

# Understanding and Implementing A Quality Management System Elsmar.com

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Slide 1

*Notes & Commentary*

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# Implementing An ISO 9001 Quality Management System

This powerpoint file is formatted to be read and printed in the 'Notes' view.

Explanations and detail are contained in the 'Notes' portion of the presentation. While not all slides have text in their Notes' window, most have some relevant info. If you do not see the 'notes' below this slide you are not using the 'notes' view.

This powerpoint file mainly addresses 'implementation as a project' issues.

The included file [Clause\\_Interp\\_and\\_Upgrading.doc](#) contains all interpretations issue information and details related to compliance. It is about 75 pages of detailed interpretations, details of changes from the 1994 version, suggestions and related issues.

*Included at no cost:*

Phone, Fax and e-mail support

Implementation is very company specific. If you have questions, give me a call. We can discuss the specifics of your situation.

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## *Notes & Commentary*

This is the notes pane. Notes and commentary will be found for many slides in their notes pane.

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# An Open Source Document

This document is an **Open Source** document!

Huh?

- This means it is the result of the input of many people and resources.
- This means **YOU** can and may participate. If you want something included or have a suggestion, please let me know. You can send some slides in e-mail. Or write me and tell me about what has not been addressed but that you believe should be addressed. If your suggestion is incorporated into the document you will be given credit in the document. You will get updates for free as long as the file is undergoing updates (rumour is I may die someday or decide to do something else with my life so I can't really use the word *forever*).
- I will accept and incorporate good 'patches' and constructive criticism.
- Telling me of spelling errors doesn't count, but will be very much appreciated.
- This is how we do things in hackerland; it's a combination of individual visions and collaborative synergy that makes things work. Just as it is in the Cove forums.

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# Files Included in this Package

These files are currently included with this release of the implementation package:

**Implementation.ppt** is the main PowerPoint file.

- k **Clause\_Interp\_and\_Upgrading.doc** contains interpretations of the standard and advice on meeting specific requirements.
- k **Flow\_Charts.ppt** is a compilation of flow charts to address required documentation.
- k **ISO9K\_Imp\_Forms** contains a set of templates for a number of things from rating registrars to several sample forms (I will be adding more).
- k **ISO9K\_Imp\_Misc** is a set of files with some information I believe you may find useful.
- k Updates are free for 1 year from purchase date.

Name	Date Modified	Size
Clause_Interp_and_Upgrading.doc	Today, 7:07 AM	692 K
Implementation.ppt	Today, 8:15 AM	1.6 MB
ISO9K_Imp_Forms	4/8/01, 7:33 PM	640 K
Audit_Man_Days.doc	4/1/01, 9:05 PM	32 K
Design_Rev_Example.xls	4/1/01, 8:23 PM	16 K
Document_Matrix_Example.xls	4/7/01, 8:49 PM	40 K
ISO9001-2000_Checklist.doc	4/1/01, 1:04 AM	196 K
ISO9001-2000_Compliance.xls	4/1/01, 9:00 PM	52 K
ISO9001-2000_GAP_Analy.doc	4/7/01, 5:27 AM	152 K
Mgmt_Rev_Form.xls	4/8/01, 5:18 AM	24 K
Quality_Plan_Example.xls	4/1/01, 8:21 PM	16 K
Registrar_Comparison_1.xls	4/1/01, 8:41 PM	24 K
Registrar_Comparison_2.xls	4/1/01, 8:39 PM	16 K
Responsibility_Matrix.xls	4/1/01, 8:28 PM	56 K
Supplier_Evaluation_Example.xls	4/1/01, 8:33 PM	16 K
ISO9K_Imp_Misc	Today, 8:14 AM	19 MB
Awareness_Posters.ppt	Yesterday, 12:27 AM	308 K
Doc_Review_Tracking.xls	4/8/01, 5:46 AM	32 K
FDIS_vs_Release_Text_Diffs.xls	Today, 5:34 AM	52 K
Flow_Charting_Help	Today, 8:15 AM	15.3 MB
Flow_Charts.ppt	Today, 8:09 AM	260 K
ISO9K-vs-QSR-vs-ISO9K_2000.doc	4/1/01, 1:04 AM	60 K
ISO_Info_1993.doc	3/22/01, 5:23 PM	168 K
MII-Spec_Reform.pdf	8/2/99, 8:56 AM	44 K
Odds_and_Ends	Today, 8:14 AM	1.9 MB
QT-IRS_Deduction.pdf	3/9/00, 10:45 PM	80 K
Quality_Policies_Samples.doc	4/8/01, 6:05 AM	48 K
Registrar_Rating_Article.pdf	3/10/00, 7:38 AM	124 K
Service_Design	Yesterday, 11:41 AM	148 K
Terminology.doc	10/19/00, 4:22 AM	72 K
Transition.doc	10/19/00, 4:21 AM	348 K

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## About This Document - Contents

- This document is a 'digest' from many implementations I have been involved in, information from news group snippets and forums discussions. I have tried to make it as comprehensive as possible given the extreme range of types and sizes of companies and their scopes of implementation. I have also tried to address both simple and complex issues to address the needs of the novice as well as those whose occupation is in the quality field.
- If you are the owner or manager of a small company, you may have heard about ISO 9000. Maybe not. Either way, if you have 10 people or less you probably don't have anyone with a quality assurance background. On the other hand, if there are 20,000 employees in your company you probably have a quality background which is why you're here.
- For small companies where there is no one with a quality background implementation can appear to be overwhelming. It's not that ISO is so difficult. It's that if you don't have a good understanding of some of the quality related concepts, such as nonconformance and corrective action systems, it becomes much like taking up a new occupation (after how many years?) or learning a new language.

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# Sample Flow Charts

There are several resources included.  
These are each different sets of flow charts.

- One is a directory of gifs which you can open with your picture editor. [Sample\\_Flow\\_Charts-jpg\\_Format](#) is the directory name.
- [Map\\_Examples](#) is a directory with some linked flow charts. Open the file index.html with your browser.
- The file [Flow\\_Charts.ppt](#) has a number of more current flow charts examples (ideas!).
- The file [Flowcharting.pdf](#) contains some help on how to make a flow chart.

Major flow charts have details on system requirements.

## *Notes & Commentary*

The example flow charts included are meant to give you some thoughts on how to flow chart your system. Because of the differences in companies, processes and products, these flow charts are meant to give you ideas. No one, nor any company, can give you a 'one size fits all' flow chart (or text procedure for that matter), no matter what they say.

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# Introduction

The Purpose of this Presentation is to  
Provide an **Overview** of **ISO 9000** and  
to discuss **Implementation**  
**Methodologies**

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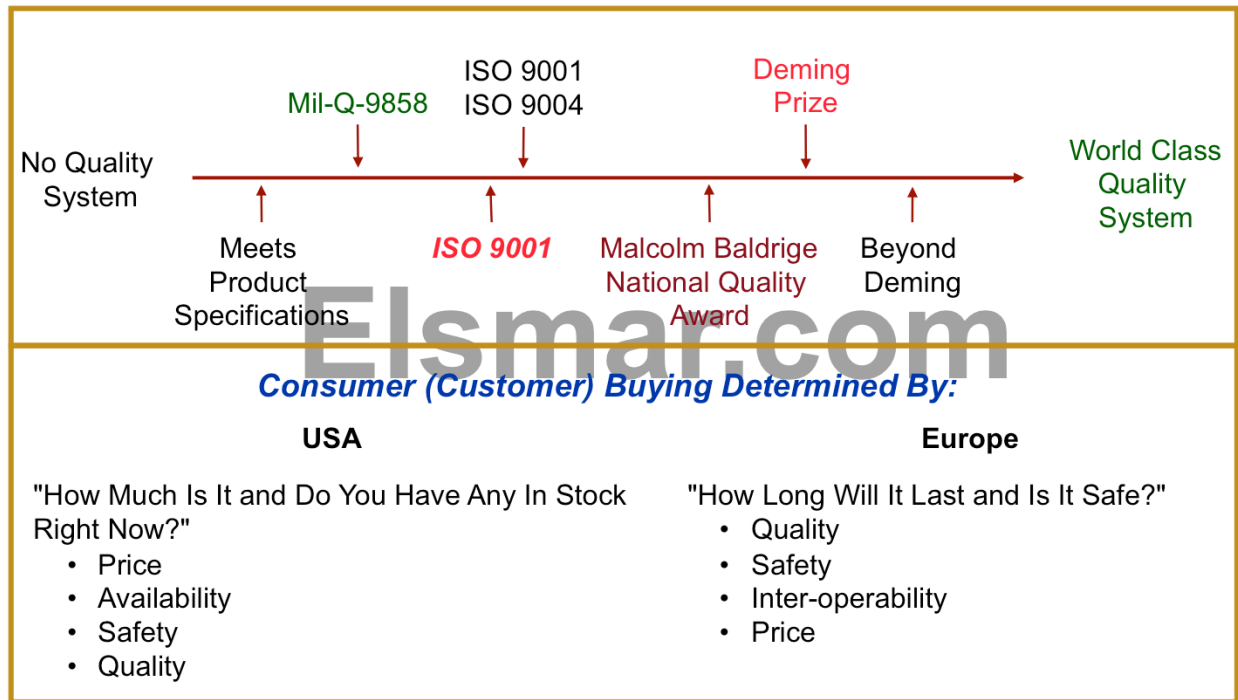
# Implementation Considerations

- You are not the first. Over 345,000 organizations have registered to ISO 9000 by early 2001.
- A main point to remember as you traverse this tome is that **each company is different**. There is no way I can address every possible type and size of company. The contents represent the basis of a methodology I have used over the last 8 years in implementing ISO 9001 and QS-9000 in facilities as large as 10,000 souls, as small as 8 persons, in companies as large and complex as Motorola, as 'unusual' as Harley-Davidson, and as unique as an insurance company. The methodology is structured. Very structured. How closely you follow the path will depend upon your specific circumstances and needs as well as your own beliefs. Some companies go slowly. Some companies do not want a complex project plan. Some companies insist on a complex project plan. But, more on this later.
- As much as anything else, you will have to assess my recommendations with consideration to your circumstances.

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# Quality Systems



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The original thrust was to provide for compliance to new EC safety directives for Regulated Products. The goal is to allow for meeting product regulations in all EC countries by providing a route to gaining approval for use of the CE (Communaute Europeene) mark. The CE mark is becoming the passport for selling **regulated** products in Europe.

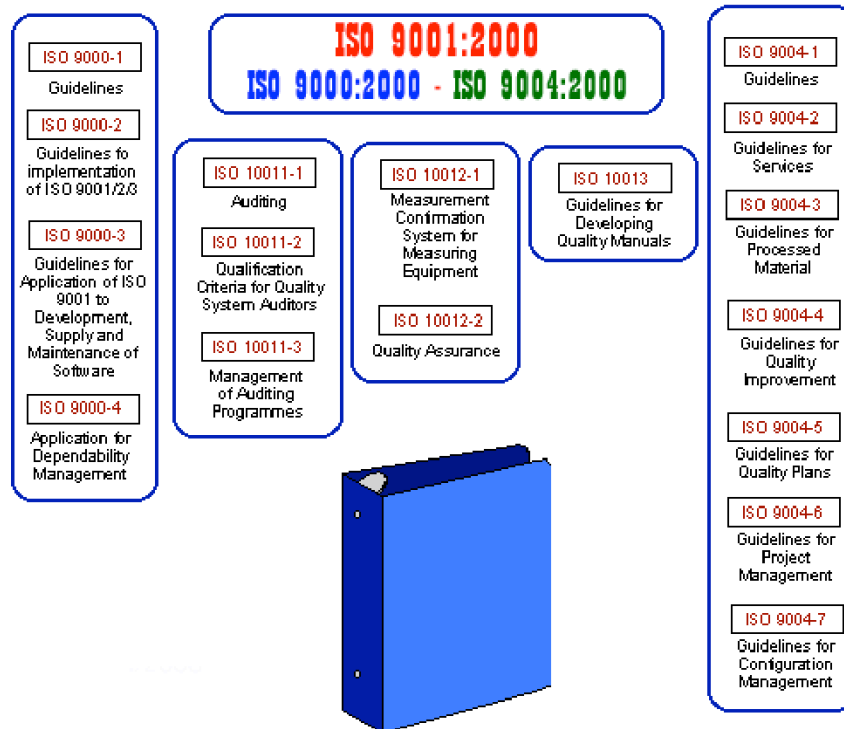
### A. **Unregulated** Products Examples

- Paper
- Furniture

### B. **Regulated** Products Examples

- Machinery
- Toys
- Personal Protection Equipment
- Medical Devices
- Telecommunications Equipment

# ISO 9000 Family of Documents



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## Notes & Commentary

This is a grouped graphic representing the main ISO 9000 Series and related documents. One should bear in mind that the landscape is 'alive' (evolving, not static). As such, there are standards being combined (as happened in the last ISO 9000 Series update). There are standards being obsoleted. There are new standards being initiated (ISO/TS 16949 is an example).

International Organization for Standardization (Isos = Equal)

TC 176 - Meets in Geneva, Switzerland

TC = Technical Committee

5 Year Review and Update Planned

Europe Wide

Must Be Registered to Sell In Europe

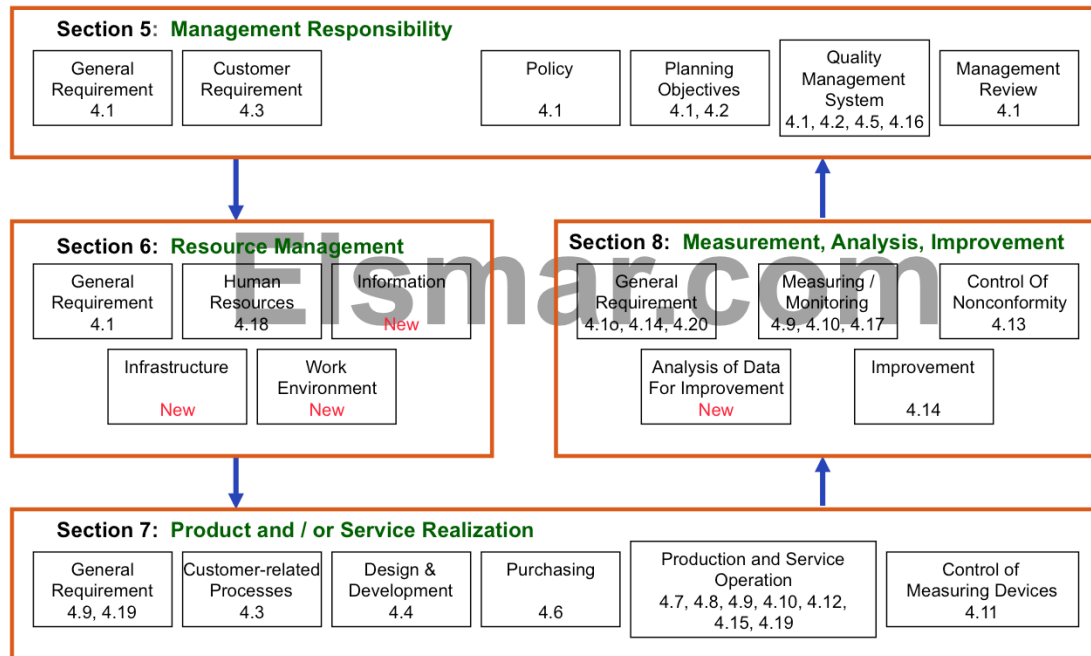
Japan is Accepting

US Military Switched From MIL-Q-9858A



# ISO9001 DIS Structure

## Section 4: Quality Management Systems Requirements 4.2



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## Notes & Commentary

I have included this slide as a historical perspective. I do not see a need to update it. Essentially it was a pictorial of the 'sections' reconciling the 1994 and 2000 versions in Appendix A.

The 'old' standard had (has) 20 sections or elements. These have been grouped into 4 sections in the year 2000 version of ISO 9001.

I have left it as it is an interesting way to look at the relationships. This will be of more interest to those going through an 'upgrade' than to you new folks.

The relationships and all details are addressed in Clause\_Interp\_and\_Upgrading.doc

# ISO 9001 Vs Baldrige

Baldrige Criteria

ISO 9001:2000		Leadership	Strategic Planning	Customer Focus	Information Analysis	Human Resources	Process Management	Business Results
4	Quality Management System							
5.1	Management Commitment							
5.2	Customer Focus							
5.3	Quality Policy							
5.4	Planning							
5.5	Resp., Authority & Communication							
5.6	Management Review							
6.1	Provision of Resources							
6.2	Human Resources							
6.3	Facilities							
6.4	Work Environment							
7.1	Planning of Product Realization							
7.2	Customer Related Processes							
7.3	Design and/or Development							
7.4	Purchasing							
7.5	Production and Service Operations							
7.6	Control of Measuring and Monitoring Devices							
8.1	General							
8.2	Measurement and Monitoring							
8.2.1	Customer Satisfaction							
8.2.2	Internal Audit							
8.2.3	Measurement and Monitoring of Processes							
8.2.4	Measurement and Monitoring of Product							
8.3	Nonconforming Product							
8.4	Analysis of Data							
8.5	Improvement							
8.5.2	Corrective Action							
8.5.3	Preventive Action							

Aligned   
 Somewhat Aligned   
 Not Aligned 

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## Notes & Commentary

For those of you interested in the Baldrige program, stop by <http://Elsmar.com> and search for Baldrige. NOT Baldrige!!!

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## Malcolm Baldrige National Quality Award Criteria Circa 4/2001

### 1. Leadership

- Organizational Leadership
- Public Responsibility and Citizenship

### 2. Strategic Planning

- Strategy Development
- Strategy Deployment

### 3. Customer and Market Focus

- Customer and Market Knowledge
- Customer Relationships and Satisfaction

### 4. Information and Analysis

- Measurement and Analysis of Organizational Performance
- Information Management

### 5. Human Resource Development and Management

- Work Systems
- Employee Education, Training and Development
- Employee Well-Being and Satisfaction

### 6. Process Management

- Product and Service Processes
- Business Processes
- Support Processes

### 7. Business Results

- Customer Focused Results
- Financial and Market Results
- Human Resources Results
- Organizational Effectiveness Results

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# ISO 9000

The Ultimate **Goals** of ISO 9001 are:

1. To Provide **Consistent Processes**  
(Documented Systems Provide For Consistency)  
With Defined **RESPONSIBILITIES**
2. **Customer Satisfaction**
3. **Continuous Improvement**

Periodic Audits Ensure Systems Are Working

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## Notes & Commentary

ISO 9000 is a European Origin STANDARD

ISO = Greek *isos* (equal)

ISO does NOT stand for International Organization for Standardization

ISO 9001 is a Standard.

It is intended to provide for 'common' quality systems across borders.

It is derived from many quality related documents dating back to the 1950's from many countries, including documents from the United States.

The goal of common quality systems is consistent, controlled processes. It does this by requiring certain documentation telling how things are done and who is responsible for what.

# Where Did It Come From?

## Liability

By defining practices, Liability is addressed. In fact, the whole ISO 900X series is the reaction to a need to assign

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Responsibility

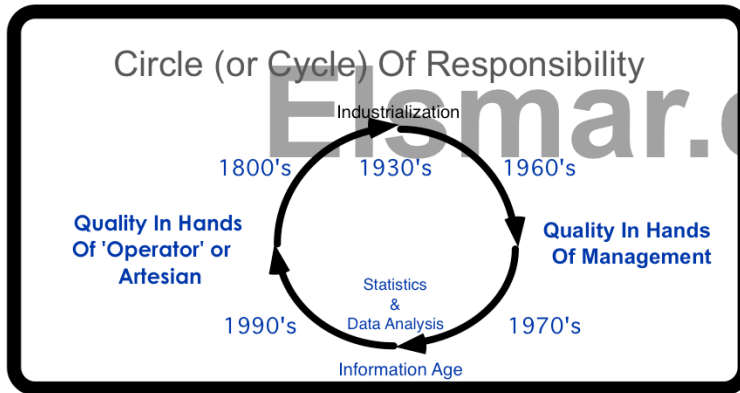
For international trade issues involved in bringing the continent together into the 'European Union'. The foundation drifted to be a 'quality standard'.

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# Liability

- The ISO 9000 series is a vehicle to address liability issues
- Driver was the European Common Market
- Is relevant locally and world wide



- [FAR Part 46](#) "Quality Assurance"
- [Mil-Std-109](#) "Quality Assurance Terms and Definitions"
- [Mil-Q-9858](#) "Quality Program Requirements"
- [Handbook 50](#) "Evaluation of a Contractor's Quality Program"
- [Mil-Std-1520](#) "Corrective Action and Disposition System for Nonconforming Material"
- [Mil-I-45208](#) "Inspection System Requirements"
- [Handbook 51](#) "Evaluation of a Contractor's Inspection System"
- [Mil-Std-45662](#) "Calibration Systems Requirements"
- [Handbook 52](#) "Evaluation of Contractor's Calibration System"
- [Mil-Std-1535](#) "Supplier Quality Assurance Program Requirements"
- [AR-92](#) "Naval Air Systems Command – Aeronautical Requirements – Quality Program Requirements"
- [Mil-Std-1521](#) "Technical Reviews for Systems, Equipments (sic) and Computer Software"

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## Notes & Commentary

During 1992 I had an opportunity to speak with a fellow who was on the old TC 176 back in the late 1970's and the 1980's. We discussed the origins of the ISO 9000 series of documents. The origins are as much a response of a need to establish a framework to address liability issues as anything else. The question was, if you live in Germany and buy something made in France, how do you address issues such as liability should the product fail or prove defective. The coming of the common market in the 1960's was a large driver for the establishment of an applicable standard.

Standards reviewed included those such as the British Standard BS 5750. Military (including NATO) standards were reviewed, as were commercial standards. 'Quality' related standards were eventually arrived at as the best way to address these issues.

The list on the right side of the slide above is a list of several US Military documents which were reviewed. Most of them are now obsolete. In fact, ISO 9001 has replaced Mil-Q-9858, Mil-Std-1520, Mil-Std-45662 (to name a few) in military procurement requirements. See Mil-Spec\_Reform.pdf.

## Origins

ISO 9000 is about responsibility (which is accountability).

Historically, quality was in the hands of the individual artisan. As industrialization occurred, especially when the theory of Interchangeable Parts was acted upon (result = assembly lines), quality came to be perceived to be a function of designers - eventually, by the 1960's, management had assumed the role as the definer of, and the responsibility for, quality.

Quality is now perceived to be what the customer expects -  
However, the responsibility for quality is again realized to be in the hands of the individual artisan.

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# ISO 9001 and Quality

- ISO 9001 Has Nothing To Do With the Quality of a Product or Service

## Cement Life Preserver The Classic Example

- The year 2000 version of ISO 9001 carries a revised title, which no longer includes the term **Quality Assurance**. This reflects the fact that the **quality management system requirements** specified in this edition of ISO 9001 address **quality assurance of product** as well as **customer satisfaction**.
- See <http://Elsmar.com/ubb/Forum5/HTML/000063.html>
- Conformance to Specifications
- Consistency of Processes

## Notes & Commentary

The 'classic' Cement Life Preserver goes back to the 'early' ISO days. The question was (is?): Can a company be registered and make a cement life preserver?

The answer is, YES - if that's what they have designed and the product meets the design.

The word quality is much overused. The definition of quality is debated every day. The evolution is evident in the document name changes.

See <http://www.qs9000.com/ubb/Forum5/HTML/000063.html> for a discussion of the definition, and to get a sense of the evolution of the definition of, Quality.



# The Main ISO 900x Documents

- **ISO 9000**

NEW: Quality Management Systems - Fundamentals and Vocabulary

OLD: Replaces the old ISO 8402:1994

- **ISO 9001**

NEW: Quality Management Systems - Requirements

OLD: Quality Systems - Model for Quality Assurance in **Design, Development**, Production, Installation and Servicing

- **ISO 9004**

NEW: Quality Management Systems - Guidelines for Performance Improvement

OLD: Quality Management and Quality System Elements - **Guidelines**

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# The Stated Intent of ISO 9001

## 0 INTRODUCTION

### 0.1 General

This International Standard specifies requirements for a **quality management system** that can be used by an organization to address **customer satisfaction**, by **meeting customer and applicable regulatory requirements**. It can also be used by internal and external parties, including certification bodies, to assess the organization's ability to meet customer and regulatory requirements.

The adoption of a quality management system needs to be a strategic decision of the organization. The design and implementation of an organization's quality management system is influenced by varying needs, particular objectives, the products provided, the processes employed and the size and structure of the organization. It is not the purpose of this International Standard to imply uniformity in the structure of quality management systems or uniformity of documentation.

It is emphasized that the quality management system requirements specified in this International Standard are **complementary to technical requirements** for products.

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Taken from the year 2000 draft, this shows the emphasis is on a Management System, not on product quality

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# Differences In Sectors

## 1.2 Permissible exclusions

The organization may only exclude quality management system requirements that neither affect the organization's ability, nor absolve it from its responsibility, to provide product that meets customer and applicable regulatory requirements. **These exclusions are limited to those requirements within clause 7** (see also 5.5.5), and may be due to the following:

- (a) the nature of the organization's product;
- (b) customer requirements;
- (c) applicable regulatory requirements.

Where permissible exclusions are exceeded, conformity to this International Standard should not be claimed. This includes situations where the fulfillment of regulatory requirements permits exclusions that exceed those allowed by this International Standard.

## Notes & Commentary

ISO 9000 was originally quite physical product production (manufacturing) centric. In an attempt to address related issues there were 3 versions of the standard. They were identical with one exception: each ascending document was a subset of the previous document. ISO 9001 was the complete document. ISO 9002 was a subset of ISO 9001 - Design was omitted. ISO 9003 was a subset of ISO 9002 - this was originally the document which addressed servicing companies.

Each company is different. Each type of business is different. Interpretations often come into play. Design is a good example. One typically thinks of a physical product when the word Design is used. However, many things are designed, including systems. An example is hospital registration where design applies to their systems, such as Code Blue response, individual treatment plans and evacuation plans.

The year 2000 version addresses these issues through the exclusion clause. Note that there are no significant differences between ISO 9001 and ISO 9001:2008.

# Service As A Product

## 3.1 - product - result of a process

NOTE 1: There are four agreed generic product categories:

- hardware,
- software,
- services,
- processed materials.

Most products are combinations of some of the four generic product categories. Whether the combined product is then called hardware, processed material, software or service depends on the dominant element.

## Notes & Commentary

- > I was just hoping that you could clarify this a little for me. I have no
- > experience with service based industries. Do you treat their service as you
- > would a product?

Yes. A tire dealership's main product is the installation of tires. But there are other products. If they do alignment, one product would be alignment. No different from a company which makes both air valves and electric motors. They have several products. **List the specific services you provide and you have a list of your products.**

- > Their processes, I assume are how they carry out the
- > service. This is a tire shop I'm dealing with.

Their processes are many: Taking orders from customers. Installing tires. Balancing tires. Aligning front ends. Placing orders with suppliers. Training employees.

Most tire shops do a lot more now. The place I go does brakes and some other minor repairs and such. These are all processes.

# Why Do It?

- I'll bet either a **customer requirement** or your **sales / marketing** folks dreamed this up for you to do, right? **Almost all implementations are the result of one or the other.** I have never had a client which simply decided to do it because they felt doing so would be beneficial to the company. This is not to say improvement is not an issue. It almost always very much is. **But that has never been the spark that initiated the process.**
- Many of you know I'm not a proponent of registration per se. For some companies it is a good thing. They lack the internal discipline necessary to ensure people are doing what they are supposed to be doing.
- I am a gung ho proponent of the implementation process. In the very least, it necessitates a serious housekeeping effort. The process typically opens everyone's eyes to what they are doing and why. Often I refer to the early stages of implementation as the Discovery Phase. I cannot tell you how many times I have heard **"I didn't know we were doing that!"** Sometimes it's scary thinking how far in the dark some people are in so far as knowing and understanding what they're supposed to be doing goes. Which is pretty far. I have never seen an implementation which did not benefit the company in some way.

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## Notes & Commentary

Let us be clear. ISO 9001 has **nothing to do with quality**. Nothing. ISO 9001 is titled "Quality Management Systems - Requirements". So - How can I say it has absolutely nothing to do with quality?

The name is essentially derived from documents which ISO 9001 evolved from. But look at what ISO 9001 requires:

Consistency of Product by Business as a Process

Defined Responsibilities

The 'life preserver' example is often cited with respect to quality. You can make concrete life preservers if that's what the design calls for and be registered to ISO 9001. What comes into play here is the definition of quality. Our paradigm tells us a concrete life preserver would be of no use for saving lives. One must admit, however, that the design intent may be for a decorative life preserver and as such floatation and flexibility are not issues.

## Why Do It?

- Process Improvements
  - Theoretically, as you implement the system, you have the opportunity to improve your processes. You will outline the current process, add the requirements of the standard and then optimize the process with input from the process users.
- Increased Quality Awareness
  - Theoretically, as the system is implemented, quality awareness will increase because all staff must be trained on ISO 9000, staff must be trained on processes as they are implemented and staff will have "ownership" of processes they are involved in developing and improving.

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# Project Duration

## How long will it take?

- An implementation project will typically take about 6 to 9 months, but will range from 3 to 20 months.
- Factors that will affect the timeline include:
  - Size and complexity of the organization.
  - Existing systems
  - How much existing documentation is available which can be used.
  - Amount of resources available for the project
  - ISO expertise available.

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# Simple Schedule

Month:	1	2	3	4	5	6	7	8	9	10	11	12
Planning	■											
Development	■											
Implementation:		■	■	■	■	■	■	■	■			
Developing processes		■	■	■	■	■	■	■	■			
Documenting processes		■	■	■	■	■	■	■	■			
Running the system:			■	■	■	■	■	■	■	■	■	■
Collecting records						■	■	■	■	■	■	■
Internal Audits						■	■	■	■	■	■	■
Management review		■				■				■		
Registration												■

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## Notes & Commentary

When you think about a project schedule, remember a gap analysis is Job 1. If you don't do a gap analysis you have no idea what you have to do!

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# Typical Costs

Annual Sales Volume	Average Annual Savings	Average Cost per Company
Less than \$11 million	\$25,000	\$62,300
\$11 million - \$25 million	\$77,000	\$131,000
\$25 million - \$50 million	\$69,900	\$149,700
\$50 million - \$100 million	\$140,000	\$188,800
\$100 million - \$200 million	\$195,000	\$208,700
\$200 million - \$500 million	\$227,000	\$321,700

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# Payback

- Companies **minimize deficiencies** in supply and support of products and services.
- Companies **identify problem areas** and address them quicker.
- Companies **identify customer needs** more accurately.
- Companies **become more consistent** in their product and services.



MEASURE OF IMPACT	BEFORE	CURRENT	DIFFERENCE
• PPM Defect Level	3345	1698	49% decrease
• Number of Returns	749	346	54% decrease
• Warrantee Cost (x000)	700	667	5% decrease
• Scrap Percent	4.3	3.7	14% decrease
• Rework Percent	24	19	26% decrease
• Cost of Nonconformance	94	44	53% decrease
• Return on Investment	-	-	158%



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## Notes & Commentary

The above was from a real company which went through implementation. They reported the figures above.

If there is an inconsistency it is in that the figures were taken shortly after registration. I have not seen any long term studies. This is not surprising. Many companies are undergoing some type of improvement program at any given time so after implementation the next program can also affect these figures. One of my clients was undergoing TPM, 5-S and QS-9000 implementation at the same time. To try to assign cause to any one of them for better numbers observed is difficult, if not impossible.

When a company goes through the implementation process there is typically a very close look at, and an evaluation of, what is going on. While it happens, it is unusual not to see some type of spike (at least) in numbers. A heightened awareness exists. This is to say the implementation process alone is a learning experience. The question becomes '...how long will this last?'

Please do not misunderstand - I don't believe there are many companies which do not profit from implementation. Often it is hard to translate savings to \$, however.

# Who's Doing It & General Issues

## The ISO organization publishes a yearly assessment of the ISO 9001 distribution.

- ISO9K-8thCycleSurvey.pdf (through December 1998)
- ISO9K-9thCycleSurvey.pdf (through December 1999)

## The Magical Demystifying Tour of ISO 9000 and ISO 14000

- <http://www.iso.ch/9000e/magical.htm>

## Notes & Commentary

The above files are available from <http://iso.ch>

Each year there is an analysis of how far ISO is spreading and other factors they deem important. I believe you should take a read through the latest survey to get an idea how far and wide ISO 9K series has spread.

The ISO "Magical Demystifying Tour of ISO 9000 and ISO 14000" is on the web and gives a somewhat simplistic overview of the standard. It's mostly a promo, but does contain some pertinent information.

But watch out what you get from the ISO folks. Well meaning, there is a slight delay from time to time. For example, as of April 2001 their document meant to help companies decide which standard to apply (Selection and Use) is still posted, though it is obsolete (disk file name is 9000-selusee.pdf).

As with any other *Miracle Cure*, ISO registration is not the answer to all. If a business is being run poorly, ISO 9001 registration is not likely to significantly improve things. Companies have personalities which are typically set by upper management. They rarely 'Find Religion', so to speak, because of an ISO implementation process. So - don't expect miracles.

# A Quality Management System? Elsmar.com

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*Notes & Commentary*

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# System vs. Process

- System

Pronunciation	<b>sI</b> stEm
Definition	A group of related things or parts that function together as a whole.
Example	The school system in our city.

- Process

Pronunciation	<b>pra</b> sehs
Definition	A systematic sequence of actions used to produce something or achieve an end.
Example	An assembly-line process.

A System is made up of Processes

*Notes & Commentary*

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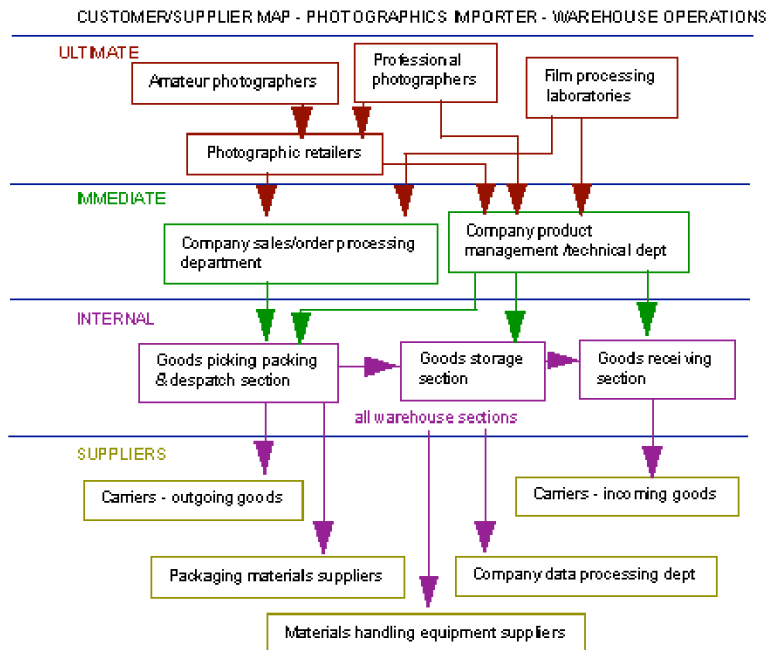
# What is a System?

- Collection of interacting parts functioning as a whole.
- Collection of subsystems that support the larger system.
- Collection of processes oriented toward a common goal.
- The organization as a system.

*Notes & Commentary*

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# Trade Relationships



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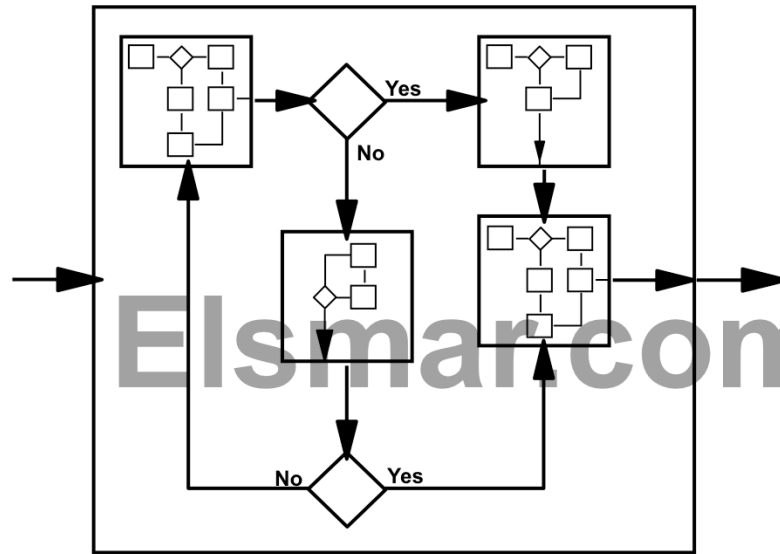
## Notes & Commentary

On the highest level, you can look at your company in terms of how it fits into a trade scheme. Your company is a part of a complex relationship with many other companies and individuals. This is a simple diagram. It does not address issues such as feedback loops. Here we're interested in getting the high level flow. As you will see, we can take any high level system and break it down into its constituent parts.

With the rise in specialization throughout the centuries, the role any given company has, as with workers, increasingly specialized. If you map out your company and its interactions the implementation process will be very much easier.

If used correctly, these high level maps, like your process maps, can also be used as the backbones for problem solving. Use your maps to lay out the backbone for a cause-and-effects diagram any time trouble arises. While the discussion of cause-and-effects diagrams is beyond the scope of this guide, suffice it to say I personally see cause-and-effects diagrams to be a very important part of problem solving.

## The Organization as a System, Subsystems, and Processes



Every company is made up of systems / processes. These interact. And they extend beyond the company 'walls'.

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## Notes & Commentary

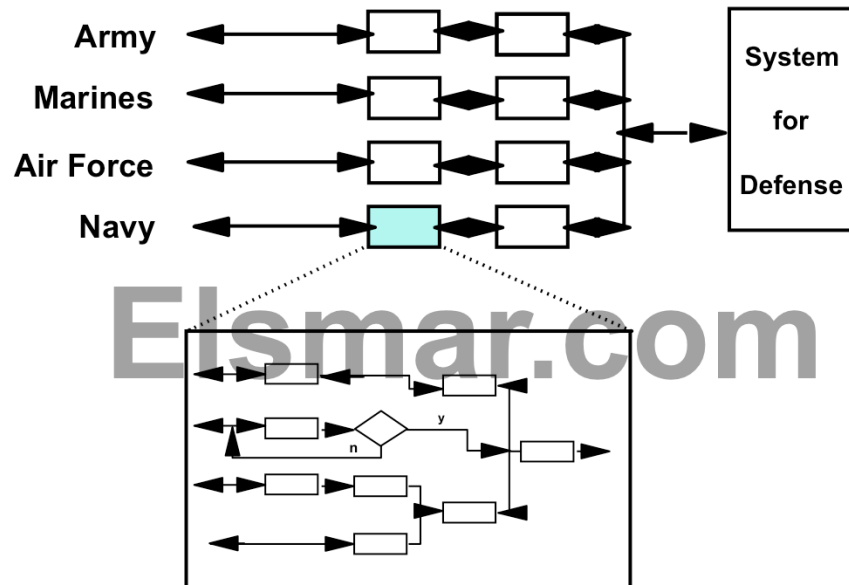
Every high level system can be broken down into sub-systems. Soon we will talk about distinguishing between what is a system and what is a process. I want to warn you now that the distinction is as much a part of what resolution you are looking at as anything else. This is to say that if you are looking at a system and its sub-systems, often times those sub-systems are referred to as processes. If you go to the next detail level, what was referred to as a process now looks is the 'system' and ITS sub-systems are now the 'processes'.

My point here is to say do not get wrapped up in trying to label what is a system and what is a process. To some degree, they are the same thing.

We should also note that many peoples idea of a process is where something is being physically changed. For example, if I plate a part I am processing it. If I take a piece of metal plate and form it in a press I am processing it. This is a narrow interpretation of the word process. In English it is a verb: To process something.



# Systems and Subsystems



There are high level systems and low level systems. High level systems are composed various sub-systems.

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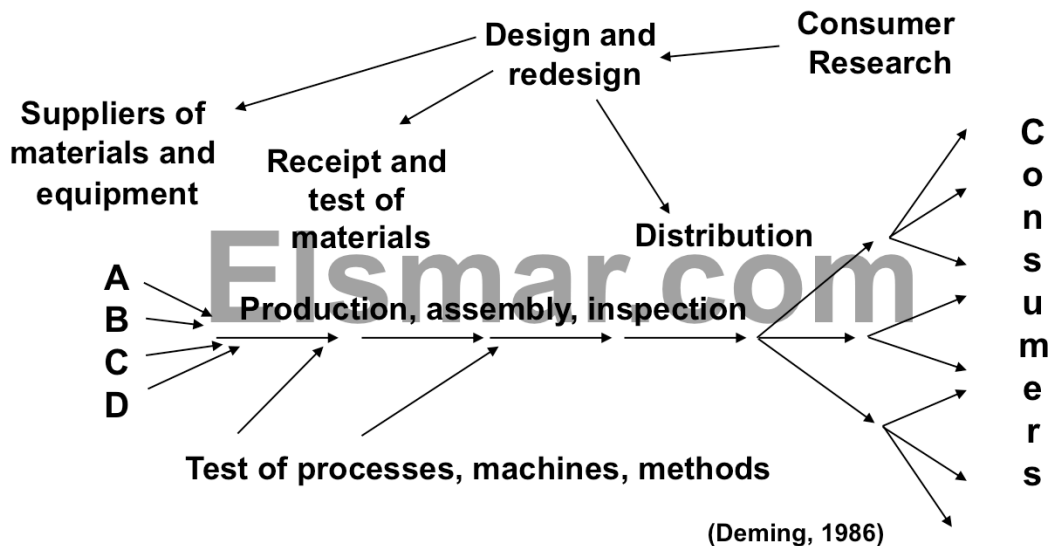
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## Notes & Commentary

This is a brief example of 'exploding' a sub-system for a more detailed look at the various interactions.

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# Organization As An Extended System



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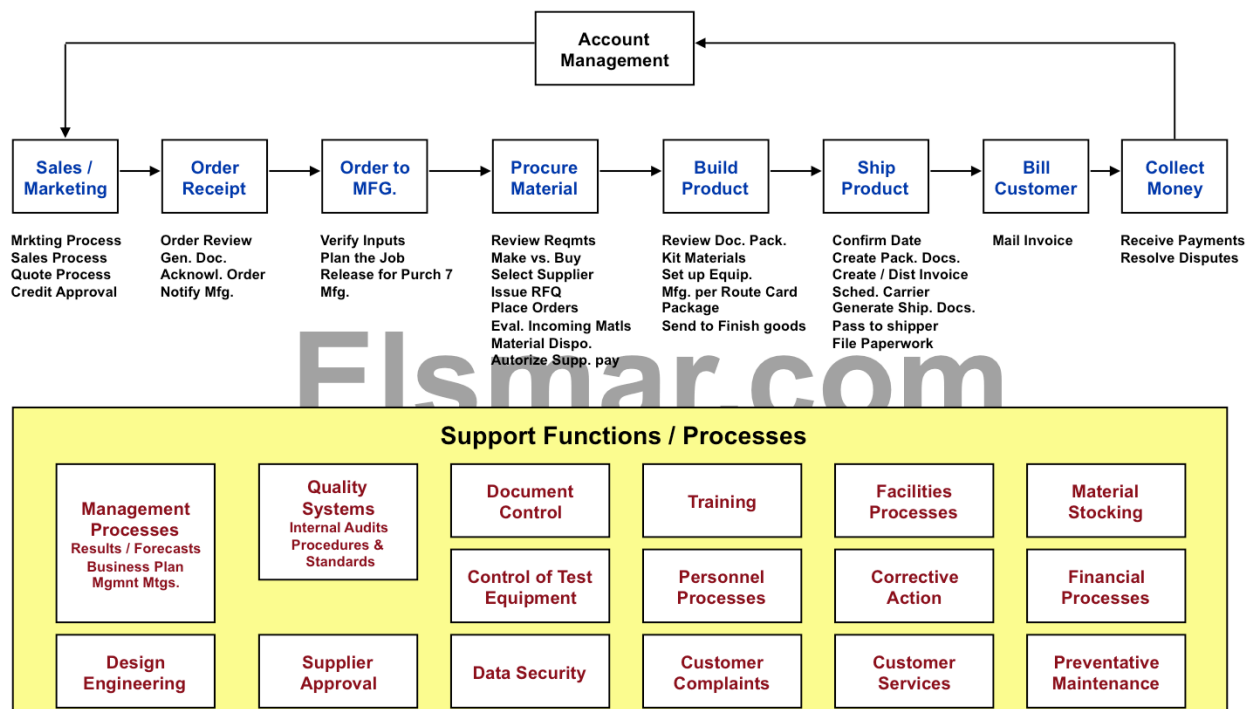
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# Organization As An Extended System



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## Notes & Commentary

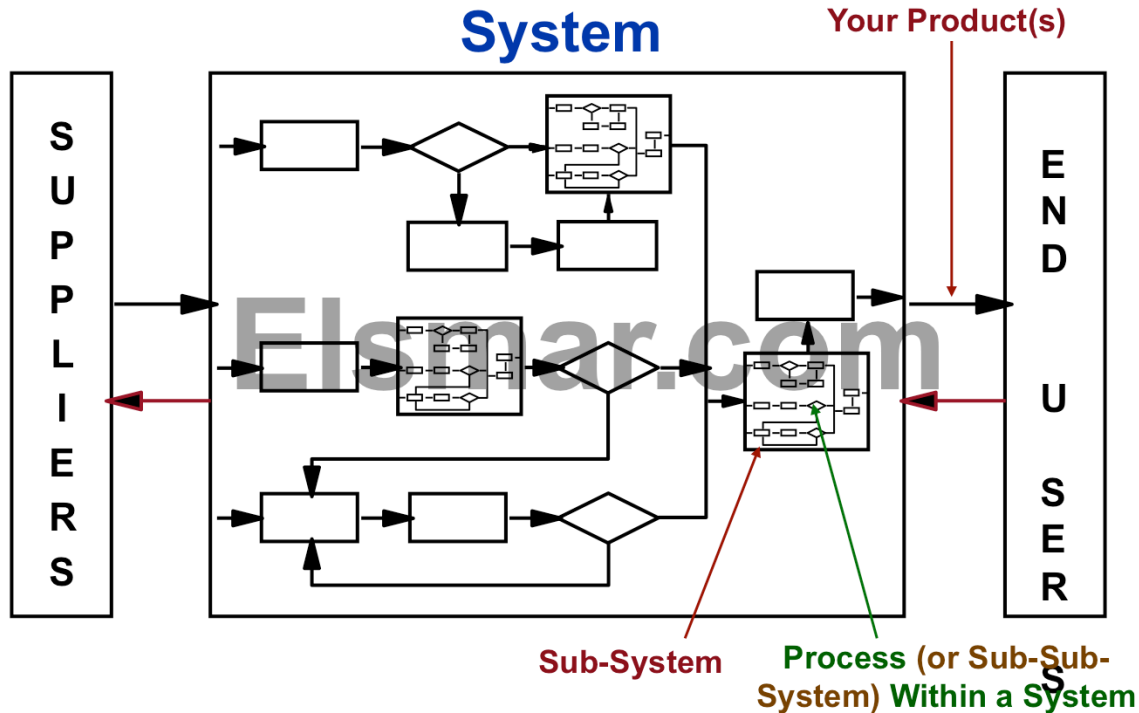
This is a representation of a 'typical' company. Notice the flow, but also note what are defined as **support functions**. Most companies align to this basic representation to a large degree. Even service companies when you come to think about it. The most common problem in service implementations is to associate these functions with a company's actual functional departments. One service client had a position titled Process Improvement Manager. That position was responsible for 'quality' related functions in the organization. Initially, one might have heard the title and equated it with a 'production manager' or similar.

My point here is to make sure you look closely and ensure your functional areas are well defined and the related responsibilities are clear. At that point you can start to align your functional representatives (management) with requirements.

ISO 9001 does not proscribe any particular functional division. It only requires that you define what each functional division is responsible for. You may not find a direct equivalence in your company with each function in the above. For example, if you are a service company you may (or may not) have equipment to calibrate. If you do repair work, you may not immediately notice it, but material stocking will probably be applicable.

Again, common sense has to come into play as you consider function responsibilities.

# Extending Outside the Organization



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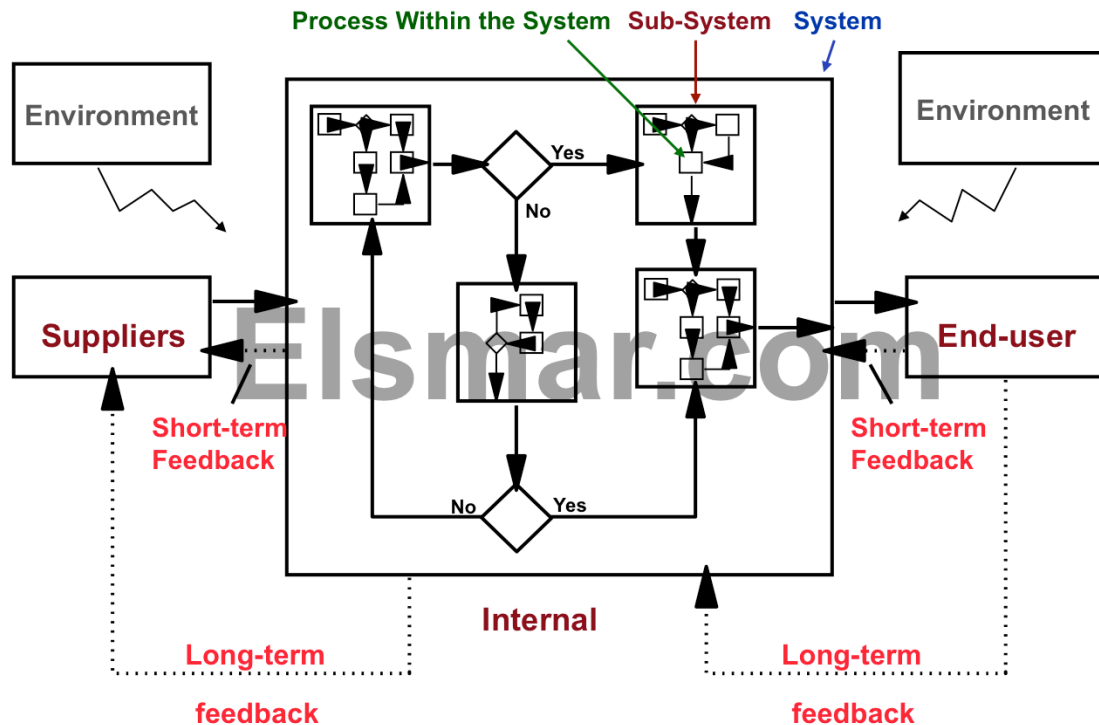
## Notes & Commentary

This is another way of looking at the extended system with a focus on the details of your company and its internal systems and processes. You will soon see that this is approaching the ISO 9001 'model'.

As is evident on the right side of the system, your end users are the product recipients. When defining what your products are, you should be looking here.

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# An Extended System



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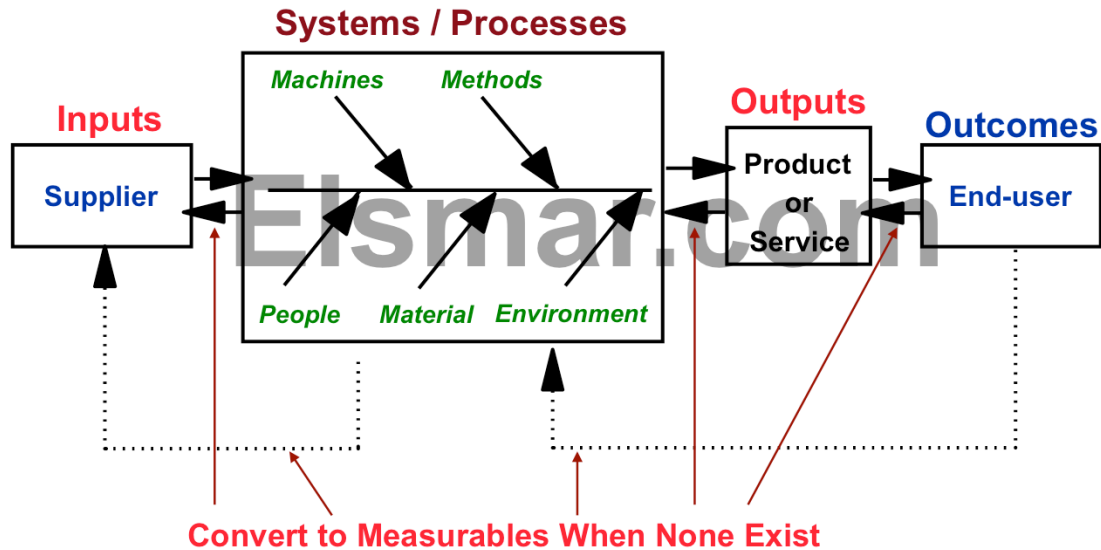
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## Notes & Commentary

Here we add several 'influences' on the company systems, including feedback loops. The feedback loops become important in ISO 9001. To most companies this is already a given. Feedback is historically important to most companies. While we can always cite examples of companies we believe do not care about any feedback (telecos, public utilities and government agencies are always being accused of not caring about customers), the truth is most companies are looking for and evaluating feedback. Sales is looking for information about their customers and what people want. Internally, manufacturing is always feeding back information to the design folks.

The biggest problem in the feedback loop is effectiveness of communications. As an internal example, I have seen very high walls between departments. Design and manufacturing and quality all often have very high walls. Manufacturing feeds back to design problems they have or are encountering where they think a design change should be evaluated and design says "Tough. We have our own problems." Sometimes this is the result of a lack of resources but typically it's a combination of that and a failure to work as a team. I believe this is one reason Japanese manufacturing works so well. My experiences with Mexican companies has also been that there is more of a team work atmosphere.

# Measures In The Extended System



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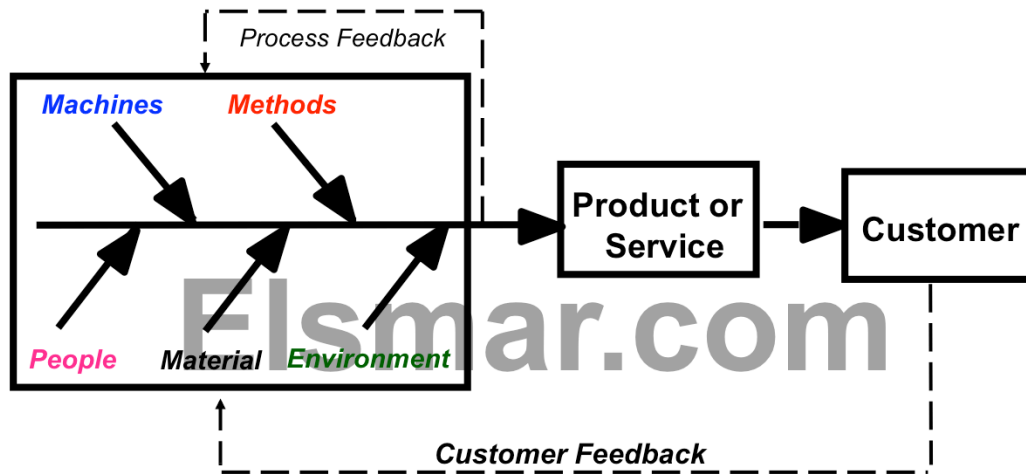
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## Notes & Commentary

No matter what extended systems exist in your company, it is important that it is understood that feedback has to be evaluated. To do that, in 99% of the cases, some type of measurables have to be evolved. For example, in your quality policy you are required to state quality objectives. In addition, they qualify their requirement by requiring that objectives must be measurable. The logic is simple. If they are not measurable you cannot know if you are meeting your goals.

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# Quality Through Process Improvement



Feedback is a cornerstone, so to speak, of ISO 9001. The implication throughout the standard is that you will manage with data.

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## Notes & Commentary

Only through the **evaluation of feedback** can one learn and thus improve. Rarely does improvement come through chance. Evaluation requires **measurables**. No measurables, no evaluation. So - we need to think **DATA**!

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# What is a Process?

- A series of operations or steps that results in a product or service.
- A set of causes and conditions that work together to transform inputs into an output.

*Notes & Commentary*

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# Examples of Processes

- ◆ Loading ordnance
  - ◆ Dropping anchor
  - ◆ Arranging travel
  - ◆ Preparing a report
  - ◆ Processing payments
  - ◆ Admitting patients
  - ◆ Starting propulsion equipment
  - ◆ Purchasing supplies
  - ◆ Plating metal
  - ◆ Training people
  - ◆ Preparing a budget
  - ◆ Transporting hazardous materials
- 

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## *Notes & Commentary*

There are two ways in English to use the word. You can process something, such as physically processing a material, and there are methods of doing something. We discussed this in an earlier slide.

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# Significant and Critical Processes

- **Significant** Processes
  - Are processes by which the mission-essential work of the organization is accomplished.
  - Contribute directly to meeting the needs and requirements of customers.
  - Can be traced from output (to external customer) back to input (to the organization).
- **Critical** Processes
  - A stage within a significant process.
  - One that is deemed as most important for control and improvement.

*Notes & Commentary*

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# Special Characteristics

## With Regard to QS-9000

- The AIAG defines a Special Product Characteristic as a product characteristic for which reasonably anticipated variation could significantly affect a product's safety or compliance with governmental standards or regulations, or is likely to significantly affect customer satisfaction with a product. Ford Motor Company divides Special Characteristics into two categories: Critical Characteristics and Significant Characteristics
- Critical Characteristics are defined by Ford as product or process requirements that affect compliance with government regulation or safe product function, **and** which require special actions or controls. In a design FMEA, they are considered *Potential* Critical Characteristics. A Potential Critical Characteristic exists for any Severity rating greater than or equal to 9. In the process FMEA, they are referred to as *Actual* Critical Characteristics. Any characteristic with a Severity of 9 or 10 which requires a special control to ensure detection is a Critical Characteristic. Examples of product or process requirements that could be Critical Characteristics include dimensions, specifications, tests, assembly sequences, tooling, joints, torques, welds, attachments, and component usages. Special actions or controls necessary to meet these requirements **may involve manufacturing, assembly, a supplier, shipping, monitoring, or inspection.**

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## Notes & Commentary

Significant Characteristics require special controls because they are important to customer satisfaction. Severity ratings between 5 and 8 coupled with an Occurrence rating greater than 3 indicate Significant Characteristics. In a design FMEA, they are *Potential* Significant Characteristics. In the process FMEA, if a special control is required to ensure detection then an *Actual* Significant Characteristic exists.

Companies have not standardized a method for grouping and denoting Special Product Characteristics. Nomenclature and notation will vary.

# Characteristics I

- **CHARACTERISTIC**: A distinguishing feature, dimension or property of a process or its output (product) on which variable or attribute data can be collected. (P39 APQP)
- **CHARACTERISTIC, CRITICAL, CHRYSLER DEFINITION**: Characteristics applicable to a component, material, assembly, or vehicle assembly operation which are designated by Chrysler Corporation Engineering as being critical to part function and having particular quality, reliability and/or durability significance. These include characteristics identified by the shield, pentagon, and diamond. (49 PPAP)
- **CHARACTERISTIC, CRITICAL (INVERTED DELTA), FORD DEFINITION**: Those product requirements (dimensions, performance tests) or process parameters that can affect compliance with government regulations or safe vehicle/product function, and which require specific supplier, assembly, shipping, or monitoring and included on Control Plans. (P49 PPAP)
- **CHARACTERISTIC, CRITICAL, GM DEFINITION**: See Key Product Characteristic. (P49 PPAP)
- **CHARACTERISTIC, KEY CONTROL (KCCs)**: Those process parameters for which variation must be controlled around a target value to ensure that a significant characteristic is maintained at its target value. KCCs require ongoing monitoring per an approved Control Plan and should be considered as candidates for process improvement. (P49 PPAP)
- **CHARACTERISTIC, KEY PRODUCT (KPC)**: Those product features that affect subsequent operations, product function, or customer satisfaction. KPCs are established by the customer engineer, quality representative, and supplier personnel from a review of the Design and Process FMEA's and must be included in the Control Plan. Any KPCs included in customer-released engineering requirements are provided as a starting point and do not affect the supplier's responsibility to review all aspects of the design, manufacturing process, and customer application and to determine additional KPCs. (P49 PPAP)

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## Characteristics II

- CHARACTERISTIC, PROCESS: Core team identified process variables (input variables) that have a cause and effect relationship with the identified Product Characteristic(s) which can only be measured at the time of occurrence. (6.3 #20 APQP)
- CHARACTERISTIC, PRODUCT: Features or properties of a part, component or assembly that are described on drawings or other primary engineering information. (6.3 #19 APQP)
- CHARACTERISTIC, PRODUCT, **CRITICAL** (D), CHRYSLER DEFINITION: A defect which is critical to part function and having particular quality, reliability, and durability significance. (QS-9000)
- CHARACTERISTIC, PRODUCT, **MAJOR**, CHRYSLER DEFINITION: A defect not critical to function, but which could materially reduce the expected performance of a product, unfavorably affect customer satisfaction, or reduce production efficiency. (QS-9000)
- CHARACTERISTIC, PRODUCT, **MINOR**, CHRYSLER DEFINITION: A defect, not classified as critical or major, which reflects a deterioration from established standards. (QS-9000)
- CHARACTERISTIC, PRODUCT, **SAFETY/EMISSION/NOISE** (S), CHRYSLER DEFINITION: A defect which will affect compliance with Chrysler Corporation and Government Vehicle Safety/Emission/Noise requirements. (QS-9000)
- CHARACTERISTIC, **SAFETY**, CHRYSLER DEFINITION "Shield <S>": Specifications of a component, material, assembly or vehicle assembly operation which require special manufacturing control to assure compliance with Chrysler Corporation and government vehicle safety requirements. (QS-9000)

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## Characteristics III

- CHARACTERISTIC, **SAFETY**, CHRYSLER DEFINITION: Specifications which require special manufacturing control to assure compliance with Chrysler or government vehicle safety requirements. (P50 PPAP)
- CHARACTERISTIC, **SIGNIFICANT**, CHRYSLER DEFINITION: Special characteristics selected by the supplier through knowledge of the product and process. (QS-9000)
- CHARACTERISTIC, **SPECIAL**: Product and process characteristics designated by the customer, including governmental regulatory and safety, and/or selected by the supplier through knowledge of the product and process. (P104 APQP)
- CHARACTERISTIC, **SPECIAL, CHRYSLER** DEFINITION "Diamond" <D>: Specifications of a component, material, assembly or vehicle assembly operation which are designated by Chrysler as being critical to function and having particular quality, reliability and durability significance. (QS-9000)
- CHARACTERISTIC, **SPECIAL, CHRYSLER** DEFINITION "Diamond" <D>: Specific critical characteristics that are process driven (controlled) and therefore require SPC to measure process stability, capability, and control for the life of the part. (Appendix C QS-9000) & (Appendix C APQP)
- CHARACTERISTIC, **SPECIAL, CHRYSLER** DEFINITION "Pentagon" <P>: Limited to highlighting Critical characteristics on (Production) part drawings, tools and fixture, and tooling aid procedures where ongoing process control is not automatically mandated. (Appendix C QS-9000) & (Appendix C APQP)
- CHARACTERISTIC, **SPECIAL, CHRYSLER** DEFINITION "Shield" <S>: Engineering designated specifications or product requirements applicable to component material, assembly operation(s) which require special manufacturing control to assure compliance with governmental vehicle safety, emissions, noise, or theft prevention requirements. (Appendix C QS-9000) & (Appendix C APQP)

*Notes & Commentary*

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## Characteristics IV

- CHARACTERISTIC, **SPECIAL**, **FORD** DEFINITION "Critical Characteristic" <Inverted Delta>: Those product requirements (Dimensions, Specifications, Tests) or process parameters which can affect compliance with government regulations or safe Vehicle/Product Function and which require specific producer, assembly, shipping or monitoring actions and inclusion on the Control Plan. (Appendix C QS-9000) & (Appendix C APQP)
- CHARACTERISTIC, **SPECIAL**, **FORD** DEFINITION "Significant Characteristic - SC" <None>: Those product, process, and test requirements that are important to customer satisfaction and for which quality planning actions shall be included in the Control Plan. (Appendix C QS-9000)
- CHARACTERISTIC, **SPECIAL**, **FORD** DEFINITION "Significant/Characteristic - S/C" <None>: Characteristics that are important to the customer and that must be included on the Control Plan. (Appendix C APQP)
- CHARACTERISTIC, **SPECIAL**, **GM** DEFINITION "Fit/Function" <F/F>: Product characteristic for which reasonably anticipated variation is likely to significantly affect customer satisfaction with a product (other than S/C) such as its fits, function, mounting or appearance, or the ability to process or build the product. (Appendix C QS-9000) & (Appendix C APQP)
- CHARACTERISTIC, **SPECIAL**, **GM** DEFINITION "Safety/Compliance" <S/C>: Product characteristic for which reasonably anticipated variation could significantly affect customer the product's safety or its compliance with government regulations (such as: flammability, occupant protection, steering control, braking, etc. . .), emissions, noise, radio frequency interference, etc. . . (Appendix C QS-9000)
- CHARACTERISTIC, **SPECIAL**, **GM** DEFINITION "Safety/Compliance" <S>: Product characteristic for which reasonably anticipated variation could significantly affect customer the product's safety or its compliance with government regulations (such as: flammability, occupant protection, steering control, braking, etc. . .), emissions, noise, radio frequency interference, etc. . . (Appendix C APQP)

## Notes & Commentary

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# Characteristics V

- CHARACTERISTIC, **SPECIAL**, GM DEFINITION "Standard" <None>: Product characteristic for which reasonably anticipated variation is unlikely to significantly affect a product's safety, compliance with governmental regulations, fit/function. (Appendix C QS-9000) & (Appendix C APQP)
- CHARACTERISTIC, **SPECIAL**, PROCESS (e.g., **CRITICAL, KEY, MAJOR, SIGNIFICANT**): A process characteristic for which variation must be controlled to some target value to ensure that variation in a special product characteristic is maintained to its target value during manufacturing and assembly. (P57 FMEA)
- CHARACTERISTIC, **SPECIAL**, PRODUCT: Core team compilation of important product characteristics from all sources. All Special Characteristics must be listed on the Control Plan. (6.3 #19 APQP)
- CHARACTERISTIC, **SPECIAL**, PRODUCT (e.g., **CRITICAL, KEY, MAJOR, SIGNIFICANT**): A product characteristic for which reasonably anticipated variation could significantly affect a product's safety or compliance with governmental standards or regulations; or is likely to significantly affect customer satisfaction with a product. (P55 FMEA)
- CHARACTERISTIC, **SPECIAL**, TOOLING, CHRYSLER DEFINITION "Pentagon" <P>: Critical tooling symbol used to identify special characteristics of fixtures, gages, developmental parts, and initial product parts. (QS-9000)
- CONTROL ITEM PART, FORD DEFINITION: Product drawings/specifications containing Critical Characteristics. Ford Design and Quality Engineering approval is required for changes to Control Item FMEA's and Control Plans. (QS-9000)

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# Critical Characteristics Matrix

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## *Notes & Commentary*

This is not ISO related directly, but I include it to show some of the complexity when you look at what and how different companies define different characteristics.

QS-9000 Appendix C (page 87) Standard and Special Characteristics Symbols Matrix  
APQP Manual

- Section 1.11 (page 10) Preliminary Listing of Special Product and Process Characteristics
- Appendix B (starting on page 81) - Analytical Techniques --> Characteristics Matrix

PPAP Manual

- Appendix F.6 (starting on page 71) - Bulk Materials Example
- Section II.4.6 (Truck) on page 49

# What Is A Quality Management System?

- *In the Words of the ISO Folks:*
  - “Both ISO 9000 and ISO 14000 are known as *generic management system standards*.”
  - “Generic means that the same standards can be applied to any organization, large or small, whatever its product – including whether its ‘product’ is actually a service – in any sector of activity, and whether it is a business enterprise, a public administration, or a government department.”
- What this amounts to is the ISO 9001 requirements are what the ISO folks have determined to be ‘*Best Practices*’ in a business. The ISO folks comment that these are “...now available to small companies...”. I contend they always have been and, in fact, most of my smaller clients had well established systems which functioned quite well to begin with. It’s hard to say that their ISO registration process was particularly value added. As with the vast majority of companies, they were required by one or more customer(s) to register. Or the sales folks saw registration as a potential for increased sales (*everyone’s doing it*).

## Notes & Commentary

Also from the ISO web site:

“Management system refers to what an organization does to manage its processes / activities. In a very small organization, there is probably no “system”, as such, just “our way of doing things”, and “our way” is probably not written down, but all in the manager’s or owner’s head. The larger the organization, and the more people involved, the more the likelihood that there are some written procedures, instructions, forms or records. These help ensure that everyone is not just “doing his or her thing”, and that there is a minimum of order in the way the organization goes about its business, so that time, money and other resources are utilized efficiently.”

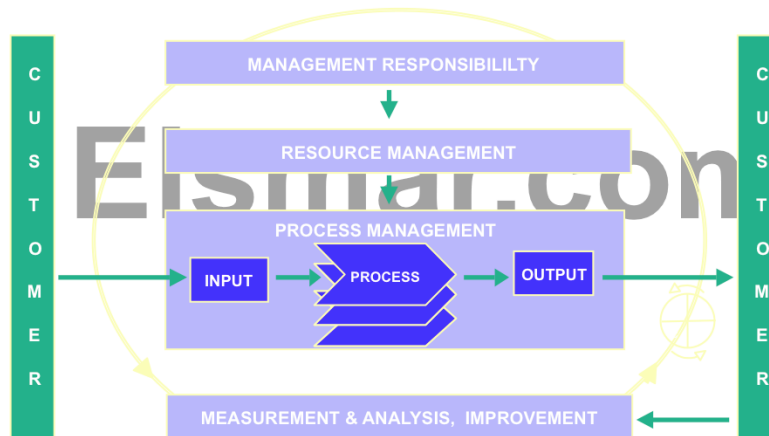
“To be really efficient and effective, the organization can manage its way of doing things by systemizing it. This ensures that nothing important is left out and that everyone is clear about who is responsible for doing what, when, how, when, why and where.”

“Management system standards provide the organization with a model to follow in setting up and operating the management system. This model incorporates the features which experts in the field have agreed upon as representing the state of the art. A management system which follows the model – or “conforms to the standard” – is built on a firm foundation of state-of-the-art practices.”

# What is a QMS?

Are we talking about ISO 9001 or QS-9000 or what, here?

To start out, let's discuss what you are planning to do. Throughout this document you will see ISO 9001 and QS-9000 cited. We are, at the bottom level, talking a **System**. With respect to ISO 9001 (and QS-9000 and TS 16949 for that matter) it is called a Quality Management System. With the ISO 9001 release, page vi defines it in a diagram. Below is the version from the DIS. ISO 14001 requires an **Environmental** Management System.



The DIS Model

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## Notes & Commentary

The process is one of implementing what they are calling a Quality Management System. Whether it's ISO9K or ISO14K or QS - it's the same thing. You have to have a defined system to address a number of issues. With ISO 9K the focus is on customer satisfaction and continuous improvement.

### Thoughts On Continuous Improvement

As a small business owner this may seem a bit much for a 10 person company. Some comments company owners have had: "Continuous improvement? We make a type of soap. We've been making it for 30 years. Same formula. Same soap. And that's what we want!" and I heard "Look what happened when management tried to improve Coke! We got Coke Classic."

There are other aspects a company **has** to consider. Delivery might be one. Process yield may be another. Auditors will want evidence that you are using numbers (read statistics) to evaluate something for improvement.

Take a step back and ask yourself: **What DO you improve upon?** What do other companies in your industry do?

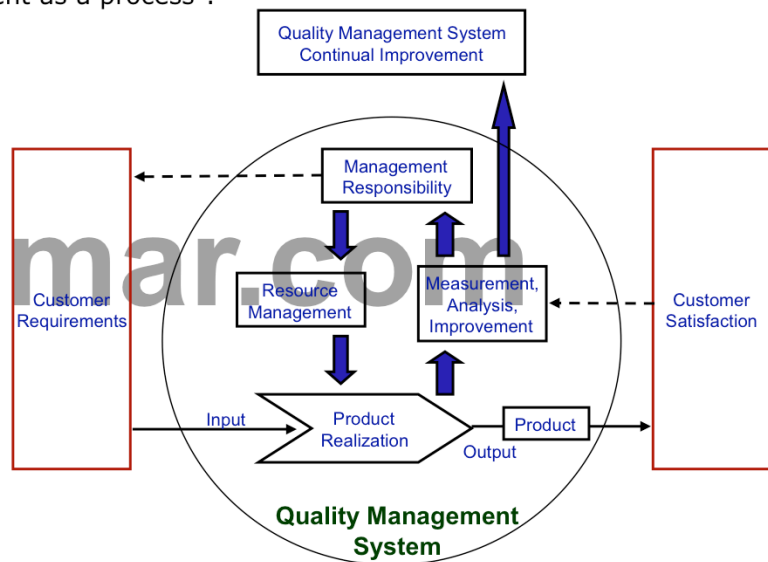
**Think of Continuous Improvement in a broad sense.**

# ISO 9001 QMS 'Process Model'

Someone recently wrote:

- >I see a lot of speculations in many articles around
- >"process approach", "system approach to management",
- >"process management", "management as a process".

I took a course in the mid-1980's called "Business as a Process". None of this is new. It is more 'Good Business Practices' which is all ISO 9001 is. When you reach the point where you can understand everything you do in terms of inter-relating processes, you can then go on to evaluate each in terms of cycle time, effectiveness of interaction, etc. The course goal was, by the way, how to ensure continuous improvement -- a relatively 'new' concept to the ISO standards folks -- and stressed the use of experiments to generate knowledge as well as process feedback for learning.



Representation 1

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## Notes & Commentary

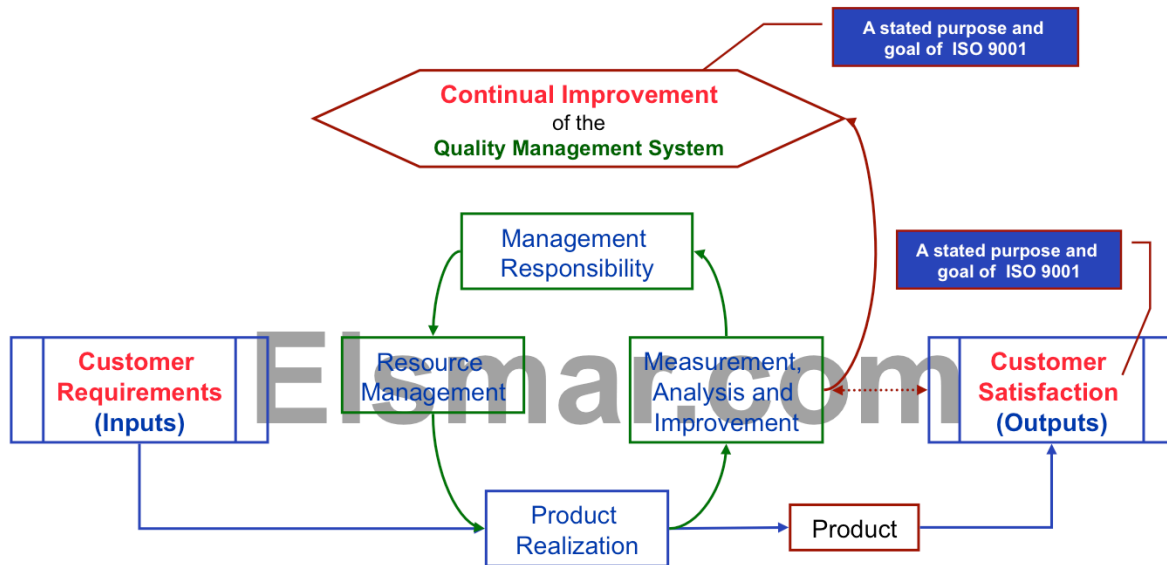
The intent of these is to bring across the requirement that you evaluate your business as a process with specific inputs and outputs expected. You should be ready to explain each of the interfaces.

This is not that complicated. I stand by my assertion that if you do what I have recommended to clients since 1994 - flow chart your systems - you will see every system is a process or processes each of which has inputs and outputs -- and inter-relationships are well defined - that's all this is about. Your internal audit system is a process or a set of processes. Purchasing is a process or a series of processes. You have a nonconformance system which is made up of processes. Taken to the extreme, almost everything can be looked at as a process.

If you take a step back and review ISO 9001 against the reality of good business practices you will find ISO 9001 is at least 10 to 15 years behind the times. If you are just now looking at your business as a series of processes with inputs and outputs, and you implement and take ISO 9001 to heart, your company will improve significantly.

I suggest you take a read through <http://Elsmar.com/ubb/Forum15/HTML/000195.html> for some other thoughts on Business as a Process.

# ISO 9001 QMS 'Process Model'



Representation 2

One of the interesting parts of this system is *Continuous Improvement* of the *Quality Management System* is specified as the result. *Not improvement of the product*. One can argue if you improve your quality system the product should improve as well. However, this is just not always the case.

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## Notes & Commentary

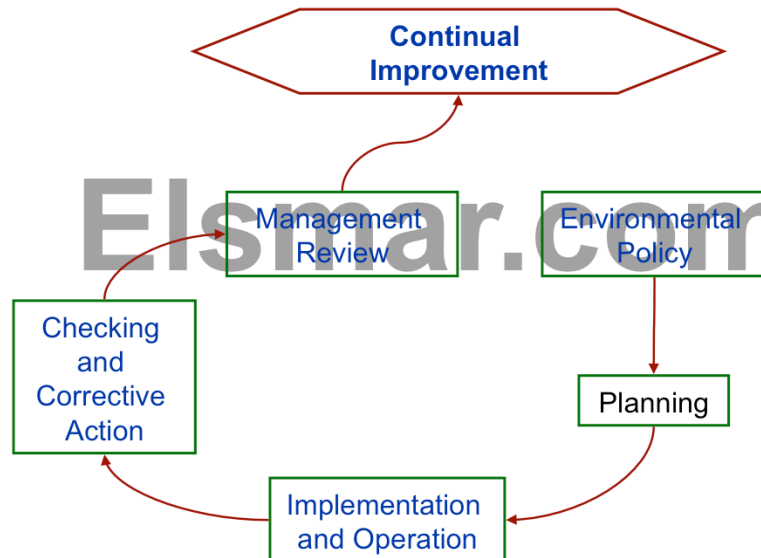
### Thoughts On Customer Satisfaction

This can be a real hot potato. If you take a close look at your company you should be able to list things you do to determine whether your customers are satisfied. One small company I worked with ensured that once a month every customer was visited by a company employee. Just to say hello, ask how things are going and (the owner said it was a big part of his decision) to see if the folks are using the product correctly. This was most interesting in that the owner stated he had not had a customer complaint in over 10 years. Sound far fetched?

The owner did not consider complaints on visits to be complaints. Every 'complaint' was addressed by the company representative on the spot. He called them 'minor problems' and since they sometimes led to a formula reformulation he didn't consider them to be complaints. His example was a company which claimed the product was not foaming (a cleaning product) 'enough' and was thus not cleaning thoroughly. My client added more of the foaming agent to the compound (reformulation). He pointed out to me that the foaming agent is a visual aspect of the product totally unrelated to its function. This was a customer perception issue.

# ISO 14001:1996 EMS 'Process Model'

The below is from page vi of ISO 14001:1996.  
Notice it is not drawn as a closed loop system as is the ISO 9001 system.



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## Notes & Commentary

The ISO folks are surely selling the world on ISO 9001 and they're pushing the ISO 14001 standard as is evident by the matrices included in the specification as Annex A. So far, acceptance of ISO 14001 has been extremely limited.

I am going to addressing ISO 14001 to some degree as we go along. If you haven't yet been affected by a requirement for ISO 14001, you should at least be aware of it. Ford, GM and Chrysler now require it of their suppliers. ISO 14001 has not really 'taken off' in the US in large part because current federal, state and local laws pretty much keep polluters in check and require some type of planning for hazardous materials including by-products of manufacturing processes.

In regard to ISO 14001, the issue is not far removed from implementing ISO 9001. The only difference is 14001 is technically called an Environmental Management System. From the cross reference in ISO 9001 Annex A (outlines the correspondence between the two documents), it is obvious 14001 is closely related to ISO 9001 in a number of places. It is expected that within a year or two 14001 will be 'aligned' with ISO 9001. Co-implementation is a minor issue.



# The ISO Standards

## **ISO 9000:2000 Quality management systems – Fundamentals and vocabulary**

Establishes a starting point for understanding the standards and defines the fundamental terms and definitions used in the ISO 9000 family which you need to avoid misunderstandings in their use.

## **ISO 9001 Quality management systems – Requirements**

This is the requirement standard you use to assess your ability to meet customer and applicable regulatory requirements and thereby address customer satisfaction.

## **ISO 9004:2000 Quality management systems – Guidelines for performance improvements**

This guideline standard provides guidance for continual improvement of your quality management system to benefit all parties through sustained customer satisfaction.

## **ISO 19011 Guidelines on Quality and/or Environmental Management Systems Auditing (currently under development)**

Provides you with guidelines for verifying the system's ability to achieve defined quality objectives. You can use this standard internally or for auditing your suppliers.

## **ISO 10005:1995 Quality management – Guidelines for quality plans**

Provides guidelines to assist in the preparation, review, acceptance and revision of quality plans.

## **ISO 10006:1997 Quality management – Guidelines to quality in project management**

Guidelines to help you ensure the quality of both the project processes and the project products.

## **ISO 10007:1995 Quality management – Guidelines for configuration management**

Guidelines to ensure that a complex product continues to function when components are changed individually.

## *Notes & Commentary*

### **ISO/DIS 10012, Quality assurance requirements for measuring equipment – Part 1: Metrological confirmation system for measuring equipment**

Give you guidelines on the main features of a calibration system to ensure that measurements are made with the intended accuracy.

### **ISO 10012-2:1997, Quality assurance for measuring equipment – Part 2: Guidelines for control of measurement of processes**

Provides supplementary guidance on the application of statistical process control when this is appropriate for achieving the objectives of Part 1.

### **ISO 10013:1995, Guidelines for developing quality manuals**

Provides guidelines for the development, and maintenance of quality manuals, tailored to your specific needs.

### **ISO/TR 10014:1998, Guidelines for managing the economics of quality**

Provides guidance on how to achieve economic benefits from the application of quality management.

### **ISO 10015:1999, Quality management – Guidelines for training**

Provides guidance on the development, implementation, maintenance and improvement of strategies and systems for training that affects the quality of products.

### **ISO/TS 16949:1999, Quality systems – Automotive suppliers – Particular requirements for the application of ISO 9001:1994**

Sector specific guidance to the application of ISO 9001 in the automotive industry.

# Required Level II Flow Charts (Procedures)

## Procedures 'Required' By the 2000 Revision

- 4.2.3 Control of Documents
- 4.2.4 Control of Quality Records
- 8.2.2 Internal Audit
- 8.3 Control of Nonconformity
- 8.5.2 Corrective Action
- 8.5.3 Preventive Action

## Partial Listing of Procedures 'Required' By the 1994 Revision

- 4.3 Contract Review
- 4.4 Design Control
- 4.5 Document and Data Control
- 4.6 Purchasing
- 4.7 Control of Customer Supplier Product
- 4.8 Product Identification and Traceability
- 4.9 Process Control
- 4.10 Inspection and Testing
- 4.11 Control of IM&TE
- 4.12 Inspection and Test Status

### Note:

A requirement for a 'documented procedure' is not a requirement for a text based document. A flow chart is readily acceptable. I've been using them in implementations for years. I personally disdain text based procedures.

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## Notes & Commentary

If you read through ISO 9001, you will find 6 places where Documented Procedures are specifically stated to be a requirement. Some folks have been saying how nice it is that the documentation requirements have been reduced. While this is technically the case, it is really a non-issue. For the most part companies are not going to be reducing their documentation significantly if at all.

What about new implementations? Will this be a big help to you? No - not really. You will have to have the 'appropriate' documents in place regardless. Take for example 7.4 Purchasing. There is very likely that your company will need a purchasing procedure. Often there are a number of purchasing 'procedures' (systems) which will require some type of documentation. The absence of the requirement does not exempt your company from having documentation 'where appropriate'. Where appropriate will be determined by a common sense look at the process in context.

One must remember that to comply with the 1994 version, most companies adopted the Level II approach - make 20 top level procedures or flow charts to address each element of the standard.



## Some Other *Expected* Process Maps

- Planning (5.4, 7.1, 8.1, 8.5.1)
- Management Review (5.6)
- Resource Management (6)
- Training (6.2.2)
- Customer Processes (7.2)
- Customer Communication (7.2.3)
- Design and Development (7.3)
- Purchasing (7.4)
- Operations Control (7.5.1)
- Product ID / Traceability ( 7.5.2)
- Customer Property (7.5.4)
- Preservation of Product (7.5.5)
- Validation of Processes (7.5.2)
- Process Measurement / Monitoring (8.2.3)
- Product Measurement / Monitoring (8.2.4)
- Analysis / Improvement (8.4, 8.5)

Note: Some of these may not be relevant to your company. An example is Product Identification and Traceability. If you are a *service* company, Product Preservation will *probably* not apply to your situation. Remember, however, that exclusions are limited to requirements within **Element 7 - Product Realization**.

As you can see, most of the documents in the above listing are parallels to the 20 'old' ISO elements. It may be that the new standard does not specifically require a document to cover each of these, however it will most often be the case that your company will have to document these systems at least minimally.

As I have stated before, the level of documentation your company will need cannot be determined by a book or reference. Your company may have relatively simple systems and on-the-job training may be utilized more than at another company. You may be a facility which is part of a corporation where there are flow-downs you will have to comply with (some of which will probably be documentation requirements). Or, your company may only consist of 8 souls who provide a service - your documentation will probably be minimal.

You have to review, within your company, what you are doing now and making some common sense determinations of where documentation is relevant and 'necessary'.

# ISO 9001 Distilled - 4

## 4 Quality management Systems

- Systemic Requirements.

### 4.1 General Requirements

- Establish your quality system.
- Develop your quality management system.
- Identify the processes that make up your quality system.
- Describe your quality management processes.
- Implement your quality management system.
- Use quality system processes.
- Manage process performance.
- Improve your quality management system.
- Monitor process performance.
- Improve process performance.

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## *Notes & Commentary*

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# ISO 9000 Distilled - 4.2

## 4.2 Documentation Requirements

- Document your quality system.

### 4.2.1 General

- Develop quality system documents.
  - Develop documents to implement your quality system.
  - Develop documents that reflect what your organization does.

### 4.2.2 Quality Manual

- Prepare a quality system manual.
  - Define the **scope** of your quality system.
  - Document your procedures.
  - Describe how your processes **interact**.

## *Notes & Commentary*

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## ISO 9000 Distilled - 4.2.3

### 4.2.3 Control of Documents

- **Approve** documents before you distribute them.
- Provide the **correct version** of documents at points of use.
- Review and re-approve documents whenever you update them.
- Specify the current revision status of your documents.
- **Monitor** documents that come from **external sources**.
- **Prevent** the **accidental use** of obsolete documents.
- Preserve the usability of your quality documents.

### 4.2.4 Control of Records

- Use your records to prove that requirements have been met.
- Develop a procedure to control your records.
- Ensure that your records are useable.

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# ISO 9000 Distilled - 5

## 5 Management Responsibility

### 5.1 Management Commitment

- Support quality and promote the importance of quality.
- Promote the need to meet customer, regulatory, statutory requirements.
- Develop and support a quality management system.
  - Formulate your organization's quality policy.
  - Set your organization's quality objectives.
  - Provide quality resources.
- Implement your quality management system
  - Provide resources to implement your quality system.
  - Encourage personnel to meet quality system requirements.
- Improve your quality management system
  - Perform quality management reviews.
  - Provide resources to improve the quality system.

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## ISO 9000 Distilled - 5.2

### 5.2 Customer Focus

- Satisfy your customers.
- Identify customer requirements.  
Expect your organization to identify customer requirements.
- Meet your customers' requirements.  
Expect your organization to meet customer requirements.
- Enhance customer satisfaction.  
Expect your organization to enhance customer satisfaction.

## *Notes & Commentary*

This is meant to give you a basic idea of the intention / requirements. A detailed discussion is presented in Clause\_Interp\_and\_Upgrading.doc.

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## ISO 9000 Distilled - 5.3

### 5.3 Quality Policy

- Define and establish your organization's **quality policy**.
  - Ensure that it serves your organization's purpose.
  - Ensure that it emphasizes the need to meet requirements.
  - Ensure that it facilitates the development of quality objectives.
  - Ensure that it makes a commitment to **continuous improvement**.
- Manage your organization's quality policy.
  - Communicate your policy to your organization.
  - Review your policy to ensure that it is still suitable.

## *Notes & Commentary*

This is meant to give you a basic idea of the intention / requirements. A detailed discussion is presented in Clause\_Interp\_and\_Upgrading.doc.

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# ISO 9000 Distilled - 5.4

## 5.4 Planning

- Carry out quality planning.

### 5.4.1 Quality Objectives

- Formulate your quality objectives
  - Ensure that objectives are set for **functional areas**.
  - Ensure that objectives are set at **organizational levels**.
  - Ensure that objectives facilitate **product realization**.
  - Ensure that objectives support the quality policy.
  - **Ensure that objectives are measurable.**

### 5.4.2 Quality Management System Planning

- Plan the **development** of your quality management system.
- Plan the **implementation** of your quality management system.
- Plan the **improvement** of your quality management system.
- Plan **modifications** of your quality management system.

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# ISO 9000 Distilled - 5.5

## 5.5 Responsibility, Authority and Communication

- Control your quality system.

### 5.5.1 Responsibility and Authority

- **Clearly define** responsibilities and authorities.
- **Communicate** responsibilities and authorities.

### 5.5.2 Management Representative

- Assign a **Management Representative**.
  - Oversees your quality management system.
  - Reports on the status of your quality management system.
  - Supports the improvement of your quality management system.

## *Notes & Commentary*

This is meant to give you a basic idea of the intention / requirements. A detailed discussion is presented in Clause\_Interp\_and\_Upgrading.doc.

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# ISO 9000 Distilled - 5.5.3

## 5.5.3 Internal Communication

- Support internal communications.
- Ensure
  - Internal communication processes are established.
  - Ensure that communication occurs throughout the organization.

## 5.6 Management Review

- Perform management reviews.

### 5.6.1 General

- Review quality management system.
- Evaluate
  - The performance of your quality system.
  - Evaluate whether your quality system should be improved.

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# ISO 9000 Distilled - 5.6.2

## 5.6.2 Review Input

### Examine

- Management review inputs.
- Audit results.
- Product conformity data.
- Opportunities to improve.
- Feedback from customers.
- Process performance information.
- Corrective and preventive actions.
- Changes that might affect your system.
- Previous quality management reviews.

## 5.6.3 Review Output

### Generate

- Management review outputs.
- Actions to improve your quality system.
- Actions to improve your products.
- Actions to address resource needs.

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## *Notes & Commentary*

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# ISO 9000 Distilled - 6

## 6 Resource Management

### 6.1 Provision of Resources

#### Identify

- Quality resource requirements.
- Resources needed to support the quality system.
- Resources needed to improve customer satisfaction.

#### Provide

- Quality system resources.
- Resources needed to support the quality system.
- Resources needed to improve customer satisfaction.

### 6.2 Human Resources

- Provide quality personnel.

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# ISO 9000 Distilled - 6.2.1

## 6.2.1 General

- Use 'competent' personnel and Ensure:
  - Your personnel have appropriate **experience**.
  - Your personnel have appropriate **education**.
  - Your personnel have appropriate **training**.
  - Your personnel have appropriate **skills**.

## 6.2.2 Competence, Awareness and Training

- **Define** acceptable levels of competence.
- **Identify** training and **awareness needs**.
- Deliver training and awareness programs.
- **Evaluate effectiveness** of training and awareness.
- Maintain a **record** of competence.

## *Notes & Commentary*

This is meant to give you a basic idea of the intention / requirements. A detailed discussion is presented in Clause\_Interp\_and\_Upgrading.doc.

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## ISO 9000 Distilled - 6.3

### 6.3 Infrastructure

- Provide an infrastructure for quality.
- Identify during planning:
  - Infrastructure needs.
  - Building needs.
  - Workspace needs.
  - Hardware needs.
  - Software needs.
  - Utility needs.
  - Equipment needs.
  - Support service needs.

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## ISO 9000 Distilled - 6.3

### 6.3 Infrastructure (continued - I)

- Provide Needed:
  - Infrastructure
  - Buildings
  - Workspaces
  - Hardware
  - Software
  - Utilities
  - Equipment
  - Support services

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## ISO 9000 Distilled - 6.3

### 6.3 Infrastructure (continued - II)

- Maintain your:
  - Infrastructure
  - Buildings
  - Workspaces
  - Hardware
  - Software
  - Utilities
  - Equipment
  - Support services

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# ISO 9000 Distilled - 6.4

## 6.4 Work Environment

- Provide a quality environment.
  - Identify needed work environment factors needed to ensure products meet requirements.
  - Manage needed work environment factors needed to ensure products meet requirements.

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# ISO 9000 Distilled - 7

## 7 Realization Requirements

### 7.1 Determination of Requirements Related to the Product

- **Control** realization planning.
- **Plan** product realization processes.
- **Define** product quality objectives and requirements.
- **Identify** your product realization needs and requirements.
- **Develop** product realization:
  - Processes
  - Documents
  - Record keeping systems
- **Methods** to control quality during product realization.

## *Notes & Commentary*

This is meant to give you a basic idea of the intention / requirements. A detailed discussion is presented in Clause\_Interp\_and\_Upgrading.doc.

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# ISO 9000 Distilled - 7.2

## 7.2 Customer Related Processes

- Control customer processes.

### 7.2.1 Identify customers' product requirements

- Identify Requirements that:
  - Customers want you to meet
  - Are dictated by the product's use
  - Are imposed by external agencies
  - Your organization wishes to meet

### 7.2.2 Review customers' product requirements

- Review requirements before you accept orders from customers.
- Maintain a record of your product requirement reviews.
- Control changes in product requirements.

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# ISO 9000 Distilled - 7.2.3

## 7.2.3 Customer Communication

- Communicate with your customers.
- Develop a process to control communications with customers.
- Implement your customer communications process.

## 7.3 Design and Development

- Control product development

### 7.3.1 Design and Development Planning

- Have a Design System (Planning).
- Define your product design and development stages.
- Clarify design and development responsibilities and authorities.
- Manage interactions between design and development groups.
- Update your design and development plans as changes occur.

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## ISO 9000 Distilled - 7.3.2

### 7.3.2 Design and Development Inputs

- Define design and development inputs.
  - Specify product design and development inputs.
  - Record product design and development input definitions.
  - Review product design and development input definitions.

### 7.3.3 Design and Development Outputs

- Define and create product design and development outputs.
- Approve design and development outputs prior to release.
- Use design and development outputs to control product quality.

## *Notes & Commentary*

This is meant to give you a basic idea of the intention / requirements. A detailed discussion is presented in Clause\_Interp\_and\_Upgrading.doc.

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## ISO 9000 Distilled - 7.3.4

### 7.3.4 Design and Development Review

- Perform and record results of product design and development reviews.

### 7.3.5 Design and Development Verification

- Perform and record results of design and development verifications.

### 7.3.6 Design and Development Validation

- Perform and record results of product design and development validations.

## *Notes & Commentary*

This is meant to give you a basic idea of the intention / requirements. A detailed discussion is presented in Clause\_Interp\_and\_Upgrading.doc.

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## ISO 9000 Distilled - 7.3.7

### 7.3.7 Control of Design and Development Changes

- Identify and record results of changes in product design and development.
- Review and record results of changes in product design and development.
- Verify changes in product design and development.
- Validate changes in product design and development.
- Approve changes before they are implemented.

## *Notes & Commentary*

This is meant to give you a basic idea of the intention / requirements. A detailed discussion is presented in Clause\_Interp\_and\_Upgrading.doc.

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# ISO 9000 Distilled - 7.4

## 7.4 Purchasing

- Control purchasing function with a system.

### 7.4.1 Purchasing Process

- Maintain control purchasing process.
  - Ensure that purchased products meet requirements.
  - Ensure that suppliers meet requirements.

### 7.4.2 Purchasing Information

- Document product purchases.
  - Describe the products being purchased.
  - Specify the requirements that must be met.

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## ISO 9000 Distilled - 7.4.3

### 7.4.3 Verification of Purchased Product

- Verify products you purchase.
  - Verify purchased products at your own premises.
  - Verify purchased products at suppliers' premises (when required).

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# ISO 9000 Distilled - 7.5

## 7.5 Production and Service Provision

- Control your operational activities.

### 7.5.1 Control of Production and Service Provision

- Control production and service:

- Processes
- Information
- Instructions
- Equipment
- Measurements
- Activities

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## *Notes & Commentary*

This is meant to give you a basic idea of the intention / requirements. A detailed discussion is presented in Clause\_Interp\_and\_Upgrading.doc.

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## ISO 9000 Distilled - 7.5.2

### 7.5.2 Validation of Processes for Production and Service Provision

- Validate production and services.
  - Prove that:
    - Special processes can produce planned outputs.
    - Process personnel can produce planned results.
    - Process equipment can produce planned results.

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### 7.5.3 Identification and Traceability

- Identify and track your products (when appropriate).
  - Establish the identity of your products (when appropriate).
  - Maintain the identity of your products (when appropriate).
  - Identify the status of your products (when appropriate).
  - Record the identity of your products (when required).

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## ISO 9000 Distilled - 7.5.4

### 7.5.4 Customer Property

- Protect property supplied by customers.
  - Identify property supplied to you by your customers.
  - Verify property supplied to you by your customers.
  - Safeguard property supplied to you by your customers.

### 7.5.5 Preservation of Product

- Preserve your products and components:
  - During internal processing.
  - During final delivery.

## *Notes & Commentary*

This is meant to give you a basic idea of the intention / requirements. A detailed discussion is presented in Clause\_Interp\_and\_Upgrading.doc.

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# ISO 9000 Distilled - 7.6

## 7.6 Control of Monitoring and Measurement Devices

- Use devices to ensure that your products meet requirements.
- Identify monitoring and measuring needs.
- Identify the monitoring and measuring that should be done.
- Select monitoring and measuring devices that meet your monitoring and measuring needs.
- Calibrate monitoring and measuring devices.
  - Perform calibrations.
  - Record calibrations.
- Protect monitoring and measuring devices.
  - Protect your devices from unauthorized adjustment.
  - Protect your devices from damage or deterioration.
- Validate monitoring and measuring software.
  - Validate monitoring and measuring software before you use it.
  - Revalidate monitoring and measuring software when necessary.

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# ISO 9000 Distilled - 8

## 8 Measurement, Analysis and Improvement

### 8.1 General

- **Plan** your measurement processes.
  - How measurement processes will be used to **assure conformity**.
  - How measurement processes will be used to **improve** the system.
- Implement and perform measurement processes.
  - Use measurement processes to demonstrate conformance.
  - Use measurement processes to improve quality management system.

## *Notes & Commentary*

This is meant to give you a basic idea of the intention / requirements. A detailed discussion is presented in Clause\_Interp\_and\_Upgrading.doc.

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## ISO 9000 Distilled - 8.2

### 8.2 Monitoring and Measurement

- Monitor and measure quality.

#### 8.2.1 Customer Satisfaction

- Monitor and measure customer satisfaction.
  - Identify ways to monitor and measure customer satisfaction.
  - Monitor and measure customer satisfaction.
  - Use customer satisfaction information.

## *Notes & Commentary*

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## ISO 9000 Distilled - 8.2.2

### 8.2.2 Internal Audit

- Plan and perform regular internal audits.
  - Set up an internal audit program.
  - Develop an internal audit procedure.
  - Plan your internal audit projects.
  - Perform regular internal audits.
- Solve problems discovered during audits.
- Verify that problems identified have been solved.

## *Notes & Commentary*

This is meant to give you a basic idea of the intention / requirements. A detailed discussion is presented in Clause\_Interp\_and\_Upgrading.doc.

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## ISO 9000 Distilled - 8.2.3

### 8.2.3 Monitoring and Measurement of Processes

- Monitor and measure quality processes.
  - Use suitable methods to monitor and measure your processes.
  - Take action when your processes fail to achieve planned results.

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### 8.2.4 Monitoring and Measurement of Product

- Monitor and measure product characteristics.
  - Verify that product characteristics are being met.
  - Keep a record of product monitoring and measuring activities.

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## *Notes & Commentary*

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## ISO 9000 Distilled - 8.3

### 8.3 Control of Nonconforming Product

- Develop a procedure to control nonconforming products.
  - Define how nonconforming products should be **identified**.
  - Define how nonconforming products should be **handled**.
- Identify and control your nonconforming products.
  - Eliminate / Correct product nonconformities.
  - Prevent the delivery or use of nonconforming products.
  - Avoid the inappropriate use of nonconforming products.
- Re-verify nonconforming products that were corrected.
  - Prove that corrected products now meet requirements.
- Control nonconforming products after delivery or use.
  - Control events when you deliver or use nonconforming products.
- Maintain records of nonconforming products.
  - Describe your product nonconformities.
  - Describe the actions taken to deal with nonconformities.

## *Notes & Commentary*

This is meant to give you a basic idea of the intention / requirements. A detailed discussion is presented in Clause\_Interp\_and\_Upgrading.doc.

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# ISO 9000 Distilled - 8.4

## 8.4 Analysis of Data

- Analyze quality information. Define:
  - Quality management information **needs**.
  - Information you need to **evaluate** your quality system.
  - Information you need to **improve** your quality system.
- Collect quality management system data.
  - Monitor and measure the **suitability** of your quality system.
  - Monitor and measure the **effectiveness** of your quality system.
- Provide quality management information:
  - About your **customers**.
  - About your **suppliers**.
  - About your **products**.
  - About your **processes**.

## *Notes & Commentary*

This is meant to give you a basic idea of the intention / requirements. A detailed discussion is presented in Clause\_Interp\_and\_Upgrading.doc.

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# ISO 9000 Distilled - 8.5

## 8.5 Improvement

- Make quality improvements

### 8.5.1 Continual Improvement

- Improve quality management system
  - Use your audits to generate improvements.
  - Use your quality data to generate improvements.
  - Use your quality policy to generate improvements.
  - Use your quality objectives to generate improvements.
  - Use your management reviews to generate improvements.
  - Use your corrective actions to generate improvements.
  - Use your preventive actions to generate improvements.

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## ISO 9000 Distilled - 8.5.2

### 8.5.2 Corrective Action

- Correct nonconformities.
  - Review your nonconformities.
  - Figure out what causes your nonconformities.
  - Evaluate whether you need to take corrective action.
  - Develop and take corrective actions to prevent recurrence when they are necessary.
  - Record the results that your corrective actions achieve.
- Examine the **effectiveness** of your **corrective actions**.

## *Notes & Commentary*

This is meant to give you a basic idea of the intention / requirements. A detailed discussion is presented in Clause\_Interp\_and\_Upgrading.doc.

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## ISO 9000 Distilled - 8.5.3

### 8.5.3 Preventive Action

- Prevent **potential** nonconformities.
  - Detect potential nonconformities.
  - Identify the causes of potential nonconformities.
  - Study the effects of potential nonconformities.
  - Evaluate whether you need to take preventive action.
  - Develop and take preventive actions to eliminate causes.
  - Record the results that your preventive actions achieve.
- Verify and document the **effectiveness** of your **preventive actions**.

## *Notes & Commentary*

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*Notes & Commentary*

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# Implementing ISO 9001

- Some of you will be implementing in small companies. Some of you will be implementing in very large companies. In this document there is a mix of information. Some is appropriate to larger companies and some is targeted to smaller companies. In general it should be obvious but the rule of thumb is the bigger the company the more complex the issues become. Multi-nationals are the most complex, as one would expect.
- While this presentation is aimed at ISO 9001, it applies to ISO 14001 and QS-9000 as well, for the most part. There are a number of additional issues associated with QS-9000, however in general the intent is the same in so far as the ISO 9001:1994 requirements basis. Implementing ISO 9001 vs. QS-9000 is no different. From sweeps to document mapping, you have to determine what you have, what you need and how you want to get to the finish line.
- Do not forget that implementing a QMS is a project.

## Notes & Commentary

Some basic tips for small companies:

Keep your documentation short and sweet. Keep a simple documentation matrix. An example is included (disk file name: Document\_Matrix.xls).

Don't over document. Often training and/or experience will be sufficient. You have to think about what documentation people need and what they don't. If you did not have documentation before (such as work instructions), what you have will probably be sufficient. The key is knowing how to explain why you do or do not have documentation with respect to how people know how to do their jobs.

One of my former clients wrote me:

You're advice was extremely important. Especially important, at least in my opinion, was your help in determining where we did not need to document every last thing (by using training, etc.). I think that without this input, we would have spent a lot more time writing things that we did not need and wasted a lot of peoples' time. We were able to get the audit done in a year while we are achieving record sales and profits. Who can argue with that?

I think that pretty much says it all. Remember. Simplicity. Common sense.

# The Fed Ex Registration

Food for thought... Discussion at: <http://Elsmar.com/ubb/Forum2/HTML/000078.html>

Subject: RE: ISO 9001 *Certified Virtual Office*

Just as a point of clarification, the Fed-Ex audit approach was an exception to the rule. You are correct in stating that registrars need to follow rules for multi-site sampling. *In this unique case, the RAB did approve the unusual approach used by the registrar.* The exception was approved due to the unique design of Fed-Ex's systems. It is unlikely that another organization will duplicate these systems. Therefore, we should not expect to see this unique audit approach used for other organizations.

Indeed it was a virtual audit because *hundreds of field offices were audited without the auditor physically being there.* My agreement of confidentiality does not allow me to share more with you. Unless you fully understand how the Fed-Ex systems is set up, it is difficult to see that conducting a virtual audit is possible. It remains a controversial certification because of the approach used and the fact that *it has not yet been used at another organization.*

## Notes & Commentary

### *One response:*

I would be extremely cautious of using the Federal Express example for doing virtual offices. Their certificate is a joke. I have called twelve of their regional offices to find they have no procedures. They do not know what their quality policy is and they do not do customer requested corrective action because they do not know what it is. In addition a call to the corporate office in Memphis resulted in pretty much the same results except when the customer service person who answered was asked about ISO they said that I would have to talk to their sales person if I wanted to get their on line tracking software. When asked a second time the person said they didn't know what I was talking about. When finally directed to the head of the corporate customer service department the lady indicated she knew they were certified and would get a hold of the person who had implemented it to have him call me and send a copy of their certificate. That never occurred.

I sent a request to their registrar for verification that all offices really had been audited and was sent a nice letter indicating they did all of the offices from Memphis and they included a copy of the page out of Federal Expresses book showing they had been registered.

I have asked for corrective action no less than 5 times from Federal Express and still can not get one from anyone in the company. In addition they fail contract review but not notifying the customer when they fail to make a delivery as scheduled.

I continue to be amazed by the fact they continue to pass their audits but then again if the auditors never get out of Memphis I guess they see only what Federal Express wants them to see.

# A Consultant?

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## *Notes & Commentary*

I was once told that a consultant rarely does more than tell you what you already know. I have heard many 'disparaging' remarks about consultants over the years. If you're considering a consultant you should ask yourself why.

If you have the expertise in-house, and you have the time, you probably don't need a consultant. A consultant cannot do any more than advise you on what you have to do and how to proceed. The most frequent failure I find is where I advise a client and the client declines the advice. A good consultant can save you time and money. One can help you avoid the common pitfalls.

I do not for a minute believe that all reports of consultant incompetence are incorrect. There are many consultants out there that are a problem. Making matters worse in the field of ISO consulting is that in the last 6 years it seems 'everyone' has become an ISO consultant. In fact, companies such as Strider International sell courses on how to be an ISO consultant. Anyone can join the fray! I have two friends who went through the Strider program. One called it garbage and one will not comment on it but I know he has made no money from it.

Of course, I take the position that if you need a consultant you should contact me!

# Basic Reasons To Consider A Consultant

- To help plan your project
  - An efficient implementation begins with a solid plan, taking into account those things you need to work on, leaving out those things which are already in place, and developing an accurate estimate of how long each implementation phase should take.
- To help interpret the standard
  - A consultant who understands the standard's requirements can prevent wasted time doing things the standard does not require, or doing things in a way that does not meet the standard. You do not want to have to undo any of your hard work.
- To allow you to benefit from experience
  - Using a consultant allows you to begin work right away without having to learn things on your own, and without having to learn by your mistakes.
- To watch your timeline
  - A consultant can work with your steering team and ISO point teams and make sure the work is done within the time allowed on the timeline.

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# Role of Consultant - Piano Teacher?

- **'Full Service'**  
On-site full-time for the duration of the project. Various roles & Responsibilities.
- **Visits - As Required**  
Track progress through interviews (meetings) and 'internal audits'.  
Address interpretations issues. Help with systems design.
- **Internet / Phone**  
Verify systems documents  
Discuss interpretations and systems  
Answer general questions

NOTES: Training can be applied to any of the above but is on-site.  
Internet / Phone is always available

## Notes & Commentary

Once a client referred to me as their 'Piano Teacher'. I still use the analogy. I tell clients I can help them learn how to play, but I can't play the concert for them. I can tell them what the problems to expect are. I can help with interpretations. But I can't take the audit for you.

If you're a golf person, you might want to think of this in terms of a golf pro. You are after their experience and insight. You want them to evaluate your swing. You want their advice. But - they can't play the game for you.

Some clients want someone there every day. Others want a consultant on an 'as needed' basis. Some want to keep costs as low as possible and opt to try to do almost everything by internet and phone. There are pros and cons to each method but it really depends upon how much and what you expect from a consultant with consideration to in-house resources.

As often as not, the middle of the road 'Visits as required' path is followed and is typically appropriate.



# Deliverables

- Dependent Upon The Client's Needs and Expectations
- Must Be Agreed To In Advance
- May Change During Project
- May Include:
  - Project Management
  - Systems Design
  - Systems Documentation
  - Training
  - Internal Auditing

## Notes & Commentary

Defining deliverables sounds easy -- it isn't always so. Deliverables can become a sticking point and problematic for a number of reasons. For example, a company wants to do most of the documentation in-house but lacks employees qualified / trained to produce it. One client gave flow chart training to every employee from supervisors on up at the beginning of the project to ensure they could not only map their systems and processes, but that they could also maintain them in the future.

*Often there is 'adjustment' during the project as strengths and weaknesses are recognized / identified. Problems ranging from resource issues to time considerations can significantly change the actual needs and requirements. When expectations are not met, changes in the project plan are to be expected.*

I was at a client facility where we had just gotten started a week earlier. We were going through the motions of finalizing a purchase order. Deliverables came up in that corporate required defined deliverables on every PO. We spent about a week discussing 'deliverables'.

Even before you contact a consultant, you should be thinking about what you expect - including deliverables. And you should expect them to change somewhat as the project proceeds.

# Implementation Guarantees

- Some companies offer 'guarantees'. Consider the details / requirements carefully.
- Typical Disclaimer Example

"The ISO 9001 Network *guarantees* that your company will achieve ISO 9001, QS-9000, or ISO 14000 certification **if you follow our program.**" -  
From <http://www.Isonet.com/Gaurantee.htm> (sic)
- The time it takes to implement a system is inversely proportional to the company's involvement and prioritization. As involvement and/or priority increases, time decreases. Pretty much a 'no brainer'.

## Notes & Commentary

I have been working with companies in implementing ISO standards since about 1993. Since then, it seems everyone and their brother has become ISO experts. Some companies offer 'Guarantees'. The one cited above is an example. Notice where they proclaim "...if you follow our program..." Often there are sweetheart deals with registrars as well.

When I first got into ISO 9001, it was because of a gal who told me about it - in 1991. She made a very good business out of implementations. One of her initial requirements was the company had to sign an agreement which said they would do everything she said was necessary. By default, she controlled the plant manager (or whoever the top dog was). She did not want to work with a company not dedicated to the effort and she would only implement 'her way'. Her program was US\$25,000 down and US\$1500 each 1/2 day visit. She would visit once or twice a month. She did quite well, actually. But she was demanding. She had one heck of a sales pitch.

I will offer the same guarantee to any client. If you give me control, if you will do everything I say (including providing various training programs when necessary), I will guarantee successful registration as well.

# Example Guarantee Program

## 8-Step Guaranteed Registration Plan

PIC has now designed a cost effective training and consulting package to help your organization achieve registration -- GUARANTEED!

Our philosophy is to assist your company in developing and applying the skills necessary to plan, implement and achieve registration.

### Our 8-Step Guaranteed Registration Plan includes:

1. ISO/QS-9000 Introduction Seminar - Training
2. ISO/QS-9000 Awareness Sessions - Training
3. ISO/QS-9000 Needs Assessment - Consulting
4. ISO/QS-9000 Implementation/Documentation - Training
5. ISO/QS-9000 System Development, Consulting, Coaching, Training
6. Choosing a Registrar - Consulting
7. Part A: ISO/QS-9000 Internal Auditor Training  
Part B: Internal Auditor Site Coaching - Training
8. Part A: Pre-Assessment Audit - Consulting  
Part B: Registration Audit - Consulting

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## Notes & Commentary

There are now many companies which give implementation guarantees. This is a typical 'guaranteed' implementation program. Please note that I do not disagree with the program they have outlined. In fact, I do endorse it as a sensible, structured approach.

When you see a guarantee promise, remember: There is no magic answer. Be sure you understand the restrictions on any guarantee you consider.

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## A Consultant? Some Last Thoughts...

1. Prepare a statement outlining the nature, scope and objectives of the assignment.
2. Circulate this written statement to the key people in your organization inviting them to comment by a specific date in terms of whether it defines the need accurately and whether the assignment should be tackled internally or external help sought.
3. Define the expertise you will need.
4. Invite the consultant for an interview.
5. Brief the staff who will be involved in the selection process.
6. Avoid organization jargon.
7. Ask the consultant to describe how the assignment will be approached.
8. Request references, in confidence, to provide real examples of previous assignments carried out and check with the referees how successfully the assignment was carried out. Do not buy on price alone.
9. Express the assignment you wish carried out in terms of the end results, i.e. outputs, that you want to achieve.
10. **IF YOU PROCEED...** Provide resources and executive commitment. **There is no point in seeking consultancy help unless you have the will, the resources and the organization resolve to follow the advice you get.**

## Notes & Commentary

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## Implementation - The Process

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## *Notes & Commentary*

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# Implementation Strategies

- **Compressed Project**

- Drop Dead Date
  - High Priority Project Management Approach
  - Intimate high level management involvement
  - Regular Scheduled Meetings

- **Business As Usual**

- Low stress
  - Low Priority Project Management Approach
  - Slipping schedule not critical
  - Irregular Meetings

- **Meandering**

- Slipping schedule not important
  - Low level management support / involvement
  - Irregular meetings
  - Project tends to 'Fade Away'

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## *Notes & Commentary*

Each company has a personality and tenor. Top management is extremely variable in how they approach, participation in and their interest in registration. Some are very involved. Some want to watch but monitor closely. Some don't want to participate at all.

Some companies are given ultimatums. Deadlines. No new business, or reduced business threats (particularly US automotive). Some companies go through the process in an attempt to improve.

These are three implementation strategies a company has to consider. It should be noted that available human resources is an important part of any implementation strategy. Unfortunately, often this aspect is a serious threat to successful implementation within the project constraints (e.g.: time).

# Project Scope Considerations

- **Single Location**

- Current company / facility status
- Scope of registration
- Training needs
- Implementation strategy
- Resource allotment

- **Multiple Locations**

- Single or shared certificate
- Degree of shared documentation
- Degree of shared data / information systems
- Network Capacity / Capability

**NOTE:** Single location considerations all apply to multiple location projects.

## *Notes & Commentary*

Different companies look at their registrations differently. Some have multiple locations on a single certificate. It's cheaper, generally, to do so. You 'make a deal' with the registrar. As with everything else, the more you want to buy in a 'chunk', the quicker they are to offer a discount.

Those who chose to have each location on a different certificate are typically looking at the weakest link aspect of a single certificate: If 1 location 'fails', all locations are affected.

The other aspects noted above should be self explanatory.

You can register 1 location in a corporation. Or you can register a corporation. You can even, theoretically, register one part of an individual facility. You address this issue in your registration **Scope** statement. You should discuss the scope of your registration very early in your contact with registrars (prior to or during the interview process).



## Implementation Commandments

- You cannot give someone a **responsibility** without publicly conferring **authority** to act.
- If top management doesn't care, no one else will care.
- If planned meetings are not attended, 'someone' isn't serious about their part in the project.
- Track the project publicly. Publicize status weekly or bi-weekly.
- Communication may not be everything, but it is the largest single stumbling block. No camps with walls.
- If people do not have enough time to begin with, they won't have time for this.

## Notes & Commentary

A common failure or cause of delay in implementations is the failure of management to assign responsibility without authority and/or oversight of the project. If you tell someone to do something and don't give them the resources and 'power' to do it, it will probably fail. Again, different companies have different tenors.

Another major failure mode is where there really aren't enough resources (personnel, particularly) to get things done in addition to regular responsibilities. A few years ago I told the plant manager that there was no way for the company to succeed in the time expected because it was evident employees were at their limit in so far as time went. He called a meeting of upper management and middle managers and said: "I realize there is a resource issue. I will take the hit for lost productivity. Quality shall not suffer even though output may. Please put your ISO responsibilities on the top of your agenda." He authorized the war room to be stocked around the clock with sandwiches, drinks and snacks. Employees worked overtime. We had a meeting every Thursday to discuss progress including resource needs, including temporaries. This plant was 3000+ souls and completed everything in 6 months.

Often, outside help is needed with documentation. A number of clients have used temp firms to get legacy paper documentation input into their preferred software, for example.



## Initial Basic Suggestions

- I suggest you make and use a 'history' binder.
- Make a list of your departmental 'responsibilities'.

Think **INPUTS** and **OUTPUTS**

- Prioritize each into 'Tiers' or 'Levels' in accordance with the Document Pyramid herein. Categorization is approximate.
- Make a Plan or Schedule for each.
- *Always ask*, as the auditor will:

*"Does this affect the quality of our product(s)?"*

## Notes & Commentary

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## 'Standard' General Registration Path

- Assess your situation (**Pre-assessment**)

Also called **Gap Analysis**

- **Consultant?**
- Define a plan with time line & begin
- Interview and choose registrar
- Documentation processes
- Manage transitional activities
- Registrar document review
- Registrar pre-assessment
- Corrective actions
- Registration audit

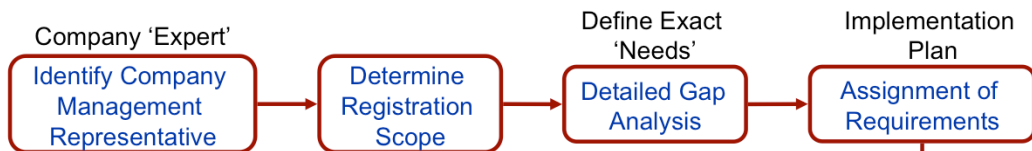
Implementation time frame: 3 months to 2 years

*Notes & Commentary*

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# Top Level Project Flow

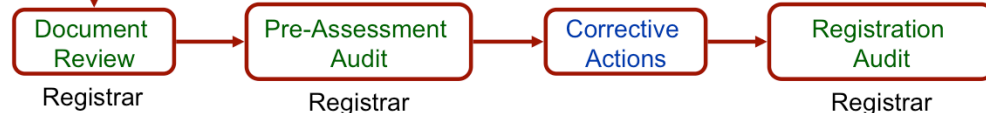
## Project Definition



## Project Actions



## Project Fulfillment



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## Notes & Commentary

This is the basic implementation flow that I recommend. Each step is a dependency on the step before. This does not mean that steps cannot be carried out simultaneously - and they typically are. However, the completion of one step is dependent on completion of the previous step as outlined here. For example, Internal Audits are often started very early in a project. But they cannot be completed until all required documentation is trained and implemented, which in turn cannot be completed until all documentation is completed. Not rocket science - Common Sense.

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## 'Typical' Detailed Implementation Steps Example

- |  |   |
|--|---|
| 1 Determine Specific Requirement(s)                          | 31 Buy-Offs On Master Systems   |
| 2 Define Time to Complete Requirement                        | 32 De-Bug & Train Supervisors/Area Leaders (Function)                     |
| 3 Define Scope of Assessment                                 | 33 De-Bug & Train Users (Awareness & Use Details)                         |
| 4 Project Set-Ups  | 34 Implement (Final De-Bug & Formal Records [Tier 4 documents] Initiated) |
| 5 Write Company Quality Systems Manual                       | 35 Review Status  |
| 6 Document Company Quality Policy                            | 36 Tier 3 and Tier 4 Documentation  |
| 7 Define Documentation Systems                               | 37 Systems Documentation  |
| 8 Document Master Numbering System                           | 38 Existing Systems Analysis & Flow Charting                              |
| 9 Establish Master Binders                                   | 39 Needs Analysis from Tier 2's   |
| 10 Procedures History Binder                                 | 40 Documentation  |
| 11 Project Master Binder                                     | 41 Buy-Offs On Sub-Systems  |
| 12 Review Status   | 42 De-Bug & Train Supervisors/Area Leaders (Function)                     |
| 13 Contact Registrar   | 43 De-Bug & Train Users (Awareness & Use Details)                         |
| 14 Agree on Scope  | 44 Implement (Final De-Bug & Formal Records Initiated)                    |
| 15 Agree On Fees (Try to Bargain)                            | 45 Process Documentation  |
| 16 Agree On Audit Date(s)                                    | 46 Process Needs Analysis   |
| 17 Submit Required Documentation                             | 47 Develop Plans to Address Deficiencies                                  |
| 18 Review Status   | 48 Follow Through on CA Plans (Worse Case Timing)                         |
| 19 Awareness & Information Meetings - Hourly                 | 49 Review Status  |
| 20 ISO 9000 Awareness  | 50 Internal Systems Audits  |
| 21 Work Instructions & Documentation                         | 51 Internal Auditor Training  |
| 22 Auditee Training  | 52 Walk-Thru Audits   |
| 23 Awareness Reinforcement                                   | 53 Internal Audits  |
| 24 Review Status   | 54 Corrective Actions   |
| 25 Tier 2 (Systems) Documentation                            | 55 Review Status  |
| 26 Gather Documentation Examples                             | 56 Escorts & Area Leaders   |
| 27 Cross-Area Teams Define & Flow Chart Master Systems       | 57 Choose Escorts   |
| 28 Systemic Needs Analysis (Data From Walk-Thrus & Audits)   | 58 Train Escorts  |
| 29 Determine & Integrate Additional Systems Requirements     | 59 Choose Area Leaders  |
| 30 Systems Procedural Documentation & Flow Chart Integration | 60 Train Area Leaders   |

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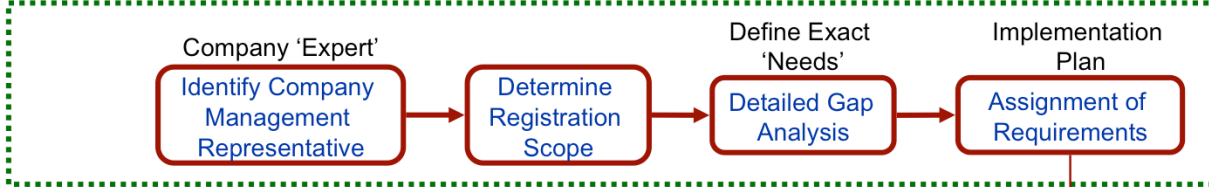
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## Notes & Commentary

- 61 Review Status
- 62 Pre-Audit
- 63 Corrective Actions
- 64 ISO 9000 Requirements Matrix
- 65 Internal Systems
- 66 Registration Audit
- 67 Corrective Actions
- 68 Submit Corrective Action Plan
- 69 ISO 9000 Requirements Matrix Failures
- 70 Internal Systems
- 71 Submit Corrective Action Results
- 72 Registration Recommendation

# Project Definition

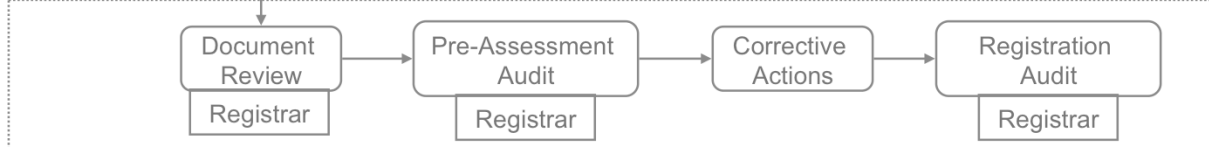
## Project Definition



## Project Actions



## Project Fulfillment



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# Notes & Commentary

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Defining Responsibilities

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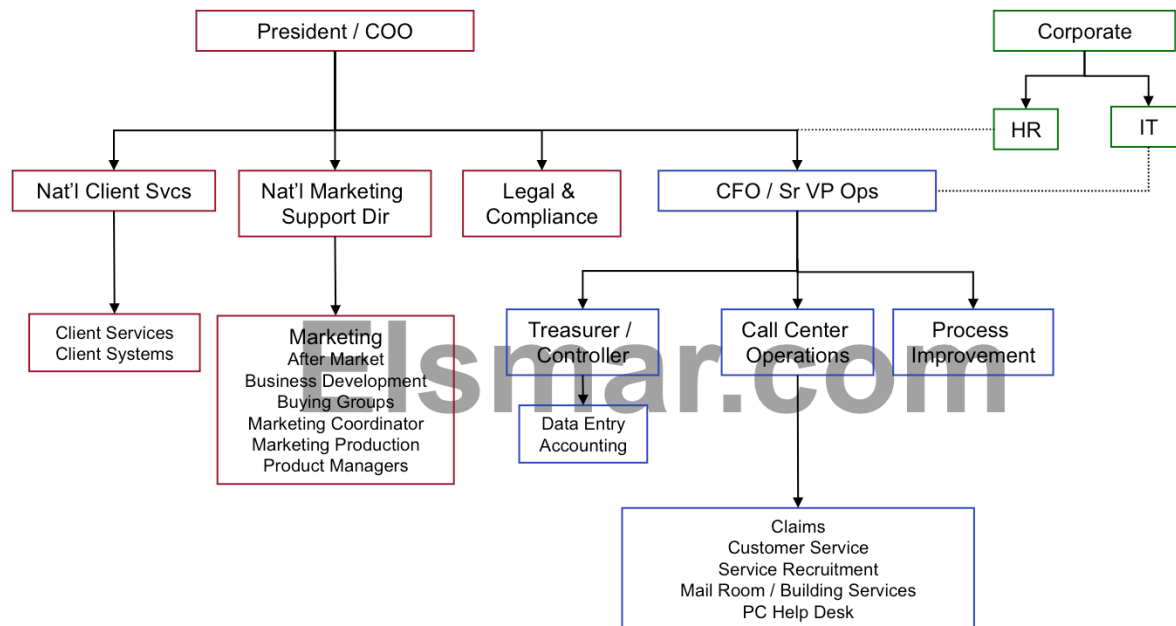
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*Notes & Commentary*

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# Example Organizational Chart



Before you do anything else, be sure you have defined responsibilities from the top down. This is the typical method - An Organizational Chart.

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## Notes & Commentary

Organizational charts are very common. The above is an example from a service organization. You may note there are no names attached. My personal opinion is it each company has to make a determination of format (such as shall we include names?) depending upon that specific company.

The questions to address include:

- The issue of personnel turn-over
- Frequency of company reorganizations
- Company size
- Technology level of the company

If you decide against names, it's no big deal as long as you can, through personnel or some other very definite, documented way, match a name to the position.

# Top Management

- ISO talks about '**Top Management**'. Pundits talk about how ISO can only succeed if '**Top Management**' is involved. Just who is **Top Management**?
- In your registration it will depend upon your company. I have argued that top management support is not always necessary for an implementation to succeed. In fact, often the 'real' top management of a company is hardly, if at all, involved. This is very common in sole proprietor situations. The owner, though involved in the business to some degree, essentially delegates all responsibility to a plant manager or other position. The owner often never even meets the registration auditors.
- You have to take a good look at your company structure to determine who, in your company or facility, will be the 'targets' (Top Management).
- See [Clause\\_Interp\\_and\\_Upgrading.doc](#) for details.

## Notes & Commentary

From a misc.industry.quality NG posting:

The problem lies in assigning equal titles and definitions to every company in the world, which cannot be done. In some companies, a "Managing Director" may be a second tier position; in others, "top management" for the facility undergoing ISO registration may be the Plant Manager, as in the case of a large corporation with multiple sites with various certifications, where the CEO might be so far removed (logically and physically) from that site he plays no role. If my company is a small 12-person software development wing of Microsoft located in Tennessee, is Bill Gates "top management"? Of course not. (Microsoft jokes to follow....)

One of my clients has empowered divisional VP's as "top management" even though the President/CEO is headquartered out of the same site; however the practical reality is that the President's role in this company requires constant international travel and macro management, so it's not practical to have him overseeing the quality system on a regular basis. Quality managers report, during management review, to the VP's, who make all the usual "top management" decisions. A report is sent annually to the President, but no action on his part is required.



# Responsibilities

## Let's talk about Responsibilities

- There are a number of ways to look at defining responsibilities.
  - Organizational Charts
    - Smaller companies usually only require a single 'org chart'. I have seen some put it right in the front of their 'quality manual'.
    - Many companies have numerous organizational charts from high level 'corporate masters' down to the level of each individual department. In larger companies, it should be noted, that these are typically in a state of flux. New 'positions' are made and others are eliminated. It is important for you to note that these are **Controlled** documents. A somewhat common failure mode is a loss of control or not defining who is responsible for the control of the organizational charts.
  - Matrices
  - Procedures

## Notes & Commentary

I have shown you an example of an organizational chart. But remember, there are other ways in which companies define responsibilities. Bear this in mind because ISO and TS require you to define responsibilities. My point is, look beyond an organizational chart. A good example is your company's procedures. If we're talking level 2's, and you're using flow charts, you can put the functional position responsible by each step. CAUTION: Remember the concept of where some companies, especially large ones and 'tech' companies, tend to 'reorganize' on a somewhat regular basis. Ask yourself this: If a reorganization occurs, what will trigger someone to update the chart? On a high level, it may be a management review output. On a lower level it is often the case that the departmental manager is responsible for his or her departmental organizational chart. Never use specific names on an org chart unless you like to make a lot of changes or are a very stable, relatively small company.

So - we can look at procedures and, in many cases, even what many call work instructions, as vehicles to define responsibilities. In some cases inter-company memos define responsibilities. Many larger companies require departmental managers to notify specific people when they are not 'available' (vacation or whatever) and to specifically define who is assuming the manager's responsibilities while the manager is not available.

## Other Responsibilities

- The following are matrices used to define responsibilities in another way. We have discussed org charts, procedures and such, but what about people knowing what they are responsible for knowing and following?
- Typically this is done during employee training. But - right now we're implementing. How do we know who is responsible for knowing about what and who is responsible for what systems.
- The following slides are from an old implementation, however they may serve to illustrate tracking a large implementation project.

## *Notes & Commentary*

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## An Example Area 'Element Responsibility' Chart

'Areas' go here.

Area responsibilities come from Organization Charts.

ISO 9001 Element	Management	Quality Assurance	Materials	New Product Eng.	Frame Weld & Paint	Machine	Tank & Fender	Chrome	Paint	Assembly - Set-Up	Maintenance
4.1 Management Responsibility	U										
4.2 Quality System	A	A									
4.3 Contract Review											
4.4 Design Control											
4.5 Document & Data Control	X	A	A	X	A	U	A	U	A	A	A
4.6 Purchasing											
4.7 Control of Customer Supplied Product											
4.8 Product Identification and Traceability		A	A	X	A	X	X	U	A	A	
4.9 Process Control		A		X	A	U	U	U	A	A	A
4.10 Inspection & Testing		A		X	A	U	X	U	A	A	
4.11 Control of I, M&TE		A		X	A	X	X	U	A	A	
4.12 Inspection & Test Status		A			A	X	X	U	A		
4.13 Control of Nonconforming Product					A	U	U	U	A		
4.14 Corrective & Preventive Action	S	A									
4.15 Handling, Storage, Preservation & Delivery				X							
4.16 Quality Records	X	S	A	X	A	X	X	U	A	A	X
4.17 Internal Quality Audits	S	A									
4.18 Training	S										
4.19 Servicing											
4.20 Statistical Techniques		A		X							

X	Not Yet Determined as of this Report Print Date
S	Known Deficiencies - No Known Resolution Plan
B	Known Deficiencies - Resolution Behind Schedule
U	Resolution Plan - Unknown Status
A	Resolution Plan On Schedule
X	Area Appears Compliant (Not Verified thru Audit)
C	Area Compliant (Verified Through Audit)

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Each area has certain QS-9000 - ISO 9001 elements it is responsible for complying with. Each should be listed and the departmental managers should know their responsible elements.

We can track each area's compliance with a matrix like this one. **Verification** and **validation** are by the use of **internal audits**.

One element every area will have to comply with is Element 4.16 'Quality Records'. Does each area manager know what quality records they have and are responsible for?

It is very important that this responsibility chart be presented during staff meetings **weekly** to ensure that there is **progress**!

## Notes & Commentary

Note that this example responsibility chart is from an ISO 9001:1994 implementation. In the package you purchased you will find the file "Responsibility\_Matrix.xls". It is already set up with the ISO 9001 elements. See the Process matrix sheet within the file.

The bottom line is this may serve to give you some ideas on how to track the project from a high level. Unless we're talking a company of 10 to 15 people, I really recommend tracking matrices. Even then it's a good idea.

Note that a master matrix can be effectively used to define what managers are responsible for understanding what elements. For example, every functional department is responsible for understanding and complying with document control procedures (4.1, 4.2). But only 'management' is responsible for Management Review (5.6).

So - you can use this matrix to track implementation (compliance) and you can use it to define which departments are responsible for compliance with each element of ISO 9001. The next slide shows this in detail.

# Department Specific Responsibility Tracking

## Functional Department: Management

Requirement	ISO 9001	Status	Comment
<b>Management Responsibility</b>	<b>4.1</b>	<b>U</b>	<b>General Element Assessment</b>
Quality Policy (and Objectives)	4.1.1	X	Corporate Origin
<b>Organization</b>	<b>4.1.2</b>	<b>B</b>	Organization Charts Needed to define reporting (responsibility) relationships.
Responsibility & Authority	4.1.2.1	B	Organization Charts Needed to define reporting (responsibility) relationships.
Resources (and Trained Personnel)	4.1.2.2	B	Must review during Management Review Meetings.
Mgmt. Representative (Quality System Responsibility)	4.1.2.3	X	Glenn K. - Executive Management - Should review Q systems during Mgmt. Review Mtng.
<b>Management Review</b>	<b>4.1.3</b>	<b>B</b>	Meetings must be 'regular', have an agenda, minutes must be taken.
<b>Quality System</b>	<b>4.2</b>	<b>A</b>	<b>General Element Assessment</b>
General	4.2.1	X	Quality Manual - Corporate
Quality System Procedures	4.2.2	A	Under Development
Quality Planning	4.2.3	S	Must be part of process.
<b>Document, Data &amp; Specification Control</b>	<b>4.5</b>	<b>X</b>	Must comply with the documented procedure as it pertains to Management Records.
<b>Corrective Action</b>	<b>4.14</b>	<b>S</b>	Must be addressed in Management Review Meetings.
<b>Quality Records</b>	<b>4.16</b>	<b>X</b>	Must comply with the documented procedure as it pertains to records such as Meeting Minutes, etc.
<b>Internal Quality Audits</b>	<b>4.17</b>	<b>S</b>	Must be addressed in Management Review Meetings.
<b>Training</b>	<b>4.18</b>	<b>S</b>	Must be addressed in Management Review Meetings.

Area Manager:  
TBD

Area Contact:  
TBD

Key:	X	Not Yet Determined as of this Report Print Date
	U	Known Deficiencies - Unknown Resolution Plan Status
	S	Known Deficiencies - No Resolution Plan
	B	Resolution BEHIND Schedule
	A	Resolution Plan On Schedule
	X	Area Appears Compliant (Not Verified thru Audit)
	C	Area Compliant (Verified)

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## Notes & Commentary

This is a more detailed example of a spread sheet used to track progress. It was used during an ISO 9001:1994 implementation, however it should serve to give you a flavour of a way to track progress and responsibilities.

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# Department Specific Responsibility Tracking

## Functional Department: Materials Management

Requirement	ISO 9001	Status	Comment
Document, Data & Specification Control	4.5	U	Must comply with the documented procedure.
Product Identification and Traceability	4.8	U	Must comply with the documented requirements.
Inspection, Measuring and Test Equipment	4.11	U	Local equipment must be in calibration system.
Inspection and Test Status (Indication Of)	4.12	U	Must comply with documented requirements.
Control of Nonconforming Product	4.13	U	Must be Nonconformance System INPUT.
Corrective Action	4.14	U	Must have CA System OUTPUT.
Handling Storage, Packaging and Delivery	4.15	X	Must comply with documented requirements.
Quality Records	4.16	X	Must control appropriate records.

Area Manager:  
TBD

Area Contact:  
TBD

Key:

X Not Yet Determined as of this Report Print Date

U Known Deficiencies - Unknown Resolution Plan Status

S Known Deficiencies - No Resolution Plan

B Resolution BEHIND Schedule

A Resolution Plan On Schedule

X Area Appears Compliant (Not Verified thru Audit)

C Area Compliant (Verified)

### General Notes / Comments:

Real concerns exist in this area in large part due to the methodology of receiving with no inspection and the lack of an 'adequate' certified supplier scheme (which, as a minimum, requires spot inspections to validate supplier data).

This area compliance will involve the MAN System.

We are arguing Receiving Inspection as certified supplier. Currently it appears 'verification' is insufficient. This has to be addressed.

Prognosis: Good.

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# Notes & Commentary

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# Department Specific Responsibility Tracking

## Functional Department: Assembly

Requirement	ISO 9001	Status	Comment
<b>Document, Data &amp; Specification Control</b>	4.5	A	Local documentation must be controlled.
<b>Product Identification and Traceability</b>	4.8	A	Must comply with documented requirements.
<b>Process Control</b>	4.9	A	Appropriate documentation must exist and be utilized as specified therein.
<b>Inspection and Tests</b>	4.10	A	General Element Assessment
	In-process Inspection & Testing 4.10.3	A	In accordance with documented procedure.
	Inspection & Test Records 4.10.5	A	And of course we keep records - specifically Inspection & Test Results.
<b>Inspection, Measuring and Test Equipment</b>	4.11	A	Equipment must be in cal. and employees must understand Cal Stickers, etc. as appropriate.
<b>Inspection and Test Status (Indication Of)</b>	4.12	A	Must comply with documented procedure.
<b>Control of Nonconforming Product</b>	4.13	B	Must comply with documented procedure.
<b>Corrective Action</b>	4.14	B	Must comply with documented procedure.
<b>Handling Storage, Packaging and Delivery</b>	4.15	A	Must comply with documented requirements.
<b>Quality Records</b>	4.16	A	And of course we keep records when appropriate.
<b>Statistical Techniques</b>	4.20	A	In accordance with Process Documents.

Area Manager:  
TBD

Area Contact:  
TBD

Key:	X	Not Yet Determined as of this Report Print Date
	U	Known Deficiencies - Unknown Resolution Plan Status
	S	Known Deficiencies - No Resolution Plan
	B	Resolution BEHIND Schedule
	A	Resolution Plan On Schedule
	X	Area Appears Compliant (Not Verified thru Audit)
	C	Area Compliant (Verified)

General Notes / Comments: This area has experienced several walk-thru's. Dan (intern) has been deeply involved. Minor problems exist however progress is evident.

Prognosis: Excellent.

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# Notes & Commentary

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# Department Specific Responsibility Tracking

## Functional Department: Inspection Laboratory

Requirement	ISO 9001	Status	Comment
Document, Data & Specification Control	4.5	A	Must comply with the documented procedure as it pertains to local documentation.
Product Identification and Traceability	4.8	X	Must comply with the documented procedure or other specified requirements.
Inspection and Tests	4.10	A	General Element Assessment
Inspection & Test Records	4.10.5	A	Appropriate control of records.
Inspection, Measuring and Test Equipment	4.11	A	Must comply with the documented procedure.
Inspection and Test Status (Indication Of)	4.12	X	Must comply with specified requirements.
Control of Nonconforming Product	4.13	A	Must be INPUT to.
Corrective Action	4.14	A	Must receive OUTPUT from and be INPUT to.
Handling Storage, Packaging and Delivery	4.15	X	Must comply with the documented procedure.
Quality Records	4.16	A	Must comply with the documented procedure.
Statistical Techniques	4.20	X	Must comply with documented procedure as it relates to inspection & test devices.

Area Manager:  
TBD

Area Contact:  
TBD

Key: X Not Yet Determined as of this Report Print Date

U Known Deficiencies - Unknown Resolution Plan Status

S Known Deficiencies - No Resolution Plan

B Resolution BEHIND Schedule

A Resolution Plan On Schedule

X Area Appears Compliant (Not Verified thru Audit)

C Area Compliant (Verified)

General Notes / Comments: Gary has been deep into this area and has plans to address all areas.

Prognosis: Good to excellent.

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# Notes & Commentary

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# Department Specific Responsibility Tracking

## Functional Department: Maintenance

Requirement	ISO 9001	Status	Comment
Document, Data & Specification Control	4.5	X	Documented system.
Process Control	4.9	A	Preventive Maintenance system must be documented.
Quality Records	4.16	X	Maintenance records.

Area Manager:

TBD

Area Contact:

TBD

Key:

X	Not Yet Determined as of this Report Print Date
U	Known Deficiencies - Unknown Resolution Plan Status
S	Known Deficiencies - No Resolution Plan
B	Resolution BEHIND Schedule
A	Resolution Plan On Schedule
X	Area Appears Compliant (Not Verified thru Audit)
C	Area Compliant (Verified)

General Notes / Comments:

This area has been working on their responsibilities since the gap analysis, however an audit is necessary to establish their current status. There has been minimal contact since April-May.

Prognosis:

Good to Excellent.

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# Notes & Commentary

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# Department Specific Responsibility Tracking

## Functional Department: Calibration Laboratory

Requirement	ISO 9001	Status	Comment
Document, Data & Specification Control	4.5	B	Must comply with the documented procedure as it pertains to local documentation.
Inspection, Measuring and Test Equipment	4.11	B	Must comply with the documented procedure(s).
Control of Nonconforming Product	4.13	B	Instruments found 'Out-Of-Cal' must be Nonconformance System INPUT.
Quality Records	4.16	B	And of course we keep records - specifically calibration records, certs, etc.
Statistical Techniques	4.20	B	Must comply with documented procedure as it relates to validation/verification of inspection & test devices.

Area Manager:

TBD

Area Contact:

TBD

Key:

X	Not Yet Determined as of this Report Print Date
U	Known Deficiencies - Unknown Resolution Plan Status
S	Known Deficiencies - No Resolution Plan
B	Resolution BEHIND Schedule
A	Resolution Plan On Schedule
X	Area Appears Compliant (Not Verified thru Audit)
C	Area Compliant (Verified)

General Notes / Comments: A lot has been invested in this area. Problems include leaking roof, no AC, etc. A proposal was presented in June. Status unknown.

Prognosis: Good

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# Notes & Commentary

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# Department Specific Responsibility Tracking

## Functional Department: Quality Assurance

Requirement	ISO 9001	Status	Comment
<b>Quality System</b>	4.2	<b>A</b>	General Element Assessment
General	4.2.1	<b>A</b>	Corporate Systems Manual, Tier IIs and York local procedures.
Quality System Procedures	4.2.2	<b>A</b>	Procedures for 20 elements - plant specific in consonance with Corporate Tier IIs.
Quality Planning	4.2.3	<b>X</b>	Elements must be documented.
<b>Design Control</b>	4.4	<b>A</b>	Will be addressed by corporate
<b>Document, Data &amp; Specification Control</b>	4.5	<b>A</b>	Must comply with documented procedure
<b>Product Identification and Traceability</b>	4.8	<b>B</b>	Documented procedure.
<b>Process Control</b>	4.9	<b>B</b>	Must be INPUT to and receive OUTPUT from.
<b>Inspection and Tests</b>	4.10	<b>A</b>	General Element Assessment
General	4.10.1	<b>A</b>	Controlling procedure originator.
In-process Inspection & Testing	4.10.3	<b>A</b>	Provide resources for.
Final Inspection & Testing	4.10.4	<b>A</b>	Provide resources for.
Inspection & Test Records	4.10.5	<b>A</b>	And of course we keep records.
<b>Inspection, Measuring and Test Equipment</b>	4.11	<b>A</b>	General Element Assessment
General	4.11.1	<b>A</b>	Controlling procedure originator.
<b>Inspection and Test Status (Indication Of)</b>	4.12	<b>A</b>	Must be INPUT to and receive OUTPUT from.
<b>Control of Nonconforming Product</b>	4.13	<b>B</b>	General Element Assessment
General	4.13.1	<b>B</b>	Controlling procedure originator.
Review & Disposition of Non-conforming Product	4.13.2	<b>B</b>	Must be INPUT to and receive OUTPUT from.
<b>Corrective Action</b>	4.14	<b>B</b>	General Element Assessment
General	4.14.1	<b>A</b>	Controlling procedure originator.
Corrective Action	4.14.2	<b>A</b>	Must be INPUT to and receive OUTPUT from.
Prevention Action	4.14.3	<b>A</b>	Must be INPUT to and receive OUTPUT from.
<b>Quality Records</b>	4.16	<b>X</b>	Controlling procedure originator.
<b>Internal Quality Audits</b>	4.17	<b>B</b>	Controlling procedure originator.
<b>Statistical Techniques</b>	4.20	<b>A</b>	Controlling procedure originator.
Identification of Need	4.20.1	<b>A</b>	Must be INPUT to and receive OUTPUT from.

Area Manager:  
TBD

Area Contact:  
TBD

<b>Key:</b>	<b>X</b>	Not Yet Determined as of this Report Print Date
	<b>U</b>	Known Deficiencies - Unknown Resolution Plan Status
	<b>S</b>	Known Deficiencies - No Resolution Plan
	<b>B</b>	Resolution BEHIND Schedule
	<b>A</b>	Resolution Plan On Schedule
	<b>X</b>	Area Appears Compliant (Not Verified thru Audit)
	<b>C</b>	Area Compliant (Verified)

General Notes / Comments: Delayed due to new model year & chrome problems.

Prognosis: Fair to good. Nonconformance & Corrective Action Systems are difficult to implement, etc.

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### Quality Management System Implementation

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# Notes & Commentary

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## Typical Failure Modes

- **Can't explain** systems and/or documentation
- **Lack of management involvement**
- **Personnel not following documentation**
- **Poor communication and/or training**
- Lack of documentation
- No or inadequate document control
- Poor record keeping and systems
- More details at <http://www.Elsmar.com/failure.html>

## *Notes & Commentary*

These are typical audit failure modes.

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## Critical Success Factors

- Dedicated 'Company Knowledgebase'  
(Coordinator and/or Management Representative)
- Pre-assessment (document and interview)
- Involved, supportive top management
- Receptive culture
- Focus on business rather than functional areas
- Prioritize processes based on customer needs, anticipated benefits, and potential for success

## Notes & Commentary

Folks, if you do not have a 'dedicated company knowledgebase' - a person - who understands the standard on a sentence by sentence basis, you are in for problems. Being able and ready to explain how everything fits together, not to mention understanding the requirements as they relate to your company, business style and product(s), is extremely important.

Sooner or later there is going to be an interpretation issue with an auditor. If you are not prepared with knowledge, you have already lost.

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# United States - IRS Deduction Ruling

- IRS Revenue Ruling 2000-4

Implementation costs are tax deductible in the **same year**.

Registration costs and registration upkeep costs are tax deductible in the **same year**.

- Internal man hours
- Internal capital expenses
- Consultant fees

I have seen combined implementation / registrar costs as low as US \$10,000 and as high as US\$10+M.

## Notes & Commentary

Date 1/6/2000 -- Business granted deduction for QA standards Businesses will gain a new tax deduction for the costs of meeting international quality standards under a ruling by the Internal Revenue Service, which reversed its previous position. The decision Thursday involves a series of quality guidelines known as ISO 9001 that businesses around the world use for goods and services. Companies get certified by the International Organization for Standardization by documenting their processes so all current and future employees will continue to meet the same standards.

The National Association of Manufacturers, the National Federation for Independent Business and other organizations petitioned the IRS in 1998 to permit companies to fully deduct the costs of gaining certification in a single year, instead of spreading the costs out over multiple years. Obtaining certification, the groups said in a joint letter, "can be both expensive and time consuming, particularly for small businesses." An average cost estimate was placed at \$60,000.

The IRS ruling says that costs incurred by businesses to "obtain, maintain and renew" the certification will now be fully tax deductible in one year, except for certain long-term costs such as creation of a company manual.

See <http://Elsmar.com/ubb/Forum2/HTML/000147.html>

# *A Plan - Think Project* Elsmar.com

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## *Notes & Commentary*

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# Example Project Plan Snippet

Task ID	Project Elements	Days	Start	Finish	1999 Qtr 4, 1999 Qtr				
					Sep	Oct	Nov	Dec	Jan
1	Define Scope of Assessment	25d	Mon 9/20/99	Fri 10/22/99					
2									
3	Kick-off Meeting	1d	Thu 10/7/99	Thu 10/7/99					
4									
5	Project Set-Ups	73d	Thu 10/7/99	Mon 1/17/00					
6	Establish Master Binders	43d	Thu 10/7/99	Mon 12/6/99					
7	Procedures History Binder (Scott)	1d	Thu 10/7/99	Thu 10/7/99					
8	Project Master Binder (Scott)	1d	Thu 10/7/99	Thu 10/7/99					
9	Define Documentation Systems	25d	Tue 11/2/99	Mon 12/6/99					
10	Document Company Quality Policy	35d	Tue 11/2/99	Mon 12/20/99					
11	Tailor Company Quality Systems Manual	30d	Tue 12/7/99	Mon 1/17/00					
12									
13	Registrar Selection	110d	Mon 10/11/99	Fri 3/10/00					
14	Preparation, Initial Selection	35d	Mon 10/11/99	Fri 11/26/99					
15	Contact, Complete Rating Sheet	30d	Mon 11/29/99	Fri 1/7/00					
16	Interviews (2 to 4)	15d	Mon 1/10/00	Fri 1/28/00					
17	Agree on Scope, Fees, Audit Dates	30d	Mon 1/31/00	Fri 3/10/00					
18									
19	Awareness & Mapping Meeting - Management	94d	Wed 10/27/99	Mon 3/6/00					
20	ISO Overview	1d	Wed 10/27/99	Wed 10/27/99					
21	Process Mapping	1d	Wed 10/27/99	Wed 10/27/99					

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## Quality Management System Implementation

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# Notes & Commentary

This is a snippet from a Project Plan in project software. I am a firm believer in project plans. Even smaller companies should use a plan. I am also aware of how often they change with circumstances.

I highly recommend a tracking method. One of the worst things you can do in an implementation is lose control of the status of the project on a level of individual responsibilities. At Motorola in Guadalajara we help meetings every Thursday. It was in the 'War Room'. Chairs were removed from the conference room. Each element had been assigned to a point person. Systems documents and status were posted on the walls as well as an overall progress chart. Every 'point person' had 5 minutes to state the status of their element and 5 minutes more to answer questions. The plant manager and all upper management attended each meeting. Absences were simply not allowed and there were none.

This forced communication and an honest assessment weekly (we did the implementation in 6 months - ~4000 souls). If someone had a resource issue, this meeting is where it was to be brought up for immediate resolution (no waiting while upper management 'thinks about it').

**See slide titled: 'Typical' Detailed Implementation Steps Example**

# Support of Upper Management?

On 2/7/01 12:31 PM in article jEfg6.51\$t52.2005@bgtnsc05-news.ops.worldnet.att.net, WL at xxxx@worldnet.att.net wrote :

>> You could bet your house on the statement "never, ever has  
>> there been an implementation of any quality system without  
>> top management's full support".  
>>  
>> Many champions of change have tried, and been fired for their  
>> insubordination.

Nonsense. Many implementations do, in fact, succeed without the 'full' support of top management. Change your statement to read "...without *some* support from top management..." and I'll agree. *Also see the Project Kickoff slide herein.*

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## Notes & Commentary

I have seen implementations where the company owner refused to take any part of the process - top management did only what they had to (like holding management review meetings which the owner did not attend). One specific company (of several) I have in mind I worked with closely. They did the implementation and registration because a customer required them to. ISO has done nothing for the business other than to be a yearly expense and to satisfy one 3rd tier automotive customer. How is this so? At best, ISO 9K is no more than good business sense. The company was well run before it was ISO. As the owner said, I need this for what? He termed it for what it is to him - a new 'cost of doing business'. Nothing less than another tax.

Another is a supplier of transportation services to Ford. Ford required ISO 9K so they did it. But, as the owner wryly observed, Ford needs ISO one hell of a lot more than they do - and he is right. The Ford plant they service is QS-9000 (well, there was a threat to take their cert away in 2000 so there was a crash compliance program). The owner of that trucking company also refused to be part of the ISO process. Top management there also does only what is required to keep their certificate. But again, the company is well run to begin with. To them ISO is common sense. They do very little differently than they did before registration. To them it is simply a new **tax** - a cost of doing business in today's world.



## A Management Committee

Most companies establish a **management committee** (**Steering Committee**) to ensure buy-in and to ensure communication. No one likes dictates and surprises in an implementation project.

Obviously if there are only 25 employees in your company a committee may not make sense. However, this does not reduce the necessity to appropriately (*we must use common sense here*) communicate with employees to ensure everyone has a chance to **buy into the process**, **provide inputs** and to respond to **outputs**.

## Notes & Commentary

Understand that the existence of a 'steering committee' does not guarantee success.

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# Project Kickoff

Many companies schedule a *Kickoff Meeting* to establish the project as official. While it is typical for 'upper management' (the 'top dog') to play a mostly invisible part in the project, the 'top dog' should be at this meeting as well as other 'upper' and middle management folks. The 'top dog' should (must?) voice his/her total support for the project.

This is where top management personally pledges support for the project.

## Notes & Commentary

Time to let everyone know what's happening!

For example, an ISO introduction seminar and awareness training is also a good idea. But do you train everyone, including hourly? One client did just that. It was a 3 day course / rolling project. All shifts. With most of my clients I leave awareness training on that level to managers and to internal auditors during the first complete phase of internal auditing.

My only point here is that training is necessary but how this is done is variable. With Motorola Phoenix, I attended meetings regularly on a rolling basis visiting all the groups on the managers level. We also gave several large training 'seminars' and went into the fabs and other manufacturing areas. Some members of upper management were given one-on-one training. Line level personnel were trained by managers and internal auditors.

## What Does This Mean To YOU?

- Check your local newspaper 'Help Wanted' advertisements.
- You will see ISO9000 Experience Preferred or ISO9000 Experience Required.
- No matter where you go in the world, working in an ISO 9000 environment is a Plus in employment.

## *Notes & Commentary*

This is a slide you may want to use in explaining what to expect to employees.

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# Premise

- **Old:**

The other shift must have done that.

That's not my job.

I'm manufacturing (or quality or whatever...)

They brought it to me that way.

- **New:**

Check incoming.

It is everyone's job to Be Involved and to Care.

We're all one company! It's your job, too!

Communicate!

## *Notes & Commentary*

This is a slide you may want to use in explaining what to expect to employees.

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## Discovery! The Sweeps!

- Open your eyes during this **Discovery** Period - there are **things you can't see**.
- Ask yourself about **what** your jobs are and the **details** of each job.
- Self Inspection - Be aware of the output of your jobs. **You are responsible**.
- Be looking for **improvements** at all times.
- Remember that we are not here to **blindly document everything**.

## *Notes & Commentary*

This is a slide you may want to use in explaining what to expect to employees.

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## Success Based Upon

- Communication - ensure your 'borders', talk to your neighbors.
- Communication - your business is a machine where many parts must 'talk' to each other.
- Communication - tell your neighbor your problems and listen to your neighbor's problems.

## *Notes & Commentary*

This is a slide you may want to use in explaining what to expect to employees.

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## Old and New

- Most of your audits up until now have been **Product** and **Process** audits by **Customers**.
- ISO9000 is a **Systems** audit which focuses on all systems and all products. A significant feature is a focus on *process interactions*.

**Second Party  
Audit**

**Third Party  
Audit**

## *Notes & Commentary*

This is a slide you may want to use in explaining what to expect to employees.

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## Remember -- The Idea is NOT....

- To start a lot of **new** documentation. Scott Adams is wrong (Dilbert). Not everything, like handling (often), has to be documented. But - we must use **common sense**.
- To change the way you do things every day.
- To 'Right Every Wrong'. Take the easy stuff and change it. Take the 'Hard' stuff - Identify it and make a Plan to address the issue

## *Notes & Commentary*

This is a slide you may want to use in explaining what to expect to employees.

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# The Basics

## Say What You Do

This means document your systems so you will consistently do the job the same way every time. We must make sure we have appropriate documentation. Use **common sense!**

## Do What You Say

This is what the auditors want to see. Objective evidence that what you say you are doing in your documentation is what you are doing in practice.

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## *Notes & Commentary*

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## Things to Know

- **Know what documentation affects YOU!**

You must know what documentation applies to your job. This should have been told to you when you were trained to do the job. If you are not sure what documentation applies to you, ASK YOUR SUPERVISOR or TRAINER **before** the audit.

- You must **follow all documentation** that applies to you. If it says you do something a certain way, you **must** do it that way.
- You must **complete all forms**. If you are supposed to initial and date when you do something, the auditors will check to ensure you complete the form the way you are supposed to.
- **Know what training you have had**. If you do not know, ASK YOUR SUPERVISOR **NOW! Don't wait until the audit!**

## *Notes & Commentary*

This is a slide you may want to use in explaining what to expect to employees.

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## Organization and Friendliness

- Look at shelves, work areas.
  - Are they obviously **orderly**?
  - Are they '**friendly**' to work with?
  - Are shelf labels **correct**?
- Common sense
  - Are carriers **stacked correctly**?
  - Are there any **old** labels or other identification on carriers?

## *Notes & Commentary*

This is a slide you may want to use in explaining what to expect to employees.

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## Managers Should Think About...

- **Hand Revisions**

Have Any Work Instructions, Visual Aids, or Other Process Documentation Been Updated By Hand?

If So, Are They Signed and Dated?

What is your company policy on white-out?

- **Measurement & Test Equipment**

Is All Measurement and Test Equipment Calibrated and properly Labeled?

- **Defective Material**

Is Defective Material Identified and Segregated?

Is A Defective Material HOLD Area Identified?

## *Notes & Commentary*

This is a slide you may want to use in explaining what to expect to employees.

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## Last Things to Think About

- **Employee Training - System in Process**
  - Do You Know the Training Requirements Of Your Job Position?
  - Is Each Employee Trained?
  - Where Are Training Records Kept?
  - Are Training Records Up To Date?
- **SPC**
  - Are People Keeping SPC Charts Trained in SPC?
  - Are SPC Charts Current and Being Utilized?
  - Are Trends Identified and is Corrective Action Taken?
- **Work Areas**
  - Are Work Areas Clean and Orderly?
- **Baskets, Boxes, Racks, Shelves & Other Containers**
  - Is Each Properly Labeled (Identified)?
  - Are They Where They Are Supposed To Be?

## Notes & Commentary

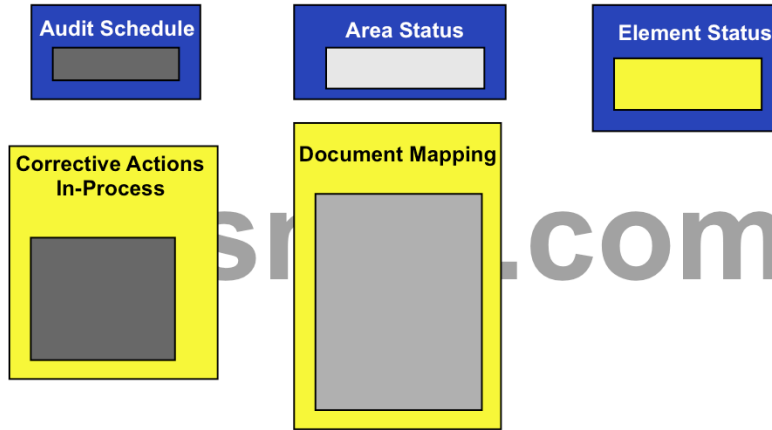
This is a slide you may want to use in explaining what to expect to employees.

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# A "War Room"

(Status and Tracking)

## QS-9000 / ISO 9001 War Room Wall



We need a way to track **What is Happening**, **Who is Responsible** for **What**, and what the **Status** is! I suggest a 'War Room'. One place where everything is visible and available. Updates should be by the responsible persons and the team should discuss each on a weekly basis. From this, the future **focus** can be determined. The focus may change from week to week.

**General status and focus should be reviewed weekly in the Staff Meeting.**

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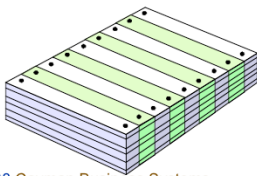
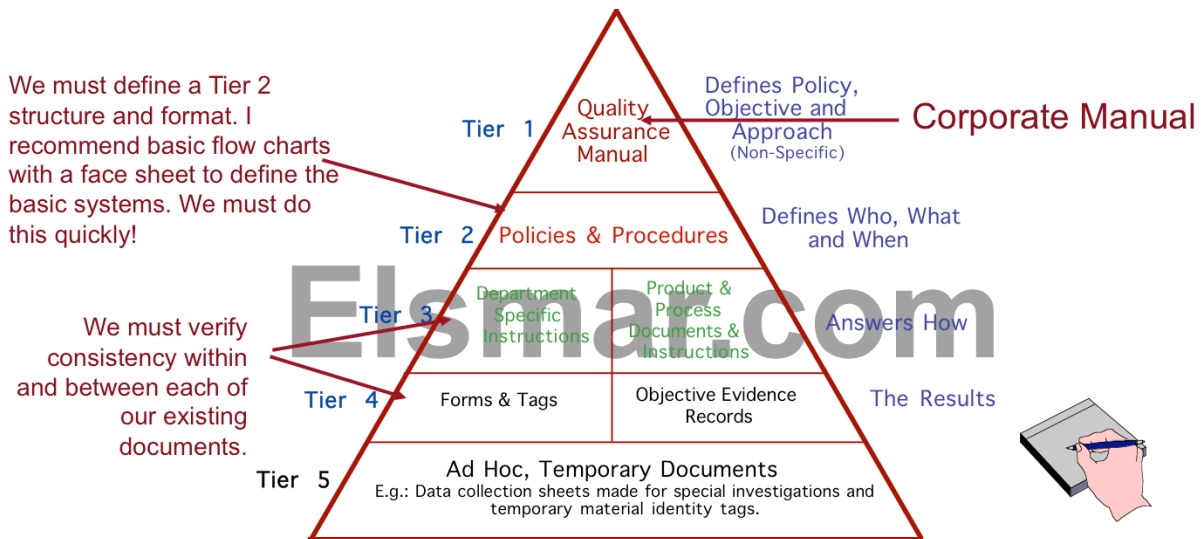
## *Notes & Commentary*

A war room is of little importance in very small firms. In larger companies (>50 employees) it really depends upon how quickly you want to move your project as well as how organized and disciplined your company is to begin with. In larger companies it offers a good way to control and track the project. It is more important when the project is a fast-track project.

I have seen resistance to establishing a war room. I like them, personally, particularly when it is an accelerated project.

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# Discovery and Classification



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We know we have to comply with the corporate Quality Systems manual. We also know the corporate manual is insufficient and in many places is totally incorrect. We must determine a corporate contact to communicate inconsistencies to. We must map the inconsistencies. We must then map our internal documentation in the same way. All references must follow in numbering, subject and expected content.

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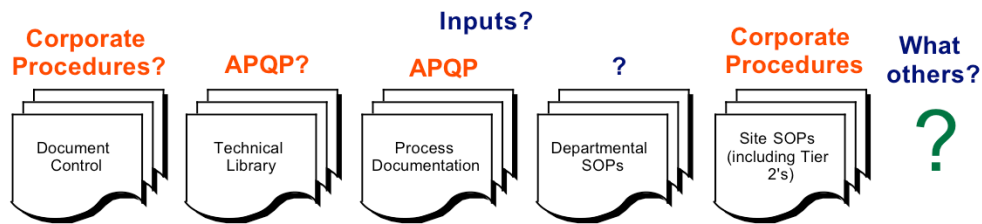
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# Notes & Commentary

Prior to going through your Discovery Sweeps, it is necessary for you to determine specifically what document classifications exist in your company. In a small company this may not be a big issue. In larger companies it often is in large part because of the way documents evolve in some larger companies. Some companies are already well structured and the structure is understood, but in many it is not. It is more common than say 10 years ago for companies to have some control over documents. But - don't leave to chance. Make sure your structure is well defined, particularly if you are in a bigger company where corporate procedures will effect your procedures through Flow Downs. Please don't scrimp here. It is important that all of your documentation be clear and consistent. Links between documents **must** be valid and appropriate.

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# Define Document Types (Classifications)



Is Control Methodology Documented?  
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We need to **verify** document links - **LINKS** are Connections to and from other documents. We also need to verify that the links are what we expect.

We need to **validate** document contents - Are the contents being followed?

Are terms **within** and **between** documents **Consistent**?

Are we all using the same Terminology (names, for example) when referring to a specific document or process?

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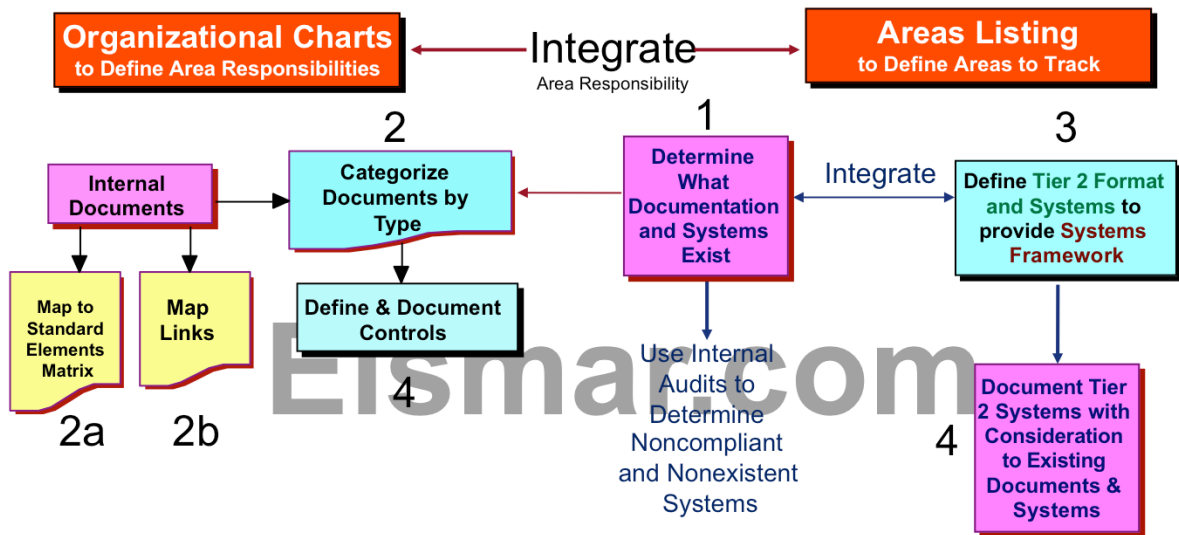
## *Notes & Commentary*

This is an example from one former client where we discussed a document classification structure. This was from a discussion session. We looked at document types and where they came from.

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## More on Documentation



Also use Internal Audits to identify weak and non-compliant areas and to track corrective actions (drive compliance efforts).

### Example Measurables:

- Internal Audits Results
- Compliance to Standard Matrix
- Area Responsibilities Matrix

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## Notes & Commentary

This is the strategy we used at Harley-Davidson. Note that we established 3 measurables. These were used to track project progress. A War Room was established early in the project.

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Interviewing A Registrar

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*Notes & Commentary*

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## Basics

- I want to remind you that choosing a registrar is like choosing a **life partner**. While it may not be 'Until death do us part', it is quite close.
- The intent herein is **not** for every question to be asked, but rather as a sort of check list to jog your thoughts with respect to **YOUR** company's requirements.

**Do remember that anything not discussed early is subject to interpretation later!**

- **Some important starters:**

Who (e.g.: RAB) is the registrar approved by?

Will the registrar provide client names and references?

How many Man days and how many Auditors? (Registration vs Surveillance)

How do they conduct surveillance visits? Scheduled or unscheduled?

**Note:** There is some redundancy of questions within this presentation.

## *Notes & Commentary*

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## Inform & Discuss

- **Plant Layout** - Have a copy to give them for planning.
- **Number of shifts and employees per shift** - What shifts will be audited? What hours?
- **Pre-assessment Audit?** - If so, **Scope**. I prefer the preassessment to be limited to an in-house document and systems review (**Quality Manual, all tier [level] 2's and any related documentation**). My concern is less 'are the folks following documentation' than 'is the documentation and are the systems acceptable' to the registrar. We can assure the folks are following documentation internally. **Note: One company I spoke with charged for a Pre-assessment whether you had one or not. I was told that if they did not do a pre-assessment they would have to spend more time during the registration assessment.**  
**NOTE: Documentation failure is the most common registration failure mode.**
- **DoD and other Sensitive Areas** - Make sure everyone agrees on how they will address the 'Secret' / 'Top Secret' aspects of your company's business. This will probably be a function of scope.

## *Notes & Commentary*

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## About The Auditors

- What are the registrar's qualifications requirements for auditors? (for hiring or using an auditor) Are the auditors trained and certified under ISO 10011 (guidelines for auditing quality systems)?
- How many organizations has the typical auditor certified? (Audits per year)
- How many assessors does the registrar have?
- What is the turnover rate for assessors in the registrar's company? If there is high turnover that will affect the consistency of the assessment service they provide.
- How are auditor substitutions handled?
- Does the company provide training for auditors and other personnel to keep them abreast of developments in their specific discipline? Are there training records? Frequency of training?
- Will he/she/they (auditor[s]) be available for an interview for your company to assess their suitability? (I doubt you will really want to do this, but many big companies do this.)

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# Questions & Thoughts 1

- What are your requirements as a registrar above and beyond ISO9001?
  - Request hard copy of their 'Contract Requirements'
  - Ask if there are any requirements not on their 'Contract Requirements' listing.
- Are the registrar's auditors **direct hire full-time** employees or are they **contract**?
- Will your company have the **same** Lead Auditor **every** audit (a Project Lead Auditor)?
  - NOTE: Most registrars 'appoint' a specific person as a project manager (project lead auditor or what ever the registrar calls it). Ask about how the registrar you are interviewing structures their projects.
- Will the registrar send the Project Lead Auditor on each audit or will a substitute be assigned for surveillance audits?
- Will only the Lead Auditor have experience in the industry or will every member of the audit team?

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## Questions & Thoughts 2

- How far in advance do they **notify you of an impending audit**, and **provide you with an audit schedule**. This will help you prepare for the audit easily if they provide **at least** 6 weeks.
- How many **hours per day** is planned during an audit? **Some companies consider a day in-plant as 6 hours saying the other time is 'report writing' time.**
- Ask the registrar to explain the **details of their billing**.
- Are there any **extra charges** and **tie this down in a written quote**. **Are travel and lodging expenses covered by the bid? Rental car(s)? There are stories of some companies charging extra for each non-conformance report.**
- What quality system does the registrar have in place? **Request a copy of their Quality Manual.**
- Will they provide you with **their** internal audit schedule and results of audits and corrective and preventative action?

## *Notes & Commentary*

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## Questions & Thoughts 3

- How long will it take them to issue you a certificate once they have recommended you for approval?
- How long has the registrar been in business, and do they have any European or Far East affiliates in the registration business?
- If you will one day be going for ISO14000, does the registrar support this standard as well, and would they be able to combine (thereby reducing the man-days at your site, and \$s) the ISO9000 audit with the 14000 audit?
- Who does documentation assessment and who does the audit? What is their experience / qualifications?

## *Notes & Commentary*

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# The Audits

- How many **Man Days**?  
Registration Audit  
Surveillance Audits
- How many weeks in advance do they provide the **detailed audit schedule**?
- Is there a '**Complete**' re-audit every three years? Or do they audit on a '**continuous**' basis?
- **Surveillance Audits**  
Frequency - Every 6 months or yearly? (Ask their thoughts)  
How much is audited in each surveillance audit?

## *Notes & Commentary*

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## Communications

- I want to address this briefly, but note it is very important. One registrar I dealt with took over a month to respond to questions. A week maximum is appropriate. I've seen phone calls to be returned forgotten. This area can be critical to your company. You want a **responsive** registrar.

How long does it take their office to respond to questions (typically)?

If it becomes necessary to speak with the Project Lead Auditor, how is that done and how soon after the request will the Project Lead Auditor contact your company?

## *Notes & Commentary*

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# Specification Interpretations

One of the biggest complaints with ISO9001 is **interpretation of the standard**. Each auditor has his/her own paradigm and thus expectations. This is one of the reasons why having the same auditors is preferred. This is also the reason why I prefer the pre-assessment be limited to an on-site document review where the auditors set up in offices or a conference room. There they review the Quality Manual against the level 2's in interviews. Level 3 documents are reviewed and objective evidence provided as requested - however, this is all done in the conference room, NOT on the floor. In short - Are our systems acceptable.

This type of audit is a **Verification** Audit as opposed to a **Validation** Audit which is where they actually hit the floor. Now - the 2 big questions:

- 1) How are disputes with an audit finding handled? Ask them to explain their system. **(Request a copy of their procedure!)**
- 2) How does the registrar **ensure consistency of interpretations** within their company? Some companies have weekly in-house meetings, some have conference calls, some do nothing. **THIS IS IMPORTANT!!!**

*Notes & Commentary*

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## What's In A Contract Anyway?

- When you get a copy of the registrar's contract, **read every word** and try to **imagine the worst possible scenario**. Some time back when I was casting about for a registrar, one sent me a contract which stated the following for audit costs:
- XXXXXX "reserves the right to increase charges during the certification period".
- Another said: "...approximately 45 days prior to the anniversary date of certificate issuance, XXXXXX shall notify the client in writing of the annual costs to maintain the certificate."
- These appear to me to be licenses to steal. It would seem prudent to get these things tied down in your initial contract.
- Remember: **Contract Review!**

## *Notes & Commentary*

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## Audit Nonconformance Questions

- How shall we be notified of non-conformancies or deficiencies?
- What is the **typical response time allowed** for initial response to a nonconformance identified during an audit:

**Major nonconformance**

**Minor nonconformance**

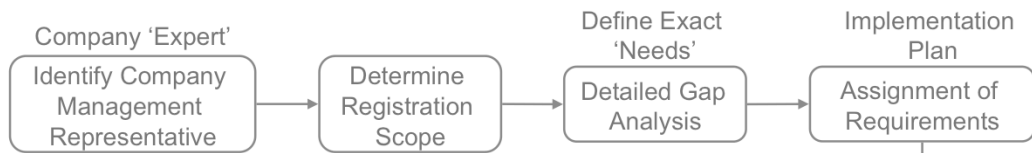
- Will a nonconformance during the initial assessment require a partial or **follow up assessment** to verify corrective action? If yes, what shall the **cost of follow up audits** be?  
**NOTE:** Typically if there are 1 or more MAJOR non-conformances, they have to make a return visit. Minors are typically followed up by mail, FAX, etc.
- Can we be recommended for certification if there are still some minor open non-conformances? Determine details.
- How many months of internal audit records do you require before scheduling an audit?

*Notes & Commentary*

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# Project Actions

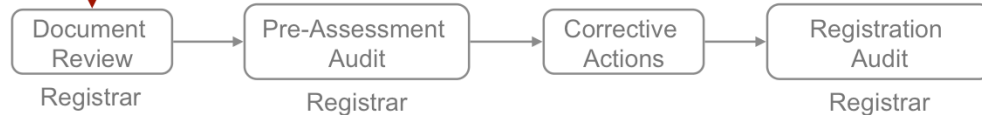
## Project Definition



## Project Actions



## Project Fulfillment



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# Notes & Commentary

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Sweeps - The *Discovery* Phase

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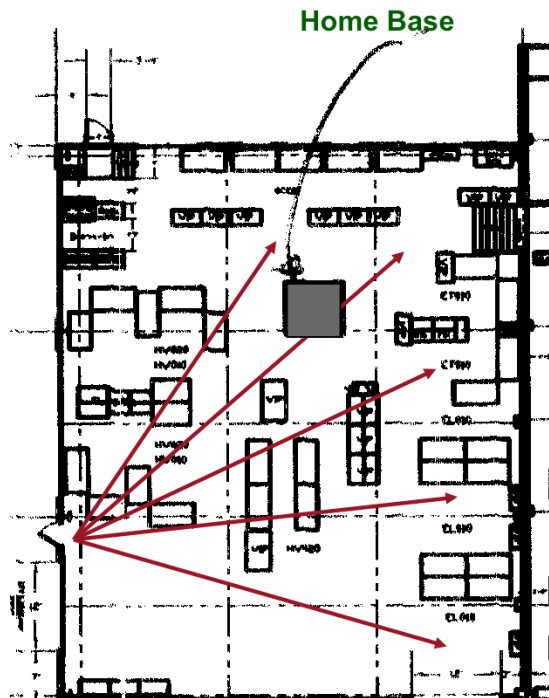
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*Notes & Commentary*

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# Sweeps



## Methodologies:

1. Decide on a **Home Base**
2. From a corner of the room, radiate out as a team.  
Or  
Divide the area up into sectors with one person per sector.
3. **Collect samples** of or make copies of forms, tags and other 'documents'. Bring to **Home Base**.
4. **Make notes** of problems you find.
5. **Mark** each wall, desk, shelf, etc. that you have visited.

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## Notes & Commentary

The first thing I want a client to do is to 'Sweep' their facility. Every room. Every office.

**If you don't know what you have, you can't address everything.**

One of the things that never ceases to amaze me is how many things companies find. In one manufacturing area in 1998 we found a specification from 1984. No one knew what it was there for. Probably a project from long ago. In some companies I have seen memos that were 5 years old on bulletin boards. You might find, in one building, that some bulletin boards are always up to date while others are years out of date. A sampling will not catch this type of problem.

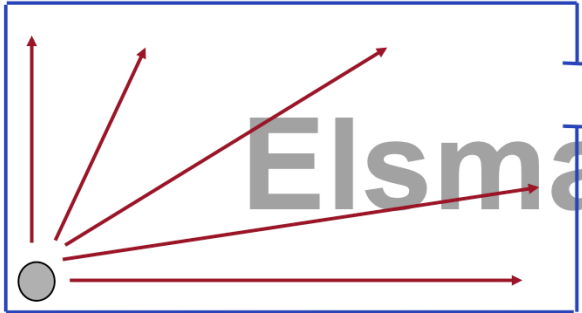
The most common type of problem identified during sweeps is that of 'work instructions' at work stations, in cubicles on walls and similar spaces. Post-it notes are famous 'work instructions'.

Be on the lookout for use of white-out and ensure its use, if any, reflects company policy.



## Where to Start - Documentation

### Discovery *Inventory*



Documents of External Origin **MUST** be included

Ideas to start with:

- Document Type List ,
- A 'Standard' Check List, and
- A Problems Found Log.

Choose a Method of Control

Take a corner of the room and begin a sweep.

Look in every drawer, on every shelf, at every machine and all inspection and test equipment.

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## *Notes & Commentary*

The sweeps at one client facility of about 200 employees produced over 2 dumpsters of outdated 'junk' documents of all kinds. A number of hazardous chemicals were identified in storage rooms which had long ago been 'forgotten' about. In the lab outdated reagents were identified. On the surface the facility was neat, organized and clean. The detailed sweeps revealed the soft underbelly of the reality.

If you decide sweeps are not necessary in your implementation, be prepared for surprises.

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# Identification

- Choose a method of verifying a swept area.
- One method I have used it to obtain some sheets of adhesive labels (we used the small coloured dots). You might want to make sure they are 'easy peel' labels. Label every drawer, shelf and other area swept 'as you go'. Person checking initials, dates and places the dot where it is easily seen.

## *Notes & Commentary*

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# Sweeping An Area - I

## Things to look for:

### Documents

- Local "How To..." documents
- Specifications
- Prints

### Forms, Tags

### Measurement and Test Equipment

## Where to look:

On every shelf

In every drawer

At every work station

On every wall

**Under** every table, desk, etc.

## Notes & Commentary

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## Sweeping An Area - II

### Things to ask yourself as you look:

#### Documents

- Is there a date on the document?
- Does it appear to be 'valid' ([current](#))?
- If it is a hand written document or a company 'memo', is there a name or department on it? Whose is it?
- Is it a system document? What system?

#### Shelves

- What is on the shelf? Is it garbage?
- Is the shelf labeled? Are some shelves labeled and some not labeled? If so, why?
- If the shelf is labeled, does what is on the shelf match the shelf label?

*Notes & Commentary*

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# Some Things To Think About...

## Work Instructions

- Does Your Job Have Relevant Work Instructions? Does It Need Work Instructions?
- Are Work Instructions Controlled?
- Is Each Signed & Dated?
- Who is the Keeper of a Master List & Where is it Kept?

## Hand Revisions

- Have Any Work Instructions, Visual Aids, or Other Process Documentation Been Updated By Hand?
- If So, Are They Signed and Dated?

## Measurement & Test Equipment

- Is All Measurement and Test Equipment Calibrated and properly Labeled?

## Equipment Preventive Maintenance

- Are All Equipment PMs Up To Date and to a Schedule?

## Notes & Commentary

As you go through the 'advice' in these slides, remember that your company may not, for example, have paper work instructions. You have to look at your company and decide exactly what to look for and look at.

Make up a check list (example follows) and keep to it!

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# More(!) Things to Think About

## Defective Material

- Is Defective Material Identified and Segregated? How?
- Is A Defective Material 'HOLD' Area Identified?

## Work Areas

- Are Work Areas Clean and Orderly?

## Baskets, Boxes, Racks, Shelves & Other Containers

- Is Each Properly Labeled (Identified)?
- Are They Where They Are Supposed To Be?

## Employee Training

- Do You Know the Training Requirements Of Your Job Position?
- Is Each Employee Trained? How do we know?
- Where Are Training Records Kept?
- Are Training Records Up To Date?

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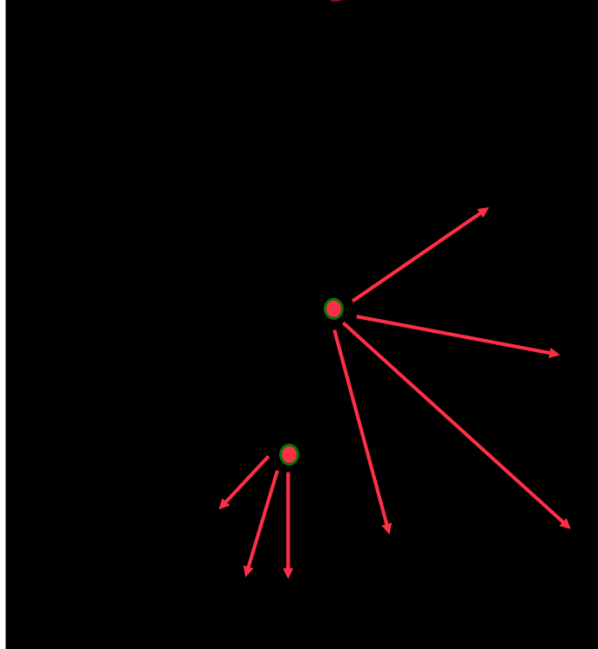
## Organization and Friendliness

- Look at shelves, work areas.
  - Are they obviously **orderly**?
  - Are they '**friendly**' to work with?
  - Are shelf labels **correct**?
  - Is there anything like glue or ink which has an **expiration date**?
- Common sense
  - Are carriers **stacked correctly**?
  - Are there any **old** labels or other identification on carriers?

## *Notes & Commentary*

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# Discovery Phase (Sweeps) Check List



**Ensure your entire area is swept! Check your map!**

## Places to Check for *Documents*

- ☐ Drawers
- ☐ Book shelves
- ☐ Storage shelves
- ☐ Walls
- ☐ On manufacturing equipment
- ☐ On measurement and test equipment
- ☐ Work areas / benches

## A word about *Order...*

When the auditors come in they will be looking for ORDER. In short, a place for everything and everything in its place. This means much more than you may think! The theory among auditors is that the more orderly a place is the more 'in control' the place is.

And - that is generally a truism! It's a good idea!

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## *Notes & Commentary*

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# Discovery Phase Check List

Area \_\_\_\_\_ Date \_\_\_\_\_ Responsible Mgr. \_\_\_\_\_

## Process Documentation

- ☐ What do you do when you know process documentation is incorrect?
- ☐ How do you know your documentation is the most current version?

## Process Equipment I

- ☐ Are there any hand written settings, instructions or other 'documentation' on equipment?
- ☐ Is Preventive Maintenance identified & performed?

## Documents of External Origin

- ☐ Are there any specifications or other documents not originated within our company? If so, is the Document TYPE on the Documentation Hierarchy Matrix?

## Process Equipment II

- ☐ Can it be explained what gages or other measurement instruments on production equipment should be calibrated or why calibration is **not** necessary?
- ☐ Are there any stickers, pointers or written settings on any of gages or controls? If so, are they 'legal'?

## Miscellaneous Documents

- ☐ Do you have any personal 'Cheat Sheets' which you use to do your job? Are they 'legal'?
- ☐ Are there any 'unofficial' process related documents posted at work stations or on walls?

- ☐ Do you have equipment or other instruction manuals? How are they 'controlled'?

## Housekeeping

- ☐ Can you explain why some shelves are labeled and some are not?
- ☐ Are all labeled shelves correctly labeled?
- ☐ Are work areas neat and orderly?

## Handling and Storage

- ☐ Are carriers properly stacked?
- ☐ Are carriers properly labeled?
- ☐ Is the ESD policy understood and followed?

## Communication

- ☐ For every 'job' there are inputs and outputs. Inputs are typically from other people and often from other 'departments'. Can you identify your inputs and outputs?
- ☐ Are you communicating problems you find with the appropriate person and department?

## Measurement & Test Equipment (Calibration)

- ☐ Does every piece of Measurement and Test equipment have an 'appropriate' label?
- ☐ Are there any hand written labels / specs / instructions on equipment?

## Nonconforming Product

- ☐ Is nonconforming product isolated from the immediate production area?
- ☐ Is the local system for Nonconforming Product understood and followed?

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## Notes & Commentary

Here we have a 'Discovery Phase Check List'. What about service companies? Service folks don't have traditional Measurement and Test Equipment, for example.

You do, probably, have 'process documentation'. You do have Documents of External Origin. You do have process equipment (maybe computers in a call centre). You do have Nonconforming Product.

Here is where thought comes into play. Sometimes a service industry has a difficult time defining their 'product' initially. The next big step of determining and defining exactly what nonconforming product is tends to be a stumper. For example, if you sell insurance - What will you define as nonconforming product?

For now, take a close look at the above check sheet. You might want to change it a bit but the concept applies. Obviously, I'm a Check List fanatic...

## Documentation - The Details

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*Notes & Commentary*

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## Why the Stress on Documentation?

- The majority of failures in both QS and ISO 9000 registration efforts has been, and continues to be, 4.2 Documentation Requirements (QS element 4.5).
- This issue is almost always evident from my first visit and I believe we all know this is typically a *deep* problem.
- *Discontinuity* is often discovered in the documentation. Even Quality Manuals are shown to have invalid links.
- Auditors will focus on the *continuity* and flow of documentation. Inconsistencies can keep the facility from passing the registration audit.

## Notes & Commentary

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# What is Documentation?

- Documentation is much talked about. There are different types. At Motorola, for example, there are corporate 12M's. Sectors each have SOPs and maintains a Quality Systems Manual. Each facility has their own specific documentation (which must correlate with Sector and corporate documentation. There is also process documentation in the manufacturing areas.
- Everyone uses documentation outside of work. If you buy something (like a clock), there are [instructions](#) in the box. That is documentation.
- [Think of documentation as instructions](#). Documentation explains how to do things.
- The auditor's job is to make sure everyone is 'Following Instructions'.

*Notes & Commentary*

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## An Everyday Work Instruction

This is the 'Work Instruction' which comes with an aquarium heater. It gives the user some basic information. Note that there are graphics (several in multiple languages) in addition to the basic text. There is also a 'selection' guide for the purchaser.

**VISI-THERM**

VISI-THERM is a submersible aquarium heater with these important features:

- D- Unique direct reading temperature setting feature eliminates guesswork. The desired temperature is indicated directly on the thermometer scale and is accurately maintained by the precision thermostat.
- E- Long-life power lamp indicates on and off cycles of heater.
- F- Local controls for the heating elements are safe and light weight. Unlike heavy ceramic or sand-filled heaters, the perfect balance permits most effective use of suction cups which will not be constantly loosened by excessive weight.

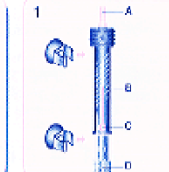
**DIRECTIONS**  
Write the letter of the correct answer in the space provided.

- You will find the surface cups inside the package. Attach the two pairs of insulated cover 1. Do not attach surface cups at any point on the heating element area of the tube.
- Set temperature by turning control stem until the thermometer scale on the front of the heater shows the approximate desired temperature. Read the point where the moving red line touches the longer outer scale. The right side shows the desired temperature in degrees Fahrenheit; the left side shows degrees Centigrade. However, the temperature should be confirmed by use of an accurate thermometer with the aspirin.
- A small difference between the reading of the thermometer and the temperature setting of the heater is acceptable.
- Position heater where there is continuous circulation of water (Fig. 4).

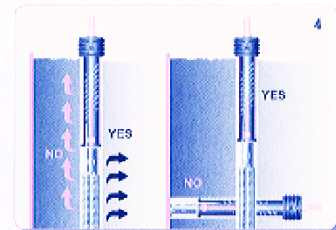
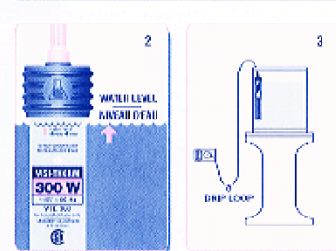
## LIMITED WARRANTY

[illegible]

SPARE PARTS  
PIECES DETACHEES  
PIEZAS DE REPUESTO



## FIGURES



## SELECTION GUIDE

Temp	25	50	75	100	150	200	250	300
6°C 9°F	25	50	50	75	100	150	200	250
10°C 18°F	25	50	75	100	150	200	250	300
19°C 27°F	75	150	150	200	300	2 x 200	2 x 250	2 x 300
Gallons	8	16	20	25	40	50	63	75

$\Delta t^0 = \frac{1}{t^0} - \frac{1}{t^0}$

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## Notes & Commentary

This is an example of a Work Instruction for operation of a commercial product. Their importance is often over looked. The notable trials at Christmas time and birthdays by parents of children is excellent anecdotal evidence for this. We're in a hurry or the product manufacturer provides poor instructions and we have stories for later in life about the birthday where mom and/or dad had to assemble a bicycle.

When I was young I build a number of plastic and wood models. From the ‘Visible man’ to a ‘working’ submarine to a balsa model of the Kon Tiki to many aircraft - I built quite a few models. The instructions played an important part in every project. From sequence to “...insert tab A in slot A...”, the instructions tell what has to be done.

Your internal work instructions are no different, really. The important part is knowing where you should have work instructions and where training or experience negates the need for work instructions. There are no hard and fast rules. It is mostly common sense.

Another aspect of work instructions is how they fit into your overall system. Some companies have exacting software, often databases, which link documentation, make documents available to users and such. Some companies buy canned software and some companies write their own. I have had several clients who hired an outside firm to write their databases to their specifications.

## What is Controlled Documentation?

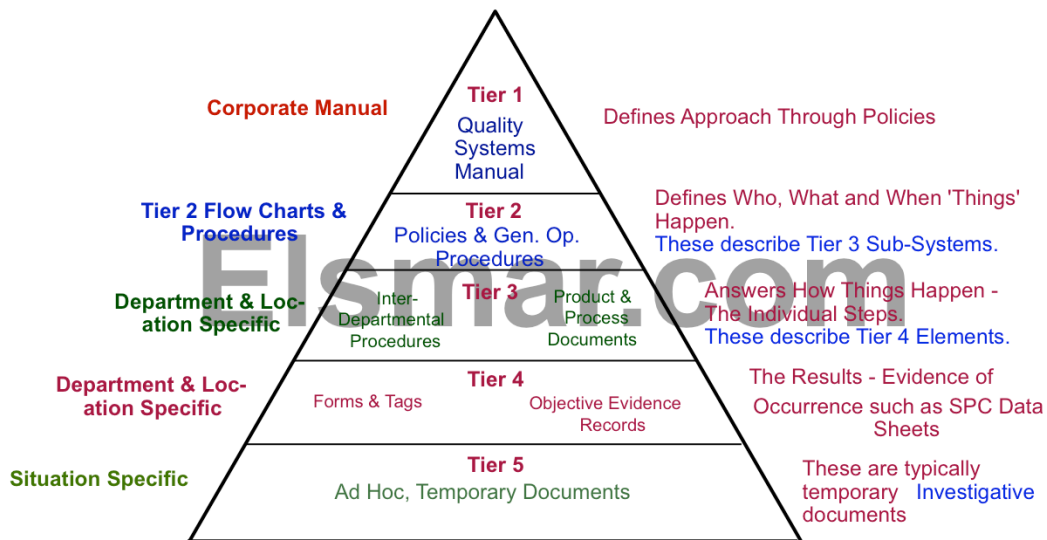
- A **controlled document** is typically one that is **Revision sensitive** - BUT - **Not always!!**
- If a controlled document is changed, a **record of the change** has to be made. This means we must have a **History of All Changes**.
- If a document is **changed**, **people who use it must know about the change**. This means there has to be a distribution list or other **effective** way to **let everyone who uses it know the document has changed**.
- Every employee must know how to check to see if documentation they are using is the **most current version**.

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# 'Standard' Documentation Pyramid



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## Notes & Commentary

This is a 'standard' documentation pyramid.

Tier 1 = Policies

Tier 2 = Think of these as Overviews of major systems (e.g.: Nonconformance system, Purchasing system, etc).

Tier 3 = The actual systems in detail

Tier 4 = Objective evidence - Proof that the systems are functioning as well as a source of data for various evaluations (such as inspection & test data).

# Documentation

- Organization Charts
- Procedures
- Forms
- Tags
- Prints
- Specifications
- Statistical Data
- Inspection & Test Results

## *Notes & Commentary*

These are examples of documentation. Documentation may be:

On Paper, A Computer File or Electronic Media, a Book

Documentation provides 'Rules' on how certain things *\*must\** be done or describes ATTRIBUTES.

A word about procedures:

Procedures do not have to be long text documents. They can be:

VERBAL, a simple FLOW CHART, or a TEXT DOCUMENT.

Procedures.



# Myths vs. Truths

- Documentation Is Meant To Be Easily Changed
- The Less Documentation, The Better

## Notes & Commentary

There may be some changes in the way you do the things you do but they should be minor, if any.

A common misconception is that once there is documentation, there is no easy way to change the documentation if it is wrong or ineffective or if it should be changed for another reason. This is NOT true. Documentation will be easily and quickly changed when necessary.

The idea is NOT to simply put in tons of 'written procedures' for people to follow. No procedure will be written detailing how to go to the bathroom or how to go to lunch, for example. It is difficult to quantify 'adequate', but the idea is to provide documentation which is 'adequate' to ensure quality and consistency of processes.

# Basic Rules

- Your Job & Documentation

**SAY** What You **Do**

Documentation

**DO** What You **Say** You Do

Actions

- If It's **Not WRITTEN** Down, It **DIDN'T** Happen

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## *Notes & Commentary*

Say what you do - this is the documentation (Tiers 2 & 3) which describes how jobs are performed.

Moves - Train: This means for every person doing a job, ensure training so that they can perform the function.

Doesn't - Calibrate: If it takes a measurement or provides a certain measurement (e.g.: torque tools), it **MUST** be calibrated.

If people do not complete forms and tags as necessary, there is no evidence that the event happened.

# Quality Records

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## *Notes & Commentary*

It is important for you to identify quality records as you go through your documents. Ensure where records are defined within a procedure or by a system, that it exists and is controlled. I have been into a number of companies where a procedure would call out a record which at some time was eliminated. The procedure was never revised to reflect the system change.

In the simple document matrix we are using as an example (Document\_Matrix\_Example.xls) you can see there are forms [blue type] (which are controlled documents) which become controlled records [red type]. The procedure calling out each record is, in this type of matrix, closely identified by sequence [procedure then form then record].

It is becoming more and more common for these to be electronic. That does not change the requirements, but many companies do not have a related matrix - they just rely on directory listings or something similar. While I have no problem not having a matrix which relates the documents (in large corporations this isn't feasible), remember there are typically many links / relationships which, over time, tend to 'get lost' in complicated systems.

## What Are Quality Records?

- Any record where data is taken where the data is a result of inspection and/or test
- Any record which provides for traceability
- Nonconformance related documents

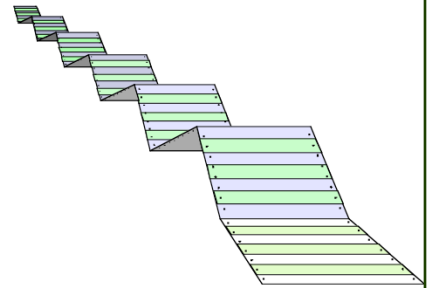
The bottom line here is we have to review our documents in a general sense and identify those which relate to quality issues

*Notes & Commentary*

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# Typical Types of Records

- Management Review Records
- Contract Review Records
- Purchasing (Purchase Orders)
- Identification and Traceability
- Process Control
- Inspection and Test Reports and Records
  - Qualification Reports
  - Validation Reports
  - Material Review Reports
- Control of Measurement and Test Equipment
  - Calibration Reports/Data
- Non-conforming Product
  - Disposition Records
- Corrective and Preventive Action
- Internal Quality Audits
- Training Records



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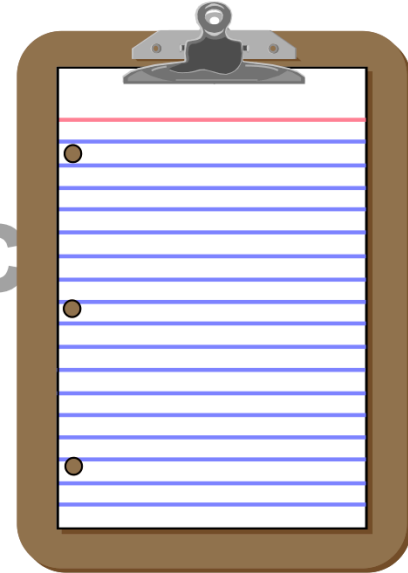
## Notes & Commentary

A complete listing of records expected (required) by ISO 9001 is in [Clause\\_Interp\\_and\\_Upgrading.doc](#). See the section titled **Records Required** around page 15.

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# Records Management Activities

- Management of Active records
- Records creation (forms)
- Design of records system
  - Retention schedule
  - Vital records protection
- Development of records procedures
  - Indexing
  - Filing
  - Access
  - Disposition



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# Records Required By ISO 9001

- 5.6.1 Management review minutes / etc.
- 6.2.2 (e) Education, training, skills and experience.
- 7.1 (d) Evidence that the realization processes and resulting product fulfill requirements.
- 7.2.2 Results of the review of requirements relating to the product and actions arising from the review.
- 7.3.2 Design and development inputs.
- 7.3.4 Results of design and development reviews and any necessary actions.
- 7.3.5 Results of design and development verification and any necessary actions.
- 7.3.6 Results of design and development validation and any necessary actions.
- 7.3.7 Results of the review of design and development changes and any necessary actions.
- 7.4.1 Results of supplier evaluations and actions arising from the evaluations.
- 7.5.2 (d) As required by the company to demonstrate the validation of processes where the resulting output cannot be verified by subsequent monitoring or measurement.
- 7.5.3 The unique identification of the product, where traceability is a requirement.
- 7.5.4 Customer property that is lost, damaged or otherwise found to be unsuitable for use.
- 7.6 (a) Standards used for calibration or verification of measuring equipment where no international or national measurement standards exist.
- 7.6 Validity of previous results when measuring equipment is found not to conform with its requirements.
- 7.6 Results of calibration and verification of measuring equipment
- 8.2.2 Internal audit results.
- 8.2.4 Evidence of product conformity with the acceptance criteria and indication of the authority responsible for the release of the product.
- 8.3 Nature of the product nonconformities and any subsequent actions taken, including concessions obtained.
- 8.5.2 Results of corrective actions.
- 8.5.3 Results of preventive actions.

## Notes & Commentary

These are the records called for in the standard. But don't get your hopes up. Your company will undoubtedly have plenty of other records which are quality records. One of the important parts of the effort is to define what your quality records are.

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# Document Mapping

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# Document Mapping

- In a structured system, there are 'levels' of documentation. In general terms we have the description of documentation in levels or tiers. As we learned earlier there are typically 4 tiers of documentation in an organization (excluding *Ad Hoc* documents).
- The top tiers normally guide the **content** and **focus** of the bottom tiers. In short, each successive lower tier is **DEPENDENT** upon the upper tier which defines it. This is said to be a 'Flow Down' of requirements.
- Higher level documents normally cite lower level documents. These citations are important as they form a 'trail' which can be followed. The top level documents tend to be general and to some extent vague while the lower level documents provide increasing detail.
- Sometimes the reverse also happens - lower level documents cite higher level documents internally. There is controversy as to whether this is 'good' practice. In my opinion, **requirements** should **Never** flow up.
- Document mapping is more important now than ever as mature companies shift towards interdisciplinary (**cross-functional**) communication and operation. The old way was for departments to 'pass off' to another department. The new way causes everyone to be involved. In short, the rise of the importance of **Teams** requires documentation to be more integrated and consistent - and thus the need for control is greater. This is also the reason for the 'review' requirement.

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## Notes & Commentary

Document mapping is typically done during and after the Discovery Sweeps. Until the sweeps are finished you may not know what all the documents are you have. This being the case, it is a dependency.

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## Mapping Aspects

- Mapping starts at the top with the QA Systems Manual. This may be a sector manual or it may be a local manual.
- **Validation** - When you map documents, you 'verify' links between documents (where one document cites another within it). The first thing to verify is that the cited document exists.
- A second aspect of mapping is to **verify that the content of the citation is relative**. This is to say that the links should 'make sense'. If a citation in one document says something like "The **audit will be performed** in accordance with procedure **ABC-1234**" and procedure **ABC-1234** is titled '**Calibration of Pressure Gages**', it is evident that the link is **NOT Valid!** It does not make sense!
- After verifying that the linked document both exists and that the links are 'relative' and make sense, the document is mapped to the matrix relative to the mapping project. In our case the matrix is QS 9000 line items against the document 'class'.

## Notes & Commentary

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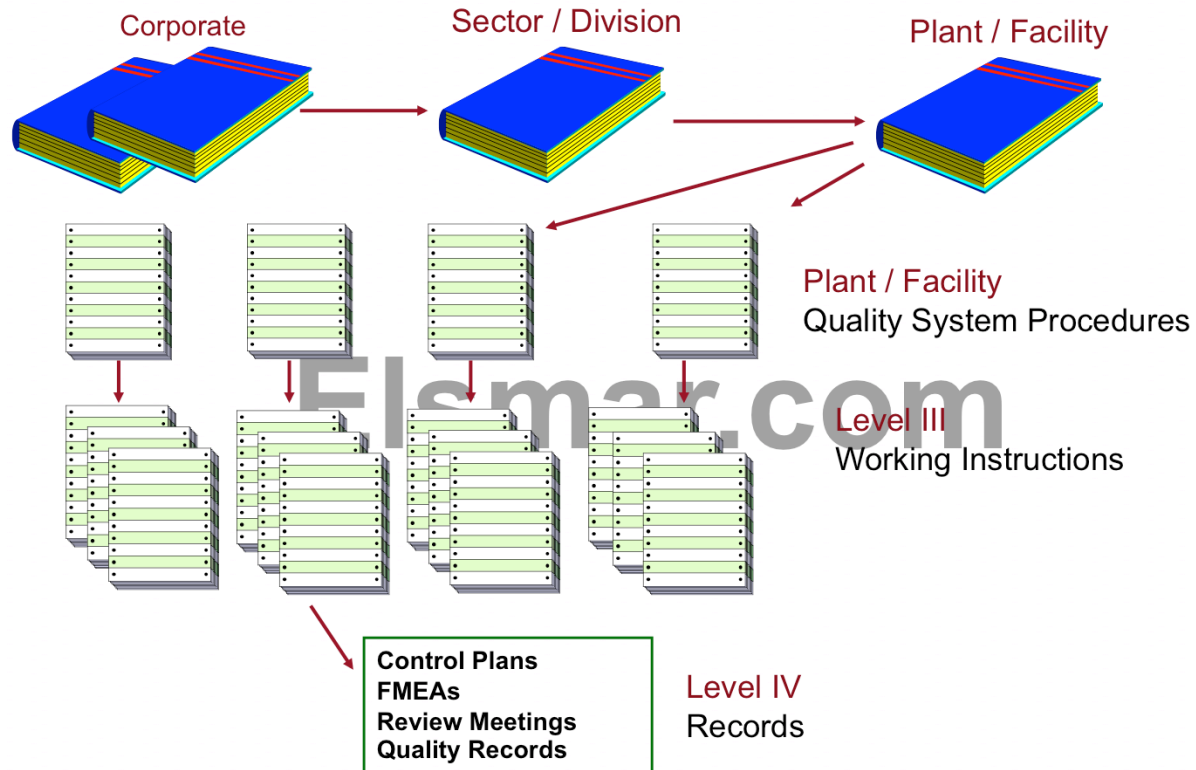
# Document Tiers & Classes

- It is uncommon to find 'Pure' documents. That is to say, it is not very often you find a document which one can clearly define as 'only' Tier I or Tier II or Tier III. In almost all cases there is some cross over. A good example is a Tier III **Procedure** with some places which will eventually be filled with data - which will then make it a **Record** (Tier IV).
- The idea of a defined border and thus a pure document is fine, but is seldom actually seen. Normally the closest you will come is with the Quality Systems Manual. A QSM will normally be the 'purest' document you will find within any given system.
- Purity is to some degree a function of company size. A company with only 20 to 50 employees with simple processes will generally have little need for 'pure' structure. The necessity of structure in very large companies necessitates a more defined documentation structure in large part due to necessary overall complexity.
- Also consider the idea of document classes. Classes may include **production** documents, **engineering** documents, **Human Resources** documents, **maintenance** documents, etc. From this we should understand *there are usually several classes of documents in any given tier.*
- Document classes are related to document tiers. In most companies there are multiple document 'classes'. These classes are always Tier II or lower.

## Notes & Commentary

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## High Level Documentation Structure



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## Notes & Commentary

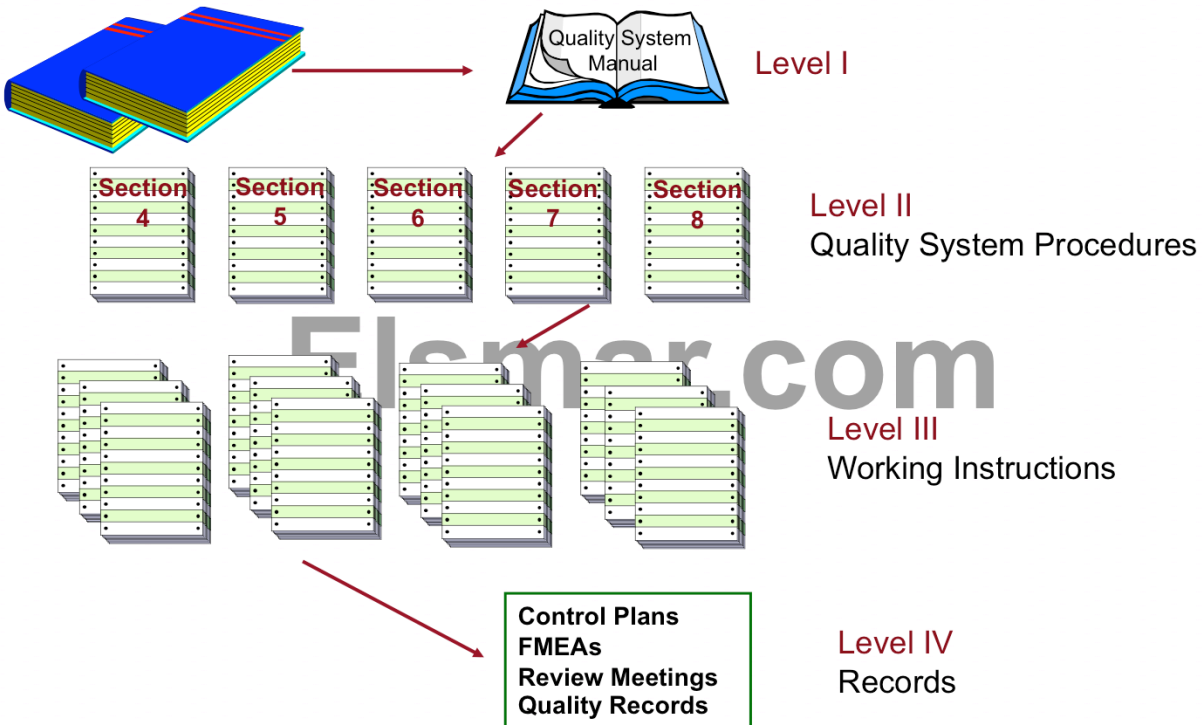
In large, complex companies, when mapping documents one has to take into account top documentation from corporate. Policies, procedures, forms and records. There is typically quite a lot of 'odds and ends' passed down the ladder. Policies such as sexual harassment and spending policies are typical.

Remember that we have to address communication which, if there is a corporate level, includes that corporate level.

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## Local Documentation Tiers

QS-9000 / ISO 9001,  
ISO 14001, Etc.



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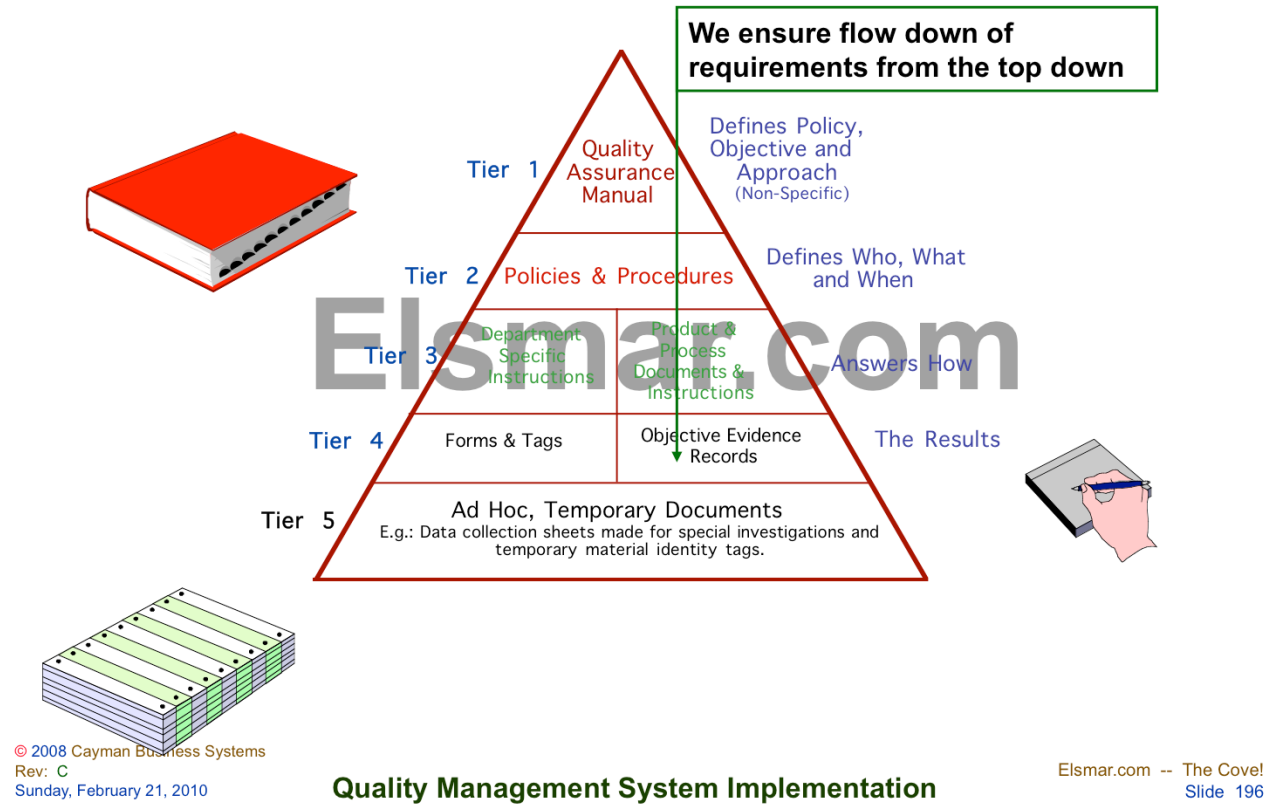
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## Notes & Commentary

This is the 'classic' representation and is typically seen in smaller, less complex companies. The typical pyramid representation is on the next slide.

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# Typical Documentation Tiers



## Notes & Commentary

This is the representation which everyone and their brother uses to represent a 'standard' document structure. It is supposed to represent the dependence of one on the other. I will admit that often when I see this I think it should be placed up-side down because I see the 'Quality Manual' or Systems Manual as the foundation upon which the others are based. This representation, to me, better relays the understanding of the quantity of documents in a particular level. This 'normal' representation also is easier to follow as the requirements flow down which seems easier to comprehend than if the representation flows up - but maybe this is just my being used to the 'normal' representation.

You should note that there is a level or tier 5 in my documentation pyramid which is not on 'normal' representations. I include this level / tier because every company has 'ad hoc' documentation of some sort from time to time. For example, a process engineer may have a temporary (ad hoc) document to gather some specific information about a process for analysis. The documentation is not part of the 'normal' process, but... The operator (or whoever) is taking data. Was the operator trained for this? Is there a procedure or is the form 'self evident'? Just a few thoughts.



## Flow Up vs Flow Down

- Not all documents have flow down requirements.
- Flow downs are normal.
- Flow downs generally reference lower level documents, but references are not mandatory.
- Flow Ups MUST **\*NEVER\*** be found.

## Notes & Commentary

What do we mean by 'Flow Up' and 'Flow Down'? A flow down is where, in a document, it proscribes (requires) another document (or part of a document) which must exist. For example, if your quality manual says your company will track training in accordance with procedure A-12BC, then that procedure (A-12BC) must exist. The quality manual is, in effect, 'flowing down' the requirement to a sub-document.

A Flow Down requirement does **NOT** have to be specified by a reference. A Policy, for example, normally states something shall happen or be complied with. An example is a policy which states: "All employees shall comply with ESD policies and procedures" implies these exist without actually referencing them (not always a good idea). This is definitely a flow down requirement.

It's a good idea to provide references, but often this is not possible. In the case of sector policies, for example, there may be many locations which are expected to comply. We comply by providing 'local' documentation which fulfills the sector policy requirements.

# Documentation Compliance Considerations

## Document **Verification** and **Validation**

### Systems & Documentation Compliance to ISO 9001.

1. Corporate Quality Systems Manual Compliant to ISO 9001.
2. Internal Plant Systems (Tier 2) Compliance to each specific ISO 9001 Element Line Item.

### Documentation Compliance to Corporate Documentation

3. Systems (Tier 2) Compliance to each specific Corporate Quality Systems Manual Element Line Item.

### Plant Personnel Compliance to Plant Documentation

4. Plant Personnel Compliance to Internal Plant Systems (Tier 2) .

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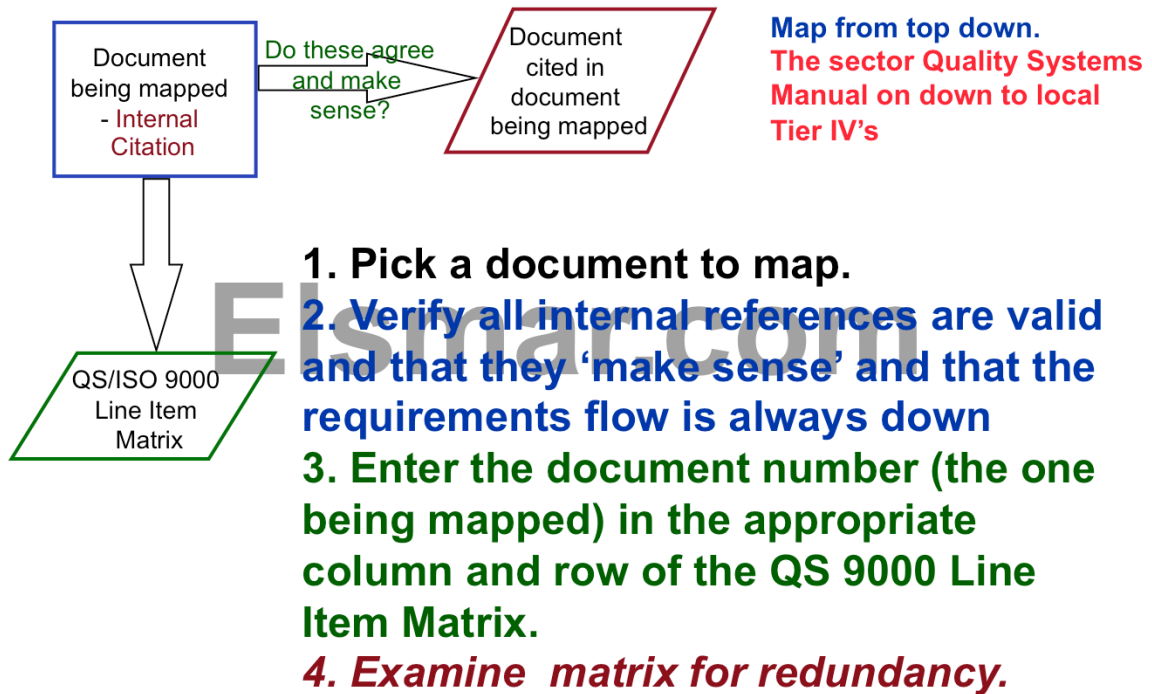
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## Mapping - Two Aspects



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# Line Item Matrix Mapping

After verifying internal links for existence and continuity, one maps the document to the requirements matrix which checking for redundancy.

Matrix Class (Document Type) Listing is Descending Tier Hierarchy

Requirement	QS 9000	QA Man.	AIAG Ref.	Corp SOP	PIO	12MRM-
Analysis and Use of Company-Level Data	4.1.5	X		SOP 4-15, SOP 8-13		
Customer Satisfaction & Customer Complaints	4.1.6	X				
<b>Quality System</b>	4.2					
General	4.2.1	X		SOP 4-9		
Quality System Procedures	4.2.2	X				
Quality Planning (per APQP & CP)	4.2.3	X	APQP	SOP 4-15		
Use Of Cross Functional Teams (per APQP & CP)	4.2.3	X				
Feasibility Reviews (per APQP & CP)	4.2.3	X				
Control Plans (Prototype, Pre-Launch & Production)	4.2.3	X				
PFMEA (per PFM&EA Ref. Manual)	4.2.3	X				12MRM96619A
Key/Critical/Special Characteristics	4.2.3	X				
<b>Contract Review</b>	4.3			SOP 3-47		
General	4.3.1	X				12MRM95827A

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## Determination of Required Documents

- Once you have completed mapping your documents, you want to revisit your requirements matrix. You have gone through an initial **Gap Analysis** where a determination was made as to what systems exist and which ones do not. Typically the Gap Analysis gives you an idea of what Level II documents and systems are required. At this point we want to look at what Level IIIs and Level IVs exist.

## *Notes & Commentary*

As always, I'll point out that this is going to depend upon the size and complexity of your company.

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## Summary

### *Mapping internal documents is:*

- **Verify** internal **reference documents exist** and that the **names** and **numbers** 'make sense'
- **Verify** that the link **subject matter makes sense** and that **requirements flow down**
- **Find** where the document **fits** in the **ISO 9001 line item matrix**
- *Examine matrix for redundancy*

## *Notes & Commentary*

The document mapping effort is extremely important.

It **MUST** include **communication** with **corporate** not only in regard to Quality Systems Manual inconsistencies, but at all documentation levels where there is a system, team and/or documentation interface requirement.

It must be **detailed** and **precise**. **All** inconsistencies must be addressed!

Remember:

After you **map** your documentation (**Verification**), you have to **Validate** your documentation.

You **Validate** your document(s) by stepping through the actual process in step with the associated document.

Each step must exist and must be in the order of the documents' procession.

# Process Mapping

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# Why Process Maps?

Maps draw a picture that allows the reader to **'visualize'** the process flow. *"A picture is worth a thousand words"*

These Process 'pictures' allow the reader to see the process **inputs and outputs** as well as **links** to other processes.

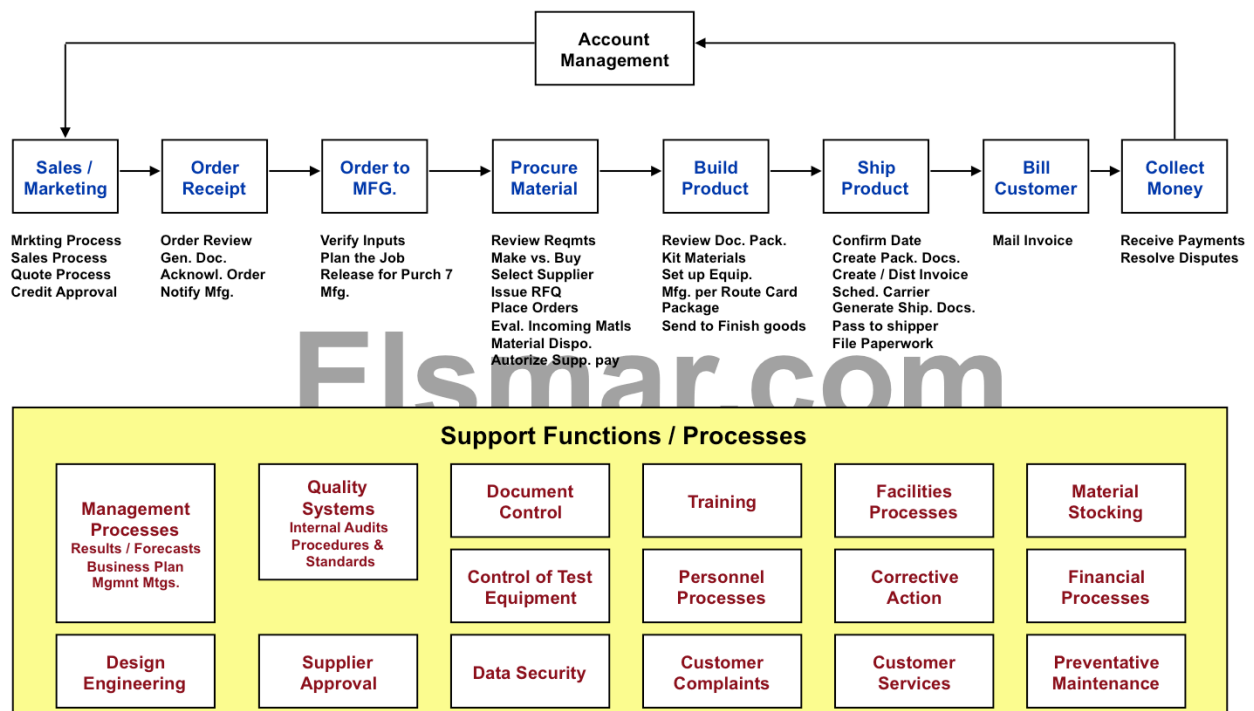
By 'linking' all the process maps together, we can **verify** that all the individual **processes flow** appropriately and that **references** from one Map to another make sense.

*This makes its easier for auditors as well!*

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# Typical Top Level Operations Flowchart



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This is a representation of a 'typical' company. Notice the flow, but also note what are defined as **support functions**. Most companies align to this basic representation to a large degree. Even service companies when you come to think about it. The most common problem in service implementations is to associate these functions with a company's actual functional departments. One service client had a position titled Process Improvement Manager. That position was responsible for 'quality' related functions in the organization. Initially, one might have heard the title and equated it with a 'production manager' or similar.

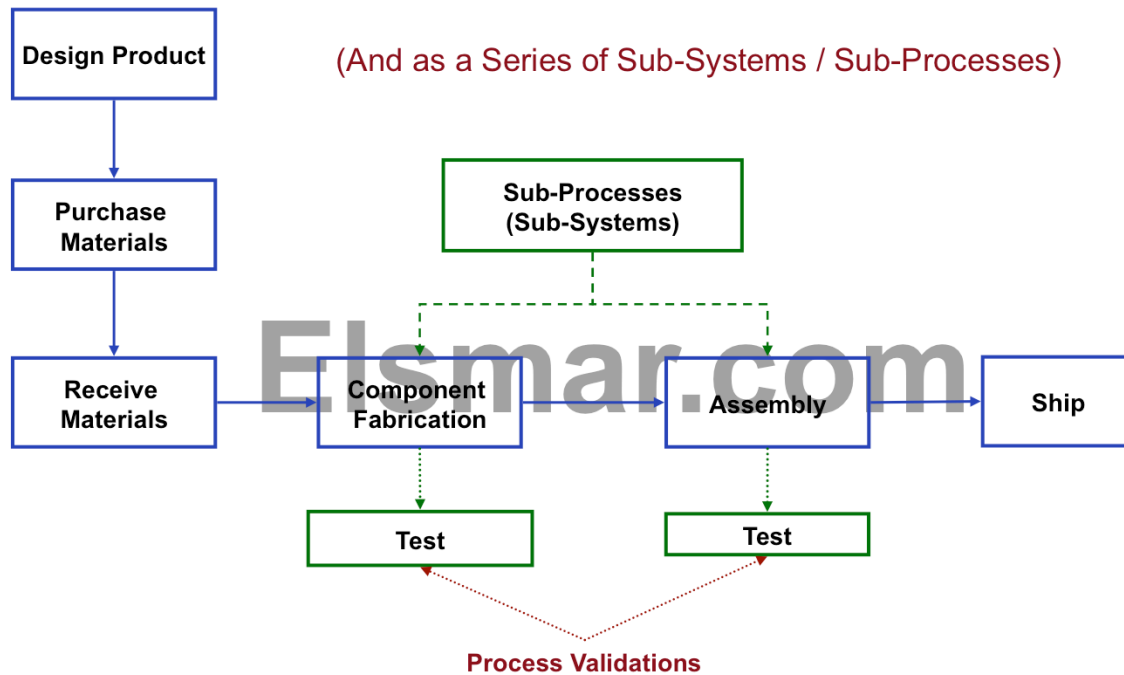
My point here is to make sure you look closely and ensure your functional areas are well defined and the related responsibilities are clear. At that point you can start to align your functional representatives (management) with requirements.

ISO 9001 does not proscribe any particular functional division. It only requires that you define what each functional division is responsible for. You may not find a direct equivalence in your company with each function in the above. For example, if you are a service company you may (or may not) have equipment to calibrate. If you do repair work, you may not immediately notice it, but material stocking will probably be applicable.

Again, common sense has to come into play as you consider function responsibilities.

# Business As A System (Process)

(And as a Series of Sub-Systems / Sub-Processes)



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## Use a Process Flow Chart!

### *Because:*

- You want to *understand* your current process
- You are looking for *opportunities to improve*
- You want to illustrate a potential solution
- You have improved a process and want to document the new process

## *Notes & Commentary*

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# Creating a Process Flow Chart

1. **Identify the process or task** you want to analyze. Defining the scope of the process is important because it will keep the improvement effort from becoming unmanageable.
2. **Ask the people** most familiar with the process to help construct the chart.
3. **Agree on the starting point and ending point.** Defining the scope of the process to be charted is very important, otherwise the task can become unwieldy.
4. **Agree on the level of detail** you will use. It's better to start out with less detail, increasing the detail only as needed to accomplish your purpose.

## *Notes & Commentary*

See Flowcharting.pdf

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# Creating a Process Flow Chart

## 5. Look for areas for improvement

- Is the process **standardized**, or are the people doing the work in different ways?
- Are steps repeated or **out of sequence**?
- Are there steps that **do not add value** to the output?
- Are there steps **where errors occur frequently**?
- Are there **rework loops**?

## 6. Identify the sequence and the steps taken to carry out the process.

## 7. Construct the process flow chart either from left to right or from top to bottom, using the standard symbols and connecting the steps with arrows.

## 8. Analyze the results.

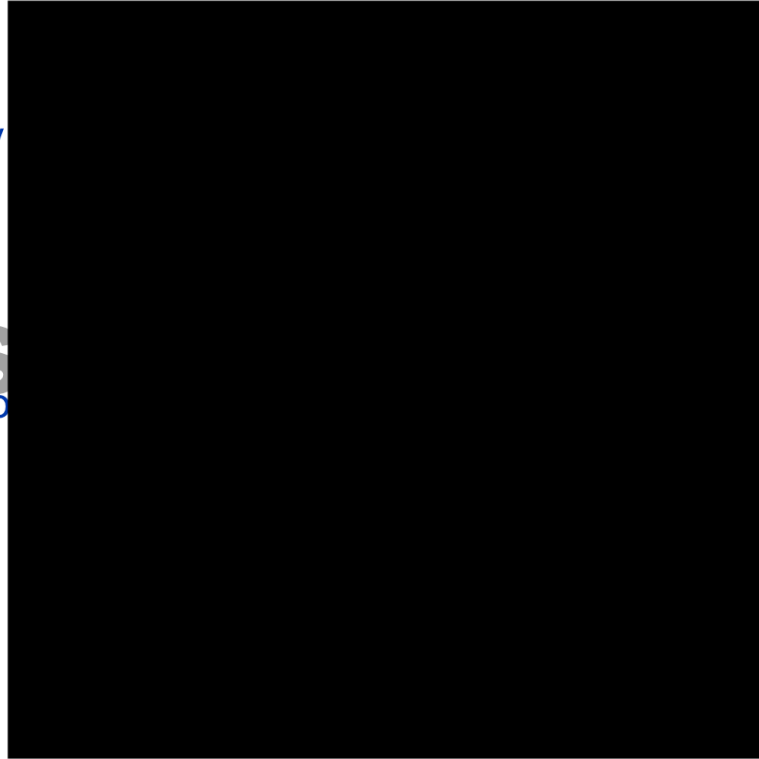
- Where are the **rework loops**?
- Are there process steps that **don't add value** to the output?
- Where are the differences between the current and the desired situation?

## Notes & Commentary

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## Early Process Flow Diagram

- Inspection Points
- Inspection Frequency
- Instrument
- Measurement Scale
- Sample Preparation
- Inspection/Test Method
- Inspector
- Method of Analysis



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# Flowchart

**A diagram that uses graphic symbols to depict the nature and flow of the steps in a process**

## **Benefits of Using Flowcharts**

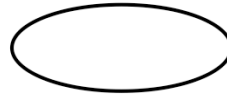
- Promotes understanding of a process
- Identifies problem areas and opportunities for process improvement
- Provides a way of training employees
- Depicts customer-supplier relationships

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# Symbols Used In Flowcharts

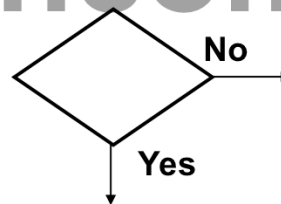
**Start / End**



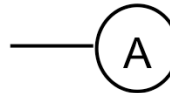
**Process Step**



**Decision**



**Connector**



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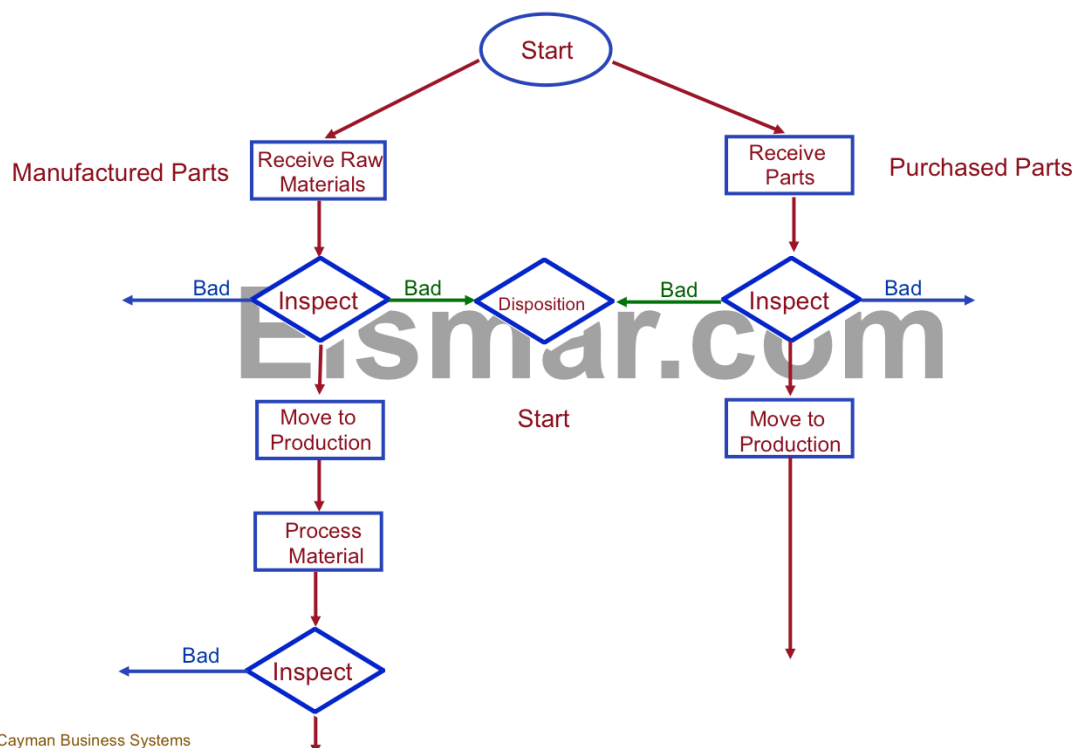
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## Basic Flow Chart Example - High Level



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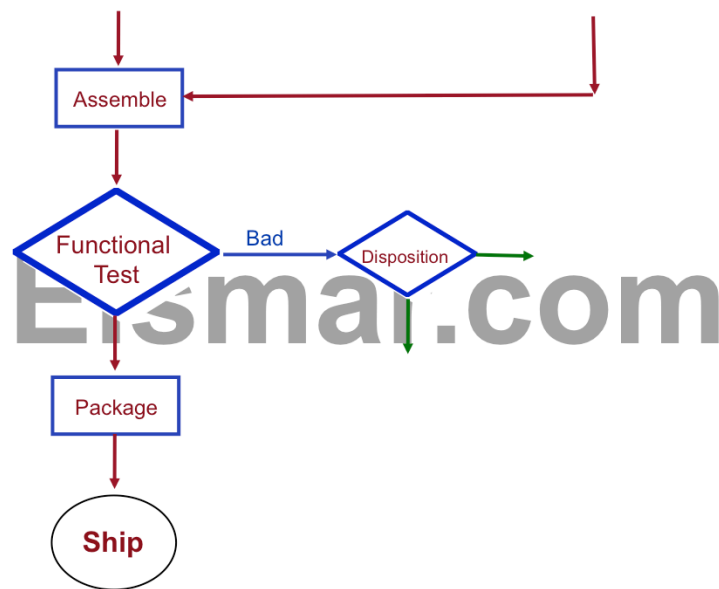
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## Basic Flow Chart Example - High Level



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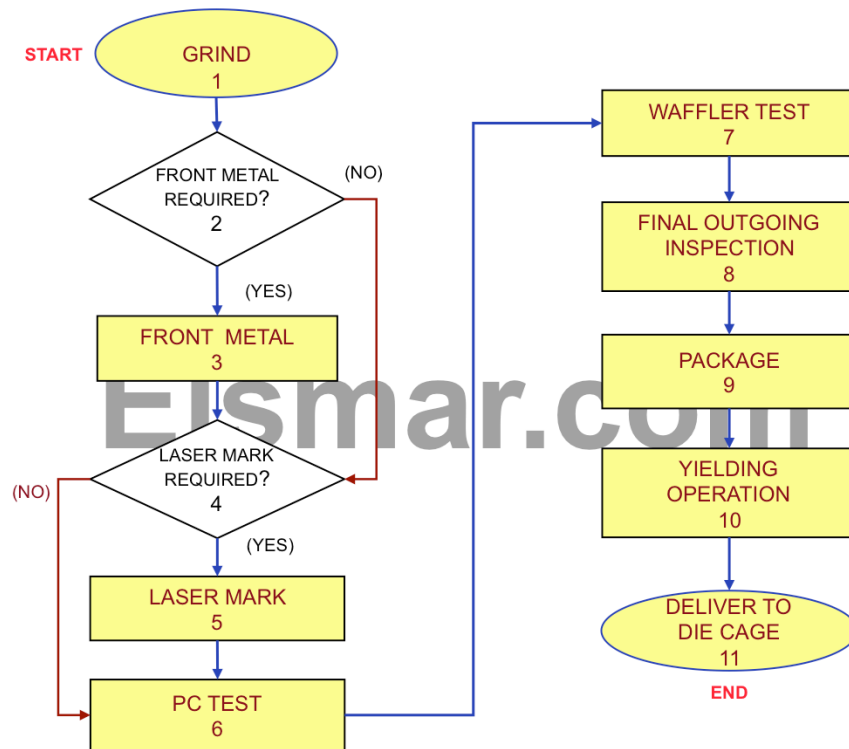
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## Flow Chart Example - Low Level



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G. WASHINGTON(1/1776)

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Remember, there is a file in this package with example flow charts in it.

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# Process Map Elements

**There are 8 elements / sections to a Process Map**

- 1) Purpose Statement
- 2) Scope Statement
- 3) Main Process Inputs
- 4) Main Process Outputs
- 5) Process Responsibilities Listing
- 6) Process Flow Chart
- 7) Essential Controls Listing
- 8) Quality Measure

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# Process Map Elements

## 1) Purpose Statement

This should be a single sentence stating what process the procedure is describing

Example: The purpose of this procedure is to describe the process by which Company X will approve suppliers.

## 3) Main Process Inputs

A list of the Main Process Inputs and where they *come from*.

Example:  
Request for new Supplier from the Purchasing Process

## 2) Scope Statement

This should be 1 or 2 sentence describing the boundaries of the process described in the procedure. Also use this section for defining abbreviations and jargon as well as referencing other documents

Example: This procedure applies to the approval of all suppliers of materials that make up the final products shipped to Company X' customers.

## 4) Main Process Outputs

A list of the Main Process Outputs and where they *go to*.

Example:  
Approved Supplier to the Approved Supplier List

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# Process Map Elements

## 5) Process Responsibilities

A list of the major / critical responsibilities associated with the process. This list is typically 3 - 5 items long.

**Example:** It is the responsibility of the Purchasing Agent to ensure that they are purchasing production material from Approved Suppliers.

## 7) Essential Controls

A list of elements that must happen or be in place for the process to be successful. This list is typically 3 - 5 items long.

**Example:** An Approved Supplier List is generated and maintained. Disqualified suppliers are maintained on a Disqualified Supplier List.

## 6) Process Flow Chart

A flow chart showing the process inputs & outputs as well as the process sequence with defined functional responsibilities.

*See Flow Chart examples.*

## 8) Quality Measure

A statement describing the 1- 2 (maximum) measures that will be used to monitor the successful execution of the process.  
**Remember: If we say we do it we have to!**

**Example:** The number of number supplier caused defects found at Incoming Inspection.

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# 7 Steps to Process Mapping

- 1) Gather and Review all existing documentation (**Document Mapping**)
- 2) **Identify Weaknesses** of the current documentation / process
- 3) Identify **Inputs** and **Outputs** of the Process
- 4) **Generate** a Draft Procedure
- 5) **Review** Draft Procedure with Implementation Team
- 6) **Develop** an Implementation **Plan**
- 7) **Implement/Train** the Process, **Release** the **Document**, and **Audit**

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# Process Mapping Worksheets

The following sheets have been designed to help your team organize your thoughts and actions as you work through the mapping of your process. Please fill out all sections as completely as possible. If you have any questions feel free to give me a call at 513 777-3394.

Thanks!

Team Members:

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---

Process Name:

Date Started

\_\_\_\_\_

**Projected Step Completion Dates**

Step 1: \_\_\_\_\_

Step 5: \_\_\_\_\_

Step 2: \_\_\_\_\_

Step 6: \_\_\_\_\_

Step 3: \_\_\_\_\_

Step 7: \_\_\_\_\_

Step 4: \_\_\_\_\_

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## Process Mapping Step 3

Step 3: **Identify** the Main Process **Inputs** and the **Outputs**.

**Input**

**From**

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**Output**

**To**

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## Process Mapping Step 4

**Step 4: Generate a Draft of the Process Map.**

**6.0 Process Flowchart** *As a team, flowchart the the process before writing the rest of the document's sections. Attach a copy of the flowchart to the back of this sheet.*

*After you have completed your flow chart, fill in the rest of the sections of the Map.*

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**1.0 Purpose:** \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

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# Process Mapping Step 4

## Step 4: Generate a draft of the Process Map. *Continued*

2.0 Scope: \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

Definitions:

Abbreviations:

References:

_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____

3.0 Main Process Inputs

4.0 Main Process Outputs

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# Job Descriptions

- At this time you should be looking at what job descriptions you have and determining what job descriptions you need.

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- Please don't forget job descriptions!

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# Process Mapping Step 4

## Step 4: Generate a draft of the Process Map. *Continued*

5.0 Process Responsibilities \_\_\_\_\_

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7.0 Essential Controls \_\_\_\_\_

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---

8.0 Quality Measure \_\_\_\_\_

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## Process Mapping Step 5

**Step 5: Review the Draft Process Map with the Implementation Team.**

**Review Results:**



OK to Implement



Changes Recommended

**Record Of Recommended Changes:**

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

**Date of Next Review:** \_\_\_\_\_

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## Process Mapping Step 6

Step 6: Create an **Implementation Plan** for the Process and Documentation.

What	Who	When	How	Status
Disposition of old documents				
Training				
Communicating				
Quality Measure Implementation				
Get on Audit Schedule				

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Internal Audits

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## Internal Audits

- You **must** complete at least 1 full round of internal audits prior to your registration. In addition, you have to show at least one example of where a nonconformance was identified and corrected. You must also show where you **verified the effectiveness** of the corrective action.
- **Drive** your implementation through Internal Audits.
- You can use internal audits as a method of **training** departmental managers and others. As you go through the audit, you explain the basics of that person's responsibilities with respect to ISO 9001. You can also explain the basics of ISO 9001, go over the Quality Policy, etc.
- These internal audits may prove to be long and problematic. This should be expected because employees are all learning about ISO 9001 and the requirements. Sometimes they're learning new systems and such as well.
- You may want to take a read through <http://Elsmar.com/Audit/>

## Notes & Commentary

Going into the details of how to do an internal audit is beyond the scope of this document. However, very soon I will have a file for sale addressing internal auditing.

At <http://Elsmar.com/Audit/> there are some slides on internal auditing. However, the changes to ISO 9001 have somewhat changed how audits are expected to be performed. Because of this the file is due for updating.

If you want the file and just can't wait until I update it, shoot me an e-mail.

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# The Internal Audit

The **Systematic** Investigation  
of the **Intent, Implementation, and  
Effectiveness**  
of Selected Aspects of the **Systems**  
of an **Organization**  
or One or More of It's **Departments**

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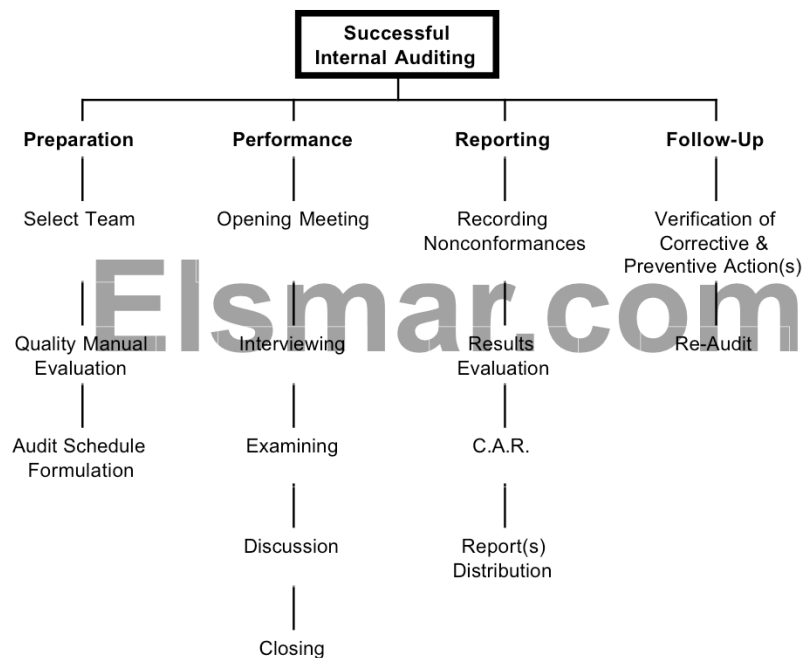
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## A Typical Audit Process



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Internal Audit Goal  
To Collect  
***Objective Evidence***  
To Permit An  
**Informed Judgment**  
About The  
*Status and Effectiveness*  
*Of The Systems Audited*

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## Objective Evidence

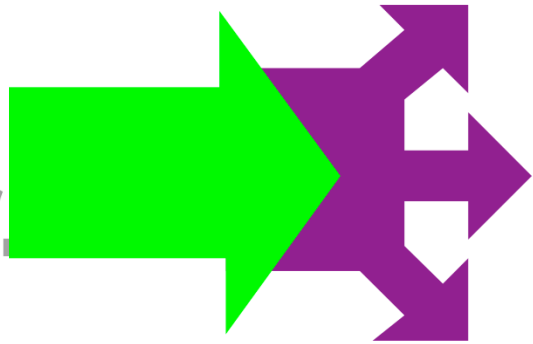
- It exists
- Not influenced by emotion or prejudice
- Based on observation
- Verbal or documented
- Verifiable
- May be quantitative
- Within the systems being audited

## *Notes & Commentary*

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# Many Requirements

**QS/ISO 9001**  
**Contract Requirements**  
**Company System Requirements**  
(Policy, Procedures, Instructions)  
**OSHA**  
**EPA**  
**Federal and State Regulatory**



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# Internal Audits

**Say What You Do!**

**Do What You Say!**

**QS/ISO 9000,  
Systems Manual,  
SOPs, WIs, Records**

**Internal  
Practices**



**Check What is Done!**

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# Schedule Example

	May							June							July							August											
	20	5	10	12	19	20	26	27	28	8	9	10	11	12	15	16	17	18	19	22	23	24	25	26	29	30	31	1	2	5	6	7	8
	M	W	M	W	W	TH	W	TH	F	M	T	W	TH	F	M	T	W	TH	F	M	T	W	TH	F	M	T	W	TH	F	M	T	W	TH
Management																																	
Purchasing																																	
Resident Engineering																																	
New Product Eng.																																	
Quality Assurance																																	
Inspection Lab																																	
Calibration Lab																																	
Audit																																	
Roll Test																																	
Wire Harness																																	
Wheel Area																																	
Weld & Frame																																	
Press																																	
Machine																																	
Tank & Fender																																	
Chrome																																	
Paint																																	
FLT Assembly																																	
FX Assembly																																	
XL Assembly																																	
Assembly Set-Up																																	
Human Resources																																	
Maintenance																																	
Shipping/Receiving																																	
P&A																																	
MIS																																	

- I = Planned - Supervised
- M = Planned - Internal Auditors Monitor
- P = Planned - Internal Auditors Plan and Execute
- N = Audit Executed - No Non-conformances
- O = Audit Executed - Open Non-conformances
- C = Audit Executed - Nonconformances Closed

NOTES: "I" audits from present to 22 July.  
 "M" audits from 22 July through August 21.  
 "P" audits from August 22 onward.

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## Notes & Commentary

This is an example of an audit schedule which was used in an implementation project. During the first part we are bringing internal auditors on-board and training them and then monitoring them through their first audit. This is schedule is somewhat complex because it was part of training, part of the implementation driver, and part systems validation. In addition, the facility was approximately 2500 souls.

Bottom line is - Get your internal auditing going early.

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## Outsourcing Internal Audits

- Many smaller companies outsource internal audits.
- Many large companies have a distinct department which carries out internal audits at facilities world-wide.
- There are a number of possible failure modes in internal auditing. You will have to make your own decision. My opinion is to outsource internal audits.
- Details are discussed in two threads:
  - <http://Elsmar.com/ubb/Forum13/HTML/000041.html>
  - <http://Elsmar.com/ubb/Forum2/HTML/000123.html>

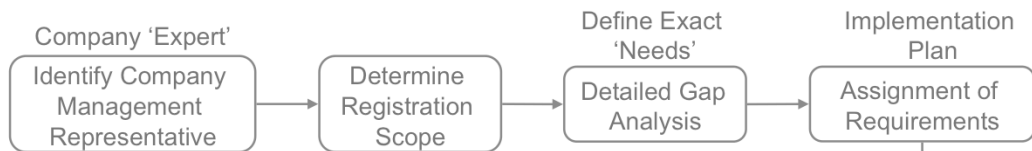
## *Notes & Commentary*

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# Project Fulfillment

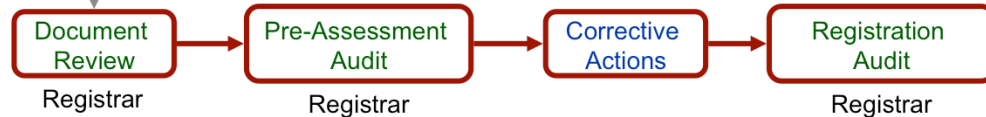
## Project Definition



## Project Actions



## Project Fulfillment



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Enter The Registrar  
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## The Registrar's Document Review

- Prior to a pre-assessment, your registrar will want to review your documentation. Typically, they want your Systems Manual (Quality Manual) and a copy of your level II documents. However, some registrars only require your quality manual. ASK them specifically what they want submitted for review.
- You should not let the registrar wait to 'the last minute' do a document review. I often see this done. The client gets the review back at or just prior to the pre-assessment. Folks, this does not allow you any time to deal with any problems if any are encountered during the review. Try to get your review done **6 weeks or more prior** to pre-assessment.

## Notes & Commentary

Document reviews typically run about \$800 to \$1250 US. In my opinion, they are often too short and, I would wager, sometimes not even done. I say this from experiences where the registrar came in for the pre-assessment and found problems with documentation which should have been identified during the document review. A document review is NOT like an audit. It is not supposed to be a sampling. That's why they charge so much for them.

Make sure you get the most from your registrar's document review.

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## Pre-Assessment Audit

- Some registrars require a pre-assessment. Some do not.
- A pre-assessment is a valuable tool. Your relationship with your registrar is going to be an intimate one. Interpretation of the requirements with respect to your company and 'the intent' is a big factor in a registration. During this visit you will 'get to know' your registrar.
- The man-days for the pre-assessment are typically about 1/3 or less than for the registration audit.
- The pre-assessment is, like the registration audit, a sample. Everything will not be looked at.

## Notes & Commentary

Get the most out of your pre-assessment.

I have seen registrars take different directions in pre-assessments. My advice is to approach it from the point of view of document validation. Yes - you've gone through a document review. Now is the time to go a bit further and to have the individuals involved actively involved - explaining their systems. But - try to keep things limited to your major systems. At this point there is not much use in having the lowest level employees go through the inquisition. The compliance to the standard issues are important to validate now.

Hopefully you will have been driving your implementation project in part through internal audits. These should have brought home to the 'masses' the idea of the audit. You should have already identified whether or not everyone understands their documentation, is completing forms as required, etc., etc.

In short, make sure you come out of the pre-assessment knowing that major required systems are in place, compliant and are implemented and being used. During the assessment audit you can withstand a few minor nonconformances, but 1 major and - well, you might as well have put the audit off because the registrar will be back before they 'recommend' you for registration.

## Assessment Audit

- This is the fun audit! This is where everyone is fair game. Not much else I can say.
- This is, like all audits, a sample. But it is a big sample. They look at a representative sample of each system.
- The following slides tell you what to expect.

## *Notes & Commentary*

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## Reasons For Third Party Audits

- Everyone is familiar with the idea of audits. One place we are all aware of audits is in the banking industry. For years, the government has required banks to submit to periodic audits by government agencies and/or external companies who specialize in auditing. Few people want to put their money in a bank where there are no controls such as periodic audits. If there are no audits, you have no way of knowing if your bank is using your money well. If the bank is not 'using your money well' the bank could easily fail - then you could lose all of your money.
- Audits in other service industries and in manufacturing industries are not new. Customer audits have been going on for years. But only recently has the idea of **third party** audits become reality. This is in large part due to the adoption in Europe of ISO 9001 and other international standards.

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## Reasons For Third Party Audits 2

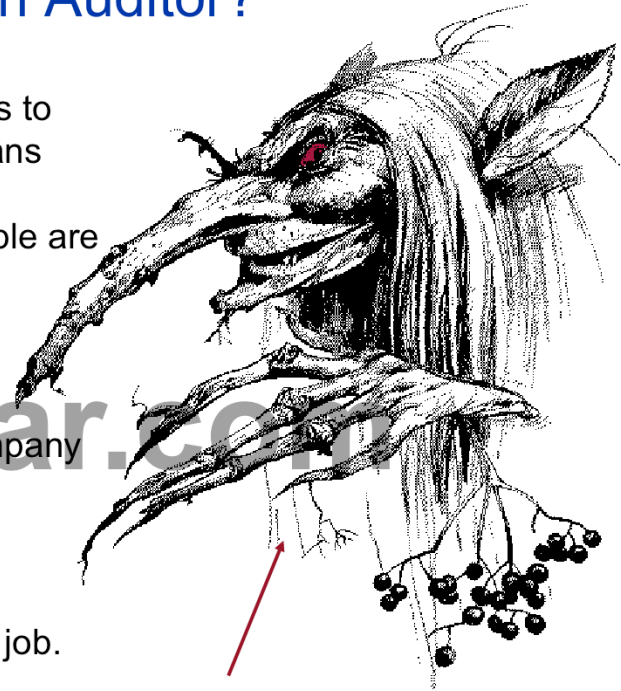
- The intent of third party audits is to provide assurance that a company complies with a standard or specification.
- Many people say that third party audits will eliminate customer audits. This has not been the case up to now in part because customers still see the need to ensure compliance to their specific requirements. Even QS-9000, specific to Ford, GM and Chrysler suppliers, does not eliminate customer audits.

*Notes & Commentary*

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## What is an Auditor?

- An auditor is a person. Their job is to validate documentation. This means they look at documentation (instructions) and make sure people are following the documentation.
- Auditors go from company to company validating documentation.
- Auditors are just people who ask questions about how you do your job.



NOT an Auditor!

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# Auditors Are Not!!!

- Inquisitors
- Fault Finders
- Rock Throwers
- Avenging Angels  
(Biased For or Against)
- Dishonest
- Overactive



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## What Will The Auditors Do?

- The auditors will **look at written procedures** and policies (verification).
- The auditors will then look at and **ask how people** in the company **do things**. They will **look to make sure each person is following written procedures and policies** (systems / process validation).
- They will look at records to ensure everyone is **properly completing paperwork** (examples would be process related documentation and SPC charts).
- They will look to make sure **everyone** is properly **trained** to do their job.

## *Notes & Commentary*

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## Who Will Be Audited?

- Absolutely **Everyone** whose **job affects quality** (almost everyone's job does in some way) is **subject to the audit**.
- And the farther up the corporate tree you go, the more difficult the audit is. This is because as you go up the tree (eventually to the CEO), job duties and responsibilities increase.
  - Corporate Personnel
  - Plant Manager
  - Departmental managers
  - Supervisors
  - Engineers
  - Technical personnel
  - Associates

## *Notes & Commentary*

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## The Audit Team

- When you are visited by an auditor, he/she will **NOT** be alone. At the very minimum, there will be:
  - The Auditor
  - A **Company Escort** - This will be someone from within the company who knows the area and the specification well. The escort will try to provide structure to the audit and will try to help out when he/she can. Often this will be the management representative.
  - The **Area Supervisor and/or Manager** - The area supervisor or other person directly responsible for the area will be present.
- Remember - **YOU ARE NOT ALONE!**

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# Types of Audits

## Internal Audit

An audit of internal systems and/or procedures. An internal audit is most often performed by people who directly work for the company. Many companies hire outside firms (see third party below) to perform the audits.

## External Audit

### Second Party - Customer Audits

- Customer audits are those where a customer (or a customer representative) performs the audit. A customer audit is not 'objective' because the customer is intimately involved with your company (the supplier to the customer). This involvement can BIAS the audit.

### 'Third Party' Audits

- Third party audits are like those you think of when you think of bank audits. Banks (and other financial institutions) must hire a company or person to audit their books and procedures. The company or person hired to do the audit cannot have an 'interest' in the business it is auditing. This is known as an 'Independent Audit'. Your registrar audit is a third party audit.

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## What Will Happen If...

- If an auditor finds a problem, s/he will let the person being audited know **immediately** that a possible problem may exist. In NO case will the auditor 'find a problem' and not discuss it with the auditee 'on the spot'. They **always** tell the auditee the suspected problem. Many registrars (registrars do \*NOT ALWAYS\* require this) will ask the auditee (or other company official present) to sign a **statement of fact** of what was found (**statement of objective evidence**). The auditee should know that signing the statement is **NOT an admission** of a problem. It is an **agreement of facts found**. Whether or not it is a problem is discussed during end-of-day and final review meetings.
- If an auditor leaves your area and says nothing about a possible problem, you can be sure no problem(s) were found. Auditors do NOT report findings to management without discussing it with the **personnel involved FIRST**. **There are no tricks**. Nothing is 'hidden' until later.

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## Things to Know

- **Know what documentation affects YOU!**
  - You must know what documentation applies to your job. This should have been told to you when you were trained to do the job. If you are not sure what documentation applies to you, ASK YOUR SUPERVISOR or TRAINER **before** the audit.
- You must **follow all documentation** that applies to you. If it says you do something a certain way, you must do it that way.
- You must **complete all forms**. If you are supposed to initial and date when you do something, the auditors will check to ensure you complete the form the way you are supposed to.
- **Know what training you have had**. If you do not know, ASK YOUR MANAGER **NOW! Don't wait until the audit!**

## *Notes & Commentary*

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## Things to Do

- **Listen closely** before answering any question(s). If you are not sure you **understand** the question, ask the auditor to repeat it. If you still do not understand the question, tell the auditor you do not understand it. The auditor will try to better explain him/herself. **Never answer a question you do not understand!**
- **Never say “Sometimes I....”**. When you do something differently because of different circumstances, explain that “When ----- happens, I...., and when +++++ happens, I....”. **Be specific.**
- Always **tell the Truth**. Don't ever try to hide something. You may think you are helping someone - you are not. One lie can destroy confidence. Just like in a marriage, if one spouse lies to the other and the other finds out, the relationship may be in real danger. One lie could ruin the entire audit.
- Be patient. **Wait for the auditor to ask a question.**

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## Things NOT to Do

- **If you do not know the answer to a question, tell the auditor that you do not know the answer.** Don't attempt to 'fake it'. If the auditor tries to explain again and you still do not understand the question, tell him/her again that you do not understand the question. The Escort will attempt to help if this happens.
- **Do NOT try to answer a question for another person.** (often registrars will \*test\* people for this) If the question is not about the job you are doing and you know who does that job, **tell** the auditor who they should ask if you know.
- **Do NOT try to answer a question about another job.** The only question an auditor is supposed to ask is about YOUR job. If the auditor asks you a question about someone else's job, you should answer "That is not my job." The escort or the other company person with the auditor must take the lead from this point.
- **Do NOT try to hide from the auditor.** All the auditor wants is to ask you about your job and how to do it. You know your job. You can tell the auditor about as easily as you can tell anyone else.

*Notes & Commentary*

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## General Things To Know and Do

- **Auditors are NOT trying to test your memory.** If you have to look something up in your documentation, tell the auditor. The auditor will then tell you whether to look up the information or not.
- **Only answer the auditor's question.** Do NOT volunteer information. Do NOT try to 'help' the auditor with additional information.
- **Answer with the shortest, simplest answer you can think of.** If you can answer with a Yes or No, that's all you should do.
- **Don't try to explain things beyond the question asked.** The auditor will ask questions to help him/her understand. Your job is to only answer questions asked.
- **Do not tell stories or speculate** what 'may' happen.
- **Right NOW!!!** If there is any documentation which you are using that you think or know is not correct, contact your supervisor immediately!

*Notes & Commentary*

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## Typical Audit Questions to Expect

- What is QS-9000 / ISO 9001?
- What is the quality policy?
- What does the quality policy mean to you?
- What documentation do you follow? Where is it?
- How do you know you are using the most recent documentation?
- Who is the **Management Representative**?
- How do you know what to do? Tell me about your job and your duties.
- Do you ever have problems come up? How do you handle them?
- When you find nonconforming product, what do you do?
- What are your quality responsibilities?
- What are controlled documents?
- If your documentation says you should do something a specific way and someone else tells you to do it differently, what do you do?
- What do you do if your machine jams?

If you do not know the answer to any of these questions, talk to your supervisor SOON! DO NOT WAIT!

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# Supervisors Should Think About...

## Work Instructions

- Does Every Job Have Relevant Work Instructions?
- Are Work Instructions Controlled?
- Is Each Signed & Dated?
- Who is the Keeper of a Master List & Where is it Kept?

## Hand Revisions

- Have Any Work Instructions, Visual Aids, or Other Process Documentation Been Updated By Hand?
- If So, Are They Signed and Dated?

## Equipment PMs

- Are All Equipment PMs Up To Date and to a Schedule?

## Measurement & Test Equipment

- Is All Measurement and Test Equipment Calibrated and properly Labeled?

## Defective Material

- Is Defective Material Identified and Segregated?
- Is A Defective Material HOLD Area Identified?
- Is DMR Material Dispositioned in a Timely Manner?

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## Last Things to Think About

- **Employee Training**

Do You Know the Training Requirements Of Your Job Position?

Is Each Employee Trained?

Where Are Training Records Kept?

Are Training Records Up To Date?

- **SPC**

Are People Keeping SPC Charts Trained in SPC?

Are SPC Charts Current and Being Utilized?

Are Trends Identified and is Corrective Action Taken?

- **Work Areas**

Are Work Areas Clean and Orderly?

- **Baskets, Boxes, Racks, Shelves & Other Containers**

Is Each Properly Labeled (Identified)?

Are They Where They Are Supposed To Be?

*Notes & Commentary*

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## QS-9000 / ISO 9001 Reminders

- Does **NOT** define **quality**
- Is **NOT** a **one-time** process
- Is **NOT** easy
- Requires **commitment**
- Requires **resources**

*Notes & Commentary*

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# Real Life

What **QS-9000 / ISO 9001** Means To You!

You **MUST**:

Know Your **Job Duties**

Know What **Training** Your Job Requires

Be Able To Tell **About How You Were Trained**

Know **What Documentation Involves YOU!**

Know **How To Find Out** What The 'Latest' Version' Is

Know **What The Documentation Says**

Know **How** The Documentation **Applies To YOU!**

Know What The **INTENT** of the Documentation

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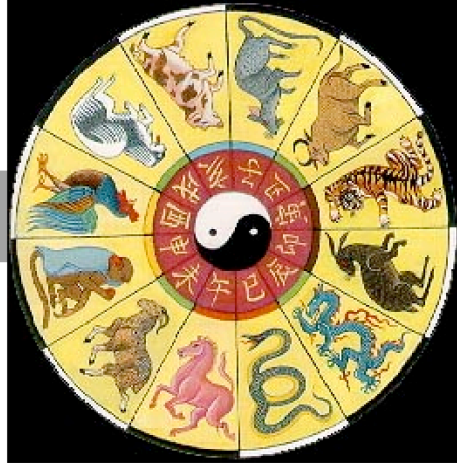
These are items which every employee must know. The auditors will ask these questions of individual employees at all levels of the organization.

Two aspects are represented.

Job requirements, etc., and the requisite documentation.

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Good Luck!



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