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ISO 9001 Lead Auditor Sample Exam Questions and Answers:

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

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

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

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

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

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

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

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

Topic	Details
Topic 1	• Closing an ISO 9001 audit: The topic focuses on concluding a QMS audit and conducting audit follow-up activities.
Topic 2	• Quality management system (QMS) requirements: It assesses your abilities to point out and explain different requirements for a quality management system based on ISO 9001.
Topic 3	• Fundamental audit concepts and principles: Questions about interpreting and applying the main concepts and principles related to a QMS audit appear in this topic.

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PECB QMS ISO 9001:2015 Lead Auditor Exam Sample Questions (Q95-Q100):

NEW QUESTION # 95
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 and the name of the retailer supplied appears on the product packaging. Sales turnover has increased significantly over the past five years. The organisation uses a software programme called SWIFT, which is used to record sales, plan production, purchase supplies, print despatch notes, track new product development, perform traceability exercises, carry out mass balance checks, raise invoices, create budgets, and support financial control.
You are nearing the end of the audit and you are reviewing your audit notes. You notice a recurring trend concerning the SWIFT database as shown below:

Your audit notes	Status
Production Planner: SWIFT database version 202	Requires audit trail
Manufacturing Manager: SWIFT database version 169	Requires audit trail
Manufacturing Supervisor: SWIFT database version 169	Requires audit trail
Product Development Manager: SWIFT database version 169	Requires audit trail
Logistics Supervisor: SWIFT database version 182	Requires audit trail
Quality Manager: SWIFT database version 205	Requires audit trail

You ask the Quality Manager to explain how the SWIFT database is controlled. You learn that the Operations Director is responsible for determining and progressing SWIFT software updates. You decide to meet the Operations Director (OD).
You: "Good afternoon."
OD: "Good afternoon."
You: "What responsibility do you have concerning the SWIFT database?"
OD: "I maintain it. If anyone wishes to propose an update to the database, they send me an email with details of their proposal. I then either process the database update myself, or I send the request to the consultant who designed the database 20 years ago. The necessary software changes are made, and the amended software is immediately released to users." You: "Would you explain how the software amendments are controlled?" OD: "Of course. I personally update every computer myself." You: "Do you inform the database users of the changes?" OD: "No I don't. They find out for themselves by using the software, or they come to see me if they have any questions." You: "How do you ensure that the database users use the latest version?" OD: "That's easy, I update every computer myself." You: "During the audit, I noted there were several versions of SWIFT in use (you refer to your audit notes)." OD: "I know. That's because some versions work better than others, and depending on user needs and experiences, we allow users to revert to using an earlier version if they find it works better for them." Based on the scenario, which two of the following statements are true? There is evidence of nonconformity with a requirement defined in ...

- A. ... clause 7.5.2 Documented information - Creating and updating
- B. clause 7.5.1 Documented information - General
- C. ... clause 7.1.4 Environment for the operation of processes
- D. ... clause 7.5.3 Control of documented information
- E. clause 7.1.3 Infrastructure

Answer: B,D

Explanation:
Based on the scenario provided, there is evidence of nonconformity with the requirements defined in:

C). Clause 7.5.1 Documented information - General: The scenario indicates that there is no formal process for informing users about updates to the SWIFT database, which suggests a lack of control over documented information. This could lead to users being unaware of important changes and not using the latest version of the software, which is required by the quality management system1.

E). Clause 7.5.3 Control of documented information: The Operations Director's approach to updating the SWIFT database and the lack of communication to users about these updates indicate that the documented information is not adequately controlled. Allowing users to revert to earlier versions of the software at their discretion further suggests that the organization does not have a proper mechanism in place to ensure the integrity and suitability of documented information2.

These clauses are part of the ISO 9001:2015 standard, which requires organizations to have a systematic approach to controlling and managing documented information as part of their quality management system.

The scenario described shows a casual approach to managing critical software updates, which could affect the organization's ability to consistently meet customer and regulatory requirements.

NEW QUESTION # 96

How much time is usually spent on the Stage 1 audit?

- A. 20% of the total audit time
- B. 30% of the total audit time
- C. 40% of the total audit time

Answer: B

Explanation:
Comprehensive and Detailed In-Depth Explanation:
According to ISO 17021-1:2015 (Conformity Assessment - Requirements for Certification Bodies), Clause 9.3.1.2, the Stage 1 Audit typically consumes around 30% of the total audit time.
This time is allocated to:
Reviewing documented information.
Assessing the readiness for Stage 2.
Identifying potential nonconformities.
A 20% allocation (Answer A) is too low, and 40% (Answer C) is excessive, as the majority of the audit should be spent on Stage 2 (on-site verification).
Reference:
ISO 17021-1:2015, Clause 9.3.1.2 (Determination of Audit Time)

NEW QUESTION # 97

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

Answer: B

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

C (Changes to legal and regulatory requirements) # Addressed under Clause 4.2 (Interested Parties' Requirements).

D (Leadership responsibilities) # Covered under Clause 5.1 (Leadership and Commitment), not 8.5.6.

Reference:

ISO 9001:2015, Clause 6.3 - Planning of Changes

ISO 9001:2015, Clause 8.5.6 - Control of Changes

NEW QUESTION # 98

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

Answer:

Explanation:

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 # 99

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, 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.
- B. Yes, considering only the resources available for the audit is sufficient for determining the audit feasibility.
- C. Yes, because the audit team leader has final authority over audit feasibility.
- D. No, the audit feasibility should be determined by TD's top management.

Answer: A

Explanation:
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.

NEW QUESTION # 100

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