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

Topic	Details
Topic 1	<ul style="list-style-type: none">Managing an ISO 9001 audit program: This topic evaluates your abilities to establish and managing a QMS audit program.
Topic 2	<ul style="list-style-type: none">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	<ul style="list-style-type: none"> • Conducting an ISO 9001 audit: It evaluates your skills to conduct a QMS audit.
Topic 4	<ul style="list-style-type: none"> • Preparing an ISO 9001 audit: This topic covers sub-topics related to preparing a quality management system audit.
Topic 5	<ul style="list-style-type: none"> • Fundamental principles and concepts of a quality management system: The main objective of this domain is to evaluate your skills of explaining and applying ISO 9001 principles and concepts.

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

NEW QUESTION # 58

Below are four of the seven principles on which ISO 9000 series are based. Match a potential benefit to each of the quality management principles (QMP).

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Quality management principles

Customer focus	<input type="text"/>
Engagement of people	<input type="text"/>
Improvement	<input type="text"/>
Evidence-based decision-making	<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, drag and drop each of the following potential benefits to a QMP.

Enhanced drive for innovation	Better communication between levels and functions of the organisation	Improved operational effectiveness and efficiency	Enhanced trust and collaboration throughout the organisation
Increased ability to demonstrate effectiveness of past actions	Increased revenue and market share	Common understanding of objectives and values among interested parties	

Answer:

Explanation:

Below are four of the seven principles on which ISO 9000 series are based. Match a potential benefit to each of the quality management principles (QMP).

Quality management principles

Customer focus	Increased revenue and market share
Engagement of people	Enhanced trust and collaboration throughout the organisation
Improvement	Enhanced drive for innovation
Evidence-based decision-making	Increased ability to demonstrate effectiveness of past actions

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, drag and drop each of the following potential benefits to a QMP.

Enhanced drive for innovation	Better communication between levels and functions of the organisation	Improved operational effectiveness and efficiency	Enhanced trust and collaboration throughout the organisation
Increased ability to demonstrate effectiveness of past actions	Increased revenue and market share	Common understanding of objectives and values among interested parties	

Explanation:

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Quality management principles	
Customer focus	Increased revenue and market share
Engagement of people	Enhanced trust and collaboration throughout the organisation
Improvement	Enhanced drive for innovation
Evidence-based decision-making	Increased ability to demonstrate effectiveness of past actions

According to the ISO 9000:2015 document, the seven quality management principles are:

Customer focus

Leadership

Engagement of people

Process approach

Improvement

Evidence-based decision making

Relationship management

For each principle, the document provides a statement, a rationale, key benefits, and actions you can take to apply the principle in your organization.

Based on the document, here is a possible way to match a potential benefit to each of the four quality management principles you mentioned:

Table

Quality management principle

Potential benefit

Customer focus

Increased revenue and market share

Engagement of people

Enhanced trust and collaboration throughout the organization

Improvement

Enhanced drive for innovation

Evidence-based decision making

Increased ability to demonstrate effectiveness of past actions

NEW QUESTION # 59

You are carrying out an audit at an organisation seeking certification to ISO 9001 for the first time. The organisation offers health and safety training to customers. Training courses are offered either as open courses, delivered at a public venue, or online, or as courses that are tailored to meet specific requirements.

The business operates from a single office and those who deliver the training are either full-time employees or subcontractors.

You are interviewing the Training Manager (TM).

You: "What quality objectives apply to the training process?"

TM: "One of the quality objectives we aim for is a 90% minimum exam pass rate for all open training courses." You: "How do you measure this objective?" The Training Manager shows you a record on her computer and you see the following:

Month	Exam pass rates (%)					
	Course 1	Course 2	Course 3	Course 4	Course 5	Course 6
1	92	87	89	78	95	97
2	93	86	88	77	94	98
3	94	87	87	79	93	97
4	92	89	86	80	95	96
5	93	88	88	79	96	95
6	95	87	89	77	96	97

Which two of the following statements are true?

- A. You would determine how the exam pass rate figures were analysed.
- B. You would determine the relative difficulty of each training course by reviewing them.

- C. You would check the training of personnel.
- D. You would raise a nonconformity as a requirement in clause 10.2 has not been fulfilled.
- E. You would raise a nonconformity as a requirement in clause 8.7 has not been fulfilled.
- F. You would determine what corrective action was being taken to address the low pass rates.

Answer: A,F

Explanation:

In this scenario, the organization has set a quality objective of achieving a 90% minimum exam pass rate for all courses. The auditor's task is to assess whether this objective is being monitored effectively and if appropriate actions are taken when the objective is not met.

B: You would determine how the exam pass rate figures were analysed: ISO 9001:2015, particularly Clause 9.1 (Monitoring, measurement, analysis, and evaluation), requires organizations to evaluate performance data.

The auditor should verify how the organization analyses the pass rate data to ensure trends are identified, and corrective actions are planned based on this analysis.

D: You would determine what corrective action was being taken to address the low pass rates: When performance falls short of the objective, as seen with Course 4 (where the pass rate is below 90% in all months), Clause 10.2 (Nonconformity and corrective action) requires organizations to take corrective actions to address issues. The auditor would need to check if corrective actions have been initiated to address consistently low pass rates.

Statements A, C, E, and F do not directly address the monitoring and corrective action required under ISO 9001:2015 in this context.

NEW QUESTION # 60

In a third-party audit to ISO 9001, select two options of when the organisation is required to act in response to reported findings.

- A. A finding of conformity is reported.
- B. A recommendation is given in the report.
- C. A finding of good practice is reported.
- D. A major non-conformity is raised.
- E. An opportunity for improvement is raised.
- F. A minor non-conformity is raised.

Answer: D,F

Explanation:

According to ISO 19011:2018, clause 6.6.2, a nonconformity is the non-fulfilment of a requirement. A nonconformity can be classified as either major or minor, depending on the nature and extent of the deviation from the audit criteria. A major nonconformity is a nonconformity that affects the ability or the integrity of the organization's management system to achieve the intended results. A minor nonconformity is a nonconformity that does not affect the ability or the integrity of the organization's management system to achieve the intended results, but is a deviation from the audit criteria¹.

According to ISO/IEC 17021-1:2015, clause 9.4.9, the organization is required to analyze the cause and describe the specific correction and corrective actions taken, or planned to be taken, to eliminate detected nonconformities, within a defined time. The organization is also required to provide the certification body with records and evidence of the implementation and effectiveness of the correction and corrective actions taken. The certification body will then verify the correction and corrective actions taken by the organization and decide on the certification status².

Therefore, the two options of when the organization is required to act in response to reported findings are D and F, as they indicate the presence of nonconformities that need to be corrected and prevented from recurring. The other options are not correct, as they do not require the organization to act in response to reported findings:

*A. A recommendation is given in the report: A recommendation is a suggestion for improvement that is not related to a nonconformity. A recommendation is not binding for the organization and does not affect the certification status. The organization may choose to accept or reject the recommendation, but it is not required to act on it.

*B. A finding of good practice is reported: A finding of good practice is a positive observation that indicates a strength or a best practice of the organization's management system. A finding of good practice is not related to a nonconformity and does not affect the certification status. The organization may choose to acknowledge or share the finding of good practice, but it is not required to act on it.

*C. An opportunity for improvement is raised: An opportunity for improvement is a potential area where the organization's management system can be enhanced or optimized. An opportunity for improvement is not related to a nonconformity and does not affect the certification status. The organization may choose to pursue or ignore the opportunity for improvement, but it is not required to act on it.

*E. A finding of conformity is reported: A finding of conformity is a confirmation that the organization's management system fulfils the

audit criteria. A finding of conformity is not related to a nonconformity and does not affect the certification status. The organization may choose to celebrate or communicate the finding of conformity, but it is not required to act on it.

References: ISO 19011:2018(en), Guidelines for auditing management systems, ISO/IEC 17021-1:2015(en), Conformity assessment - Requirements for bodies providing audit and certification of management systems
- Part 1: Requirements

NEW QUESTION # 61

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:

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

Answer: B,C

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 # 62

You are carrying out an annual audit at an organisation that offers home security services. You are interviewing the Quality Manager (QM) You: "Would you tell me about your management review process?" QM: "The senior management team plans to review the management system every six months. The review follows a set agenda and records are maintained." You: "May I see the records from the last two management reviews?" Narrative: The Quality Manager gives you the latest record, which shows the last

management review took place nine months ago.

The Quality Manager then gives you the previous management review record, which took place one year before the latest review.

You: "Are there any other review reports in the last two years?"

QM: "No, these are the only ones."

You decide to raise a nonconformity.

Nonconformity report	
ISO 9001 Clause Number:	<input type="text"/>
Nature of problem:	<input type="text"/>
ISO 9001 requirement that has not been fulfilled:	<input type="text"/>

To complete the nonconformity report 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.

9.3.1

Issues raised at management review are not being actioned.

9.3.3

ISO 9001 - "Top management shall review the organization's quality management system."

ISO 9001 - "Top management shall review the organization's quality management system at planned intervals."

Management review has not been conducted at the defined frequency.

ISO 9001 - "The organization shall retain documented information as evidence of the results of management review."

Management review records are not being retained.

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Answer:

Explanation:

Explanation:

Nonconformity report

ISO 9001 Clause Number: 9.3.1 Nature of problem: Management review has not been conducted at the defined frequency. ISO 9001 requirement that has not been fulfilled: ISO 9001 - "Top management shall review the organization's quality management system at planned intervals." Evidence: The last management review took place nine months ago, and the previous one took place one year before the latest review. The planned interval is six months.

NEW QUESTION # 63

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