



*When Recognition Matters*



# **EXAM PREPARATION GUIDE**

**PECB Certified ISO 9001 Lead Implementer**

The objective of the “**PECB Certified ISO 9001 Lead Implementer**” examination is to ensure that the candidate has acquired the necessary skills and competencies to support an organization in establishing, implementing, managing and maintaining a Quality Management System (QMS) based on ISO 9001.

**The target population for this examination is:**

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

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 Implementer 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"> <li>1. Understand and explain the operations of the ISO organization and the development of Quality Management standards.</li> <li>2. Ability to identify, analyze and evaluate the Quality Management compliance requirements for an organization.</li> <li>3. Ability to explain and illustrate the main concepts in Quality Management.</li> </ol>	<ol style="list-style-type: none"> <li>1. Knowledge of the application of the seven ISO management principles in Quality Management.</li> <li>2. Knowledge of the main standards in Quality Management.</li> <li>3. Knowledge of the different sources of Quality Management requirements for an organization: laws, regulations, international and industry standards, contracts, market practices, internal policies.</li> <li>4. Knowledge of the main Quality Management concepts and terminology as described in ISO 9001.</li> <li>5. Knowledge of the concept of risk-based thinking and its application in Quality Management.</li> </ol>

## Domain 2: Quality Management System (QMS)

**Main objective:** To ensure that the ISO 9001 Lead Implementer candidate can understand, interpret and provide guidance on how to implement and manage Quality Management requirements based on the best practices of ISO 9001.

Competencies	Knowledge statements
<ol style="list-style-type: none"> <li>1. Ability to identify, understand, classify, and explain the requirements of the clauses of ISO 9001.</li> <li>2. Ability to detail and illustrate the requirements and best practices through concrete examples.</li> <li>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.</li> <li>4. Ability to select and demonstrate the best Quality Management solutions in order to address the Quality Management objectives set by the organization.</li> <li>5. Ability to create and justify an action plan to implement a Quality Management by listing the related activities.</li> <li>6. Ability to analyze, evaluate and validate action plans to implement a specific requirement.</li> </ol>	<ol style="list-style-type: none"> <li>1. Knowledge of operational planning and control.</li> <li>2. Knowledge of various quality management methodologies and their incorporation in the organizational quality management system based on ISO 9001.</li> <li>3. Knowledge of Quality Management strategies.</li> <li>4. Knowledge of establishing and implementing Quality Management procedures.</li> <li>5. Knowledge of the best practices in Quality Management.</li> <li>6. Knowledge of the requirements of clauses 4 to 10 of ISO 9001.</li> <li>7. Knowledge on continual improvement and practical implementation based on ISO 9001.</li> </ol>

## Domain 3: Planning a QMS implementation based on ISO 9001

**Main objective:** To ensure that the ISO 9001 Lead Implementer candidate can plan the implementation of a QMS to prepare for an ISO 9001 certification.

<b>Competencies</b>	<b>Knowledge statements</b>
<ol style="list-style-type: none"> <li>1. Ability to manage a QMS implementation project by following the best practices of project management.</li> <li>2. Ability to observe, analyze and interpret the necessary information to plan the QMS implementation.</li> <li>3. Ability to observe, analyze and interpret the internal and external environment of an organization.</li> <li>4. Ability to perform a Gap Analysis and clarify the Quality Management objectives of an organization.</li> <li>5. Ability to state and justify a QMS scope based on the quality objectives of an organization.</li> <li>6. Ability to select and justify the selected approach and methodology adapted to the needs of the organization.</li> <li>7. Ability to perform the different steps of the risk assessment and risk treatment phases.</li> </ol>	<ol style="list-style-type: none"> <li>1. Knowledge of the main project management concepts, terminology, process and best practices.</li> <li>2. Knowledge of the principal approaches and methodology frameworks to implement a QMS.</li> <li>3. Knowledge of the main concepts and terminology related to organizations</li> <li>4. Knowledge of an organization's internal and external environment.</li> <li>5. Knowledge of the main interested parties related to an organization and their characteristics.</li> <li>6. Knowledge of the techniques to gather information on an organization and perform a Gap Analysis of a management system.</li> <li>7. Knowledge of the characteristics of a QMS scope in terms of organizational, quality system and physical boundaries.</li> <li>8. Knowledge of the different approaches and main methodology characteristics to perform a risk assessment.</li> <li>9. Knowledge of the main activities of the risk identification, estimation, evaluation related to the environment included in the QMS of an organization.</li> </ol>

## Domain 4: Implementing a QMS based on ISO 9001

**Main objective:** To ensure that the ISO 9001 Lead Implementer candidate can implement the processes of a QMS required for an ISO 9001 certification.

Competencies	Knowledge statements
<ol style="list-style-type: none"> <li>1. Ability to understand and analyze the needs and provide guidance on the attribution of roles and responsibilities in the context of the QMS implementation and management.</li> <li>2. Ability to define the documentation and record management processes needed to support the implementation and operations of a QMS.</li> <li>3. Ability to define and design processes and properly document them.</li> <li>4. Ability to define and write QMS policies and procedures.</li> <li>5. Ability to implement the required processes of the QMS.</li> <li>6. Ability to define and implement appropriate Quality Management training, awareness and communication plans.</li> <li>7. Ability to define and implement a customer support process based on Quality Management principles and best practices.</li> <li>8. Ability to transfer a QMS project to operations and manage the change management process.</li> </ol>	<ol style="list-style-type: none"> <li>1. Knowledge for the roles and responsibilities of the key interested parties during and after the implementation and operation of a QMS.</li> <li>2. Knowledge of the main organizational structures applicable for an organization to manage Quality Management System.</li> <li>3. Knowledge of the best practices on documentation and record management processes and the documentation management lifecycle.</li> <li>4. Knowledge of the characteristics and the differences between the different documents related to QMS: policies, procedures, guidelines, standards, worksheets, etc.</li> <li>5. Knowledge of model-building controls, process techniques and best practices.</li> <li>6. Knowledge of implementing processes, controls, best practices and techniques.</li> <li>7. Knowledge of the techniques and best practices to write Quality Management policies, procedures and other types of documentation included in a QMS.</li> <li>8. Knowledge of the characteristics and the best practices to implement Quality Management training, awareness and communication plans.</li> <li>9. Knowledge of the characteristics and the main processes of a quality management customer support process based on best practices.</li> <li>10. Knowledge of best practices and techniques in change management.</li> </ol>

## Domain 5: Performance evaluation, monitoring and measurement of a QMS based on ISO 9001

**Main objective:** To ensure that the ISO 9001 Lead Implementer candidate can evaluate, monitor and measure the performance of a QMS in the context of an ISO 9001 certification.

<b>Competencies</b>	<b>Knowledge statements</b>
<ol style="list-style-type: none"> <li>1. Ability to monitor and evaluate the effectiveness of a QMS.</li> <li>2. Ability to verify to what extent the identified Quality Management requirements have been met.</li> <li>3. Ability to define and implement an internal audit program for ISO 9001.</li> <li>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.</li> <li>5. Ability to define and implement a management review process and counsel management on it.</li> </ol>	<ol style="list-style-type: none"> <li>1. Knowledge of the techniques and best practices to monitor the effectiveness of a QMS.</li> <li>2. Knowledge of the main concepts and components related to a Quality Management Measurement Programme: measures, attributes, indicators, dashboards, etc.</li> <li>3. Knowledge of the characteristics and differences between operational, tactical and strategic Quality Management indicators and dashboards.</li> <li>4. Knowledge of the techniques and methods to define and document adequate and reliable indicators.</li> <li>5. Knowledge of the main concepts and components related to the implementation of a QMS internal audit program.</li> <li>6. Knowledge of the differences between the concepts of major and minor nonconformities, anomalies and observations.</li> <li>7. Knowledge of the guidelines and best practices to write a nonconformity report.</li> <li>8. Knowledge of the best practices on how to perform management reviews.</li> </ol>

## Domain 6: Continual improvement of a QMS based on ISO 9001

**Main objective:** To ensure that the ISO 9001 Lead Implementer candidate can provide guidance on the continual improvement of a QMS in the context of ISO 9001.

Competencies	Knowledge statements
<ol style="list-style-type: none"> <li>1. Ability to understand the principles and concepts related to continual improvement.</li> <li>2. Ability to counsel an organization on how to continually improve the effectiveness and the efficiency of a QMS.</li> <li>3. Ability to implement QMS continual improvement processes in an organization.</li> <li>4. Ability to determine the appropriate business improvement tools to support continual improvement processes of an organization.</li> <li>5. Ability to identify, analyze the root-causes of nonconformities and propose action plans to treat them.</li> <li>6. Ability to identify, analyze the root-cause of potential nonconformities and propose action plans to treat them.</li> </ol>	<ol style="list-style-type: none"> <li>1. Knowledge of the main concepts related to continual improvement.</li> <li>2. Knowledge of the characteristics and differences between the concepts of effectiveness and efficiency.</li> <li>3. Knowledge of the concepts and techniques to perform benchmarking.</li> <li>4. Knowledge of the main processes, tools and techniques used by professionals to identify the root-causes of nonconformities.</li> <li>5. Knowledge of the characteristics and the differences between corrective and preventive actions.</li> <li>6. Knowledge of the main processes, tools and techniques used by professionals to develop and propose the best corrective and preventive action plans.</li> </ol>



## Domain 7: Preparing for a QMS certification audit

**Main objective:** To ensure that the ISO 9001 Lead Implementer candidate can prepare and assist an organization for the certification of a QMS against the ISO 9001 standard.

Competencies	Knowledge statements
<ol style="list-style-type: none"> <li>1. Ability to understand the main steps, processes and activities related to an ISO 9001 certification audit.</li> <li>2. Ability to understand, explain and illustrate the audit evidence approach in the context of an ISO 9001 audit.</li> <li>3. Ability to counsel an organization to identify and select a certification body that meets their needs.</li> <li>4. Ability to review the readiness of an organization for an ISO 9001 certification audit.</li> <li>5. Ability to coach and prepare an organization's personnel for an ISO 9001 certification audit.</li> <li>6. Ability to argue and challenge the audit findings and conclusions with external auditors.</li> </ol>	<ol style="list-style-type: none"> <li>1. Knowledge of the evidence based approach in an audit.</li> <li>2. Knowledge of the different types of evidence: physical, mathematical, confirmative, technical, analytical, documentary and verbal.</li> <li>3. Knowledge of the differences between Stage 1 and Stage 2 audits.</li> <li>4. Knowledge of Stage 1 audit requirements, steps and activities.</li> <li>5. Knowledge of the documentation review criteria.</li> <li>6. Knowledge of Stage 2 audit requirements, steps and activities.</li> <li>7. Knowledge of follow-up audit requirements, steps and activities.</li> <li>8. Knowledge of surveillance audits and recertification audit requirements, steps and activities.</li> <li>9. Knowledge of the requirements, guidelines and best practices to develop action plans following an ISO 9001 certification audit.</li> </ol>

Based on these 7 domains and their relevance, 12 questions are included in the exam, as summarized in the following table:

		Level of Understanding (Cognitive/Taxonomy) Required		Number of Questions per competenc y domain	% of test devoted to each competenc y domain	Number of Points per competency domain	% of Points per competency domain	
		Points per Question	Questions that measure Comprehensio n, Application and Analysis					Questions that measure Synthesis and Evaluation
Competency/Domains	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 a QMS implementation based on ISO 9001	5	X	1	8.33	5	6.67	
	Implementing a QMS based on ISO 9001	10		X	2	16.67	15	20.00
		5		X				
	Performance evaluation, monitoring and measurement of a QMS based on ISO 9001	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 passing score is **70%**.

After successfully passing the exam, candidates will be able to apply for the credential of PECB Certified ISO 9001 Lead Implementer, 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 prove 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 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](mailto: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](mailto:examination@pecb.com). For more information, please refer to [www.pecb.com](http://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 (1<sup>st</sup> 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 (2<sup>nd</sup> 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 (3<sup>rd</sup> 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 2<sup>nd</sup> 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 the 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. 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.*

### **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 sessions.*