THE VICTORIA GROUP

INTRODUCTION TO ISO 9001:2008 HANDBOOK

by Roderick S.W. Goult

THE VICTORIA GROUP

CAUGHT UP IN THE ISO 9000 REVOLUTION AND NEED TO KNOW WHAT IT ALL MEANS?

If you are one of the millions of people from board room to factory floor whose company is implementing ISO 9000, you need to understand what it means for the whole organization. Not in detail, but enough to understand the overall goals and objectives of this worldwide standard, what its use implies for the company — from product line to bottom line. This handbook gives you that background, up to and including the certification process.

No more confusion — not after you have read this

INTRODUCTION TO ISO 9001:2008 HANDBOOK

A user-friendly, uncomplicated explanation of the structure, use and meaning of ISO 9001:2008

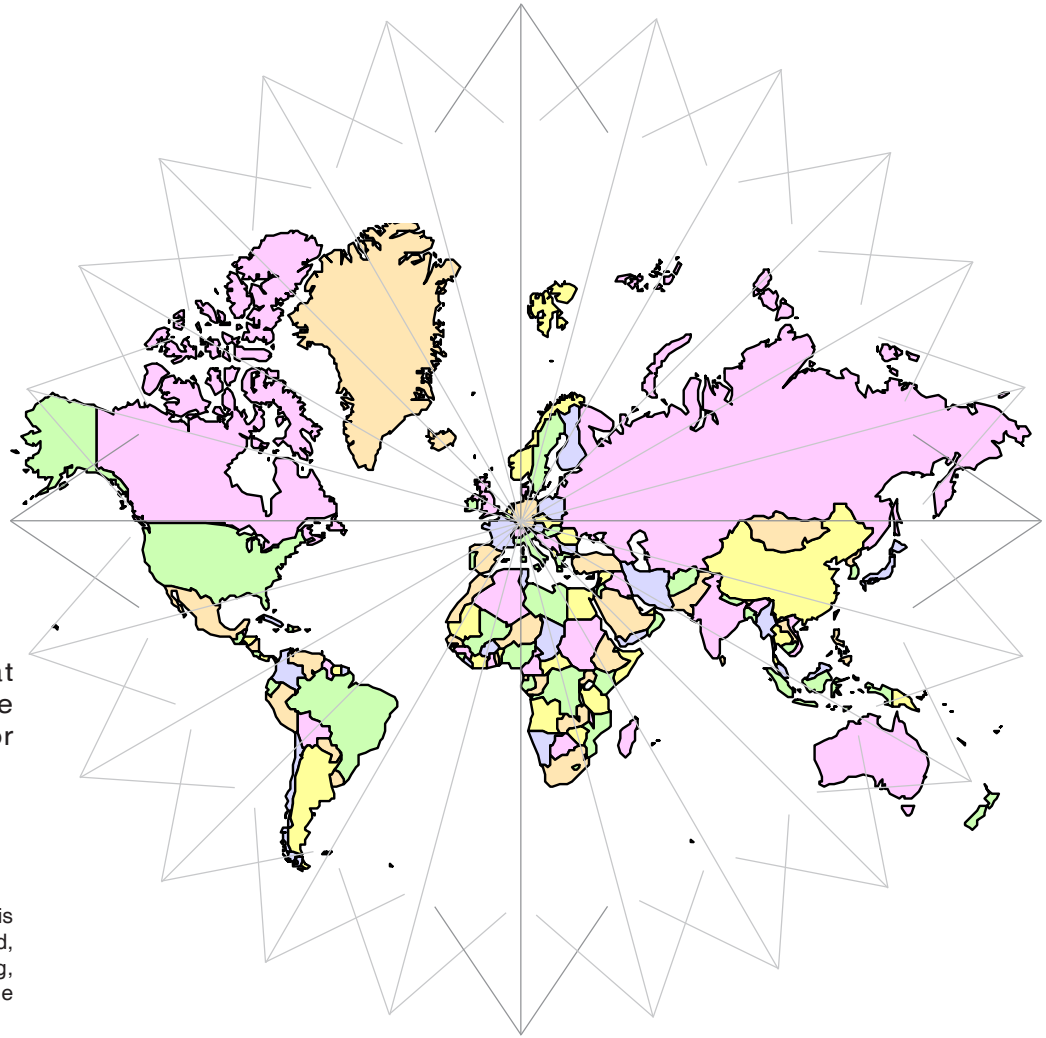
by

Roderick S.W. Goult

Published by The Victoria Group.

The Victoria Group, Incorporated
P.O. Box 478
North Salem, NH 03073, U.S.A.
Phone: 978-681-8404
Fax: 978-416-0873

First Printed February 2001
Second Edition June 2005
This Edition October 2009



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PREFACE

The third millennium is here. So is a major shift in the balance of power in the economies of the world. The developed western economies of the US and Europe are coming under ever increasing pressure from the 'Tiger' economies of the Far East, and added to that is the inevitability that within ten or twenty years the largest economic trading block in the world will be China.

How is this challenge to be met? The economic supremacy which the west has come to take for granted is under threat. The changing world economic scene calls for increased efficiencies and more effective management processes. Some managers put their heads in the sand, and pretend that what is happening is all down to low wages and semi-slave labor in the developing nations. These managers call for their governments to introduce protectionist policies and try to make the rest of us believe that all would be well if we prevented "unfair trading practices" stealing our markets.

Others face up to the new reality and take vigorous steps to reconstruct their businesses to meet the challenges and opportunities of the emerging new world order.

One way that many companies are overhauling and restructuring their organizations is by introducing management operating systems based on the ISO 9000 Standards for Quality Systems. Not only does this provide the opportunity to undertake a complete overhaul of their operating systems, but it also enables the company to obtain an external, third-party certification of the effectiveness of that revised system through a registration audit.

This then helps them to tell their customers how effective their management systems are. As of the Fall of 2009, more than 1,000,000 companies worldwide and over 60,000 in the US have chosen to take this route to reconstruction. US companies choosing ISO 9000 as their vehicle for system reconstruction range from Rice Aircraft, a small specialist distributor of aircraft fastenings, through many mid-sized outfits up to multinational giants such as Hewlett-Packard and Ford Motor Company.

The ISO 9000 phenomenon, for that seems to be the only way to describe it, has been around since 1987. In the US, it started slowly, initially regarded as another one of those European things to create trade barriers.

Once the truth was recognized, which happened about 1992, some major US companies started implementing the standards, and then began reaping the rewards of implementing ISO 9001 or ISO 9002.

The pace of its acceptance quickened.

Today there can be few serious professionals in the quality world who do not recognize that ISO 9000-based management systems have a great deal to offer.

The one real regret that I have in viewing the current scene is that there is so much division and small-minded "not invented here" thinking among the very professionals who should be seizing and using every tool they can which will help their organizations improve. The quality profession — if it is worthy of such a term — frequently shows itself to be small-minded, insecure, inefficient and out of touch with the commercial world in which we all have to live and breathe and have our being.

No wonder that back in 1971 Phil Crosby told us, "the quality profession will never be allowed to work on tomorrow until we have proved that we can help with today." In far too many companies that proof is yet to be demonstrated.

The President of the US Registrar Accreditation Board, George Lofgren, speaking for an article in *Quality Progress,* January 1996, said, "people like to over simplify things; they look for the silver bullet in quality. They ask what is the one thing I need to do? One of the biggest frustrations is that there is no one thing. Quality encompasses a very broad spectrum. It is a process of which ISO 9000 is just one part."

This is the ultimate truth.

There is no "one thing." Baldrige has its place; total quality in any one of its many guises has a role. Contrary to Dr. Deming, I would argue that management by objectives has a part to play. So does investor confidence, environmental, health and safety policy, social awareness, customer satisfaction, employee motivation, benefits and remuneration and all the thousand other aspects of running a business today.

The art of running a quality organization is a broad spectrum, complex business where all of us should use every tool we can lay our hands on to improve the way we operate on a daily basis. Rather as the journey of a thousand miles begins with one step, so the journey to the company of tomorrow comes with a recognition that what we are doing today isn't good enough — ever. ISO 9000 can help take your organization forward. If the management commit to its disciplines, if the employees all cooperate, if the process of creating the system is fed out into the entire company and staff are truly empowered by the activity.

If.... that huge tiny word. ISO works if you work. Otherwise, it is just another plaque on the wall in reception.

Good luck!

Rod Court

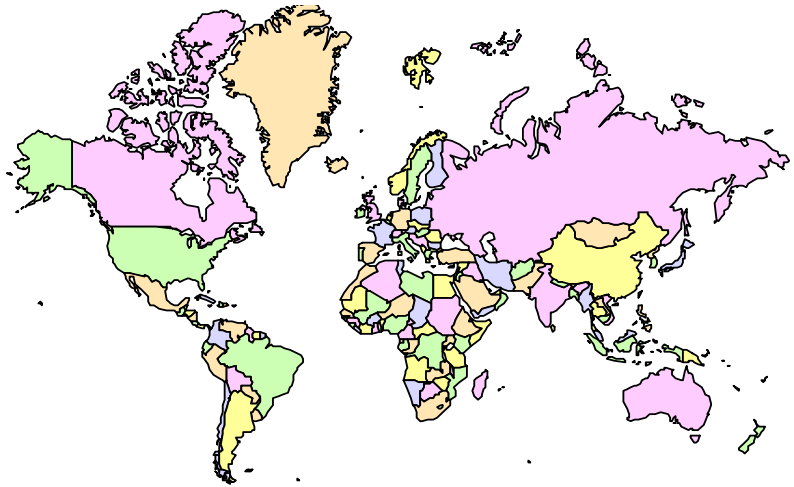
Galesville, Maryland,
October, 2000

INTRODUCING ISO 9000

What is this thing called ISO 9000?

Most people in industry have heard of it by now, but unfortunately far too many people still have very little idea of what it really is all about. A bunch of paperwork with no real benefit, say many. A big expense, say others. No help to the customer is commonly heard. Companies with ISO 9000 certification still ship junk, critics argue.

All of these criticisms can be true. There are companies — far too many of them — for whom some or all of these are the truth of their ISO 9000 efforts. But it need not be that way. For many organizations implementing ISO 9000 standards and obtaining third party certification has produced enormous benefits, and most report reductions in scrap, rework and customer returns. Having an ISO 9000 management system will never prevent things going wrong, however having an operational system which effectively tracks business processes can help ensure that errors are tracked, rectified and prevented from recurring. Without such a system this activity is extremely difficult, with the result that error-correction is rarely successful or reliable.



ISO 9001 is no more than documented common sense. It recognizes that top management are the people who set the style and tone of the entire operation, and therefore requires that they demonstrate their commitment to the management system.

Top management need to recognize that the reason for the existence of any organization is to satisfy its customers and stakeholders and to structure its operations around that basic premis. To help achieve customer satisfaction top management is required to commit to a meaningful quality policy, create customer focussed quality objectives, and deploy them throughout the organization.

Customers want consistency. Achieving consistency in the identification of customer requirements and the conversion of those requirements into deliverable products and services requires stable processes. What ISO 9001 requires is that top management shall

- establish such processes;
- implement them;
- monitor them at appropriate intervals;
- find ways of understanding customer perceptions of performance, and
- continually seek to improve the effectiveness of the system, the processes and the products or services being supplied.

That's all.

Nothing special.

Nothing that reputable organizations are not trying to do anyway.

What ISO 9001 provides is a convenient, internationally recognized framework within which to operate these processes and activities. It also provides the opportunity for an organization to obtain third party certification for the processes which it has in place.

Where does ISO 9000 come from?

A BRIEF BACKGROUND TO ISO 9000

The ISO 9000 management system standards were developed during the 1980s. They were derived from many similar individual national standards around the world which had been developed from about 1970 onwards. Neighbors in Canada had their Z299 standards, the Australians had AS3900, and here in the US, the nuclear industry had the NQA-1 standard. The defense industry had been using similar standards for years — many will be familiar with MIL-Q-9858A.

Probably the best recognized non-defense management system initiative was established in the United Kingdom in 1983 when the British government created the National Accreditation Council for Certification Bodies, now the National Accreditation of Certification Bodies (NACB).

This was created to monitor the activities of companies like BSi, Lloyds and BVQi performing third-party audits on management systems implemented by British businesses using the British standard for quality management systems, known as BS5750:1979. BS5750 became one of the strongest models reviewed by the international committees of the International Organization for Standardization as they started to develop the ISO 9000 standards.

The Structure of the ISO 9000:2008 Standards

ISO 9000:2005

Quality management systems — Fundamentals and vocabulary

APPLICATION

ISO 9001:2008

Quality management systems — Requirements

GUIDANCE

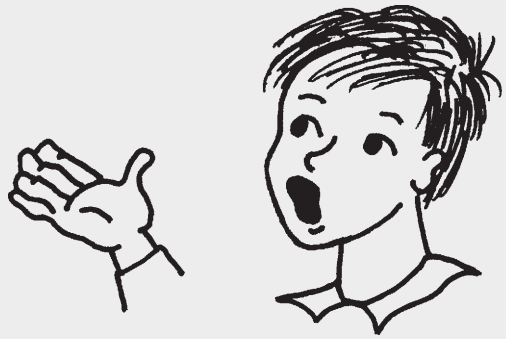
ISO 9004:2009

due out soon

Managing for the sustained success of an organization — A quality management approach

THE HISTORY OF ISO 9000
Why ISO 9000?

- Developed during the 1980s
- Followed on from many similar quality standards around the world
- Similar to the BS5750:1979 management system initiative which had proved highly successful
- The standard has been around — ISO 9000 standards were first issued in 1987, reissued in 1994, 2000 and again in 2008
- Now adopted by over 101 nations
- Every major trading partner of the US and the EC recognizes and is using ISO 9000
- Many customers now prefer ISO 9000 certified suppliers



The ISO 9000 standards were first issued in 1987, reissued in 1994, the third edition was published in December 2000 and the current version in November 2008. They rapidly became very popular, and have now been adopted by over 101 nations worldwide[1] — including every major trading partner of the US and the European Community. For any organization seeking an internationally-recognized model for management systems, here is the perfect answer. Not only are the standards already written, but hundreds of thousands of companies have implemented them successfully, achieving third-party certification to prove it. In addition, many customers are starting to look for ISO certification from those with whom they choose to do business.

[1]*Quality Systems Update*, Volume 7, Number 1, January 1997

Who or what is "ISO?"

No one!

The ISO in ISO 9000 comes from the Greek, and means "the same as." It is the same prefix as is found in the word "isobar" meaning a line on a weather map which connects areas where the air pressure is all the same.

What is the ISO organization, and where are they?

Lots of people from lots of countries all over the world.

The ISO standards are published by the International Organization for Standardization, which has its offices in Geneva, Switzerland. It is a small office, with very few permanent staff, and all it does is to coordinate the activities of a whole lot of committees, called Technical Committees (TCs), and publish their work when it is completed. Individual countries then decide whether or not to use the standards that the International Organization for Standardization publishes.

The ISO 9000 standards were written by TC 176, which has a wide representation from many countries including the US, and they have been adopted by the national standards organizations of countries worldwide. When a national standards body "adopts" an ISO document, it usually gives it a national number — hence, in the UK the ISO 9000 standards are called BS5750, in the European Community they are the EN29000 standards, and here in the US they are known as the ANSI/ISO/ASQ Q9000 series.

Why are they called something different if they are all the same?

Well, they are and they aren't!

That covers most options... An ISO standard which has been "adopted" by a national standards body of a country will undergo some minor changes for reasons of translation, use of language or local interpretation. Hence, in the ANSI/ISO/ASQ standards, the spelling varies from international English, and the words "International Standard" have been changed to "American National Standard."

ISO 9001:2008 has a whole big section on Design - I don't do that. What do I do?

You will need to take a good look at the scope of your business, review the standard, and decide which parts of clause 7 do not apply. You will then need to make a statement to that effect in your quality manual, which will also need to be revised somewhat to ensure that it covers all the requirements of the new standard.

If you are just starting, then you need to determine what your scope of business is, and that determines which parts of section seven of the standard you can ignore. Ask yourself these two questions:

1. Do my customers come to me because I have an excellent design of product or service?
2. Do my customers come to me with a problem expecting me to design a solution for them?

If the answer to either of these questions is YES, then probably all of section seven will apply.

I don't do design work — I have a stable, mature product that is slightly modified occasionally; I also make things for other people who provide me with all of the information. What do I do?

You design a scope statement which excludes design activity, and your quality manual will take an exception to the design part of section seven.

You will have retained the key elements of a management system for a company which ensures that the customer gets the right thing by having control over everything it does from buying materials through to delivering the product — and may also extend through to installing and servicing that product.

So why can't a company just use the ISO standards for the inspection and test part of their operations and exclude everything else?

After all, they are the people in the company who make sure the customers only get good stuff aren't they?

Hopefully not — not in a well run company anyway.

Every part of the operation contributes to what the customer receives. It will all depend on how your registrar chooses to interpret the guidelines issued by the accreditation boards.

In the UK, the organization which oversees the activities of the registrars has made it very clear that any system certification must cover all of the key activities involved in a company keeping its customers happy. None of the reputable registrars will tolerate partial certification, nor should they.

What are ISO 9000 and ISO 9004 then? Everything seems to be covered by ISO 9001.

Not quite.

Not everyone knows what sort of things should be included in a management system, or a quality management system as the ISO authors call it. So they wrote ISO 9000 to help people understand the type of issues to think about when putting together a system. They also decided to reduce the number of documents which had to be used, and so the quality vocabulary which used to be contained in ISO 8402 has been transferred over to ISO 9000. There is a lot of it, by the way.

ISO 9004 is a guidance document, and the new version due soon provides commentary on "Managing for the sustained success of an organization — A quality management approach". It has the identical layout to the ISO 9001 document, and actually incorporates all the text of the ISO 9001 standard. For each section of the 'requirements' document, ISO 9004 provides guidance on how to use the management system to enhance performance of the organization. It is not a document against which an audit can be conducted, it is purely meant to inform and assist. There is no need for anyone to look at ISO 9004 if they don't want to, but it contains a lot of good ideas, and along with ISO 9000 it provides a philosophical background to the requirements standard.

So what's all this stuff about philosophy if ISO 9000 is all about basic management principles?

Any management system needs some sort of baseline philosophy if it is to be coherent.

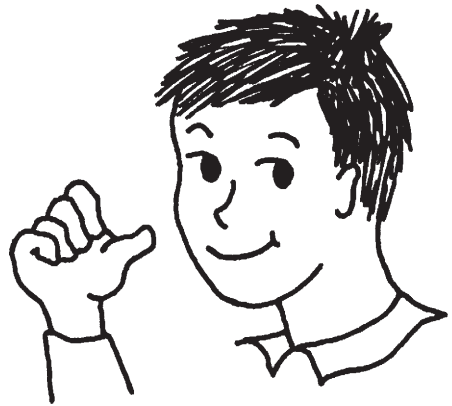
It need not be complex; indeed it doesn't even have to be anything new and exciting. Apart from anything else many managers are fed up with new and exciting management ideas — they have had a bellyfull of them in the past few decades and in the reality of application few of them have been particularly exciting nor even particularly successful.

The ISO 9000 family has always been based on simple basic management principles, and with the publication of the year 2000 version TC 176 decided that it would be a good idea to articulate eight core principles of management which have been taken into consideration during the development of the standard.

The standard is not directly based on these eight principles, but before seeking to implement a system based on ISO 9001:2008 an organization should at least take a look at them.

They are to be found in ISO 9000:2005.

A summary of the eight principles can be found on the next page, and a more detailed explanation is on the two pages following.



The Eight Quality Management Principles

Principle 1

Customer focus: **organizations depend on their customers and therefore should understand current and future customer needs; meet customer requirements and strive to exceed customer expectations.**

Principle 2

Leadership: **leaders establish unity of purpose and direction of the organization. They should create and maintain the internal environment in which people can become fully involved in achieving the organization's objectives.**

Principle 3

Involvement of people: **people at all levels are the essence of an organization and their full involvement enables their abilities to be used for the organization's benefit.**

Principle 4

Process approach: **a desired result is achieved more efficiently when related resources and activities are managed as a process.**

Principle 5

System approach to management: **identifying, understanding and managing a system of interrelated processes for a given objective improves the organization's effectiveness and efficiency.**

Principle 6

Continual Improvement: **continual improvement should be a permanent objective of the organization.**

Principle 7

Factual approach to decision making: **effective decisions are based on the analysis of data and information.**

Principle 8

Mutually beneficial supplier relationships: **an organization and its suppliers are interdependent, and a mutually beneficial relationship enhances the ability of both to create value.**

THE QUALITY MANAGEMENT PRINCIPLES

Principle 1.

Customer focus: Understanding what the customer wants is the first step in being able to fulfill customer expectations. Many organizations don't take the trouble to understand what their customers want but make assumptions which can be very inaccurate. The first step along the road of fulfilling customer expectations is that of understanding exactly what is required.

Principle 2.

Leadership: Top management in any organization set the tone for its operations. This is why top management are required to create the policy and objectives and carry out regular reviews to assess the effectiveness of the system.

Top management is required to take a lead in communicating the importance of meeting customer and statutory requirements, in setting quality objectives and deploying them throughout the organization, and in ensuring effective communication throughout the organization.

Principle 3.

Involvement of people: There can be no more basic truth than this statement. Without people no organization exists — it matters not how wonderful the technology or how great the investment. The heart of every organization in the world is the people who make it operate. Nothing is as important.

Principle 4.

Process approach: The standard promotes a process approach to the construction of a management system. The only effective way to both create and implement any such system is to map the processes involved from initial concept or customer enquiry through to final product/service fulfillment. The processes are then documented taking due notice of relevant inputs and outputs at all stages of the activities.

Principle 5.

System approach to management: This obviously links closely with Principle 4. The standard documents the basic requirements for an effective management system. This systemic approach to management has proved itself to be an engine for improvement and efficiency for many years.

Principle 6.

Continual Improvement: The ability to identify opportunities for improvement and implement those improvements has always been a core part of the ISO 9000 Standards. The processes of corrective and preventive action, internal audit and management review are the principal engines which drive continuous improvements of products, processes and systems. The standard also commits top management to seeking ways to continually improve the effectiveness of the quality management system. Improved effectiveness means added value.

Principle 7.

Factual approach to decision making: The standard has always provided a basis for data-driven decision making. The performance metrics which are a core part of ISO 9001 remain key to the effective operation of any management system.

Principal 8.

Mutually beneficial supplier relationships: This principle seems to have been overlooked! The standard contains no requirements which will enhance supplier relationships with the single exception that the 'criteria for selection, evaluation and reevaluation' are to be specifically defined. There is also specific reference to outsourcing, which is obviously a significant activity.

MANAGEMENT SYSTEM CONCEPTS

Good implementations of the ISO 9000 standards have always been focussed on process activities and customer satisfaction. ISO 9001:2008 places considerable emphasis on both of these.

The role of top management is very prominent and the concept of continuous improvement is a thread woven right through the requirements. The core of the management system are the product realization processes.

The basics of understanding a customer's requirements and having methods in place which ensure that they are consistently met are as old as trade itself.

A management system is a collection of resources comprising capital, people, processes and procedures which ensures that a customer's requirements for quality are met by the supplier organization. To really make sense of this statement it is necessary to understand what is meant by 'quality' in the context of ISO 9001.

Quality is not goodness, scale or niceness. Quality is conformance to defined specifications in terms of performance, price and delivery. The technique used to achieve that conformance is called quality assurance or quality management — hence the term 'quality management system'. The system is a means whereby the organization's management can plan what they are trying to achieve in terms of delivering a quality product to their customers, plan how they should go about fulfilling that intent, and plan how to provide everyone involved with the tools, techniques, training and instructions necessary to fulfill their tasks effectively.

In doing all this,
remember that 'simple is efficient'.

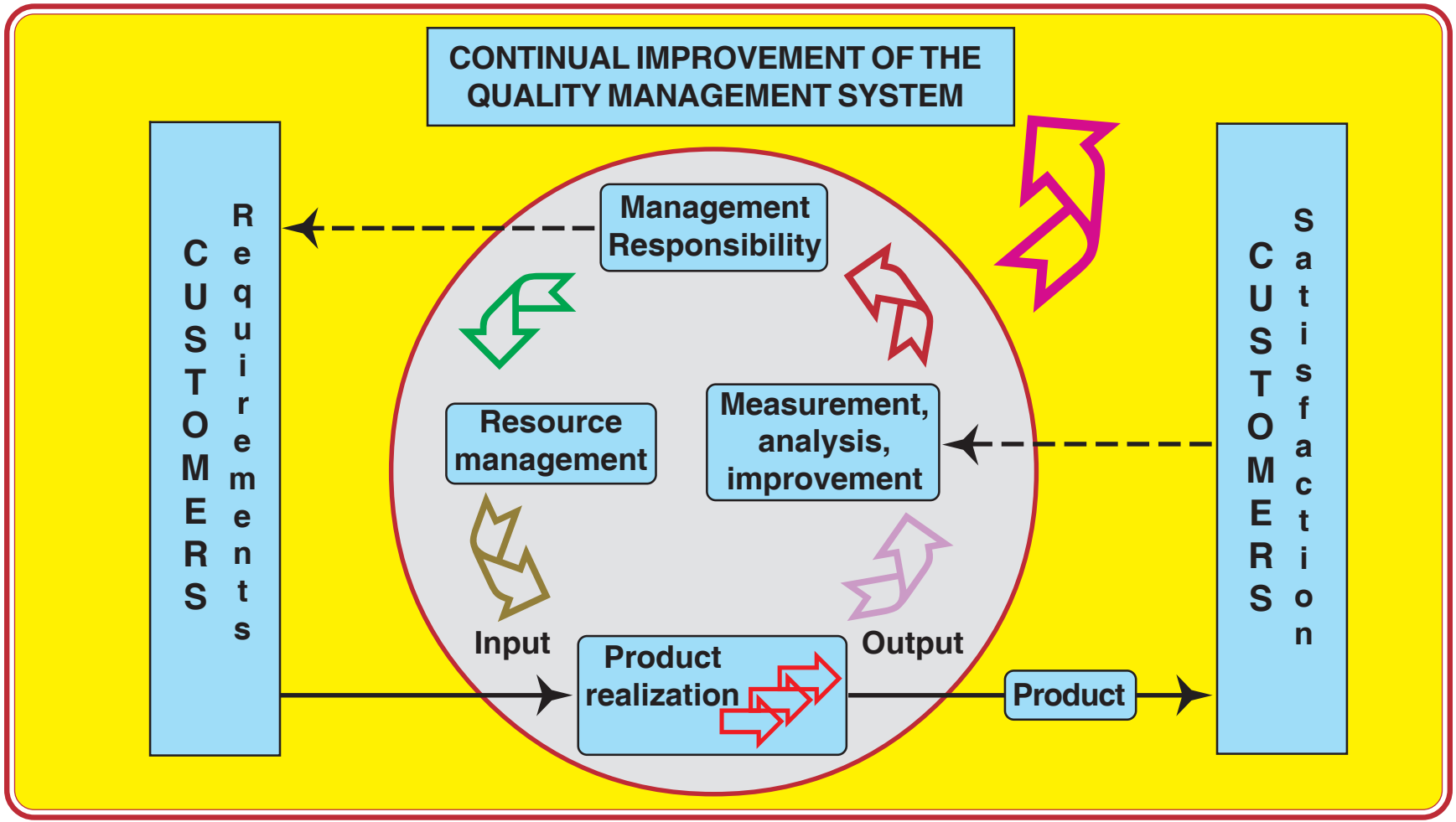
Some organizations have the luxury of their customers telling them precisely what they want, and then they go of and fulfill those requirements. Other companies start on more difficult ground, and one of the first things that they have to do is to figure out what their customers want — in other words, they have to develop the specifications against which they will provide the deliverable.

This activity embraces the concept sometimes called 'the voice of the customer' — which is the process of listening to end-user feedback — as well as addressing the need to comply with regulatory requirements, anticipate what new regulations may be in force when the product or service is ready for delivery, being aware of what the competition is doing now, and trying to guess what they may be doing down the road. Guessing where client taste is likely to be by the time the deliverable hits the streets adds yet another dimension, and for some organizations, all this has to be done on a global scale.

Once the design is determined, the organization then has to create the production process, purchase materials, arrange delivery methods, handle orders and all of the million and one other details which go into the successful development, manufacturing and delivering of a product or service to the customer. A management system is the series of processes and methods whereby all this is done; an ISO 9000 management system is one based upon the precepts of the ISO 9000 Series of Standards. This framework which has been found to be extremely effective in improving the operational activities of many companies.

The concept of the management system as a series of interconnected processes whereby customer requirements and associated external requirements such as statutory, product, health and safety or environmental specifications or needs, are integrated to provide a stable methodology for the creation of customer satisfaction is the practical application of the 'Plan — Do — Check — Act' cycle variously known as the Shewart, Deming or human activity cycle. Diagram 1 shows how ISO 9001 activities reflect the PDCA model, and is shown on the following page.

Figure 1 - Diagram 1



On the next page, Diagram 2 shows the ISO 9001 version of the model, and shows how the elements follow the process cycle.

Starting at the top right hand side of the picture, Paragraphs 1 through 4 of the Standard address issues which effectively shape and direct all the activity within the management system.

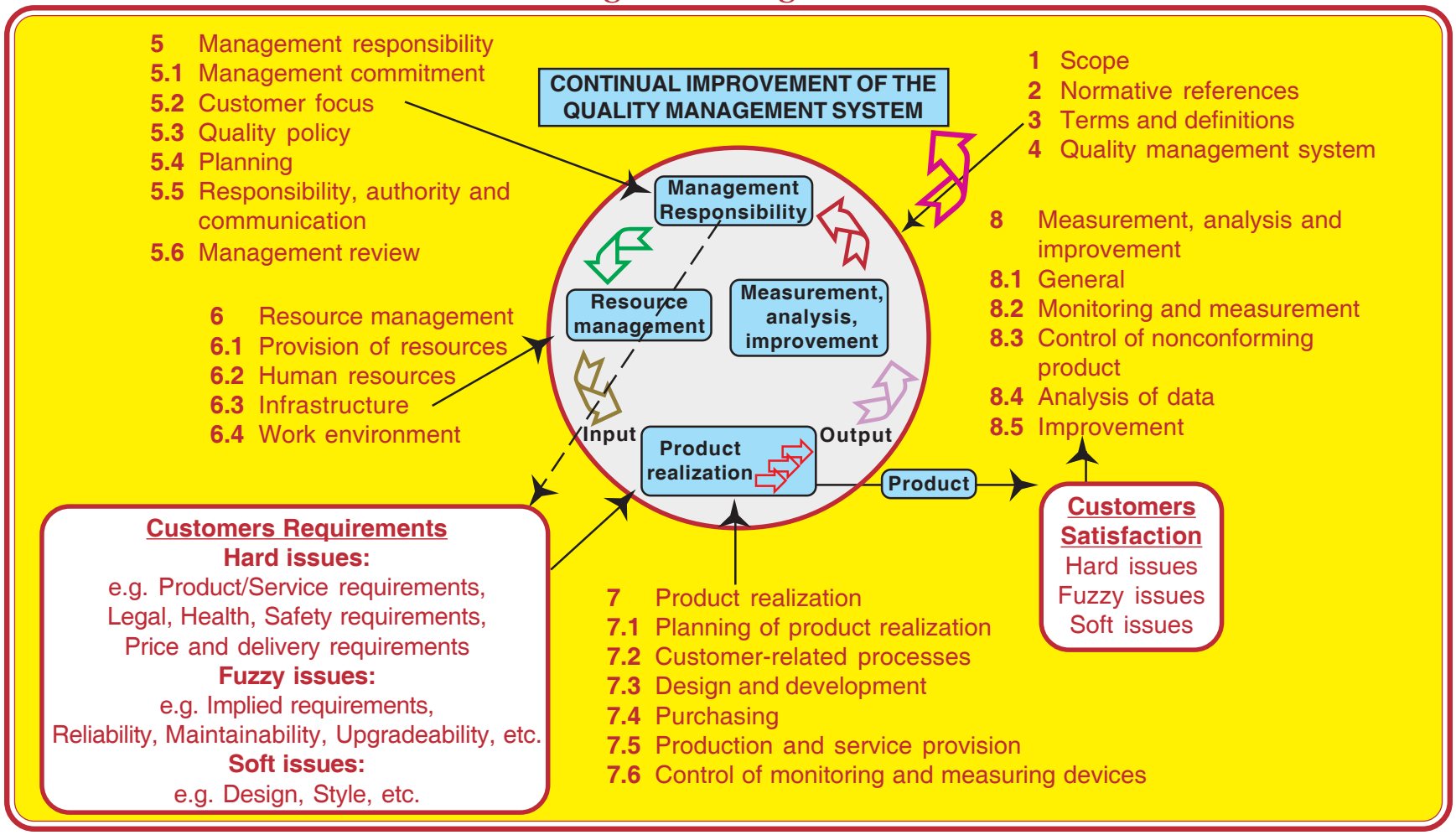
Moving to the top left of the diagram, the illustration lists the five clauses which identify the responsibilities of management within the overall system.

Moving counterclockwise the next set of activities to be encountered are those of resource management.

The box entitled 'product realization' is where the identification of customer needs and the translation of those needs into deliverables is addressed.

The final block in the diagram on the next page addresses measuring, monitoring and improvement. It covers planning, implementation, control of errors, analysis of data and using this information to drive value-added improvement of products, processes and the system.

Figure 2 - Diagram 2



THE ISO 9000:2008 FAMILY

The year 2000 family of standards was radically different from its predecessors. There was only one requirements document, which was ISO 9001:2000, and the text tried to shift the focus of the system to processes. The 2008 version continues this.

ISO standard	Title and description of content
ISO 9000:2005	**Quality management systems — Fundamentals and vocabulary**
	Revision of ISO 8402:1994 and ISO 9000:1994
ISO 9001:2008	**Quality management systems — Requirements**
	Revision of ISO 9001:1994, ISO 9002:1994 and ISO 9003:1994
ISO/FDIS 9004:2009	**Managing for the sustained success of an organization — A quality management approach**

ISO 9000:2005 provides information and guidance on the fundamentals of management systems and the concepts behind them. It also contains ten sections containing eighty-six definitions of terms relating to quality, management, organization, process and product, characteristics, conformity, document, examination, audit and quality assurance for measurement purposes.

The remainder of the document is concerned with what it describes as the 'fundamentals of quality management systems.'

ISO/FDIS 9004:2009 has a brand new function which is to provide guidance on ways of managing sustained success.

Be careful — it is very specifically *not* a guideline for implementation.

UNDERSTANDING ISO 9001:2008

Continual Improvement

Continual improvement is fundamental to the implementation of the standard. A management system provides data which can be used to predict likely points of failure and provide for action to be taken to avoid those failures. It will also capture data on actual failures and take action to correct the situation and prevent its recurrence.

Requirements for documentation

The requirements for documentation are lean. The term 'documented procedure' appears just six times. The mandatory procedures are for the control of

- documents,
- records,
- internal audits,
- nonconforming product,
- corrective action,
- preventive action.

The standard also requires

- a quality manual,
- a statement of quality policy, and
- quality objectives.

Apart from these, the rest is up to you — whatever you decide is necessary to ensure control of your processes and continual improvement of the effectiveness of the management system.

It might be light on required documents, but it certainly isn't in terms of records. Specific statements requiring that records are maintained appear twenty one times, and at least five other records are implied.

In theory you could have a management system which only maintains the minimal list of documents given above, and yet which still complies with the standard. Every other activity which the organization undertakes could be defaulted to training and experience — but this really isn't a recommended approach if you are serious about having an effective system.

Legal and regulatory issues

The standard is heavy on regulatory issues as well. There are seven separate references to these matters, and these are in the sections which deal with the general intent of the system, its scope and application, the commitment of management, the determination of product requirements, and the input to design activity. Top management are expected to ensure that they are operating within the law.

Customer satisfaction

The primary intention of any management system should be one of assuring customer satisfaction through the prevention of defects. The ISO 9000 family are no exception.

The purpose of a management system

Why bother?

What is the system trying to achieve?

The answer is this

1. to ensure that an organization has a defined, consistent, managed process to capture customer requirements including technical, price and delivery requirements;
2. to convert those requirements into the appropriate deliverable (product, service, etcetera) through the use of a controlled, monitored and reported process;
3. ensure that the deliverable remained in conformance with the customer's requirements until the contractual obligations of the organization end; and
4. provide management with hard performance data which can be used to prevent future product, system or process failures, thereby driving continual improvement.

That's what ISO 9001 is all about.

Implementing a management system isn't an operational issue. It is a strategic decision which must be driven by top management. The purpose of having a management system is to meet customer and regulatory requirements. This, after all, is what keeps any organization in business. The system has to be the core business system. Meeting customer expectations has to be the central business requirement; along with that are responsibilities to staff, shareholders and society at large. For many organizations the customer is often all these others as well, and meeting customer expectations involves satisfying every stakeholder. ISO 9001 can be used by any organization — production, service, retail, voluntary. Even religious congregations have found benefit in the process model for fulfillment of goals and objectives.

THE REQUIREMENTS

The next section of the book is numbered to align with the clauses and paragraphs of ISO 9001:2000 to help anyone who is reading this book in conjunction with the standard.

1 Scope

2 Normative references

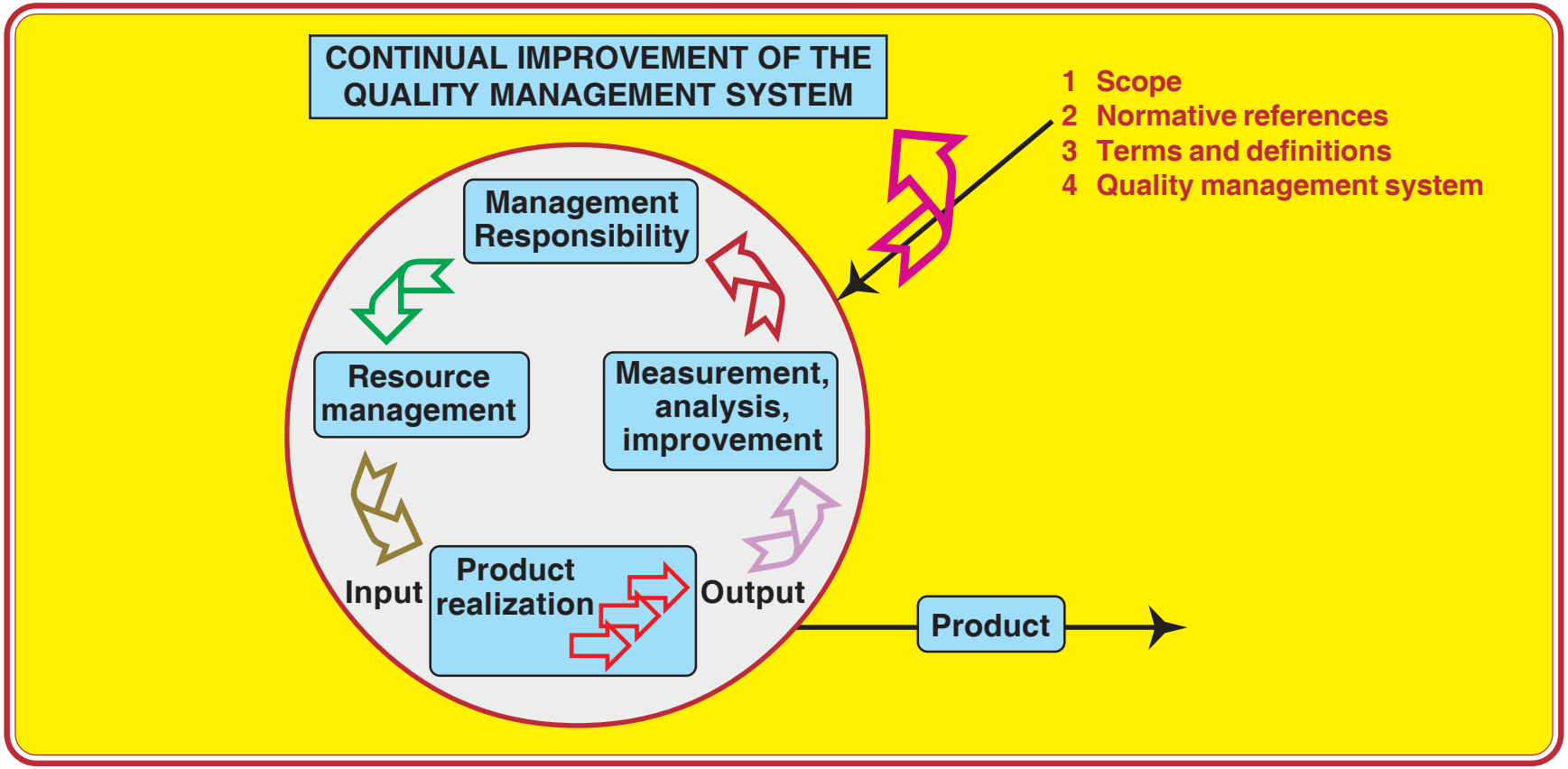
3 Terms and definitions

4 Quality management system

THE REQUIREMENTS

This section of the book is numbered to align with the clauses and paragraphs of ISO 9001:2008 to help anyone who is reading this booklet in conjunction with the standard.

Figure 3



1. Scope

1.1 General

The system for the management of quality is prevention.

One of the four Quality Absolutes propounded by American Quality guru Phil Crosby is found in the first paragraph of ISO 9001. The Crosby maxim that 'Quality is Conformance to Specification' perfectly reflects this application. The effective implementation of an ISO 9001 system is based upon the ability to define requirements and measure the achievement of those requirements.

A very important 'NOTE' attached to clause 1.1 explains that the system developed to manage the business and conform with the standard is intended for the products and services being delivered to external customers. Things done for internal use only need not be done in accordance with the same systems and processes.

For example vendor controls don't have to apply to things bought for in-house use, such as canteen facilities, main services, stationary, maintenance of non product-related machinery, etc. Only those items which have a direct impact on the deliverable need to be controlled.

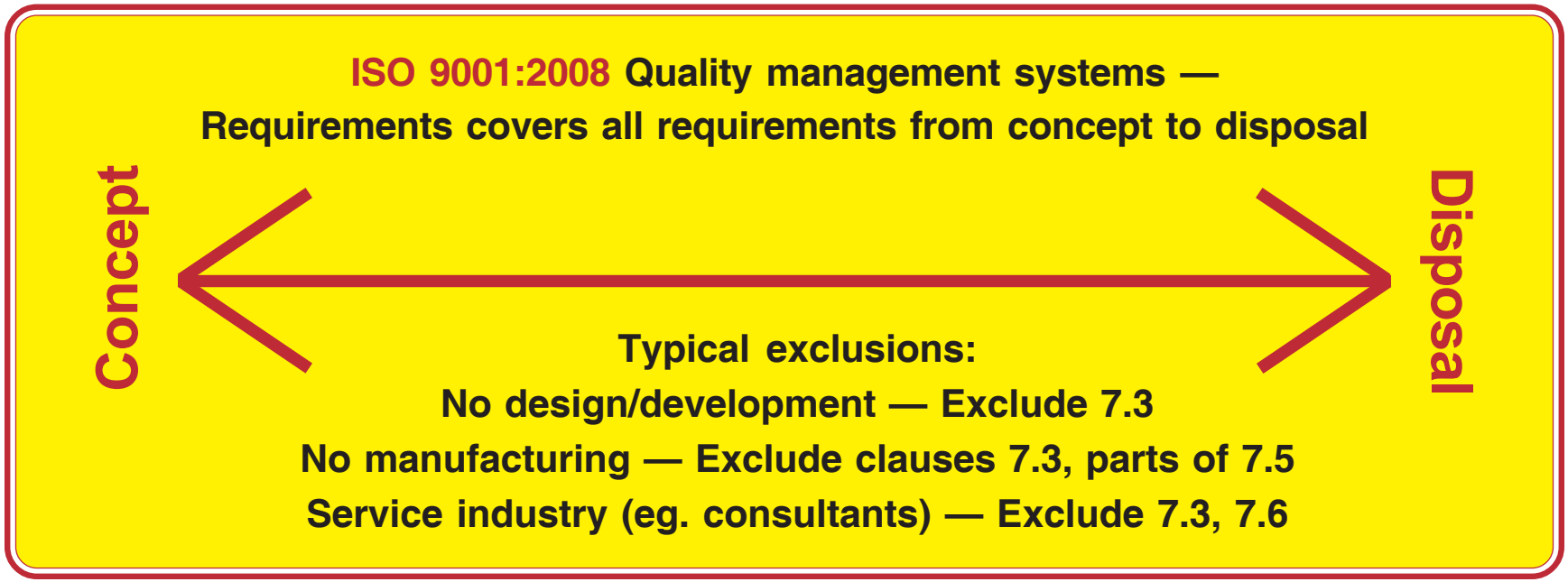
Defining System Scope

The system scope statement is the way in which prospective customers can identify the activities which the ISO 9001 system covers. Paragraph 1.2 explains which parts of the requirements can be considered for exclusion from the system. Basically, if an organization doesn't do something, then that 'something' is out of scope. If you do it and it impacts on the deliverables in any way, then the activity is 'in scope'. Only those activities described in clause seven can be excluded, and even then you must be sure that anything that is excluded doesn't *"affect the organization's ability, or responsibility, to provide product that meets customer and applicable regulatory requirements."*

If you don't do design, then all the design and development requirements can be excluded. If you buy nothing which impacts on the customer then control of purchasing and suppliers isn't relevant.

The concept to disposal continuum demonstrates the concept of scope and how it applies to an ISO system — see figure 4 below.

Figure 4 - The Concept to Disposal Continuum



2. Normative References

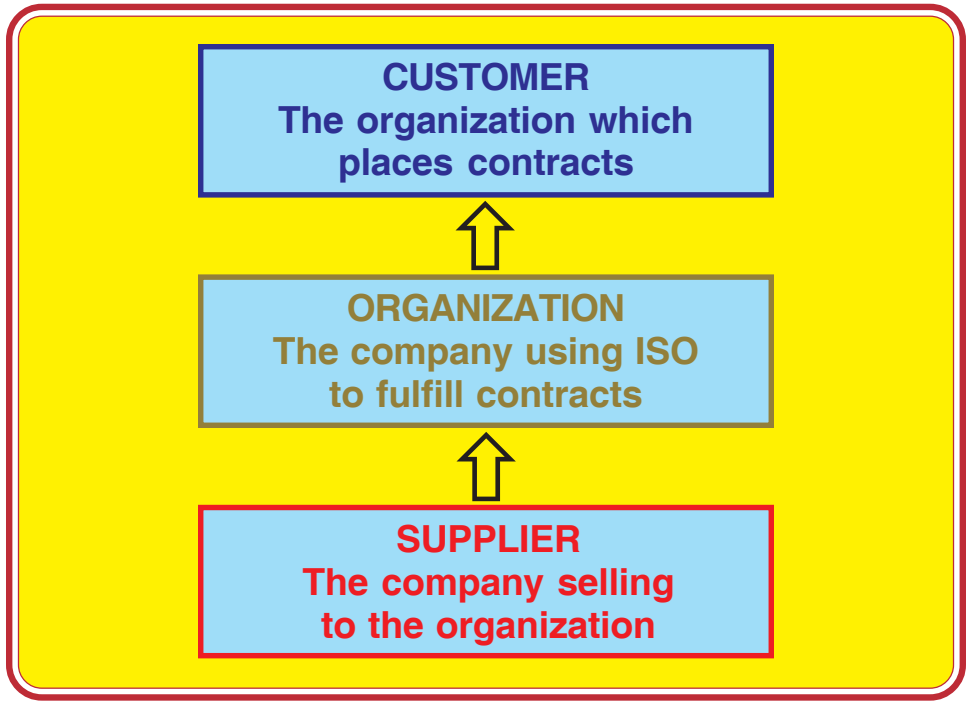
The terms used in ISO 9000 are the 'official' language of the ISO 9000 world. Any organization which uses the same words in a way which is at variance with ISO 9000 — which can easily happen — will need to document those variances way to avoid confusion. In the absence of any such changes, an external auditor will default to the meanings found in ISO 9000:2005.

3. Terms and definitions

ISO 9001:2008 contains no definitions. It defers to ISO 9000:2005. This paragraph does point out that wherever the word "product" occurs, it can also mean "service". Note the use of *also.* Manufacturers often provide services as well.

The relationship between 'customer', 'organization' and 'supplier' as used in the ISO 9000 standards is the intuitive relationship which most people would understand.

Figure 5 - The relationship between Customer, Organization and Supplier



The diagram illustrates the way the terms will be used in this book unless specifically stated otherwise.

4. Quality management system

This paragraph summarizes the structural requirements of a management system.

4.1 General requirements

This paragraph identifies the core internal processes of the organization which the system needs to address together with their interrelationships, monitoring and control and the continual improvement of the processes, the system and the products it produces. It also specifies that any outsourced processes are also required to be under the control of the management system, thereby making vendor management a top strategic issue.

There are three 'Notes' after this paragraph, and two of these emphasise the importance of control of outsourced processes.

4.2 Documentation requirements

Paragraph 4.2 neatly packages all the documentation requirements for the system into one section of the standard.

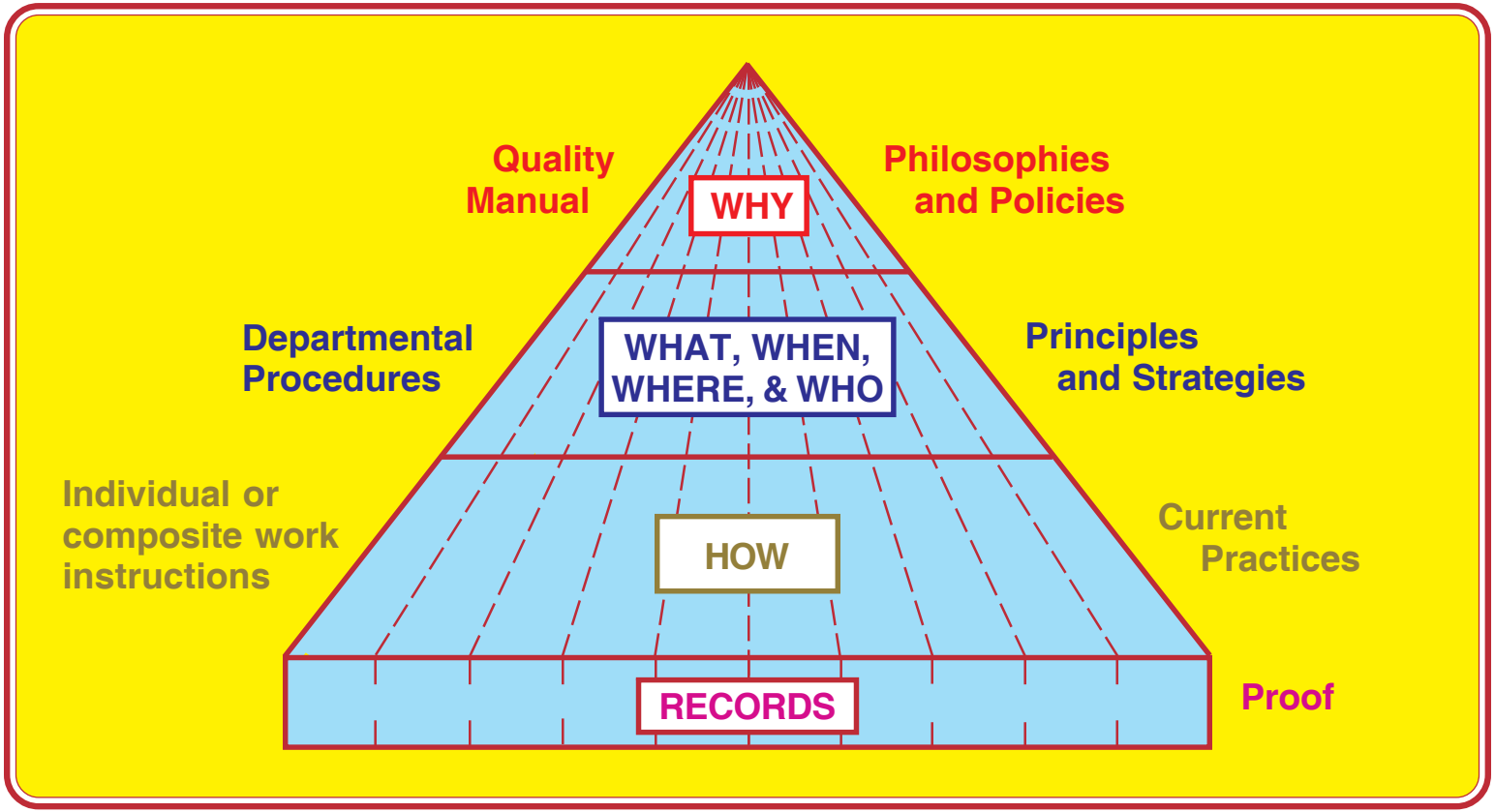
4.2.1 outlines the documentation required for the management system. This clause effectively describes the overall structure of the typical management system, with the required content of the quality manual contained in 4.2.2, the controls required of formal system documents in 4.2.3 and control of system records in 4.2.4.

The mandatory documentation requirements have already been listed — they are the manual, half a dozen procedures, the policy and objectives, and whatever other stuff you think you need.

The quality policy must be endorsed by top management and it must be widely distributed through out the organization. Management must also ensure that the quality objectives are appropriate to the needs to the customer and the organization and that they are deployed to the appropriate levels of the organization.

Management systems are most often illustrated with the pyramid diagram — see figure 6 on the next page — this reflects the fact that there tends to be more documentation as you get closer to the where the hands-on work is done. Most of the documentation which comprises the structure of this pyramid will be determined by the organization itself, as described earlier. The exception is the record-keeping requirement.

Figure 6 — The classic model of the Management System



Note 3 after clause 4.2.1 reminds the reader that these 'documents' can be in any form or type of medium. They can be paper, electronic, film, video, audio, etcetera. Whatever works for the organization is OK within the requirements of ISO!

Regardless of whether a document is required by the standard or the organization, if it is put into the system then it must be controlled. It must be also reviewed and approved by appropriate personnel before being issued and again every time it's changed. The organization needs to know what version number of each document is, and in order to be able to exercise effective control someone has to know where each document is.

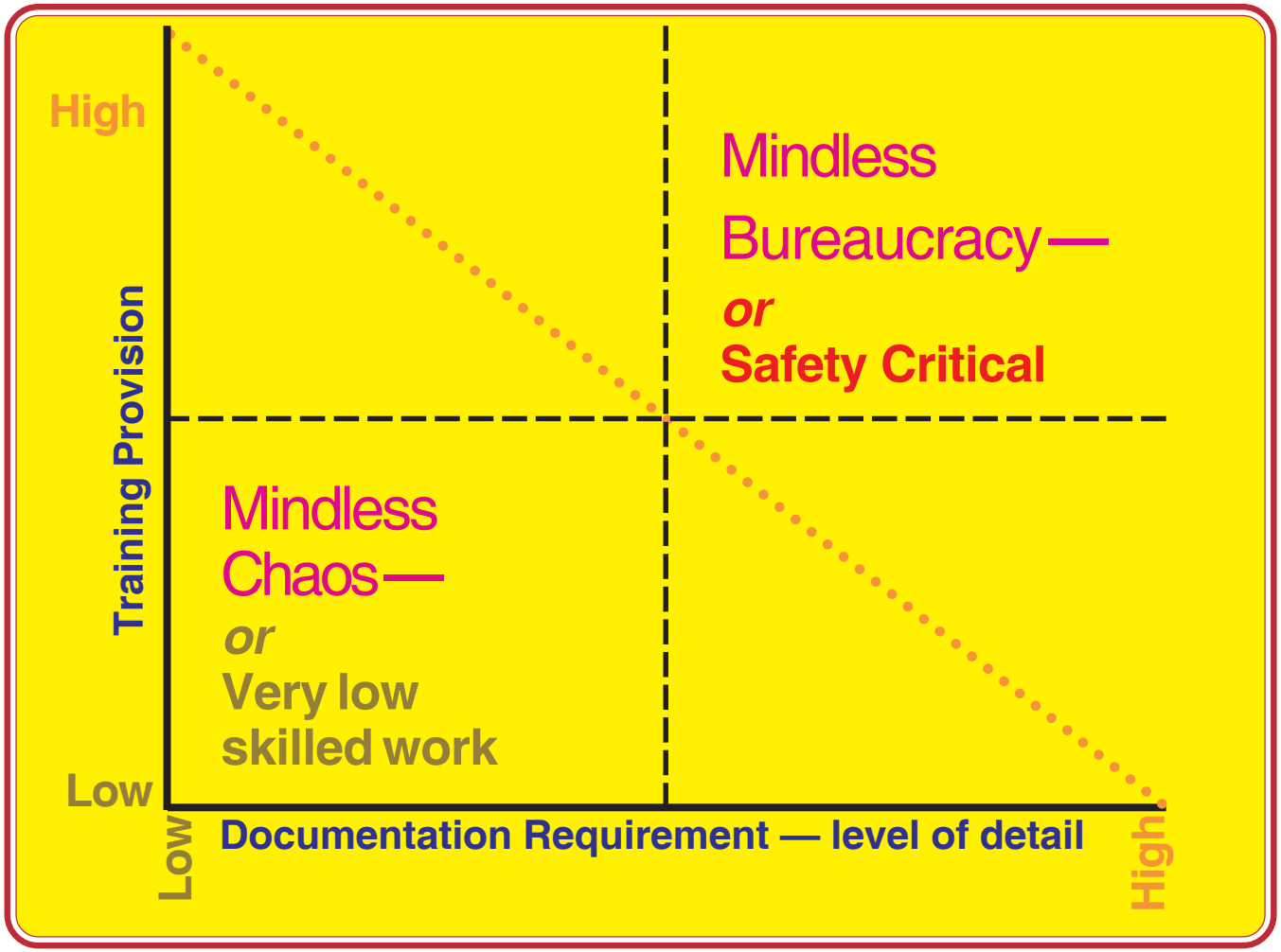
When documents are retained after they have been withdrawn appropriate steps must be taken to make sure that the obsolete documents are not used accidentally. Apply the four '**R**'s to ensure that —

- **the Right information,**
- **in the Right place,**
- **at the Right time,**
- **to do the Right job.**

Remember that the level of detail in the system documents you create will vary according to the type of work being performed, the complexity of the processes and the degree of training and experience of people doing the work. The standard calls this the 'competency' of the staff. The figure 7 on the next page explains this concept.

External documents must also be controlled. These are things like specifications and standards, e.g. ISO or IEEE standards, safety and regulatory documents like MSDS sheets and customer-supplied documents such as drawings or specifications.

Figure 7 - Documentation Requirement — level of detail



Paragraph 4.2.4 describes the requirements for records. There are twenty-six types of records directly or indirectly identified in the standard, and they are listed below and on the next page.

1)	5.6.1	Management Reviews
2)	6.2.2	Competence, awareness and training
3)	7.1	Planning of product realization
4)	7.2.2	Review of requirements
5)	7.3.1	Design planning output
6)	7.3.2	Design and development inputs
7)	7.3.3	Design and development output
8)	7.3.4	Design and development review
9)	7.3.5	Design and development verification
10)	7.3.6	Design and development validation
11)	7.3.7	Design and development changes
12)	7.4.1	Purchasing process
13)	7.5.1	Control of production and service provision
14)	7.5.1	Control of production and service provision
15)	7.5.2	Validation of processes for production and service provision
16)	7.5.3	Identification and traceability
17)	7.5.4	Customer property

18)	**7.6**	Control of monitoring and measurement devices
19)	**7.6**	Control of monitoring and measurement devices
20)	**7.6**	Control of monitoring and measurement devices
21)	**8.2.2**	Internal audit
22)	**8.2.4**	Monitoring and measurement of product
23)	**8.3**	Control of nonconforming product
24)	**8.4**	Analysis of data
25)	**8.5.2**	Corrective action
26)	**8.5.3**	Preventive action

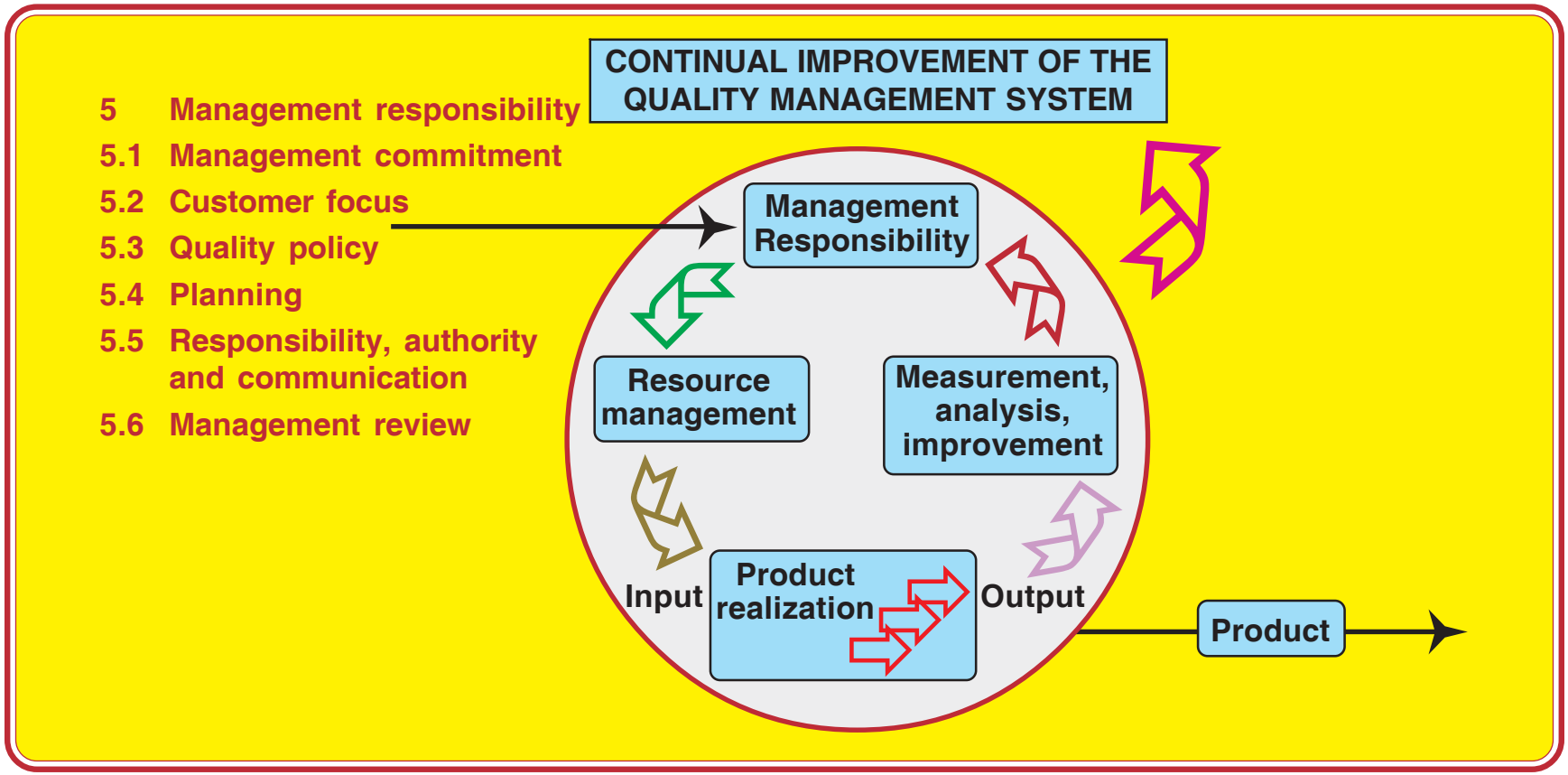
The purpose of these records is to demonstrate that the management system is working as planned. They have to be looked after; there are six key issues which the records management program needs to address, and they are

- identification,
- storage,
- protection,
- retrieval,
- retention and
- disposition.

With the exception of retention, these are all aspects over which you exercise complete control. Retention time will depend on legal, customer and organizational requirements. Very occasionally the preferences of a registration body may be considered for one or two types of record, although the wishes of a certification body should be low down on the list.

The next section deals with Management Responsibility

Figure 8 - Management Responsibility



5. Management responsibility

Paragraph five deals with top management issues. They are

- commitment, (5.1)
- policy, (5.2)
- objectives, (5.3)
- planning, (5.4)
- responsibility and authority and (5.5)
- management review (5.6).

In ISO 9000 language, 'top management' means the people who have executive authority to direct and control the organization. Section 5.1 describes the requirement for management to provide leadership to the organization by

a) demonstrating a commitment to meeting customer requirements and meeting statutory and regulatory requirements;

b) defining the quality policy of the organization and ensuring that it is understood and maintained;

c) defining the quality objectives of the organization and seeing that they are successfully deployed;

d) ensuring that they regularly review the operation of the management system to drive ongoing development and improvement of the operations of the organization; and

e) ensuring that there are adequate resources available to implement and maintain the system.

Each of these top management responsibilities is linked to a description of the requirements elsewhere in the standard.

5.2 Customer focus

This places a general obligation on top management to ensure that customer needs and expectations are central to the way that the organization does business.

5.3 Quality policy

The quality policy must be defined by top management. It must be documented and under formal control. It must be appropriate to the needs of the organization and its customers, must provide a commitment to continually improve, must provide a framework for the review of quality objectives and must itself be reviewed at regular intervals.

The policy needs to be communicated and understood throughout the organization. It is usually an expected that every member of staff will have an understanding of the quality policy and how to apply it in their day to day work.

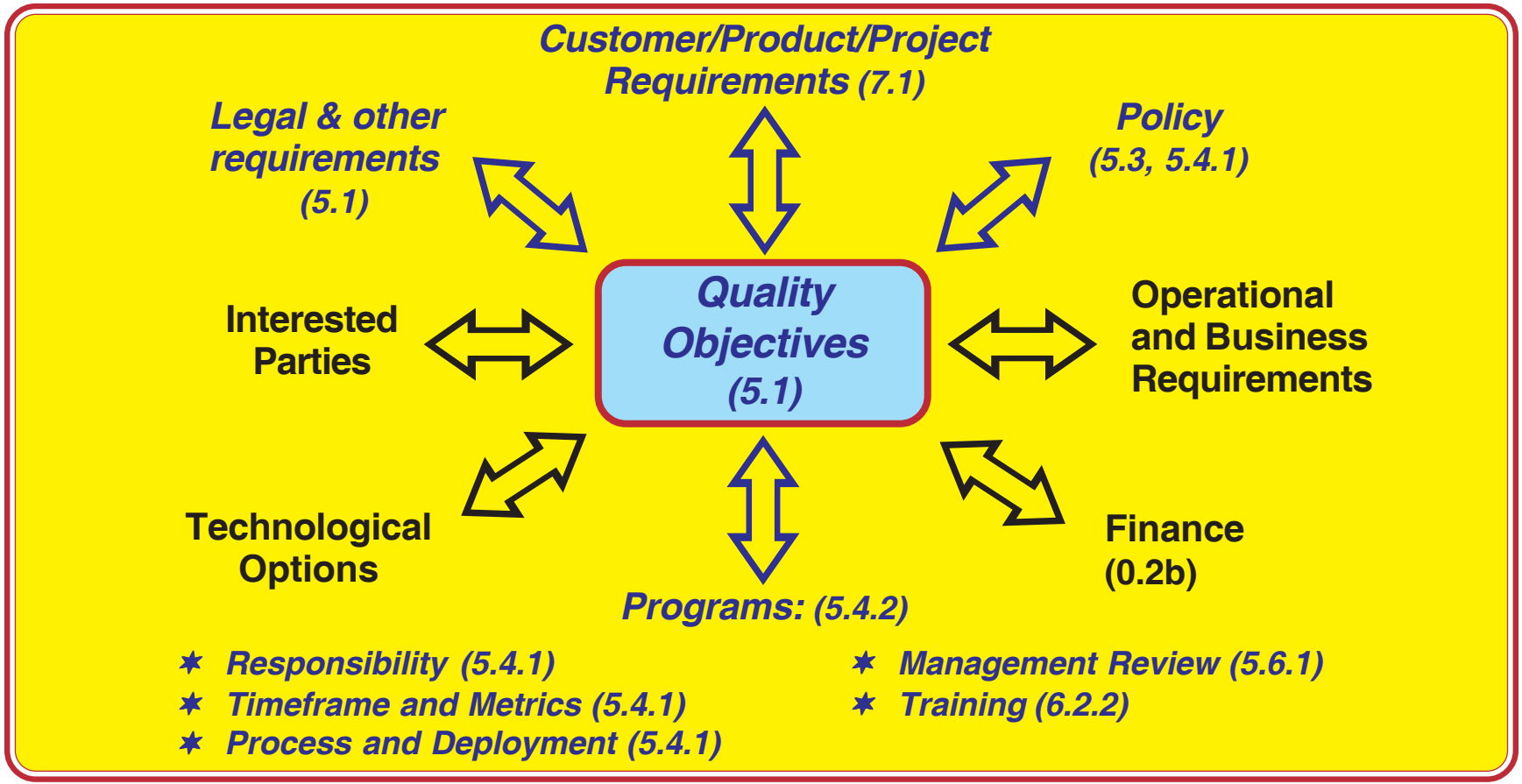
5.4 Planning

Planning falls into two categories; planning to fulfill the quality objectives, (5.4.1) and planning to fulfill product requirements and the integrity of the management system (5.4.2).

Quality objectives have to be defined and deployed at all ***"relevant functions and levels"*** of the organization. Management must define what levels are relevant and then ensure that processes exist which will ensure that the objectives are achieved. The activities which surround the creation and deployment of quality objectives are demonstrated in the diagram on the next page.

The best definition of 'relevant' is 'all'.

Figure 9 - Elements of Quality Objectives



Italicized text indicates issues which are specifically referenced in ISO 9001.

Normal text indicates issues which should be considered for business reasons in evaluating and establishing quality objectives.

The second type of quality planning is the fulfillment of the requirements of 4.1 and figuring out how to maintain the integrity of the management system when changes are made. Both of these are top management responsibilities.

ISO 9001:2008 tries to help a better understanding of the concepts of quality planning by differentiating between planning for the management system, which is addressed in this paragraph (5.4), and planning for the product realization process, which is dealt with in paragraph 7.1.

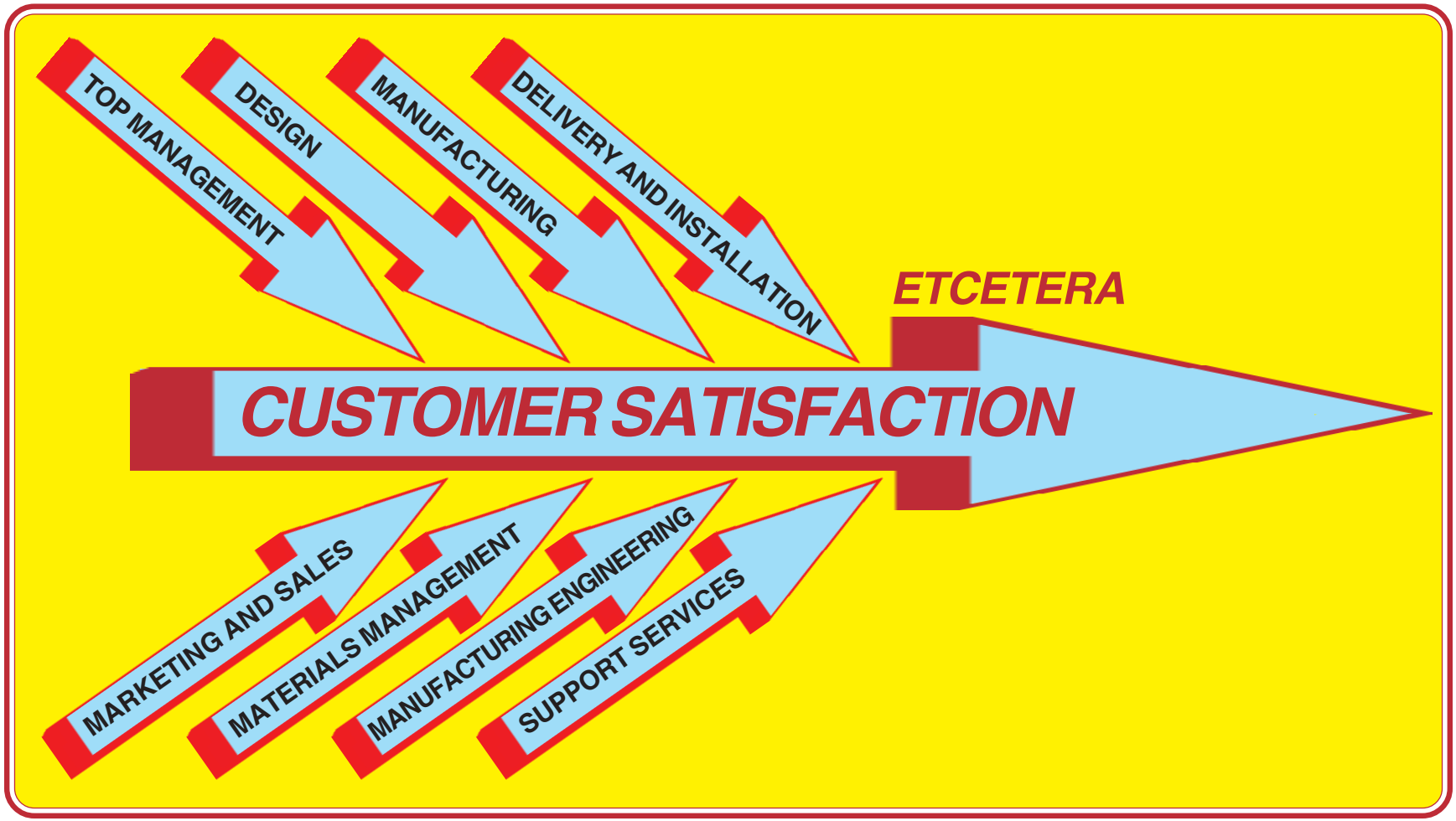
The activity described in paragraph 5.4.2 is that of 'planning for quality' across the scope of the entire management system. Part of this activity is ensuring that changes to the management system are managed in a way which ensures that control is maintained. This requirement needs to be considered in creating the document control procedure. The effective management of document control processes includes the management of the introduction of changes to processes and systems.

5.5 Responsibility, authority and communication

Everyone in an organization does work which affects quality, and effective interaction between functions and operations is the key to success. Within any organization the effective fulfillment of customer, organizational and societal requirements is dependant upon the contributions of all the various functions of the organization. Figure 10 shows how every activity contributes to the effectiveness of the whole, conceptually providing a seamless horizontal process flow. Unfortunately no-one has yet managed to figure out how to run an effective organization using a fishbone management structure.

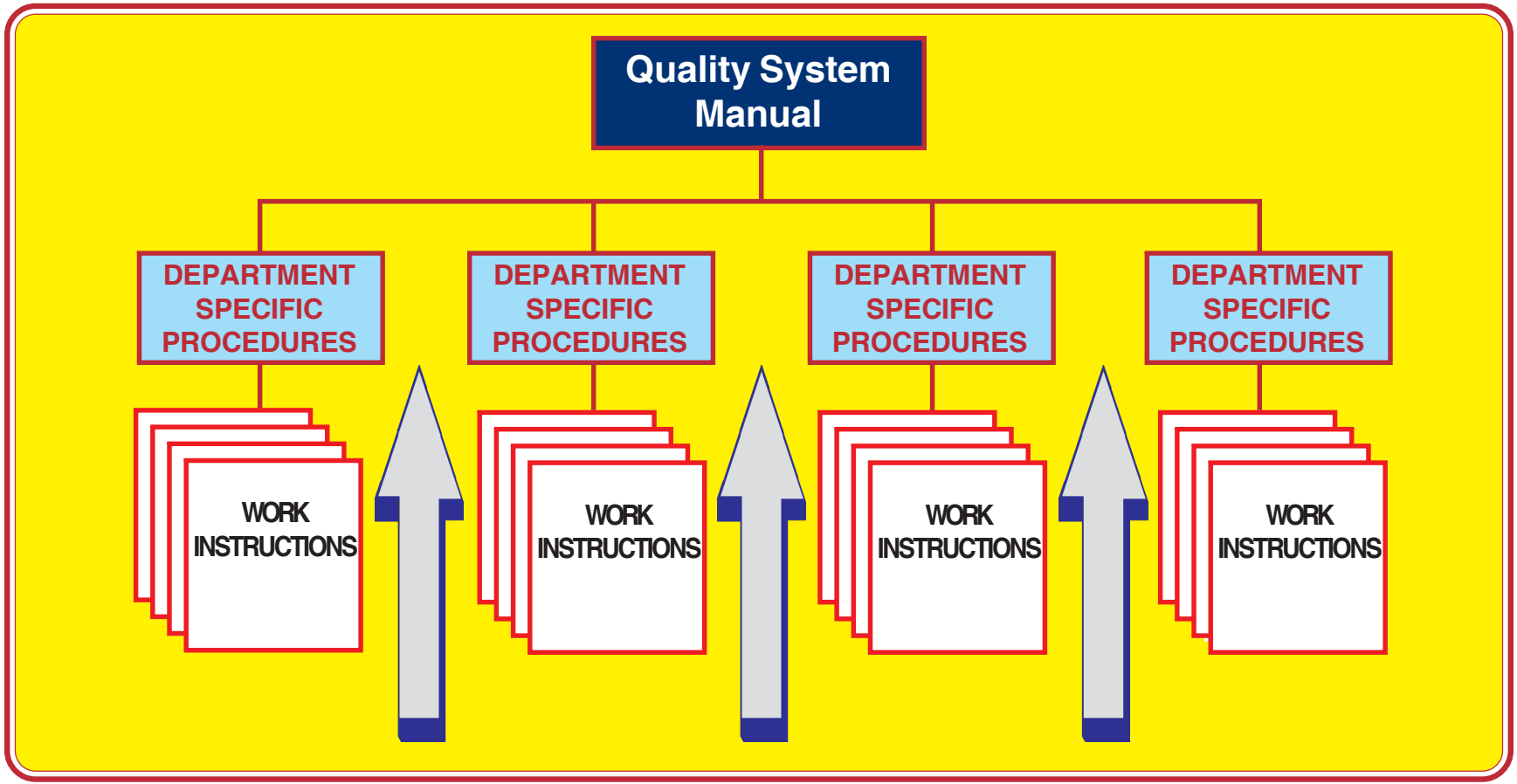
A diagram illustrating the fishbone management structure is shown on the next page — figure 10.

Figure 10 - A fishbone management structure



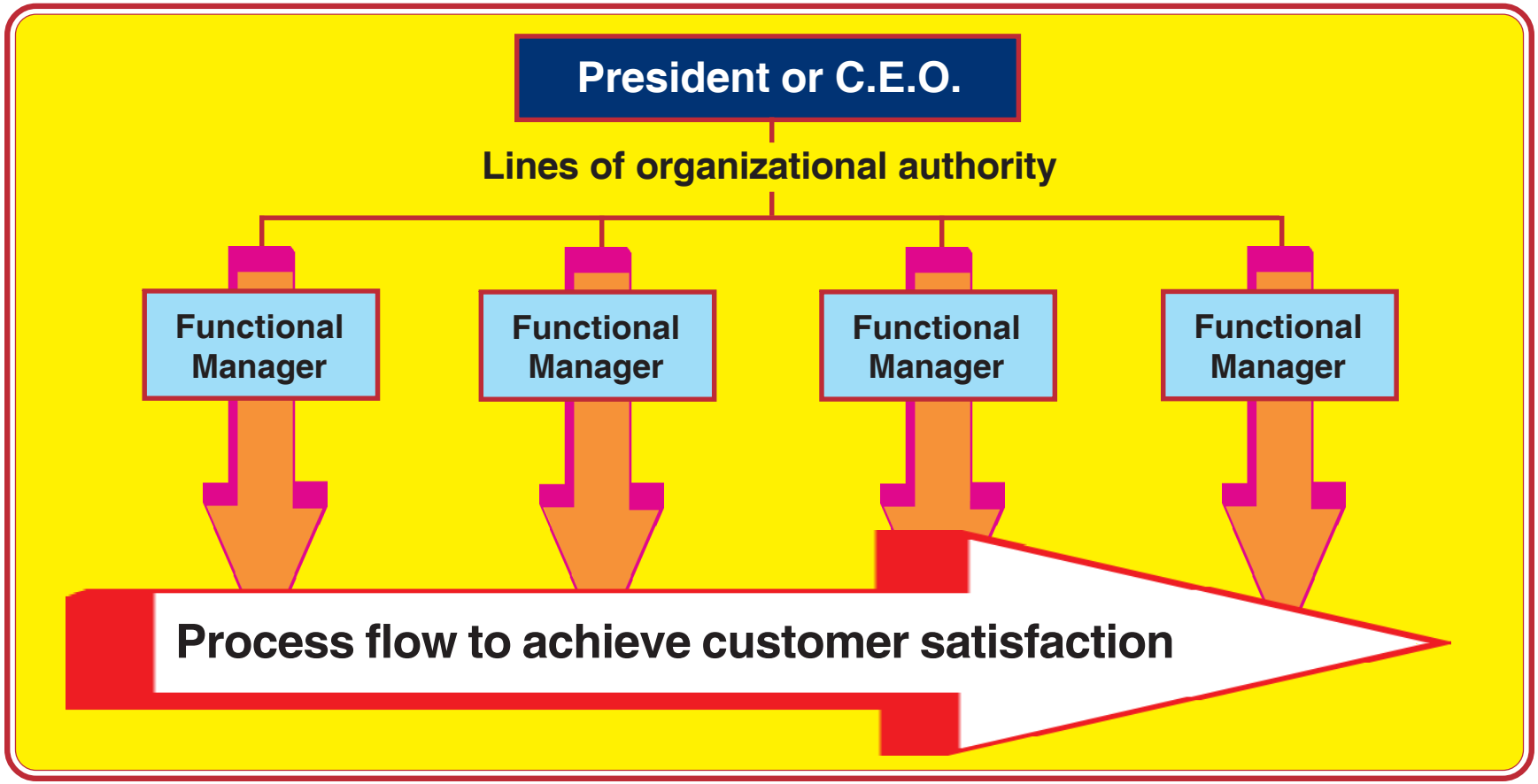
The typical organizational structure is hierarchical and too often documents follow the same pattern, thereby creating the organizational 'white space' which is so often the cause of communication breakdowns and problems.

Figure 11 - The typical hierarchy of documents



Taking the horizontal process flow demonstrated in the fishbone diagram which is required to achieve overall stakeholder satisfaction and superimposing that concept on the hierarchical structure of most organizations results in the situation illustrated by Figure 12.

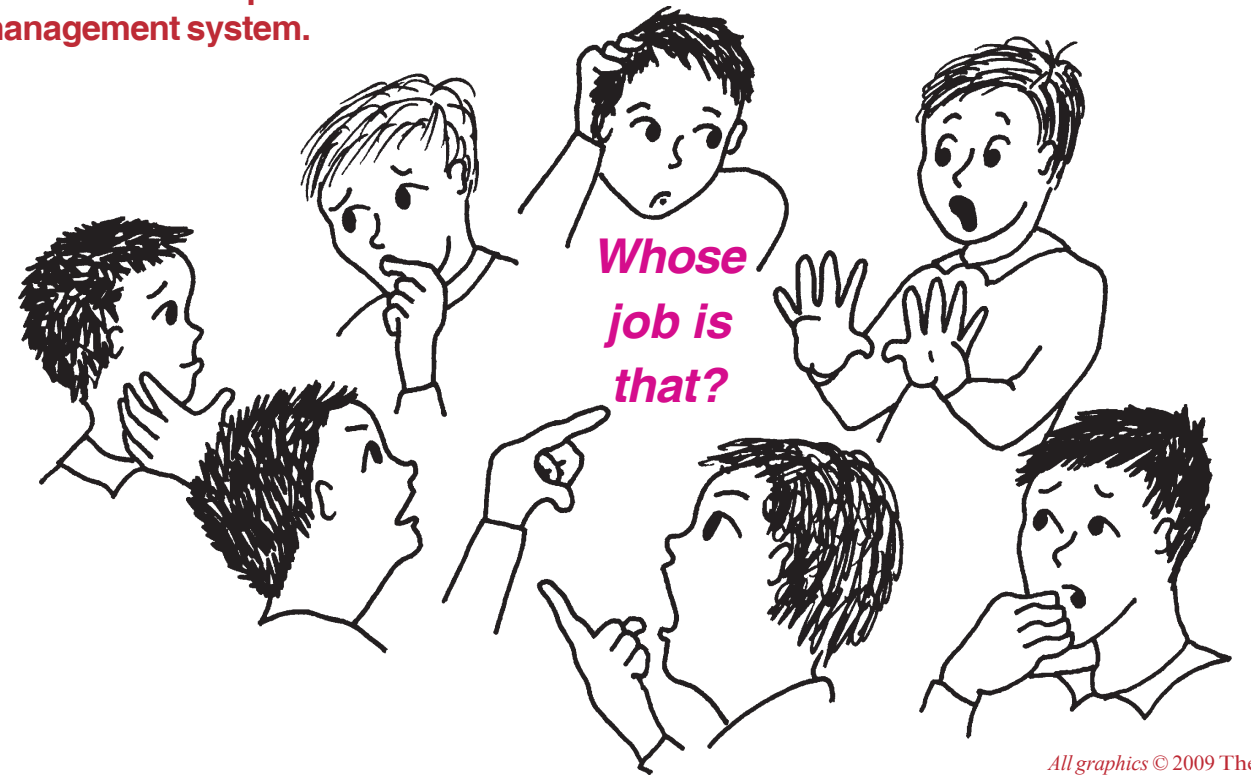
Figure 12. Management Structures vs. Customer-related Processes



A structured management system provides the opportunity for horizontal processes to be operated successfully within a vertical organizational structure; it creates the process inter-linkage between functional activities, and is used to document the responsibilities and authorities of operational functions.

There are many choices of ways of documenting responsibilities and authorities available to an organization, and ISO 9001 mandates no process or method. The important issue is that the structure and interrelationships are visible and clear to all concerned.

***'Whose job is that?'* is not a question which should ever need to be asked in a well-structured and clearly documented management system.**



5.5.2 Management representative

The management representative is the person who has delegated authority from top management to ensure that the system is properly established and implemented and effectively maintained. The management representative must have full authority to fulfil that role.

For the management system to support the goals and objectives of the organization, top management must know what is going on and how things are working. One of the most important jobs which the standard gives to the management representative is reporting to top management on how the system is working. In order to be able to do this data must be collected on the effectiveness of the system and used it to identify those areas where improvement is possible. The top management team can then implement those improvements and monitor their effectiveness.

The management representative must also ensure that awareness of customer requirements is actively promoted throughout the organization, and this is another task which he or she should bring to top management for fulfillment.

Typically the management representative also looks after all third-party certification issues, the internal audit program and any external enquiries about the system.

Being a management representative should not be a full-time job; the maintenance of the system may not even be a primary responsibility. Remember everyone is responsible for the quality of their own work. In a well managed organization there should be little need for a formal Quality Department and the Standard accepts and even encourages that concept.

5.5.3 Internal communication

This requirement has migrated to ISO 9001 from ISO 14001, although the scope of the clause is totally different. One of the main purposes of establishing a management system is to have a means for communicating organizational and customer requirements to staff. Now top management is being asked to communicate back to the organization information on how effective the system is.

Remember that the effectiveness of a management system is a measure of the effectiveness of the management team. The standard requires that this information is shared.

5.6 Management review

It is vitally important that top management keep watch on how the organization is working, and the standard calls this process 'management review'. The requirements are that there should be regular reviews; that reviews address defined issues and that the output of the activity are relevant to core system goals.

By the way, keep records of these meetings!

The purpose of management review is to assess how effectively the system is fulfilling the quality policy and objectives, its continuing suitability and adequacy to fulfill those objectives, and to identify opportunities for improving the effectiveness of the system.

The mandatory inputs to management review are:

- consideration of the continuing suitability of the quality policy;
- review of the quality objectives and their measurement;
- action items from previous meetings;
- positive and negative customer feedback;
- data on how processes are performing and how well products and/or services are meeting requirements;
- the results of internal audits;
- what preventive and corrective actions have been taken and the status of those activities;
- any impending changes which could affect the operation of the management system, and
- any recommendations for system, process or product improvement which need to be considered by top management.

The required outputs from management review activities are all and any decisions and actions which relate to:

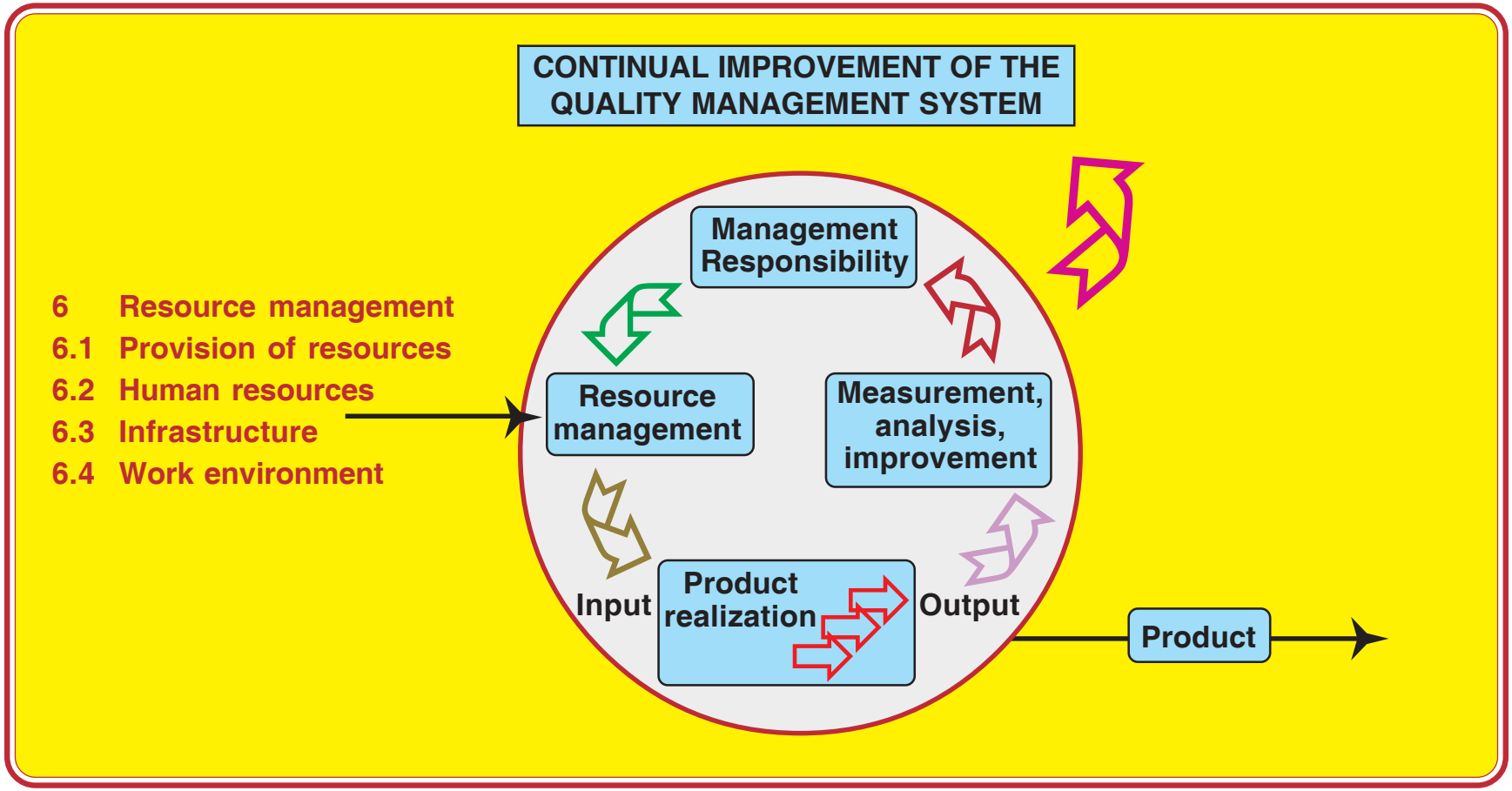
- the improvement of the effectiveness of the system;
- the improvement of the effectiveness of processes;
- the improvement of product with respect to customer requirements, and
- any resource needs identified as a result of the review activity.

Records of reviews and resultant actions must be maintained in accordance with 4.2.4.

By the way, keep records of these meetings!

The next section deals with Resource Management

Figure 13 - Resource management



6. Resource management

The first resource requirement states that all staff performing work affecting quality must be competent.

The sub-paragraphs then define three areas of resource management.

6.2.2 specifies how to handle issues of staff competency and the records required to demonstrate those competencies;

6.3 defines the infrastructure issues which must be addressed, and

6.4 the required work environment.

The art of management is always the art of managing scarce resources. Resources comprise a supply side and a demand side. The supply side consists of people and capital – including facilities and equipment. The demand side consists of stakeholder needs. Getting the balance right between the supply side and the demand side is the art of management.

Determining and providing resources is what top management does on a daily basis. The standard places a particular focus on the resources needed to implement and maintain the management system, continually improve its effectiveness and meet customer requirements, thereby enhancing customer satisfaction. Resources extend down the supply chain which is why paragraph 4.1 contains the requirement for any outsourced processes to be under the control of the organization's system.

Management must determine and provide the infrastructure it needs to achieve product conformity. This may include premises and associated facilities, sub-contracted supplier organizations, equipment and software and services such as transport and communications. The identification of all these issues should be an output from the quality planning function along with any maintenance requirements.

The management of the work environment should cover such issues as

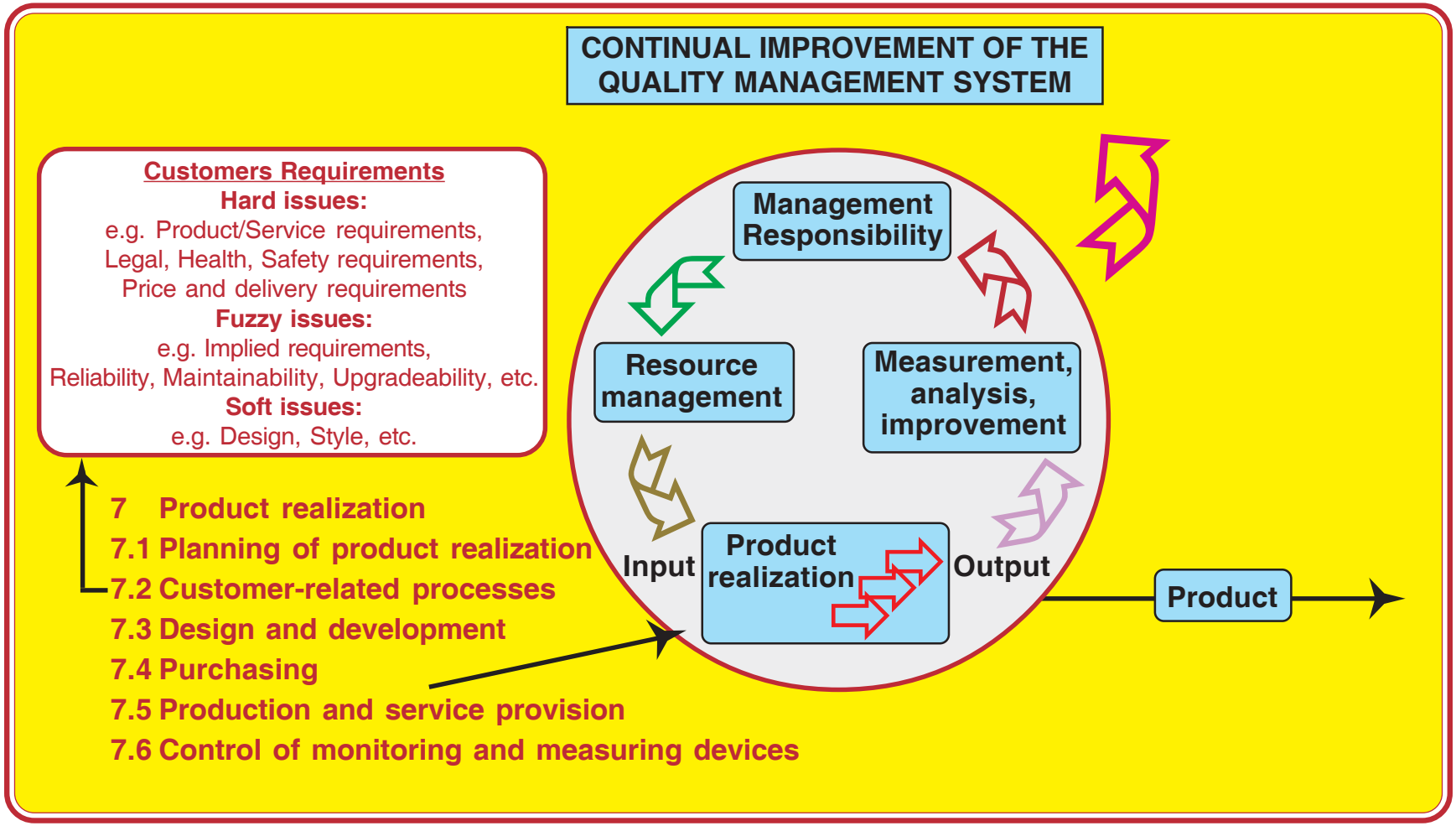
a) assuring legal compliance with health and safety requirements,
b) identifying and controlling any special environmental requirements,
c) ensuring that housekeeping is reasonable for the type of work being performed.

These issues link with the requirements found under 7.5.1, operations control, and 7.5.5, preservation of product. Both address issues which might be considered to be work environment. The use of a clean room or implementing Electrostatic Discharge (ESD) precautions can be managed under any of these three clauses. It doesn't matter what label is put on these matters, so long as they are taken care of.

Assure legal compliance with health and safety requirements!

The next section deals with Product Realization

Figure 14 - Product realization



7. Product realization

This term is the generic heading for all the activities which cover everything from initial customer contact to post-delivery maintenance, when required. In most organizations these activities are performed by separate management functions which are sometimes geographically remote from each other. The bucket of requirements found under this heading have to be distributed across the organizational structure.

In summary clause seven of the standard addresses the following issues:

7.1 Planning of product realization

This covers all the things which used to be called quality planning, and addresses how the organization makes appropriate arrangements for meeting customer requirements.

7.2 Customer-related processes

These are broken into three areas; identification of product requirements, the review of requirements and managing customer communications.

7.3 Design and development

Next comes design. Section 7.3 is divided into seven sub-sections.

7.4 Purchasing

Following on from the design and/or development requirements come those devoted to the subject of procurement activity.

7.5 Production and service provision

This covers process controls and validation, product identification and traceability, customer property and product preservation

7.6 Control of monitoring and measuring devices

7.6 addresses the issues of the control of calibration and use of test and inspection equipment and other measurement devices.

That is the big picture. Now for the detail.

7.1 Planning

Planning for product realization is product quality planning. It deals with identifying what has to be done, figuring out the process by which it will be done, the equipment and resources needed, the way in which the product will be checked and the records which will be maintained.

The activities are all *"as appropriate"*, which means that management determine which of the requirements are applicable and how they will be implemented. In many organizations 'planning for product realization' will be the natural result of just following the management system. Others will need to produce product, process or contract-specific quality plans. Which way you work depends on the nature of the activities and how much customer requirements vary from order to order.

A quality plan need not be a complicated or massive document.

***A quality plan is a* "document specifying the quality management system elements and the resources to be applied in a specific case".**

A specific case can mean a product, process, project or contract. A quality plan can be as simple as a product router or as complex as a multi-volume document which is constantly updated and changed as a major contract proceeds.

Activities to be considered are

1) Product specifications, quantity and delivery requirements;
2) How the product (or service, of course) is going to be created and the facilities required;
3) How the product or service is going to be verified at all stages of the process, and the criteria against which verification is going to be assessed;
4) What records will be kept to demonstrate conformity of process and product.

When planning and developing the product realization processes refer back to the guidance provided in section 4.2, then add in anything imposed through customer or regulatory requirements.

Be particularly careful of any inspection, test or record keeping activity.

Most systems use quality plans to some extent. Any document used by an organization to identify specific customer requirements can be called a quality plan, even if the information is restricted to quantity and delivery date.

7.2 Customer-related processes

These are broken into three areas of activity, which are:

1. **The identification of product requirements, both those provided by customers and those which the organization itself identifies including any statutory and regulatory requirements. Include delivery and any post-delivery activities within the framework of the *"specified or intended use, where known"*, which is an important comment in contract terms.**

The system should provide answers to the following questions:

a) Technical — are the requirements clearly defined?

b) Are they within the capabilities of the organization, or can the capabilities be acquired within the time constraints of the contract?

c) Can the organization provide the product or service on time?

d) Is the infrastructure in place to support the activity, or can it be acquired in time?

The one missing item is consideration of the organization's ability to meet the agreed price. This is an important part of both availability and support.

If the price is wrong — specifically if it is too low — then there may be inadequate resources available to provide the necessary support to the customer either during or after delivery.

2. Reviewing those requirements, ensuring that they are adequate and that the organization has the ability to meet the requirements.

This should be done before an order is accepted. If a quote has been provided, then the terms of the quotation should be checked against the related order to ensure that quote and the subsequent order match. Once an order is placed, any changes need to be managed and communicated within the organization. Records of this activity are required.

3. Managing customer communications, including contract issues, issues of customer satisfaction and customer complaints.

There is nothing in the ISO Standard which would prevent a company taking on a contract knowing that certain technical capabilities have to be developed during the course of the task, or knowing that capacity to meet delivery and post-delivery support has to be developed. The development of such capabilities may even form part of the contract itself. The important thing — what the Standard requires — is that the situation is properly understood and under control. Depending upon the nature of the business, the contract review stage of the process can either be very simple or extremely complex.

These days more and more retail and commercial business is being done through catalogs and the internet. The review of the accuracy of the published data forms part of contract review. The technical requirements are defined by the published information, and the individual contract review is then only of quantity and delivery information.

Depending upon the nature of the business, the contract review stage of the process can either be very simple or extremely complex.

7.3 Design and development

Design and development activities are described in seven discrete statements, each identifying a specific aspect of design and development activity.

- **7.3.1** Design and development planning
- **7.3.2** Design and development inputs
- **7.3.3** Design and development outputs
- **7.3.4** Design and development review
- **7.3.5** Design and development verification
- **7.3.6** Design and development validation
- **7.3.7** Control of design and development changes

This looks like the commonly used waterfall methodology for design and development, but you can demonstrate conformity to the requirements of the standard in any way you choose.

There is a complete absence of any requirement for documented procedures to describe the design and development process.

A 'note' attached to paragraph 7.1 suggests that organizations may want to use the principles described in 7.3 as a framework for designing their management system activities, particularly product realization processes. *Remember, 'Notes' are not requirements.*

At each stage of process the inputs and outputs must be documented and the records maintained. The emphasis is on defining what it is that the activity is trying to achieve and then recording what has been achieved. It is sufficient to demonstrate a framework of controls which assure that the design-phase outputs meet the design-phase inputs.

7.3.1 Design and development planning

Design and development planning involves the assignment of responsibility and authority for activities, defining the stages of the activity, identifying the reviews, verification and validation activities appropriate to each stage, the definition and management of functional interfaces and the update of planning activities as the design and development tasks proceed. Planning output must be updated as the activity progresses.

7.3.2 Design and development inputs

Design inputs must be determined and records maintained. These form part of the quality management system records. There are four classifications of information which must be considered for inclusion in the design input document. These are

- **a)** The functional and performance requirements for the design;
- **b)** Any statutory or regulatory requirements which may be relevant to the product or service:
- **c)** Any useful history which can be included from past experience in designing similar items including 'lessons learned' from past activities;
- **d)** Other requirements such as
- **e)** customer requirements for packaging,
- **f)** disposal after use,
- **g)** recycling of materials,
- **h)** process requirements,
- **i)** storage and maintenance requirements,
- **j)** interchangeability,
- **k)** upgradeability, etcetera.

The design organization must take all reasonable steps to ensure that every design requirement is identified at the front end of the design process rather than being found at final acceptance test.

Design inputs must be reviewed for adequacy and a record of this review maintained to provide audit evidence of the activity. This review must ensure that requirements are clear and not in conflict with each other. Any requirements which fail this litmus test must be resolved prior to design work continuing. If customer requirements are not properly identified at this stage of the process, the product will fail.

7.3.3 Design and development outputs

Design output is the next information which must be recorded and it must contain or reference information which does four things:

i. be approved prior to release,
ii. contain relevant information for the purchasing, production and servicing requirements of the product,
iii. provide criteria against which the product can be verified,
iv. address any safety aspects associated with the use of the product.

7.3.4 Design and development review

Some form of design review is mandatory for each design and development. The review activities which are to be undertaken at each step of the process are decided during the design planning stage, as is which functions need to be at each review.

There are three fixed agenda items required by the standard

i. evaluation of the ability of the design to meet the requirements, and
ii. identification of any problems, and finally
iii. appropriate action to follow-up and resolve any issues identified during the review.

Records of the outcome of the review and of any actions undertaken as a result must be maintained.

7.3.5 Design and development verification

Design proving appears as two activities called verification and validation. Good design practice includes design verification activities as part of a design stage review.

The type of activities which can be utilized in performing design verification are

- performing alternative calculations,
- comparing the new design with a similar proven design,
- undertaking tests,
- reviewing the documents before release.

Design verification should provide a clear audit trail for the design process which demonstrates the design has been shown to meet the design input.

7.3.6 Design and development validation

This is the second part of design proof. Verification should demonstrate that design output meets the design input. Design validation is intended to confirm that regardless of whether or not the design outputs meets the specification of the design input, does the resulting product fulfill the customer's needs in the real world?

The intent behind validation is obvious — check out the design in as close as possible to a real-world environment.

7.3.7 Control of design and development changes

The mandatory activities related to changes in design are quite extensive, but there is no requirement for a documented process. Design change activity must ensure that changes are identified, verified and validated and approved prior to their introduction. The impact of each change on the entire supply chain, including already delivered product, is to be evaluated. Records of all this activity must be maintained.

ISO 10007 Guidelines for configuration management, will provide more information for anyone faced with having to develop a complex change management process.

7.4 Purchasing

This section creates the requirements for the control of procurement operations. It is divided into three areas of activity — selection, evaluation and control of suppliers, the creation and development of purchasing information, and the verification of purchased product.

7.4.1 Purchasing process

If you want to make sure that purchased products and services meet your requirements, then check out the capabilities of the supplier. If the organization you are going to buy from doesn't have the technical ability or the capacity to provide what you want, then the items supplied will be wrong, or late, or both. Part of the art of being a good buyer is finding the right source.

The standard asks the organization to take a look at what it is buying, decide, item by item, how important they are to the product or service being supplied, and the determine what sort of control is needed over the supplier. Some things can be bought on the basis of price and delivery, others items are so critical that it is vital to ensure that the supplier is capable of meeting the requirements and to keep verifying that capability at regular intervals.

Records of approved suppliers, and the methods used to approve them are required.

7.4.2 Purchasing information

Once suppliers are selected, the next trick is to provide them with appropriate, accurate and reliable information. Purchase orders must be appropriately detailed and must identify any special requirements which attach to products, procedures, processes or equipment. This identification may be a reference to an additional document such as a national or international standard.

The same rules apply to any specific requirements for the qualification of personnel.

Examples of such requirements could include release status of electronic components (e.g. MIL883B) or ASME certification of welds on pressure vessels — which could also involve the ASME certification of the welder, the process and the equipment.

You don't have to buy from ISO registered organizations, but if that is a requirement, then include the statement on the purchase order.

If either your customer or your own organization want to verify product at the supplier's site prior to delivery then you had better say so on the PO, and you must also tell the supplier how you intend to carry out the verification and release of the product. Once all necessary information is on the PO, make sure that it is verified before it is sent out.

7.4.3 Verification of purchased products

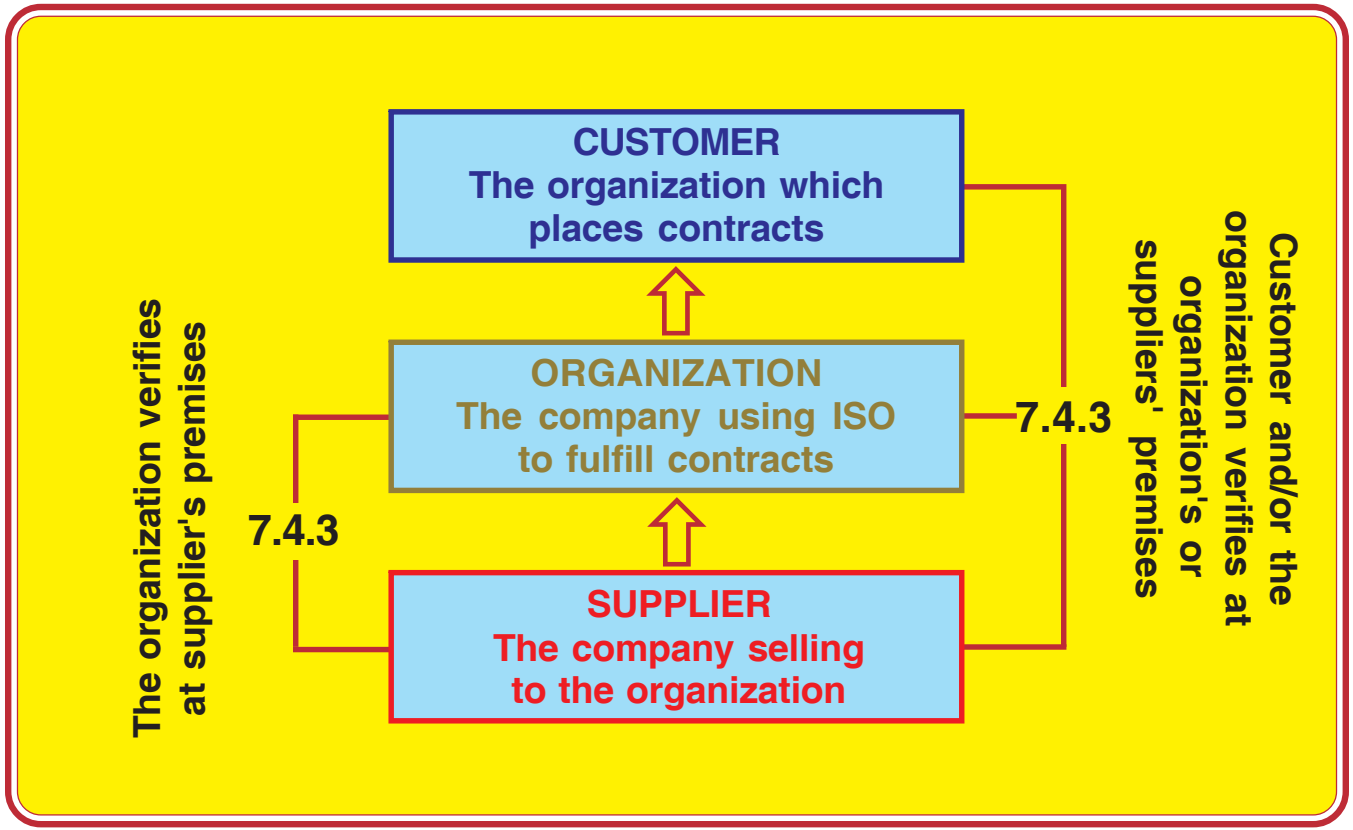
This covers all verification activities including receiving inspection. Basic requirements for monitoring and measurement of product also appear in 8.2.4. Put them all together and what's needed is to

- define the acceptance process,
- keep records of accepted product,
- identify who did the accepting, and
- ensure those personnel are appropriately trained and authorized.

This paragraph also addresses site acceptance. The four requirements above apply to this activity as well. Figure 15 on the following page illustrates this point

Ensure personnel are appropriately trained and authorized

Figure 15 - Verification of purchased products



7.5 Production and service provision

O.K. We've identified the requirements for the product, we've designed it, we've bought all the bits. Now it has to be put together. Section 7.5 in ISO 9001:2008 identifies the requirements for the control of that process. There are some general requirements which apply to all processes, and others which only apply to processes which cannot be fully verified.

7.5.1 Control of production and service provision

This section defines the controls for how the actual deliverable is created. It says that *"production and service provision"* is to be planned and carried out *"under controlled conditions."* Remember that 'production' can be the provision of a service. So the requirement for 'controlled conditions' apply to any activities of an organization which are concerned with the generation of something which is delivered to a customer.

There are six areas in which control is required.

1. The system is to provide information which describes the characteristics of the product. The information must fulfil customer, statutory, regulatory and the organization's own requirements.

   This covers everything from technical aspects to delivery requirements.

   Strangely enough there is nothing in the standard which directly addresses production planning and control (manufacturing resource planning). Resource and materials planning is one of the most important activities in achieving customer satisfaction, so it is important that these functions are included in the system.

2. Next comes a requirement for work instructions are made available, as necessary. In deciding what's necessary remember 4.2!

   Take full advantage of the education, training and experience of the staff.

3. Having addressed planning and documentation, the next requirement is for the provision of suitable equipment with which to carry out the work.

   Make sure that there is an appropriate maintenance plan in place, and keep records of the maintenance performed.

4. Next comes the requirement to ensure that measuring and monitoring devices are available and in use, as required. In many service organizations it is difficult to see what measuring and monitoring devices might be used.

   It is likely that this 'shall' will be no more than whatever form of in-process checks are carried out during service provision.

5. The standard encourages a process approach, and processes need to be monitored in some manner to ensure that the process output is that which is intended. The nature of these activities will vary enormously from one organization to another; in some environments process controls will be complex, in others no more than infrequent checks on final product.

   Records will be required in order to demonstrate the effectiveness of the controls in use.

6. Once the product realization processes are completed, final release happens and the product is delivered to the customer. A formal process is required for product release, and this must provide audit evidence that such a process exists and is used consistently.

   The same applies for delivery activities. There must be defined processes for both delivery and any required post-delivery activities such as installation, warranty support, etcetera.

   Don't forget to ensure that these activities produce audit evidence.

7.5.2 Validation of processes for production and service provision

These are processes which cannot be reliably certified by non-destructive monitoring or measuring (read this as meaning inspection and test in some form or other). Because of this problems may only come to light once the product is in use — or the service has been delivered. Any processes like this are required to be validated and have the necessary validation methods established and demonstrated, i.e. more records.

Process validation consists of all or some of these

a) the qualification of the process,
b) the qualification of the equipment,
c) the qualification of the personnel,
d) the use of defined methods,
e) the use of defined procedures,
f) the need for process and process validation records,
g) the need for process re-validation.

7.5.3 Identification and traceability

This clause of the Standard addresses three separate individual requirements. All are to be applied, as appropriate, at all stages of the process from raw materials to post-delivery activities.

1. Identification

It is actually difficult to imagine a business operation where identification is not both required and maintained in some way or other. The standard requires that where appropriate methods are developed and used for identifying the product at all stages of its life-cycle.

2. Status

Status relates to the usability of the product. Like the requirement for identification it applies at all stages of the process. Identification of status is related to the monitoring and measuring activities which have been identified, planned for and provided for the product. There are three basic states — useable; not useable; not sure!

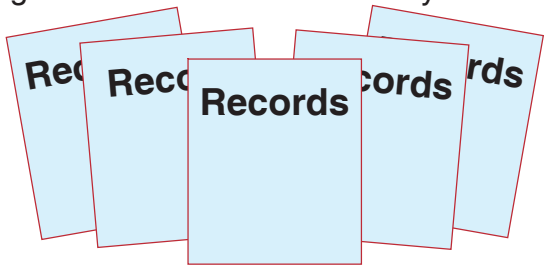
The configuration status can be used to create the necessary identification and traceability. This book would be an example of such a product.

3. Traceability

Traceability is a completely different concept from the previous two. The number of processes where traceability is a requirement is small. This is very much a *"where appropriate"* requirement. It only applies if there are contractual obligations, regulatory requirements or industry norms which require traceability unless you decide yourself that some form of traceability would be useful.

7.5.4 Customer property

The control asked for here applies to raw materials, component parts, packaging materials, transportation or services in connection with either the product being supplied or installation activity which is an integral part of the contract. Customer property can also include software, firmware, specifications, personnel ..... the list is almost endless. Information such as the handling and control of data received through EDI (Electronic Data Exchange) can also be customer property which needs to be considered. In this increasingly electronic world, good record keeping can also means identifying, filing and maintaining records of e-mail messages between an organization and its customers. Any customer property must be identified, verified and safeguarded while under your control. Anything which cannot be used for any reason must be reported to the customer — ***and keep records of all of it!***



7.5.5 Preservation of product

ISO 9001 is basically just documented common sense, and nowhere is that more obvious than here. This clause requires that operations are managed so as to keep products and component parts secure from deterioration, loss or damage from the start of the process until responsibility passes to someone else. The requirements apply to the entire operation, and sometimes even to the supply chain if special provisions for handling, storage, packaging and delivery need to be imposed upon a subcontractor.

7.6 Control of monitoring and measuring devices

This is all about control and calibration of the test and measuring equipment which is used to prove that product conforms to specifications.

Every measurement, inspection, test activity or process control should be evaluated to determine whether the activity is used to perform a process check or to confirm a contractual requirement. Equipment which isn't directly concerned with assurance of conformity need not be calibrated.

Don't try to draw too tight a circle around the range of items requiring calibration or validation. Often a measurement taken during a receiving inspection process is the only one which can demonstrate that the item meets requirements. The standard does require that devices are 'capable', and sometimes calibration is the best way of creating that assurance.

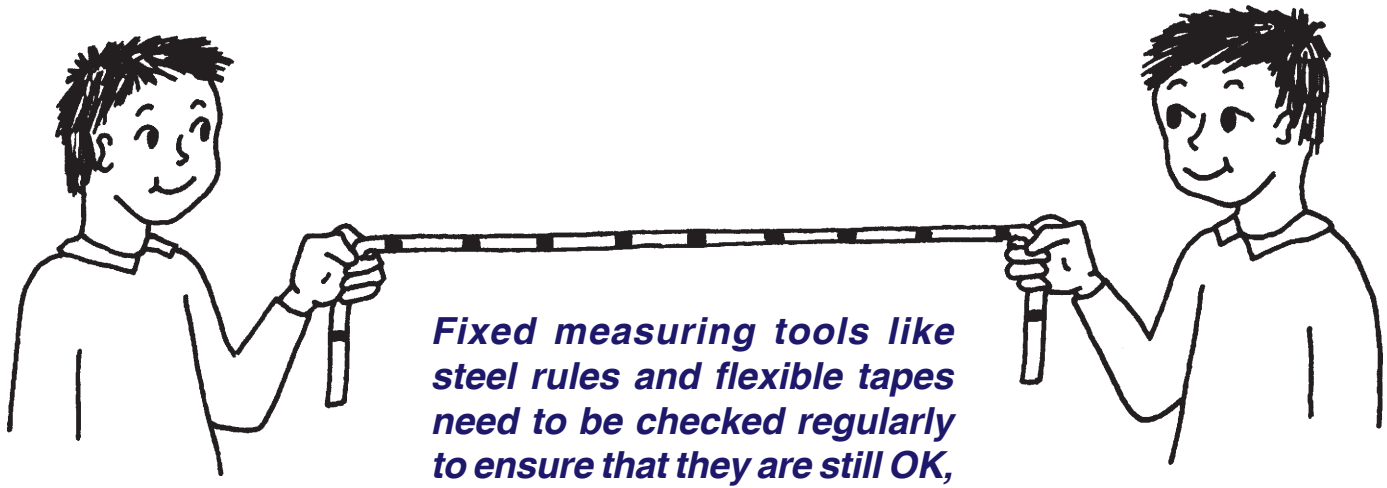
It is important to remember and recognize that not all items of 'measuring equipment' are subject to random variation, nor capable of adjustment to bring them back into specification. Examples would be software used to perform tests, and fixed measuring tools like steel rules and flexible tapes. Such items need to be checked regularly to ensure that they are still OK and not damaged or worn in a way which affects their useability but they usually don't require to be calibrated.

Once the exceptions are identified, all remaining inspection, measuring and test equipment, and all process measurement and monitoring devices which are used to verify product conformity must to be calibrated or suitably validated at appropriate intervals.

The process must ensure that

- **i)** the calibration interval for each item is specified,
- **ii)** the items are calibrated against a recognized national or international standard, (if there isn't a standard, the process which is used to verify the accuracy of the item must be described),
- **iii)** the equipment is identified in a manner which covers
  - **a)** the equipment type,
  - **b)** the unique identification of the item,
  - **c)** where the item is.

Without these data it will be difficult to demonstrate either that devices are properly identified or that they can be controlled.



Fixed measuring tools like steel rules and flexible tapes need to be checked regularly to ensure that they are still OK, but they cannot be calibrated!

Steps must be taken to ensure that the measuring and monitoring devices, facilities, software and hardware, are protected as far possible from user adjustments which would invalidate the calibration or validation. There are lots of ways of doing this depending on the type of equipment concerned.

As well as doing your best to ensure that calibrations cannot be accidentally invalidated, it is also important to ensure that equipment is handled and stored in a way that prevents damage or deterioration. Special handling and storage requirements will often be described in the suppliers' manuals or handbooks.

And, of course, records of all this activity are required!

Typical data required is

i) equipment/device type,
ii) equipment/device identification (serial number, location, etcetera)
iii) calibration interval,
iv) whether the device was within specification when received for calibration, and if not what the measurement error was,
v) the traceability record to the national or international standard used for calibration purposes.

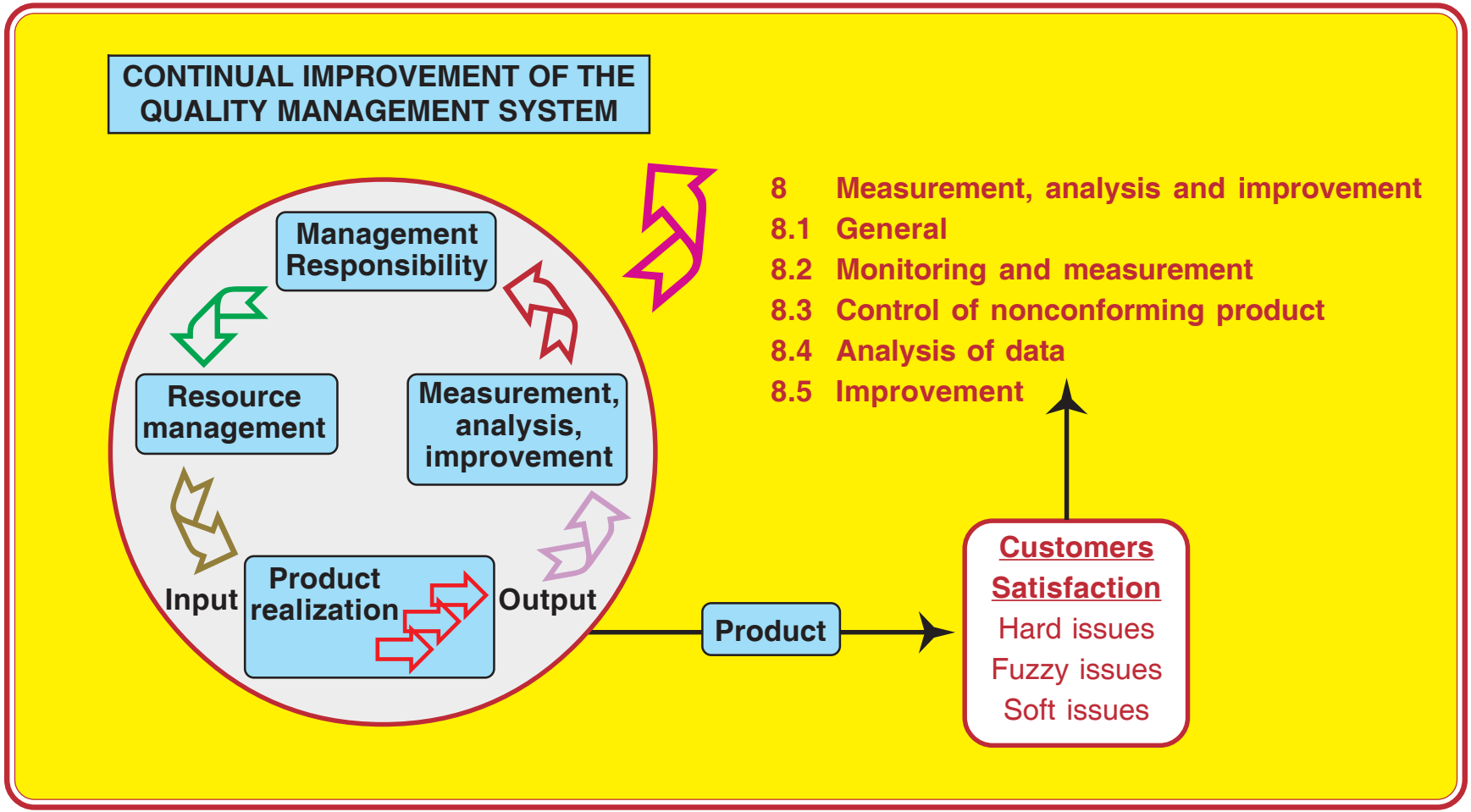
What happens if something is out of specification when it is checked?

Usually expletives and crossing of fingers!

But when this happens, someone in authority needs to take a look and see if there is a significant risk, what product might be affected, and then decide what to do about it. The answer can be anything from doing nothing in the short-term because there is no traceability to a full product recall. In the 'do nothing' situation, the organization should monitor returns and complaints and ensure proper response to the problem.

The next section deals with Measurement, Analysis and Improvement

Figure 16 - Measurement, analysis and improvement



8. Measurement, analysis and improvement

The activity this section of the standard creates is one of planning for 'quality' events to happen in all areas of the organization. The process flow needs to be examined from inception to delivery. All activities need to be carefully considered to see where cost effective measurement and monitoring can be applied. An example could be the monitoring of deliveries from suppliers. This can be done by looking at what they deliver, by going to see them or even by doing acceptance testing. The result is that organization is monitoring the activity and gathering information from which informed actions can follow.

The concept needs to be applied from start to finish of the realization process — including looking at any statutory or regulatory issues such as environmental compliance.

In addition to product or service issues, the management system itself should also be monitored and wherever possible measured, to see if the results of system activities are what was intended. One of the tools which can be used for this is internal audit, but always remember that measurement of product and process outputs also provide indications as to how well the system controls are operating.

The purpose of performing measurement and monitoring is to show that the product is what was intended, that the management system is operating properly, and to provide data which enables the effectiveness of activities to be continually and cost-effectively improved. Activities like process controls and test and inspection procedures should not be ad hoc or random, but systematically planned and implemented with records providing evidence that the work has been carried out.

It is important to recognize the difference between improving the effectiveness of the management system and improving the system. Constant change is not necessarily required — a process may be perfectly well designed, but not being operated effectively. There is a subtle but very important difference between continual improvement and continually improving effectiveness.

This clause also makes reference to the possible use of statistical techniques. It is left up to you to decide if, when and how to use them. They can be anything from Statistical Process Control (SPC) and inspection sampling to the simple Pareto chart through to sophisticated design tools like finite element analysis and Failure Mode Effect Analysis (FMEA).

8.2 Monitoring and measurement

8.2.1 Customer satisfaction

The requirement is to have some measure of customer perceptions of whether or not requirements have been met. Our perceptions become our realities — so maybe looking at customer perceptions is a better way of establishing any need for improvement than looking at actual data. So the task is to find some means of gathering reliable data on customer perceptions and then seeing what can be done to improve those perceptions.

The methods used to monitor customer satisfaction and dissatisfaction might be anything from questionnaires, customer surveys or blind customer response studies all the way to independent surveys by companies like J. D. Powers. An organization can use any suitable data as its information source.

8.2.2 Internal audit

The internal audit process must be established which can verify, on a regular basis, that the system is continuing to meet the requirements of its own processes and procedures and those of the standard.

The core audit activity should be focussed on the system documentation, processes and products. This is the activity which will best drive continual improvement, and the verification against the standard can be done intermittently as an occasional sanity check.

An effective program of quality audits is probably the most powerful tool for the continuous improvement of system, process and product that any company can ever utilize. The regular review of operating documentation, processes and results enables an organization to constantly find new and better ways of doing things which can then be formally incorporated into the system. Audits of conformity with documented procedures then ensure that processes remain stable.

A formal procedure is needed to define the activity, which must define the responsibilities and authorities for the audits, the planning process and how audits are to be conducted. The methods of reporting have to be specified and what records are maintained.

The frequency of audits must depend on the importance of the activities and processes and the results of previous audits. Significant activities may be audited more frequently and activities where audits find nonconformities should receive more frequent scrutiny.

Audits must be performed by people independent of the activity — you cannot audit yourself! Make sure that the audit proces makes provision for the audit of the audit process.

Guidance on the management and performance of audits and on training of auditors can be found in ISO 19011:2002.

8.2.3 Monitoring and measurement of processes

Remember the 'input — activity — output = process' concept? Well this clause can be applied to every process in the management system. It isn't restricted to product issues although obviously for many manufacturing and service organizations the direct mapping is to process control activity.

The standard says to plan the necessary activities, carry them out, and use the resulting data to fix any problems which arise, both in the short term and in the long term.

In terms of the system, the sort of activity which could be considered would be recording of the results of the adequacy reviews performed on purchasing documents prior to release. An analysis of the number of documents found with errors might provide an opportunity for improvement which reduces cost by reducing rework activity. Other measures of process effectiveness include cycle-time and reaction times.

8.2.4 Monitoring and measurement of product

This complicated description is actually talking about how an organization ensures that the products and services it provides meet specification. It includes activities like inspection and test. These activities are not compulsory; what is required is that the company can demonstrate evidence that products and services conform to requirements, and that evidence must also provide a record of who determined that things were OK when a product is released to the customer.

The standard provides for the organization to decide for itself what to do and how to do it. The intention is the same throughout the standard —

decide what to do, write it down, do it and keep records to prove that it has been done.

Where it is becoming increasingly difficult for test penetration to achieve significant levels as the complexity of products gets progressively greater, the methodology and approach to inspection and test continually grows in importance. Part of the answer lies in the thoroughness of test planning, and in many cases this is linked into the design and development activity. A significant element in effectively managing the problem is in the creation of clear and reasonable performance specifications for each stage in the process. Remember to include any customer, regulatory or other oversight-body test witnessing which may be required.

Is measurement and monitoring of product mandated by the standard?

The requirement is to measure and monitor "at appropriate stages".

Can an organization comply with the Standards and not perform any inspection or test?

Technically it may be possible if it can be shown that nothing is "appropriate".

The ISO 9001:2008 standard does not encourage a return to old fashioned so-called quality control activities, nor does it require that there is an independent test and inspection function. Self-inspection and self-test are perfectly okay. All that is asked is that the activities should be planned, not random, and should be based on rational decision making, not what someone had for breakfast that day...

Proof that the organization has fulfilled these requirements in accordance with their own documented procedures must be provided and include customer approval when required.

8.3 Control of nonconforming product

> [2] The best-laid schemes o' mice an' men
> Gang aft agley,
> An'lea'e us nought but grief an' pain,
> For promis'd joy!
>
> *Robert Burns, 1785*

These lines from Robert Burns famous poem written over two hundred years ago say it all! However hard we try, things still manage to go wrong and result in mistakes happening and duff product. The trick is to ensure that as far as is humanly possible the management system will trap this and take it off-line before it gets delivered to the customer. The goal is that the safety net provided by the monitoring and measurement activity will ensure that anything which is defective in any way is identified and segregated before there is any risk of *unintended* use or delivery.

How you achieve this is up to you. Just make sure that you have a written procedure for the process which defines how:

- **i)** nonconforming product or service is identified and segregated (if possible);
- **ii)** all the relevant functions both inside and outside the organization to be informed;
- **iii)** what is to be done with the problem items, which may be:
  - **iv)** reworked back to specification;
  - **v)** used 'as is';
  - **vi)** regraded and specified for an alternate use; or
  - **vii)** scrapped.

[2] *Colloquially translated this means that the best-laid plans often go pear shaped and leave us with a bunch of grief when we were expecting everything to be just coozy.*

The procedure must also define who has the responsibility and authority throughout the organization, and this can be different people at different stages of the process.

Records must be maintained of all nonconforming product, and anything which is repaired or reworked must be verified as OK before it is released.

There is always a possibility that something will be found after delivery has started, and if this is possible then the procedures must describe the action to be taken in such cases, which must be appropriate to the possible effects of the problem.

8.4 Analysis of data

All too often organizations spend a great deal of time collecting data and then proceed to do nothing with it.

This is the 'file and forget' syndrome!

This clause is intended to make management take more notice of the data their system provides.

There are four specific issues listed for management to examine through the use of data analysis. These are

- Customer satisfaction.
- Conformance to product requirements.
- Characteristics and trends of processes and product including opportunities for preventive action.
- Suppliers

The analyses can be as sophisticated or as simple as the organization chooses.

8.5 Improvement

8.5.1 Continual improvement

The whole idea of a formal management system is to have a means of operating which provides consistent results and the opportunity for continually providing cost-effective improvements in products, services and the effectiveness of operations. There are some key system-based ways in which this improvement can be driven. They are:

- management commitment to the quality policy;
- quality objectives;
- results from internal audits;
- data analysis;
- corrective and preventive action, and
- management review.

These activities can provide individual opportunities for improvement. The formal management review of all these collated data can be used to review the system objectives and amend or modify them in the light of the information provided.

Using these data enables the management review team to evaluate the overall effectiveness of the management system in fulfilling the quality policy, goals and objectives of the organization.

8.5.2 Corrective action

When things go wrong, fix them! Have a documented process for doing so, keep records of what has happened, what was done about it, and why it happened. Consider the implications of each event and decide whether further action is needed to prevent the problem recurring. If such action is required, then make sure that whatever is done is kept under review until everyone is happy that the problem has been fixed.

By the way — remember that every customer complaint is by definition something which requires a corrective action; even if the complaint is unjustified something needs to be done to make the complaint go away and the customer happy again!

There is obviously a close link between control of nonconforming product and corrective action, and always remember that corrective action applies equally well to issues concerning product or service, process or the management system.

The corrective action taken must be appropriate to the impact of the problem. Little impact requires little action, major impact requires major action. This is risk management, and root cause analysis of the reasons behind every failure are neither required nor necessary.

Records of corrective action must be kept, and these records must include those listed.

Records of corrective action that must be kept, must include:

- the date of the event;
- the item, product or process involved;
- the nature of the problem:
- the cause (if not self-explanatory);
- the action taken to resolve the issue;
- any preventive action thought appropriate;
- the results of any follow-up action taken to review the effectiveness of the corrective and/or preventive actions taken.

8.5.3 Preventive action

Preventive action is all about trying to error-proof the system, the processes and products to prevent nonconformities arising. It forms an integral part of planning for quality.

Some actions which might be described as 'preventive' are the type of activities which are part of professionally managed and operated organizations — a well managed materials management program ensures that there will be no material shortages to impact work-flow.

Shipments to customers can be planned to happen earlier than the drop-dead date to ensure on-time delivery, process capability studies can be carried out to ensure that the required product specifications are achievable by the planned method of operation.

These would all be preventive actions.

A further source of inspiration for preventive actions includes the output of the data analysis which the system requires and which may reveal adverse trends in process or product performance, thereby making it possible to correct the situation before problems actually occur.

Field repair, warranty and field failure data can also assist in this form of trend detection and in the initiation of preventive action.

Another valuable source of data are the lessons learned from new design introduction; any problems resulting from the introduction of a new product design should be fed back to those responsible for design and/or development work in order that they can avoid similar problems in the future.

There are five specific process operations required to be covered and they are listed on the following page.

The five specific process operations required to be covered must be part of a documented procedure. The activities are:

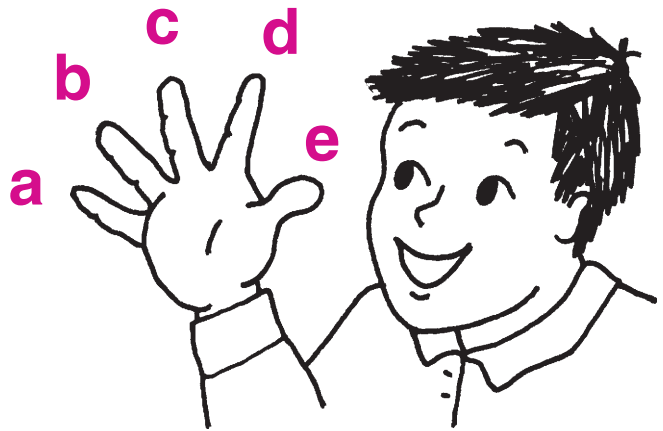
a) identifying potential problems, and of course why they may happen;

b) decide what the risk is, and whether anything should be done about it;

c) if something is to be done, figure out what and do it;

d) keep records of everything that has been done — including those situations where nothing is done;

e) check back and see if the action taken worked, and monitor when action wasn't taken to make sure that the decision was valid.



THIRD-PARTY REGISTRATION

The next section deals with Third-Party Registration

The Structure of the Accredited Certification Process for International Recognition

Some form of Government oversight; often limited

For the UK this is to the Secretary of State for Trade and Industry

For the Dutch this is to the Dutch Trade Minister

In the US it is through NIST but only for the NVCASE program

A National Accreditation Body is structured around ISO Guides 40 & 48 and the EN45000 Series Standards.

UK has **UKAS** which is the **NACB** and **NAMAS**

Holland has **RvA**

US has **American National Accreditation Board**

Australia and New Zealand have **JASANZ... etc.**

These organizations audit and accredit registrars for specific audit scope. Registrars build systems around ISO 17021:2006.

There are over 100 US based registrars including:

LRQA; NQA; NSF-ISR; ABS-QE; BVQ; BSI QA: QSR; TÜV Essen.

Auditor Training and Certification

To ensure that audits done by registrars are effective, a formal auditor training and certification process is frequently used.

The **International Register of Certificated Auditors (IRCA)** is operated by the IQA in the UK.

RABQSA International operates the US ans Australasian program as well as having offices around the world.

There are also Internationally recognised training courses for auditors, including

The Victoria Group, Inc.

THIRD-PARTY REGISTRATION

What is third-party registration?

The registration (or certification) process involves an external organization auditing your company's activities and processes against the requirements of ISO 9001 and your documented management system. The audit process is limited to the scope of the business activities being audited, as agreed in advance with the registrar.

One of the most important factors in determining which registrar to use is ensuring that the registrar has properly accredited scope for your business. This is determined by the process whereby a registrar becomes a properly accredited organization. No company should use a registrar which is not part of this system, as the resulting certificate will be next to useless.

The structure of the accreditation process used in most countries is shown on the previous page — the examples given of national accreditation councils are those for the United Kingdom and Holland, which are the two oldest and most well-established schemes in the world, and the US scheme, which became operational in 1991.

What happens during an audit?

The audit process is divided into two major activities. The first being the adequacy or desk audit, the second is the compliance audit. During the desk audit, auditors compare the company's documented system with the requirements of the standard. They are looking for the system to meet the fundamentals of the ISO requirements. This initial audit produces an audit report, and as a result of this report — assuming all is well — the decision is made to proceed with the second part of the audit.

During the compliance audit, auditors are on site talking to staff, asking questions about what they do and how they do it, what documents they have to have, what records they maintain, and who has all this stuff.

During the course of the audit, questions are asked of staff at all levels in the organization. The auditors will be following a predetermined plan, an advance copy of which will be given to the area's management representative. Each auditor is accompanied by a guide whose job it is to escort the individual from place to place, and to help the auditor identify to whom they need to speak about the issues they want to examine. Answer questions honestly, but only answer what is asked.

Lots of notes are taken during the audit — these are the audit findings. Most of what the auditor writes down will be about activities that they have found to be compliant with the standard and the documented system. Some will be things that are not right, and these may become audit nonconformances by the end of the process. Everything that is reported as a nonconformance will be supported by "objective evidence" — in other words, the auditor has to be able to reference a clear requirement of either the standard or the management system which is not being followed in order to write a nonconformance. Findings are witnessed by the guide signing off on them.

At the end of the audit, the audit team will decide what they want to report and what they do not. This results in the audit report and findings which are issued to the company, together with the decision as to whether the system is regarded as acceptable or not.

Every area of the company can expect to receive nonconformances. The site being audited may contain many hundreds, even thousands, of people, documents, instruments needing to be calibrated, stock items and materials and so on.

The auditors are likely to find a few things out of place in every facility — and it doesn't matter if they do. A number of minor nonconformances will not impact the ability of any company to achieve certification.

The auditors will assess the overall effectiveness of the system. The key issues which the auditors will be reviewing and seeking objective evidence of compliance for are these:

- Are all the relevant requirements of ISO 9001 being met?
- Is there clear evidence that staff know their role in operating the system?
- Are records generated as required and stored properly?
- Is the internal audit process robust and effective?
- Is there an adequately resourced and effective corrective and preventive action program in place?
- Is the management review process solid and operating effectively?
- Do quality objectives demonstrate improvement in the management system?

During the internal audit training, which all companies implementing ISO will need at some stage, the trainee auditors will learn more about what to look for and how to evaluate the significance of an individual finding. That information will be utilized in the operation of the internal audit program and should help resolve a lot of these issues for the staff. The audit is nothing to fear — it is a collaborative, cooperative process... and you are the customer.

Once the main audit is successfully completed, you will encounter surveillance audits on a regular basis — probably about every six months. On a sample basis, auditors will revisit various parts of the company for short follow-up audits to ensure that the system remains fully operational. These surveillance audits will usually encompass a sample of activities, typically one or two elements of the ISO 9001 standard will be addressed in addition to the mainstream elements. There are four subjects which typically get audited every time the auditors come around.

These are:

8.5.1 Continual Improvement

The intent of this requirement is to make management use the tools embedded in the management system to achieve improvement;

5.6 Management Review

The records of this process demonstrate that the system is being properly and effectively maintained;

8.5.2 and 8.5.3 Corrective and Preventive Action

This element demonstrates that the company is reacting to problems which it runs into and identifies through either product, process or system review activities.

Good corrective and preventive action processes mean that the system is being highly reactive and proactive to continuously improve.

8.2.2 Internal Audit

The third item falls into the same category, but is exclusively system related. Internal audit activity and the records it generates, tell the auditor whether the system is operating successfully in between surveillance audits and is driving continual improvement.

Probably the biggest change which occurs as a result of the ISO 9001 implementation is the initiation of the internal management system audit process. This is one of the most powerful tools a company can use for driving continuous improvement — it also happens to be the one which costs the least. An effective internal audit process also enables management to measure its own effectiveness in controlling the operation of the company in the manner intended.

Constant review of the workings of the management system reveal opportunities for improvement in the system, in the training of personnel, and in overall process control. Along with management review, the effective maintenance of the internal audit program is a vital part of the system. Both activities should take place at regular intervals if management seriously intends to maintain the system.

The internal audit process will be an ongoing activity, continually auditing different parts of the system and covering all areas of the organization on an established basis. Areas of the company where the audit findings are adverse should receive more frequent audits until such time as the audit results stabilize; particularly important activities should also be audited more frequently.

What sort of things do audits usually find?

The typical audit findings tend to center around issues of documentation, calibration, training records, closeout of corrective actions and audit findings, the use of unapproved suppliers, an absence of work instructions, inadequate planning, poor training records and a lack of management review.

Like all other areas of the company, control of documentation is an important issue, as is ensuring that personnel do not have obsolete documents or controlled documents which are marked up in an inappropriate manner. Document control issues typically account for 70 percent of the findings reported by auditors during certification audits.

In conclusion.....

There it is.

That is ISO 9001.

No black magic, no complicated, overkill demands, just simple, practical applied common sense requirements which many companies already have in place.

Very often the major task in achieving compliance is no more than documenting and formalizing existing structures, systems and methodologies within the organization, and the benefits of doing this can be immense. The elimination of duplication, redundancy and process variability typically pays off in a very short time. Many cost recoveries can be seen and measured — lower cycle times, lower inventory, less failures both in-house and in the field.

The intangible benefits of increased customer satisfaction may be less visible, but will almost certainly lead to greater business stability, not to mention the increased market access companies with registered firm status almost invariably report.

About the author...

Roderick S.W. Goult is President and Chief Executive Officer of The Victoria Group, Inc. Rod has over twenty years of experience in a wide range of industries. His work has involved medium and high volume design and manufacturing and service industries. He has extensive experience managing and implementing quality systems based upon Def-Stan 05-24, ISO 9001, BABT340, AQAP-1 and MIL-Q-9858A.

He is the principal author of many ISO training programs including an RABQSA recognized Lead Auditor training course, and has conducted hundreds of Lead Auditor training programs worldwide. He is a widely published author on ISO 9001. For several years he was a member of the Board of Directors of the International Auditor and Training Certification Association, now IPCA. He is both an RABQSA and an IRCA ISO 9001:2008 Registered Lead Auditor.

The Victoria Group, Inc. is a diverse company offering a wide range of consulting, training and consulting support services covering ISO 9001 and ISO 14001 management systems; a unique small business development program and team building products to enhance management development efforts.

The Victoria Group services include consulting, gap and pre-assessment audits, and training. The company is a recognized source for ISO 9001 and related services for organizations as diverse as Ford Motor Company, the FAA, the US Army Corps of Engineers, Hewlett-Packard, Eastman-Kodak, Hach Company and Hitachi Automotive.

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- **Internal Auditor training (IRCA Registered)**
- **How to Implement and Document ISO 9000 training**
- **ISO 9001 in the software environment training**

These programs are also available when ISO 14001 or AS9100 conformity is required.

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The Victoria Group, Inc.

One of the first organizations to offer IRCA approved Lead Auditor training in the US, and has been helping US companies with their ISO 9000 implementation since 1990, and their ISO 14001 needs since 1996.

Our team of consultants have several hundred successful certifications behind them, and every one has been a first audit success story. The staff come from widely diverse backgrounds ranging from nuclear submarines to space technology. All consultants are IRCA or RABQSA Certified Lead Auditors, and between them they have several hundred successful certifications.

Not one client has ever failed their registration audit.

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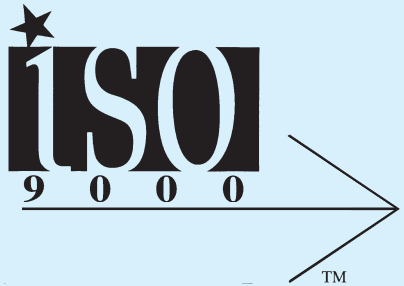

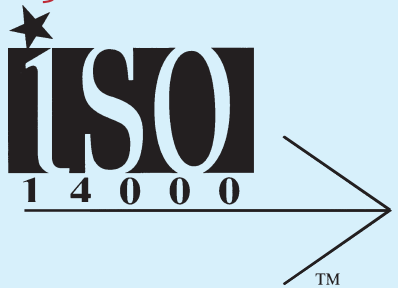

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Designer Viv Miller