

# PECB



MASTERING THE AUDIT OF A QUALITY MANAGEMENT SYSTEM (QMS) BASED ON ISO 9001, IN COMPLIANCE WITH THE REQUIREMENTS OF ISO 19011 AND ISO 17021

#### **SUMMARY**

This five-day intensive course enables participants to develop the necessary expertise to audit a Quality Management System (QMS) based on ISO 9001:2015 and ensure that the organization is competent in maintaining its quality management system. The Lead Auditor training will equip participants with the skills and ability to perform audits by applying widely recognized audit principles, procedures and techniques. During this training, the participant will acquire the necessary knowledge and skills to proficiently plan and perform internal and external audits in compliance with ISO 19011; the certification process according to ISO 17021. Based on practical exercises, the participant will develop the skills (mastering audit techniques) and competencies (managing audit teams and audit program, communicating with customers, conflict resolution, etc.) necessary to efficiently conduct an audit.





## WHO SHOULD ATTEND?

- Internal auditors
- Auditors wanting to perform and lead Quality Management System (QMS) certification audits
- Project managers or consultants wanting to master the Quality Management System audit process
- Persons responsible for the Quality conformity in an organization
- Members of a Quality team
- ▶ Expert advisors in Quality Management Systems
- ► Technical experts wanting to prepare for a Quality audit function

# COURSE AGENDA DURATION: 5 DAYS

## Introduction to Quality Management and ISO 9001

- Course objectives and structure
- Standard and regulatory framework
- Certification process
- ► Fundamental principles of quality management
- Quality Management System (QMS)

## Audit principles, preparation and launching of an audit

- ▶ Fundamental audit concepts and principles
- Audit approach based on evidence and risk
- ▶ Initiating the audit
- Stage 1 audit
- ▶ Preparing the stage 2 audit (on-site audit)
- ► Stage 2 audit (Part 1)

#### On-site audit activities

- ▶ Stage 2 audit (Part 2)
- ► Communication during the audit
- Audit procedures
- Creating audit test plans
- ▶ Drafting audit findings and non-conformity reports

#### Closing the audit

- Documentation of the audit and quality review
- Closing the audit
- Evaluating action plans by the auditor
- Beyond the initial audit
- Managing an internal audit programme
- Competence and evaluation of auditors
- Closing the training

#### **Certification Exam**

## LEARNING OBJECTIVES

- ▶ To acquire the expertise to perform an ISO 9001 internal audit following ISO 19011 guidelines
- ► To acquire the expertise to perform an ISO 9001 certification audit following ISO 19011 guidelines and ISO 17021 specifications
- ▶ To acquire the necessary expertise to manage a QMS audit team
- ▶ To understand the operation of an ISO 9001 conformant Quality Management System
- ► To understand the relationship between a Quality Management System and compliance with the requirements of different stakeholders of the organization
- ► To improve the ability to analyze the internal and external environment of an organization, and audit decision-making in the context of a QMS

## **EXAMINATION**

The "PECB Certified ISO 9001 Lead Auditor" exam fully meets the requirements of the PECB Examination and Certification Programme (ECP). The exam covers the following competence domains:

## Domain 1: Fundamental principles and concepts in Quality Management

Main Objective: To ensure that the ISO 9001 Lead Auditor candidate can understand, interpret and illustrate the main Quality Management concepts related to a Quality Management System (QMS)

#### Domain 2: Quality Management System (QMS)

Main Objective: To ensure that the ISO 9001 Lead Auditor candidate can understand, interpret and illustrate the main concepts and components of a Quality Management System based on ISO 9001

#### Domain 3: Fundamental Audit Concepts and Principles

Main Objective: To ensure that the ISO 9001 Lead Auditor candidate can understand, interpret and apply the main concepts and principles related to a QMS audit in the context of ISO 9001

#### Domain 4: Preparation of an ISO 9001 Audit

Main Objective: To ensure that the ISO 9001 Lead Auditor candidate can prepare appropriately a QMS audit in the context of ISO 9001

#### Domain 5: Conduct of an ISO 9001 Audit

Main Objective: To ensure that the ISO 9001 Lead Auditor candidate can conduct efficiently a QMS audit in the context of ISO 9001

## Domain 6: Conclusion and follow-up of an ISO 9001 Audit

Main Objective: To ensure that the ISO 9001 Lead Auditor candidate can conclude a QMS audit, and conduct the follow-up activities in the context of ISO 9001

#### Domain 7: Management of an ISO 9001 Audit Program

Main Objective: To ensure that the ISO 9001 Lead Auditor understands how to establish and manage a QMS audit program

- ► The "PECB Certified ISO 9001 Lead Auditor" exam is available in different languages (the complete list of languages can be found in the examination application form)
- Duration: 3 hours
- ▶ For more information about exam, refer to PECB section on ISO 9001 Lead Auditor Exam



## **CERTIFICATION**

► A certificate will be issued to participants who successfully pass the exam and comply with all the other requirements related to the selected credential

Credential	Exam	Professional Experience	QMS Audit Experience	Other Requirements
PECB Certified ISO 9001 Provisional Auditor	PECB Certified ISO 9001 Lead Auditor Exam	None	None	Signing the PECB code of ethics
PECB Certified ISO 9001 Auditor	PECB Certified ISO 9001 Lead Auditor Exam	Two years One year of QMS audit related work experience	QMS audit activities totaling 200 hours	Signing the PECB code of ethics
PECB Certified ISO 9001 Lead Auditor	PECB Certified ISO 9001 Lead Auditor Exam	Five years Two years of QMS audit related work experience	QMS audit activities totaling 300 hours	Signing the PECB code of ethics

# **GENERAL INFORMATION**

- ► Certification fees are included in the exam price
- ▶ A student manual containing over 450 pages of information and practical examples will be distributed to participants
- ▶ A participation certificate of 31 CPD (Continuing Professional Development) credits will be issued to participant
- ▶ In case of failure of the exam, participants are allowed to retake the exam for free under certain conditions