



The 9000 Store

The tools you need to Achieve and Maintain ISO 9001

(877) 942-6572

View all Standards Certifications



ISO 9001:2015 Internal Auditor Training



Trainer's Guide



Overview

These course materials are meant to train people to conduct internal quality audits within your organization, which are necessary to meet the internal audit requirements of the ISO 9001:2015 standard.

The course is divided into two sections:

1. Understanding the ISO 9001:2015 requirements for quality management system
 - Review the actual ISO 9001:2015 Standard (*not included* – [click here to buy](#))
 - Detailed clause-by-clause review of the standard
 - Approx. 4 Hours
2. Learning and practicing the auditing process.



QUALITY TOOL, Inc.

- The students will go through all the steps required for an audit, with hands on involvement in performing each step by conducting a mock audit of a fictitious company. (*Quality Tool Inc.*)
 1. Scheduling the audit
 2. Planning the audit
 3. Opening meeting
 4. Audit the areas
 5. Auditors document findings
 6. Final audit report
 7. Closing meeting
 8. Creating the audit file
- Approx. 8 hours depending on the number of students

We recommend that you print this guide as you'll need the PowerPoint speaker notes to lead the class. This guide contains everything the instructor needs to lead the class.

Notes:

- It is assumed that the instructor has the education, credentials and/or equivalent experience. This is not meant as a self study course.
- It is recommended that the first audit the student is involved with be under the leadership of a lead auditor who has audit experience.
- *The ISO 9001:2015 standard is referenced for educational purposes only.*

Introduction: Why are you here?

- To learn more about ISO 9001:2015
- To be able to evaluate you own area and make improvements.
- To understand the audit process
- To be able to participate in the audit process

7.1 Resources

7.1.6 – cont'd -- Organizational knowledge

Organizational knowledge includes information such as intellectual property and lessons learned.

To obtain knowledge, consider:

- Internal sources such as learning from failures and successful projects, capturing knowledge and experience of internal experts, and identifying opportunities and risks.
- External sources such as standards, conferences, academia, gathering knowledge with customers or providers

Copyright (c) 2015 The9000Store.com

44

The Quality team / ISO steering committee is responsible for determining the organizational knowledge necessary for the operation of its processes and to achieve conformity of products and services.

Organizational knowledge includes information such as intellectual property and lessons learned.

To obtain knowledge, consideration is given to:

Internal sources such as learning from failures and successful projects, capturing undocumented knowledge and experience of internal experts, and identifying opportunities and risks.

External sources such as standards, academia, conferences, gathering knowledge with customers or providers.

7.5 Documented Information

7.5.3 – cont'd -- Control of documented information

In controlling documented information, you must consider distribution, access, retrieval and use, storage, preservation, control of changes, retention and disposition.

Your company must identify and control the documented information from external sources that is determined to be necessary for the planning and operation of the QMS.

Copyright (c) 2015 The9000Store.com

53

For the control of documented information, consideration is given to distribution, access, retrieval and use, storage.

Documented information from external origin and determined to be necessary for the planning and operation of the quality management system shall be identified as appropriate, and controlled.

Documented information from external sources and determined by your company to be necessary for the planning and operation of the quality management system is identified and controlled. Customer documents are controlled as defined in procedure for Customer related processes.

When completed, the forms required and used in the operation of the QMS, become documented information or records.

A table works well for listing all your quality records, where they are generated and stored, how long they are stored and who is responsible for them.

Include a requirement in your procedure that says quality records must be legible.

8 Operation

The requirements for clause 8 are:

- 8.1 Operational planning and control
- 8.2 Requirements for products and services
- 8.3 Design and development of products and services
- 8.4 Control of externally provided products and services
- 8.5 Production and service provision
- 8.6 Release of products and services
- 8.7 Control of nonconforming process outputs, products and services

Copyright (c) 2015 The9000Store.com

54

This clause requires that your company plan, implement and control the processes required for the QMS and to implement the actions to address risks and opportunities associated with them.

Operational planning and control include systems for customer related processes, design and development, control of external providers, control of production and service provision, and including identification and traceability, preservation of products, and control of nonconforming outputs.

8.1 Operational planning and control

8.1 – cont'd -- Operational planning and control

The output of this planning must be in a format suitable for your company's operations.

Your company must control planned changes and review the consequences of unintended changes, and take action to mitigate any adverse effects,

Your company must ensure that outsourced processes are controlled – (more information in clause 8.4).

Copyright (c) 2015 The9000Store.com

57

In support of the Operations manager, the Quality team / ISO steering committee plans, implements and controls the processes needed to meet requirements for the provision of products and services and implements actions needed to address risks and opportunities by:

The output of this planning is in a format suitable for the company's operations, that is what works best for you.

The organization must control planned changes and review the consequences of unintended changes, taking action to mitigate any adverse effects, as necessary.

The organization must ensure that outsourced processes are controlled in accordance with 8.4.