When Recognition Matters

EXAM PREPARATION GUIDE

PECB Certified ISO/IEC 17025 Lead Implementer

The objective of the "PECB Certified ISO/IEC 17025 Lead Implementer" examination is to ensure that the candidates have developed the necessary expertise to support an organization in implementing and managing a Laboratory Management System based on ISO/IEC 17025.

The target population for this examination is:

- Individuals involved in Testing and Calibration Laboratories
- Managers or consultants seeking to master the implementation of a Laboratory Management System
- Laboratory technicians responsible for maintaining conformance with Testing and Calibration Laboratories Accreditation requirements
- Individuals responsible for supporting the operations of a Testing and Calibration Laboratory
- Technical experts seeking to prepare for Testing and Calibration Laboratories competence assessment

The exam content covers the following domains:

- **Domain 1:** Fundamental principles and concepts of a Laboratory Management System (LMS)
- **Domain 2:** Laboratory Management System (LMS)
- **Domain 3:** Planning a LMS based on ISO/IEC 17025
- **Domain 4:** Implementing a management system based on ISO/IEC 17025
- **Domain 5:** Performance evaluation, monitoring and measurement of a LMS based on ISO/IEC 17025
- **Domain 6:** Continual improvement of a LMS based on ISO/IEC 17025
- **Domain 7:** Preparing for an accreditation

The content of the exam is divided as follows:

Domain 1: Fundamental principles and concepts of a Laboratory Management System (LMS)

Main objective: To ensure that the ISO/IEC 17025 Lead Implementer candidate can understand, interpret and illustrate the main testing and calibration laboratories concepts related to Laboratory Management System (LMS)

Competencies	Knowledge statements
1. Understand and explain the operations of the ISO organization and the development of Laboratory Management System (LMS) 2. Ability to identify, analyze and evaluate the Laboratory Management System (LMS) compliance requirements for an organization 3. Ability to explain and illustrate the main concepts in Laboratory Management System (LMS).	1. Knowledge of the management principles in Laboratory Management System (LMS) 2. Knowledge of the main standards in Laboratory Management System (LMS) 3. Knowledge of the different sources of Laboratory Management System (LMS) requirement for an organization: laws, regulations, international and industry standards, contracts, market practices and internal policies 4. Knowledge of the Laboratory Management System (LMS) concepts and terminology as described in ISO/IEC 17025

Domain2: Laboratory Management System (LMS)

Main objective: To ensure that the ISO/IEC 17025 Lead Implementer candidate can understand, implement and manage a Laboratory Mangement System (LMS) requirements based on ISO/IEC 17025

Competencies	Knowledge statements
1. Understand and explain the components of a Laboratory Management System (LMS) based on ISO/IEC 17025 and its principal processes 2. Ability to interpret and analyze ISO/IEC 17025 requirements 3. Understand, explain and illustrate the main steps to establish, implement, operate, monitor, review, maintain and improve the Laboratory Management System (LMS)	1. Knowledge of the concepts, principles and terminology related to Laboratory Management System (LMS) 2. Knowledge of the principal characteristics of Laboratory Management System (LMS) 3. Knowledge of the main advantages of Laboratory Management System (LMS) 4. Knowledge of the ISO/IEC 17025 requirements presented in the clauses 4 to 5. 5. Knowledge of the main steps to establish policies, objectives, processes and procedures relevant to managing risk and improving Laboratory Management System (LMS) to deliver results in accordance with an organization's overall policies and objectives (Awareness level) 6. Knowledge of the basic principles behind ISO/IEC 17025

Domain 3: Planning a LMS based on ISO/IEC 17025

Main objective: To ensure that the ISO/IEC 17025 Lead Implementer candidate can plan the implementation of a LMS in preparation for an ISO/IEC 17025 accreditation

Competencies	Knowledge statements
1. Ability to plan and implement a LMS implementation 2. Ability to gather, analyze and interpret the necessary information to plan the LMS implementation 3. Ability to observe, analyze and interpret the external and internal environment of an organization 4. Ability to perform a gap analysis and clarify the Laboratory Management System objectives of an organization 5. Ability to state and justify the scope adapted to the Laboratory Management System objectives of a specific organization 6. Ability to select and justify the selected approach and methodology adapted to the needs of the organization	1. Knowledge of the main Laboratory Management System concepts, terminology, process and best practices 2. Knowledge of the principal approaches and methodology frameworks to implement a LMS 3. Knowledge of the main concepts and terminology related to organizations 4. Knowledge of an organization's external and internal environment 5. Knowledge of the main interested parties related to an organization and their characteristics 6. Knowledge of techniques to gather information on an organization 7. Knowledge of the characteristics of a LMS scope in terms of organizational, technological and physical boundaries

Domain 4: Implementing a management system based on ISO/IEC 17025

Main objective: To ensure that the ISO/IEC 17025 Lead Implementer candidate can implement the processes of LMS that are required for an ISO/IEC 17025 accreditation

Competencies	Knowledge statements
1. Ability to understand, analyze needs and provide guidance on the attribution of roles and responsibilities in the context of the implementation and management of a LMS 2. Ability to define the document and record management processes needed to support the implementation and the operations of a LMS 3. Ability to define Laboratory Management System processes and to document them 4. Ability to define and write a LMS policy and procedures 5. Ability to implement the required processes and requirements of a LMS 6. Ability to define and implement appropriate Laboratory Management System training, awareness and communication plans 7. Ability to define and implement an incident management process based on Laboratory Management System best practices	1. Knowledge of the roles and responsibilities of the key actors during the implementation of a LMS and in its operation 2. Knowledge of the main organizational structures applicable for an organization to manage Laboratory Management System (LMS) 3. Knowledge of the characteristics and the differences between the different documents related to LMS: policy, procedure, requirements, standard, baseline and worksheet. 4. Knowledge of model-building controls and processes techniques and best practices 5. Knowledge of controls and processes deployment techniques and best practices 6. Knowledge of the characteristics and the best practices to implement Laboratory Management System training, awareness and communication plans 7. Knowledge of the characteristics and main processes of incident that can happen during the implementation of LMS 8. Knowledge of the techniques of change management that refer to the best practices

Domain 5: Performance evaluation, monitoring and measurement of a LMS based on ISO/IEC 17025

Main objective: To ensure that the ISO/IEC 17025 Lead Implementer candidate can evaluate, monitor and measure the performance of a LMS in the context of an ISO/IEC 17025 standard

Competencies	Knowledge statements
1. Ability to monitor and evaluate the effectiveness of a LMS in a laboratory 2. Ability to verify the extent to which identified Testing and Calibration Laboratories requirements have been met 3. Ability to perform regular and methodical reviews regarding the suitability, adequacy, effectiveness and efficiency of a LMS 4. Ability to define and implement a management review process in order to ensure the effectiveness of the LMS	1. Knowledge of the techniques and best practices to monitor the effectiveness of a LMS. 2. Knowledge of the main concepts and components related to Laboratory Management System: measures, attributes, indicators and dashboard. 3. Knowledge of the characteristics and the differences between an operational, tactical and strategic Laboratory Management System indicators and dashboard 4. Knowledge of the techniques and methods to define and document an adequate and reliable indicator 5. Knowledge of the main concepts and components related to the implementation and operation of a LMS internal audit program 6. Knowledge of the differences between the concepts of major nonconformity, minor nonconformity, anomaly and observation 7. Knowledge of the best practices to write the nonconformity report 8. Knowledge of the best practices on how to perform management reviews

Domain 6: Continual improvement of a LMS based on ISO/IEC 17025

Main objective: To ensure that the ISO/IEC 17025 Lead Implementer candidate can provide guidance on the continual improvement of a LMS in the context of ISO/IEC 17025

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

Domain 7: Preparation for an accreditation

Main objective: To ensure that the ISO/IEC 17025 Lead Implementer candidate can prepare and assist an organization for the accreditation against the ISO/IEC 17025 standard

Competencies	Knowledge statements
1. Ability to understand the main steps, processes and activities related to a ISO/IEC 17025 accreditation 2. Ability to understand, explain and illustrate the assessment evidence approach 3. Ability to coach and prepare the personnel for the accreditation of an organization based on ISO/ IEC 17025	1. Knowledge of the evidence based approach in an assessment 2. Knowledge of the different types of evidences: physical, mathematical, confirmative, technical, analytical, documentary and verbal 3. Knowledge of the documentation review criteria 4. Knowledge of follow-up assessment requirements, steps and activities 5. Knowledge of the requirements, guidelines and best practices to develop action plans for the assessment of a laboratory

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

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			Level of Understanding (Cognitive/Taxonomy) Required					
		Points per Question	Questions that measure Comprehension, Application and Analysis	Questions that measure Synthesis and Evaluation	Number of Questions per competency domain	% of test devoted to each competency domain	Number of Points per competency domain	% of Points per competency domain
Competency/Domains	Fundamental principles and concepts of a Laboratory Management System (LMS)	5	X		3	25.00	15.00	20.00
		5	X					
		5	X					
	Laboratory Management System (LMS)	10	X		1	8.33	10	13.33
	Planning a LMS based on ISO/IEC 17025	5		X	1	8.33	5	6.67
	Implementing a management system based on ISO/IEC 17025	5		X	3	25.00	20	26.67
		5		X				
		10	X					
	Performance evaluation monitoring and measurement of a LMS based on ISO/IEC 17025	10		X	2	16.67	15	20.00
		5		X				
	Continual improvement of a LMS based on ISO/IEC 17025	5		X	1	8.33	5	6.67
	Preparation for an accreditation	5		X	1	8.33	5	6.67
	Total points 75							
	Number of Questions per level of understanding		7	5				
	% of Test Devoted to each level of understanding (cognitive/taxonomy)		58.33	41.67				

The passing score is established at **70%.**

After successfully passing the exam, candidates will be able to apply for the credentials of PECB Certified ISO/IEC 17025 Lead Implementer, depending on their level of experience

TAKE A CERTIFICATION EXAM

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

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

The exam duration is three (3) hours.

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

As the exams are "open book"; the candidates are authorized to use the following reference materials:

- A copy of the ISO/IEC 17025 standard;
- Course notes from the Participant Handout;
- Any personal notes made by the student during the course and;
- A hard copy dictionary

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

All attempt to copy, collude or otherwise cheat during the exam will automatically lead to the exam's failure.

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

RECEIVE YOUR EXAM RESULTS

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

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

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

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

EXAM RETAKE POLICY

There is no limitation on how many times a candidate can retake the same exam. However, there are some limitations in terms of allowed time-frame in between exams.

When candidates fail the examination, they are only allowed to retake the examination once within 12 months after the first attempt. If second examination is unsuccessful, candidates will be allowed to retake the exam only after 1 year (12 months). *(Please note that retake fee will be applied).*

Only candidates, who have completed a full PECB training but fail the written exam, are eligible to retake the exam for free, under one condition:

"A candidate can only retake the exam once and this retake must occur within 12 months from the initial exam's date."

When candidates fail the same examination for the second time, their file is automatically closed for 1 year.

CLOSING FILES

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

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

EXAMINATION SECURITY

A significant component of a successful and respected professional certification credential is maintaining the security and confidentiality of the examination. PECB relies upon the ethical behaviour of certificate holders and applicants to maintain the security and confidentiality of PECB examinations. When someone who holds PECB credentials reveals information about

PECB examination content, they violate the PECB Code of Ethics. PECB will take action against individuals who violate PECB Policies and the Code of Ethics. Actions taken may include permanently barring individuals from pursuing PECB credentials and revoking certifications from those who have been awarded the credential. PECB will also pursue legal action against individuals or organizations who infringe upon its copyrights, proprietary rights, and intellectual property.

SAMPLE EXAM QUESTIONS AND POSSIBLE ANSWERS

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.

4.11 Corrective actions:

Possible answers:

- 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.

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.

- **4.15 Management Review**

Possible answers:

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

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 answers:

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.