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BEYOND RECOGNITION

Exam Preparation Guide

ISO 9001 Lead Implementer

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The objective of the "PECB Certified ISO 9001 Lead Implementer" exam is to ensure that the candidate has the necessary competence to support an organization in establishing, implementing, managing, and maintaining a quality management system (QMS).

The ISO 9001 Lead Implementer exam is intended for:

- Managers or consultants involved in quality management
- Expert advisors seeking to master the implementation of a quality management system
- Individuals responsible for maintaining conformance with QMS requirements
- QMS team members

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:** Planning the QMS implementation
- **Domain 4:** Implementing a QMS
- **Domain 5:** Performance evaluation, monitoring and measurement of a QMS
- **Domain 6:** Continual improvement of a QMS based on ISO 9001
- **Domain 7:** Preparing for a QMS certification audit

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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 and is able to interpret ISO 9001 principles and concepts

Competencies	Knowledge statements
1. Ability to understand and explain an ISO operations and the development of the ISO 9001 standard 2. Ability to identify, analyze and evaluate the quality management compliance requirements for an organization 3. Ability to explain and illustrate the main concepts in quality management	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: laws, regulations, international and industry standards, contracts, market practices, internal policies 4. Knowledge of the main quality management concepts and terminology as described in ISO 9001 5. Knowledge of the concept of risk-based thinking and its application in quality management

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Domain 2: Quality management system (QMS)

Main objective: Ensure that the candidate understands, is able to interpret, and provide guidance on how to implement and manage a quality management system requirements based on the best practices of ISO 9001

Competencies	Knowledge statements
1. Ability to identify, understand, classify, and explain the requirements of the clauses of ISO/IEC 9001	1. Knowledge of operational planning and control.
2. Ability to detail and illustrate the requirements and best practices through concrete examples	2. Knowledge of various quality management methodologies and their incorporation in the organizational quality management system based on ISO 9001
3. Ability to compare possible solutions to a quality management issue of an organization and identify/analyze the strengths and weaknesses of each proposed solution	3. Knowledge of quality management strategies.
	4. Knowledge of establishing and implementing quality management procedures
4. Ability to select and demonstrate the best quality management solutions in order to address the quality management objectives set by the organization	5. Knowledge of the best practices in Quality Management
	6. Knowledge of the requirements of clauses 4 to 10 of ISO 9001
5. Ability to create and justify an action plan to implement a quality management by listing the related activities	7. Knowledge on continual improvement and practical implementation based on ISO 9001
6. Ability to analyze, evaluate and validate action plans to implement a specific requirement	

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Domain 3: Planning the QMS implementation

Main objective: Ensure that the candidate is able to plan the implementation of the QMS based on ISO 9001 certification

Competencies	Knowledge statements
1. Ability to manage a QMS implementation project by following the best practices of project management 2. Ability to observe, analyze and interpret the necessary information to plan a QMS implementation 3. Ability to observe, analyze and interpret the internal and external environment of an organization 4. Ability to perform a gap analysis and clarify the quality management objectives of an organization 5. Ability to state and justify a QMS scope based on the quality objectives of an organization 6. Ability to select and justify the selected approach and methodology adapted to the needs of the organization 7. Ability to perform the different steps of the risk assessment and risk treatment phases	1. Knowledge of the main project management concepts, terminology, process and best practices 2. Knowledge of the principal approaches and methodology frameworks to implement a QMS 3. Knowledge of the main concepts and terminology related to organizations 4. Knowledge of an organization's internal and external environment 5. Knowledge of the main interested parties related to an organization and their characteristics 6. Knowledge of the techniques to gather information on an organization and perform a Gap Analysis of a management system 7. Knowledge of the characteristics of a QMS scope in terms of organizational, quality system and physical boundaries 8. Knowledge of the different approaches and main methodology characteristics to perform a risk assessment 9. Knowledge of the main activities of the risk identification, estimation, evaluation related to the environment included in a QMS of an organization

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Domain 4: Implementing a QMS

Main objective: Ensure that the candidate is able to implement the processes of a QMS required for an ISO 9001 certification

Competencies	Knowledge statements
1. Ability to understand and analyze the needs and provide guidance on the attribution of roles and responsibilities in the context of a QMS implementation and management 2. Ability to define the documentation and record management processes needed to support the implementation and operations of a QMS 3. Ability to define and design processes and properly document them 4. Ability to define and write QMS policies and procedures 5. Ability to implement the required processes of a QMS 6. Ability to define and implement appropriate quality management training, awareness and communication plans 7. Ability to define and implement a customer support process based on quality management principles and best practices. 8. Ability to transfer a QMS project to operations and manage the change management process	1. Knowledge for the roles and responsibilities of the key interested parties during and after the implementation and operation of a QMS 2. Knowledge of the main organizational structures applicable for an organization to manage quality management system 3. Knowledge of the best practices on documentation and record management processes and the documentation management lifecycle 4. Knowledge of the characteristics and the differences between the different documents related to QMS: policies, procedures, guidelines, standards, worksheets, etc. 5. Knowledge of model-building controls, process techniques and best practices 6. Knowledge of implementing processes, controls, best practices and techniques 7. Knowledge of the techniques and best practices to write quality management policies, procedures and other types of documentation included in a QMS 8. Knowledge of the characteristics and the best practices to implement quality management training, awareness and communication plans 9. Knowledge of the characteristics and the main processes of a quality management customer support process based on best practice. 10. Knowledge of best practices and techniques in change management

Domain 5: Monitoring, measurement, analysis and evaluation of a QMS

Main objective: Ensure that the candidate is able to evaluate, monitor and measure the performance of a QMS

Competencies	Knowledge statements
1. Ability to monitor and evaluate the effectiveness of a QMS 2. Ability to verify to what extent the identified quality management requirements have been met 3. Ability to define and implement an internal audit program for ISO 9001 4. Ability to perform regular and methodical reviews regarding the suitability, adequacy, effectiveness and efficiency of a QMS based on the policies and objectives of the organization 5. Ability to define and implement a management review process and counsel management on it	1. Knowledge of the techniques and best practices to monitor the effectiveness of a QMS 2. Knowledge of the main concepts and components related to a quality management measurement programme: measures, attributes, indicators, dashboards, etc. 3. Knowledge of the characteristics and differences between operational, tactical and strategic quality management indicators and dashboards 4. Knowledge of the techniques and methods to define and document adequate and reliable indicators. 5. Knowledge of the main concepts and components related to the implementation of a QMS internal audit program 6. Knowledge of the differences between the concepts of major and minor nonconformities, anomalies and observations 7. Knowledge of the guidelines and best practices to write a nonconformity report 8. Knowledge of the best practices on how to perform management reviews

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Domain 6: Continual improvement of a QMS

Main objective: Ensure that the candidate is able to provide guidance on the continual improvement of a QMS

Competencies	Knowledge statements
1. Ability to understand the principles and concepts related to continual improvement	1. Knowledge of the main concepts related to continual improvement
2. Ability to counsel an organization on how to continually improve the effectiveness and the efficiency of a QMS	2. Knowledge of the characteristics and differences between the concepts of effectiveness and efficiency
3. Ability to implement QMS continual improvement processes in an organization	3. Knowledge of the concepts and techniques to perform benchmarking
4. Ability to determine the appropriate business improvement tools to support continual improvement processes of an organization	4. Knowledge of the main processes, tools and techniques used by professionals to identify the root-causes of nonconformities
5. Ability to identify, analyze the root-causes of nonconformities and propose action plans to treat them	5. Knowledge of the characteristics and the differences between corrective and preventive actions
6. Ability to identify, analyze the root-cause of potential nonconformities and propose action plans to treat them	6. Knowledge of the main processes, tools and techniques used by professionals to develop and propose the best corrective and preventive action plans

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Domain 7: Preparing for a QMS certification audit

Main objective: Ensure that the ISO 9001 Lead Implementer candidate is able to prepare and assist an organization for the certification against ISO 9001

Competencies	Knowledge statements
1. Ability to understand the main steps, processes and activities related to an ISO 9001 certification audit 2. Ability to understand, explain and illustrate the audit evidence approach in the context of an ISO 9001 audit 3. Ability to counsel an organization to identify and select a certification body that meets their needs 4. Ability to review the readiness of an organization for an ISO 9001 certification audit 5. Ability to coach and prepare an organization's personnel for an ISO 9001 certification audit certification audit 6. Ability to argue and challenge the audit findings and conclusions with external auditors	1. Knowledge of the evidence based approach in an audit 2. Knowledge of the different types of evidence: physical, mathematical, confirmative, technical, analytical, documentary and verbal 3. Knowledge of the differences between Stage 1 and Stage 2 audits 4. Knowledge of Stage 1 audit requirements, steps and activities 5. Knowledge of the documentation review criteria 6. Knowledge of Stage 2 audit requirements, steps and activities 7. Knowledge of follow-up audit requirements, steps and activities 8. Knowledge of surveillance audits and recertification audit requirements, steps and activities 9. Knowledge of the requirements, guidelines and best practices to develop action plans following an ISO 9001 certification audit

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					
	Points per question	Questions that measure comprehension, application and analysis	Questions that measure synthesis and evaluation	Number of questions per competency domain	% of test devoted to each competency domain	Number of points per competency domain	% of points per competency domain
Fundamental principles and concepts of a quality management system (QMS))	5	X		2	16.67	10	13.33
	5	X					
Quality management system (QMS)	5	X		2	16.67	15	20.00
	10	X					
Planning the QMS implementation	5	X		1	8.33	5	6.67
Implementing a QMS	10		X	2	16.67	15	20.00
	5		X				
Performance evaluation, monitoring and measurement of a QMS	10		X	1	8.33	10	13.33
Continual improvement of a QMS based on ISO 9001	5		X	3	25.00	15	20.00
	5		X				
	5		X				
Preparing for a QMS certification audit	5		X	1	8.33	5	6.67
Total points	75						
Number of questions per level of understanding		5	7				
% of test devoted to each level of understanding (cognitive/taxonomy)		41.67	58.33				

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

After successfully passing the exam, candidates will be able to apply for the "PECB Certified ISO 9001 Lead Implementer" 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

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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.

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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.

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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.

Exam Security

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: Interpretation of ISO clauses

For each of the following clauses of ISO 9001, please provide an action plan with at least two concrete actions that would be acceptable to ensure conformity to the clause and fulfill control objectives.

Clause 5.2.2 Communicating the quality policy

Possible answer:

- *Organize awareness sessions to communicate the quality policy and its importance to all employees within the organization*

- *Develop a communication strategy and document it*

Question 2: Recommendations

The organization's management would like you to provide recommendations to improve the processes in place to comply with the requirements of ISO 9001 on control of documents.

Possible answer:

- *Document and implement a procedure for the control of documents*

- *Maintain a log for document changes with records of the approvals*

- *Communicate the new process and organize the training session*