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# ISO 9001:2008

## 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 9001:2008 standard.

The course is divided into two sections:

1. The first section will familiarize the students with the requirements ISO 9001 quality management system.
  - Allow 4 hours for this section.
2. The second section is devoted to the auditing process. 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.
  - Allow 8 hours for this section.

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

## Notes:

- It is assumed that the instructor has certified Lead Auditor credentials 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.



## Course Materials

The supplies you will need are:

- PowerPoint: **Guide to Internal Auditing** (included).
- PowerPoint: **Requirements of ISO 9001** (included).
  - A complete version with Speaker Notes is in this Trainer's Guide
- PowerPoint: **Steps of Internal Audit** (included).
  - A complete version with Speaker Notes is in this Trainer's Guide
- Student Manual (included).
  - Print one copy for **each student**
  - You may wish to have extra copies of the CPAR form
  - It includes reduced versions of all the PowerPoints.
- Sticky Bubble Gum Company Documents and Records (included).
  - Print one copy for **each team** of two or three students.

Qty	Sticky Bubble Gum Documents and Records	# of Pages
1	Quality Manual .....	10
1	Internal Audit Master Schedule .....	1
1	P-4.2-009 Control of Documents Procedure.....	2
1	Master Document List .....	1
1	P-5.0-002 Management Responsibility Procedure.....	3
1	SBG Organizational Chart .....	1
2	Management Review Minutes.....	2
1	P-7.2-005 Customer Related Processes Procedure.....	2
4	Quotes with Client PO's.....	8
1	P-7.4-004 Purchasing Procedure.....	2
1	F-7.4-005 Approved Vendor List Form.....	1
7	SBG PO's to SBG Vendors .....	7
3	F-7.4-003 Subcontractor Problem Log Form.....	3
1	Product Flow Chart.....	1
1	750-W-30 Bulk Gum Batching Work Instructions.....	2
1	750-W-140 Texturizing Work Instructions.....	2
1	P-8.3-003 Control of Nonconforming Product Procedure.....	1
1	P-8.5-001 Corrective Action Procedure.....	2
1	F-8.5-002 Corrective Action Log Form.....	1
11	F-8.5-001 Corrective Action Request (CAR) Form.....	11
2	F-852-001-A Corrective/Preventive Action Request (CPAR) Form...	4

- The ISO 9001:2008 Standard (**NOT Included\***)
  - One copy for every 2-3 students.
  - Standards are available electronically from  
[http://www.the9000store.com/Buy\\_standards.aspx](http://www.the9000store.com/Buy_standards.aspx)

\* The ISO 9001:2008 Standard is a copyrighted document and we are unable to include it.



# Agenda

## I. The Standard

- Introduction to Auditing
- 0:15 Presentation: Guide to Internal Auditing 9001
- 0:15 Review Document: ISO 9001:2008
- 0:30 Exercise: Is it a Requirement?
- 2:00 Presentation: Requirements of ISO 9001:2008
- 0:45 Exercise: Find the Requirement
- 0:15 Questions

## II. The Audit

- 0:30 Scheduling the Audit
- 0:30 Planning the Audit
- 0:45 Opening Meeting
- 0:45 Audit 4.2 Documentation
- 0:45 Audit 5.0 Management Responsibility
- 0:45 Audit 7.2 Customer-Related processes
- 0:45 Audit 7.4 Purchasing
- 0:45 Audit 8.5 Corrective Action
- 0:30 Auditors Document Findings
- 0:30 Final Audit Report
- 0:30 Closing Meeting
- 0:30 Creating the Audit File

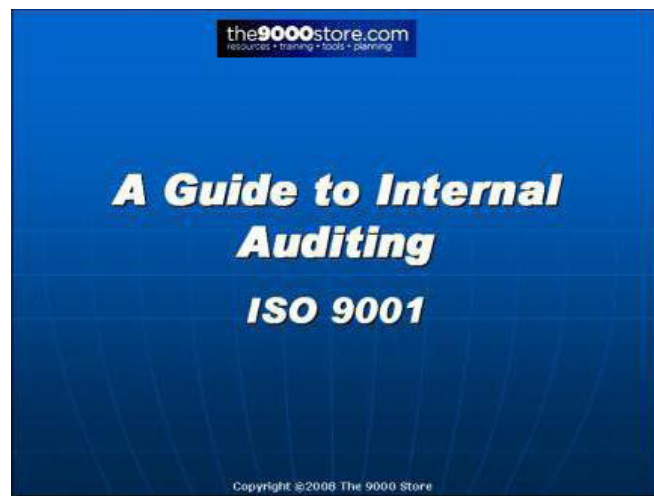


# The Standard

## Introduction to Auditing

This section will familiarize the students with the requirements ISO 9001:2008 quality management system (QMS).

1. Review the “**Guide to Internal Auditing 9001**” Power Point Presentation with the group.
2. Review and discuss the organization of the ISO 9001:2008 document so the students can familiarize themselves with how the standard is structured.
3. Complete the exercise “Is it a Requirement?” below.



### **Exercise:** Is it a Requirement?

Have the students open to “**Is it a Requirement**” in the student manual.

Working in groups of 2 or 3, have them determine whether or not:

- The statement is true or false
- Write down the clause of the standard where they found it.

### **Notes:**

- This is not a test, but an exercise to get them familiar with the standard, so the trainer can go around and help the teams, particularly the slower teams.
- This can be done individually ahead of time to reduce class time

After one or two teams finish, or after a maximum of about 45 minutes, you can go through the statements and discuss the answers.

- An answer key is on the next page.
- Remind the students that there are some things that are mentioned in more than one place in the standard, so there could be more than one correct answer in some cases.



## Is it a Requirement? *(Answer Key)*

<b><i>The standard requires that:</i></b> If the requirement is true, circle True and list the clause. If it is false, circle False and list the clause used.	<b>True</b>	<b>False</b>
1. Verbal orders may not be accepted.	T <i>Clause:</i>	F <i>Clause:</i> 7.2.2
2. Management must review the quality system every quarter.	T <i>Clause:</i>	F <i>Clause:</i> 5.6.1
3. A procedure must be written for contract review (receiving and processing of customer orders).	T <i>Clause:</i>	F <i>Clause:</i> 7.2
4. The effectiveness of employee training must be assessed.	T <i>Clause:</i> 6.2.2.c	F <i>Clause:</i>
5. Statistics must be used to monitor processes. <b>Note: the intent of the new standard is to clarify the standard to the extent that the use of statistical techniques is a stated requirement.</b>	T <i>Clause:</i> 8.1	F <i>Clause:</i>
6. Customer complaints are handled by management.	T <i>Clause:</i>	F <i>Clause:</i> 8.5.2.a
7. The results of corrective actions taken must be documented.	T <i>Clause:</i> 8.5.2.e	F <i>Clause:</i>
8. Release of product for delivery must be authorized.	T <i>Clause:</i> 8.2.4	F <i>Clause:</i>
9. There must be a documented procedure for purchasing of product. <b>Caution: 4.2.1.d still applies</b>	T <i>Clause:</i>	F <i>Clause:</i> 7.4
10. A list of approved suppliers must be maintained.	T <i>Clause:</i>	F <i>Clause:</i> 7.4.1
11. All non-usable customer supplied product must be returned to the customer.	T <i>Clause:</i>	F <i>Clause:</i> 7.5.4
12. Work instructions may be changed if quality assurance approves the changes.	T <i>Clause:</i>	F <i>Clause:</i> 4.2.3



## ISO 9001:2008 Requirements

Now that the students are familiar with the organization of the standard, this section will outline *the requirements* of each section – what it is really asking them to do.

**Requirements of ISO 9001:2008** Power Point presentation



First, there is a brief 7-page introduction to serve as a review:

- What is ISO 9001?
- Steps to registration
- Benefits of registration
- The Process Model/Process Approach

Second, the rest of this presentation outlines the requirements of ISO 9001.

- If you use the speaker's notes this review could take about 2 hours
- Students can take notes in their manual.
- We've included the presentation in this Trainer's Guide so you can review the notes while presenting.

1. Review "**Requirements of ISO 9001:2008**" Power Point presentation
2. Complete the exercise "Find the Requirement" below.
3. Answer questions about ISO 9001:2008 to ensure they understand the material.

**Exercise:** Find the Requirement.

1. Introduce the 2nd exercise "**Find the Requirement**" in their student manual.
2. Have them find the clause in the standard that applies.
3. Have them work in groups as in the previous exercise.
4. Discuss the answers together.

To conclude this first section of the course, open it up to questions and answers on the standard.

## ***Questions we will cover today:***

- What is ISO 9001?
- Steps to registration
- Benefits of registration
- The Process Model/Process Approach
- What are the requirements of ISO 9001?

## 4.2 Documentation Requirements

- Control of Quality Records
  - Quality records must be controlled and protected, quality records are your evidence of complying with your quality system
  - Have a process in place that identifies what quality records you have, where they are kept, how long they are kept, how they are protected from damage

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*Refer to the standard clause 4.2.4*

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.

The procedure must address storage, retention times and disposition. If you archive records either on-site or off-site include your process in your procedure.

ISO does not specify how long you have to keep your records, but remember that the auditor will want to see six months to a year worth of records.

## **7.1 Planning of Product Realization**

- Plan product realization processes.
  - Determine quality objectives for the product, project or contract
  - Determine the need to establish processes and documentation, and provide resources and facilities specific to the product
  - Determine if validation is required
  - Identify what records will be needed to provide evidence of conformity

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We saw an earlier requirement for planning of the QMS. Here is the requirement to plan the product realization processes.

- Identify work instructions needed to control processes. What processes require documentation in order to be performed with consistency between employees?
- A Quality Planning Worksheet could be developed for new products or processes that would be completed each time a new product or process or equipment is brought in.
- Special Processes must be identified and validated. A special process is defined as a process for a product or service that cannot be inspected to determine conformance.

## 8.2 Monitoring and Measurement

- Customer Satisfaction
  - Customer satisfaction must be monitored as one of the measurements of performance of the QMS

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Measuring customer satisfaction is a critical aspect of the QMS.

Remember, customer satisfaction is an output of the process model that was reviewed early.

*(refer to process model slide again, if necessary)*

Customer satisfaction data is a key measurement indicating how the QMS is performing.

It is up to the organization to determine how to measure customer satisfaction. Some things to consider include:

Complaints

Returns

Surveys

Benchmarking

Communication from customers



## The Audit

The second section is devoted to the auditing process. Normally the class size will vary from 4 to 12, and it is recommended that you divide the class into teams of 2-3. It works best to have an even number of teams for holding opening and closing meetings.

**>>>Allow 8 hours for this section.**

The students will go through all the steps required for an audit, with hands on involvement in performing each step by conducting an audit of a fictitious company (Sticky Bubble Gum Company or SBG) including:

- Scheduling the Audit
- Planning the Audit
- Opening Meeting
- Audit sections of the Sticky Bubble Gum Company's QMS:
  - 4.2 Documentation
  - 5.0 Management Responsibility
  - 7.2 Customer-Related processes
  - 7.4 Purchasing
  - 8.5 Corrective Action
- Auditors Document Findings
- Final Audit Report
- Closing Meeting
- Creating the Audit File

You will lead this section using the **"Steps of ISO 9001 Internal Audit"** Power Point presentation the entire time, using the materials in this package. The Speaker Notes in the PowerPoint will guide you along as an outline.



## ***Basic Steps for an Audit***

- Scheduling the audit
- Planning the audit
- Opening meeting
- Audit the areas
- Auditors document findings
- Final audit report
- Closing meeting
- Creating the audit file

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Review the Basic Steps for an Audit

This will show the class what steps they will be going through for the balance of the class.

## ***Prepare your checklists: 4.2 Control of documents***

- Read the procedure and Quality Manual for 4.2 Control of documents
- Review the checklist for 4.2
- Write any additional question you would like to ask to verify that SBG is following their procedure

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Have the students turn their manual to the **Audit checklist for 4.2 Control of documents.**

The students are now ready to audit Sticky Bubble Gums Control of Documents.

They should make all their notes on the checklist.

To audit, use:

- The SBG Quality Manual
- P 4.2-009 the Procedure for Control of Documents
- Master Document List.

They should check the rest of the procedures in the manual, to see if they match the master list.

Have the students write down their questions on the checklist.

## ***Write up the Nonconformance***

- Identify the requirement
  - Identify the procedure and what it requires
- Identify the nonconformance
  - What is happening that does not follow the procedure?

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In the student manual there are copies of the Corrective/Preventive Action Request.

- Have the students each write one nonconformance on a CPAR for each clause of the standard that they audited
- It should be different from the ones their teammates are writing. If they took good notes on the checklist this should not be difficult. (Remind them of that for future audits.)
- Emphasize the importance of being specific so those following up with the corrective actions know what they mean.

***What is the requirement, and what was the nonconformance?***

## **Nonconformances: 4.2 Control of Documents**

- Procedure P 5.0-002 has no signature to indicate approval as required by the procedure.
- Procedure 4.2 – 009, dated 7/27/08 does not match the Master List (6/29/08 rev.008).
- Obsolete document distributed. Procedure 7.4 – 004 dated 5/15/08. Master list says 6/14/08.
- Revisions have no Italics indicating changes as required by the procedure.
- No record of approval on the Quality Manual
- Does not address Documents of External Origin.



## Conclusion

After the students have completed their presentations, you can:

1. Show them the final slides in the **“Steps of ISO 9001 Internal Audit”** Power Point presentation outlining the nonconformances for each section.
  - Remember, there is often more than one way to look at a situation, especially in a fictitious setting like SBG. Therefore, encourage open discussion on why they consider items a nonconformance.
  - You may want to add their suggestions to the course material for next time.
2. If you feel that the student has satisfactorily understood the material, you may issue them a certificate (this is a separate MS Word file in your package). Use your judgment to issue this based upon:
  - Participation
  - Ideas
  - Leadership
  - Approach
  - Etc.
3. Schedule an audit of your facility to reinforce the material.

