PECB

When Recognition Matters

EXAM PREPARATION GUIDE

PECB Certified ISO/IEC 17025 Lead Assessor

The objective of the "PECB Certified ISO/IEC 17025 Lead Assessor" examination is to ensure that the candidate possesses the needed expertise to assess the competence of Testing and Calibration Laboratories (TCL) based on ISO/IEC 17025, manage a team of assessors by applying widely recognized assessment principles, procedures and techniques. The aim of the exam is to evaluate that the candidate possesses necessary knowledge and skills to proficiently plan and perform internal and external assessment in compliance with the certification process.

The target population for this examination is:

- Individuals who want to become assessors for an ISO/IEC 17025 Accreditation Body
- Assessors seeking to perform Testing and Calibration Laboratory competence assessment
- Managers or consultants seeking to master an ISO/IEC 17025 assessment
- Laboratory technicians responsible for maintaining conformance with requirements for the competence of Testing and Calibration Laboratories
- 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:** Fundamental assessment concepts and principles
- **Domain 4:** Preparation of an ISO/IEC 17025 assessment
- **Domain 5:** Conducting and ISO/ IEC 17025 assessment
- **Domain 6:** Closing an ISO/IEC 17025 assessment
- **Domain 7:** Managing an ISO/IEC 17025 assessment program

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 Assessor candidate can understand, interpret and illustrate the requirements of the ISO/IEC 17025 to assess a Quality Management System for Testing and Calibration activities.

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

Domain 2: Laboratory Management Sytem (LMS)

Main objective: To ensure that the ISO/IEC 17025 Lead Assessor candidate can understand, interpret and illustrate the operations of Testing and Calibration Laboratories based on ISO/IEC 17025

Competencies	Knowledge statements
1. Understand and explain the components of Testing and Calibration Laboratories (TCL) 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 Testing and Calibration Laboratories (TCL)	1. Knowledge of the concepts, principles and terminology related to Testing and Calibration Laboratories (TCL) 2. Knowledge of the principal characteristics of Testing and Calibration Laboratories (TCL) 3. Knowledge of the main advantages of Testing and Calibration Laboratories (TCL) 4. Knowledge of the ISO/IEC 17025 requirements presented in the clauses 4 and 5. 5. Knowledge of the main steps for the competence to carry out specific tests or types of calibrations test 6. Knowledge of the basic principles behind ISO/IEC 17025

Domain 3: Fundamental assessment concepts and principles

Main objective: To ensure that the ISO/IEC 17025 Lead Assessor candidate can understand, interpret and apply the main concepts and principles related to Testing and Calibration Laboratories (TCL) based on ISO/IEC 17025

Competencies	Knowledge statements
1. Understand, explain and illustrate the application of the principles in the context of an ISO/IEC 17025 assessment 2. Ability to identify and judge situations that would discredit the professionalism of the assessor and the PECB code of ethics 3. Ability to identify and evaluate ethical problems taking into account the obligations related to sponsors, law enforcement or regulatory authorities 4. Ability to explain, illustrate and apply the evidence approach in the context of an ISO/IEC 17025 5. Ability to explain and compare the types and characteristics of evidences 6. Ability to determine and justify what type of evidence and how much evidence will be required in the context of a specific TCL assessment 7. Ability to determine and evaluate the level of materiality and apply the risk based approach during the different phases of an ISO/IEC 17025 assessment 8. Ability to judge the appropriate level of reasonable assurance needed for a specific ISO/IEC 17025 assessment	1. Knowledge of the assessment concepts and terminology 2. Knowledge of the following assessment principles: integrity, fair presentation, due professional care, professional judgment, professional skepticism, confidentiality and independence 3. Knowledge of professional responsibility of an assessor and the PECB code of ethics 4. Knowledge of evidence based approach in an assessment 5. Knowledge of the different types of evidences: physical, mathematical, confirmative, technical, analytical, documentary and verbal 6. Knowledge of different factors that will influence the assessment procedures 7. Knowledge of the risk based approach in an assessment and the different types of risk related to assessment activities 8. Knowledge of the concept of materiality and its application in an assessment 9. Knowledge of the concept of reasonable assurance and its applicable in an assessment

Domain 4: Preparation of an ISO/IEC 17025 assessment

Main objective: To ensure that the ISO/IEC 17025 Lead Assessor candidate can prepare appropriately a TCL assessment in the context of ISO/IEC 17025

Competencies	Knowledge statements
1. Understand and explain the steps and activities for the preparation of a TCL assessment taking in consideration the specific context and conditions of the mission 2. Understand and explain the roles and responsibilities of the team leader, team members and technical experts in a TCL assessment 3. Ability to determine, evaluate and confirm the assessment objectives, the assessment criteria and the assessment scope for a specific ISO/IEC 17025 TCL assessment 4. Ability to do a feasibility study of an assessment in the context of ISO/IEC 17025 assessment 5. Ability to develop working papers and to elaborate appropriate assessment test plans in the context of a specific ISO/IEC 17025 assessment	1. Knowledge of the main responsibilities of the assessment team leader and team members 2. Knowledge of the roles and responsibilities of technical experts used for an assessment 3. Knowledge of the main assessment objectives, scope and criteria 4. Knowledge of the difference between the TCL scope and the assessment scope 5. Knowledge of the elements to review during the feasibility study of an assessment 6. Knowledge of the cultural aspects to consider in an assessment 7. Knowledge of the characteristics of assessment terms of engagement and the best practices to establish a first contact with an Assessor 8. Knowledge of the preparation of an assessment plan 9. Knowledge of the preparation and development of assessment working paper 10. Knowledge of advantages and disadvantages of using assessment checklists 11. Knowledge of the best practices of assessment test plans

Domain 5: Conducting an ISO/IEC 17025 assessment

Main objective: To ensure that the ISO/IEC 17025 Lead Assessor candidate can plan, lead and follow up on assessments and accreditation

Competencies	Knowledge statements
1. Ability to organize and conduct the opening meeting in the context of an ISO/IEC 17025 assessment 2. Ability to conduct an ISO/IEC 17025 assessment taking into account the documentation review conditions and criteria for the application of the best practices 3. Ability to explain, illustrate and apply statistical techniques and main assessment sampling methods 4. Ability to gather appropriate evidences objectively from the available information in an assessment and to evaluate them objectively	1. Knowledge of the objectives and the content of the opening meeting of an assessment 2. Knowledge of the documentation review criteria 3. Knowledge of the documentation requirements stated in ISO/IEC 17025 4. Knowledge of best practices of communication during an assessment 5. Knowledge of the roles and responsibilities of guides and observers during an assessment 6. Knowledge of the conflict resolution techniques 7. Knowledge of evidence collection procedures: observation, documentation review, interviews, analysis and technical verification 8. Knowledge of evidence analysis procedures: corroboration and evaluation 9. Knowledge of main concepts, principles and statistical techniques used in an assessment 10. Knowledge of the main assessment sampling methods and their characteristics

Domain 6: Closing an ISO/IEC 17025 assessment

Main objective: To ensure that the ISO/IEC 17025 Lead Assessor candidate can conclude a TCL assessment and conduct follow-up activities in the context of ISO/IEC 17025

Competencies	Knowledge statements
1. Ability to explain and apply the evaluation process of evidences to draft assessment findings and conclusions 2. Understand, explain and illustrate the different levels of conformity and the concept of benefits of doubt 3. Ability to report appropriate assessment observations in order to help a laboratory to improve their Testing and Calibration activities. 4. Ability to complete assessment working documents and do a quality review of an ISO/IEC 17025 Assess 5. Ability to draft conclusions and present them to the top management 6. Ability to organize and conduct an assessment closing meeting 7. Ability to write an ISO/IEC 17025 assessment report and justify an accreditation recommendation 8. Ability to conduct the activities following an initial assessment including the evaluation of action plans, follow up activities, surveillance assessment and re-accreditation	1. Knowledge of the evaluation process of evidences to draft assessment findings and prepare assessment conclusions 2. Knowledge of the differences and the characteristics between the concepts of conformity, minor nonconformity, major nonconformity, anomaly and observation 3. Knowledge of the guidelines and best practices to write nonconformity report 4. Knowledge of the guidelines and best practices to draft and report assessment observation 5. Knowledge of the principle of benefits of doubt and his application in the context of an assessment 6. Knowledge of the guidelines and best practices to complete assessment working documents 7. Knowledge of the best practices to present assessment findings and conclusions 8. Knowledge of the possible recommendations that an Assessor can issue to the accreditation decision process 9. Knowledge of the best practices to evaluate action plans 10. Knowledge of follow-up assessment, surveillance assessment and re-accreditation assessment requirements, steps and activities 11. Knowledge of the conditions for modification, extension, suspension or withdrawal of an accreditation of a Laboratory

Domain 7: Managing an ISO/IEC 17025 assessment program

Main objective: To ensure that the ISO/IEC 17025 Lead Assessor understands how to establish and manage an assessment program for TCL

Competencies	Knowledge statements
1. Understand and explain the establishment of an assessment program 2. Understand and explain the implementation of an ISO/IEC 17025 assessment program 3. Understand and explain the responsibilities to protect the integrity, availability and confidentiality of assessment records 4. Understand the requirements related to the components of the management system of an assessment program 5. Understand the evaluation of the efficiency of the assessment program by monitoring the performance of each Assessor 6. Understand and explain the way combined assessment are handled in an assessment program 7. Ability to demonstrate the application of the personal attributes and behaviors associated to professional Assessors	1. Knowledge of the management of an assessment program 2. Knowledge of requirements, guidelines and best practices regarding assessment resources, procedures and policies 3. Knowledge of the types of tools used by professional assessors 4. Knowledge of requirements, guidelines and best practices regarding the management of assessment records 5. Knowledge of the application of the concept of continual improvement to the management of an assessment program 6. Knowledge of the management of combined assessment activities 7. Knowledge of the concept of competency and its application to Assessors 8. Knowledge of the personal attributes and behavior of a professional Assessor

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

Competency/Domains		Question Number	Points per Question	Level of Understanding (Cognitive/Taxonomy) Required		Number of Questions per competency domain	% of test devoted to each competency domain	Number of Points per competency domain	% of Points per competency domain
				Questions that measure Comprehension, Application and Analysis	Questions that measure Synthesis and Evaluation				
	Fundamental principles and concepts of a Laboratory Management System (LMS)	3	5	X		1	8.33	5	6.67
	Laboratory Management System (LMS)	1	5	X		1	8.33	5	6.67
	Fundamental assessment concepts and principles	4	10	X		2	16.67	15	20.00
		5	5	X					
	Preparation of an ISO/IEC 17025 assessment	2	5	X		3	25.00	15	20.00
		6	5	X					
		7	5	X					
	Conducting an ISO/IEC 17025 assessment	8	10		X	2	16.67	15	20.00
		9	5		X				
	Closing an ISO/IEC 17025 assessment	11	5		X	2	16.67	15	20.00
		12	10						
	Managing an ISO/IEC 17025 assessment program	10	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 Assessor, 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 proctor and the exam confirmation letter.

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 17025:2005 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). Retake fee applies.

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. Evidence in an assessment

For each of the following clauses of the ISO/IEC 17025 standard, please provide at least two different evidences that would be acceptable to ensure conformity to the clause.

Clause 4.11 Corrective action:

> **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. Evaluation of corrective actions

You have received a plan for corrective actions. Evaluate the adequacy of the proposed corrective actions. If you agree with the corrective actions, explain why. If you disagree, explain why and propose what you think would be some adequate corrective actions.

<u>**Non-conformity 1**</u>**: The Assessor has indicated non-conformity because preventive actions have not been determined.**

<u>**Corrective action plan 1**</u>**: The internal assessor will determine preventive actions for the next assessment**

> **Possible answers:**
>
> Do not agree. The internal assessor should do a preventive action immediately after she/he has found non-conformity.

3. Writing of a test plan

You have received a corrective action plan to review. Please evaluate the effectiveness of the corrective actions that are proposed. If you agree with these corrective actions, explain why. If you do not agree, explain why, and propose what would be minimal adequate corrective action

<u>**Non-conformity 2**</u>**: The Assessor has indicated non-conformity because the quality objectives are not being measured.**

<u>**Corrective action plan 2**</u>**: At the next management review, the laboratory manager will redefine metrics to evaluate the quality objectives**

Possible answer

Agree. Laboratory manager should review metrics and update after each measurements.