Name of auditees and auditors

Answer: D,F (LEAVE A REPLY)

According to ISO 19011:2018, clause 6.3.2, an audit plan should include the following information:

The audit objectives, scope, and criteria

The audit team members and their roles and responsibilities

The audit schedule, including the sequence and timings of audit activities, such as opening meeting, document review, interviews, observations, closing meeting, etc.

The expected time and duration of each audit activity and location

The name and contact details of the auditee's representative and other relevant parties The allocation of appropriate resources to support the audit activities The audit methods and techniques to be used, such as interviews, observations, sampling, etc.

The audit documents and records to be prepared and retained

The audit language and communication methods

The audit risks and opportunities and how to address them

The audit follow-up arrangements, if applicable

Therefore, the correct answer is D and F, as they are essential elements of an audit plan. The other options are either irrelevant or optional for an audit plan. References:

ISO 19011:2018(en), Guidelines for auditing management systems, clause 6.3.2 ISO 19011: Guidelines for Auditing Management Systems | ASQ, section "Making audit arrangements" ISO 19011 Management Systems Audit Checklist | Process Street, task 6.3.2

NEW QUESTION: 92

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.
Which statement below represents the level of responsibility demonstrated by the audit team in scenario 3?
A. No negligence, the audit team has demonstrated diligence during the audit and followed the best practices.
B. Ordinary negligence, the audit team has demonstrated lack of diligence.
C. Gross negligence, the audit team has demonstrated a total lack of diligence.
D. Willful misconduct, the audit team intentionally disregarded audit procedures.
Answer: A (LEAVE A REPLY)
Comprehensive and Detailed In-Depth Explanation:
ISO 19011:2018 requires auditors to conduct audits professionally and diligently.
Clause References:
ISO 19011:2018, Clause 4.4 - Professional Care: Auditors must exercise due diligence in conducting audits.
ISO 9001:2015, Clause 9.2 - Internal Audit: Requires objective and systematic audits to evaluate QMS effectiveness.
Why is the Correct Answer A?
The audit team followed best practices by gathering verifiable audit evidence through interviews, document reviews, and observations.
They ensured fair presentation of findings in the final audit report.
They complied with ISO 9001 and ISO 19011 guidelines for audit procedures.
Why are the Other Options Incorrect?
B (Ordinary negligence) # No evidence of negligence; the team followed structured audit processes.
C (Gross negligence) # No indication that the auditors ignored important responsibilities.
D (Willful misconduct) # The auditors acted professionally and did not intentionally disregard rules.
Reference:
ISO 19011:2018, Clause 4.4 - Professional Care
ISO 9001:2015, Clause 9.2 - Internal Audit

NEW QUESTION: 93

Select the term which best describes the quality management system process of modifying a non-conforming product to bring it within acceptance criteria.

A. Concession

B. Correction

C. Corrective action

D. Preventive action

Answer: B (LEAVE A REPLY)

According to the ISO 9000:2015 - Quality management systems - Fundamentals and vocabulary, correction is defined as "action to eliminate a detected nonconformity". A nonconformity is defined as "non-fulfilment of a requirement". Therefore, the process of modifying a non-conforming product to bring it within acceptance criteria is a correction, as it eliminates the non-fulfilment of the product specification. The other options are not correct, as they have different definitions and purposes:

*Concession: permission to release or use a nonconforming product, service or process

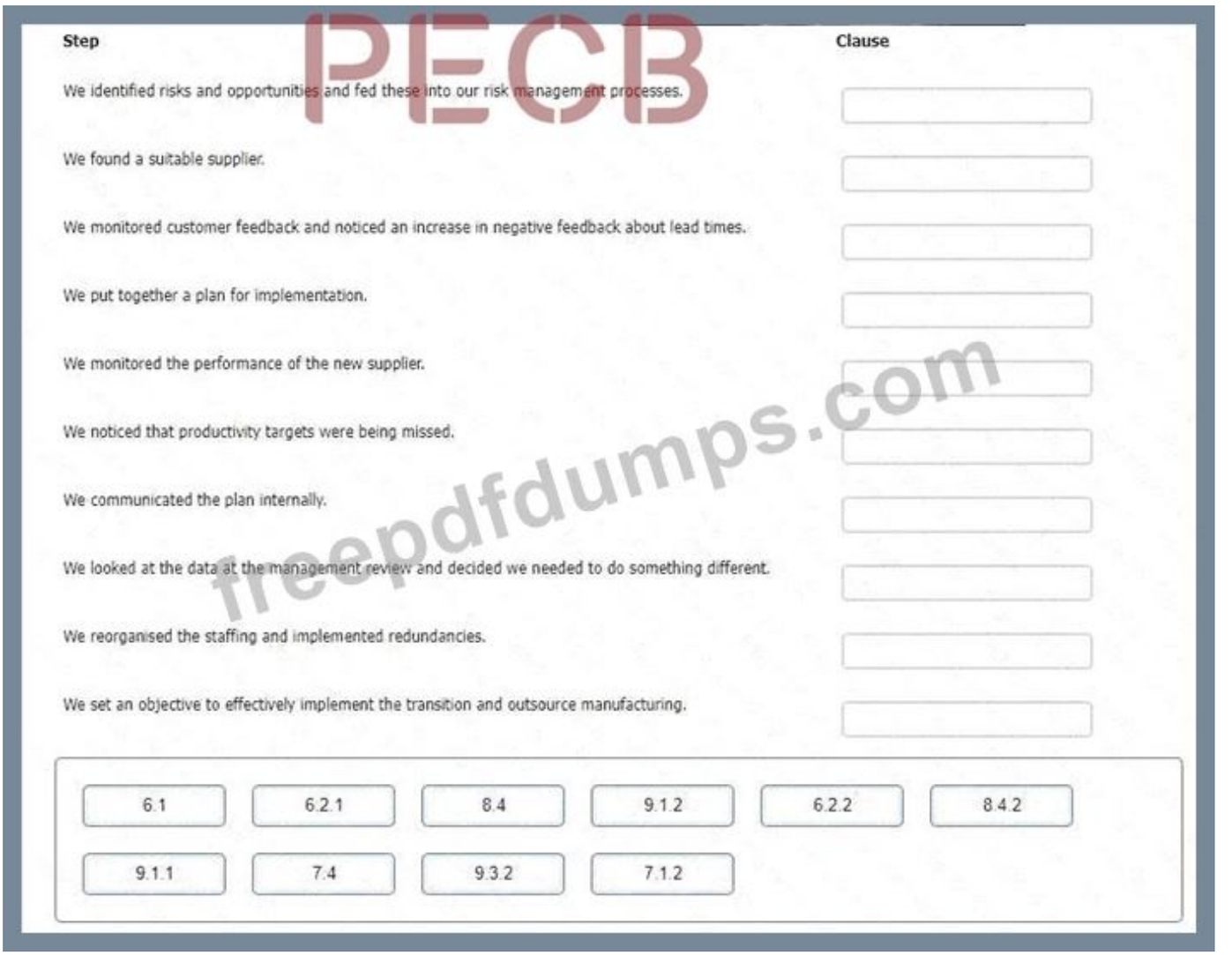
*Corrective action: action to eliminate the cause of a nonconformity and to prevent recurrence

*Preventive action: action to eliminate the cause of a potential nonconformity or other undesirable potential situation References: ISO 9000:2015 - Quality management systems - Fundamentals and vocabulary, ISO 9001 nonconforming product: How to understand dispositions - Advisera

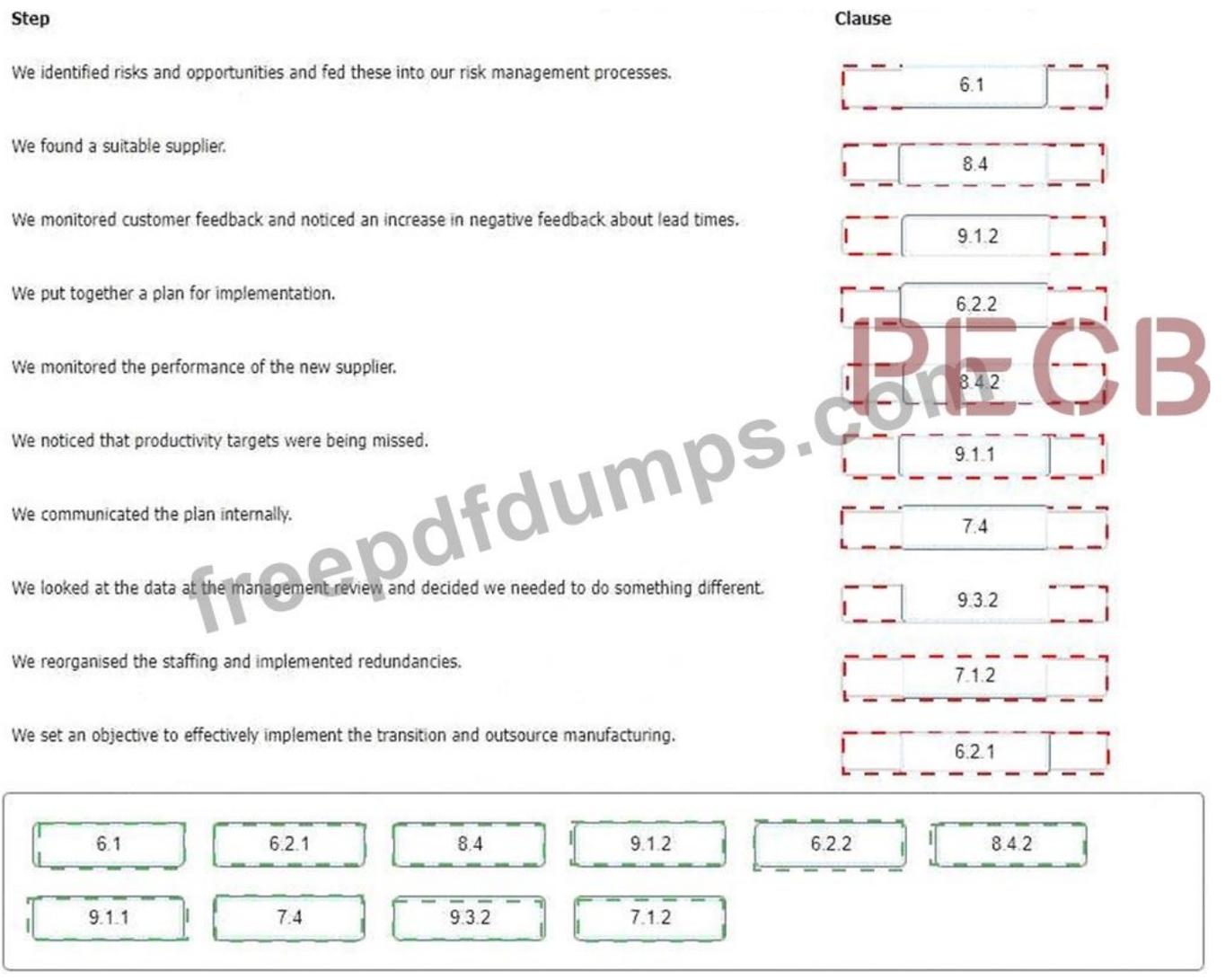
NEW QUESTION: 94

You, as auditor, are in dialogue with the quality lead and managing director of a small business that supplies specialist laboratory equipment and furniture.

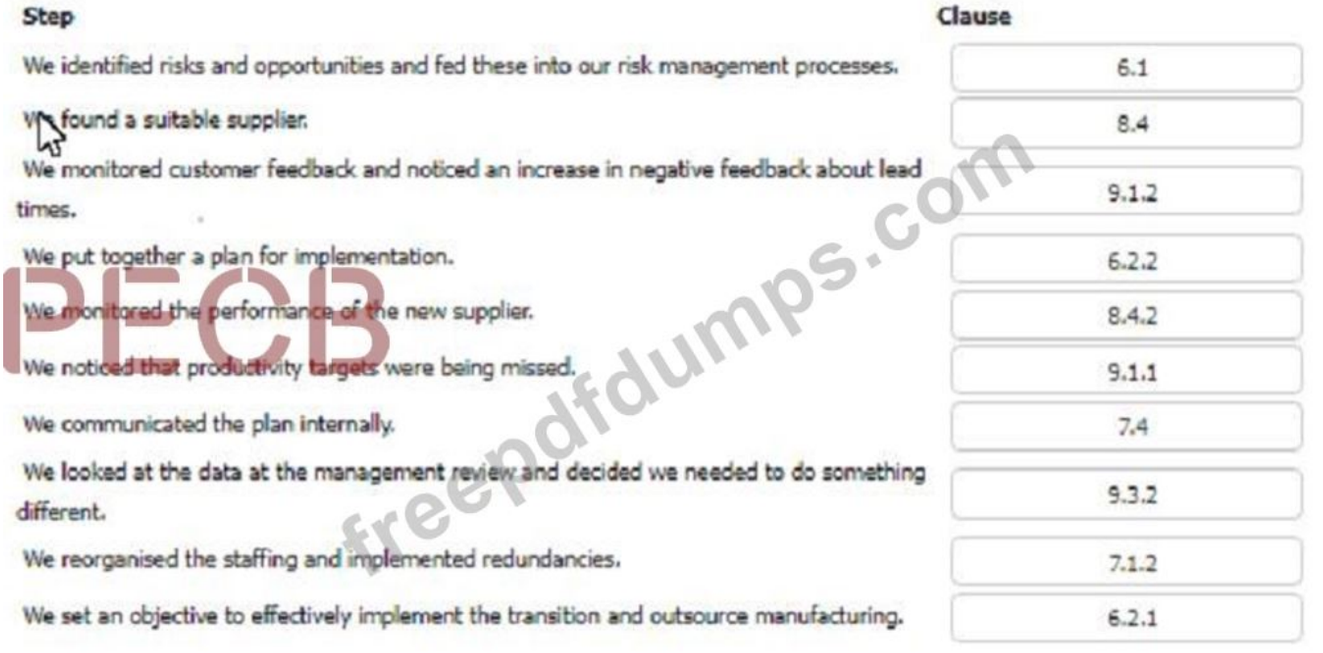
You: "I'd like to look at how you manage change in the organisation. What changes have you made as a business, say, over the last 12 months?" Auditee: "We have made some strategic changes, the main one being that we no longer manufacture our own products in house." You: "That sounds like quite a significant change. What has been the impact of that?" Auditee: "We now mainly sell other manufacturers' products, under their brand names, and have outsourced manufacture of our own brand products to one of our suppliers. Unfortunately, we had to make six members of our staff redundant. This represents about 20% of our workforce, so this has been quite a challenging time." You: "I'm sure. What were the reasons for making the change?" Auditee: "Our manufacturing section was a small operation, and we struggled to cope with fluctuations in demand. During busy periods, we found it hard to meet lead times, and in quiet periods we had staff with little to do. This was having an impact on customer satisfaction and meant we had to charge premium prices that made our product uncompetitive." You: "How did you go about the change?" In relation to the auditor's question about how the change was managed, the auditee mentions the steps listed below. Match the ISO 9001 clauses to the steps. To complete the table, click on the blank section you want to complete so it is highlighted in red and then click on the ISO 9001 clauses listed below. Alternatively, drag and drop each clause to show which step the requirement applies to.



Answer:



Explanation:



Here is the correct matching of ISO 9001:2015 clauses to the steps mentioned in the change management process:

We identified risks and opportunities and fed these into our risk management processes.
Clause 6.1 (Actions to address risks and opportunities)
We found a suitable supplier.
Clause 8.4 (Control of externally provided processes, products, and services) We monitored customer feedback and noticed an increase in negative feedback about lead times.
Clause 9.1.2 (Customer satisfaction)
We put together a plan for implementation.
Clause 6.2.2 (Planning to achieve quality objectives)
We monitored the performance of the new supplier.
Clause 8.4.2 (Type and extent of control of external providers)
We noticed that productivity targets were being missed.
Clause 9.1.1 (Monitoring, measurement, analysis, and evaluation)
We communicated the plan internally.
Clause 7.4 (Communication)
We looked at the data at the management review and decided we needed to do something different.
Clause 9.3.2 (Management review inputs)
We reorganised the staffing and implemented redundancies.
Clause 7.1.2 (People)
We set an objective to effectively implement the transition and outsource manufacturing.
Clause 6.2.1 (Quality objectives and planning to achieve them)
This aligns the steps of the change process with relevant ISO 9001:2015 clauses related to risk, planning, communication, and monitoring.

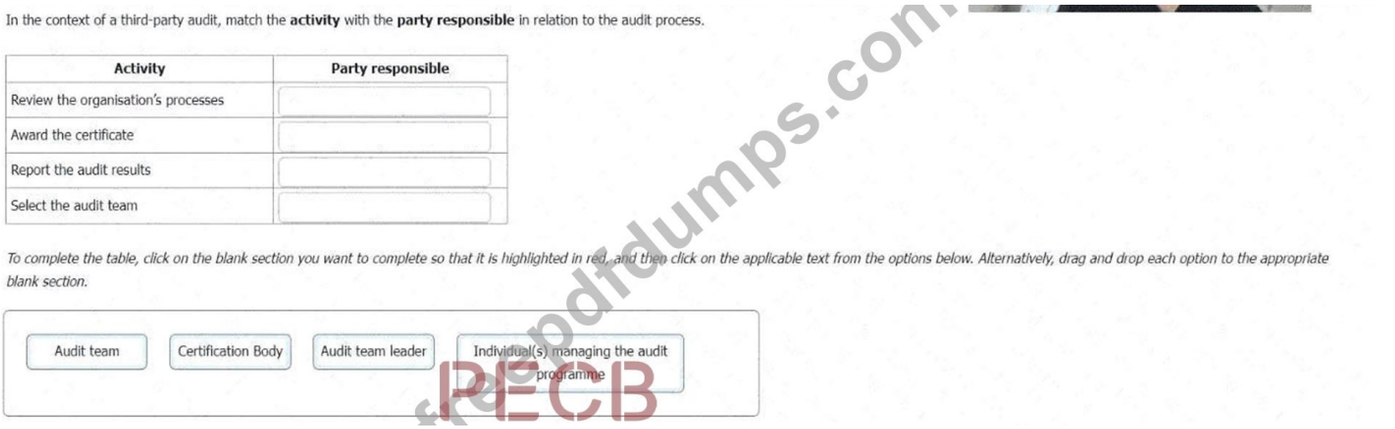
NEW QUESTION: 95
You have been just hired as the Internal Lead Auditor of a large organisation, responsible for internal audits.
Your first job is to analyse the answers to nonconformities included in the report of a recent internal audit to Top Management.
The report contained one nonconformity as follows:
There is no evidence of Top Management ensuring the availability of resources to operate the QMS, the establishment of objectives, the promotion of continual improvement, and the promoting of the process approach.
Which four of the following Top Management actions can be considered 'corrections to the nonconformity'?
A. All these actions will be reviewed during the Top Management meetings
B. Top Management completed a course on ISO 9001
C. Process approach has been communicated to the personnel
D. Top Management review will be carried out every six months instead of annually
E. Top Management appoints a senior manager to oversee the quality manangement system
F. Improvement action has been promoted

G. Objectives have been established
H. Resources have been provided
Answer: (SHOW ANSWER)

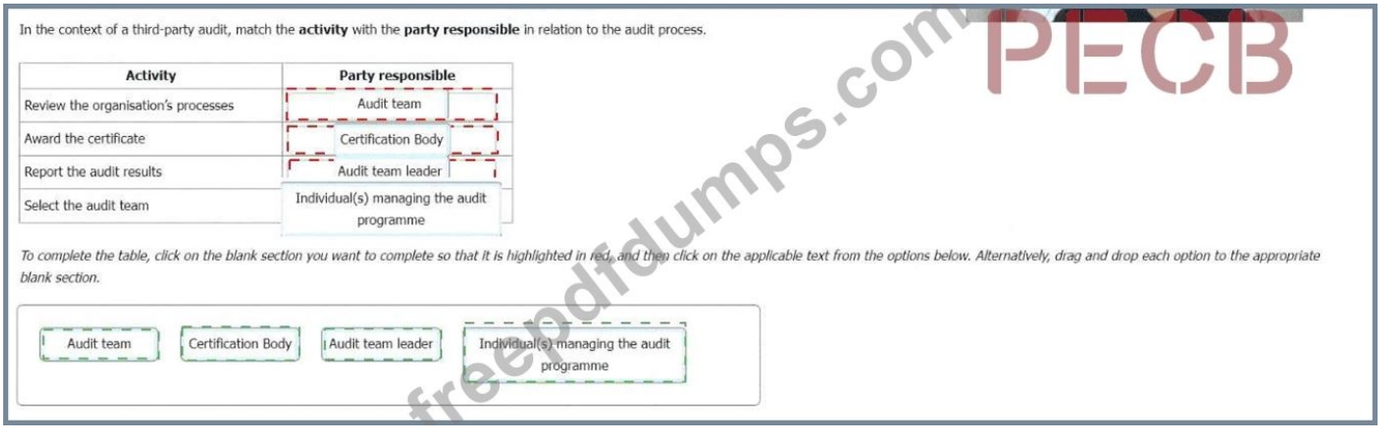
NEW QUESTION: 96
Select the two statements that are true.
A. The audit team leader shall only communicate any concerns to the auditee during the closing meeting.
B. Inform the general manager if the auditor finds uncontrolled documents.
C. Where the available audit evidence indicates that the audit objectives are unattainable, the individual(s) managing the audit programme shall be immediately informed.
D. Changes to the audit scope, which become apparent during the audit, shall be approved with the auditee.
E. During the audit, the audit team leader shall periodically assess audit progress.
F. An immediate and significant risk to the audit shall be informed to the auditee and if possible to the certification body.
Answer: (SHOW ANSWER)
* Analyzing Each Statement:
* A.Incorrect. The audit team leader must communicate concerns as they arise, not just during the closing meeting. Per ISO 19011:2018 Clause 6.4.9, significant concerns should be shared promptly with the auditee and audit client during the audit process to allow for immediate understanding and potential resolution.
* B.Incorrect. The auditor or team leader is not specifically required to inform the general manager about uncontrolled documents. Instead, the issue is communicated within the framework of the audit findings to the audit client or auditee, as appropriate.
Reference: ISO 19011:2018, Clause 6.6.2.
D:Incorrect. Changes to the audit scope require the approval of the audit client (e.g., the certification body), not just the auditee. The scope is agreed upon in advance, and significant changes must be communicated with all stakeholders.
E:Correct. The audit team leader is responsible for periodically assessing the audit progress to ensure it aligns with the audit objectives and planned scope.Reference: ISO 19011:2018, Clause 6.4.5.
F:Incorrect. While immediate and significant risks should be communicated to the auditee, notifying the certification body is not an immediate responsibility of the audit team leader. The communication process depends on the procedures defined by the audit programme manager.
Why Options C and E Are Correct:
C: Communicating unattainable audit objectives ensures the audit remains effective and prevents unnecessary effort or misalignment with goals.
E: Periodic assessments by the team leader help in maintaining alignment with the scope, objectives, and time constraints, ensuring the audit's success.
Relevant References from ISO Standards:

ISO 19011:2018, Clause 6.6.2: Describes procedures for when audit objectives are unattainable.
ISO 19011:2018, Clause 6.4.5: Emphasizes the audit team leader's responsibility for ongoing assessment of audit progress.

NEW QUESTION: 97
In the context of a third-party audit, match the activity with the party responsible in relation to the audit process.



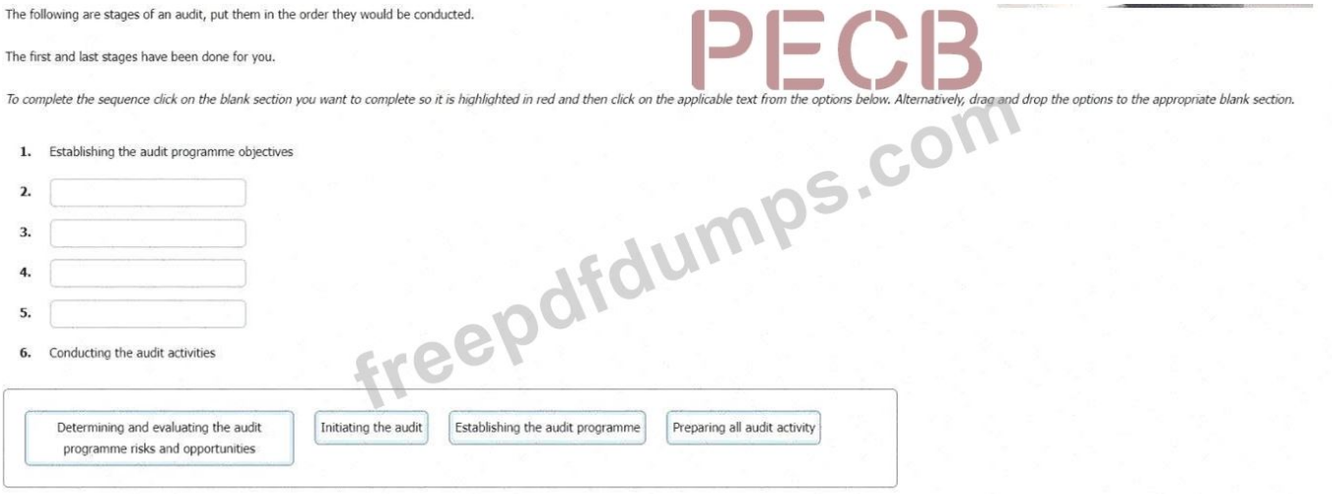
Answer:



Explanation:
In the context of a third-party audit, the activities and the parties responsible can be matched as follows:
Review the organization's processes: This is typically the responsibility of the audit team. They examine the processes to ensure they comply with the specified standards1.
Review the audit results: The audit team leader usually reviews the audit findings to ensure accuracy and completeness before they are finalized1.
Issue the certificate: The certification body is responsible for issuing the certificate if the audit is successful and the organization meets the required standards1.
Select the audit team: The individual(s) managing the audit programme are responsible for selecting the audit team. This ensures that the team has the appropriate skills and knowledge for the audit1.
These roles are essential to maintain the integrity and effectiveness of the audit process. The audit team conducts the actual audit, the team leader oversees the audit process, the certification

body grants the certification, and the management of the audit program ensures that the right team is in place to conduct the audit1.
Based on the description of the image you've provided, here's how the activities match with the responsible parties in the context of a third-party audit:
Review the organization's processes: This activity is typically the responsibility of the Audit Team. They are tasked with examining the processes to ensure they meet the requirements of the standard being audited.
Review the audit results: The Audit Team Leader is usually responsible for this activity. They oversee the audit process and are in charge of reviewing the findings and ensuring that the audit objectives are met.
Issue the certificate: The Certification Body is responsible for issuing the certificate if the organization's management system is found to be in compliance with the standard.
Select the audit team: The Individual(s) managing the audit programme are responsible for selecting the audit team. They ensure that the team has the appropriate competence and resources to effectively conduct the audit.
These roles are defined within the framework of ISO 9001:2015 and are essential for the proper conduct of a third-party audit. The audit team and its leader play a critical role in the operational aspects of the audit, while the certification body and those managing the audit programme have overarching responsibilities for the audit' s governance and integrity.

NEW QUESTION: 98
The following are stages of an audit, put them in the order they would be conducted.



Answer:

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: 99
State the correct sequence of events in the certification process for an organisation to obtain third-party accredited certification to ISO 9001.

Answer:

State the correct sequence of events in the certification process for an organisation to obtain third-party accredited certification to ISO 9001.

	Event
1	Programme initial certification audit
2	Conduct certification audit stages
3	Award ISO 9001 certificate
4	Accredit Certification Body

To complete the sequence, 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 the options to the appropriate blank section.

Reference: ISO 9001:2015 Clause 9.2 emphasizes the planning of audits and their scheduling to achieve desired results.

Step 2: Conduct Certification Audit StagesThe certification process includes a two-stage audit.

Stage 1 Audit: Review of documentation to verify readiness and understanding of the Quality Management System (QMS).

Stage 2 Audit: A detailed evaluation of the implementation and effectiveness of the QMS against ISO 9001 requirements.Reference: Clause 8.1 of ISO 9001:2015 discusses operational planning and control, which includes the preparation for audit activities.

Step 3: Award ISO 9001 CertificateAfter successfully completing the certification audits and resolving any identified non-conformities, the certification body awards the ISO 9001 certificate. This certificate demonstrates that the organization's QMS meets the ISO 9001 standard.Reference: Clause 10 of ISO 9001:

2015 focuses on continual improvement and conformity, which leads to the certification issuance.

Step 4: Accredit Certification BodyCertification bodies must be accredited to ensure they meet international standards for certification. Accreditation is conducted by bodies like UKAS (United Kingdom Accreditation Service) or ANAB (ANSI National Accreditation Board), ensuring the credibility and global acceptance of the certification process.Reference: Clause 7.1.5 of ISO 9001 covers resource monitoring, which supports the integrity of the certification process.

By following these steps, organizations can ensure an effective and compliant certification process, achieving ISO 9001 certification.

NEW QUESTION: 100

Who assigns a guide to assist the audit team?

A. The certification body

B. The auditee

C. The audit team leader

Answer: (SHOW ANSWER)

Comprehensive and Detailed In-Depth Explanation:

According to ISO 19011:2018, Clause 6.4.3 (Roles and Responsibilities of Guides and Observers):

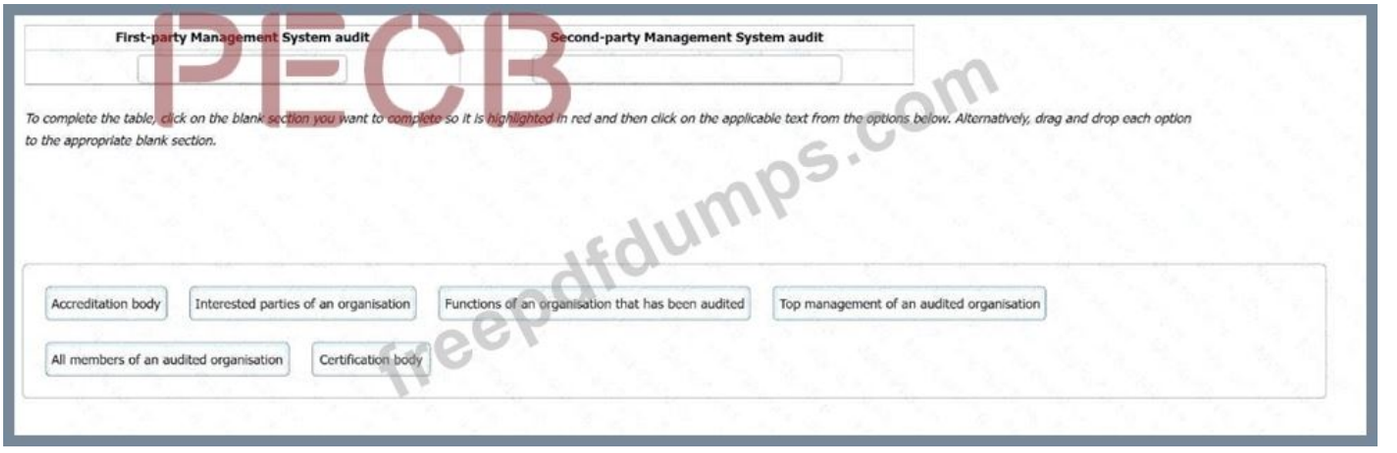
* The auditee assigns a guide to assist the audit team.
* The guide provides logistical support, helps with navigation, and arranges access to necessary personnel and records.
* The audit team leader does not assign the guide, but they may request one.

Reference:

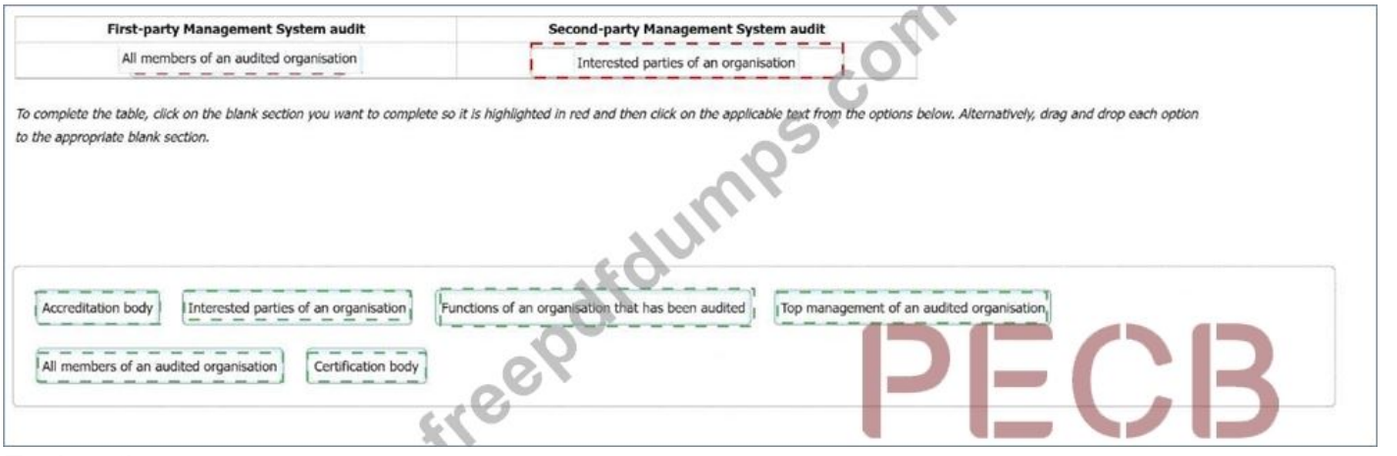
ISO 19011:2018, Clause 6.4.3 (Roles and Responsibilities of Guides and Observers)

NEW QUESTION: 101

Match the following potential audit client options to the type of audit.



Answer:



Explanation:

First-party Management System audit # All members of an audited organisation Second-party Management System audit # Interested parties of an organisation According to ISO 19011:2018 (Guidelines for Auditing Management Systems) and as reinforced in ISO 9001 Lead Auditor training materials, audit types are defined as:

* First-party audit - conducted by the organization itself, or on its behalf (internal audit).# The audit client is all members of the audited organisation, because the audit is internal, involving all functional areas under the organization's control.
* Second-party audit - conducted by a customer or other person on behalf of a customer (external but not by a certification body).# The audit client includes interested parties of an organisation,

such as customers who want to verify if their suppliers meet contractual or regulatory requirements.
These definitions are directly aligned with ISO 19011:2018, Clause 3.13 - Types of audits.
Why Other Options Are Incorrect:
* Certification body / Accreditation body # These relate to third-party audits, not first or second.
* Top management / Functions of an audited organisation # Refer to auditees or audit participants, not the audit client itself.
References:
ISO 19011:2018 Clause 3.13 - Types of audits
ISO 9001:2015 Clause 9.2 - Internal audit
ISO Definitions for First-party, Second-party, and Third-party audits

NEW QUESTION: 102
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.

<table>
<tr><td colspan="3">Quality Improvement Request</td><td>QI/12/20/HR-3</td></tr>
<tr><td colspan="2">To: HR Manager</td><td colspan="2">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</td></tr>
<tr><td>Update by: 01/20XX</td><td>Update by: 02/20XX</td><td>Update by: 03/20XX</td><td>Signed:
(QM)</td></tr>
<tr><td colspan="3">Notes:
Use of external resources for this action must be approved by senior management.</td><td>Action Completed:
(Signature)

Date:</td></tr>
</table>

After further auditing, the issues below were found. Select three statements that apply to the term 'audit trail'

A. Decisions on improvement action timescales not involving departmental managers.
B. Evaluation of the results of the improvement action not always documented by the Quality Manager.
C. Limited knowledge of the content of Quality Improvement Requests by departmental staff.
D. Quality improvements not aligning with the quality policy.
E. The single quality objective set for the organisation 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: A,B,C (LEAVE A REPLY)
Based on the scenario and the concept of an 'audit trail' within the context of ISO 9001, the three statements that apply would likely be:
A). Decisions on improvement action timescales not involving departmental managers. This indicates a lack of involvement and communication with those responsible for implementing the improvements, which is a key part of an effective audit trail1.
B). Evaluation of the results of the improvement action not always documented by the Quality Manager.
Proper documentation is essential for an audit trail, as it provides evidence that actions have been evaluated and are effective1.
C). Limited knowledge of the content of Quality Improvement Requests by departmental staff. An audit trail should ensure that all relevant parties are aware of and understand the actions being taken, which is not the case here1.
These points suggest issues with the communication, documentation, and involvement of relevant personnel in the quality management system processes, which are crucial for maintaining an effective audit trail and, by extension, a robust quality management system.

NEW QUESTION: 103
You are conducting an ISO 9001 audit of a Materials Recycling Facility (MRF). The organisation processes waste plastics into raw materials for plastic bottle manufacturers. You reach the manual picking line where operators are removing contaminant materials from incoming products, such as plastic bags, plastic film and badly contaminated items that would compromise the recycling process. You interview the line supervisor.
You: "Why are these plastic items being rejected at this stage?"
Auditee: "They do not meet our processing standards."
You: "What is the reason for that?"
Auditee: "These items are likely to damage the machinery down the line. They can also compromise our quality standards. We need to protect our reputation for good quality output materials." You: "What happens to the rejected items?" Auditee: "Some get melted down in another process later on and some are disposed of as waste products that cannot be recycled."
You: "What happens to the waste products?" Auditee: "I'm not sure. I suppose they go to landfill."
Which two. of the following actions would you take to investigate further?
A. Check the process for handling nonconforming items.

B. Ask to review the percentage of waste materials.
C. Find out if operators have regular hearing tests.
D. Determine what happens to the waste products.
E. Ask about operator PPE (Personal Protective Equipment).
F. Determine whether there are quality objectives for reducing rejected material.
Answer: (SHOW ANSWER)
According to the ISO 9001:2015 standard, clause 8.7 requires that an organization identify and control any nonconforming outputs that do not conform to the requirements of the customer or other relevant requirements. Nonconforming outputs are any outputs from the process, product or service that do not meet the specified quality criteria. Nonconforming outputs must be dealt with in one or more of the following ways:
Correction of the nonconformity
Segregation, containment, return or suspension of provision of products and services Informing the customer Authorisation for acceptance under concession The organization must also retain documented information on the description of the nonconformity, the actions taken, any concessions obtained, and the identification of the authority deciding the action to resolve the nonconformity.
In this scenario, you have interviewed a line supervisor who is responsible for managing a manual picking line where operators are removing contaminant materials from incoming products. The supervisor has explained that these plastic items are rejected at this stage because they do not meet their processing standards and they can damage their machinery and compromise their quality standards. The supervisor has also mentioned that some of these rejected items are melted down in another process later on and some are disposed of as waste products that cannot be recycled.
Based on this information, you can investigate further by taking two actions:
A: Check the process for handling nonconforming items: You can verify whether there is a documented procedure for identifying, segregating, containing, returning or suspending provision of nonconforming items at this stage. You can also check whether there is a system for informing customers about any nonconforming items that may affect their satisfaction or expectations.
D: Determine what happens to the waste products: You can verify whether there is a documented procedure for disposing of waste products that cannot be recycled as per environmental regulations and customer requirements.
These two actions would help you to determine whether there are any nonconforming outputs at this stage and how they are controlled by the organization.

NEW QUESTION: 104
ABC is a fast food shop that receives orders by phone or the internet. The normal menu includes 15 different types of hamburgers; however, in the last two days, due to a shortage of a special type of meat, they can only prepare six of the 15 varieties.
You are performing a third-party audit of ABC; you observed that the menu offering food on the website is still the normal one, with 15 different hamburgers. During a 30-minute period, you

observed several customers reluctantly accepting other than the hamburger they preferred. You decided to raise the following nonconformity as follows:
"There is evidence that ABC has not reviewed the ability to provide customers the offered products".
The restaurant manager does not accept the nonconformity. She says that ABC had an extensive training programme for all personnel, which you have already seen when auditing Human Resources. This shortage of some hamburgers cannot be considered a management system failure.
Which one would be your answer from the following options?
A. I will maintain it open, and I will see what the Certification Body thinks about it.
B. I will raise it as a major nonconformity and, therefore, cannot recommend certification of the quality management system.
C. I will raise it as a minor nonconformity; you have the option to appeal to our Certification Body.
D. You are right, it is not a system failure. I will change the nonconformity to a recommendation, but it will be audited carefully next time.
Answer: C (LEAVE A REPLY)
The appropriate response in this situation would be:
C: I will raise it as a minor nonconformity; you have the option to appeal to our Certification Body.
This response acknowledges the restaurant manager's point that the shortage of some hamburgers may not constitute a management system failure. However, the fact remains that the menu was not updated to reflect the current availability of products, which led to customer dissatisfaction. This is a deviation from the ISO
9001 standard, which requires that the organization ensures the availability of resources needed to provide products and services as promised1. Raising it as a minor nonconformity allows the organization to address the issue within a specified timeframe and provides an opportunity for appeal if the organization disagrees with the auditor's decision2.

NEW QUESTION: 105
Which of the following is a principle of maintaining audit work documents?
A. Transparency
B. Fair presentation
C. Completeness
Answer: C (LEAVE A REPLY)
Comprehensive and Detailed In-Depth Explanation:
Completeness ensures that all necessary audit evidence, observations, and findings are properly documented, which is critical for traceability and accountability in an audit.
While transparency and fair presentation are principles of auditing, completeness is specifically related to maintaining audit work documents, as required in ISO 19011:2018, Clause 6.5.4 (Preparing Audit Work Documents).
Reference:
ISO 19011:2018, Clause 6.5.4 (Preparing Audit Work Documents)

NEW QUESTION: 106
A Health Trust has contracted with Servitup, a catering services organisation that has been certified to ISO
9001 for one year. It provides services to
10 small rural hospitals in remote locations involving the purchase and storage of dry goods and fresh produce, preparing meals, and loading heated trolleys for Ward Service by hospital staff.
You, as auditor, are conducting the first surveillance audit at one site with the Deputy Catering Manager (DCM).
DCM: "I apologise for the absence of the Catering Manager. He has called in sick today and we are really short of staff." You: "I see. It really shouldn't affect the QMS so the audit can progress as normal." DCM: "The Catering Manager set up the system. I'm afraid I'm not as familiar with it as he is." You: "OK, let's start with the Quality Policy. What are the main issues for the QMS here?" DCM: "Give me a minute. I need to look at the Quality Policy on the noticeboard in his office." As the audit progresses, it is clear that the DCM has a very low knowledge of the QMS. He continually has to look up the answers to your questions or ask staff members about their processes. You decide to raise a nonconformity.
Select one of the following options that best describes the nonconformity.
A. The Deputy Catering Manager is not competent to manage the QMS.
B. The Quality Policy only exists as a document in the Catering Manager's office.
C. The effectiveness of the QMS depends on the Catering Manager being present on site.
D. As a member of the management team, the Deputy Catering Manager is not sufficiently aware of the QMS.
Answer: (SHOW ANSWER)

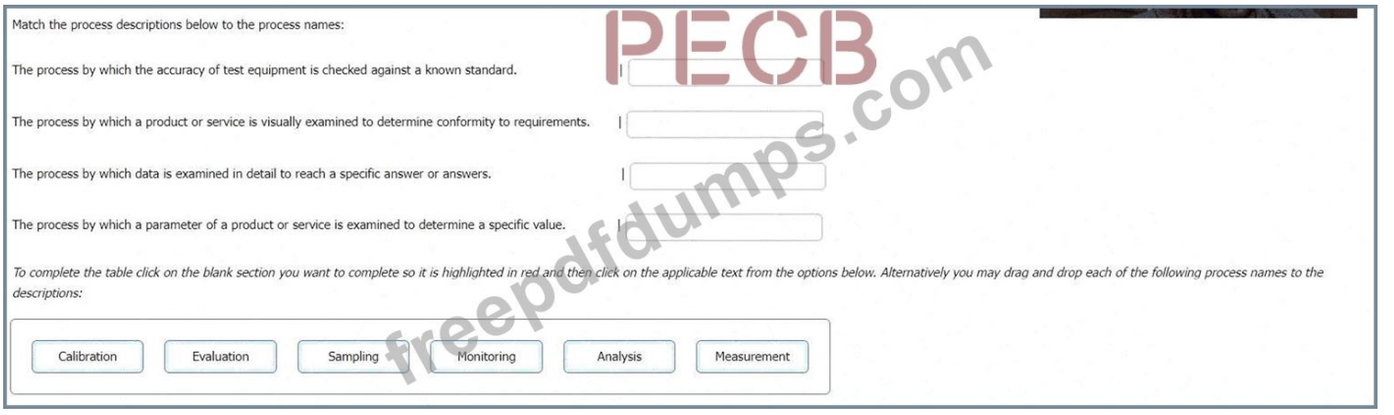
NEW QUESTION: 107
You are carrying out an audit at an organisation seeking certification to ISO 9001 for the first time. The organisation offers regulatory consultancy services to manufacturers of cosmetics. The business operates from ten regional offices.
You are nearing the end of the audit and need to decide if sufficient evidence of top management leadership and commitment with respect to the quality management system has been gathered.

Which four of the following would demonstrate top management leadership and commitment with respect to the quality management system?
A. Approving company car budgets for the fiscal year
B. Briefing staff on the development of an improvement culture
C. Chairing management review meetings
D. Conducting staff disciplinary meetings
E. Investing time and money in corrective actions arising from nonconformities
F. Not attending audit closing meeting
G. Promoting the importance of following procedures
Answer: B,C,E,G (LEAVE A REPLY)
To demonstrate top management's leadership and commitment with respect to the quality management system, the following four actions would be indicative:
B: Briefing staff on the development of an improvement culture: This shows that top management is actively involved in promoting a culture of continuous improvement, which is a key aspect of the quality management system1.
C: Chairing management review meetings: By leading these meetings, top management demonstrates their involvement in the quality management system's ongoing performance and commitment to its continual improvement1.
E: Investing time and money in corrective actions arising from nonconformities: This indicates that top management is committed to addressing issues and ensuring that the quality management system is effective and continually improving1.
G: Promoting the importance of following procedures: When top management emphasizes the importance of adherence to procedures, it reinforces the significance of the quality management system and its processes1.
These actions align with the requirements of ISO 9001:2015, which emphasizes the need for top management to take accountability for the effectiveness of the quality management system and to promote a focus on continual improvement and customer satisfaction123. Approving company car budgets, conducting disciplinary meetings, and not attending the audit closing meeting do not directly demonstrate leadership and commitment to the quality management system1.

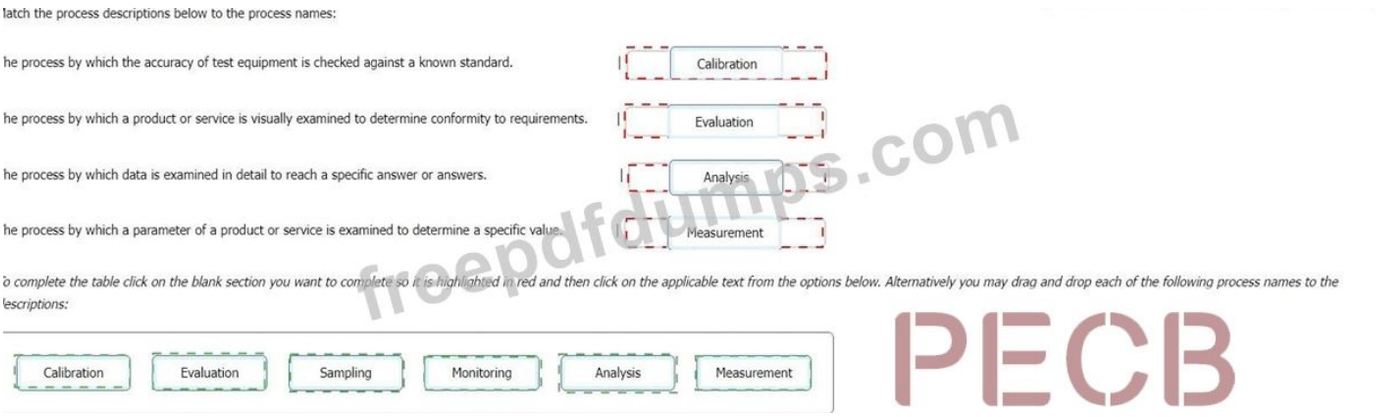
NEW QUESTION: 108
Which one of the following documents addresses audit time calculation for third-party certification audits?
A. ISO 17021-1
B. ISO 19011
C. ISO 9000
D. ISO 9001
Answer: A (LEAVE A REPLY)
ISO/IEC 17021-1 is the standard that specifies requirements for bodies providing audit and certification of management systems. It includes provisions for determining audit time for third-

party certification audits, ensuring that the audits are conducted in a consistent, comparable, and reliable manner, which can be applied to a variety of management systems, including ISO 9001.
References: ISO/IEC 17021-1; IAF Mandatory Document for the Determination of Audit Time of Quality and Environmental Management Systems Certification

NEW QUESTION: 109
Match the process descriptions below to the process names:



Answer:



Explanation:
Match the process descriptions below to the process names:
The process by which the accuracy of test equipment is checked against a known standard. = Calibration The process by which a product or service is visually examined to determine conformity to requirements. = Evaluation The process by which data is examined in detail to reach a specific answer or answers. = Analysis The process by which a parameter of a product or service is examined to determine a specific value. = Measurement According to the ISO 9000:2015 - Quality management systems - Fundamentals and vocabulary, the definitions of the process names are as follows:
Calibration: operation that, under specified conditions, in a first step, establishes a relation between the quantity values with measurement uncertainties provided by measurement standards and corresponding indications with associated measurement uncertainties and, in a second step, uses this information to establish a relation for obtaining a measurement result from an indication.
Evaluation: determination of the suitability, adequacy or effectiveness of an object to achieve established objectives.

Analysis: detailed examination of the elements or structure of something.
Measurement: process to experimentally obtain one or more quantity values that can reasonably be attributed to a quantity.
Therefore, the process descriptions can be matched to the process names based on these definitions.
References:
ISO 9000:2015 - Quality management systems - Fundamentals and vocabulary

NEW QUESTION: 110
Scenario 5: Mechanical-Electro (ME) Audit Stages
Mechanical-Electro, better known as ME, is an American company that provides mechanical and electrical services in China. Their services range from air-conditioning systems, ventilation systems, plumbing, to installation of electrical equipment in automobile plants, electronic manufacturing facilities, and food processing plants.
Due to the fierce competition from local Chinese companies and failing to meet customer requirements, ME's revenue dropped significantly. In addition, customers' trust and confidence in the company decreased, and the reputation of the company was damaged.
In light of these developments, the top management of ME decided to implement a quality management system (QMS) based on ISO 9001. After having an effective QMS in place for over a year, they applied for a certification audit.
A team of four auditors was appointed for the audit, including Li Na as the audit team leader. Initially, the audit team conducted a general review of ME's documents, including the quality policy, operational procedures, inventory lists, QMS scope, process documentation, training records, and previous audit reports.
Li Na stated that this would allow the team to maintain a systematic and structured approach to gathering documents for all audit stages. While reviewing the documented information, the team observed some minor issues but did not identify any major nonconformities. Therefore, Li Na claimed that it was not necessary to prepare a report or conduct a meeting with ME's representatives at that stage of the audit. She stated that all areas of concern would be discussed in the next phase of the audit.
Following the on-site activities and the opening meeting with ME's top management, the audit team structured an audit test plan to verify whether ME's QMS conformed to Clause 8.2.1 (Customer Communication) of ISO
9001.
To do so, they gathered information through group interviews and sampling. Li Na conducted interviews with departmental managers in the first group and then with top management. In addition, she chose a sampling method that sufficiently represented customer complaints from both areas of ME's operations.
The team members were responsible for the sampling procedure. They selected a sample size of 4 out of 45 customer complaints received weekly for electrical services and 2 out of 10 complaints for mechanical services.

Afterward, the audit team evaluated the evidence against the audit criteria and generated the audit findings.
Which stages of the audit were performed?
A. Audit follow-up and stage 1 audit.
B. Stage 1 and stage 2 audit.
C. Stage 2 audit and surveillance audit.
Answer: (SHOW ANSWER)
Comprehensive and Detailed In-Depth Explanation:
Understanding Audit Stages Based on ISO/IEC 17021-1:2015
ISO certification audits consist of two main stages:
Stage 1 Audit (Readiness Review)
The organization's documented information is reviewed to assess readiness for Stage 2.
This ensures that the QMS is developed, implemented, and prepared for full assessment.
Stage 2 Audit (On-Site Evaluation)
Auditors assess process implementation and effectiveness through interviews, observations, and evidence collection.
The audit team verifies if the organization meets ISO 9001 requirements in practice.
Why is the Correct Answer B?
The audit team reviewed ME's documents, which is a Stage 1 activity.
The audit team performed interviews, sampling, and on-site verification, which is a Stage 2 activity.
There was no mention of an audit follow-up or a surveillance audit, which occur post-certification.
Why are the Other Options Incorrect?
A (Audit follow-up and Stage 1 Audit) # Follow-up audits occur after certification, which was not the case here.
C (Stage 2 Audit and Surveillance Audit) # Surveillance audits are post-certification audits and were not conducted yet.
Reference:
ISO/IEC 17021-1:2015, Clause 9.3.1 - Initial Certification Audit (Stage 1 & 2)

NEW QUESTION: 111
In the context of a third-party certification audit, it is very important to have effective communication. Which is not the responsibility of the audit team leader?
A. If audit objectives are unattainable, reporting the reasons to the accreditation body.
B. Planning formal communication arrangements, so an auditee can communicate with the auditor any time during the audit.
C. Confirming formal communication channels between the audit team and the auditee during the opening meeting.
D. Communicating the progress, any significant findings and any concerns to the auditee and audit client, as appropriate.
Answer: A (LEAVE A REPLY)

Responsibilities of the Audit Team Leader:
ISO 19011:2018 (guidelines for auditing management systems), which supports the principles in ISO 9001:
2015, specifies the responsibilities of an audit team leader. These responsibilities include:
Planning the audit and establishing effective communication between the audit team and auditee.
Ensuring that formal communication channels are agreed upon and followed.
Reporting the audit progress, significant findings, and any concerns to the auditee or audit client as necessary.
Managing the audit team and ensuring adherence to the defined objectives and scope.
Analysis of Options:
A). Reporting unattainable audit objectives to the accreditation body:Incorrect. This is not the responsibility of the audit team leader. The accreditation body oversees the certification body and is not directly involved in specific audits. If objectives are unattainable, the audit team leader would report them to the audit client (the certification body), not the accreditation body.
B). Planning formal communication arrangements:Correct. This is one of the responsibilities of the audit team leader. They ensure auditees can communicate with auditors as needed during the audit process.
C). Confirming communication channels during the opening meeting:Correct. During the opening meeting, the audit team leader must establish clear communication protocols to ensure effective information exchange between the audit team and auditee.
D). Communicating progress, findings, and concerns:Correct. Keeping the auditee and audit client informed about progress and significant findings is a critical responsibility of the audit team leader to maintain transparency and ensure the audit objectives are met.
Why Option A is Correct:
The audit team leader does not have any obligation to report unattainable objectives to the accreditation body.
Instead, they are responsible for communicating issues to the audit client (typically the certification body).
The accreditation body operates at a higher level and is concerned with overseeing certification bodies, not individual audits.
Relevant References:
ISO 19011:2018, Clause 6.4 (Conducting the Audit): Emphasizes the responsibilities of the audit team leader, including communication with the auditee and client.
ISO 9001:2015, Clause 9.2 (Internal Audit): Highlights the importance of planning and communication during audits, which is reflected in third-party audits as well.

NEW QUESTION: 112
What competence, among others, should each audit team member have?
A. Knowledge of the industry in which the auditee operates.
B. Knowledge of the risk-based approach to auditing.
C. Expertise in each domain to be audited.

D. A formal degree in quality management.

Answer: B (LEAVE A REPLY)

Comprehensive and Detailed In-Depth Explanation:

Auditors must have competence in risk-based auditing to effectively assess an organization's QMS performance and compliance.

Clause References:

ISO 19011:2018, Clause 7.2.3 - Determining Auditor Competence:

Auditors must have knowledge of risk-based thinking to assess risk impact on processes.

ISO 9001:2015, Clause 0.3.3 - Risk-Based Thinking:

The standard emphasizes proactive risk management, which auditors must understand.

Why is the Correct Answer B?

Risk-based auditing ensures audits focus on high-risk areas, improving audit effectiveness.

Auditors must assess how organizations apply risk-based thinking in decision-making, process control, and improvement.

Why are the Other Options Incorrect?

A (Industry knowledge) # While helpful, it is not mandatory for all auditors.

C (Expertise in all domains) # Auditors are not required to be experts in all areas, just in audit methodology.

D (Formal degree in quality management) # ISO does not require a formal degree, just competence in audit principles and methods.

Reference:

ISO 19011:2018, Clause 7.2.3 - Determining Auditor Competence

ISO 9001:2015, Clause 0.3.3 - Risk-Based Thinking

NEW QUESTION: 113

'XYZ' has already sent to you a list with all documented procedures and work instructions related to the services provided to 'ABC' (a quality manual is not included in the list).

To complete the audit planning which additional information would you ask to XYZ to submit? Select four.

A. XYZ's organisational structure

B. The quality manual

C. A description of responsibilities and authorities of the key roles of XYZ

D. The number of personnel involved in activities related to the quality management system

E. Information to understand XYZ's operations

F. The results of XYZ's last internal audit

G. The results of the last two management reviews

H. The list of risks and opportunities determined by XYZ

Answer: A,C,D,E (LEAVE A REPLY)

The ISO 9001 Lead Auditor exam requires the auditor to have a thorough understanding of the ISO 9001:

2015 standard and its requirements, as well as the organization's context, processes, risks, opportunities, and performance. Therefore, the auditor needs to ask for additional information that can help them verify these aspects during the audit planning stage. Some of the information that can be useful are:
A description of responsibilities and authorities of the key roles of XYZ: This can help the auditor to identify who is accountable for what in the organization and how they communicate with each other.
The number of personnel involved in activities related to the quality management system: This can help the auditor to assess if there are enough resources and competencies to support the QMS implementation and operation.
Information to understand XYZ's operations: This can help the auditor to understand how XYZ produces or delivers its products or services and what are its main processes and inputs.
The results of XYZ's last internal audit: This can help the auditor to evaluate if XYZ has implemented corrective actions based on previous audit findings and if it has maintained its QMS effectiveness.
The results of the last two management reviews: This can help the auditor to determine if XYZ has monitored its QMS performance against its objectives and if it has identified any significant changes or opportunities for improvement.
The quality manual (B) is not a required document for ISO 9001 certification, but it may be useful for internal reference or training purposes. It is not necessary for audit planning.