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PECB QMS ISO 9001:2015 Lead Auditor Exam Sample Questions (Q195-Q200):

NEW QUESTION # 195

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 He asks that the nonconformity be withdrawn.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. Refuse to accept the documentation produced and maintain the nonconformity.
- B. Ask the auditor (you) who raised the issue, to state what you think should happen
- C. Thank the Quality Manager for his contribution but dismiss the information as irrelevant after a quick review.
- **D. Indicate that the nonconformity is evidence of a system failure that needs to be rectified.**
- **E. Advise management that the information provided will be reviewed at the audit follow-up stage.**
- F. Accept the Quality Manager's request without reviewing the documentation.

Answer: D,E

NEW QUESTION # 196

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. Act
- B. Do
- **C. Check**

Answer: C

Explanation:

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 # 197

Match the process descriptions below to the process names:

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The process by which the accuracy of test equipment is checked against a known standard.		<input type="text"/>
The process by which a product or service is visually examined to determine conformity to requirements.		<input type="text"/>
The process by which data is examined in detail to reach a specific answer or answers.		<input type="text"/>
The process by which a parameter of a product or service is examined to determine a specific value.		<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 applicable text from the options below. Alternatively you may drag and drop each of the following process names to the descriptions:

Sampling	Calibration	Evaluation	Monitoring	Analysis	Measurement
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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

To complete the table 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 each of the following process names to the descriptions:

Sampling	Calibration	Evaluation	Monitoring	Analysis	Measurement
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Explanation:

A white background with black text Description automatically generated

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

NEW QUESTION # 198

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 effectiveness of the management system
- B. Evaluate the capability of the management system to establish and achieve objectives
- C. Evaluate the satisfaction interested parties
- D. Identify opportunities for improvement
- E. Identify the need of resources
- F. Evaluate the benefits obtained since the implementation of the management system

Answer: A,B

NEW QUESTION # 199

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

Answer: D,F

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 # 200

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