



ISO 9001 Certification Scheme

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1 Purpose and summary

This document specifies the ISO 9001:2015 certification schemes of PECB in compliance with the ISO/IEC 17024:2012 standard (Conformity assessment — General Requirements for bodies operating certification of persons).

The following ISO 9001 Certifications are covered:

- ISO 9001 Lead Auditor
- ISO 9001 Lead Implementer
- ISO 9001 Master

The PECB Certification Schemes are reviewed and validated on an ongoing basis by the General Scheme Advisory Board, which acts as the governing board for certification.

1.1 ISO 9001 Lead Auditor Certification

The “ISO 9001 Lead Auditor” credential is a professional certification for individuals aiming to demonstrate the competence to audit the quality management system and lead an audit team.

ISO 9001 specifies the requirements for establishing, implementing, maintaining, and continually improving a quality management system (QMS). The most important skills required in the market are the ability to effectively plan and perform audits in conformity to the certification process master audit techniques, and manage (or be part of) audit teams and audit programs

The ISO 9001 Lead Auditor certification 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 the quality management system audit
- Expert advisors in quality management

1.2 ISO 9001 Lead Implementer Certification

The “ISO 9001 Lead Implementer” credential is a professional certification for individuals aiming to demonstrate the competence to implement the quality management system and manage an implementation project.

ISO 9001 specifies the requirements for establishing, implementing, maintaining, and continually improving a quality management system (QMS). The most important skills required in the market are the ability to support organizations in implementing and managing the quality management system, including activities such as planning, implementing, monitoring, and continually improving the QMS.

The ISO 9001 Lead Implementer certification is intended for:

- Managers or consultants involved in and concerned with the implementation of a quality management system in an organization
- Project managers, consultants, or expert advisers seeking to master the implementation of a quality management system
- Individuals responsible for maintaining conformity with the ISO 9001 requirements in an organization
- Members of a QMS implementation team

1.3 ISO 9001 Master Certification

The ISO 9001 Master credential is a professional certification for professionals needing to implement a quality management system (QMS), and to master the audit techniques to manage (or be part of) audit teams and audit program.

The Master credential is the highest credential within the PECB Certification Structure.

The principal competencies and knowledge skills needed by the market are the ability to support an organization to effectively manage and implement a quality management system as specified in ISO 9001, as well as manage an audit program.

Various professionals may apply for this certification:

- Senior managers or senior consultants seeking to master the implementation of a quality management system (QMS)
- Senior auditors wishing to master the quality management system (QMS) audit process
- Senior experts in quality management

This certification is awarded to those professionals who are BOTH certified ISO 9001 Lead Auditor and ISO 9001 Lead Implementer (or passed the respective exams), as well as being able to demonstrate increased professional QMS project and audit experience.

2 ISO 9001 Certification marks

PECB has registered the following trademarks:

- PECB Certification Marks

Applicants who get certified by PECB are entitled to use the appropriate designation. PECB uses and authorizes as equivalent the following designations:

- PECB Certified ISO 9001 Lead Auditor
- PECB Certified ISO 9001 Lead Implementer
- PECB Certified ISO 9001 Master

They can download their certificate, as well as claim their digital badge from their dashboard. For more information about downloading the certificate, click [here](#), and for more information about claiming the Digital Badge, click [here](#).

3 Objectives, domains and skills related to the certification scheme

Based on the main required skills for each job category and survey results the JTA panel proposed the following credentials and the competency domains (objectives, competencies and knowledge statements)

3.1 ISO 9001 Lead Auditor Certification

Based upon the previously described job/task analysis, ISO 19011:2018, and best practices (including, but not limited to, the International Personnel Certification Association (IPC), the American Society for Quality (ASQ), and the European Organization for Quality (EOQ) in the field, related with the ISO 9001 standard, the CEO with the panel of experts, defined 7 different domains. For each of these domains the competencies and skills are listed below, which form the basis for a candidate to show compliancy to the objectives for that domain.

These domains are:

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

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

Main objective: Ensure that the candidate is able to explain and apply ISO 9001 principles and concepts.

Competencies	Knowledge statements
1. Ability to describe the applicability and scope of ISO 9001	1. Knowledge of the ISO 9001 scope and its applicability
2. Ability to explain the connection between ISO 9001 and other ISO standards, such as ISO 9001, ISO/TS 9002, ISO 9004, etc.	2. Knowledge of the relationship between ISO 9001 and other ISO standards
3. Ability to communicate the advantages of implementing a QMS based on ISO 9001	3. Knowledge of the advantages of implementing a QMS based on ISO 9001
4. Ability to counterargument common misconceptions about ISO 9001	4. Knowledge of the common misconceptions about ISO 9001
5. Ability to explain what a management system is	5. Knowledge of the components of a management system
6. Ability to define what a quality management system is	6. Knowledge of the main concepts and terminology related to QMS and ISO 9001
7. Ability to describe ISO's quality management principles	7. Knowledge of the principal characteristics of an integrated management system
8. Ability to explain what an integrated management system is and how it can help an organization	8. Knowledge of the seven ISO quality management principles
9. Ability to describe the determinants of product and service quality	9. Knowledge of the determinants of product and service quality
10. Ability to explain the process approach and its role in a QMS based on ISO 9001	10. Knowledge of the process approach and its inclusion in the ISO 9001 requirements for a QMS
11. Ability to describe the role of Plan-Do-Check-Act (PDCA) cycle and risk-based thinking in a QMS based on ISO 9001	11. Knowledge of the Plan-Do-Check-Act cycle and risk-based thinking and their role in a QMS based on ISO 9001

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

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

Competencies	Knowledge statements
1. Ability to understand the ISO 9001 requirements and the structure of the standard 2. Ability to describe the standard's requirements with regard to the context of the organization, interested parties, and QMS scope (clause 4) 3. Ability to validate the degree to which the top management has demonstrated leadership and commitment, analyze the quality policy, and ability to identify the separation of the roles and responsibilities related to the QMS (clause 5) 4. Ability to identify risks and opportunities and to validate the appropriateness of quality objectives (clause 6) 5. Ability to analyze whether sufficient resources are available to implement, 6. operate, and maintain the QMS (clause 7) 7. Ability to determine the effectiveness of the processes and controls established as part of the QMS (clause 8) 8. Ability to use monitoring, measurement, analysis, and evaluation to support the effective management of the QMS (clause 9) 9. Ability to determine if appropriate actions were taken when nonconformities occurred and to analyze the actions taken to continually improve the suitability, adequacy, and effectiveness of the QMS (clause 10)	1. Knowledge of the requirements of ISO 9001 for establishing, implementing, maintaining, and continually improving a QMS 2. Knowledge of the common external and internal issues that affect the context of an organization and approaches to establishing the scope 3. Knowledge of the requirements with regard to top management's involvement in the QMS, establishment of the quality policy, and definition of roles and responsibilities 4. Knowledge of the approaches used in risk management and strategies used in establishing objectives 5. Knowledge of the required resources, competences, awareness, and documented information for an effective QMS 6. Knowledge of the requirements for operational planning and control 7. Knowledge of the approaches, techniques, and methods used for the monitoring, measurement, analysis, evaluation, internal audits, and management reviews 8. Knowledge of the requirement and approaches to dealing with nonconformities and initiating corrective actions, as well as the methods to continually improve a QMS

Domain 3: Fundamental audit concepts and principles

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

Competencies	Knowledge statements
1. Ability to understand, explain, and illustrate the application of the audit principles in a QMS audit 2. Ability to differentiate between first, second, and third party audits 3. Ability to identify and judge situations that would discredit the professionalism of the auditor and violate the PECB Code of Ethics 4. Ability to identify and judge ethical issues considering the obligations related to the audit client, auditee, law enforcement, and regulatory authorities 5. Ability to determine and evaluate the level of materiality and apply a risk-based approach during the different stages of a QMS audit 6. Ability to judge the appropriate level of reasonable assurance needed for a QMS audit 7. Ability to understand the legal implications related to any irregularities committed by the auditee	1. Knowledge of the main audit concepts and principles as described in ISO 19011 2. Knowledge of the differences between first, second, and third party audits 3. Knowledge of the principles of auditing: integrity, fair presentation, due professional care, confidentiality, independence, evidence-based approach, and risk-based approach 4. Knowledge of an auditor's professional responsibility and the PECB Code of Ethics 5. Knowledge of the risk-based approach to an audit and the different types of risks related to audit activities, such as inherent risk, control risk, and detection risk 6. Knowledge of the concept of materiality and its application to an audit 7. Knowledge of the concept of reasonable assurance and its application to an audit 8. Knowledge of the laws and regulations applicable to the auditee and the country it operates in, etc.

Domain 4: Preparing an ISO 9001 audit

Main objective: Ensure that the candidate is able to prepare a quality management system audit.

Competencies	Knowledge statements
1. Ability to understand and illustrate the steps and activities to prepare a QMS audit considering the specific context of the audit 2. Ability to explain and compare evidence types and their characteristics 3. Ability to determine and justify the type and amount of evidence required in a QMS audit 4. Ability to understand and explain the roles and responsibilities of the audit team leader, audit team members, and technical experts 5. Ability to determine and evaluate the level of materiality during the different stages of a QMS audit 6. Ability to determine the audit feasibility 7. Ability to determine, evaluate, and confirm the audit objectives, criteria, and scope for a QMS audit 8. Ability to explain, illustrate, and define the characteristics of the terms of the audit engagement and apply the best practices to establish the initial contact with an auditee 9. Ability to develop audit working papers and elaborate appropriate audit test plans in a QMS audit	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 3. Knowledge of the audit objectives, scope, and criteria 4. Knowledge of the difference between a QMS scope and the audit scope 5. Knowledge of the factors to take into account during the audit feasibility study 6. Knowledge of the cultural aspects to consider in an audit 7. Knowledge of the characteristics of terms of the audit engagement and the best practices to establish initial contact with an auditee 8. Knowledge of the audit plan preparation procedure 9. Knowledge of the preparation and development of audit working papers 10. Knowledge of the different types of audit evidence: physical, mathematical, confirmative, technical, analytical, documentary, and verbal 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 is able to conduct a QMS audit.

Competencies	Knowledge statements
1. Ability to conduct the stage 1 audit, taking into account the documented information evaluation criteria 2. Ability to organize and conduct an opening meeting 3. Ability to conduct the stage 2 audit by appropriately following the procedures that this stage entails 4. Ability to apply the best practices of communication to collect the appropriate audit evidence 5. Ability to consider the roles and responsibilities of all the interested parties involved 6. Ability to explain, illustrate, and apply evidence collection procedures and tools 7. Ability to explain, illustrate, and apply the main audit sampling methods 8. Ability to gather appropriate evidence from the available information during an audit and evaluate it objectively 9. Ability to explain, illustrate, and apply the audit evidence approach in a QMS audit	1. Knowledge of the objectives and the content of the opening meeting in 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 documented information evaluation criteria and ISO 9001 requirements 5. Knowledge of stage 2 audit requirements, steps, and activities 6. Knowledge of the best communication practices during an audit 7. Knowledge of the roles and responsibilities of guides and observers during an audit 8. Knowledge of the different conflict resolution techniques 9. Knowledge of the evidence collection procedures and tools, such as interview, documented information review, observation, analysis, sampling, and technical verification 10. Knowledge of the evidence analysis techniques (i.e., corroboration and evaluation) 11. Knowledge of the main concepts, principles, and evidence collection procedures used in an audit 12. Knowledge of the advantages and disadvantages of using audit checklists

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
1. Ability to explain and apply the evidence evaluation process: drafting audit findings and preparing audit conclusions 2. Ability to understand, explain, and illustrate the concept of the benefit of the doubt 3. Ability to report appropriate audit observations in accordance with audit rules and principles 4. Ability to conduct quality reviews to audit documentation 5. Ability to draft and present audit conclusions 6. Ability to complete audit working documents 7. Ability to organize and conduct a closing meeting 8. Ability to write an audit report and justify the recommendation for certification 9. Ability to conduct the activities following an initial audit, including the evaluation of action plans, audit follow-ups, and surveillance activities	1. Knowledge of the evidence evaluation process: to draft audit findings and to prepare audit conclusions 2. Knowledge of the characteristics and differences between the concepts of conformity, minor nonconformity, major nonconformity, anomaly, and observation 3. Knowledge of the guidelines and best practices to draft nonconformity reports 4. Knowledge of the guidelines and best practices to draft and report audit observations 5. Knowledge of the benefit of the doubt and its application in the management system audits 6. Knowledge of the guidelines and best practices to complete audit working documents and perform a quality review 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 an auditor can give during the certification audit 9. Knowledge of the guidelines and best practices to evaluate action plans 10. Knowledge of audit follow-ups, surveillance audits, and recertification audit requirements, steps, and activities 11. Knowledge of the conditions for the modification, extension, suspension, or withdrawal of an organization's certification

Domain 7: Managing a ISO 9001 audit program

Main objective: Ensure that the candidate is able to establish and manage a QMS audit program.

Competencies	Knowledge statements
1. Ability to understand and explain the establishment of an audit program and the application of the PDCA cycle into an audit program 2. Ability to understand and explain the importance of protecting the integrity, availability, and confidentiality of audit records and the auditors' responsibilities in this regard 3. Ability to understand the documented information management process 4. Ability to understand the process of evaluating the efficiency of the audit program by monitoring the performance of each auditor and audit team member 5. Ability to demonstrate the application of the personal attributes and behaviors	1. Knowledge of the application of the PDCA cycle 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 requirements, guidelines, and best practices regarding the management of audit records 4. Knowledge of the management of combined audits 5. Knowledge of the personal attributes and behaviors of a professional auditor

3.2 ISO 9001 Lead Implementer Certification

Based upon the job/task analysis and related with the ISO 9001 standard and best practices in project management, 7 different domains are defined. For each of these domains the competencies and skills are listed that form the basis for a candidate to show compliancy to the objectives for that domain.

These domains are:

1. Fundamental principles and concepts of a quality management system (QMS)
2. Quality management system (QMS)
3. Planning the QMS implementation
4. Implementing a QMS
5. Performance evaluation, monitoring, and measurement of a QMS
6. Continual improvement of a QMS
7. Preparing for a QMS certification audit

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

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

Competencies	Knowledge statements
1. Ability to explain what a management system is	1. Knowledge of the ISO's definition for a management system
2. Ability to explain the main concepts of the quality management system	2. Knowledge of ISO 9000's definition of a quality management system
3. Ability to explain the connection between management, quality management, and QMS	3. Knowledge of the main concepts related to management, quality management, and QMS
4. Ability to differentiate the main standards in the ISO 9000 series	4. Knowledge of the main standards in the ISO 9000 series, their applicability, and relationship between the standards
5. Ability to communicate the benefits of implementing a QMS based on ISO 9001	5. Knowledge of benefits of implementing a QMS based on ISO 9001
6. Ability to explain the common misconceptions about ISO 9001	6. Knowledge of common misconceptions about ISO 9001
7. Ability to explain other quality management methods and techniques	7. Knowledge of other quality management methods and techniques
8. Ability to explain the evolution of quality paradigms	8. Knowledge of the evolution of the quality paradigms
9. Ability to provide a coherent definition of quality	9. Knowledge of ISO 9000's definition of quality
10. Ability to describe the importance of quality	10. Knowledge of the importance of quality
11. Ability to describe the quality management principles presented in ISO 9001	11. Knowledge of the seven quality management principles set out by ISO 9001
12. Ability to explain the role and usage of process approach in a QMS based on ISO 9001	12. Knowledge of the role of the process approach in a QMS based on ISO 9001
13. Ability to explain the role of the Plan-Do-Check-Act (PDCA) cycle in a QMS based on ISO 9001	13. Knowledge of the PDCA cycle and its role in ISO 9001
14. Ability to explain risk-based thinking	14. Knowledge of the concept of risk-based thinking and its usage in ISO 9001

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

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

Competencies	Knowledge statements
1. Ability to explain the difference between the QMS implementation project and daily QMS operations	1. Knowledge of the differences between the QMS implementation project and day-to-day management of the QMS
2. Ability to explain the main approaches for a QMS implementation project	2. Knowledge of the implementation approaches for a QMS
3. Ability to initiate the QMS implementation project	3. Knowledge of the competencies of a QMS project manager, beside the knowledge of the ISO 9001 requirements
4. Ability to describe the competencies of a QMS project manager	4. Knowledge of the advantages and disadvantages of a QMS project manager being an employee or an external consultant
5. Ability to explain the importance of a business case on the implementation of a QMS	5. Knowledge of the business case on the QMS implementation, and its components
6. Ability to utilize PECB's IMS2 methodology for the QMS implementation project	6. Knowledge of the PECB IMS2 methodology for the QMS implementation project
7. Ability to utilize best practices for the implementation project	7. Knowledge of the best practices for a QMS implementation project
8. Ability to communicate the ultimate objectives of a QMS implementation project	8. Knowledge of the objectives of a QMS implementation project, regardless of the approach used

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.

Competencies	Knowledge statements
1. Ability to explain the role of top management with respect to the quality management system 2. Ability to interpret the information required to establish a quality policy 3. Ability to identify the roles and responsibilities of key interested parties during the implementation and operation of a QMS 4. Ability to determine the internal and external context of an organization 5. Ability to perform a gap analysis 6. Ability to define and justify a QMS scope specific to the organization's quality objectives 7. Ability to perform the different processes of the risk assessment 8. Ability to set relevant quality objectives 9. Ability to plan, initiate, and carry out change with regard to the QMS 10. Ability to determine the optimal resources needed for an effective QMS implementation and operation 11. Ability to determine the competencies needed for the QMS operation 12. Ability to raise awareness among the persons doing work under the organization's control with regard to the QMS 13. Ability to communicate relevant information to support the QMS and the achievement of quality objectives 14. Ability to ensure that the organization properly controls for maintaining QMS documented information	1. Knowledge of the main activities required by top management with respect to the quality management system 2. Knowledge of the importance of leadership and commitment to ensure QMS effectiveness 3. Knowledge of the main attributes of a quality policy 4. Knowledge of process for drafting a quality policy 5. Knowledge of the methods of communicating a quality policy 6. Knowledge of the main organizational structures applicable for an organization to manage a QMS 7. Knowledge of what typically constitutes an organization's internal and external context 8. Knowledge of the approaches used to understand the context of an organization 9. Knowledge of the techniques used to gather information about an organization and to perform a gap analysis of a management system 10. Knowledge of the characteristics of a QMS scope in terms of organizational, technological, and physical boundaries 11. Knowledge of the different approaches and methodologies used to perform the risk assessment process 12. Knowledge of typical quality and QMS objectives and how to achieve specific results 13. Knowledge of tools that facilitate the change management process 14. Knowledge of the typical resources required for the establishment, implementation, maintenance, and continual improvement of a quality management system 15. Knowledge of competence analysis approaches and training programs 16. Knowledge of the common strategies and approaches used for raising awareness 17. Knowledge of the principles and methods for effective communication

18. Knowledge of the actions required to ensure the control, availability, and suitability of essential documented information

Domain 4: Implementing an 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 plan, implement, and control the processes needed for the provision of products and services 2. Ability to establish mechanisms through which the organization engages in communication activities 3. Ability to plan and implement a complaints-handling process 4. Ability to establish the necessary processes for determining the requirements for products and services 5. Ability to implement and maintain a design and development process 6. Ability to determine the requirements for products and services 7. Ability to explain the typical reasons for outsourcing and main risks associated with it 8. Ability to establish measures to control externally provided processes, products, and services 9. Ability to establish measures and controls through which an organization can provide its products and services under controlled conditions 10. Ability to implement controls for the protection of property belonging to customers or external providers 11. Ability to establish processes and controls through which the organization ensures the preservation of outputs during production and service provision 12. Ability to control the nonconforming outputs 13. Ability to determine the requirements for post-delivery activities	1. Knowledge of the requirements for the provision of products and services 2. Knowledge of the details to be included when communicating with customers 3. Knowledge of the methods and tools for an effective communication with customers 4. Knowledge of principles upon which the complaints-handling process must be established 5. Knowledge of the approaches used for determining the requirements for products and services 6. Knowledge of the design and development approaches and methods, including planning, inputs/outputs, controls, and changes 7. Knowledge of the typical reasons for outsourcing and risks associated with it 8. Knowledge of the type and extent of controls for externally provided processes, products, and services 9. Knowledge of controlled conditions for production and service provision 10. Knowledge of the controls used for the protection of property belonging to customers or external providers 11. Knowledge of the typical processes and controls used for the preservation of outputs during production and service provision 12. Knowledge of the requirements for dealing with nonconforming outputs 13. Knowledge of the typical requirements for post-delivery activities and approaches to meet those requirements

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 explain the main terms related to QMS performance 3. Ability to determine measurement objectives 4. Ability to establish performance measures that are related to the organization's quality objectives 5. Ability to determine the methods for monitoring customer satisfaction 6. Ability to verify to what extent the identified QMS objectives have been met 7. Ability to establish key performance indicators 8. Ability to define and implement a QMS internal audit program 9. Ability to establish mechanisms through which top management performs regular and methodical reviews to ensure the suitability, adequacy, effectiveness, and efficiency of a QMS	1. Knowledge of the best practices and techniques used to monitor and evaluate the effectiveness of a QMS 2. Knowledge of the main terms related to QMS performance: monitoring, measurement, analysis, and evaluation 3. Knowledge of the measurement objectives in the context of a QMS 4. Knowledge of the methodologies for determining effective performance measures 5. Knowledge of the methods used for monitoring customer perceptions 6. Knowledge of the appropriate data gathering methods 7. Knowledge of the attributes of key performance indicators and steps for using them 8. Knowledge of the main concepts and components related to the implementation and operation of a QMS internal audit program 9. Knowledge of the best practices used to perform management reviews

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 determine the processes through which an organization treats nonconformities	1. Knowledge of the requirements for treating nonconformities
2. Ability to identify and analyze the root causes of nonconformities, and propose action plans to treat them	2. Knowledge of the approaches, tools, and techniques used to identify the root causes of nonconformities
3. Ability to continually improve the effectiveness and efficiency of a QMS	3. Knowledge of the process for treating nonconformities
4. Ability to implement continual improvement processes in an organization	4. Knowledge of the approaches used to develop corrective action plans
5. Ability to determine the appropriate tools to support the continual improvement of processes of an organization	5. Knowledge of the processes related to the continual monitoring of change factors
6. Ability to implement necessary measures for documenting improvements in a QMS	6. Knowledge of the maintenance and improvement of a QMS
	7. Knowledge of the typical approaches used for documenting improvements in a QMS

Domain 7: Preparing for a QMS certification audit

Main objective: Ensure that the candidate is able to prepare an organization for the certification against ISO 9001.

Competencies	Knowledge statements
1. Ability to describe the main steps, processes, and activities related to the QMS certification audit 2. Ability to explain a QMS certification audit based on the evidence-based approach 3. Ability to assist organizations in identifying and selecting the most suitable certification body that meets their needs and expectations 4. Ability to determine whether an organization is ready and prepared for the QMS certification audit 5. Ability to train and prepare an organization's personnel for the QMS certification audit 6. Ability to discuss and challenge the audit findings and conclusions with external auditors	1. Knowledge of the evidence-based approach audit 2. Knowledge of the types of audit and their differences 3. Knowledge of the differences between Stage 1 and Stage 2 audits 4. Knowledge of the Stage 1 audit requirements, steps, and activities 5. Knowledge of the documented information review criteria 6. Knowledge of the Stage 2 audit requirements, steps, and activities 7. Knowledge of the audit follow-up requirements, steps, and activities 8. Knowledge of the surveillance audits and recertification audit requirements, steps, and activities 9. Knowledge of the requirements, guidelines, and best practices for developing action plans following a QMS certification audit

4 ISO 9001 Examination Development

The test specifications are presented in the table below.

4.1 ISO 9001 Lead Auditor

Based on the abovementioned domains and their relevance, 80 questions are included in the exam, as summarized in the table below:

				Level of understanding (Cognitive/Taxonomy) required	
		Number of questions/points per competency domain	% of the exam devoted/points to/for each competency domain	Questions that measure comprehension, application, and analysis	Questions that measure evaluation
Competency domains	Fundamental principles and concepts of a quality management system (QMS)	10	12.5	X	
	Quality management system (QMS) and ISO 9001 requirements	11	13.75	X	
	Fundamental audit concepts and principles	10	12.5	X	
	Preparing an ISO 9001 audit	10	12.5	X	
	Conducting an ISO 9001 audit	18	22.5		X
	Closing an ISO 9001 audit	11	13.75		X
	Managing an ISO 9001 audit program	10	12.5		X
Total		80	100%		
Number of questions per level of understanding				41	39
% of the exam devoted to each level of understanding (cognitive/taxonomy)				51.25%	48.75%

4.2 ISO 9001 Lead Implementer

Based on the abovementioned domains and their relevance, 80 questions are included in the exam, as summarized in the table below:

				Level of understanding (Cognitive/Taxonomy) required	
		Number of questions/points per competency domain	% of the exam devoted/points to/for each competency domain	Questions that measure comprehension, application, and analysis	Questions that measure evaluation
Competency domains	Fundamental principles and concepts of a quality management system (QMS)	10	12.5	X	
	Quality management system (QMS) and ISO 9001 requirements	10	12.5	X	
	Planning the QMS implementation	17	21.25		X
	Implementing a QMS	13	16.25	X	
	Monitoring, measurement, analysis and evaluation of a QMS	12	15		X
	Continual improvement of a QMS	10	12.5		X
	Preparing for a QMS certification audit	8	10	X	
Total		80	100%		
Number of questions per level of understanding				41	39
% of the exam devoted to each level of understanding (cognitive/taxonomy)				51.25%	48.75%

5 Certification schemes requirements

With the input gathered in the previous chapters, the different PECB Certification Schemes are defined in the following sections.

5.1 Requirements for certification

5.1.1 General requirements

In general, the requirements for any ISO 9001 certification are:

- Having successfully passed the appropriate PECB certification examination;
- Having demonstrated sufficient and relevant professional experience;
- Having indicated at least two referrals in their application form;
- Having fulfilled all other requirements;
- Having paid all certification application fees.

The detailed requirements for each of the different grades are listed below.

5.1.2 ISO 9001 Lead Auditor Certification

Exam: PECB Certified ISO 9001 Lead Auditor Exam or equivalent

Candidates must pass a comprehensive examination consisting of development questions exam covering 7 domains of the audit of a Quality Management System based on ISO 9001.

Professional experience

The minimum professional experience required is:

- Five years of professional experience in total of which
- Two years of work experience in Quality Management

MS audit/assessment experience: Audit activities: 300 hours

QMS project experience: None

Other requirements: Signing the PECB Code of Ethics

Credential	Exam	Professional experience	MS audit/assessment experience	Other requirements
PECB Certified ISO 9001 Lead Auditor	PECB Certified ISO 9001 Lead Auditor Exam or equivalent	Five years; Two years of work experience in Quality Management	Audit activities: a total of 300 hours	Signing the PECB Code of Ethics

5.1.3 ISO 9001 Lead Implementer Certification

Exam: PECB Certified ISO 9001 Lead Implementer Exam or equivalent

Candidates must pass a comprehensive examination consisting of development questions exam covering 7 domains of the Implementation of a Quality Management System based on ISO 9001.

Professional experience

The minimum professional experience required is:

- Five years of professional experience in total of which
- Two years of work experience in Quality Management

MS audit/assessment experience: None

QMS project experience: Project activities: 300 hours

Other requirements: Signing the PECB Code of Ethics

Credential	Exam	Professional experience	QMS project experience	Other requirements
PECB Certified ISO 9001 Lead Implementer	PECB Certified ISO 9001 Lead Implementer Exam or equivalent	Five years Two years of work experience in Quality Management	Project activities: a total of 300 hours	Signing the PECB Code of Ethics

5.1.4 ISO 9001 Master Certification

Exam: Having successfully passed **both** ISO 9001 Lead Auditor Exam and ISO 9001 Lead Implementer Exam.

Professional experience: 20 years of experience, 10 years in the respective field

Activities experience: 5000 hours combination of auditing and project activities

Other requirements: Signing the PECB Code of Ethics

Credential	Exam	Professional experience	Activities experience	Other requirements
PECB Certified ISO 9001 Master	PECB Certified ISO 9001 Lead Auditor Exam + ISO 9001 Lead Implementer exam	20 years of experience, 10 years in a leadership role in the respective field	5000 hours combination of auditing and project activities	Signing the PECB Code of Ethics

5.2 Examination methods

Passing the Exam:

PECB will organize two different exams for the grades defined previously. These are:

1. The ISO 9001 Lead Auditor Exam
2. The ISO 9001 Lead Implementer Exam

The ISO 9001 Lead Auditor Exam is a 3h exam. The exam questions are relevant and sufficient and cover all domains defined for the “ISO 9001 Lead Auditor” Certification. The exam questions are development questions.

The ISO 9001 Lead Implementer Exam is a 3h exam. The exam questions are relevant and sufficient and cover all domains defined for the “ISO 9001 Lead Implementer” Certification. The exam questions are development questions.

A minimum score of 70% is required to pass the ISO 9001 Lead Auditor Exam

A minimum score of 70% is required to pass the ISO 9001 Lead Implementer Exam

5.3 Certification evaluation process

Examination: Candidate needs to pass the respective exam

Professional experience: Candidates are required to add information about work experience by attaching a CV and adding two references.

Professional experience is validated by requiring the applicant to indicate in the application form the following information for each employer:

1. Date started
2. End date (if applicable)
3. Business name
4. Business address
5. Project name
6. Reference position
7. Reference name
8. Reference email
9. Reference phone number
10. Reference job title
11. Reference hours
12. Experience details

QMS Audit experience: The candidate’s audit log will be checked to ensure that the candidate has the required number of audit-hours. This information can be detailed on their resume.

These audits should follow best audit practices and include the following activities:

1. Planning an audit
2. Managing an audit program
3. Drafting audit reports
4. Drafting nonconformity reports
5. Drafting audit working documents

6. Documented information review
7. On-site audit
8. Following up on nonconformities
9. Leading an audit team

QMS project experience: The applicant's application and resume will be checked to ensure that the candidate has the minimal required number of implementation-hours.

These implementation activities should follow best implementation practices and include the following activities:

1. Drafting the QMS plan
2. Initiating the QMS implementation
3. Implementing the QMS
4. Managing, monitoring, and maintaining the QMS
5. Identifying and acting upon continual improvement opportunities

Other requirements: The documents provided by the candidate will be checked. Candidates will need to read and agree with the Certification Rules and Policies, Certification Maintenance Policy, and PECB Code of Ethics.

5.4 Equivalencies clause requirements

PECB does accept certifications and exams provided from other recognized and accredited certification bodies. PECB will evaluate the requests through its equivalency process to decide whether the respective certification(s) and/or exam(s) can be accepted as equivalent to the respective PECB Certificate (e.g. ISO 9001 Lead Auditor Certificate)

The Certification Department verifies the provided information for certificates, as to whether an individual holds a current valid certification from an accredited and recognized body.

5.5 Requirements for recertification

5.5.1 Validity period of PECB certifications

PECB certifications are valid for three years. In order to maintain a certificate, PECB Certified Professionals are encouraged to demonstrate that they are performing certification related activities on an annual basis, by submitting Continuing Professional Development (CPD) credits. In addition, PECB Professionals are required to pay maintenance fee, which PECB encourages to pay on an annual basis (Annual Maintenance Fee).

PECB Certified Professional will need to provide PECB with the required hours of auditing and/or implementing related tasks they have performed, including the contact details of the individuals who can validate these tasks.

The annual reporting begins with the initial certificate date; however, the maintenance fee for the first year is included in the certification application payment.

PECB continuously notifies each PECB Professional to maintain their certificate(s). The notifications are sent several times throughout the certification cycle. Disregarding if CPDs and maintenance fees are reported/paid annually or not, all required CPDs/AMFs must be submitted/paid in full, before the end of the three-year certification cycle in order for the certification to be eligible for renewal.

5.5.2 Certification renewal process

To be able to renew a certificate, PECB Professionals will need to demonstrate that they have fulfilled the certification maintenance requirements within the three-year certification cycle. Certified Professionals are encouraged to complete CPD activities each year; however, the total required CPD hours must be achieved within the three-year certification cycle (see Appendix 1).

For example, a PECB Professional that holds a Lead Certificate has performed 20 hours of certification-related activities in year 1; 10 hours in year 2 and 60 hours in year 3. Although during the first and second year he/she did not perform sufficient certification-related activities, his/her tri-annual total is equal to the minimal tri-annual requirements. In this case, he/she fulfills the requirements to get recertified.

After three years of successful maintenance of a PECB Certificate, you can apply for a renewal of your certificate.

PECB certificate(s) can be renewed online through the PECB Member Dashboard by reporting CPDs and paying the AMF. PECB professionals can submit CPDs and AMF by clicking the respective icons under the CPD and AMF tabs in their MyPECB account at mypecb.com.

Note: Reduction of certification scope is not applicable. When the recertification requirements are not met, the certification will result in a 12-month suspension period, during which the candidate can address any outstanding AMFs and CPDs. If the candidate fails to fulfill these requirements within the suspension period, PECB may revoke (withdraw) the certification.

5.5.3 Reporting CPD and Paying AMF

Reporting of CPDs

PECB Certified Professionals will need to provide PECB with the required hours of auditing and/or implementation related tasks they have performed, including the contact details of the individuals who can validate these tasks.

Certified professionals can update their CPD credits at anytime by logging in to mypecb.com.

Note: On their MyPECB account, PECB professionals will see their certificates. To submit CPDs, they should click on the **CPD** icon next to the corresponding certificate and complete the submission process.

Payment of AMF

To submit the AMF, PECB professionals can log in to their dashboard at mypecb.com. They will see their certificates on the dashboard menu. Click on the **money** icon next to the relevant certificate to complete the AMF payment.

PECB continuously notifies each PECB Professional to maintain their certificate(s). The notifications are sent several times throughout the certification cycle. The first one is sent three months before your annual certificate issuance date, which based on the example above would be 2024-10-15. In this case, the payment of AMF would be due by 2025-04-15 (three months after the annual certificate issuance date).

For more information, go to the [Certification Maintenance](#) page on the PECB website.

5.5.4 Upgrade

PECB Professionals can apply for a higher credential once they provide evidence that proves that they fulfill the requirements of the higher credential.



PECB Certifications can be upgraded online through your dashboard by logging [here](#), clicking **My Certifications** and then the **Upgrade** button. For more information about the upgrade fee, go to the [Certification Maintenance](#) page on the PECB website.

Note: For downgraded certifications that need to be upgraded, an evaluation will be done to determine if an exam is required prior to obtain an upgraded certification.

5.5.5 Suspension

Failure to submit the CPD and AMF payment during the certification cycle will result in a 12-month suspension period, during which you can address any outstanding AMFs and CPDs.

Additional reasons for suspension can be if:

- PECB receives excessive or serious complaints by interested parties (Suspension will be applied until the investigation has been completed).
- The logos of PECB or accreditation bodies are willfully misused.
- The candidate fails to correct the misuse of a certification mark within the determined time by PECB.
- The certified individual has voluntarily requested a suspension.
- PECB deems appropriate other conditions for suspension of certification/certificate program.

Individuals whose certification has been suspended, are not authorized to further promote their certification while it is suspended.

A suspended certification can either be:

- Reinstated — if reasons for suspension are corrected within the given time frame by PECB
- Revoked — if reasons for suspension are not corrected within the given time frame by PECB

Suspended members must remediate their suspension within a maximum period of 12 months.

5.5.6 Revocation

PECB can revoke (that is, to withdraw) certification if the candidate fails to address the outstanding AMFs and CPDs during the 12-month suspension period. Candidates are then no longer allowed to represent themselves as PECB certified professionals. Additional reasons can be if candidates:

- Violate the PECB Code of Ethics
- Misrepresent and provide false information of the scope of the certification/certificate program
- Break any other PECB rules
- Any other reasons that PECB deems appropriate

Individuals whose certification has been revoked, are not authorized to use any references to a certified status.

Individuals whose certification has been revoked may file an appeal by following the complaint and appeal process ([Complaint and Appeal Policy - PECB](#)).

Appendix 1 - Certification Maintenance Requirements

Certification	Activities	3-Year/Total CPD hours
Foundation, Provisional, and Transition	None	None
Implementer	Hours of project experience, implementation or consulting-related tasks, training, private study, coaching, attendance of seminars and conferences, or other relevant activities	60 hours
Auditor, Assessor	Hours of audit or assessment-related experience, training, private study, coaching, attendance of seminars and conferences, or other relevant activities	60 hours
Manager	Hours of project experience related to the certification field, training, private study, coaching, attendance of seminars and conferences, or other relevant activities	60 hours
EBIOS, MEHARI	Hours of project experience related to the certification field, training, private study, coaching, attendance of seminars and conferences, or other relevant activities	60 hours
Six Sigma Green Belt	Hours of project experience related to the certification field, training, private study, coaching, attendance of seminars and conferences, or other relevant activities	60 hours
Lead Implementer	Hours of project experience, implementation, or consulting-related tasks, training, private study, coaching, attendance of seminars and conferences, or other relevant activities	90 hours
Senior Lead Implementer	Hours of project experience, implementation, or consulting-related tasks, training, private study, coaching, attendance of seminars and conferences, or other relevant activities	180 hours
Lead Auditor, Lead Assessor	Hours of auditing or assessment-related experience, training, private study, coaching, attendance of seminars and conferences, or other relevant activities	90 hours
Senior Lead Auditor	Hours of auditing or assessment-related experience, training, private study, coaching, attendance of seminars and conferences, or other relevant activities	180 hours
Lead Manager	Hours of project experience related to the certification field, training, private study, coaching, attendance of seminars and conferences, or other relevant activities	90 hours

Senior Lead Manager	Hours of project experience related to the certification field, training, private study, coaching, attendance of seminars and conferences, or other relevant activities	180 hours
Risk Manager	Hours of project experience related to the certification field, training, private study, coaching, attendance of seminars and conferences, or other relevant activities	60 hours
Senior Risk Manager	Hours of project experience related to the certification field, training, private study, coaching, attendance of seminars and conferences, or other relevant activities	180 hours
Lead Risk Manager	Hours of project experience related to the certification field, training, private study, coaching, attendance of seminars and conferences, or other relevant activities	90 hours
Senior Lead Risk Manager	Hours of project experience related to the certification field, training, private study, coaching, attendance of seminars and conferences, or other relevant activities	180 hours
CLFE	Hours of project experience related to certification field, assessment-related tasks, training, private study, coaching, attendance of seminars and conferences, or other relevant activities	90 hours
CLPI	Hours of project experience, implementation, or consulting-related tasks, training, private study, coaching, attendance of seminars and conferences, or other relevant activities	90 hours
CDPO	Hours of project experience related to the certification field, training, private study, coaching, attendance of seminars and conferences, or other relevant activities	90 hours
CLSIP	Hours of project experience related to the certification field, training, private study, coaching, attendance of seminars and conferences, or other relevant activities	90 hours
Master	Hours of implementation, management, or auditing-related tasks, training, private study, coaching, attendance of seminars and conferences, or other relevant activities	270 hours

6 Revision History

Version	Change description	Date
1.0	Initial release	2012-03-23
1.1	Reviewed by Certification Manager: Updated competency domains and recertification requirements	2017-03-28
2.0	Reviewed by Certification Manager: Updated competency domains and recertification requirements	2017-09-29
2.1	Reviewed by Certification Processing Manager: Updated the requirements for Master	2018-07-01
2.2	Reviewed by Certification Processing Manager: Updated competency domains, certification marks, recertification requirements, equivalency requirements, examination and evaluation process	2018-10-03
2.3	Reviewed by Certification Processing Manager: Added Suspension, and Revocation	2019-01-25
2.4	Reviewed by Certification Manager: - Updated the document with the brand-new logo - Added the scheme committee members	2019-10-09
2.5	Reviewed by Certification Associate Supervisor: - Updated the flowchart - Updated the tables based on new surveys by 2019	2020-10-30
2.6	Reviewed by Certification Specialist: - Added reference validation, surveillance method - Updated scheme committee members	2021-08-19
2.7	Reviewed by Certification Specialist: Updated data from ISO survey	2021-11-10
2.8	Reviewed by Compliance Director: Updated examination development section adding table for competency domains and exam questions.	2022-03-23
2.9	Reviewed by Chief Compliance Officer: - Added date of latest review of the General Scheme Advisory Board members and interested parties represented by the General Scheme Advisory Board members. - Revised RACI of the Process flowchart.	2022-08-22
3.0	Reviewed by Chief Compliance Officer: - Updated the titles of roles from: - CD to CCO - CS to CD-CD - Updated 5.1 tables based on the ISO 2021 survey - Updated the ISO 9001 LA and ISO 9001 LI based on the updated ISO 9001 Candidate Handbooks	2023-01-26
3.1	Reviewed by CD-CD: - Added information about digital badges - Updated competency domains	2023-07-11

	- Updated the criteria for revocation - Updated policy code from 08200 to 05071	
3.2	Reviewed by CD-CD: - Updated the AMF price from \$100 to \$120 - Removed RACI table	2023-10-02
3.3	Reviewed by TL-CD Updated the term PECB Surveillance Method/Surveillance Audit to CPD Verification	2023-11-14
3.4	Reviewed by CD-CD: - Updated General Scheme Advisory Board members - Updated ISO Survey data	2024-01-10
3.5	Reviewed by TL-CD - Updated the header - Removed footnote regarding the transition period for multiple-choice and essay-type exams	2024-10-17
3.6	Reviewed by AL, CD-CD: - Removed the Education Requirements - Updated the number of sections in chapter 2 - Removed the reference validation - Updated the Appendix 1 - Certification Maintenance Requirements - Removed Appendix 2 - Removed a member of the General Scheme Advisory Board - Reworded and updated sections 7.5.5, 7.5.6, and 7.5.8 - Updated the 'Related Documents' section in the table.	2025-07-01
3.7	Reviewed by CD-CD: - Updated the links in Chapter 3 - Updated the wording in section 7.5.2, 7.5.3, 7.5.5, 7.5.6, 7.5.7	2025-10-20
3.8	Reviewed by TL-CD Updated tables based on the ISO 2024 survey	2025-12-17