ISO 9001-14001 All In One Certification Package

Contents

- Combined EMS-QMS Manual *
- ISO 9001 Online Project Implementation Training
- (3) PowerPoint Presentations
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- ISO 9001 & ISO 14001 Gap Analysis Checklists*
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- ISO 9001*& ISO 14001 Internal Auditor Training Materials
- ISO 9001 & ISO 14001 Employee Newsletters

*Sample Included

ISO 9001:2008

QUALITY MANAGEMENT SYSTEM

*****

ISO 14001:2004

ENVIRONMENTAL MANAGEMENT SYSTEM

*****

QMS / EMS MANUAL

Type Your Company Name

Street Address

City, State Zip

Introduction

Your Company developed and implemented an integrated Quality and Environmental Management System in order to document the company's best business and environmental practices, better satisfy the requirements and expectations of its customers, stakeholders and improve the overall management of the company.

Quality Manual

The Quality Management System of *Your Company* meets the requirements of international standard ISO 9001:2008). This system addresses the design, development, production, installation, and servicing of the company's products.

The quality manual is divided into eight sections that correlate to the Quality Management System sections of ISO 9001:2008. Each section begins with a policy statement expressing *Your Company's* obligation to implement the basic requirements of the referenced Quality Management System section. Each policy statement is followed by specific information pertaining to the procedures that describe the methods used to implement the necessary requirements.

This manual describes the Quality Management System, delineates authorities, inter relationships and responsibilities of the personnel responsible for performing within the system. The manual also provides procedures or references for all activities comprising the Quality Management System to ensure compliance to the necessary requirements of the standard.

This manual is used internally to guide the company's employees through the various requirements of the ISO standard that must be met and maintained in order to ensure customer satisfaction, continuous improvement and provide the necessary instructions that create an empowered work force.

This manual is used externally to introduce our Quality Management System to our customers and other external organizations or individuals. The manual is used to familiarize them with the controls that have been implemented and to assure them that the integrity of the Quality Management System is maintained and focused on customer satisfaction and continuous improvement.

Environmental Manual

The Environmental Management System of *Your Company* meets the requirements of the international standard ISO 14001:2004 and addresses the environmental issues associated with *YOUR COMPANY's* activities, operations, services and products.

Additional environmental manual information is provided in a separate section that follows the Quality section of the manual.

President: _____ Date: _____

4.2   Documentation Requirements

4.2.1 General

The QMS documentation includes:

§   A documented Quality Policy and Quality Objectives

§   This Quality Manual

§   Documented Procedures

§   Documents identified as needed for the effective planning, operation and control of our processes, and

§   Quality Records

The EMS documentation includes:

§   A documented Environmental Policy and Objectives

§   This Environmental Manual

§   Documented Procedures

§   Documents identified as needed for the effective planning, operation and control of our processes, and

§   Environmental Records

4.2.2 Quality and Environmental manual

This Manual has been prepared to describe *Your Company's* integrated Quality and Environmental management system. Each section of the manual references documented procedures and instructions relating to the requirements outlined in that section.

4.2.3 Control of documents

All of the QMS and EMS documents are controlled according to the procedure, **P-423** for document control**.**

The procedure defines the process for:

§   Approving documents for adequacy prior to issue

§   Reviewing and updating as necessary and re-approving documents

§   Ensuring that changes and current revision status of documents are identified

§   Ensuring that relevant versions of applicable documents are available at points of use

§   Ensuring that documents remain legible and readily identifiable

§   Ensuring that documents of external origin are identified and their distribution controlled, and

§   Preventing the unintended use of obsolete documents and to apply suitable identification to them if they are retained for any purpose.

Procedures, work instructions, forms and attachments are numbered using a number scheme as described in the work instruction **WI-423-001** for documentation.

8.5.2 Corrective action

Your Company takes action to eliminate the cause of nonconformities in order to prevent recurrence. Corrective actions are appropriate to the effects of the nonconformities encountered.

A documented procedure **P-852** defines requirements for

§   Reviewing nonconformities (including customer complaints),

§   Determining the causes of nonconformities,

§   Evaluating the need for action to ensure that nonconformities do not recur,

§   Determining and implementing action needed,

§   Records of the results of action taken, and

§   Reviewing corrective action taken.

8.5.3 Preventive action

Your Company determines action to eliminate the causes of potential nonconformities in order to prevent their occurrence. Preventive actions are appropriate to the effects of the potential problems.

A documented procedure **P-853** defines requirements for:

§   Determining potential nonconformities and their causes

§   Evaluating the need for action to prevent occurrence of nonconformities

§   Determining and implementing action needed

§   Records of results of action taken

§   Reviewing preventive action taken

QMS Section 8 - Related Documents

Management Responsibility	P-500
Customer Related Processes	P-720
Monitoring, Measuring and Analysis of Customer Satisfaction	P-821
Internal Audits	P-822
Monitoring and Measuring of Product and Realization Processes	P-824
Control of Nonconforming Product	P-830
Corrective Action	P-852
Preventive Action	P-853

Section 4.3 Planning

4.3.1 Identification of Environmental Aspects

Your Company establishes, implements, documents and maintains a system to identify environmental aspects and related impacts that the company can control or have influence over, and determine those which are significant to the company. A consistent risk analysis process is used to determine the significance of the impacts.

The procedure **P-431** is used to assist the company identify how its activities, products, and services affects the environment by identifying the aspects, setting the priorities for them, using the EMS to manage, control, improve upon the impacts and continually improve the system.

4.3.2 Legal and Other Requirements

Your Company establishes, implements, documents and maintains a system to explain how the information regarding its legal and other requirements is obtained, and how it makes that information known to relevant functions within the company and incorporated into the EMS.

The procedure **P-432** is used to identify the legal and other requirements, and to determine if these requirements have environmental aspects and significant impacts. It follows that high significance impacts identified (with the above 4.3.1 and 4.3.2) become candidates for environmental programs (4.3.3 below) and environmental programs are candidates for operational controls (4.4.6 below).

4.3.3 Objectives, Targets, and Programs

Your Company establishes, implements, documents and maintains a system to ensure that the objectives and targets are consistent with the policy, which includes the commitments to compliance with legal and other requirements, continual improvement, and prevention of pollution.

The procedure **P-433** is used to describe the process of setting the objectives and targets to achieve the commitments in *YOUR COMPANY* Environmental Policy. In addition, consideration is given to significant aspects, legal and other requirements, views of interested parties, and technological, financial, and business issues when deciding what is to be accomplished as an objective. The objectives and targets exist at relevant functions and levels of the company, and where practical are measurable.

The procedure **P-434** provides for the development of the environmental programs required to achieve the objectives and targets, and provides for the process of developing action plans for those identified environmental programs.

Environmental programs that result focus on the three basic pollution prevention needs associated with:

"The Water we Drink, the Air we Breathe, and the Earth we Inhabit"

Integrating ISO 14001 & ISO 9001

MANAGEMENT SYTEMS OVERVIEW

ISO 9001

QUALITY MANAGEMENT SYSTEM

ISO 14001

ENVIRONMENTAL MANAGEMENT SYSTEM

Integrating ISO 9001 and ISO 14001

- **Fundamentals**
- **What is ISO 9000?**
- **Benefits of ISO 9001**
- **Management Principles**
- **Process Approach/PDCA Approach**
- **Components of ISO 9001:2008**
  - **Sections 4-8**
- **What is ISO 14000?**
- **Components of ISO 14001**
  - **Sections 4.1-4.6**
- **Why ISO 14000?**
- **Benefits of ISO 14000**
- **Integrating ISO 9001 and ISO 14001**

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Integrating ISO 9001 / ISO 14001

Common requirements:

- **Document Control**
  ISO 9001 par 4.2.3 – ISO 14001 par 4.4.5

- **Records**
  ISO 9001 par 4.2.4 – ISO 14001 par 4.5.4

- **Responsibility and Authority**
  ISO 9001 par 5.5.1 – ISO 14001 par 4.4.1

- **Management Review**
  ISO 9001 par 5.6   – ISO 14001 par 4.6

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Integrating ISO 9001 / ISO 14001

Cont'd - Common requirements:

- **Training, Competency, Awareness**
  ISO 9001 par 6.2.2 – ISO 14001 par 4.4.2

- **Internal Audit**
  ISO 9001 par 8.2.2 – ISO 14001 par 4.5.5

- **Corrective and Preventive Actions**
  ISO 9001 par 8.5.2   – ISO 14001 par 4.5.3

- **Infrastructure, Work Environment**
  ISO 9001 par 6.3-6.4 – ISO 14001 par 4.4.6

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Integrated QMS-EMS Implementation

2. Review and Update your existing QMS procedures

In most cases, the procedures common to QMS & EMS are:
- Document control,
- Control of records,
- Responsibility and authority,
- Training, awareness and competency,
- Maintenance of resources,
- Control of measuring equipment,
- Corrective and preventive action,

The upgrade of the procedures will involve the minor addition of a general statement that the requirements in the particular procedure apply to both the QMS and the EMS.

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2. Review your existing procedures and upgrade the ones that are common to both the QMS and the EMS.

In most cases, the (10) common procedures are:

Document control,

Control of records,

Responsibility and authority,

Training, awareness and competency,

Maintenance of resources,

Control of measuring equipment,

Corrective and preventive action,

Generally, the procedures that need the most updates are:

Management review,

Purchasing and out sourcing,

Internal auditing.

*The above 3 items are treated as new procedures and listed in item 4 below:

Steps to perform Gap Analysis

1. Prepared your audit schedule,
2. Assigned responsibility to your auditors for different areas or processes to audit
3. Copy each section of the checklist for the auditors working with that section.
4. As you work through the checklist
   a. Identify the areas that need to be developed for the I.
   b. Make reference procedures or other documents that you have and that will provide information for the new QMS.
   c. Take notes on the status of the documents:
      i. will they need to be revised for the new system?
      ii. Or can they be used as is?
      iii. Also note where processes are in place, but documentation is needed.

Focus on what is in place, and what needs to be developed. While you do want to know if procedures and processes are being complied with, **compliance is not your main objective for this audit**. *Remember that the final outcome of this audit should be a list of things that your organization needs to do to comply with ISO 9001:2008.*

Help Preparing for ISO 9001 Certification

We offer several other tools to help your organization transition to ISO 9001: 2008.
- ISO 9001 QMS –
  o Complete Quality Manual, Procedures, Forms and Flowcharts
- ISO 9001 Project Implementation Training
  o
- Employee Training – PC based training which can be taken via the web.
  o It can be customized to give you better record keeping and automated deployment.
- PowerPoints - reviewing clause by clause review of ISO 9001
- Audit Checklist - to help you audit to the Standard
- Internal Auditor Training – which includes the materials to train your auditors on the standard.
- Problem Solving Training
  o Root Cause Analysis with Corrective Action
  o Mapping Work Flows
  o 6 Sigma, Lean & More.

ISO 9001 All in One Documentation and Training Package has everything you need to prepare for certification.

4 QUALITY MANAGEMENT SYSTEM

	REQUIREMENTS	CURRENTLY IN PLACE (List documents or evidence)	COMPLIANT Y/N? Estimated % Complete	ITEMS NEEDED
4.1	**General Requirements**			
	This clause asks you to identify how management applies the process approach to achieve the effective and efficient control of processes, resulting in performance improvement. Specifically this section is looking for an overall process evaluation of all quality related processes and their interrelationships. Look to see that your organizational processes are defined and that consideration is given to those items described in a) through f).			
	a) Look for documentation of the processes included in the QMS			
	b) Look for information on the relationship and sequence of the QMS processes.			
	c) Ask Management if operation and control of processes is effective. How do they know if it is effective?			
	d) Ask how they are able to know if resources and information needed to support processes have been provided.			
	e) Is there any information on the effectiveness of processes?			
	f) How are improvements made to processes?			
	▪ What processes does your organization outsource? How is the process controlled?			

ISO 14001:2004 Environmental Management System - The Gap Analysis Checklist

GUIDELINES FOR USE OF THE GAP ANALYSIS CHECKLIST
_____

This gap analysis checklist is prepared for use in evaluating your Environmental Management System against the requirements of ISO 14001.

Each requirement is expressed as a question that the auditor can use to evaluate your EMS capabilities. Along with the checklist, you will need to have a copy of the ISO 14001:2004 standard so that you can see exactly what the requirements are and can refer to the guidance section in Annex A.

After you have prepared an audit schedule, and assigned responsibility to the auditors for different areas to audit, copy each section of the checklist for the auditors working with that section. As the auditors work through the checklist, they need to take notes on what is in place, and what needs to be developed.

Reference the procedures or other documents that are reviewed and that will provide information for the new EMS. Take notes on the status of the documents, will they need to be revised for the new system, or can they be used as is? Also note where processes are in place, but documentation is needed.

Focus on what is in place, and what needs to be developed. While you do want to know if procedures and processes are being complied with, compliance is not your main focus for this audit.

Remember that the final outcome of this audit should be a list of things that your organization needs to do to comply with ISO 14001:2004.

ISO 14001:2004 Environmental Management System - The Gap Analysis Checklist

4   ENVIRONMENTAL MANAGEMENT SYSTEM

REQUIREMENTS	CURRENTLY IN PLACE (List documents or evidence)	COMPLIANT YES / NO?	IF NO Estimated % complete	ITEMS NEEDED
4.1 General Requirements				
This clause introduces the general requirements for an environmental management system that is intended to result in improved environmental performance. Look to see that your organization has a system with a defined scope for an EMS that can be reviewed and evaluated to identify and implement opportunities for improvements.				
Has the organization established, documented, implemented and maintained an EMS as required by ISO 14001:2004?				
How does the organization determine if the requirements of the standard are fulfilled?				
Is the scope of the EMS defined & documented? -- are all activities, products and services within the scope addressed by the EMS?				
4.2 Environmental Policy				
This clause addresses the requirement for your organization's environmental policy which is the driver for implementing and improving the Environmental Management System.				
Is the organization's environmental policy appropriate to its activities, products, services?				
Does the policy reflect the commitment of top management to: -- prevent pollution and to continually improve? -- comply with legal & other requirements?				
Does the policy provide for a framework to: -- set & review objectives and targets? -- document, implement & maintain the policy? -- communicate the policy to persons working for or on behalf of the organization? -- is available to the public?				

ISO 14001:2004

ENVIRONMENTAL MANAGEMENT SYSTEM

INTERNAL AUDIT CHECKLIST

_____

GUIDELINES FOR USE OF THE ENVIRONMENTAL MANAGEMENT SYSTEM

1.   This checklist is based on the November 2004 released ISO 14001:2004 standard for *"Environmental Management Systems – Requirements"*.

2.   The checklist is used by auditors to evaluate or assess EMS requirements based on ISO 14001:2004.

3.   The auditors are expected to be competent and in a position to conduct the audit in an impartial and objective manner. Evidence for visible top management commitment and environmental management action must be looked for and determined to be present.

4.   The bold numerical typescript used in the checklist with titles shall be treated as the *"Requirements"*.

5.   During assessment of each requirement, auditors record the status of the evaluation by indicating in the right hand column a:

> **Yes**   **- for Acceptable condition**
> or
> **No**   **- for Deficient condition**

As required during the audit, the assessments do not need to follow the order or sequence shown in the checklist.

6.   The auditors must keep in mind that the requirement provided in the Annex A of the standard are guidance for use of the ISO 14001:2004 standard and therefore must not be misinterpreted as required by this standard.

4 Environmental Management System	Observation/Comments	Results
4.1 General Requirements	**Observation/Comments**	**Results**
Has the organization established and maintained an environmental management system as required by clause 4 of ISO 14001:2004? Has the organization defined and documented the scope of the EMS? Are the boundaries to which the EMS applies clearly defined? Are all activities, products and services within the scope addressed by the EMS? **Additional questions** To prove that the organization 'Does what it says it does', what records are completed for this section?		
4.2 Environmental Policy		
Has the environmental policy been formulated by the top management? Is the environmental policy aligned with the defined scope of the EMS? Does the policy express commitment to compliance to legal and other requirements which relate to the environmental aspects? Has the environmental policy been communicated to all persons working on behalf of the organization? **Additional questions** To prove that the organization 'Does what it says it does', what records are completed for this section?		
4.3 Planning **4.3.1 Environmental Aspects**	**Observation/Comments**	**Results**
Has the organization established and maintained a procedure to identify the environmental aspects for its activities, products or services? Can the organization control and have an influence on those activities, products or services? Has the organization determined which of those environmental aspects have significant impacts on the environment? Do the environmental aspects take into account the planning of existing conditions or new developments that are within the scope of the EMS?		

Audit Conducted by: _____ Date: _____ 2

ISO 9001:2008

Internal Auditor Training

Trainer's Guide

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

* 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
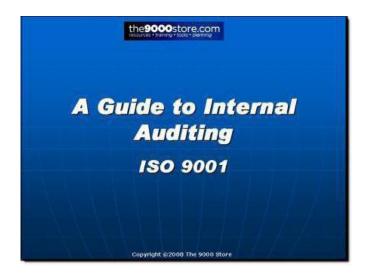0:30   Closing Meeting
0:30   Creating the Audit File

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 that one place in the standard, so there could be more than one correct answer in some cases.