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PECB QMS ISO 9001:2015 Lead Auditor Exam Sample Questions (Q106-

Q111):

NEW QUESTION # 106
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 three statements that apply to the term 'audit trail'

- A. Decisions on improvement action timescales not involving departmental managers.
- B. Limited knowledge of the content of Quality Improvement Requests by departmental staff.
- C. The single quality objective set for the organisation by the Quality Manager.
- D. Top management claim not to be aware of the improvement request (QI/12/20/HR-3) initiated by the Quality Manager.
- E. Evaluation of the results of the improvement action not always documented by the Quality Manager.
- F. Quality improvements not aligning with the quality policy.

Answer: A,B,E

Explanation:
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 # 107
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. Try to obtain a consensus between you and the second auditor after a discussion of the different opinions.
- B. Immediately overule the objection of the second auditor with no discussion of the clause.
- C. Invite you and the second auditor to fully explain your point of view and then decide which clause to select.
- D. Review the evidence with you and the second auditor, and then decide which clause of ISO 9001 would best apply.
- E. Advise that he will think about the clause and announce his decision during the Closing meeting.
- F. The audit team leader will refer to the quality manager to determine which clause they agree with.
- G. Suggest that neither clause is accurate and instead propose clause 9.1.3 as the best one for the nonconformity.
- H. Immediately agree with the second auditor that clause 9.1.1 would be better.

Answer: A,C,D

Explanation:
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 # 108
You are conducting an audit at a single-site organisation seeking certification to ISO 9001 for the first time.
The organisation manufactures cosmetics for major retailers and the name of the retailer supplied appears on the product packaging.
Sales turnover has increased significantly over the past five years.
You are interviewing the new Product Development Manager. You note that a software application called SWIFT is used to help control the product development process.
You have gathered audit evidence as outlined in the table. Match the ISO 9001 clause 8.3 extracts to the audit evidence.

Answer:

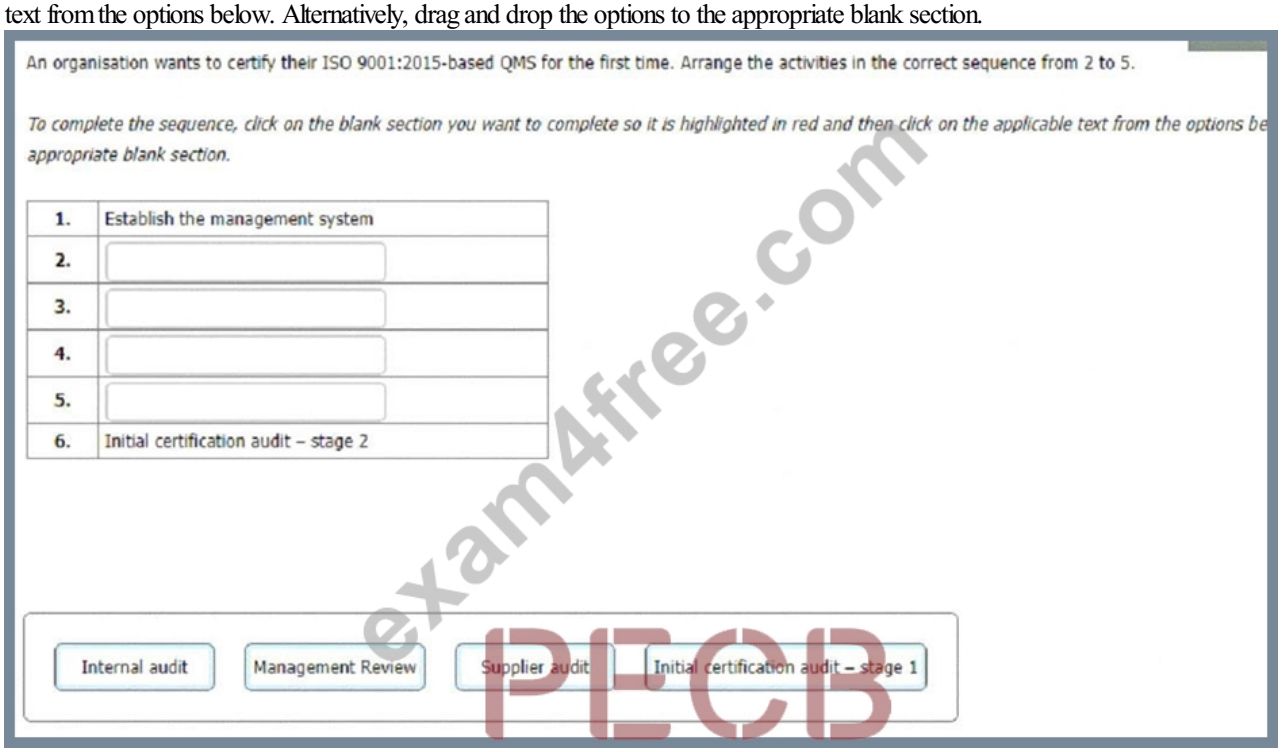
Explanation:
A screenshot of a computer AI-generated content may be incorrect.

Audit Evidence	Correct ISO 9001 Clause Extract
1. Half of all new products launched in the past 12 months were late. The Product Development Manager explains he lacks people to cope with demand.	8.3.2 e) ... internal ... resource needs for the design and development of products ...
2. Many changes are made to cosmetic formulations during product development due to retailer feedback. Final formulations are documented in SWIFT.	8.3.6 ... retain documented information ...
3. Customer confirms approval to proceed with a new formulation via email. These emails are stored in SWIFT.	8.3.5 ... retain documented information ...
4. Consumer trials are carried out before full-scale launch.	8.3.4 d) ... conducted to ensure that the resulting products and services meet the requirements ...
5. Shelf-life stability testing is done by an approved external lab during product development.	8.3.2 e) ... external ... resource needs for the design and development of products ...

Comprehensive and Detailed In-Depth Explanation:

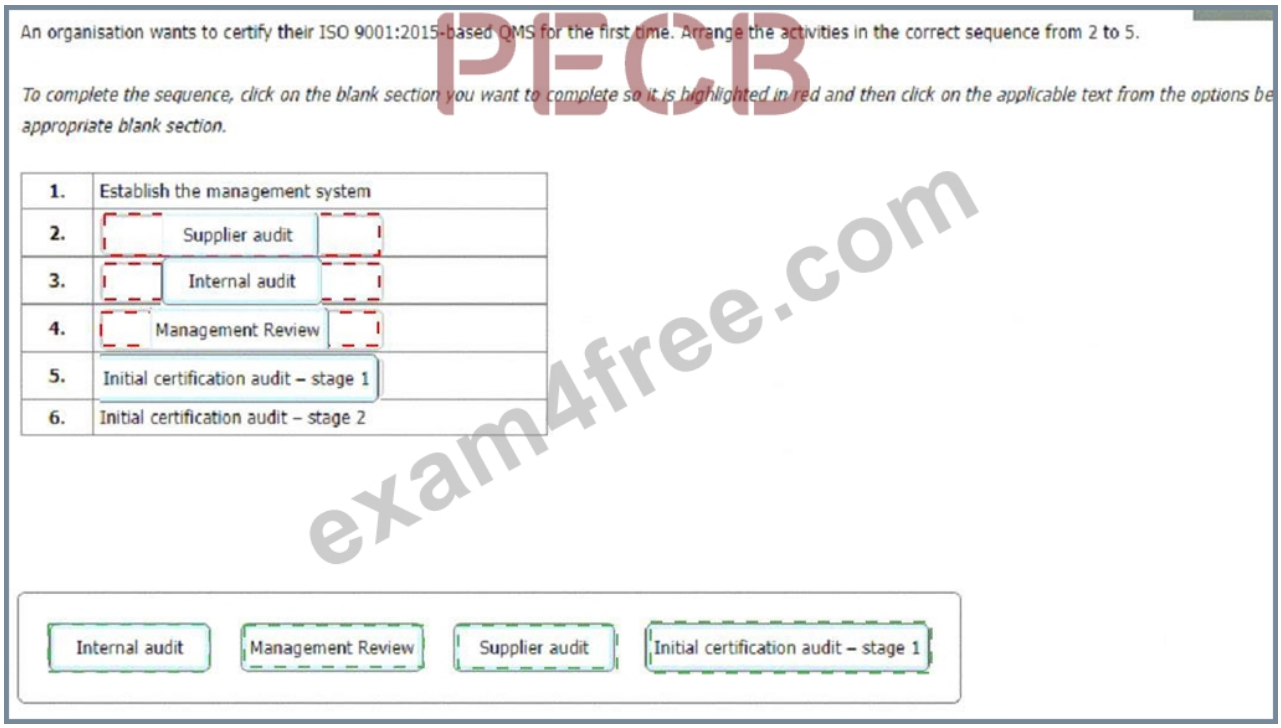
Clause 8.3.2 e) - Internal Resource Needs:Delays due to staff shortages highlight a lack of internal resources, directly relating to this clause that requires internal resource planning for design and development.
Clause 8.3.6 - Design and Development Changes:Ongoing formulation changes due to feedback need to be documented and reviewed. This clause requires retention of documented information on changes.
Clause 8.3.5 - Design and Development Outputs:Customer approvals for formulations are outputs of the design process and must be retained as documented information, as per this clause.
Clause 8.3.4 d) - Design and Development Controls:Consumer trials are a validation activity. This clause ensures such trials are conducted to confirm that resulting products meet defined requirements.
Clause 8.3.2 e) - External Resource Needs:Shelf-life tests done by an external lab are part of the external resources needed for development and are referenced here.

NEW QUESTION # 109
An organisation wants to certify their ISO 9001:2015-based QMS for the first time. Arrange the activities in the correct sequence from 2 to 5.
To complete the sequence, click on the blank section you want to complete so it is highlighted in red and then click on the applicable text from the options below. Alternatively, drag and drop the options to the appropriate blank section.



Answer:

Explanation:



Explanation:
To certify an organization's ISO 9001:2015-based Quality Management System (QMS) for the first time, the correct sequence of activities would be:
* Establish the management system (already in place).
* Supplier audit
* Internal audit
* Management review
* Initial certification audit - stage 1
* Initial certification audit - stage 2 (already in place).
This sequence follows the typical path for preparing and ensuring that a QMS is functioning as required, leading up to certification.

NEW QUESTION # 110
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:
According to Scenario 6, the audit team required DC's top management to submit corrective action plans within two weeks. Is this action acceptable?

- A. No, because the deadline for the client to present a corrective action plan is at least within 7 days
- B. Yes, because a deadline from 10 to 60 days is a best practice for the submission of action plans
- C. No, because the decision for the deadline should have been suggested by the top management

Answer: B

Explanation:
Comprehensive and Detailed In-Depth Explanation:ISO 17021-1:2015, Clause 9.4.9 (Corrective Actions) states:
* The auditor can set a reasonable deadline for corrective actions.
* 10 to 60 days is a best practice timeframe for the auditee to respond.
* The auditee must propose corrective actions, but the audit team has the authority to set the deadline
.
A 7-day deadline (A) is too short, and the audit team-not the auditee-determines the timeframe (B).

NEW QUESTION # 111
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