

# ISO/IEC 17025 LEAD IMPLEMENTER

**Candidate Handbook** 

# **Table of Contents**

SECTION I: INTRODUCTION	3
About PECB	
The Value of PECB Certification	4
PECB Code of Ethics	5
Introduction to ISO/IEC 17025 Lead Implementer	6
SECTION II: EXAMINATION PREPARATION, RULES, AND POLICIES	
Preparing for and scheduling the exam	
Competency domains	9
Taking the exam	18
Exam Security Policy	21
Exam results	22
Exam Retake Policy	22
SECTION III: CERTIFICATION PROCESS AND REQUIREMENTS	23
PECB ISO/IEC 17025 credentials	23
Applying for certification	24
Professional experience	24
Professional references	24
LMS project experience	24
Evaluation of certification applications	25
SECTION IV: CERTIFICATION POLICIES	26
Denial of certification	26
Certification status options	26
Upgrade and downgrade of credentials	27
Renewing the certification	27
Closing a case	27
Complaint and Appeal Policy	27
SECTION V: GENERAL POLICIES	28
Exams and certifications from other accredited certification bodies	28
Non-discrimination and special accommodations	28
Behavior Policy	28
Refund Policy	28

### **SECTION I: INTRODUCTION**

#### **About PECB**

PECB is a certification body that provides education<sup>1</sup>, certification, and certificate programs for individuals on a wide range of disciplines.

Through our presence in more than 150 countries, we help professionals demonstrate their competence in various areas of expertise by providing valuable evaluation, certification, and certificate programs against internationally recognized standards.

#### Our key objectives are:

- Establishing the minimum requirements necessary to certify professionals and to grant designations
- 2. Reviewing and verifying the qualifications of individuals to ensure they are eligible for certification
- 3. Maintaining and continually improving the evaluation process for certifying individuals
- 4. Certifying qualified individuals, granting designations and maintaining respective directories
- Establishing requirements for the periodic renewal of certifications and ensuring that the certified individuals are complying with those requirements
- 6. Ascertaining that PECB professionals meet ethical standards in their professional practice
- 7. Representing our stakeholders in matters of common interest
- 8. Promoting the benefits of certification and certificate programs to professionals, businesses, governments, and the public

#### **Our mission**

Provide our clients with comprehensive examination, certification, and certificate program services that inspire trust and benefit the society as a whole.

#### **Our vision**

Become the global benchmark for the provision of professional certification services and certificate programs.

### **Our values**

Integrity, Professionalism, Fairness

<sup>&</sup>lt;sup>1</sup> Education refers to training courses developed by PECB and offered globally through our partners.



#### The Value of PECB Certification

### **Global recognition**

PECB credentials are internationally recognized and endorsed by many accreditation bodies, so professionals who pursue them will benefit from our recognition in domestic and international markets.

The value of PECB certifications is validated by the accreditation from the International Accreditation Service (IAS-PCB-111), the United Kingdom Accreditation Service (UKAS-No. 21923) and the Korean Accreditation Board (KAB-PC-08) under ISO/IEC 17024 – General requirements for bodies operating certification of persons. The value of PECB certificate programs is validated by the accreditation from the ANSI National Accreditation Board (ANAB-Accreditation ID 1003) under ANSI/ASTM E2659-18, Standard Practice for Certificate Programs.

PECB is an associate member of The Independent Association of Accredited Registrars (IAAR), a full member of the International Personnel Certification Association (IPC), a signatory member of IPC MLA, and a member of Club EBIOS, CPD Certification Service, CLUSIF, Credential Engine, and ITCC. In addition, PECB is an approved Licensed Partner Publisher (LPP) from the Cybersecurity Maturity Model Certification Accreditation Body (CMMC-AB) for the Cybersecurity Maturity Model Certification standard (CMMC), is approved by Club EBIOS to offer the EBIOS Risk Manager Skills certification, and is approved by CNIL (Commission Nationale de l'Informatique et des Libertés) to offer DPO certification. For more detailed information, click <a href="heepto:h

#### High-quality products and services

We are proud to provide our clients with high-quality products and services that match their needs and demands. All of our products are carefully prepared by a team of experts and professionals based on the best practices and methodologies.

#### **Compliance with standards**

Our certifications and certificate programs are a demonstration of compliance with ISO/IEC 17024 and ASTM E2659. They ensure that the standard requirements have been fulfilled and validated with adequate consistency, professionalism, and impartiality.

#### **Customer-oriented service**

We are a customer-oriented company and treat all our clients with value, importance, professionalism, and honesty. PECB has a team of experts who are responsible for addressing requests, questions, and needs. We do our best to maintain a 24-hour maximum response time without compromising the quality of the services.

#### Flexibility and convenience

Online learning opportunities make your professional journey more convenient as you can schedule your learning sessions according to your lifestyle. Such flexibility gives you more free time, offers more career advancement opportunities, and reduces costs.

#### **PECB Code of Ethics**

The Code of Ethics represents the highest values and ethics that PECB is fully committed to follow, as it recognizes the importance of them when providing services and attracting clients.

The Compliance Division makes sure that PECB employees, trainers, examiners, invigilators, partners, distributors, members of different advisory boards and committees, certified individuals, and certificate holders (hereinafter "PECB professionals") adhere to this Code of Ethics. In addition, the Compliance Division consistently emphasizes the need to behave professionally and with full responsibility, competence, and fairness in service provision with internal and external stakeholders, such as applicants, candidates, certified individuals, certificate holders, accreditation authorities, and government authorities.

It is PECB's belief that to achieve organizational success, it has to fully understand the clients and stakeholders' needs and expectations. To do this, PECB fosters a culture based on the highest levels of integrity, professionalism, and fairness, which are also its values. These values are integral to the organization, and have characterized the global presence and growth over the years and established the reputation that PECB enjoys today.

PECB believes that strong ethical values are essential in having healthy and strong relationships. Therefore, it is PECB's primary responsibility to ensure that PECB professionals are displaying behavior that is in full compliance with PECB principles and values.

PECB professionals are responsible for:

- Displaying professional behavior in service provision with honesty, accuracy, fairness, and independence
- 2. Acting at all times in their service provision solely in the best interest of their employer, clients, the public, and the profession in accordance with this Code of Ethics and other professional standards
- 3. Demonstrating and developing competence in their respective fields and striving to continually improve their skills and knowledge
- 4. Providing services only for those that they are qualified and competent and adequately informing clients and customers about the nature of proposed services, including any relevant concerns or risks
- 5. Informing their employer or client of any business interests or affiliations which might influence or impair their judgment
- 6. Preserving the confidentiality of information of any present or former employer or client during service provision
- 7. Complying with all the applicable laws and regulations of the jurisdictions in the country where the service provisions were conducted
- 8. Respecting the intellectual property and contributions of others
- 9. Not communicating intentionally false or falsified information that may compromise the integrity of the evaluation process of a candidate for a PECB certification or a PECB certificate program
- Not falsely or wrongly presenting themselves as PECB representatives without a proper license or misusing PECB logo, certifications or certificates
- 11. Not acting in ways that could damage PECB's reputation, certifications or certificate programs
- 12. Cooperating in a full manner on the inquiry following a claimed infringement of this Code of Ethics

To read the complete version of PECB's Code of Ethics, go to Code of Ethics | PECB.

## Introduction to ISO/IEC 17025 Lead Implementer

ISO/IEC 17025 specifies the requirements for establishing, implementing, maintaining, and continually improving a laboratory management system (LMS). It is applicable to all those organizations performing tests and/or calibrations. These include, for example, first, second and third-party laboratories, and laboratories where testing and/or calibration form part of the inspection and product certification.

ISO/IEC 17025 is applicable to any laboratory, regardless of the number of personnel or the extent of the scope of testing and/or calibration activities. When a laboratory does not undertake one or more of the activities covered by ISO/IEC 17025, such as sampling and the design/development of new methods, the requirements of those clauses do not apply.

ISO/IEC 17025 is for use by laboratories in developing their management system for quality, administrative and technical operations. Laboratory customers, regulatory authorities and accreditation bodies may also use it to confirm or recognize the competence of laboratories. ISO/IEC 17025 is not intended to be used as the basis for certification of laboratories.

There are two main clauses in ISO/IEC 17025 – Management Requirements and Technical Requirements. Management requirements are related to the operation and effectiveness of the quality management system within the laboratory, and this clause has similar requirements to ISO 9001. Technical requirements include factors which determine the correctness and reliability of the tests and calibrations performed in laboratory namely competence of staff; environment control; testing methodology; equipment and measurement traceability; and reporting of test and calibration results.

Many countries around the world have one or more organizations responsible for the accreditation of their nation's laboratories. Most of these accreditation bodies have now adopted ISO/IEC 17025 as the basis for accrediting their country's testing and calibration laboratories. This has helped countries employ a uniform approach to determining laboratory competence. It has also encouraged laboratories adopt internationally accepted testing and measurement practices, where possible. In order the accreditation bodies (at different parts of the world) recognize each other's accreditations, the International Laboratory Accreditation Cooperation (ILAC) worked to establish methods of evaluating accreditation bodies against another ISO standard (ISO/IEC Guide 58 - which became ISO/IEC 17011). Around the world, geopolitical regions such as the European Community, and Asia-Pacific, the Americas and others, established regional cooperation's to manage the work needed for such mutual recognition. These regional bodies (all working within the ILAC umbrella) include the European Accreditation Cooperation (EA), Asia Pacific Laboratory Accreditation Cooperation (APLAC), Southern Africa Accreditation Cooperation (SADCA) and the Inter-American Accreditation Cooperation (IAAC).

#### Benefits:

- Increase of confidence in testing/calibration data and of personnel performing work.
- Better control of laboratory operations and feedback to laboratories as to whether they have sound quality assurance system and are technically competent.
- Potential increase in business due to enhanced customer confidence and satisfaction.
- Customers can search and identify the laboratories accredited by The Accreditation Member Body for their specific requirements from their website or Directory of Accredited Laboratories.

- Users of accredited laboratories will enjoy greater access for their products, in both domestic and international markets, when tested by accredited laboratories.
- Savings in terms of time and money due to reduction or elimination of the need for re-testing of products.
- Improved national and global reputation and image of the laboratory.
- Continually improving data quality and laboratory effectiveness.

The "ISO/IEC 17025 Lead Implementer" credential is a professional certification for individuals aiming to demonstrate the competence to implement the information security management system and lead an implementation team.

Considering that implementing is one of the most in-demand professions, an internationally recognized certification can help you exploit your career potential and reach your professional objectives.

PECB certifications are not a license or simply a membership. They attest the candidates' knowledge and skills gained through our training courses and are issued to candidates that have the required experience and have passed the exam.

This document specifies the PECB ISO/IEC 17025 Lead Implementer certification scheme in compliance with ISO/IEC 17024:2012. It also outlines the steps that candidates should take to obtain and maintain their credentials. As such, it is very important to carefully read all the information included in this document before completing and submitting your application. If you have questions or need further information after reading it, please contact the PECB international office at <a href="mailto:certification.team@pecb.com">certification.team@pecb.com</a>.



## SECTION II: EXAMINATION PREPARATION, RULES, AND POLICIES

## Preparing for and scheduling the exam

All candidates are responsible for their own study and preparation for certification exams. Although candidates are not required to attend the training course to be eligible for taking the exam, attending it can significantly increase their chances of successfully passing the exam.

To schedule the exam, candidates have two options:

- Contact one of our authorized partners. To find an authorized partner in your region, please go to <u>Active</u>
   <u>Partners</u>. The training course schedule is also available online and can be accessed on <u>Training Events</u>.
- 2. Take a PECB exam remotely through the <u>PECB Exams application</u>. To schedule a remote exam, please go to the following link: <u>Exam Events</u>.

To learn more about exams, competency domains, and knowledge statements, please refer to Section III of this document.

# Rescheduling the exam

For any changes with regard to the exam date, time, location, or other details, please contact <a href="mailto:online.exams@pecb.com">online.exams@pecb.com</a>.

## Application fees for examination and certification

Candidates may take the exam without attending the training course. The applicable prices are as follows:

Lead Exam: \$1000²
Manager Exam: \$700
Foundation Exam: \$500
Transition Exam: \$500

The application fee for certification is \$500.

For the candidates that have attended the training course via one of PECB's partners, the application fee covers the costs of the exam (first attempt and first retake), the application for certification, and the first year of Annual Maintenance Fee (AMF).

<sup>&</sup>lt;sup>2</sup> All prices listed in this document are in US dollars.

## **Competency domains**

The objective of the "PECB ISO 17025 Lead Implementer" exam is to ensure that the candidate has acquired the necessary expertise to support an organization in establishing, implementing, managing and maintaining the Laboratory Management System (LMS).

The ISO/IEC 17025 Lead Implementer certification is intended for:

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

The content of the exam is divided as follows:

- Domain 1: Fundamental principles and concepts of a laboratory management system (LMS)
- Domain 2: Laboratory management system (LMS) and ISO/IEC 17025 requirements
- **Domain 3:** Planning the LMS implementation
- Domain 4: Implementing an LMS
- Domain 5: Performance evaluation, monitoring, and measurement of an LMS
- Domain 6: Continual improvement of an LMS
- Domain 7: Preparing for an LMS certification audit



# Domain 1: Fundamental principles and concepts of a laboratory management system (LMS)

**Main objective:** Ensure that the candidate understands and is able to interpret ISO/IEC 17025 principles and concepts.

	Competencies		Knowledge statements
1.	Ability to understand and explain the main	1.	Knowledge of the laboratory laws, regulations,
	concepts of the laboratory management system		international and industry standards, contracts, market practices, internal policies, etc., an
2.	Understand and explain the operations of the		organization must comply with
	ISO organization and the development of	2.	Knowledge of the main concepts and
	laboratory management system (LMS)		terminology of ISO/IEC 17025
3.	Ability to explain and illustrate the main	3.	Knowledge of the management principles in a
	concepts in laboratory management system		laboratory management system (LMS)
	(LMS).	4.	Knowledge of the main standards in a
			laboratory management system (LMS)



# Domain 2: Laboratory management system (LMS) and ISO/IEC 17025 requirements

**Main objective:** Ensure that the candidate understands and is able to interpret and identify the requirements for a laboratory management system based on ISO/IEC 17025.

	Competencies		Knowledge statements
1.	Ability to understand the ISO/IEC 17025	1.	Knowledge of the supporting standards of
	requirements and the structure of the standard		ISO/IEC 17025
2.	Ability to understand the components of a	2.	Knowledge of the concepts, principles and
	laboratory management system based on		terminology related to laboratory management
	ISO/IEC 17025 and its principal processes		system (LMS)
3.	Ability to understand, interpret, and analyze the	3.	Knowledge of the principal characteristics of
	requirements of ISO/IEC 17025		laboratory management system (LMS)
4.	Ability to understand, explain, and illustrate the	4.	Knowledge of the main advantages of
	main steps to establish, implement, operate,		laboratory management system (LMS)
	monitor, review, maintain, and improve an	5.	Knowledge of the ISO/IEC 17025 requirements,
	organization's LMS		clauses 4 to 10, and others, if applicable
		6.	Knowledge of the main steps for establishing
			LMS policies, objectives, processes, and
			procedures relevant to managing risks and
			improving a laboratory management system
		7.	Knowledge of the concept of continual
			improvement and its application to an LMS
		8.	Knowledge of the "Plan-Do-Check-Act" (PDCA)
			cycle
		9.	Knowledge of the principal characteristics of
			an integrated management system



# **Domain 3: Planning the LMS implementation**

**Main objective:** Ensure that the candidate is able to plan the implementation of the LMS based on ISO/IEC 17025.

	Competencies		Knowledge statements
1.	Ability to collect, analyze, and interpret the	1.	Knowledge of the main project management
	information required to plan an LMS implementation		concepts, terminology, processes, and best practices
2.	Ability to understand and set laboratory	2.	Knowledge of the principal approaches and
3.	management and LMS objectives Ability to identify and interpret LMS risks and their impacts	3.	methodology used to implement an LMS Knowledge of typical laboratory management and LMS objectives and how to achieve
4.	Ability to analyze and consider the internal and		specific results
5.	external context of an organization Ability to identify the resources required for the	4.	Knowledge of the main concepts and terminology related to organizations
	LMS implementation	5.	Knowledge of the main interested parties
6.	Ability to state and justify the scope adapted to the laboratory management system objectives		related to an organization and their characteristics
	of a specific organization	6.	Knowledge of what typically constitutes an
7.	Ability to select and justify the selected approach and methodology adapted to the	7.	organization's internal and external context Knowledge of the approaches used to
	needs of the organization	/.	understand the context of an organization
8.	Ability to manage, estimate, and monitor the	8.	Knowledge of the techniques used to gather
	required resources for the LMS implementation		information on an organization and to perform a gap analysis of a management system
9.	Ability to identify the roles and responsibilities of key interested parties during and after the	9.	Knowledge of a LMS project plan and an LMS project team
	implementation and operation of an LMS	10.	Knowledge of the resources required for an
10.	Ability to draft, file, and review an LMS project plan	11.	LMS implementation  Knowledge of the main organizational
11.	Ability to perform a gap analysis and clarify the laboratory management objectives		structures applicable for an organization to manage an LMS
12.	Ability to define and justify an LMS scope adapted to the organization's specific	12.	Knowledge of the characteristics of an LMS scope in terms of organizational,
13.	laboratory management objectives Ability to develop and establish an LMS policy	13.	technological, and physical boundaries Knowledge of the best practices and
14.	Ability to perform the different steps of the risk assessment process		techniques used to draft and establish laboratory management policies and procedures
		14.	Knowledge of the different approaches and methodologies used to perform the risk assessment process

# **Domain 4: Implementing an LMS**

**Main objective:** Ensure that the candidate is able to implement the processes of an LMS required for an ISO/IEC 17025 certification.

	Competencies		Knowledge statements
1.	Ability to identify, analyze, and evaluate risks	1.	Knowledge of resource management in an
	and opportunities		LMS implementation processes
2.	Ability to understand, analyze needs and	2.	Knowledge of the roles and responsibilities of
	provide guidance on the attribution of roles		the key actors during the implementation of a
	and responsibilities in the context of the	2	LMS and in its operation  Knowledge of the main organizational
3.	implementation and management of a LMS Ability to manage capacity building processes	3.	structures applicable for an organization to
٥.	for the successful implementation of an LMS		manage Laboratory Management System
4.	Ability to define the documentation and record		(LMS)
	management processes needed to support the	4.	Knowledge of the process of identifying,
	implementation and operations of an LMS		analyzing, and evaluating risks and
5.	Ability to define, design and implement		opportunities
	processes necessary for the operation of an	5.	Knowledge of the best practices on
	LMS and properly document them		documented information life cycle
6.	Ability to define and write a LMS policy and		management
	procedures	6.	Knowledge of the characteristics and the
7.	Ability to understand, manage, and evaluate		differences between the different documented
	organizational knowledge		information related to an LMS policy,
8.	Ability to define and implement appropriate		procedure, guideline, standard, baseline,
	laboratory management training and	7	worksheet, etc.
	awareness programs, and communication plans	7.	Knowledge of model-building controls and processes techniques and best practices
9.	Ability to establish an LMS communication	8.	Knowledge of controls and processes
۶.	plan to assist in the understanding of an	0.	deployment techniques and best practices
	organization's laboratory management issues,	9.	Knowledge of the characteristics and the best
	policies, performance, and providing inputs or		practices of implementing LMS training and
	suggestions for improving the performance of		awareness programs and communication
	the LMS		plans
10.	Ability to define and implement an incident	10.	Knowledge of the communication objectives,
	management process based on Laboratory		activities, and interested parties to enhance
	Management System best practices		their support and confidence
		11.	Knowledge of the characteristics and main
			processes of incident that can happen during
		10	the implementation of LMS
		12.	Knowledge of the techniques of change
			management that refer to the best practices



# Domain 5: Monitoring, measurement, analysis and evaluation of an LMS

**Main objective:** Ensure that the candidate is able to evaluate, monitor, and measure the performance of an LMS.

	Competencies		Knowledge statements
1.	Ability to monitor and evaluate the	1.	Knowledge of the best practices and
	effectiveness of an LMS		techniques used to monitor and evaluate the
2.	Ability to verify to what extent the identified		effectiveness of an LMS
	LMS objectives have been met	2.	Knowledge of the concepts related to
3.	Ability to define and implement an LMS		measurement and evaluation
	internal audit program	3.	Knowledge of the main concepts and
4.	Ability to perform regular and methodical		components related to the implementation and
	reviews to ensure the suitability, adequacy,		operation of an LMS internal audit program
	effectiveness, and efficiency of an LMS based	4.	Knowledge of the characteristics and the
	on the policies and objectives of the		differences between an operational, tactical
	organization		and strategic Laboratory Management System
5.	Ability to define and perform a management		indicators and dashboard
	review process	5.	Knowledge of the techniques and methods to
			define and document an adequate and reliable indicator
		6.	Knowledge of the difference between a major and a minor nonconformity
		7.	Knowledge of the guidelines and best
			practices to draft a nonconformity report
		8.	Knowledge of the best practices used to
			perform management reviews



# Domain 6: Continual improvement of an LMS

**Main objective:** Ensure that the candidate is able to provide guidance on the continual improvement of an LMS.

	Competencies		Knowledge statements
1.	Ability to understand the principle and concepts related to continual improvement	1.	Knowledge of the main processes, tools, and techniques used to identify the root causes of
2.	Ability to track and take action on nonconformities	2.	nonconformities  Knowledge of the treatment of
3.	Ability to identify and analyze the root causes		nonconformities process
	of nonconformities, and propose action plans to treat them	3.	Knowledge of the main processes, tools, and techniques used to develop corrective action
4.	Ability to counsel an organization on how to	,	plans
	continually improve the effectiveness and efficiency of an LMS	4.	Knowledge of the characteristics and the difference between corrective actions and
5.	Ability to implement continual improvement	_	preventive actions
6.	processes in an organization Ability to determine the appropriate tools to	5.	Knowledge of the main concepts related to continual improvement
	support the continual improvement processes	6.	Knowledge of the processes related to the
7.	of an organization Ability to identify, analyze the root-cause of	7.	continual monitoring of change factors Knowledge of the maintenance and
	potential nonconformities and proposed action plans to treat them		improvement of an LMS



# Domain 7: Preparing for an LMS certification audit

**Main objective:** Ensure that the candidate is able to prepare an organization for the certification against ISO/IEC 17025.

	Competencies		Knowledge statements
1.	Ability to understand the main steps, processes, and activities related to the ISO/IEC	1.	Knowledge of the evidence-based approach to an audit
	17025 certification audit	2.	Knowledge of the types of audit and their
2.	Ability to understand, explain, and illustrate the		differences
3.	audit evidence approach in an LMS audit Ability to counsel an organization to identify	3.	Knowledge of the differences between Stage 1 and Stage 2 audits
	and select a certification body that meets their expectations	4.	Knowledge of the Stage 1 audit requirements, steps, and activities
4.	Ability to determine whether an organization is ready and prepared for the ISO/IEC 17025	5.	Knowledge of the documented information review criteria
5.	certification audit Ability to train and prepare an organization's	6.	Knowledge of the Stage 2 audit requirements, steps, and activities
	personnel for the ISO/IEC 17025 certification audit	7.	Knowledge of the audit follow-up requirements, steps, and activities
6.	Ability to argue and challenge the audit	8.	Knowledge of the surveillance audits and
	findings and conclusions with external auditors		recertification audit requirements, steps, and activities
		9.	Knowledge of the requirements, guidelines, and best practices for developing action plans following an ISO/IEC 17025 certification audit



Based on the above-mentioned domains and their relevance, the exam contains 12 questions, as summarized in the table below:

			Level of und (Cognitive/Taxo					
		Points per question	Questions that measure comprehension, application, and analysis	Questions that measure evaluation	Number of questions per competency domain	% of the exam devoted to each competency domain	Number of points per competency domain	% of points per competency domain
		5	Х					
	Fundamental principles and concepts of a laboratory management system (LMS)	5	Х		3	25	15	20
		5	Х					
S	Laboratory management system (LMS) and ISO/IEC 17025 requirements	10	Х		1	8.33	10	13.33
Competency domains	Planning the LMS implementation	5		Х	1	8.33	5	6.67
ncy de	Implementing an LMS	5		Х				
peter		5		Х	3	25	20	26.67
Com		10	Х					
	Monitoring, measurement, analysis and evaluation of an	10		Х	2	16.67	15	20
	LMS	5		Х	2	10.07	13	20
	Continual improvement of an LMS	5		Х	1	8.33	5	6.67
	Preparing for an LMS certification audit	5		Х	1	8.33	5	6.67
	Total points	75						
	Number of questions und	per level of lerstanding	7	5				
	% of the exam devoted to ex understanding (cognitive)		58.3	41.7				

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

After successfully passing the exam, candidates will be able to apply for obtaining the "PECB Certified ISO/IEC 17025 Lead Implementer" credential.



### Taking the exam

#### General information about 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

- 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 Partner 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 information about online exams, go to the PECB Online Exam Guide.

PECB exams are available in two types:

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

This exam comprises essay-type questions. Essay-type questions 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 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.

This is an open-book exam. The candidate is allowed to use the following reference materials:

- A hard copy of the ISO/IEC 17025 standard
- Training course materials (accessed through the PECB Exams app and/or printed)
- Any personal notes taken during the training course (accessed through the PECB Exams app and/or printed)
- A hard copy dictionary

A sample of exam questions will be provided below.

**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).

For specific information about exam types, languages available, and other details, please contact <a href="mailto:examination.team@pecb.com">examination.team@pecb.com</a> or go to the <a href="mailto:List of PECB Exams">List of PECB Exams</a>.



#### Sample exam questions

#### Question 1: Interpretation of ISO clauses

For each of the following clauses of the ISO/IEC 17025 standard, 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 4.11 Corrective actions

#### Possible answer:

- Elaboration and communication of a documented procedure defining how to identify corrective actions and how to treat them.
- Maintenance of an updated list of corrective actions showing the responsible person, the status and the deadline for each corrective action.

#### **Question 2: Development of metrics**

For each of the following clauses of the ISO/IEC 17025 standard, please provide two examples of metrics that would be acceptable to measure the conformity to the clause.

Clause 4.15 Management Review

#### Possible answer:

- Total of management review meetings completed according to the annual planning
- Average participation rates in management review meetings to date

#### **Ouestion 3: Recommendations**

The management of the organization would like to receive recommendations from you to improve the processes in place to comply with the requirements of ISO/IEC 17025 on control of documents

#### Possible answer:

- 1. Document the procedures and implement it for the control of documents
- 2. Maintain a log for documents changes with records of the approvals.
- 3. Communicating the new process and organize training session.

## **Exam Security Policy**

PECB is committed to protect the integrity of its exams and the overall examination process, and relies upon the ethical behavior of applicants, potential applicants, candidates and partners to maintain the confidentiality of PECB exams. This Policy aims to address unacceptable behavior and ensure fair treatment of all candidates.

Any disclosure of information about the content of PECB exams is a direct violation of this Policy and PECB's Code of Ethics. Consequently, candidates taking a PECB exam are required to sign an Exam Confidentiality and Non-Disclosure Agreement and must comply with the following:

- The questions and answers of the exam materials are the exclusive and confidential property of PECB.
   Once candidates complete the submission of the exam to PECB, they will no longer have any access to the original exam or a copy of it.
- 2. Candidates are prohibited from revealing any information regarding the questions and answers of the exam or discuss such details with any other candidate or person.
- Candidates are not allowed to take with themselves any materials related to the exam, out of the exam room.
- Candidates are not allowed to copy or attempt to make copies (whether written, photocopied, or otherwise) of any exam materials, including, without limitation, any questions, answers, or screen images.
- 5. Candidates must not participate nor promote fraudulent exam-taking activities, such as:
  - Looking at another candidate's exam material or answer sheet
  - · Giving or receiving any assistance from the invigilator, candidate, or anyone else
  - Using unauthorized reference guides, manuals, tools, etc., including using "brain dump" sites as they are not authorized by PECB

Once a candidate becomes aware or is already aware of the irregularities or violations of the points mentioned above, they are responsible for complying with those, otherwise if such irregularities were to happen, candidates will be reported directly to PECB or if they see such irregularities, they should immediately report to PECB.

Candidates are solely responsible for understanding and complying with PECB Exam Rules and Policies, Confidentiality and Non-Disclosure Agreement and Code of Ethics. Therefore, should a breach of one or more rules be identified, candidates will not receive any refunds. In addition, PECB has the right to deny the right to enter a PECB exam or to invite candidates for an exam retake if irregularities are identified during and after the grading process, depending on the severity of the case.

Any violation of the points mentioned above will cause PECB irreparable damage for which no monetary remedy can make up. Therefore, PECB can take the appropriate actions to remedy or prevent any unauthorized disclosure or misuse of exam materials, including obtaining an immediate injunction. PECB will take action against individuals that violate the rules and policies, including permanently banning them from pursuing PECB credentials and revoking any previous ones. PECB will also pursue legal action against individuals or organizations who infringe upon its copyrights, proprietary rights, and intellectual property.

#### **Exam results**

Exam results will be communicated via email.

- 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 a re-evaluation by writing to <a href="mailto:examination.team@pecb.com">examination.team@pecb.com</a> within 30 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 days from the date they received the reevaluated exam results to file a complaint through the <a href="mailto:PECB Ticketing System">PECB Ticketing System</a>. Any complaint received after 30 days will not be processed.

### **Exam Retake Policy**

There is no limit to the number of times a candidate can retake an exam. However, there are certain limitations in terms of the time span between exam retakes.

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

**Note:** Candidates who have completed the training course with one of our partners, and failed the first exam attempt, are eligible to retake for free the exam within a 12-month period from the date the coupon code is received (the fee paid for the training course, includes a first exam attempt and one retake). Otherwise, retake fees apply.

For candidates that fail the exam retake, PECB recommends they attend a training course in order to be better prepared for the exam.

To arrange exam retakes, based on exam format, candidates that have completed a training course, must follow the steps below:

- 1. Online Exam: when scheduling the exam retake, use initial coupon code to waive the fee
- 2. Paper-Based Exam: candidates need to contact the PECB Partner/Distributor who has initially organized the session for exam retake arrangement (date, time, place, costs).

Candidates that have not completed a training course with a partner, but sat for the online exam directly with PECB, do not fall under this Policy. The process to schedule the exam retake is the same as for the initial exam.



# **SECTION III: CERTIFICATION PROCESS AND REQUIREMENTS**

## PECB ISO/IEC 17025 credentials

All PECB certifications have specific requirements regarding education and professional experience. To determine which credential is right for you, take into account your professional needs and analyze the criteria for the certifications.

The credentials in the PECB ISO/IEC 17025 scheme have the following requirements:

Credential	Credential Education E		Professional experience	MS project experience	Other requirements	
PECB Certified ISO/IEC 17025 Provisional Implementer		At least secondary education  PECB Certified ISO/IEC 17025 Lead Implementer exam or equivalent	None	None	·	
PECB Certified ISO/IEC 17025 Implementer	B Certified EC 17025 lementer		At least ISO/IEC 17025 management		Project activities: a total of 200 hours	Signing the
PECB Certified ISO/IEC 17025 Lead Implementer			Five years: Two years of work experience in laboratory management	Project activities: a total of 300 hours	PECB Code of Ethics	
PECB Certified ISO/IEC 17025 Senior Lead Implementer					Ten years: Seven years of work experience in laboratory management	Project activities: a total of 1,000 hours

To be considered valid, the implementation activities should follow best implementation and management practices and include the following:

- 1. Drafting the LMS plan
- 2. Initiating the LMS implementation
- 3. Implementing the LMS
- 4. Managing, monitoring, and maintaining the LMS
- 5. Identifying and acting upon continual improvement opportunities
- 6. Implementing metrics
- 7. Implementing corrective or preventive action
- 8. Performing a management review
- 9. Performing a risk assessment
- 10. Managing incidents
- 11. Managing a TCLA team

### **Applying for certification**

All candidates who successfully pass the exam (or an equivalent accepted by PECB) are entitled to apply for the PECB credential they were assessed for. Specific educational and professional requirements need to be fulfilled in order to obtain a PECB certification. Candidates are required to fill out the online certification application form (that can be accessed via their PECB account), including contact details of individuals who will be contacted to validate the candidates' professional experience. Candidates can submit their application in English, French, German, Spanish or Korean languages. They can choose to either pay online or be billed. For additional information, please contact <a href="mailto:certification.team@pecb.com">certification.team@pecb.com</a>.

The online certification application process is very simple and takes only a few minutes:

- Register your account
- Check your email for the confirmation link
- <u>Log in</u> to apply for certification

For more information on how to apply for certification, click here.

The Certification Department validates that the candidate fulfills all the certification requirements regarding the respective credential. The candidate will receive an email about the application status, including the certification decision.

Following the approval of the application by the Certification Department, the candidate will be able to download the certificate and claim the corresponding Digital Badge. For more information about downloading the certificate, click <a href="here">here</a>, and for more information about claiming the Digital Badge, click <a href="here">here</a>.

PECB provides support both in English and French.

## **Professional experience**

Candidates must provide complete and correct information regarding their professional experience, including job title(s), start and end date(s), job description(s), and more. Candidates are advised to summarize their previous or current assignments, providing sufficient details to describe the nature of the responsibilities for each job. More detailed information can be included in the résumé.

#### **Professional references**

For each application, two professional references are required. They must be from individuals who have worked with the candidate in a professional environment and can validate their laboratory management experience, as well as their current and previous work history. Professional references of persons who fall under the candidate's supervision or are their relatives are not valid.

### LMS project experience

The candidate's LMS project log will be checked to ensure that the candidate has the required number of implementation hours.

## **Evaluation of certification applications**

The Certification Department will evaluate each application to validate the candidates' eligibility for certification or certificate program. A candidate whose application is being reviewed will be notified in writing and, if necessary, given a reasonable time frame to provide any additional documentation. If a candidate does not respond by the deadline or does not provide the required documentation within the given time frame, the Certification Department will validate the application based on the initial information provided, which may lead to the candidates' credential downgrade.

### **SECTION IV: CERTIFICATION POLICIES**

#### **Denial of certification**

PECB can deny certification/certificate program if candidates:

- Falsify the application
- Violate the exam procedures
- Violate the PECB Code of Ethics

Candidates whose certification/certificate program has been denied can file a complaint through the complaints and appeals procedure. For more detailed information, refer to **Complaint and Appeal Policy** section.

The application payment for the certification/certificate program is nonrefundable.

### **Certification status options**

#### Active

Means that your certification is in good standing and valid, and it is being maintained by fulfilling the PECB requirements regarding the CPD and AMF.

#### Suspended

PECB can temporarily suspend candidates' certification if they fail to meet the requirements. Other reasons for suspending certification include:

- 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.

#### Revoked

PECB can revoke (that is, to withdraw) the certification if the candidate fails to satisfy its requirements. In such cases, candidates are no longer allowed to represent themselves as PECB Certified Professionals. Additional reasons for revoking certification can be if the candidates:

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

Candidates whose certification has been revoked can file a complaint through the complaints and appeals procedure. For more detailed information, refer to **Complaint and Appeal Policy** section.

#### Other statuses

Besides being active, suspended, or revoked, a certification can be voluntarily withdrawn or designated as Emeritus. To learn more about these statuses and the permanent cessation status, go to <a href="Certification Status">Certification Status</a> <a href="Options">Options</a>.

## Upgrade and downgrade of credentials

#### **Upgrade of credentials**

Professionals can upgrade their credentials as soon as they can demonstrate that they fulfill the requirements.

To apply for an upgrade, candidates need to log into their PECB account, visit the "My Certifications" tab, and click on "Upgrade." The upgrade application fee is \$100.

#### **Downgrade of credentials**

A PECB Certification can be downgraded to a lower credential due to the following reasons:

- The AMF has not been paid.
- The CPD hours have not been submitted.
- Insufficient CPD hours have been submitted.
- · Evidence on CPD hours has not been submitted upon request.

**Note:** PECB certified professionals who hold Lead certifications and fail to provide evidence of certification maintenance requirements will have their credentials downgraded. The holders of Master Certifications who fail to submit CPDs and pay AMFs will have their certifications revoked.

## Renewing the certification

PECB certifications are valid for three years. To maintain them, PECB certified professionals must meet the requirements related to the designated credential, e.g., they must fulfill the required number of continual professional development (CPD) hours. In addition, they need to pay the annual maintenance fee (\$120). For more information, go to the <a href="Certification Maintenance">Certification Maintenance</a> page on the PECB website.

### Closing a case

If candidates do not apply for certification within one year, their case will be closed. Even though the certification period expires, candidates have the right to reopen their case. However, PECB will no longer be responsible for any changes regarding the conditions, standards, policies, and candidate handbook that were applicable before the case was closed. A candidate requesting their case to reopen must do so in writing to <a href="mailto:certification.team@pecb.com">certification.team@pecb.com</a> and pay the required fee.

#### Complaint and Appeal Policy

Any complaints must be made no later than 30 days after receiving the certification decision. PECB will provide a written response to the candidate within 30 working days after receiving the complaint. If candidates do not find the response satisfactory, they have the right to file an appeal.

For more information about the Complaint and Appeal Policy, click here.



## **SECTION V: GENERAL POLICIES**

#### Exams and certifications from other accredited certification bodies

PECB accepts certifications and exams from other recognized accredited certification bodies. PECB will evaluate the requests through its equivalence process to decide whether the respective certification(s) or exam(s) can be accepted as equivalent to the respective PECB certification (e.g., ISO/IEC 27001 Lead Implementer certification).

## Non-discrimination and special accommodations

All candidate applications will be evaluated objectively, regardless of the candidates' age, gender, race, religion, nationality, or marital status.

To ensure equal opportunities for all qualified persons, PECB will make reasonable accommodations<sup>3</sup> for candidates, when appropriate. If candidates need special accommodations because of a disability or a specific physical condition, they should inform the partner/distributor in order for them to make proper arrangements<sup>4</sup>. Any information that candidates provide regarding their disability/special needs will be treated with confidentiality. To download the Candidates with Disabilities Form, click here.

### **Behavior Policy**

PECB aims to provide top-quality, consistent, and accessible services for the benefit of its external stakeholders: distributors, partners, trainers, invigilators, examiners, members of different committees and advisory boards, and clients (trainees, examinees, certified individuals, and certificate holders), as well as creating and maintaining a positive work environment which ensures safety and well-being of its staff, and holds the dignity, respect and human rights of its staff in high regard.

The purpose of this Policy is to ensure that PECB is managing unacceptable behavior of external stakeholders towards PECB staff in an impartial, confidential, fair, and timely manner. To read the Behavior Policy, click <a href="here">here</a>.

## **Refund Policy**

PECB will refund your payment, if the requirements of the Refund Policy are met. To read the Refund Policy, click <u>here</u>.

<sup>&</sup>lt;sup>3</sup> According to ADA, the term "reasonable accommodation" may include: (A) making existing facilities used by employees readily accessible to and usable by individuals with disabilities; and (B) job restructuring, part-time or modified work schedules, reassignment to a vacant position, acquisition or modification of equipment or devices, appropriate adjustment or modifications of examinations, training materials or policies, the provision of qualified readers or interpreters, and other similar accommodations for individuals with disabilities

<sup>&</sup>lt;sup>4</sup> ADA Amendments Act of 2008 (P.L. 110–325) Sec. 12189. Examinations and courses. [Section 309]: Any person that offers examinations or courses related to applications, licensing, certification, or credentialing for secondary or post-secondary education, professional, or trade purposes shall offer such examinations or courses in a place and manner accessible to persons with disabilities or offer alternative accessible arrangements for such individuals.

