



Exam Preparation Guide

ISO 9001 Lead Auditor

GENERAL

The objective of the “PECB Certified ISO 9001 Lead Auditor” exam is to ensure that the candidate has the necessary competence to: perform a quality management system (QMS) audit in compliance with the ISO 9001 standard requirements; manage an audit team by applying widely recognized audit principles, procedure, and techniques; and, lastly, plan and carry out internal and external audits as per the guidelines of ISO 19011 and in compliance with the ISO/IEC 17021-1 certification process.

The ISO 9001 Lead Auditor exam is intended for:

- Auditors seeking to perform and lead quality management system (QMS) audits
- Managers or consultants seeking to master the quality management system audit process
- Individuals responsible to maintain conformity with the QMS requirements in an organization
- Technical experts seeking to prepare for a quality management system audit
- Expert advisors in quality management

The exam covers the following competency domains:

- **Domain 1:** Fundamental principles and concepts of a quality management system (QMS)
- **Domain 2:** Quality management system (QMS)
- **Domain 3:** Fundamental audit concepts and principles
- **Domain 4:** Preparing an ISO 9001 audit
- **Domain 5:** Conducting an ISO 9001 audit
- **Domain 6:** Closing an ISO 9001 audit
- **Domain 7:** Managing an ISO 9001 audit program

The content of the exam is divided as follows:

Domain 1: Fundamental principles and concepts of a quality management system (QMS)

Main objective: Ensure that the candidate understands, is able to interpret ISO 9001 principles and concepts

Competencies	Knowledge statements
<ol style="list-style-type: none"> 1. Ability to understand and explain the ISO operations and the development of the ISO 9001 standard 2. Ability to identify, analyze and evaluate the ISO 9001 requirements 3. Ability to understand the Quality Management tools and techniques 4. Ability to explain and illustrate the main concepts in Quality Management System 	<ol style="list-style-type: none"> 1. Knowledge of the application of the seven fundamental ISO management principles in QMS. 2. Knowledge of the main standards in Quality Management 3. Knowledge of the different sources of Quality Management requirements for an organization, including: laws, regulations, international and industry standards, contracts, market practices, internal policies 4. Knowledge of Quality Circles, Total Quality Management, Six Sigma, Lean, Kaizen, Just-in-Time, etc. 5. Knowledge of the main Quality Management concepts and terminology as described in ISO 9001 6. Knowledge of the concepts of process approach and risk-based thinking in Quality Management

Domain 2: Quality management systems (QMS) and ISO 9001 requirements

Main objective: Ensure that the candidate understands, is able to interpret, and identify the requirements for a quality management system based on ISO 9001

Competencies	Knowledge statements
<ol style="list-style-type: none"> 1. Ability to understand and explain the components of a Quality Management System based on ISO 9001 and its principal processes. 2. Ability to interpret and analyze the requirements of ISO 9001 3. Ability to understand, explain and illustrate the main steps to establish, implement, operate, monitor, review, maintain and improve an organization's QMS 	<ol style="list-style-type: none"> 1. Knowledge of the concepts, principles and terminology related to management systems and the "Plan-Do-Check-Act" (PDCA) model 2. Knowledge of the principal characteristics of an integrated management system 3. Knowledge of the main advantages of a certification for an organization 4. Knowledge of the ISO 9001 requirements presented in clauses 4 to 10 5. Knowledge of the main steps to establish the QMS, policies, objectives, processes and procedures relevant to managing risk and improving Quality Management to deliver results in accordance with an organization's overall policies and objectives (awareness level) 6. Knowledge of the concept of continual improvement and its application to a QMS

Domain 3: Fundamental audit concepts and principles

Main objective: Ensure that the candidate can understand, is able to interpret, and apply the main concepts and principles related to a QMS audit

Competencies	Knowledge statements
<ol style="list-style-type: none"> 1. Ability to understand, explain and illustrate the application of the audit principles in the context of an ISO 9001 audit 2. Ability to identify and judge situations that would discredit the professionalism of the auditor and the PECB Code of Ethics 3. Ability to identify and evaluate ethical problems taking into account the obligations related to the audit client, auditee, and law enforcement and regulatory authorities 4. Ability to explain, illustrate and apply the audit evidence approach in the context of an ISO 9001 audit 5. Ability to explain and compare the types and characteristics of evidence 6. Ability to determine and justify what type of evidence and how much evidence will be required in the context of a specific QMS audit mission 7. Ability to determine and evaluate the level of materiality and apply the risk-based approach throughout the different phases of an ISO 9001 audit 8. Ability to judge the appropriate level of reasonable assurance needed for a specific ISO 9001 audit mission 	<ol style="list-style-type: none"> 1. Knowledge of the main audit concepts and terminology as described in ISO 19011 2. Knowledge of the differences between first party, second party and third party audits 3. Knowledge of the following audit principles: integrity, fair presentation, due professional care, professional judgment, professional skepticism, confidentiality, independence and risk-based approach 4. Knowledge of the professional responsibility of an auditor and the PECB Code of Ethics. 5. Knowledge of evidence-based approach in an audit 6. Knowledge of the different types of evidences: physical, mathematical, confirmative, technical, analytical, documentary and verbal 7. Knowledge of the quality of audit evidences (competent, appropriate, reliable and sufficient) and the factors that will influence them 8. Knowledge of the risk-based approach in an audit and the different types of risks related to audit activities 9. Knowledge of the concept of materiality and its application in an audit 10. Knowledge of the concept of reasonable assurance and its applicable in an audit

Domain 4: Preparing an ISO 9001 audit

Main objective: Ensure that the candidate is able to prepare a QMS audit

Competencies	Knowledge statements
<ol style="list-style-type: none"> 1. Ability to understand and explain the steps and activities to prepare a QMS audit taking into consideration the specific context and conditions of the audit mission 2. Ability to understand and explain the roles and responsibilities of the audit team leader, audit team members and technical experts 3. Ability to determine, evaluate and confirm the audit objectives, the audit criteria and the audit scope for a specific ISO 9001 audit mission 4. Ability to conduct a feasibility study of an audit in the context of a specific ISO 9001 audit mission 5. Ability to explain, illustrate and define the characteristics of the audit terms of engagement and apply the best practices to establish a first contact with an auditee in the context of a specific ISO 9001 audit mission 6. Ability to develop audit working papers and elaborate appropriate audit test plans in the context of a specific ISO 9001 audit mission 	<ol style="list-style-type: none"> 1. Knowledge of the main responsibilities of the audit team leader and audit team members 2. Knowledge of the roles and responsibilities of technical experts in an audit 3. Knowledge of the definition of audit objectives, audit scope and audit criteria 4. Knowledge of the difference between the QMS scope and the audit scope 5. Knowledge of the elements to review during the feasibility study of an audit 6. Knowledge of the cultural aspects to consider in an audit 7. Knowledge of the characteristics of audit terms of engagement and the best practices to establish a first contact with an auditee 8. Knowledge of the preparation of an audit plan 9. Knowledge of the preparation and development of audit working papers 10. Knowledge of the advantages and disadvantages of using audit checklists 11. Knowledge of the best practices for the creation of audit test plans

Domain 5: Conducting an ISO 9001 audit

Main objective: Ensure that the candidate can efficiently conduct a QMS audit

Competencies	Knowledge statements
<ol style="list-style-type: none"> 1. Ability to organize and conduct the opening meeting in the context of a specific ISO 9001 audit mission 2. Ability to conduct a stage 1 audit in the context of a specific ISO 9001 audit mission and taking into account the documentation review conditions and criteria 3. Ability to conduct a stage 2 audit in the context of a specific ISO 9001 audit mission by applying the best practices of communication to collect the appropriate evidence and taking into account the roles and responsibilities of all people involved 4. Ability to explain, illustrate and apply statistical techniques and main audit sampling methods. 5. Ability to objectively gather appropriate evidence from the available information during an audit and evaluate it objectively 	<ol style="list-style-type: none"> 1. Knowledge of the objectives and the content of the opening meeting of an audit 2. Knowledge of the difference between stage 1 audit and stage 2 audit 3. Knowledge of stage 1 audit requirements, steps and activities 4. Knowledge of the documentation review criteria 5. Knowledge of the documentation requirements stated in ISO 9001 6. Knowledge of stage 2 audit requirements, steps and activities 7. Knowledge of the best practices of communication during an audit 8. Knowledge of the roles and responsibilities of guides and observers during an audit 9. Knowledge of the conflict resolution techniques 10. Knowledge of evidence collection procedures: observation, documentation review, interviews, analysis and technical verification 11. Knowledge of evidence analysis procedures: corroboration and evaluation 12. Knowledge of the main concepts, principles and statistical techniques used in an audit 13. Knowledge of the main audit sampling methods and their characteristics

Domain 6: Closing an ISO 9001 audit

Main objective: Ensure that the candidate is able to conclude a QMS audit and conduct audit follow-up activities

Competencies	Knowledge statements
<ol style="list-style-type: none"> 1. Ability to explain and apply the evaluation process of evidences to draft audit findings and prepare audit conclusions 2. Ability to understand, explain and illustrate the different levels of conformity and the concept of the benefit of the doubt 3. Ability to report appropriate audit observations in order to help an organization improve a QMS with respect to audit rules and principles 4. Ability to complete audit working documents and conduct a quality review of an ISO 9001 audit 5. Ability to draft audit conclusions and present these to the management of the audited organization 6. Ability to organize and conduct an audit closing meeting 7. Ability to write an ISO 9001 audit report and justify a certification recommendation 8. Ability to conduct the activities following an initial audit including the evaluation of action plans, follow-up audits, surveillance 	<ol style="list-style-type: none"> 1. Knowledge of the evaluation process of evidences to draft audit findings and prepare audit conclusions 2. Knowledge of the differences and the characteristics between the concepts of conformity, minor nonconformity, major nonconformity, anomaly and observation. 3. Knowledge of the guidelines and best practices to write nonconformity reports 4. Knowledge of the guidelines and best practices to draft and report audit observations 5. Knowledge of the principle of the benefit of the doubt and its application in the context of an audit. 6. Knowledge of the guidelines and best practices to complete audit working documents and perform a quality review of an audit 7. Knowledge of the guidelines and best practices to present audit findings and conclusions to the management of an audited organization 8. Knowledge of the possible recommendations that an auditor can issue in the context of a certification audit and the certification decision process 9. Knowledge of the guidelines and best practices to evaluate action plans 10. Knowledge of follow-up audits, surveillance audits and recertification audit requirements, steps and activities 11. Knowledge of the conditions for modification, extension, suspension or withdrawal of a certification for an organization

Domain 7: Managing an ISO 9001 audit program

Main objective: Ensure that the understands how to establish and manage a QMS audit program

Competencies	Knowledge statements
<ol style="list-style-type: none"> 1. Ability to understand and explain the establishment of an audit program and the application of the PDCA model 2. Ability to understand and explain the implementation of an ISO 9001 audit program (first party, second party and third party) 3. Ability to understand and explain the responsibilities to protect the integrity, availability and confidentiality of audit records. 4. Ability to understand the requirements related to the components of the management system of an audit program as quality management, record management, and complaint management 5. Ability to understand the evaluation of the efficiency of the audit program by monitoring the performance of each auditor, each team and the entire certification body 6. Ability to demonstrate the application of the personal attributes and behaviors associated with professional auditors 	<ol style="list-style-type: none"> 1. Knowledge of the application of the PDCA model in the management of an audit program 2. Knowledge of the requirements, guidelines and best practices regarding audit resources, procedures and policies 3. Knowledge of the types of tools used by professional auditors 4. Knowledge of the requirements, guidelines and best practices regarding the management of audit records 5. Knowledge of the application of the concept of continual improvement to the management of an audit program 6. Knowledge of the particularities to implement and manage a first, second or third party audit program 7. Knowledge of the management of combined audit activities 8. Knowledge of the concept of competency and its application to auditors 9. Knowledge of the personal attributes and behavior of a professional auditor

Based on the above mentioned domains and their relevance, 12 questions are included in the exam, as summarized in the following table:

		Level of understanding (Cognitive/Taxonomy) required				% of test devoted to each competency domain	Number of points per competency domain	% of points per competency domain
		Points per question	Questions that measure comprehension, application and analysis	Questions that measure synthesis and evaluation	Number of questions per competency domain			
Competency domains	Fundamental principles and concepts of a quality management system (QMS)	5	X		1	8.33	5	6.67
	Quality management systems (QMS)	5	X		3	25.00	20	26.67
		10	X					
		5	X					
	Fundamental audit concepts and principles	5	X		1	8.33	5	6.67
	Preparing an ISO 9001 audit	5	X		1	8.33	5	6.67
	Conducting an ISO 9001 audit	10		X	3	25.00	20	26.67
		5		X				
		5		X				
	Closing an ISO 9001 Audit	5		X	2	16.66	15	20.00
		10		X				
	Managing an ISO 9001 audit program	5		X	1	8.33	5	6.67
Total points		75	6	6				
Number of questions per level of understanding								
% of the exam devoted to each level of understanding (cognitive/taxonomy)			50.00	50.00				

The exam passing score is **70%**.

After successfully passing the exam, candidates will be able to apply for the “PECB Certified ISO 9001 Lead Auditor” credential depending on their level of experience.

General Information on the Exam

Candidates are required to arrive/be present at least 30 minutes before the exam starts. Candidates who arrive late will not be given additional time to compensate for the late arrival and may not be allowed to sit for the exam.

Candidates are required to bring a valid identity card (a national ID card, driver's license, or passport) and show it to the invigilator.

If requested on the day of the exam (paper-based exams), additional time can be provided to candidates taking the exam in a non-native language, as follows:

- 10 additional minutes for Foundation exams
- 20 additional minutes for Manager exams
- 30 additional minutes for Lead exams

PECB Exam Format and Type

1. Paper-based: Exams are provided on paper, where candidates are not allowed to use anything but the exam paper and a pen. The use of electronic devices, such as laptops, tablets, or phones, is not allowed. The exam session is supervised by a PECB approved Invigilator at the location where the Reseller has organized the training course.

2. Online: Exams are provided electronically via the PECB Exams application. The use of electronic devices, such as tablets and cell phones, is not allowed. The exam session is supervised remotely by a PECB Invigilator via the PECB Exams application and an external/integrated camera.

For more detailed information about the online format, please refer to the [PECB Online Exam Guide](#).

PECB exams are available in two types:

1. Essay-type question exam
2. Multiple-choice question exam

This exam comprises essay-type questions. They are used to determine and evaluate whether a candidate can clearly answer questions related to the defined competency domains. Additionally, problem-solving techniques and arguments that are supported with reasoning and evidence will also be evaluated.

The exam is open book and is not intended to measure memorizing or recalling information. It aims to evaluate candidates' comprehension, analytical skills, and applied knowledge. Therefore, candidates are required to provide logical and convincing answers and explanations in order to demonstrate that they have understood the content and the main concepts of the competency domains.

Since the exam is “open book,” candidates are authorized to use the following reference materials:

- A hard copy of ISO 9001 standard
- Training course materials (accessed through PECB Exams app and/or printed)
- Any personal notes made by the candidate during the training course (accessed through PECB Exams app and/or printed)
- A hard copy dictionary

Any attempts to copy, collude, or otherwise cheat during the exam session will automatically lead to failure of the exam.

PECB exams are available in English and other languages. For the availability of the exam in a particular language, please contact examination@pecb.com.

Note: PECB will progressively transition to multiple-choice exams. They will also be open book and comprise scenario-based questions that will allow PECB to evaluate candidates' knowledge, abilities, and skills to use information in new situations (apply), draw connections among ideas (analyze), and justify a stand or decision (evaluate). All PECB multiple-choice exams have one question and three alternatives, of which only one is correct.

For specific information about exam types, languages available, and other details, visit the [List of PECB Exams](#).

Receiving the Exam Results

Exam results will be communicated via email. The only possible results are *pass* and *fail*; no specific grade will be included.

- The time span for the communication starts from the exam date and lasts three to eight weeks for essay type exams and two to four weeks for multiple-choice paper-based exams
- For online multiple-choice exams, candidates receive their results instantly

Candidates who successfully complete the exam will be able to apply for one of the credentials of the respective certification scheme.

For candidates who fail the exam, a list of the domains where they have performed poorly will be added to the email to help them prepare better for a retake.

Candidates that disagree with the results may request for a re-evaluation by writing to results@pecb.com within 30 working days of receiving the results. Re-evaluation requests received after 30 days will not be processed. If candidates do not agree with the results of the reevaluation, they have 30 working days from the date when they received the reevaluated exam results to file a complaint through the [PECB Ticketing System](#). Complaints received after 30 days will not be processed.

Exam Retake Policy

There is no limit on the number of times that a candidate may retake an exam. However, there are certain limitations in terms of the allowed time frames between exam retakes.

- If a candidate does not pass the exam on the 1st attempt, they must wait 15 days from the initial date of the exam for the next attempt (1st retake). Retake fees apply.

Note: *Candidates who have completed the training course but failed the exam are eligible to retake the exam once for free within a 12-month period from the initial date of the exam.*

- If a candidate does not pass the exam on the 2nd attempt, they must wait three months after the initial date of the exam for the next attempt (2nd retake). Retake fees apply.

Note: *For candidates that fail the exam in the 2nd retake, PECB recommends them to attend a training course in order to be better prepared for the exam.*

- If a candidate does not pass the exam on the 3rd attempt, they must wait six months after the initial date of the exam for the next attempt (3rd retake). Retake fees apply.
- After the 4th attempt, the waiting period for further retake exams is 12 months from the date of the last attempt. Retake fees apply.

To arrange exam retakes (date, time, place, costs), candidates need to contact the PECB Reseller/Distributor who has initially organized the session.

Reschedule the Exam

For any changes with regard to the exam date, time, location, or other details, please contact examination@pecb.com.

Closing a Case

If a candidate does not apply for the certificate within three years, their case will be closed. Candidates whose case has been closed due to the expiration of the certification period have the right to request to reopen their case. However, PECB will no longer be responsible for any changes in the conditions, standards, policies, candidate handbook, or exam preparation guide that were applicable before the case was closed. A candidate requesting their case to reopen must do so in writing and pay the required fee.

A significant component of a successful and respected professional certification credential is maintaining the security and confidentiality of the exam. PECB relies upon the ethical behavior of certificate holders and applicants to maintain the security and confidentiality of PECB exams. Any disclosure of information about the content of PECB exams indicates violation of PECB's Code of Ethics. PECB will take action against individuals who violate PECB Policies and the Code of Ethics. These actions include permanently barring individuals from pursuing PECB credentials and revoking the awarded credentials. PECB will also pursue legal action against individuals or organizations who infringe upon its copyrights, proprietary rights, and intellectual property.

Sample Exam Questions

Question 1: Evaluation of Corrective Actions

You have received a corrective action plan for review. Please evaluate the effectiveness of the proposed corrective actions. If you agree with these corrective actions, please explain why. If you do not agree, please explain why and propose an alternative more adequate corrective action.

- Nonconformity: A nonconformity was observed because the Human Resources team was not aware of a procedure that requires them to record the education, training, and experience of all employees

Corrective action: Inform (Timeframe: immediately) and train (Timeframe: within 6 months) the Human Resources team about this procedure and require that each member of the team follow it

Possible answer:

I agree with the proposed corrective action. This solves the problem of the lack of knowledge about the existence of a procedure. As an auditor, a sampling will be performed during the surveillance audit to find out if the procedure is followed correctly

Question 2: Writing of a Test Plan

Write a test plan to validate conformity to the following clause by identifying the different applicable audit procedures (observation, documented information review, interview, technical verification and analysis):

Clause 7.5.3 Control of documented information:

Possible answer:

<p>Clause 7.5.3 Control of documented information: Documented information required by the quality management system and by ISO 9001 shall be controlled to ensure:</p> <ul style="list-style-type: none"> a) It is available and suitable for use, where and when it is needed b) It is adequately protected (e.g. from loss of confidentiality, improper use or loss of integrity) 	
Observation	<i>Observe how employees ensure the protection of documented information and whether those actions are consistent with the organization's policies and procedures</i>
Documented information	<i>Policy on documented information management and procedures on information lifecycle management: their identification, storage, backup, protection, accessibility and conservation</i>
Interview	<i>Members of management (to confirm the policies and the organization's needs related to documented information) and the personnel responsible for information management and archiving (to obtain the documented information management details)</i>
Technical verification	<i>Validate the electronic structure for classifying and storing documented information, verify their protection mechanisms, and observe the compilation of the automated journals report</i>
Analysis	<i>Select documented information samples and verify if they respect the documentation structure and policy criteria on documented information</i>

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PECB Help Center

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