



When Recognition Matters



EXAM PREPARATION GUIDE

PECB Certified ISO 9001 Lead Auditor

The objective of the “**PECB Certified ISO 9001 Lead Auditor**” examination is to ensure that the candidate possesses the necessary expertise to perform a Quality Management System (QMS) audit and to manage an audit team by applying widely recognized audit principles, procedures and techniques. The aim of the exam is to evaluate that the candidate possesses the knowledge and skills to proficiently plan and carry out internal and external audits in compliance with ISO 19011 and ISO/IEC 17021-1 certification process.

The target population for this examination is:

- Auditors seeking to perform and lead Quality Management System (QMS) certification audits
- Managers or consultants seeking to master a Quality Management System audit process
- Individuals responsible for maintaining conformance with QMS requirements
- Technical experts seeking to prepare for a Quality Management System audit
- Expert advisors in Quality Management

The exam content 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:** Preparation of 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: To ensure that the ISO 9001 Lead Auditor candidate can understand, interpret and illustrate the main Quality Management concepts related to a Quality Management System (QMS).

Competencies	Knowledge statements
<ol style="list-style-type: none"> 1. Understand and explain the operations of the ISO organization and the development of Quality Management standards. 2. Ability to identify, analyze and evaluate the Quality Management compliance requirements for an organization. 3. Understand the Quality Management tools and techniques. 4. Ability to explain and illustrate the main concepts in Quality Management. 	<ol style="list-style-type: none"> 1. Knowledge of the application of the seven ISO management principles in Quality Management. 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)

Main objective: To ensure that the ISO 9001 Lead Auditor candidate can understand, interpret and illustrate the main concepts and components of a Quality Management System based on ISO 9001.

Competencies	Knowledge statements
<ol style="list-style-type: none"> 1. 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. 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: To ensure that the ISO 9001 Lead Auditor candidate can understand, interpret and apply the main concepts and principles related to a QMS audit in the context of ISO 9001.

Competencies	Knowledge statements
<ol style="list-style-type: none"> 1. 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 during 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 and independence. 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: Preparation of an ISO 9001 audit

Main objective: To ensure that the ISO 9001 Lead Auditor candidate can prepare a QMS audit in the context of ISO 9001 appropriately.

Competencies	Knowledge statements
<ol style="list-style-type: none"> 1. 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. 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: To ensure that the ISO 9001 Lead Auditor candidate can efficiently conduct a QMS audit in the context of ISO 9001.

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: To ensure that the ISO 9001 Lead Auditor candidate can conclude a QMS audit and conduct follow-up activities in the context of ISO 9001.

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. 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: To ensure that the ISO 9001 Lead Auditor understands how to establish and manage a QMS audit program.

Competencies	Knowledge statements
<ol style="list-style-type: none"> 1. Understand and explain the establishment of an audit program and the application of the PDCA model. 2. Understand and explain the implementation of an ISO 9001 audit program (first party, second party and third party). 3. Understand and explain the responsibilities to protect the integrity, availability and confidentiality of audit records. 4. Understand the requirements related to the components of the management system of an audit program as quality management, record management, and complaint management. 5. 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 these 7 domains and their relevance, twelve (12) questions are included in the exam, as summarized in the following table:

		Points per Question	Questions that measure Comprehension, Application and Analysis	Level of Understanding (Cognitive/Taxonomy) Required		% of test devoted to each competency domain	Number of Points per competency domain	% of Points per competency domain
				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 System (QMS)	10	X		2	16.67	15	20.00
		5	X					
	Fundamental audit concepts and principles	5	X		2	16.67	10	13.33
		5	X					
	Preparation of an ISO 9001 Audit	5	X		2	16.67	10	13.33
		5	X					
	Conducting an ISO 9001 audit	5		X	3	25.00	20	26.67
		5		X				
		10		X				
	Closing an ISO 9001 Audit	5		X	1	8.33	5	6.67
	Managing an ISO 9001 audit program	10		X	1	8.33	10	13.33
Total points		75						
Number of Questions per level of understanding			7	5				
% of Test Devoted to each level of understanding (cognitive/taxonomy)			58.33	41.67				

The passing score is **70%**.

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

TAKE A CERTIFICATION EXAM

Candidates will be required to arrive at least thirty (30) minutes before the beginning of the certification exam. Candidates that arrive late will not be given additional time to compensate for the late arrival, and may be denied entry to the exam room (if they arrive more than 5 minutes after the beginning of the exam scheduled time).

All candidates will need to present a valid identity card with a picture such as a driver's license or a government ID to the invigilator.

The exam duration is three (3) hours.

The questions are essay type questions. This type of format was chosen because the intent is to determine whether an examinee can write a clear coherent answer/argument and to assess problem solving techniques. Because of this particularity, the exam is set to be "open book" and does not measure the recall of data or information. The examination evaluates comprehension, application, analysis, synthesis and evaluation, which means that even if the answer is in the course material, candidates will have to justify and give explanations, to show they really understood the concepts. At the end of this document, you will find sample exam questions and their possible answers.

As the exams are "open book"; candidates are only authorized to use:

- A copy of the ISO 9001:2015 standard;
- Course notes from the Participant Handout;
- Any personal notes made by the student during the course; and
- A hard copy dictionary.

The use of electronic devices, such as laptops, cell phones, etc., is not allowed.

All attempts to copy, collude or otherwise cheat during the exam will automatically lead to a disqualification.

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

RECEIVE YOUR EXAM RESULTS

Results will be communicated by email in a period of 6 to 8 weeks, after taking the exam. The results will not include the exact grade of the candidate, only a mention of pass or fail

Candidates who successfully complete the examination will be able to apply for a certified scheme.

In case of a failure, the results will be accompanied with the list of domains in which the candidate had a low grade, to provide guidance for exams' retake preparation.

Candidates who disagree with the exam results may file a complaint by writing to examination@pecb.com. For more information, please refer to www.pecb.com.

EXAM RETAKE POLICY

There is no limit on the number of times a candidate may retake an exam. However, there are some limitations in terms of allowed time-frame in between exam retakes, such as:

- If a candidate does not pass the exam on the first attempt, he/she must wait 15 days for the next attempt (1st retake). Retake fee applies.

Note: *Students, who have completed the full training but failed the written 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 second attempt, he/she must wait 3 months (from the initial date of the exam) for the next attempt (2nd retake). Retake fee applies.
- If a candidate does not pass the exam on the third attempt, he/she must wait 6 months (from the initial date of the exam) for the next attempt (3rd retake). Retake fee applies.

After the fourth attempt, a waiting period of 12 months from the last session date is required, in order for candidate to sit again for the same exam. Regular fee applies.

For the candidates that fail the exam in the 2nd retake, PECB recommends to attend an official training in order to be better prepared for the exam.

To arrange exam retakes (date, time, place, costs), the candidate needs to contact the PECB partner who has initially organized the session.

CLOSING FILES

Closing a file is equivalent to rejecting a candidate's application. As a result, when candidates request that their file be reopened, PECB will no longer be bound by the conditions, standards, policies, candidate handbook or exam preparation guide that were in effect before their file was closed.

Candidates who want to request that their file be reopened must do so in writing, and pay the required fees.

EXAMINATION SECURITY

A significant component of a successful and respected professional certification credential is maintaining the security and confidentiality of the examination. PECB relies upon the ethical behaviour of certificate holders and applicants to maintain the security and confidentiality of PECB examinations. When someone who holds PECB credentials reveals information about PECB examination content, they violate the PECB Code of Ethics. PECB will take action against individuals who violate PECB Policies and the Code of Ethics. Actions taken may include permanently barring individuals from pursuing PECB credentials and revoking certifications from those who have been awarded the credential. PECB will also pursue legal action against individuals or organizations who infringe upon its copyrights, proprietary rights, and intellectual property rights.

SAMPLE EXAM QUESTIONS AND POSSIBLE ANSWERS

1. Evaluation of corrective actions

You have received a corrective action plan. Please evaluate the adequacy of the proposed corrective actions. If you agree with the corrective actions, please explain why. If you disagree, please explain why and propose the 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. This solves the problem of a 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.

2. Writing of a test plan

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

- *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:*
 - o *it is available and suitable for use, where and when it is needed;*
 - o *it is adequately protected (e.g. from loss of confidentiality, improper use or loss of integrity).*

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"> • it is available and suitable for use, where and when it is needed; • it is adequately protected (e.g. from loss of confidentiality, improper use or loss of integrity). 	
Observation	<p>Observe how employees ensure the protection of documented information and whether those actions are consistent with the organization's policies and procedures.</p>

Document	Policy on documented information management and procedures on information lifecycle management: their identification, storage, backup, protection, accessibility and conservation.
Interview	Member 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).
Technical verification	Validate the electronic structure for classifying and storing documented information, verify their protection mechanisms, and observe the compilation of the automated journals report.
Analysis	Select documented information samples and verify if they respect the documentation structure and policy criteria on documented information.