



ISO 9001 LEAD AUDITOR



I9001LA Versión 122021

CertiProf[®]

ISO 9001 LEAD AUDITOR I9001LA

Syllabus V122021

Introduction	3
Learning Objectives	3
Exam Format and Duration	3
Eligibility for Certification	3
Content	4



Introduction

This certification covers the international standard published by the International Organization for Standardization (ISO), which establishes the requirements for the implementation of a quality management system. ISO 9001 ensures that organizations can take actions to continually improve process performance, establish the objectives and processes necessary to achieve results in accordance with customer requirements and organizational policies, track and measure processes and products against policies, objectives and product requirements, and report results and finally implement processes.

ISO 9001 is the only standard to which an organization can be certified.

Learning Objectives

- Understand the operation of a Quality Management System under the process management approach
- Understand the process approach, PDCA cycle and risk-based thinking in quality management systems as the basis of ISO 9001:2015
- Interpret and apply the requirements of a Quality Management System under ISO 9001:2015 in the high-level structure

Exam Format and Duration

This study program has a test that the candidate must pass to obtain the certification in ISO 9001 Lead Auditor.

- Format: Multiple choice
- Questions: 40
- Language: English/Spanish
- Pass Score: 32/40 or 80 %
- Duration: 60 minutes maximum
- Open book: No
- Delivery: This examination is available Online
- Supervised: It will be at the Partner's discretion

Eligibility for Certification

Anyone interested in learning about ISO 9001 and how to execute and report on an ISO 9001:2015 audit.

Content

Phase 1: Fundamentals of a Quality Management - QMS

- Fundamentals of a Management System
 - What is Standardization?
- Objectives of Standardization
- Standardization Levels
- ISO Worldwide Recognition
- Workshop: Identification of Standards Applicable to Products
- Workshop: Terms and Definitions - Quality Management System
 - What is Quality?
- Workshop: Identification of Needs and Expectations
- Quality Concept Timeline
- Main Actors in the Evolution of Quality
- Evolution of ISO Standards for Quality Management Systems
- ISO 9000 Family of Standards
 - What is a Management System?
 - Principles of Management Systems

Process Management

- Fundamentals of Process Management
 - What is a process?
 - Every process must comply with...
- Process Typologies
- Process Map
- Process Map
- Representation of a Process Map (Hospital) - Example
- Representation of a Process Map (Hotel) - Example
- Representation of a Process Map (Courier Company) - Example
- Workshop: Process Identification
- Process Documentation
- Example Applied
- Workshop: Process Documentation

ISO 9001:2015 Standard Requirements - Quality Management System

- Interpretation of Standard Requirements
- Structure of ISO 9001:2015
- Key Issues to Understand ISO 9001:2015

Clause 4: Context of the Organization

- 4.1. Understanding the Organization and its Context
 - Explanation of the Number or Suggested Implementation Actions
 - Examples of Evidence to Implement in the Clause
 - Workshop: Context Analysis
- 4.2 Understanding the Needs and Expectations of Interested Parties
 - Explanation of the clause or Suggested Implementation Actions
 - Examples of Evidence to Implement in the Clause

Workshop: Interested Parties Identification

4.3. Determining the scope of the Quality Management System

Explanation of the Clause or Suggested Implementation Actions

Examples of Evidence to Implement in the Clause

4.4 Quality Management System and its Processes

Explanation of the Clause or Suggested Implementation Actions

Examples of Evidence to Implement in the Clause

Clause 5: Leadership

5.1 Leadership and Commitment

Explanation of the Clause or Suggested Implementation Actions

Examples of Evidence to Implement in the Clause

5.2. Quality Policy

5.3. Roles, Responsibilities and Authorities in the Organization

Explanation of the Clause or Suggested Implementation Actions

Conclusions Clauses 4 and 5

Clause 6: Planning

6.1. Actions to Address Risks and Opportunities

Explanation of the Clause or Suggested Implementation Actions

Examples of Evidence to Implement in the Clause

6.2. Quality Objectives and Planning to Achieve Them

Examples of Evidence to Implement in the Clause

Workshop: Deploying the Strategy

Workshop: Deploying the Strategy "SUPER PACKAGING"

6.3. Planning for Changes

Explanation of the Clause or Suggested Implementation Actions

Examples of Evidence to Implement in the Clause

Conclusions Clause 6

Clause 7: Support

Clause 7: Support

Examples of Evidence to Implement in the Clause

Conclusions Clause 7

Clause 8: Operation

Analysis of Clauses Under the PDCA Cycle Approach

Examples of Evidence to Implement in the Clause

Workshop: Planning Processes and Resources

Examples of Evidence to Implement in the Clause

Design and Development

Design and Development Planning

Stages of Design and Development - Example

Design and Development Controls

8.4 Control of Externally Provided Products and Services

Examples of Evidence to Implement in the Clause

8.5 Production & Service Provision

Examples of Evidence to Implement in the Clause

8.6. Release of Products and Services

Examples of Evidence to Implement in the Clause

Conclusions Clause 8

Clause 9: Performance Evaluation

9.1 Monitoring, Measurement, Analysis and Evaluation

Examples of Evidence to Implement in the Clause

Clause 9 Conclusions

Clause 10: Improvement

10. Improvement

Examples of Evidence to Implement in the Clause

Clause 10. Conclusions

Phase 2. Design and Implementation of a QMS

Design and Implementation of a QMS

Workshop: Develop Diagnosis and Implementation Plan

Phase 3. QMS Risk Management

Why Perform Risk Management?

Risk Management Process

Risk Management

Risk Identification Steps

1. Identify Risks

Source of Risks

1. Identify Risks

Workshop: Identifying Risks

2. Analyze and Assess Risk

3. Risk Treatment

Workshop: Risk Assessment

Phase 4. Internal Audits with Emphasis on Lead Auditor Competencies

ISO 19011:2018

Structure of ISO 19011:2018

ISO 19011:2018 - Scope

Audit

Types of Audit

Audit Criteria

Audit Evidence

Audit Results

Conclusions of the Audit

Audit Client

Audited

Auditor

Audit Team

Technical Expert

Observer

Guide

Audit Program

Audit Scope

Audit Plan

Conformity
Non-Conformity
Audit Tests
Audit Methods
Clause 4: Principles of Auditing
Clause 5: Management of an Audit Program
Clause 5: Audit Program
Clause 6: Conducting an Audit
Audit Activities
Clause 7: Competence and Evaluation of Auditors
Methods for Evaluating Auditors
Clause 7: Personal Attributes
Clause 7: Generic Knowledge and Skills
Establishment of Audit Program Objectives
Identification and Evaluation of Risks and Opportunities of the Audit Program
Establishing the Audit Program
Competence of the Individual(s) Managing the Audit Program
Establishing the Scope of the Audit Program
Determining the Audit Program Resources
Implementation of the Audit Program
Definition of Objectives, Scope and Criteria for an Individual Audit
Selection and Determination of Audit Methods
Selection of Audit Team Members
Assignment of Responsibilities to the Audit Team Leader for an Individual Audit
Management of Audit Program Results
Manage and Keep Audit Program Records
Review and Improvement of the Audit Program
Establish Contact with the Auditee
Audit Viability Determination
Review of Documented Information
Audit Planning
Assignment of Tasks to the Audit Team
Roles and Responsibilities of Guides and Observers
Preparation of Working Papers
Possible Advantages of Checklists
Using Checklists
Opening Meeting
Review of Documentation in the Audit
Communication During the Audit
Methods for Collecting Information
The Interview
Key Auditor Questions
Type of Questions
Running the Audit
Conducting Interviews

- Time Management
- Managing Difficult Situations
- Audit Results
- How We Write
- What is a Finding?
- Positive Findings: Strengths
- Negative Findings: Opportunities for Improvement
- Negative Findings: Non-conformity
- Recommendations for Writing Non-conformities

Prepare Audit Conclusions

- Audit Conclusions
- Audit Report
- Closing Meeting
- Preparation and Distribution of the Audit Report
- Performing Audit Follow-Up
- Follow-up Audits

Auditor Skills and Workshops

- Workshop: Audit Planning – Case Study "Super Packaging"
- Example: Audit Plan
 - Workshop: Audit Planning – SUPER PACKAGING – Case Study
- Interview Planning – Types of Questions
- Audit Checklist
- Checklist Example
- Annexes