

ISO-9001-Lead-Auditor Real Dumps, ISO-9001-Lead-Auditor Free Pdf Guide

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.	<input type="text"/>
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.	<input type="text"/>
The NPD Manager explains that the customer confirms their approval to proceed with a new formulation by email. These emails are kept on SWIFT.	<input type="text"/>
The NPD Manager shows you evidence of consumer trials that are carried out for some new products prior to full-scale launch.	<input type="text"/>
The NPD Manager explains that an approved external laboratory is used to perform shelf-life stability trials on some formulations during product development.	<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 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 ..."

"8.3.2 e) ... external ... resource needs for the design and development of products ..."

"8.3.4 d) ... conducted to ensure that the design and development outputs meet ..."

"8.3.5 ... retain documented information ..."

"8.3.6 ... retain documented information ..."

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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"> Fundamental audit concepts and principles: Questions about interpreting and applying the main concepts and principles related to a QMS audit appear in this topic.

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Pdf Guide

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PECB QMS ISO 9001:2015 Lead Auditor Exam Sample Questions (Q178-Q183):

NEW QUESTION # 178

Audit criteria are a set of requirements used as a reference against which objective evidence is compared.

Which two of the following are not potential audit criteria?

- A. Verbal agreements with interested parties
- B. Verbal statements by the general manager
- C. Health and safety notices
- D. Organisation's documented information
- E. Environmental aspects register
- F. ISO management system standards
- G. Written agreements with interested parties
- H. Commitment to follow principles issued by an NGO
- I. Commercial advertisements
- J. Claims made on the organisation's website

Answer: I,J

Explanation:

According to ISO 19011:2018, clause 3.2, audit criteria are a set of policies, procedures or requirements used as a reference against which objective evidence is compared. Audit criteria are usually selected by the audit client or by agreement between the audit client and the auditee, and they should be appropriate for the audit scope and objectives¹. Audit criteria may include, but are not limited to, the following sources²:

*ISO management system standards, such as ISO 9001, ISO 14001, ISO 45001, etc.

*Verbal statements by the general manager or other top management, as long as they are consistent with the documented policies and objectives of the organisation

*Verbal agreements with interested parties, such as customers, suppliers, regulators, etc., as long as they are documented and approved by the relevant authorities

*Health and safety notices, such as posters, signs, labels, etc., that communicate the organisation's legal obligations, policies, or procedures

*Written agreements with interested parties, such as contracts, orders, specifications, etc., that define the requirements and expectations of the parties involved

*Organisation's documented information, such as policies, procedures, manuals, records, etc., that describe the organisation's management system and its processes

*Commitment to follow principles issued by an NGO, such as the United Nations Global Compact, the International Labour Organization, etc., as long as they are relevant to the organisation's context and objectives

*Environmental aspects register, such as a list of the environmental impacts and risks associated with the organisation's activities, products, and services Therefore, the two options that are not potential audit criteria are F and H, as they are not reliable or verifiable sources of information, and they may not reflect the actual performance or conformity of the organisation's management system. Commercial advertisements and claims made on the organisation's website are forms of marketing communication that may be exaggerated, misleading, or inaccurate, and they are not subject to the same level of scrutiny or approval as the other sources of audit criteria.

References: ISO 19011:2018(en), Guidelines for auditing management systems, What are audit criteria? - ISO Update

NEW QUESTION # 179

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.

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Requirements	Records
Define product requirements	<input type="text"/>
Criteria for selection	<input type="text"/>
Evaluation of potential external provider	<input type="text"/>
External provider selection	<input type="text"/>
Communicate requirements	<input type="text"/>
Monitoring of performance	<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 appropriate record from the options listed. Alternatively, drag and drop the appropriate record to the requirement of clause 8.4 that applies.

Answer:

Explanation:

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.

Requirements	Records
Define product requirements	<input type="text" value="Product specification"/>
Criteria for selection	<input type="text" value="List of requirements to be met by the external provider"/>
Evaluation of potential external provider	<input type="text" value="External provider questionnaire"/>
External provider selection	<input type="text" value="Approved external provider list"/>
Communicate requirements	<input type="text" value="Purchase order"/>
Monitoring of performance	<input type="text" value="External provider delivery times and quality issues"/>

To complete the table click on the blank section you want to complete so it is highlighted in red and then click on the appropriate record from the options listed. Alternatively, drag and drop the appropriate record to the requirement of clause 8.4 that applies.

Explanation:

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

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

NEW QUESTION # 180

You are the supervisor in Production of a medium size manufacturing organisation. You are qualified as an internal auditor. The Quality Manager asks you to lead the next internal audit of Production and Logistics Dispatch. The audit team includes two other internal auditors.

Dispatch. The audit team includes two other internal auditors.

If practicable

You should not ...

ou need not ...

ou must ...

ou must not ...

ou should ...

To complete the sentences 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.

audit production

carry out a formal opening meeting

raise audit findings if necessary

change the audit team

send the audit report to the Quality Manager

Answer:

Explanation:

You are the supervisor in Production of a medium size manufacturing organisation. You are qualified as an internal auditor. The Quality Manager asks you to lead the next internal audit of Production and Logistics / Dispatch. The audit team includes two other internal auditors.

*If practicable
 *You should not ...
 You need not ...
 You must ...
 You must not ...
 You should ...

audit production
 change the audit team
 raise audit findings if necessary
 send the audit report to the Quality Manager
 carry out a formal opening meeting

To complete the sentences 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.

audit production carry out a formal opening meeting raise audit findings if necessary change the audit team send the audit report to the Quality Manager

Explanation:

Here is the correct matching of actions to the statements in the context of leading the internal audit:

- * If practicable carry out a formal opening meeting
- * You should not audit production (as you are a supervisor in that area, and this would compromise audit objectivity)
- * You need not change the audit team (unless there is a specific reason, such as conflict of interest)
- * You must raise audit findings if necessary (this is a key responsibility of an auditor when nonconformities are found)
- * You must not send the audit report to the Quality Manager (the audit report must be reviewed first; it is typically part of the internal audit process to go through necessary channels before final submission)
- * You should send the audit report to the Quality Manager (after appropriate reviews and approvals) This reflects key principles of conducting an internal audit according to ISO 9001:2015, ensuring objectivity, proper documentation, and clear reporting procedures.

NEW QUESTION # 181

Which of the following is a principle of maintaining audit work documents?

- A. Transparency
- B. Fair presentation
- C. Completeness

Answer: C

Explanation:

Comprehensive and Detailed In-Depth Explanation: Completeness ensures that all necessary audit evidence, observations, and findings are properly documented, which is critical for traceability and accountability in an audit.

While transparency and fair presentation are principles of auditing, completeness is specifically related to maintaining audit work documents, as required in ISO 19011:2018, Clause 6.5.4 (Preparing Audit Work Documents).

NEW QUESTION # 182

Among others, what does Clause 4.4 (Quality Management System and Its Processes) of ISO 9001 require from organizations?

- A. To change the QMS quarterly
- B. To review the QMS annually
- C. To continually improve the QMS
- D. To conduct a QMS gap analysis every two years

Answer: C

Explanation:

Comprehensive and Detailed In-Depth Explanation:

ISO 9001:2015 emphasizes continual improvement as a fundamental requirement of an effective Quality Management System (QMS).

Clause Reference:

* Clause 4.4.1 (Quality Management System and Its Processes) states that organizations must:

* Determine processes needed for the QMS

* Establish criteria and methods for process effectiveness

* Ensure continual improvement of the system

Why is the Correct Answer C?

* Continual improvement is a core principle of ISO 9001.

* Organizations must regularly assess and enhance their QMS to adapt to new challenges and maintain effectiveness.

Why are the Other Options Incorrect?

* A (To change the QMS quarterly) # ISO 9001 does not mandate a specific frequency for system changes.

* B (To review the QMS annually) # QMS reviews must be conducted as needed, not strictly annually.

* D (To conduct a QMS gap analysis every two years) # Gap analysis is useful but is not a mandatory requirement under Clause 4.4.

Reference:

ISO 9001:2015, Clause 4.4 - Quality Management System and Its Processes

NEW QUESTION # 183

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