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## PECB QMS ISO 9001:2015 Lead Auditor Exam Sample Questions (Q58-Q63):

### NEW QUESTION # 58

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

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

Event	
1	
2	
3	
4	

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.

Conduct certification audit stages	Accredit Certification Body	Award ISO 9001 certificate	Programme initial certification audit
------------------------------------	-----------------------------	----------------------------	---------------------------------------

### Answer:

### Explanation:

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.

Conduct certification audit stages	Accredit Certification Body	Award ISO 9001 certificate	Programme Initial certification audit
------------------------------------	-----------------------------	----------------------------	---------------------------------------

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: Accredite 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 # 59**

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.

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.

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.	<input type="text"/>
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.	<input type="text"/>
The NPD Manager explains that the customer confirms their approval to proceed with a new formulation by email. These emails are kept on SWIFT.	<input type="text"/>
The NPD Manager shows you evidence of consumer trials that are carried out for some new products prior to full-scale launch.	<input type="text"/>
The NPD Manager explains that an approved external laboratory is used to perform shelf-life stability trials on some formulations during product development.	<input type="text"/>

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 ..."

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

"8.3.4 d) ... conducted to ensure that the resulting products and services meet the requirements ..."

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

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

**Answer:**

**Explanation:**

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.

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.	"8.3.5 ... 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.	"8.3.6 ... retain documented information ..."
The NPD Manager shows you evidence of consumer trials that are carried out for some new products prior to full-scale launch.	"8.3.4 d) ... conducted to ensure that the resulting products and services meet the requirements ..."
The NPD Manager explains that an approved external laboratory is used to perform shelf-life stability trials on some formulations during product development.	"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 ..."

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

"8.3.4 d) ... conducted to ensure that the resulting products and services meet the requirements ..."

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

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

**Explanation:**

#### Audit evidence

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.

#### ISO 9001 Clause 8.3 extract

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

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

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

"8.3.4 d) ... conducted to ensure that the resulting products and services meet the requirements ..."

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

The table below shows the possible matching of the ISO 9001 Clause 8.3 extract to the audit evidence.

Table

Audit evidence

ISO 9001 Clause 8.3 extract

Half of all new products launched in the past 12 months were late. The NPD Manager explains he has not got enough people on his team to cope with the demand for new products.

"8.3.2 e) ... internal ... resource needs for the design and development of products ..." The NPD Manager explains many changes are made to cosmetic formulations during product development owing to retailer feedback. Only when confirmed by the retailer is the agreed formulation documented on SWIFT.

"8.3.5 ... 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.

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

The NPD Manager shows you evidence of consumer trials that are carried out for some new products prior to full-scale launch.

"8.3.4 d) ... conducted to ensure that the resulting products and services meet the requirements ..." The NPD Manager explains that an approved external laboratory is used to perform shelf-life stability trials on some formulations during product development.

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

#### NEW QUESTION # 60

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, as long as top management is informed, the policy can be established by any responsible employee.
- C. No, the quality policy must be established and approved only by the quality manager.
- D. Yes, the quality policy can be established by the QMS implementation team and be approved by top management.

Answer: A

Explanation:

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 # 61**

Select the word that best completes the sentence:

Select the word that best completes the sentence:

"The purpose of a management system standard is to \_\_\_\_\_ the performance of an organisation."

To complete the sentence with the best word, click on the blank section you want to complete so it is highlighted in red and then click on the applicable text from the option(s) below. Alternatively, drag and drop the option(s) to the appropriate blank section.

manage    monitor    improve    dictate

**Answer:**

**Explanation:**

Select the word that best completes the sentence:

"The purpose of a management system standard is to improve the performance of an organisation."

To complete the sentence with the best word, click on the blank section you want to complete so it is highlighted in red and then click on the applicable text from the option(s) below. Alternatively, drag and drop the option(s) to the appropriate blank section.

manage    monitor    improve    dictate

**Explanation:**

"The purpose of a management system standard is to improve the performance of an organisation."

According to the ISO - Management system standards page, the key benefits of an effective management system include improved operational effectiveness and efficiency, improved risk management and protection of people and the environment, and enhanced drive for innovation. The Integrated Use of Management System Standards (IUMSS) handbook also states that the purpose and objectives of management system standards are to help organizations improve their performance by specifying repeatable steps that organizations consciously implement to achieve their goals and objectives.

Therefore, the complete sentence is:

"The purpose of a management system standard is to improve the performance of an organisation."

**NEW QUESTION # 62**

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
Update by: 01/20XX	Update by: 02/20XX	Update by: 03/20XX	Action by: 31/03/20XX
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	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. Limited knowledge of the content of Quality Improvement Requests by departmental staff.
- B. Top management claim not to be aware of the improvement request (QI/12/20/HR-3) initiated by the Quality Manager.
- C. Decisions on improvement action timescales not involving departmental managers.
- **D. No quality objectives planned for the top management team**
- **E. Quality improvements not aligning with the quality policy.**
- F. Evaluation of the results of the improvement action not always documented by the Quality Manager.

**Answer: D,E**

Explanation:

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 # 63

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