

ISO-9001-Lead-Auditor考題免費下載 & ISO-9001-Lead-Auditor最新題庫

You decide to raise a nonconformity.

Nonconformity report

ISO 9001 Clause Number:

Nature of problem:

ISO 9001 requirement that has not been fulfilled:

Evidence: 40 cleaning records are available for 63 batches.

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 test from the options below. Alternatively, you may drag and drop the options to the appropriate blank section.

Cleaning and sanitising not always completed.

ISO 9001 - "The organization shall implement planned arrangements, at appropriate stages, to verify that the product requirements have been met."

Cleaning and sanitising records are not available for every batch.

8.7

8.5.4

ISO 9001 - "The organization shall ensure the outputs during production provision to the extent necessary to ensure conformity to requirements."

ISO 9001 - "The organization shall implement production provision under controlled conditions."

Cleaning and sanitising are not always completed by trained staff.

6.2.1

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PECB ISO-9001-Lead-Auditor 考試大綱：

主題	簡介
主題 1	<ul style="list-style-type: none">Conducting an ISO 9001 audit: It evaluates your skills to conduct a QMS audit.
主題 2	<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.
主題 3	<ul style="list-style-type: none">Preparing an ISO 9001 audit: This topic covers sub-topics related to preparing a quality management system audit.
主題 4	<ul style="list-style-type: none">Closing an ISO 9001 audit: The topic focuses on concluding a QMS audit and conducting audit follow-up activities.

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最新的 ISO 9001 ISO-9001-Lead-Auditor 免費考試真題 (Q225-Q230):

問題 #225

How can an organization ensure the objectivity and impartiality of the internal audit function?

- A. By having a representative of top management involved during the internal audit process
- B. By always outsourcing the internal audit function to a third party
- C. By assigning internal auditors that do not have operational roles related to the QMS

答案： C

解題說明：

Comprehensive and Detailed In-Depth Explanation: According to ISO 19011:2018, Clause 5.1 (Impartiality):

* Internal auditors must not audit areas where they have direct responsibilities to avoid conflicts of interest.

* Outsourcing (C) is not required, as long as impartiality is maintained internally.

Thus, B is the correct answer.

問題 #226

The following list gives examples of records that may be evidence of how an organisation has fulfilled the requirements of clause 8.4 of ISO 9001. Match the records to the appropriate requirement of clause 8.4.

答案：

解題說明：

Explanation:

The following table shows the possible matching of the records to the requirements of clause 8.4:

Table

Requirements

Records

Define product requirements

Product specification

Criteria for selection

List of requirements to be met by the external provider

Evaluation of potential external provider

External provider questionnaire

External provider selection

Approved external provider list

Communicate requirements

Purchase order

Monitoring of performance

External provider delivery times and quality issues

Comprehensive and Detailed Explanation: = According to clause 8.4 of ISO 9001:2015, the organization should ensure that externally provided processes, products, and services conform to the specified requirements. To do so, the organization should:

Define the product requirements that are relevant for the external provision, such as specifications, drawings, standards, codes, etc. These should be documented and communicated to the external provider. A record of the product specification can be used as evidence of this requirement.

Establish the criteria for the selection, evaluation, and re-evaluation of external providers, based on their ability to provide processes, products, and services in accordance with the requirements. The criteria should be documented and applied consistently. A record of the list of requirements to be met by the external provider can be used as evidence of this requirement.

Evaluate the potential external providers before selecting them, using the established criteria. The evaluation methods may include questionnaires, audits, references, samples, etc. The results of the evaluation should be documented and reviewed. A record of the external provider questionnaire can be used as evidence of this requirement.

Select the external providers that have demonstrated their competence and conformity to the requirements.

The selection should be based on the evaluation results and the organization's needs. The selection should be documented and approved. A record of the approved external provider list can be used as evidence of this requirement.

Communicate the requirements for the processes, products, and services to be provided by the external provider, including the

verification and validation activities, the acceptance criteria, the documentation requirements, the changes control, etc. The communication methods may include purchase orders, contracts, agreements, etc. The communication should be clear, complete, and timely. A record of the purchase order can be used as evidence of this requirement.

Monitor the performance and conformity of the external provider, using the established criteria and methods.

The monitoring methods may include inspections, tests, audits, feedback, complaints, etc. The monitoring results should be documented and analyzed. A record of the external provider delivery times and quality issues can be used as evidence of this requirement.

References: ISO 9001:2015, [ISO 9001 Auditing Practices Group Guidance on Scope], Mastering the Scope of ISO 9001 Quality Management Systems

問題 #227

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 managers, inform them that the report will be sent within 10 days, close the meeting and leave the site.
- B. Present the nonconformities to the whole group and inform that you will recommend your company to remove them from the approved suppliers list.
- C. Ask the General Manager to have a private conversation in which you present the nonconformities only to him because of their sensitive nature.
- **D. Present the nonconformities to the whole group and analyse with them how to overcome this situation.**

答案: D

解題說明:

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.

問題 #228

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 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.

Which of the following options for the best description of the nonconformity?

- A. Release of the product without acceptable test results has been accepted by the customer for Project DK.
- B. The untested product was not recalled until the galvanic efficiency of the anodes was verified.
- C. A retrospective concession was not sought from the customer once the test results had been approved by the Quality Manager.
- **D. Products for Project DK have been released before product approval through the quality control process.**

答案： D

解題說明：

Clause Reference - ISO 9001:2015 Clause 8.6 (Release of Products and Services):

ISO 9001 requires that products and services are not released to the customer until:

* All planned verification activities have been completed.

* Acceptance criteria have been met.

* Any necessary approvals have been obtained.

In this scenario:

* The sacrificial anodes for Project DK were shipped before the galvanic efficiency test results were analyzed.

* This constitutes a nonconformity against Clause 8.6 because the products were released without completing the required tests.

Option Analysis:

* A. A retrospective concession was not sought from the customer once the test results had been approved by the Quality Manager: Incorrect. While obtaining a concession might mitigate the situation, the nonconformity pertains to the process failure of releasing the products without completing required tests, not the absence of a concession.

* B. Release of the product without acceptable test results has been accepted by the customer for Project DK: Incorrect. The customer was not informed before the release, and there is no indication that this was accepted beforehand. Furthermore, ISO 9001 requires planned processes to be followed, regardless of later acceptance.

* C. Products for Project DK have been released before product approval through the quality control process: Correct. This description accurately reflects the nonconformity. The quality control process required test results to be analyzed and verified before release, which did not happen.

* D. The untested product was not recalled until the galvanic efficiency of the anodes was verified:

Incorrect. The issue is not about recalling the product but about releasing it without completing the required tests. Recalling the product is not mentioned in the scenario.

Why C is Correct:

* The nonconformity is a clear breach of Clause 8.6, where the products were released without meeting the planned verification requirements.

* This demonstrates a failure in adhering to quality control processes, which is a critical aspect of ISO 9001 compliance.

Key ISO 9001 Reference:

* Clause 8.6: Products and services shall not be released to the customer until all planned activities (e.g., testing) have been satisfactorily completed, or the customer has approved the release with knowledge of deviations.

問題 #229

Takitup is a small fabrication organisation that manufactures steel fencing, stairs and platforms for the construction sector. It has been certified to ISO 9001 for some time and has appointed a new Quality Manager. The audit plan during a surveillance audit covers the organisation's improvement actions and the auditor asks to see the most recent management review meeting minutes.

The auditor finds that the management review report records that none of the improvement actions set by the previous review has been realised for a second time. A new Quality Manager has been brought in at the middle management level to rectify the situation as the organisation is concerned that it might lose its certification.

Select three options that would provide evidence of conformance with clause 10.3 of ISO 9001.

- A. An increase in the number of quality staff.
- **B. Considering results from the analysis of the effectiveness of corrective actions to determine improvement opportunities.**
- **C. An enhanced customer satisfaction survey score than in the previous year.**
- **D. A quality objective to achieve lower reject rates by quality control.**
- E. Removing expensive external providers from the database.

- F. Outsource more processes to external providers
- G. Automate the fabrication process to increase profitability.
- H. The certification body auditor reporting fewer nonconformities.

答案：B,C,D

問題 #230

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