

ISO-9001-Lead-Auditor Exam, ISO-9001-Lead-Auditor Prüfungs

ISO 9001 Lead Auditor Sample Exam Questions and Answers:

There are 4 sections in the ISO 9001 QMS Lead Auditor examination as illustrated in table 1 below. In this ISO 9001 lead auditor sample exam questions and answer article, we will examine one question per section and provide their answers.

In table 1 you can find the question break-ups and the passing scores.

Table 1: ISO 9001 Exam Section and Question break-up

Section	No of Questions	Minimum Pass Mark	Maximum Pass Mark
1	5	4.5	10
2	4	9.5	20
3	3	14.5	30
4	3	14.5	30
Total	15	62.5	90

Table 1 shows us the total available and minimum marks to pass each section. It is mandatory to pass each section. For example: if you have scored 6 marks on section 1, 18 marks on section 2, 10 marks on section 3 & 30 marks on section 4, your subtotal would be 64 marks. Though you have scored a total of 64 marks, since you haven't scored the minimum passing marks on section 3, it will still be considered a failure.

Now let's look at a few sample exam questions in each section.

Section 1:

This section has 5 questions and each carries 2 marks,

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>> ISO-9001-Lead-Auditor Exam <<

PECB ISO-9001-Lead-Auditor Prüfungs, ISO-9001-Lead-Auditor Fragen Und Antworten

Wir ZertFragen sind der zuverlässige Rückhalt für jede, die auf die PECB ISO-9001-Lead-Auditor Prüfung vorbereiten. Alle, was Sie bei der Vorbereitung der PECB ISO-9001-Lead-Auditor Prüfung brauchen, können wir Ihnen bieten. Nachdem Sie gekauft haben, werden wir Ihnen weiter hingehend helfen, die PECB ISO-9001-Lead-Auditor Prüfung zu bestehen. Einjährige

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PECB QMS ISO 9001:2015 Lead Auditor Exam ISO-9001-Lead-Auditor Prüfungsfragen mit Lösungen (Q100-Q105):

100. Frage

Who maintains ownership of the audit report?

- A. The audit team leader
- **B. The certification body**
- C. The auditee

Antwort: B

Begründung:

Comprehensive and Detailed In-Depth Explanation: According to ISO 17021-1:2015, Clause 9.4.8 (Audit Reporting):

* The certification body retains ownership of the audit report as it is responsible for the certification decision.

* The auditee may receive a copy, but it does not own the report.

* The audit team leader compiles the report but does not own it.

Thus, C is the correct answer.

101. Frage

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

Antwort: B

Begründung:

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.

102. Frage

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 DC's 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:

The audit team delayed audit activities until DC's top management submitted their action plans. Is this acceptable?

- A. Yes, the audit report can be prepared once the auditee submits the action plans in cases of minor nonconformities
- B. Yes, DC's top management promised the submission of action plans within a short period of time
- **C. No, the audit report should be prepared and submitted to the certification body prior to the submission of action plans by the auditee**

Antwort: C

Begründung:

Comprehensive and Detailed In-Depth Explanation: According to ISO 17021-1:2015, Clause 9.4.8 (Audit Reporting):

- * The audit report must be submitted to the certification body regardless of corrective actions.
- * Corrective actions are reviewed after the audit, but the audit process should not be delayed.
- * Certification decisions should be made based on the audit findings and evidence, not pending corrective actions.

Thus, delaying audit activities until corrective actions are submitted is not acceptable.

103. Frage

You work as an external quality consultant for an organisation, 'A', which provides packaged food to the public. You are asked to lead a team (you as the leader and two other auditors) to audit a supplier, 'B', to ISO

9001 which provides packaging materials to your organisation. It is 4 pm and the audit is close to an end; you are having an internal meeting with the team to decide what will be presented to the auditee during the Closing meeting. The Closing meeting was scheduled at 5 pm.

You, as Audit Team Leader, audited top management. You explain to the audit team that you identified two nonconformities:

a. There is no documented information on Top Management Reviews, as required in clause 9.3 of ISO 9001:2015.

b. There is no evidence of Top Management Commitment as required in clause 5.1 of ISO 9001:2015. (e.g., not ensuring the availability of resources to operate the QMS, not ensuring the establishment of objectives, no promotion of improvement, no promotion of the process approach).

All agreed to present these two nonconformities. They went to meet the Top Management of 'B' and noticed that the General Manager and three other managers (Production, Human Resources, and Sales) were present in the meeting room.

Considering the seriousness of the two nonconformities to Top Management, as audit team leader, from the following select the best option:

- **A. Present the nonconformities to the whole group and analyse with them how to overcome this situation.**
- B. Present the nonconformities to the managers, inform them that the report will be sent within 10 days, close the meeting and leave the site.

- C. Present the nonconformities to the whole group and inform that you will recommend your company to remove them from the approved suppliers list.
- D. Ask the General Manager to have a private conversation in which you present the nonconformities only to him because of their sensitive nature.

Antwort: A

Begründung:

According to the guidance on conducting the audit closing meeting¹, the audit team leader should provide a summary of the audit findings and conclusions, invite discussions, and agree on timelines for any corrective actions. The audit team leader should also be respectful, constructive, and objective when presenting the nonconformities, and avoid any personal or emotional comments. The audit team leader should also consider the impact of the disruptive event (such as the Covid-19 pandemic) on the auditee's context, interested parties, and risks², and acknowledge any good practices or improvements observed during the audit. Therefore, option D is the best option, as it follows the best practices for the closing meeting and allows the auditee to understand the nonconformities and their implications, and to participate in the analysis and resolution of the issues. Option A is not correct, as it is not respectful, constructive, or objective, and it does not invite any discussion or feedback from the auditee. It also assumes that the audit team leader has the authority to recommend the removal of the supplier from the approved list, which may not be the case. Option B is not correct, as it does not provide enough information or explanation to the auditee, and it does not allow any discussion or feedback from the auditee. It also does not follow the best practices for the closing meeting, such as providing a summary of the audit, acknowledging any good practices, and agreeing on timelines for corrective actions. Option C is not correct, as it does not involve the other managers who are responsible for the functions or processes that were audited, and who may have valuable input or information to share. It also does not follow the best practices for the closing meeting, such as providing a summary of the audit, inviting discussions, and agreeing on timelines for corrective actions. References: 1: Conducting the Audit Closing Meeting: Sharing the Results²: Auditing ISO 9001:2015 in the Context of a Disruptive Event.

104. Frage

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.	
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.	

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 ..."

Antwort:

Begründung:

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

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 ..."

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 ..."

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"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.

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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 ..."

105. Frage

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Wie kann man die Schulungsunterlagen von PECB ISO-9001-Lead-Auditor Zertifizierungsprüfung kaufen, die preiswert und doch von guter Qualität sind? ZertFragen wird den Wunsch der breiten Kandidaten erfüllen, dadurch dass ZertFragen ihnen die echten Testaufgaben und Antworten mit niedrigem Preis und hoher Qualität bietet. Im Vergleich zu den kollegen in der selben Branche liegt

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