

Free Questions for ISO-9001-Lead-Auditor by actualtestdumps

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Question Type: MultipleChoice

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	<mark>95</mark>	96			
5	93	88	88	79	96	95			
6	95	87	89	77	96	97			

Which two of the following statements are true?

Options:

A- You would check the training of personnel.

- B- You would determine how the exam pass rate figures were analysed.
- C- You would determine the relative difficulty of each training course by reviewing them.
- **D-** You would determine what corrective action was being taken to address the low pass rates.
- E- You would raise a nonconformity as a requirement in clause 10.2 has not been fulfilled.
- F- You would raise a nonconformity as a requirement in clause 8.7 has not been fulfilled.

Answer:

Question Type: MultipleChoice

You are carrying out an annual audit at an organisation that has been certificated to ISO 9001 for two years. The organisation offers home security

services. The scope of the quality management system covers alarm installation, alarm servicing, alarm monitoring and response. The business

operates from a single office and employs subcontract installers and service technicians across the country.

You have just completed the opening meeting. You are interviewing the Managing Director (MD).

You: "I would like to gain an understanding of how the quality management system has been supporting your business and its strategic direction."

MD: "We are continuing to face difficult times. The market is extremely competitive, and customers typically look for the least expensive option when

choosing home security services. We have not yet seen any business benefit from our quality management system."

You: "Tell me how you determine external and internal issues."

MD: "We use SWOT analysis (Strengths Weaknesses, Opportunities, Threats)."

You: "How have the outputs from your SWOT been used?"

Select two of the following audit trails would you take to explore the extent to which the SWOT analysis and the outputs from this

have been used to enable the business to achieve the intended results(s) of its quality management system according to ISO 9001.

Options:

- A- Establish how many interested parties need to be consulted
- B- Establish how the organisation reviews information about external and internal issues
- C- Establish how the organisation shares information with external interested parties
- D- Establish what actions were taken to improve the QMS
- E- Establish whether the SWOT analysis has been reviewed by the procurement manager
- F- Establish whether the SWOT analysis is focussed solely on the QMS

Answer:			
B, D			

Explanation:

Question no: 22 Verified Answer: = B. Establish how the organisation reviews

According to ISO 9001:2015, clause 10.3, the organisation must continually improve the suitability, adequacy, and effectiveness of the quality management system. The organisation must also consider the results of analysis and evaluation, and the outputs from management review, to determine if there are any needs or opportunities for improvement. SWOT analysis can help the organisation to identify the areas where improvement is needed or possible, such as addressing the weaknesses and threats, or exploiting the strengths and opportunities. However, the SWOT analysis alone is not sufficient to comply with the requirement, as the organisation also needs to take actions to implement the improvement, such as setting objectives, allocating resources, assigning responsibilities, and evaluating the effectiveness. Therefore, another audit trail would be to establish what actions were taken to improve the QMS, such as what, when, by whom, how, and with what results. 124 Reference:

1: ISO 9001:2015 - Quality management systems --- Requirements

2: Advisera, "Context of the organization in ISO 9001:2015 explained", https://advisera.com/9001academy/knowledgebase/how-to-identify-the-context-of-the-organization-in-iso-90012015/

3: ISO Templates, "ISO 9001 - Clause 4: Context of the organisation explained", https://resources.iso-templates.com/blog/iso-9001clause-4-context-of-the-organisation-explained

4: Advisera, "How to implement continual improvement in ISO 9001", https://advisera.com/9001academy/knowledgebase/how-to-implement-continual-improvement-in-iso-9001/

Question 3

Noitol is an organisation specialising in the design and production of e-learning training materials for the insurance market. During an ISO 9001 audit

of the development department, the auditor asks the Head of Development about the process used for validation of the final course design. She states that they usually ask customers to validate the product with volunteers. She says that the feedback received often leads to key improvements.

The auditor samples the design records for a recently completed course for the 247 Insurance organisation. Design verification was carried out but there was no validation report. The Head of Development advises that this customer required the product on an urgent basis, so the validation stage

was omitted. When asked, the Head estimates that this occurs about 50% of the time. She confirms that they always ask for feedback and often make changes. There is no record of feedback in the design file for the course.

The auditor raises a nonconformity against ISO 9001. Which one of the following options is the basis for the nonconformity?

Options:

A-8.3.5 - The improvements made to course designs are not documented. Feedback from customers is not always actioned.

B- 8.3.2.c - Design planning does not include design validation. Design verification is part of the planning process.

C- 8.3.4.d - Design validation is not always conducted. It is omitted about half of the time.

D-8.6 - Course materials are released without proper approval. A course for 247 Insurance was released on an urgent basis.

С

Question 4

Question Type: DragDrop

You, as auditor, are in dialogue with the quality lead and managing director of a small business that supplies

specialist laboratory equipment and furniture.

You: "I'd like to look at how you manage change in the organisation. What changes have you made as a

business, say, over the last 12 months?"

Auditee: "We have made some strategic changes, the main one being that we no longer manufacture our own products in house."

You: "That sounds like quite a significant change. What has been the impact of that?"

Auditee: "We now mainly sell other manufacturers' products, under their brand names, and have outsourced manufacture of our own brand products to one of our suppliers. Unfortunately, we had to make six members of our staff redundant. This represents about 20% of our workforce, so this has been quite a challenging

time."

You: "I'm sure. What were the reasons for making the change?"

Auditee: "Our manufacturing section was a small operation, and we struggled to cope with fluctuations in demand. During busy periods, we found it hard to meet lead times, and in quiet periods we had staff with little to do. This was having an impact on customer satisfaction and meant we had to charge premium prices that made our product uncompetitive."

You: "How did you go about the change?"

In relation to the auditor's question about how the change was managed, the auditee mentions the steps listed below. Match the ISO 9001 clauses to the steps.

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 clauses listed below. Alternatively, drag and drop each clause to show which step the requirement applies to.

Step	Clause
We identified risks and opportunities and fed these into our risk management processes.	
We found a suitable supplier.	
We monitored customer feedback and noticed an increase in negative feedback about lead times.	
We put together a plan for implementation.	
We monitored the performance of the new supplier.	
We noticed that productivity targets were being missed.	
We communicated the plan internally.	
We looked at the data at the management review and decided we needed to do something different.	
We reorganised the staffing and implemented redundancies.	
We set an objective to effectively implement the transition and outsource manufacturing.	
6.2.1 6.2.1 8.4 9.1.2	6,2.2 8.4.2
7.1.2 1 7.4 9.3.2 7.1.2	

Question Type: MultipleChoice

Which two of the following work documents are not required for audit planning by an auditor conducting a certification audit?

Options:

A- A career history of the quality manager

B- A checklist

C- A list of interested parties

- D- An audit plan
- E- An evidence sampling strategy
- **F-** An organisation's financial statement

Answer:

A, F

Question Type: MultipleChoice

During a Stage 1 audit, the Quality Manager asks that the audit includes coverage of a new work area they have expanded into since the application was made.

Which of the following two actions should the auditor take?

Options:

A- Advise the Quality Manager that an extension of the scope is possible but will have to go through established procedures.

B- Advise the Quality Manager that the audit scope has been set and the audit will proceed as planned.

C- Advise the Quality Manager that, within the existing scope, the new work area can be included without any problem.

D- Determine whether the Quality Management System covers the new work area and, if so, proceed with the audit.

E- Suggest that she will advise the programme manager that the audit scope should be revised to include the new work area. Suggest that the Quality Manager cancels the audit contract and reapplies for the new situation.

Answer:

Α, Ε

Explanation:

Question no: 14 Verified Answer: =

A) Advise the Quality Manager that an extension of the scope is possible but will have to go through established procedures. and E. Suggest that she will advise the programme manager that the audit scope should be revised to include the new work area. Comprehensive But Short = A Stage 1 audit is a preliminary assessment to evaluate the readiness of the organisation for the Stage 2 certification audit. The audit scope is defined by the audit client and the certification body based on the application and the contract. If the organisation wants to include a new work area that was not part of the original scope, the auditor should advise the Quality Manager that an extension of the scope is possible but will have to go through established procedures, such as submitting a formal request, providing relevant information, and paying additional fees. The auditor should also suggest that the Quality Manager will advise the programme manager, who is responsible for managing the audit programme, that the audit scope should be revised to include the new work area. The programme manager will then decide whether to approve or reject the request, and communicate the decision to the auditor and the Quality Manager. The auditor should not proceed with the audit of the new work area without the approval of the programme manager and the confirmation of the audit scope. 1234 Reference:

1: ISO 19011:2018 - Guidelines for auditing management systems

- 2: ISO 9001 Certification Audits | Stage 1 and Stage 2 9001. Simplified
- 3: What is the difference between Stage 1 and Stage 2 Audits? ISO Update
- 4: Getting Certified to ISO 9001 the Stage 1 Audit

Question Type: MultipleChoice

Read the following role descriptions. Select two roles that are not directly involved in the audit process.

Options:

- A- An auditor-in-training a person who accompanies the audit team leader or team members during the audit.
- B- A technical expert a person who provides specific knowledge or expertise to the audit team but is not normally an auditor.
- C- An audit team leader a person responsible for managing an audit until the audit is completed.
- **D-** An interpreter a person who witnesses the audit to assist the auditors with language issues.
- E- An observer a person who sees the performance of the audit team leader, audit team members and/or auditee.
- F- A guide a person who is appointed by the auditee to assist the audit team during the audit.

Answer:	
D, E	

Question 8

Which one of the following options is the definition of the context of an organisation?

Options:

A- Combination of internal and external issues that can have an effect on an organisation's approach to developing and achieving its objectives.

B- Comparison of internal and external issues that can have an effect on an organisation's desire to achieve its objectives.

C- Complexity of internal and external issues that can have an effect on an organisation's approach to developing and achieving its purpose.

D- Coordination of internal and external issues that can have a positive or negative effect on an organisation's success.

Answer:

A

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