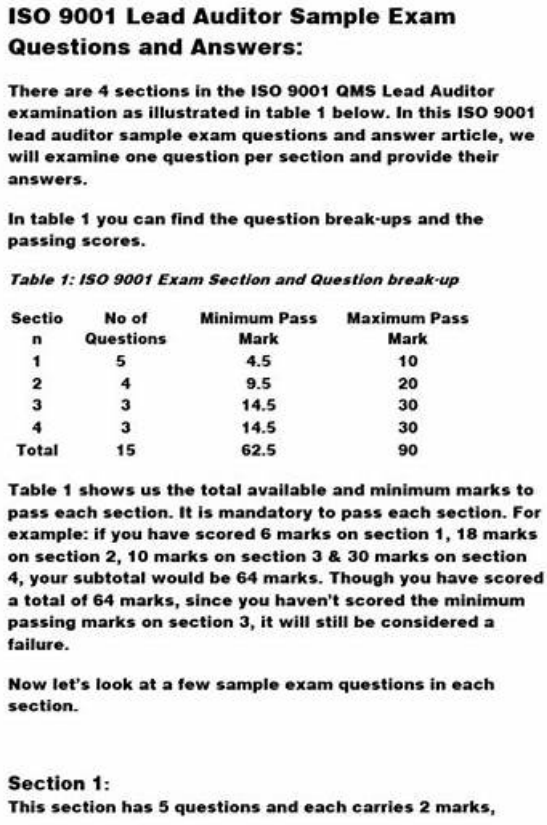
Certification ISO-9001-Lead-Auditor Sample Questions - ISO-9001-Lead-Auditor Quiz



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 QMS ISO 9001:2015 Lead Auditor Exam Sample Questions (Q172-Q177):

NEW QUESTION # 172
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. Determine what happens to the waste products.
- B. Find out if operators have regular hearing tests.
- C. Ask to review the percentage of waste materials.
- D. Ask about operator PPE (Personal Protective Equipment).
- E. Determine whether there are quality objectives for reducing rejected material.
- F. Check the process for handling nonconforming items.

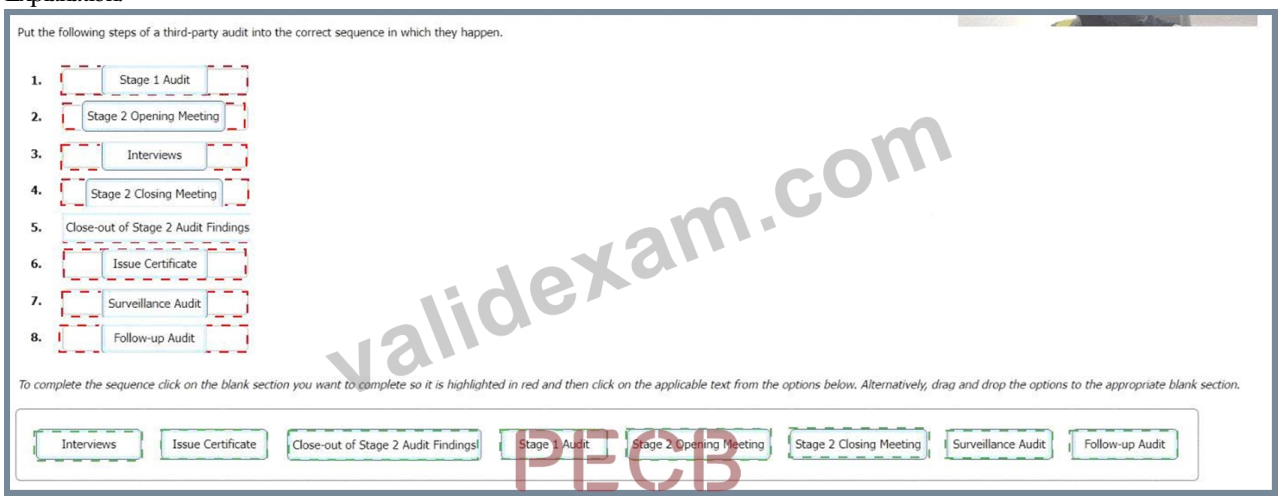
Answer: A,F

Explanation:
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 # 173
Put the following steps of a third-party audit into the correct sequence in which they happen.

Answer:

Explanation:



Explanation:

Sequence:

Stage 1 Audit

Stage 2 Opening Meeting

Interviews

Stage 2 Closing Meeting

Close-out of Stage 2 Audit Findings

Issue Certificate

Surveillance Audit

Follow-up Audit

To complete the sequence, you can drag and drop the options to the appropriate blank section.

Here is a brief explanation of each step:

Stage 1 Audit: This is the initial audit that aims to assess the readiness of the organization for the stage 2 audit. It involves reviewing the documentation of the quality management system, evaluating the scope and objectives of the audit, and identifying any major gaps or nonconformities34.

Stage 2 Opening Meeting: This is the meeting that marks the start of the stage 2 audit. It involves confirming the audit plan, the audit criteria, the audit scope, and the audit team. It also provides an opportunity for the auditee to ask any questions or raise any concerns34.

Interviews: This is the main activity of the stage 2 audit, where the audit team collects evidence by interviewing the personnel involved in the quality management system, observing the processes and activities, and examining the records and documents. The audit team uses various techniques, such as sampling, measurement, analysis, and evaluation, to verify the conformity and effectiveness of the quality management system345.

Stage 2 Closing Meeting: This is the meeting that marks the end of the stage 2 audit. It involves presenting the audit findings, the audit conclusions, and the audit report to the auditee. It also provides an opportunity for the auditee to provide feedback, ask questions, or dispute any findings34.

Close-out of Stage 2 Audit Findings: This is the process of verifying that the auditee has taken appropriate corrective actions to address any nonconformities or opportunities for improvement identified during the stage

2 audit. The audit team may request evidence or conduct a follow-up visit to confirm the effectiveness of the corrective actions34.
Issue Certificate: This is the process of issuing a certificate of conformity to the auditee, if the audit team is satisfied that the quality management system meets the requirements of the standard and that there are no major nonconformities or unresolved issues. The certificate is valid for a specified period, usually three years, and is subject to periodic surveillance audits34.
Surveillance Audit: This is the process of conducting periodic audits, usually once a year, to monitor the continued conformity and effectiveness of the quality management system. It involves reviewing the changes, improvements, and performance of the quality management system, and identifying any new nonconformities or opportunities for improvement34.
Follow-up Audit: This is the process of conducting an additional audit, usually in response to a significant change, a complaint, or a major nonconformity, to verify the impact and the corrective actions taken by the auditee. It may result in the suspension, withdrawal, or renewal of the certificate, depending on the outcome of the audit34.

NEW QUESTION # 174
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.
Scenario 4 mentions that Anne received a document that contained the audit scope, criteria, duration, and the limits to the audit engagement. What did Anne receive in this case?

- A. The audit plan.
- B. The audit mandate.
- C. The audit offer.
- D. The certification agreement.

Answer: C

Explanation:
Comprehensive and Detailed In-Depth Explanation:
Before conducting an audit, the certification body must provide an audit offer, which outlines the audit scope, criteria, and duration.
Clause References:
* ISO/IEC 17021-1:2015, Clause 9.1.2 - Audit Planning: Requires the certification body to communicate key audit details before finalizing the audit process.
Why is the Correct Answer C?
* The audit offer includes scope, criteria, duration, and engagement limits before the certification agreement is signed.
* The certification body sends this to the auditee before finalizing the contract.
Why are the Other Options Incorrect?
* A (Certification Agreement) # This is the contract signed after the audit offer is accepted.
* B (Audit Plan) # The audit plan details the day-to-day audit schedule and is created after the agreement.
* D (Audit Mandate) # This is an internal document for the certification body.
Reference:
ISO/IEC 17021-1:2015, Clause 9.1.2 - Audit Planning

NEW QUESTION # 175
Select the term which best describes the quality management system process of modifying a non-conforming product to bring it within acceptance criteria.

- A. Corrective action
- B. Preventive action
- C. Concession
- D. Correction

Answer: D

Explanation:
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 # 176
During an internal audit, it was discovered that the calibration of a spectrometer used daily for production had expired, causing a nonconformance under Clause 7.1.5.2 of ISO 9001:2015. The root cause was the organization not considering the risk of the calibration provider leaving the country.
Which corrective action is the best one?

- A. We will look for a local company to provide this service.
- B. We will have the results on one out of ten of our routine production samples double-checked by an external local laboratory.
- C. We will add this to our external issue register, assess its associated risk, and plan action to address that risk.
- D. We will select one sample, which we will send to an external laboratory and will use it as our internal standard.

Answer: C

Explanation:
Understanding Clause 7.1.5.2 - Measurement Traceability:ISO 9001:2015 requires organizations to ensure that measuring equipment (e.g., spectrometers) is calibrated and traceable to recognized standards. The failure to maintain calibration within valid dates directly violates this clause and raises concerns about the reliability of the measurement results.
Root Cause of the Nonconformity:The organization failed to plan for the possibility that the calibration service provider (X-TECH) might become unavailable, leading to expired calibration. This indicates inadequate risk-based thinking, which is required under Clause 6.1 of ISO 9001:2015.
Option Analysis:
A). Select one sample for external lab analysis to use as an internal standard:Incorrect. While using an internal standard could provide short-term verification of results, this action does not address the root cause (failure to consider risks associated with external providers).
B). Look for a local company to provide this service:Incorrect. While finding a new local service provider resolves the immediate calibration issue, it does not address the risk of future provider unavailability.
C). Double-check one out of ten samples externally:Incorrect. This corrective action ensures some quality assurance for batch release but does not resolve the nonconformance related to expired calibration.
D). Add this issue to the external issue register, assess its associated risk, and plan action to address that risk:
Correct. This approach directly addresses the root cause (failure to anticipate the calibration provider leaving) and ensures proper risk management. ISO 9001:2015 emphasizes risk-based thinking under Clause 6.1, requiring organizations to identify risks and opportunities and implement plans to mitigate them.
Why D is the Best Option:
By adding the issue to the external issue register, the organization ensures it is monitored and tracked.
Assessing the risk ensures proactive measures are in place for similar issues in the future.
Planning actions to address the risk ensures a sustainable solution is implemented, such as identifying multiple service providers or ensuring backup plans for calibration services.
ISO 9001 References:
Clause 6.1 (Actions to Address Risks and Opportunities): Requires organizations to consider risks and opportunities that could affect the intended results of the QMS.
Clause 7.1.5.2 (Measurement Traceability): Mandates that measuring equipment must be calibrated and traceable to ensure valid results.
Clause 10.2 (Nonconformity and Corrective Action): Requires organizations to determine the root cause of nonconformities and take actions to ensure they do not recur.

NEW QUESTION # 177
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