Understanding **ISO 9001:2008** and Process-based Management Systems

Ian Rosam and Rob Peddle

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Creating a Process-based Management System for ISO 9001:2008 and beyond

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Ian Rosam and Rob Peddle
(The High Performance Organisation Group Ltd)

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This second edition published in the UK in 2009

by
BSI
389 Chiswick High Road
London W4 4AL

© British Standards Institution 2009

First edition published by BSI in 2003

ISBN 978 0 580 67656 7

BSI reference: BIP 2013

A catalogue record for this book is available from the British Library.

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Typeset by Monolith – www.monolith.uk.com

Printed by Berforts

Foreword

Standards such as ISO 9001 evolve and develop to meet the changing needs of their users and those affected by them. This reflects the changing business environment, the combined experience of past application and the application of new knowledge and techniques that have been found to work. By being updated, there continues to be an established common baseline that organizations can follow, in the knowledge that this has been designed by industry professionals and for industry, using the latest best-practice. From this wide review, there is the knowledge that these standards can continue to be applied by others who wish to use the defined approach.

Updated versions of management system standards therefore define both good and latest practice in chosen subjects and can be relied upon as a baseline in the application of good operational management. Without such revisions, standards become stale and irrelevant. The ISO 9000 series is no different in this respect and consequently, ISO 9001:2000 has been reviewed, amended and updated where necessary and the Standard reissued as ISO 9001:2008.

The aim of this book is not to explain the specific differences between the two versions in great detail (for they are relatively small and make little real difference to the Standard) but to help the reader understand and apply ISO 9001:2008 in their organization and ensure that this follows good practice. The Standard does not tell you how to do this, that is up to you, but thinking about what it is saying in the right way is critical to gaining the maximum benefit from its application.

ISO 9001:2000 introduced a significant change to the way organizations are structured and run. This is known as process management and is a subject that will be covered in this book. The 2008 version builds on this approach to management but does not introduce any major changes to either clauses or

subclauses, however, it does clarify certain issues. If, therefore, you are already registered to ISO 9001:2000 and are following the principles outlined in this book then it is likely that you would already meet the requirements of the 2008 version. Whether registered or not, if you have applied the clauses, rather then the principles of the standard, then the 2008 version is your chance to start to mature your management system to apply what the standard really intended – to start to drive the business benefits it should deliver.

The 2008 version of ISO 9001 is, in all important ways, a replica of the 2000 version, but as this has in many instances not been effectively implemented, with many systems still really a 1994 version, the text of this book will make comparison to the 1994 version. We believe that this will be useful for those who did not really make the step change that the 2000 version required.

For readers who wish to know the key changes in the 2008 update, an overview of the changes are contained at the end of Chapter 4, for reference purposes.

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1. Businesses first/standards second – The context

First of all we would like to give you a little bit of history of where things have come from and a glimpse of where we are all going in the future when it comes to process-based management systems and management system standards.

Management standards initially centred on quality control, with the introduction of BS 5750 in 1987. **Quality control** focused on making sure the product or service was inspected to ensure that defective products or services did not reach the customer. Quality control clearly has limitations, not least in the level of wasted activity and increased costs associated with inspecting the product, sub-assembly or service at the end rather than at the beginning or during production. In other words, if a product was defective halfway through production then any further processing was wasteful. BS 5750 was, however, a great step forward in getting 'quality of output' on the business agenda. It certainly had significant benefits for customers who started to receive far fewer defective products from their suppliers.

The arrival of the ISO 9000 series of management system standards in 1994 formalized quality assurance. **Quality assurance** considered the activities affecting the production and delivery of the service in order o build 'quality' into the production activity rather than carry out inspections at the end. This often lead to considerable improvements in operational effectiveness, particularly if the organization's management took the intent of the standard eriously.

Unfortunately many management systems were built around the primary aim of satisfying the needs of the standard itself rather than the needs of the business. The standard is, by definition, artificial and describes the key components of a management system that could be applied to any organization, with any culture, in any part of the world.

It therefore needs to be interpreted by the organization to reflect what it actually requires. Many observers have commented that this situation has been exacerbated by consultants, registration bodies and the quality industry slavishly following clauses of the standard. The unfortunate fact is that many of these continued to adopt a 'non-thinking' approach rather than truly understanding the opportunity that the standard provides to transform a business.

The standard also excluded the role of management. This omission meant that the focus was on staff 'doing' rather than managers 'managing'. Although initially this did not cause a problem, over time the value of the standard to management in helping them run their business reduced. There are a number of reasons for this but primarily:

- ISO 9001:1994 tested compliance not effectiveness;
- management systems often focused on staff not management, although it was management who determined how the organization was run;
- management could increasingly see that results were not helping them run their business;
- there was a reliance on compliance, rather than a measure of business performance;
- there was a high reliance on documentation, which often grew out of control or practical use;
- many of the systems implemented were inflexible, making them difficult (often impossible) to adjust as requirements changed and learning took place;
- there was no requirement to link absolutely the activities covered within the system being accredited with what the customers truly required – they could, and often were, in isolation of each other.

Consequently management often disengaged from the system seeing it as a necessary evil rather than a management tool. The realization dawned for many that gaining registration to ISO 9001:1994 could be obtained by sticking to procedures even if they delivered products and services the customer didn't want or were of an inferior quality. Over time the pressure for an enhanced standard built up and, learning from past activity, ISO 9001:2000 was born. The differences between the 1994 and 2000 versions were profound, although this was not recognized or applied by many in the quality industry. The 2008 version builds on the management principles introduced in the 2000 version and, although there are no significant changes, they do clarify certain issues.

'ISO 9001:2008 is about improving business results not compliance'

The key difference between the 1994 and both the 2000 and 2008 versions is that the modern versions are based on designing and implementing a process-based management system aimed at continuously improving your rganization's performance. Put another way, they set out to establish a set of baseline organizational competences that you would expect to see in any organization managing its business effectively. Much like individual competences, these are based on knowledge and skill to demonstrate a behaviour. Instead of these being for an individual, they are for an organization.

Consequently ISO 9001:2008 includes the management disciplines that ISO 9001:1994 left out, such as business planning, asset management, IT and people management. In understanding ISO 9001:2008 it now pays not to think about *quality* management systems but *business* management systems, not to think about *quality* assurance but *business* assurance; how a business operates to deliver value, products and services to customers and other interested parties or stakeholders. Even though the concepts were introduced in the year 2000, by the time the 2008 version was issued it is surprising how many registered businesses still existed where the concept is not embedded in the organization. We will discuss the reality of designing a system later but put simply the 2008 version of the standard, like its 2000 predecessor, can be illustrated as in Figure 1.1.

ISO 9001:2008 describes a simple business cycle that should apply to any organization. The first step in this cycle that is defined in ISO 9001:2008 is to understand what customers actually want from the organization, what products and services will truly satisfy them. Organizations need to listen to what their customers' needs and expectations are before doing anything. At this level we are not talking about individual orders or requests for services but a more basic understanding of what business we are in. This area involves collecting information about the internal and external markets in which you are operating and establishing what is expected from your organization. This is market research, part of the marketing world. No organization should ever try and develop/launch a product or service without knowing there is a market for it and that it will be used by potential customers and how it will affect or be perceived by other stakeholders.

Having understood this, the next stage is to develop business objectives that will inform the actions we need to take, the equipment we need to buy, the level of sales we need, the people and the skills required to deliver what is needed. In other words a business plan that shows who will do what and

when. Business processes are then designed that describe how products and services will be created and delivered to customers at the time and in the way they expect them to be. At the same time we need to manage (typically) people, finance, assets and IT systems so that they are used efficiently and effectively to support that delivery.

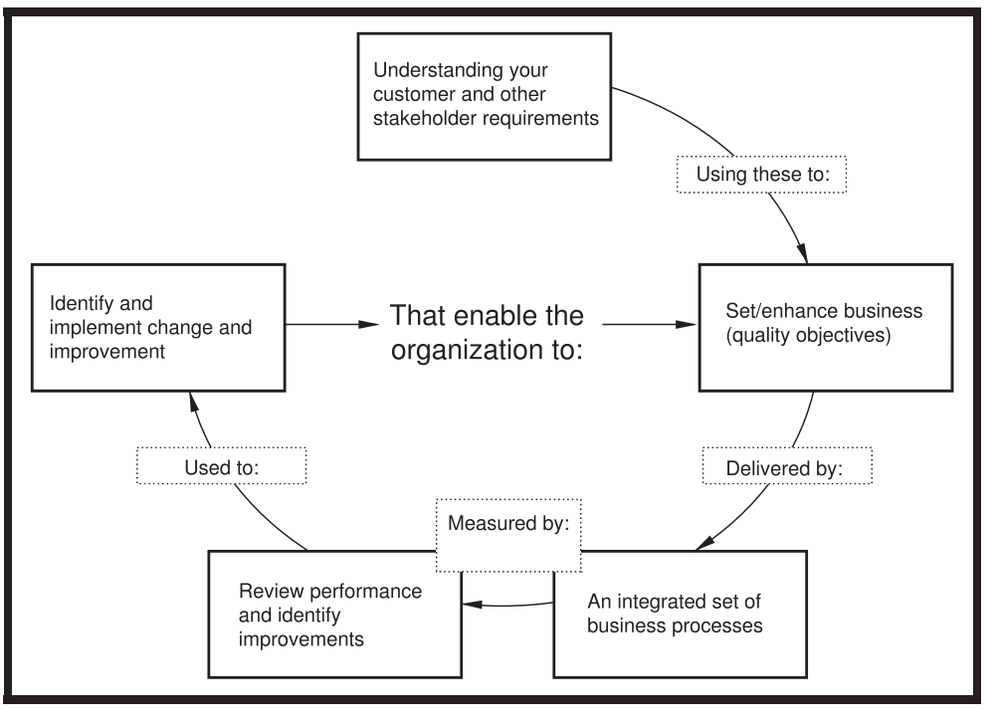

Figure 1.1 Living the business performance cycle

Often organizations plan what they do and do it. But 'good' organizations go further by identifying and using different methods to measure their performance against targets. These are used to identify improvement opportunities, which are then carried out to change how we operate to complete the business cycle or strategic improvement loop. This enables better delivery of the existing objectives or allows for enhanced objectives to be set the next time we go round the cycle. It's all about doing something, learning from the experience and then making changes so that the next time the task is carried out it is done better (in business terms) or at least consistently. Notice in Figure 1.1 the improvement activity doesn't link back to customers or stakeholders. This is because the market for your products or services, the needs of customers and other interested parties, drives what your organization does. Improvements you may carry out should be designed solely to enhance the identification, planning, design and delivery of products and services to meet these needs.

We have described a simple model or cycle that any manager should recognize, but of course you may use different words or the activities in your organization may have different names. But at this level we don't need to worry about the detail. What is important is that you see your organization, department, section or site as operating through its business cycle with every person, piece of equipment and process working together to deliver value to customers. The purpose of ISO 9001:2008 is to set out some key principles for this cycle, but it does not try to cover everything and is not a holistic model of business management. You will notice that in the earlier description of business management that finance was included, even though this is not specifically part of ISO 9001:2008 no organization can run without managing its money. What is critical to introducing and running a management system is that it reflects what actually happens in your organization. If it doesn't then experience shows that management will soon get bored with the system as the real business is done and managed elsewhere. It will then fall into disrepair like so many of its predecessors.

So, ISO 9001:2008 and it requirements have brought quality into the world of senior management and the boardroom where business decisions are made, objectives set and direction given. However, in this world, rather than use words from the Standard, you will need to talk a business language, interpreting the Standard and its requirements in such a way that drops the jargon of quality so that you can engage with the senior managers. You will need to embed quality into the business management system in your organization, so that it supports the delivery of their objectives. The content of this book uses this language to help you. This is illustrated in Figure 1.2.

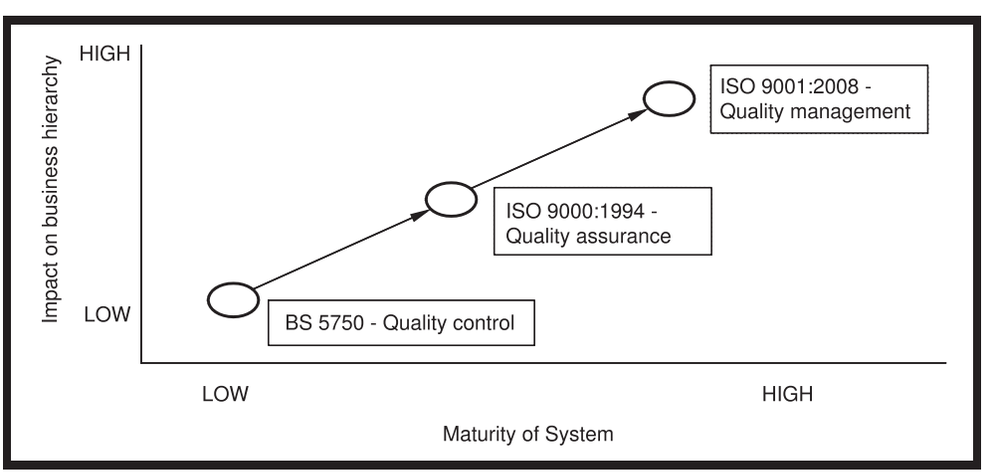

Figure 1.2 Evolution of quality standards

If you have understood this idea of your organization as a business cycle you are well on the way to understanding ISO 9001:2008, even without picking up the Standard. The main differences between the 1994 version of ISO 9001 and the 2000 and 2008 versions are given in Table 1.1.

Table 1.1 The standards compared

ISO 9001:1994	ISO 9001:2008
A reliance on compliance	Effectiveness is critical
Procedure and detail driven	Business performance driven
Concentrates on doing things right	Concentrates on doing the right things in the first place
Focuses on what you do	Focuses on why you do it
Internally focused	Externally driven
Based on consistency of delivery	Based on improving customer satisfaction

If you are to fully benefit from using a process-based management system it depends on how you interpret the standard and use known best practices on process management. Experience tells us that there are many people and organizations who will tell you how to do it, some in a matter of hours, but to implement process management effectively takes planning to avoid the pitfalls and determination to make it work. Some even propose short cuts by asking you to buy predetermined processes or pre-formatted documentation. Beware of this approach, as every organization is different and has its own culture and characteristics and therefore every system is unique, but more about this later.

But this is not quality I hear you cry!

So there we have it, understanding ISO 9001:2008 is not really about understanding the specific detail of the Standard and its numerous requirements. It is about how an organization carries out its business. We haven't talked about the Standard in any detail at all yet, but without this overview the detail is irrelevant. This overview creates the framework within which decisions can be made about how it works best for you to apply ISO 9001:2008.

At the time of writing this, we are involved in helping organizations implement process-based management systems and it never ceases to amaze us how many 'quality' professionals, registration bodies and consultants cannot understand that at its simplest level ISO 9001:2008 is about doing business. They still do not seem to accept that the whole emphasis has changed from their interpretation of ISO 9001:1994, and if they have accepted they don't seem to have modified their behaviour, products or services. Consequently business managers challenge the thinking behind ISO 9001:2008, rather than the interpretation that has been presented to them.

Of course to business managers, both in the public and private sectors, who are concerned with business performance it is just common sense. Sure they may have gaps or may not be applying the logic in its purest form but that doesn't matter: they see ISO 9001:2008 and process management as a management tool to improve business performance, which is what counts. ISO 9001:2008 is a mechanism by which they can understand, prioritize and address their 'gaps' and make tomorrow better than today.

Another misconception is that it is complicated. Reading many 'quality' journals and other academic research you would think the approach and ISO 9001:2008 are beyond the average human being to understand and are shrouded in mystery. To some, it all seems to be in the land of 'Management Consultant' speak. Well it is not, provided you understand the following:

- Organizations of any size operating in any sector, serving any type of customer operate in a cycle as we have discussed. What that cycle looks like when applied to a specific organization is another issue, and it will be different for everyone.
- Organizations operate by a set of integrated processes that describe this cycle and that follow the work across people, sites, departments and even countries. Again more detail later.

So that leaves us with the question as to whether or not we are talking about quality. Let's think about what quality actually is to a customer or business manager. There are many definitions of 'quality' but as a customer of an organization what we expect is an understanding of our requirements and delivery against them without mistakes, excuses or errors.

To a business manager, 'quality' is delivered by making sure that the needs of the market, be it internal or external, are understood and then by planning resources to deliver products and services that meet those needs without mistakes, excuses or errors. Subsequently, the business manager can then find ways to improve performance to gain a competitive advantage or deliver improved products and services with reduced cost, more efficiently and effectively.

But we must remember that business managers are focused on the business and not on any one management principle, including any narrow historical definition of 'quality'. ISO 9001:2008 is concerned with business management to improve business performance and cannot be considered as a solo discipline. Therefore in understanding ISO 9001:2008 and considering implementation we must think about 'business' and not 'quality'. Using the ISO 9001:2008 maturity line we used before we can delete the word quality' and substitute 'business' – they should be the same thing; see Figure 1.3.

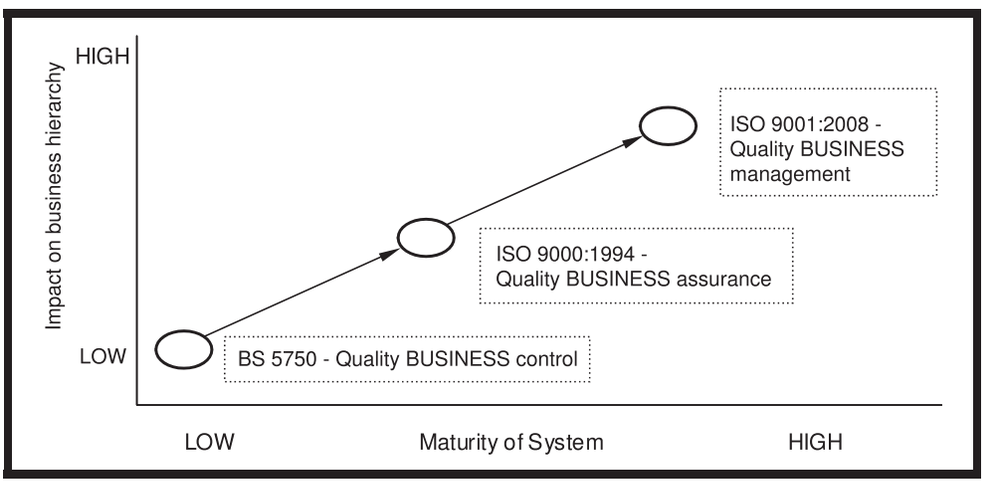

Figure 1.3 The quality to business transition

So if this is about business, what does the future look like?

Before we move on to looking at ISO 9001:2008 in more detail, it may be useful to pause and look to the future. This is important because it is very easy to create a system to meet the immediate needs of the Standard without necessarily thinking about what will be needed in the uture. If we don't do this, it may not allow the inclusion of potential needs, which would be very limiting and certainly will not maximize the value of the investment being made. In designing the system we therefore need to bear in mind that management tools, models and frameworks, including ISO 9001, will change, evolve and mature.

This 'maturity' is a global phenomenon. It is primarily driven by many sectors of industry and government based on their need for increased efficiency and effectiveness in the way organizations go about their business to deliver

the results they produce. Business improvement is an economic imperative if organizations are to remain competitive. Equally the word improvement' is being superseded by the word 'sustainable' as the 'mantra' of effective management, for example the world is moving towards business sustainability and away from business improvement. No doubt the application of the ISO 001 series will catch up, but at the time of writing this book this movement is already taking place. If you create your management system based on the principles in this book then you will be on the way to creating a business sustainability management system as well as meeting the requirements of ISO 9001:2008, i.e. you will be creating something that meets the needs of the present and the future. This is not the place to have a discussion about what sustainability is, but, just to conclude this subject for now, sustainability is about conducting business in a way that balances economic (making profit, turnover, managing budgets, etc.), environmental (green impacts) and social (jobs, people, etc.) impacts on society to deliver overall stakeholder satisfaction.

As we have seen, and as we will also see later, the management system defines the business and the business is modelled by the management system. Building a system is only the start: improving and enhancing it will mean that you are likely to have to use and incorporate other management tools – some already known, some still unknown, possibly not even invented yet. It is important therefore to make sure you have both flexibility and best practice at the heart of your management system design.

So what does the future look like? If we are to believe ISO 9001:2008, it is about improving business results using business process management and it represents a considerable challenge for us all. Just imagine every management tool, management discipline, all professional education and training, all levels in every organization and even different organizations all 'joined-up' to deliver value to customers and stakeholders. This vision is difficult to describe in words, so let's describe your business pictorially as a management system (see Figure 1.4).

But the biggest change rests with us as individuals. To put it bluntly, those managers and staff who can't or won't embrace change to work in this 'joined-up' environment will not survive. This includes the uge support industry of management consultants, registration bodies and professionals, who have inadvertently marginalized the 'quality' industry, making it tactical and of low-value, whereas it should be mainstream, strategic and highly valued. If we do not change ourselves, then nobody else will.

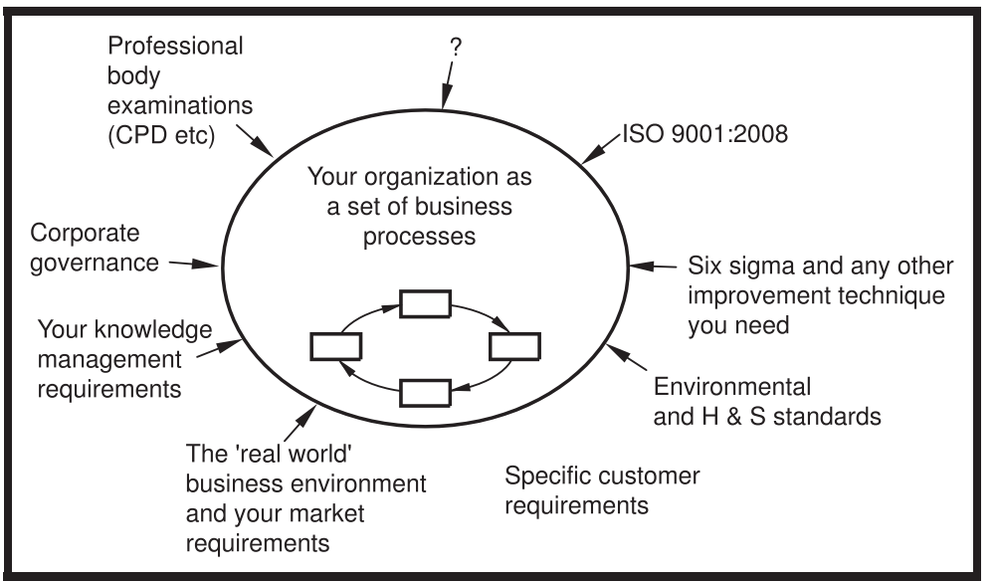

Figure 1.4 Your organization as a system in the 'real world'

Summary of key points

- Always build a management system that meets the business objectives and needs of the business *first*, into which the required standards are embedded. It can then be assessed against any standard, model or framework and any improvements made. Never build a system to meet just a single standard: it will fail in the long run.
- To understand how an ISO 9001:2008 management system is constructed think about how a business works.
- Quality is business and business is quality.
- Reliance on compliance leads to ineffective business. The financial meltdown proved this to be the case as audits tested compliance to death – but the systems and processes still failed. We can not let the same thing happen to our own systems and processes.
- When creating your process-based management system, consider future needs, not just today's priorities.
- Management systems have traditionally been built around the primary aim of satisfying the Standard rather than the needs of the business.
- The key difference between the 1994 and new versions of the Standard is that ISO 9001:2008 is based on designing and implementing a process-based management system aimed at continuously improving your organization's performance.

- The first step in ISO 9001:2008 is to understand what your customers actually want from the organization.
- If you understand the idea of your organization as a business cycle you are well on the way to understanding ISO 9001:2008.
- Every organization is different and has its own culture and characteristics and therefore every system is unique.

2. ISO 9001:2008 in overview – The 'what'

In the first chapter we discussed and described an organization as a business system with processes aimed at delivering business results. Although there is much detail to add to complete the picture, the principles described are the basics needed to understand ISO 9001:2008. With these principles in mind we can now look at the standard and its clauses in more detail and see how they support an organization and provide a framework, which, when interpreted correctly, can be used as a management tool to manage and improve overall business performance.

The complementary pair

The first thing we need to realize is that the ISO 9000:2000 series comes, primarily, in two parts, ISO 9001:2008 and ISO 9004:2000 (it has yet to be updated but is still relevant) and are known as the 'complementary pair'. ISO 9001:2008 describes the 'baseline' upon which process-based management is designed; it provides the framework that i o be used. It describes the 'what' you need to demonstrate. It does not, however, ay 'how' you should go about it.

Contrary to popular belief – and promoted by many consultants and registration bodies – it does not describe the language you have to use in your organization: that is for you to decide. For example, ISO 9001:2008 requires that management reviews are carried out at defined intervals. What this actually means is that management need to review the performance of their organization. This could take place in a board meeting, team meeting or by any other mechanism and so you don't necessarily have to call it a 'management review'. Equally 'defined intervals' could be monthly, bimonthly or even daily – you

decide based on your own business dynamics. Your registration body should assess the effectiveness of your approach and not dictate or pass comment on how your business is run.

Sometimes organizations literally take the words as gospel, as they are written, and implement the standard accordingly. The effect is that they then try to impose language, culture and practices that are alien to the organization with the inevitable result of the system being rejected by management because 'this is not how we do business around here'. Interpretation and approach are therefore critical for successful implementation. We will discuss this further when we look at the Standard in more detail, but for the moment back to our overview.

Whilst ISO 9001:2008 describes the baseline, ISO 9004:2000 provides guidance not on how ISO 9001:2008 is implemented but how a process-based management system, once created, can be improved. The two standards are therefore 'complementary' with the aim of helping the organization achieve 'organizational excellence', not that any organization will ever actually get there. It is a goal, a journey, something to strive for and a way of stimulating business improvement, or, in the future, business sustainability. The two standards together therefore provide advice and guidance for implementing and improving the way in which you do business, and to ultimately improve your business performance (see Figure 2.1). Both are based upon well researched business practice that has been shown to deliver significant value if applied sensibly.

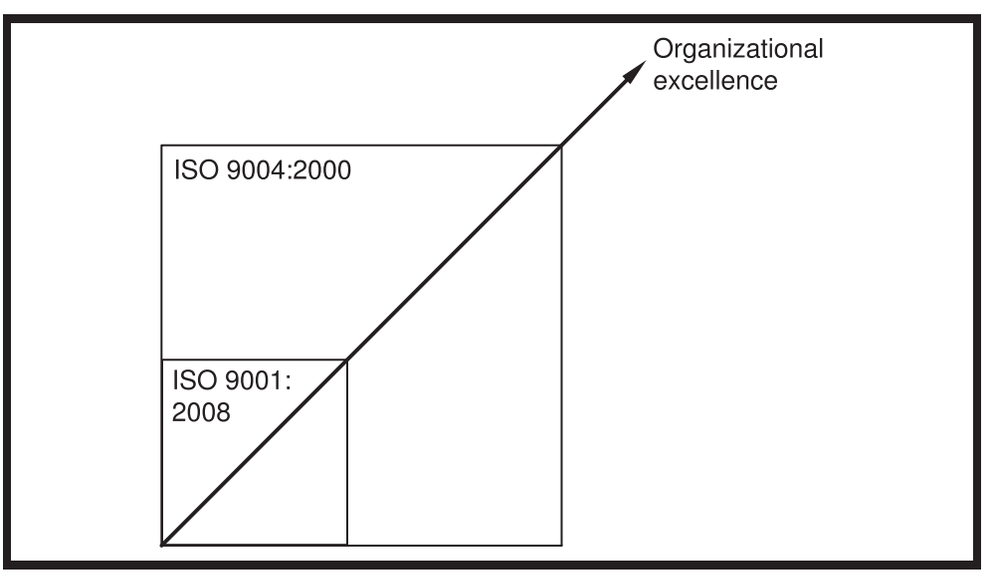

Figure 2.1 Using standards to achieve organizational excellence

Getting started with implementation

Having said that it is critical to interpret ISO 9001:2008 correctly, the question most often asked is 'Where do I start?' It would be glib to say at the beginning, but it is nonetheless correct. Unless you are a start-up organization, you will have a number of business objectives that will have been defined by your senior management team. These should drive whatever you do as an organization. Even as a start-up, you will have defined some deliverables you are aiming to achieve in your first year(s); if not formally documented, you will at least know where you are trying to go. These should be the focus of what your processes are designed to deliver.

To start to build the system you therefore need to describe the framework of key business processes that run your organization and deliver your objectives. These should then be used as the basis for developing your system. You don't start by analysing ISO 9001:2008 and trying to work out what your processes should be.

ISO 9001:2008 covers the principles you need to interpret for your business, but it won't tell you what is right for you in detail. Your organization's processes are unique to you and what fits one organization will not necessarily fit another.

In addition your organization is likely to be addressing issues outside the strict definition of ISO 9001:2008 but they are, nonetheless, part of your organization and how you deliver results. They should therefore be included, as whatever you do to achieve these will have an effect on your customer delivery.

Sometimes organizations exclude activities from their system and although this may be thought of as correct from a 'standard focused' perspective, the management system when implemented may not reflect the business that managers and staff recognize.

If this is the case, there is every likelihood that it will not be adopted or used by management to support the business. Just think about how quality management systems were adopted in many organizations in the past!

Your organization and its performance always come before ISO 9001:2008, so the task is to design a system that describes your organization first, then compare this against the standard and fill any gaps. Don't do it the other way round as it simply won't work in the long term and you won't get the benefits from using ISO 9001:2008. We can show this in Figure 2.2.

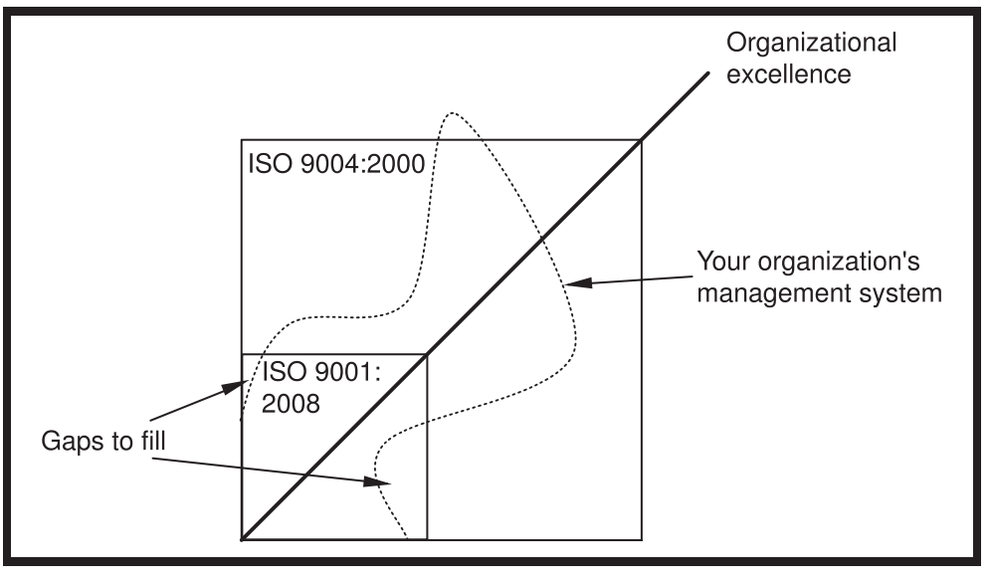

Figure 2.2 Focus on business needs first

Tell me more about the principles on which ISO 9001:2008 is based

The ISO 9000 series is based on eight key principles. Taking these into account we could carry out a test to see how effectively an organization implements these principles – indeed, this should be the key check that any third-party certification body should do. Even before discussing ISO 9001:2008 we should be able to see these principles in the management system, so in understanding ISO 9001:2008 it pays to spend some time considering what these principles are and how they might be applied within your organization (see Table 2.1).

How do we implement these principles in a more structured way?

Principles are all very well, but do not really help us understand things in a practical way. ISO 9001:2008 therefore provides a model that helps us to:

- understand these principles;
- identify the scope of our processes;
- create a framework in which to show these processes so they all 'join-up';
- consider the activities that may be included.

The model is shown in Figure 2.3.

Table 2.1 The eight key principles

Principle	What it means
1. Customer focus	Understanding what customers need and expect from the organization as a whole, now and in the future, and not just from an individual request or order
2. Leadership	Management (anyone responsible for the activity of others) at all levels creating and maintaining an environment in which others can most effectively operate, aimed at achieving the business objectives
3. Involvement of people	Ensuring that all are involved in order that their abilities can be used and enhanced to maximum benefit for themselves and the organization
4. Process approach	Objectives are more likely to be achieved when activities are seen, understood, managed and delivered through clear business processes, with resources aligned accordingly
5. Systems approach to management	Systematically managing the business through a framework of individual business processes – i.e. treating the business as a system through which results and objectives are delivered efficiently and effectively
6. Continual improvement	Improving business performance should be the objective of any organization – it must improve and change over time to survive as no change means going backwards
7. Factual approach to decision making	Effective decisions are based on real-world information that has been analysed, not purely on a feeling of what needs to be done
8. Mutually beneficial supplier relationships	Enhanced value is created by working closely with suppliers that can affect your deliverables and not against them – it is really a case of 1 + 1 = 3! – based upon their criticality to your business objectives

Step 1. It all starts at the beginning

In the previous chapter we outlined a business as a cycle that any organization of any size in any market sector could follow. The ISO 9001 model is no different.

It starts with the first principle: customer focus. This is the line at the top left-hand corner of Figure 2.3. It requires you to understand, strategically,

what your customers expect and require from you as an organization – not an individual order or request for a product or service but a long-term view. In 'non-standard speak' this helps you to understand what business you are in and the market, be that internal or external, you need to satisfy. This is your market intelligence, the listening posts in your organization that provide information that management use to set business objectives and the direction of the organization. It provides your longer-term view on what your organization needs to achieve.

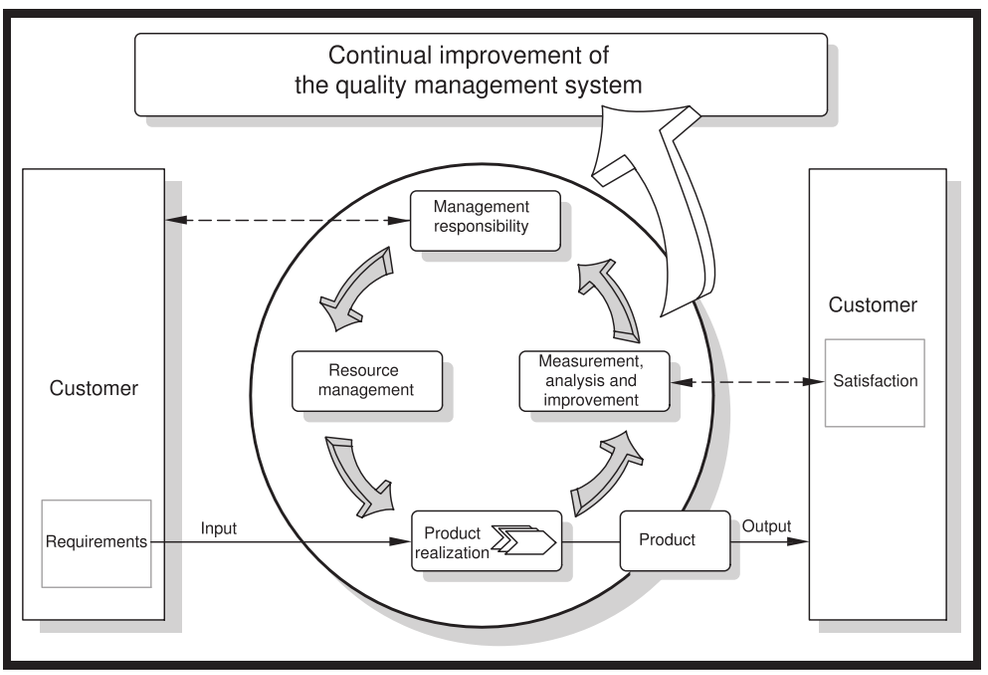

Figure 2.3 Model of a process-based quality management system

Step 2. What are management responsible for?

With this information management are responsible for setting business objectives, aligning resources to deliver these objectives and cascading the objectives down the organization so that everyone knows what they have to achieve. This also includes defining how these objectives will be achieved – in our terms, the system and processes that will be used. This activity is covered in the management responsibility clause. It also includes reviewing performance and the communication of results.

Step 3. Make sure you are managing your resources!

With the objectives defined and agreed, the next step is to obtain, set up (testing), manage, maintain and ultimately dispose of your resources to ensure they are capable or competent of delivering the objectives set. Resources can be human and capital assets such as plant, buildings, equipment, as well as infrastructure support areas such as IT, communication systems and activities to manage the work environment like air conditioning systems, etc. Increasingly, it also includes knowledge resources, which are now, for many, as valuable as the more tangible assets. In a world of increasing specialization and collaboration, it also means third parties who you need to be successful.

Step 4. Delivering the product or service

This is about your core delivery of products and services that meet customer needs. It is about making sure that you design and develop products and services that meet the requirements of your customers. It includes communicating and selling these to your customers, taking orders and making and delivering the products and services required by the customer. This means not only what you do, but how you do it, as in the eyes of most customers, 'service' is important as 'product' in driving their satisfaction. Inevitably this will mean making sure that correct consumables are purchased and that managers and staff know how to deliver the product or service. This includes such things as tracking and identifying the product or service, protecting and storing it properly and ensuring that any equipment used to measure its performance is itself correct. The product realization clause is really about your 'core' business and the way in which you m your customers' expectations.

Step 5. Having done 'it', let's do 'it' better

Having delivered the product or service, the next step involves learning from the experience and bringing about changes and improvements that will move overall performance forward. There are obviously many ways you can learn about your performance but, for ISO 9001:2008, there are essential elements that you need to measure:

- the performance of your processes;
- how customers perceive the 'value' of the product or service being delivered. You also need to demonstrate the direct link between customer requirements and customer satisfaction (the linkage between the two sides as outlined in Figure 2.3);
- testing yourself in the form of audits or assessments;
- measuring complaints.

This information needs to be collected, collated and analysed to identify trends and improvement opportunities. These improvements are then prioritized and implemented in a structured manner to prevent problems occurring in the future and to correct past errors.

In overview, the clauses of the standard cover exactly the same business cycle we have been talking about from the start. The words and phrases may be different but nonetheless they describe a set of organizational 'competences' that any organization, irrespective of size or sector, would be applying. Many organizations will therefore already be doing at least some, and often many, of these activities. ISO 9001:2008 helps you to organize them into a joined-up system to maximize their overall benefit.

Do I have to define processes that cover all of these areas?

As far as ISO 9001:2008 is concerned the simple answer is yes. The only exceptions are in Clause 7 of ISO 9001:2008 where you can opt out of certain areas if they do not affect your performance. Your management system should outline a set of processes that describe how you manage, control and improve your overall business performance. This will mean that to identify the correct processes needed for the system you may have to cover areas of business activity that you personally might not know anything about or even be aware of. The creation and improvement of the management system therefore becomes a 'team game' directed and controlled by management. How this c be achieved will be covered in the next book in this series, so let's not lose focus by saying too much here about creating a system, and get back to understanding ISO 9001:2008.

What are the key differences between the old and new standards?

To help explain what ISO 9001:2008 is about it is sometimes useful to look at how quality has evolved. This helps us to understand what the correct focus should be and the principles we should be adopting. To do this we are going to compare the 1994 version and the new 2008 version. Primarily the 1994 version was concerned with the 'product realization' clause of the 2008 version. Although this is a generalization, the remaining clauses of the 2008 version have enhanced the old standard and ensures that it covers business activity in its widest sense, including completing the improvement loop. A number of the key differences are given below. This is not meant to be an exhaustive list, just an indication of the step change that has taken place and to give you a sense of the scope of the 2008 version and the business aspects it covers. As mentioned earlier, the 2008 version is, in all important ways, a replica of the 2000 version, but as this has in many

instances not been effectively implemented, with many systems still really a 1994 version, the comparison will be useful.

Clause 4 – The 'critical' clause

Describes in overview what the management system and ISO 9001:2008 are really all about. This is an important clause, often overlooked by implementers, that can be used to shape the whole system. It provides us with the 'baseline' thinking behind the other clauses, tying them together into a coherent system. We will cover this in more detail in Chapter 3.

Clause 5 – Management responsibility

Table 2.2 Clause 5 compared

ISO 9001:1994	ISO 9001:2008
• Setting quality objectives • Quality as an 'extra' on top of business objectives	Setting business or organization objectives Quality as business built in Business focus Business planning Communication to managers and staff at all levels regarding performance Defining, amending and enhancing processes to deliver objectives

Clause 6 – Resource management

Table 2.3 Clause 6 compared

ISO 9001:1994	ISO 9001:2008
• Training records	Ensuring that people are competent to do their jobs at *all* levels including management, i.e. the training/development cycle Managing IT and communication systems • Managing physical assets such as equipment and buildings • Managing the working environment

Clause 7 – Product realization

The main difference between Clause 7 of ISO 9001:1994 and Clause 7 of ISO 9001:2000 is that although the issues or areas may be similar they are wider reaching and more encompassing in ISO 9001:2008 and far greater in scope.

Table 2.4 Clause 7 compared

ISO 9001:1994	ISO 9001:2008
• Primary focus	• Primary focus • Customer communication • Cannot opt out of a clause if it affects the 'quality' of the product or service being delivered • Customer property includes intellectual property

Clause 8 – Measuring analysis and improvement

Table 2.5 Clause 8 compared

ISO 9001:1994	ISO 9001:2008
• Auditing compliance • Corrective and preventive action aimed at the 'doers' – people who carry out the product or service delivery tasks	• Auditing/assessing effectiveness and compliance • Measuring customer satisfaction • Corrective and preventive action aimed at the whole organization • Measurement of results/performance • Analysing results and management information systems • Business improvement leading to sustainability

The 'critical' clause

One could argue that all the clauses are critical, but Clause 4 is probably more so given the need to understand what ISO 9001:2008 is really saying. However, as we discussed earlier, it is often overlooked by people wanting to get into the detail of the other clauses, or perhaps trying to avoid making some of the hard decisions this clause requires. Without a clear understanding of what it is saying, the others will not be adequately 'joined-up'. When we say Clause 4 we are really talking about Subclause 4.1. It is only a small subclause but its impact can be seen throughout the rest of ISO 9001:2008 and will have a significant effect on the way your management system is designed. Entitled 'General requirements' it sets out what is required follows (the words in italics are our interpretation, which we hope helps clarify the words used in ISO 9001:2008):

> 'The organization *(that's you and your management team, not the registration body or consultant!!)* shall establish *(create, make, design)*, document *(in any form you like that meets the needs of your business including electronic, traditional word-based, pictures, video)*, implement *(use it to manage your business)* and maintain *(make sure it works and continues to meet your needs)* a quality *(business)* management *(managers managing, not just staff doing)* system and continually improve *(measure performance and change where needed as a matter of routine)* its effectiveness *(we might be doing 'it' but is it delivering what we or our stakeholders intend?)* in accordance with requirements of this International Standard *(the first part of this book, the business cycle and the other requirements defined in Chapter 4)*.'

Table 2.6 provides further clarification on the points made in Subclause 4.1 of ISO 9001:2008.

The processes mentioned here cover all parts of ISO 9001:2008 and therefore need to cover all parts of your organization. Remember to focus on the business first and the Standard second when implementing, so your processes will cover subjects outside the obvious application of ISO 9001:2008, in this way the system is the business and the business the system – there is no difference. The only other point to mention is that this section also covers outsourcing. For many organizations this is a legitimate business strategy that allows it to focus on what its core activity actually is. This section makes it clear that where activities are outsourced these must be managed and controlled to ensure they are effective; in other words you need to manage and control the activities of others so that your performance is not adversely affected. This is a requirement that has often been sadly overlooked in the past, with predictable results.

In this chapter, as in the next, we have covered ISO 9001:2008 in more detail and described what you need to do. But having done so please remember that you have to interpret this for your own organization and understand what it means for you. Every organization is different and how you interpret ISO 9001:2008 may be right for you but not necessarily right for someone else. You need to think about how to implement it, not blindly follow the words it contains.

Table 2.6 Subclause 4.1 clarified

Extract from Subclause 4.1 of ISO 9001:2008	What it means
4.1a – Determine the processes needed …	What are your key business processes? Experience tells us there are somewhere between 8 and 15, but what they are is up to you and they will be specific to your situation today
4.1b – Determine the sequence and interaction of these processes	How do they link together to form a framework that describes and delivers your overall business results?
4.1c – Determine criteria and methods to ensure both operations and control of these processes are effective	What are your key control points/tests and performance checks?
4.1d – Ensure the availability of resources …	Do people operating the processes have the right information, resources and equipment to enable them to do their work properly and effectively?
4.1e – Monitor, measure, where applicable, and analyse these processes	Collect, collate and analyse your process performance and the results achieved. These are the measurements you need to understand what is really happening
4.1f – Implement actions necessary …	Use the information you have analysed to carry out improvements so that the results you are looking for are more likely to be achieved

Summary of key points

- Your processes are based on achieving your business objectives and therefore must align with each other. As your business objectives change so should your system and processes.
- ISO 9001:2008 describes a management system as a framework of business processes that covers business planning, management of resources, delivering products and services, checking and measuring performance and acting on the information to improve.
- Auditors and assessors need to check effectiveness, not just compliance, and identify where there is a risk in the objectives not being met.
- ISO 9001:2008 just describes good business/management sense or best practice.
- ISO 9001:1994 focused on quality assurance; ISO 9001:2008 focuses on quality management.
- ISO 9001:1994 focused on staff 'doing'; ISO 9001:2008 also includes managers 'managing'.
- The principles on which ISO 9001:2008 is based can be used to assess an organization and to help shape the content of the management system.
- Understanding Clause 4 gives a clear overview of the system required.
- Build a system that describes your business processes first, then compare with ISO 9001:2008 to identify gaps. This is easier than doing it the other way round and more business-oriented for your managers and staff.
- ISO 9001:2008 describes the baseline in process-based management; ISO 9004:2000 provides guidelines on how this can be improved.

3. Business process management – The 'how'

Before going into any more detail on what ISO 9001:2008 is about it is probably worth considering 'how' you are going to implement this 'what'. The technique used to implement ISO 9001:2008 we know as business process management; other titles you may have come across could include performance management, output management, deliverable management, etc.

Whatever title you use the approach is based on understanding what your business processes actually are and then managing their performance – hence business process management. It is the essence of delivering the performance you have planned to achieve and of therefore providing the best possible opportunity of meeting your business objectives.

'Joined-up' thinking

The approach is based upon seeing your organization as a series of activities that link together to deliver results, irrespective of 'artificial' boundaries that may be imposed by an organizational structure. Such boundaries may be geographic, by department or section, site, group or product/service line and they are normally created as a result of our organizational design.

Seeing an organization in this way may introduce a very different way of thinking for those of us used to managing or working for a particular department. Traditionally our loyalty is to the department, section or site rather than to the process that, by its very nature, flows across these departments or sections. This raises a number of issues about the culture of the organization and its ability to work in teams that are aligned to the processes rather than departments, sites, etc. and they need to be addressed if business process management is to be effectively delivered. We can show this in Figure 3.1.

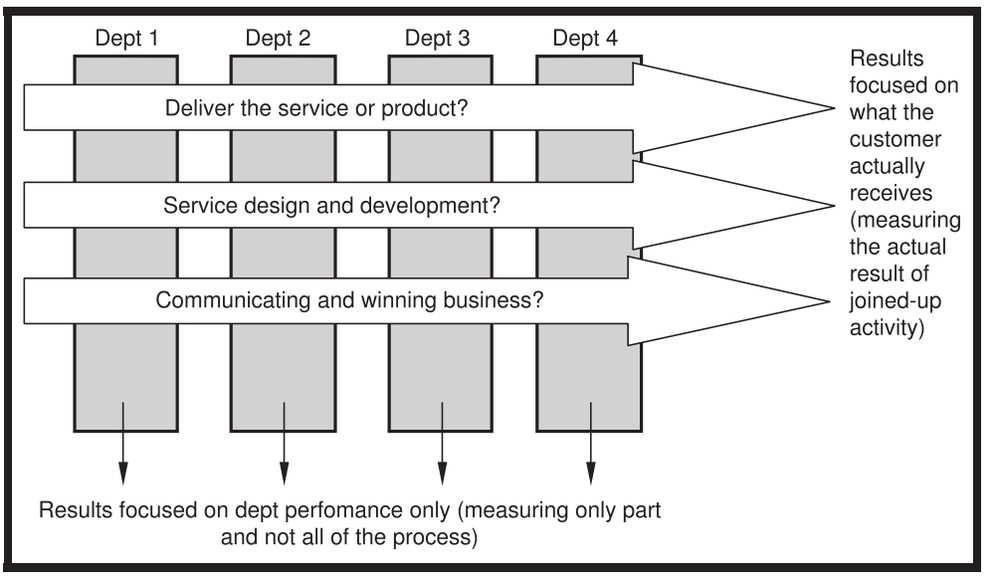

Figure 3.1 Process thinking *not* 'silo' thinking

In process thinking we therefore concentrate on our performance cross-functionally, i.e. what the customer actually sees and experiences rather than worrying unnecessarily about the individual performance of a particular department, section or person. It is really a matter of focusing on the 'right things' as much as doing 'things right'.

Of course process improvement is about identifying non-value adding or poor performing activities inside the process, which will require going back to the individual departments or sections to carry out improvements. The overall impact, however, should be enhanced results of the whole process, not just an individual department or section. Remember changing the activities in one department may improve its performance but this may have an adverse effect on another. Equally, to deliver improved overall process performance may require departments working in a way that is suboptimal for them. The right question to ask is, what effect will the change have on the overall performance of the process? The aim is to maximize the performance of the whole process not just one part of it.

Therefore to understand ISO 9001:2008 and its implementation we need to start thinking in a 'joined-up' way. This applies not only to implementing ISO 9001:2008 but more importantly to our business, requiring answers to questions like how to identify your processes, how to measure their performance and how they are audited for effectiveness and improvement. This is a team game, not one based on departmental performance.

If a process is cross-functional/departmental, how is it managed?

This leads us on to what a process is. Essentially a process is concerned with taking one or more inputs, which could be information, customer requirements, etc., and through a series of related activities delivering outputs or outcomes to the customer (see Figure 3.2a).

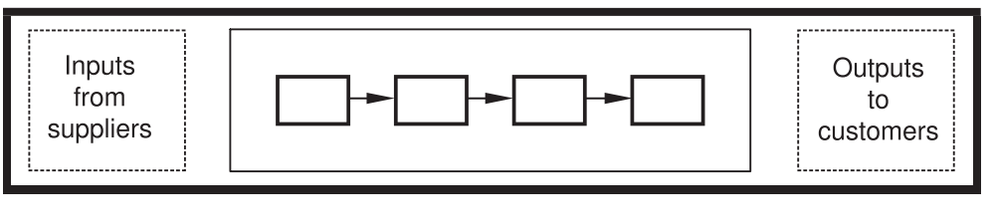

Figure 3.2a Processes transform inputs into outputs

Of course to make a process work we need equipment, people, knowledge, buildings, budget, etc. (see Figure 3.2b).

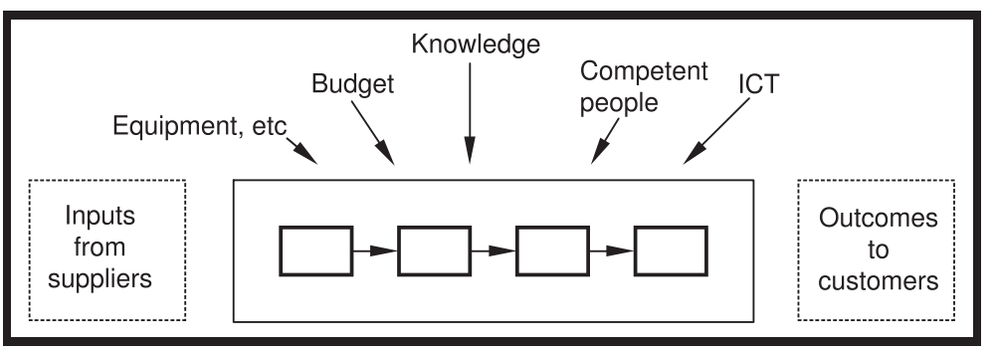

Figure 3.2b Resources impact process performance

If we are to manage this process effectively we therefore need to plan and implement its delivery using the equipment, knowledge, etc. and measure its performance against targets. These performance measures are based on its purpose (why the process exists); by measuring against the purpose we can identify gaps in overall process performance, which can form the basis for improvement activity. The aim is to analyse the actual results achieved (compared against the target), learn from the information and trends created and use the information as

a basis for change or improvement actions. This aligns totally with the clauses of ISO 9001:2008, in this case Clause 8. This is shown in Figure 3.2c.

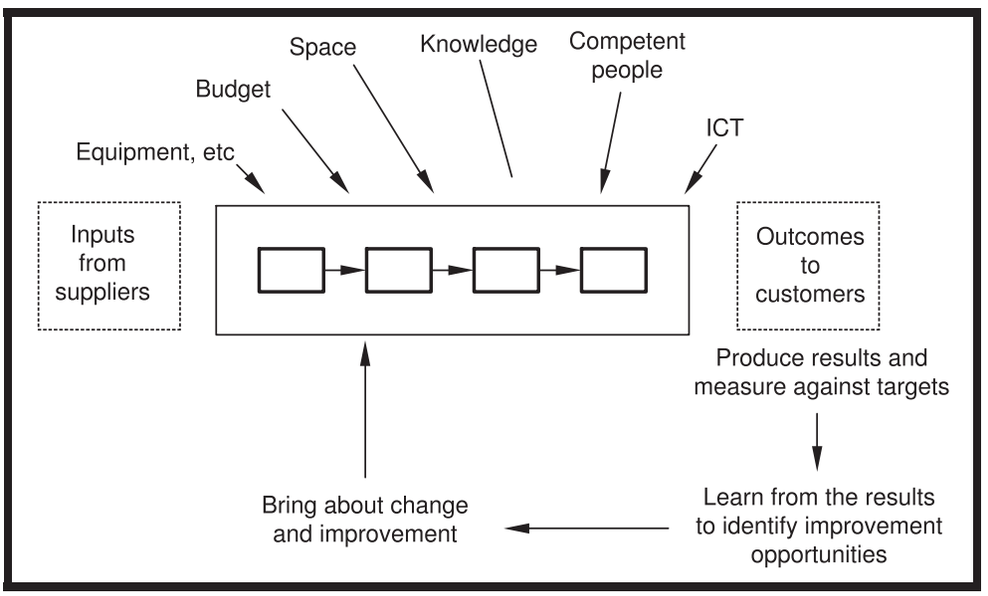

Figure 3.2c Measuring results drives improvement

The improvement can be brought about in a number of ways. Amongst these can be:

- reworking, shaping or amending the process itself and the people assigned to carry out the tasks;
- improving the external provision of resources and factors such as improving competence through training and development;
- changing equipment, making better use of knowledge, improving IT, etc.;
- changing the way we lead the team or the ways the team works together; or
- a combination of many things.

Once the improvement has been made the process runs again and new results are produced. These are then compared against the target and further analysed so that the effectiveness of the change made can be assessed. As necessary, further improvements are identified and implemented – continuous improvement in action.

These principles form the basis for business process management. You may already realize that there are a considerable number of variables that affect

process performance, some of which you can influence, others which you can not. The question is, how do you manage these in the most effective manner? A classic variable and one that is often perceived as something we are unable to change are 'constraints': the things that 'force' you to do things in a certain way. We often assume that they cannot be changed, but that is not always the case as we often impose them on ourselves!

The other point to make is that people, assets, ways of working, etc. are always changing and this will have an effect on performance. The level of performance required is also itself subject to change over time, reflecting either the improvements for which you are striving and/or the increasing demands of customers. Therefore you never actually get there: in theory there is no end point – process management becomes a way of life by which managers manage and improve their business/organization.

If there is no end point, how can I get registration if I want it?

Good question. As long as you ensure that you have the principles in place, i.e. identified your business processes, manage them and include any areas of detail covered by ISO 9001:2008, then you cannot fail. The real intention of ISO 9001:2008 is that you should apply all of the principles that it contains, in a way that is appropriate to you, and use the 'system' to continuously improve your performance If you truly are doing this, you have in place a mechanism that should not only allow registration but, more important, enhance your business results. Having a compliant system in place is just the start of your transition towards business excellence – the very beginning of a long journey.

The best advice we can give you, based on experience, is to work with your assessment body and the assessor with the overall aim of improving your organization. Your auditor should assess the effectiveness of the system and compliance against the requirements of ISO 9001:2008 and anything that 'disconnects' the logic and operation of the system. They cannot tell you or recommend to you how you should manage your business – that's your management team's job. They should, however, be making sure that you have asked yourself the right questions, and are applying the principles in a way that is appropriate for your unique situation and highlight where there are risks to the achievement of objectives – i.e. assess at both the compliance and effectiveness levels.

Let's make sure we understand the true impact of process thinking

As we have seen, processes describe activities that flow across the organization. These processes are managed by measuring the results achieved. The impact is that the results are focused on outcomes, i.e. what the customer or other interested parties are actually interested in. But let's look in Figure 3.3 at what happens when we have an internal focus on performance, rather than a process outcome focus.

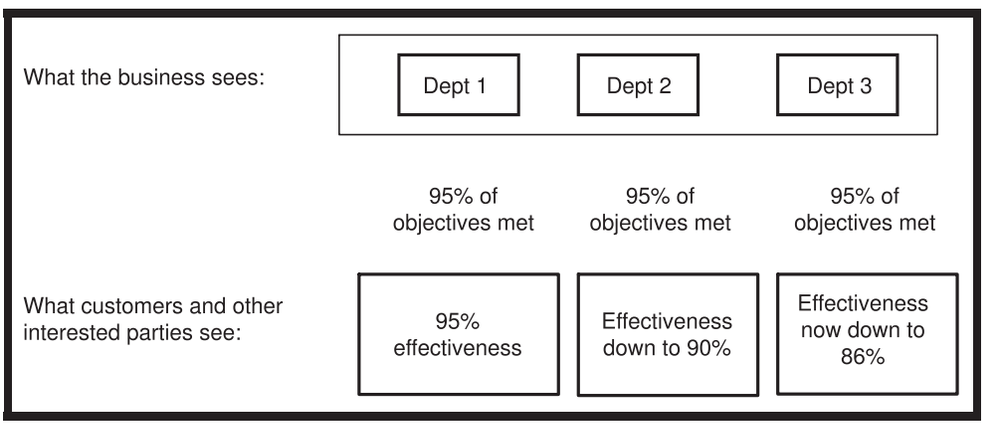

Figure 3.3 Inward focus neglects actual performance

The principle is that if Dept 1 is only 95% effective, then when the work is handed over to Dept 2 the work is already 5% wrong. Now unless Dept 2 spends time, effort and money on putting it right the customer cannot possibly get what they are looking for. But it is worse than that, as processes often cover many people and departments. If Dept 2 is also only 95% effective then the net result is 90% effectiveness overall (95% of 95%). This only gets worse as the work is now 10% wrong going into Dept 3 and if they are also only 95% effective, the overall effectiveness of the total process is now down to 86% (95% of 90%). It is this level of effectiveness that the customer and other interested parties such as shareholders, senior managers, government, etc. (as defined for the process) actually see. Remember the principle applies to any situation where work moves from person to person, department to department, section to section, location to location or any combination thereof. And this is often exacerbated further by inefficiencies in the transfer between the departments, which is often not

the management responsibility of anyone. The outside world only sees what you eventually produce, not what is happening inside and that is what they will measure you on.

One of the main reasons why process management has failed in the past is that many people have considered the organization to be a single process, designed to deliver the objectives of that organization. Whilst this is true, at this level it becomes virtually impossible to manage as a single entity because it is just too complex. The organization therefore needs to be divided into a number of smaller elements of 'key' processes, which work together jointly to deliver the objectives. These become much easier to both understand and manage, whilst their interactions with each other and with the 'outside world' become the focus of their performance and improvement.

But how can this be applied to a business?

For a whole organization, the principle is therefore a matter of scale. If we can see that an individual process is made up of a number of activities that are linked together, then on a larger scale we should be able to describe an organization as a number of processes linked together. In this example let's ay there are eight processes (see Figure 3.4a).

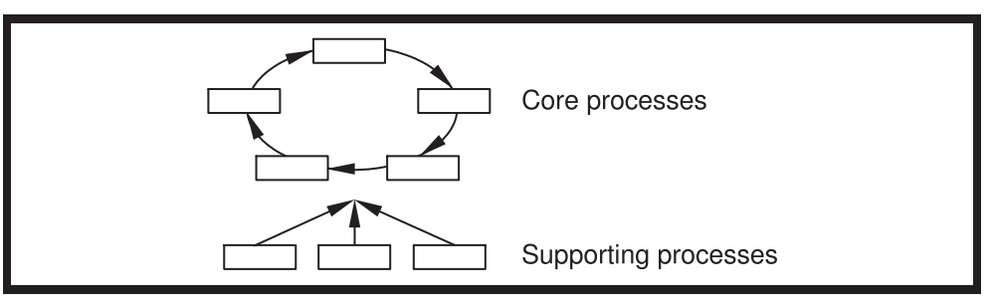

Figure 3.4a Simple system involving eight processes

Any organization or business takes inputs from the 'real world' and through its processes delivers outcomes back into the 'real world'. Therefore we can extend our process thinking a bit further and into system (or whole-business) thinking (see Figure 3.4b).

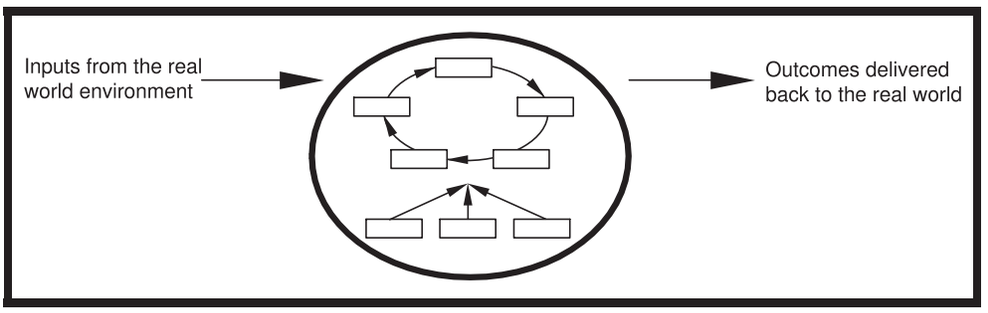

Figure 3.4b Systems interact with the outside world

Just as with a process there are factors that affect system performance. In process thinking we outlined these as equipment, knowledge, people, etc. in quite a tactical, low level way. In system thinking these are likely to be more strategic in nature (see Figure 3.4c).

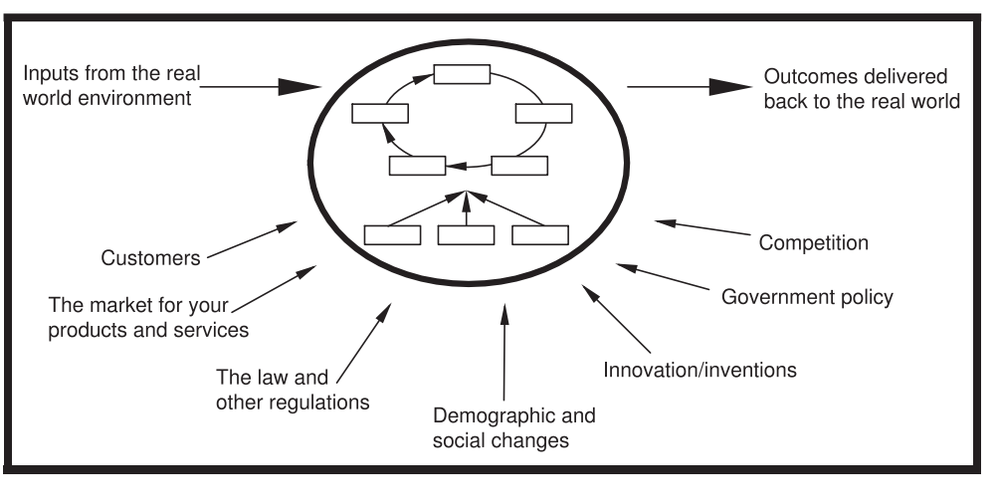

Figure 3.4c Real world influences on system performance and approach

What is the most important point to remember?

For any business/organization to be successful and meet its objectives it must understand the environment and the markets in which it operates, the constraints, risks and opportunities that exist and use this information to set business objectives. This is a key process element. If we slip back into 'standard mode', Subclause 5.2 – Customer focus, is looking at the market/your customers' needs

and expectations, and Subclause 5.1 – Management commitment, considers the need to ensure that statutory and other regulatory requirements are understood and applied. Other areas such as innovation, social and political change and policy are technically outside ISO 9001:2008 but, of course, have to be considered by your organization as they will have a major impact on its performance and well-being. These areas are more likely to be found in ISO 9004:2000, the guide to improvement (see Figure 2.2).

Is understanding our business environment where we start implementation?

In a sense yes: you need to start the creation of your management system by identifying the key business processes that make up your management system. These are the processes that jointly deliver your objectives. How you do this is another issue but in understanding ISO 9001:2008 you need to be aware that there are probably between 8 and 15 processes. It is very important that you start at this point and get it right. Think of this as being able to describe the whole business one on piece of paper.

The vital point to remember here is that these are not individual departments or sections. It is very unlikely that you will have a process that is wholly contained in any one department or section, unless you are a small, multi-skilled organization with only one group of people doing everything between them! For example, you may have a managing people process that covers recruitment, training, performance monitoring, etc., but this will cover the activities carried out by line managers (in identify training needs, etc.) as well as HR or personnel department activities and maybe also finance in making sure they are paid. Therefore there are real dangers if you call it HR as there will be a tendency for people to think this refers to what the HR department does and not the whole process of managing people, carried out across the organization.

Having identified what key processes you actually have the next stage is to define them as a series of activities. This is our 'what we o' level. Mapping processes is a bit of an art form, but essentially you will be looking for a consistent level of detail that shows movement from left to right with responsibilities and cross-functional activity highlighted; an example is given in Figure 3.5.

There are a large number of techniques and software tools available to help you create these 'process maps'. Think about what you need the map to do for your organization and choose the 'tool' most suitable to these needs. Whatever you choose, however, do make certain that it emphasizes the cross-functional transfers within the processes, provides clear definition of accountability for each activity and is easy to communicate to everyone.

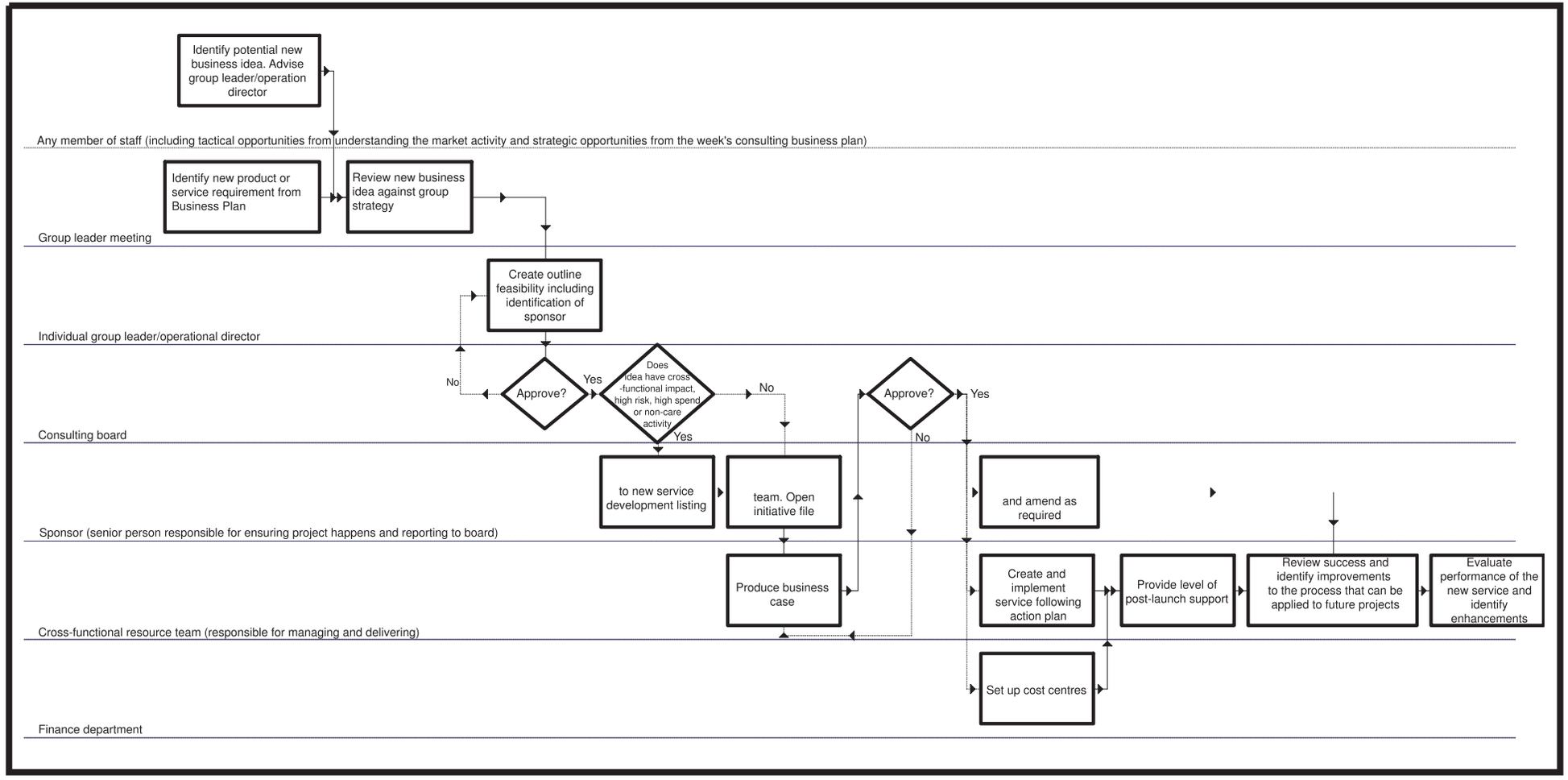

Figure 3.5 A typical process map

If we now add our process level to the system (or whole-business level) the resulting structure can be illustrated as in Figure 3.6.

Each process identified in the system is defined in sufficient detail so that it is understood, is totally transparent and describes 'what we do' to achieve results. Sub-processes are sometimes needed when the process is complicated or the business sees a need for greater detail. The level of detail at which you choose to define the process should be governed by the risks associated with the activity that need to be managed to ensure consistent delivery. If there is a high risk, you would probably wish to invest in further detail. If the risk is low, you would not. It is a very business focused decision. Measures of performance are also added to each process, as we described earlier.

Whether or not sub-processes are needed to help define each process further, the lowest level in the structure is the 'how I do it' level. The 'how I do it' level is made up of procedures and/or other support information needed by the organization. Procedures and support information can be in any format and describe or provide additional information to help someone carry out an activity. The level of detail here is again based on the risk to the organization, and is often driven by regulatory requirements, operational needs, the competence of the people carrying out the task, customer requirements, etc. ISO 9001:2008 only requires six procedures; the rest is up to you. The whole structure can be illustrated as shown in Figure 3.7.

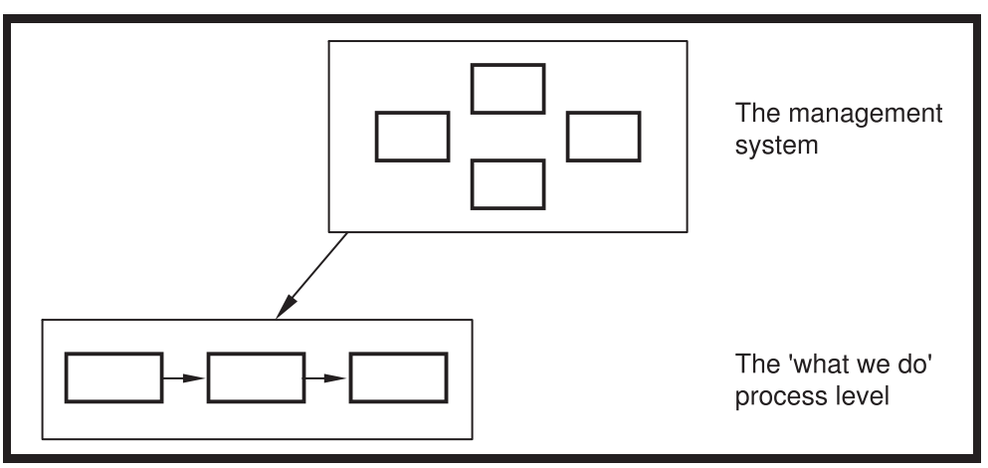

Figure 3.6 Processes directly link to the system

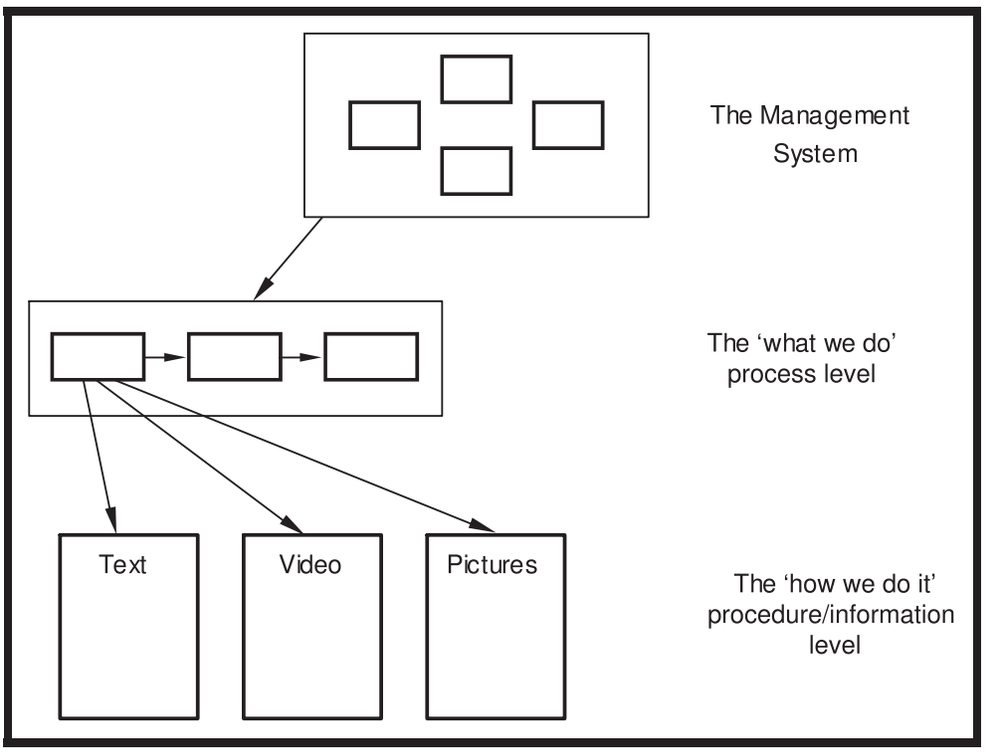

Figure 3.7 The full picture, i.e. the complete management system

The structure of a typical system is contained at three levels: system, process, and procedure or information. Notice that there are no department/section levels, etc., just system and process thinking.

Creating a management system is a considerable challenge and the purpose of this chapter is only to give you ideas and an indication of what a system may look like. There are plenty of examples, some good, some not so good that people have built and we suggest you have a look at these before putting 'pen to paper' or 'finger to keyboard'.

The most important point is that your processes should be based on your organization and its needs, not ISO 9001:2008. ISO 9001:2008 is a business model, and interpretation is down to you and your management team. Experience in building systems in the real world indicates that in order to define a 'whole-business' system there are approximately 8 15 key business processes depending on the size of the business. Some registration bodies and consultants suggest that you need only four, and guess what? They call them management responsibility, resource management, product realization, and measurement, analysis and improvement – just like the clauses of ISO 9001:2008! We have yet to come across

a management team that describes its business in such simplistic terms or ignores other external influences. There is nothing wrong with the Standard; we just have to be careful how it is interpreted in the 'real business world'.

Summary of key points

- System thinking is similar to process thinking, the only real difference being one of scale and the environment in which the individual process or system is operating.
- Processes are cross-functional and could cover a number of departments, sections or locations.
- Start with the system and don't map processes until this is right and accepted.
- Don't name a process with a department or section location name.
- An organization and the business (quality) management system does not work in a vacuum and has many external influences affecting it. Understanding customer requirements is only one item; there are many more that you need to consider.
- Identify your processes first, then compare with ISO 9001:2008 – don't use the Standard to identify your processes because won't show you them.
- Create a structure of consistent detail starting with identifying business processes, defining the process (perhaps with sub-processes) and with procedures.
- Systems are often designed to demonstrate Plan, Do, Check, Act to ensure all processes are included. Processes generally flow left to right and show cross-functional interfaces.
- Systems have inputs and outputs just like processes; both are managed.
- Managing through a system and its processes optimizes performance. Managing through departments, sites, etc. does not.
- The performance of activities in a process is affected by a range of internal and external factors; improving any one or combination will improve process performance.

4. ISO 9001:2008 in more detail – The 'gap'

In the last two chapters we covered what ISO 9001:2008 is and how it can be implemented in an organization through process management. The next stage in understanding the Standard is to consider the detail of the clauses. The purpose of these clauses is to help outline some of the activities in your system and processes. If these activities are included in your processes and the processes followed, you will be successful with your implementation of ISO 9001:2008 and achieve the benefits.

The important point to remember is that every clause or subclause describes an activity that will appear in a process somewhere. Don't forget that you build your system first; this chapter provides you with an opportunity to carry out a gap analysis against the system you create to identify improvements.

Clause 4 – Quality management system

Subclause 4.1 requires your organization to establish, document, implement and maintain a management system and continually improve its effectiveness. It therefore describes an overview of what you need to create.

NOTE The 'What it says' column contains direct extracts from ISO 9001:2008. 'What it means' is our interpretation based on practical experience. We suggest that you use the columns to the right to make notes and identify any gaps that your business may have, for future reference.

Clause No	What it says	What it means	Currently do this and in the system	Currently do this but not in the system	New to the organization
4.1a	Identify the processes needed for the management system and their application throughout the organization	You need to know what your processes are. These are unique to you and describe how your management team manage, control and improve the performance of the business.			
4.1b	Determine the sequence and interaction of these processes	Show how the processes you identified in Subclause 4.1a are linked together to form a 'framework', a sequence or order. Subclauses 4.1a and 4.1b shape the system. This is your system.			
4.1c	Determine criteria and methods needed to ensure that both the operation and control of these processes are effective	Make sure that the processes you define include the necessary control points and activities to ensure the processes are operating effectively. These activities need to describe what is happening and the outcome of the activity.			
4.1d	Ensure the availability of resources and information necessary to support the operation and monitoring of these processes	As we have seen in the other chapters, processes are not just documents. Management need to make sure that the necessary resources are available and managed for the processes to be effective. Resources may include people, facilities, plant and equipment, IT as well as information. This is why there is a resource management clause in ISO 9001:2008.			
4.1e	Monitor, measure and analyse these processes	As processes are run we need to monitor their performance by using measures or key performance indicators and			

Clause No	What it says	What it means	Currently do this and in the system	Currently do this but not in the system	New to the organization
		feedback from customers and audit results. This information should be analysed to identify trends in performance and from this, areas for improvement can be identified. Don't forget all these are activities that will appear in a process somewhere in your system.			
4.1f	Implement actions necessary to achieve planned results and continual improvement of these processes	Included in your process-based management system should be a process (or processes) that describes how improvements and changes are made and embedded in the organization. These relate to changes that either continually improve what you do or simply deliver what you planned if OK.			
Notes	Where an organization chooses to outsource any processes …	If your organization outsources activity that you would normally do internally to deliver your products and services you need to show how this is managed and controlled. You can't simply outsource it and forget it. This needs to be shown as part of the management system.			
	Processes needed for the Management System referred to above should include processes for management activities, provision of resources, product realization and measurement	All clauses need to be covered in the system and all activities carried out by all managers and staff at all levels in the organization.			

Documentation

Clause No	What it says	What it means	Currently do this and in the system	Currently do this but not in the system	New to the organization
4.2.1	The management system documentation shall include:				
	a. documented statements on a quality policy and quality objectives	a. Your management will need to document their (business) policy and what their (business) objectives are; more later in Clause 5.			
	b. a quality manual	b. You will need to create a document that outlines your management system, your organization and policy.			
	c. documented procedures required by this international standard	c. There are some procedures that you must have and include in the documented system. We will point these out when we come to them but there are only six.			
	d. documents needed by the organization to ensure the effective planning, operation and control of its processes	d. You decide what documents and records are important in enabling your organization to manage itself and deliver results.			
	e. records required by this international standard	e. You need to ensure that the documents and records that you keep include those required by ISO 9001:2008. We will point these out when we get to them.			
Note 1	Where the documented procedure appears … this means that the procedure is established, documented, implemented and maintained	Self-explanatory.			

Clause No	What it says	What it means	Currently do this and in the system	Currently do this but not in the system	New to the organization
Note 2	The extent of the management system documentation can differ from one organization to another due to: • Size and type of activity • Complexity of the processes and interaction • Competence of the people	There are no right or wrong answers to the amount of documentation you need. It will depend upon the size of your organization, how complicated it is and the competency of your managers and staff. The real test is whether or not the documentation that has been created is effective in supporting the organization.			
Note 3	The documentation can be in any form or type of medium	You can hold your management system in any form of media or any combination. There is no right or wrong method, it really depends on your organization, its needs and requirements. Don't forget the media need to be effective in providing managers and staff with the information they need, when and where they need it.			

Quality manual

Clause No	What it says	What it means	Currently do this and in the system	Currently do this but not in the system	New to the organization
4.2.2	The organization shall establish and maintain a quality manual that includes:	This is a small document that shows what the organization is about and which can be provided to customers and other interested parties to introduce the organization and the management system.			

Clause No	What it says	What it means	Currently do this and in the system	Currently do this but not in the system	New to the organization
	a. the scope of the system … and justification for any exclusions	a. The document needs to include a statement outlining what your organization is about and the products and services you supply. In this statement if there are elements of Clause 7 that you do not cover then you must mention this here.			
	b. the documented procedures or reference to them	b. You have a choice here. If you are building a system along the lines we have outlined then all you need to say is that the processes are supported by procedures where you need them. If you are not then you need to include them in the manual. Remember procedures by their nature are low level documents and should be positioned accordingly, with reference to them being preferable to including them here.			
	c. a description of the interaction between the processes	c. In the manual you need a short description showing how the processes link together. This could be a text-based description, a picture or map on the basis that a 'picture is worth a thousand words'. Of course the 'picture' can be based on the map you created to satisfy Subclause 4.1a.			

Document control

In overview, documents that make up the management system need to be controlled. This will include your processes and procedures as well as key documents that you would class as records (see Subclause 4.2.4 below). You need a procedure that describes how you do this.

Clause No	What it says	What it means	Currently do this and in the system	Currently do this but not in the system	New to the organization
4.2.3	A documented procedure shall be established to define the controls needed:				
	a. to approve documents for adequacy prior to use	a. You need to demonstrate that documents are approved before they are used. This could be covered by signing a paper-based document, by email or password-based system.			
	b. to review and update as necessary and re-approve	b. This requires that you show how documents are reviewed and re-approved. Again this could be paper- or system-based. How you do it is up to you.			
	c. to ensure that changes and the current revision status of documents are identified	c. You need to show how the current version of a document is known. This is to ensure that people use the most up to date document to carry out their work. Changes need to be highlighted either within the document itself or, for example, on a separate email, issue sheet, history, etc. Traditionally this has been paper-based but there is no reason why the version could not be included in the name of a computer file or the version created using the computer system, which often shows the date and time when the computer file was created.			

Clause No	What it says	What it means	Currently do this and in the system	Currently do this but not in the system	New to the organization
	d. to ensure that relevant versions of applicable documents are available at the points of use	d. People using the documents need to have access to them for use. You could produce paper-based copies or computer-based or a combination of both. As your documents could be in any medium that you feel fit this could include access to the information by video, email, etc., but remember not everyone needs to have everything.			
	e. to ensure that the documents are legible and readily identifiable	e. Quite simply the documents you produce must be understandable and usable. Therefore they need to be legible and identified so that it is clear what sort of document they are.			
	f. to ensure that documents of external origin are identified and their distribution controlled	f. Often organizations use documents that come from outside the organization to run their business and deliver products and services. Where this is the case you need to show how these are controlled and distributed.			
	g. to prevent the unintended use of obsolete documents	g. Sometimes organizations might use old or outdated documents for reference purposes. Where this is the case you need to show how these are identified so that people do not use the old document by mistake.			

Control of records

Records are kept mainly for regulatory, legal and business reasons and are used to either demonstrate conformity to these legal and regulatory requirements or for other reference or future use, e.g. financial, environmental, personnel and health and safety records. Other records are kept for business reasons such as business plans, product or service specifications, etc.

Clause No	What it says	What it means	Currently do this and in the system	Currently do this but not in the system	New to the organization
4.2.4	Records shall be established and maintained … Records shall remain legible, readily identifiable and retrievable	This requires you to have a procedure that describes how the records are identified, stored, protected and retrieved. Along with outlining what the documents are, etc., you also need to show how long the records are kept and how they are destroyed.			

Clause 5 – Management responsibility

This clause describes what the management's activities and responsibilities are for the management system itself and how they may demonstrate that they are 'managing' the business rather than the business managing them. This means that there is unlikely to be one process covering management responsibility, with management activities appearing in many processes depending on the level of management involved and the activity itself. Any ISO 9001 management system that includes a 'Management responsibility' process is therefore immediately suspect in terms of reflecting the real world and being of strategic use to the organization.

Management commitment

Clause No	What it says	What it means	Currently do this and in the system	Currently do this but not in the system	New to the organization
5.1	Top management shall provide evidence of commitment to the development and implementation of the management system and continually improving its effectiveness by:	Top management are the most senior people in your organization and are typically responsible for setting objectives and allocating resource, including budgets. If your management are not responsible for these areas then the scope of your system may be too small. If in doubt then contact a registration body to gather their views. Evidence that management are committed to the system and improvement does not have to be paper-based or documented. If you choose, the evidence can be non-documented. The auditor from the registration body will be able to assess the effectiveness of this non-documented evidence.			
	a. communicating to the organization the importance of meeting customer as well as statutory and regulatory requirements	a. This requires management to communicate the importance of delivering what customers need or expect from the organization as well as any legal or regulatory requirements that may be placed on the organization. These are typically activities in one or more processes and take place at the appropriate time in the process. How your management carries out this task is down to them and different methods may be used based on the audience and the message to be communicated. Your auditor			

Clause No	What it says	What it means	Currently do this and in the system	Currently do this but not in the system	New to the organization
		won't be concerned about the method but will be concerned about the effectiveness of the communication and how well it has been understood and applied.			
	b. establishing the quality policy	b. The management team need to show that they are committed to establishing the quality policy in the organization; see Subclause 5.3 below.			
	c. ensuring that the quality objectives are established	c. As we have seen in the previous sections, for 'quality' read 'business'. Management are therefore responsible for establishing their business objectives that describe what the business has set out to achieve; see Subclause 5.4.1.			
	d. conducting management reviews	d. Management need to be committed to reviewing the performance of the business at planned intervals, identifying any performance gaps and taking appropriate action; see Subclause 5.6.			
	e. ensuring the availability of resources	e. Management's role is to review the effective use of resources that support the processes. As we have seen this could be people, equipment, facilities, etc. The management need to demonstrate their commitment to providing the necessary			

Clause No	What it says	What it means	Currently do this and in the system	Currently do this but not in the system	New to the organization
		resources to meet the objectives. Of course this is often an ever-changing balancing act based on the 'risks' the organization faces, but one management are responsible for.			

Customer focus

Clause No	What it says	What it means	Currently do this and in the system	Currently do this but not in the system	New to the organization
5.2	Top management shall ensure that customer requirements are determined and are met with the aim of enhancing customer satisfaction (see 7.2.1 and 8.2.1)	Before your organization sets its business objectives it needs to understand *what would satisfy* its customers' needs and expectations. This is not about taking an individual order but the activities that describe how the organization understands its internal and/or external market for the products and services it provides. These expectations are fed into the business plan and turned into objectives; see Subclause 5.4.1. Customer service is the act of providing products and services that meet these expectations (see Subclause 7.2.1) and measuring *how satisfied* the customers are, (Customer satisfaction, Subclause 8.2.1) which is an evaluation against the original needs.			

Quality policy

Clause No	What it says	What it means	Currently do this and in the system	Currently do this but not in the system	New to the organization
5.3	Top management shall ensure that the quality policy:				
	a. is appropriate to the purpose of the organization	a. Make sure the policy links to what your organization actually does.			
	b. includes a commitment to comply with requirements and continually improve the effectiveness of the quality management system	b. Ensure that there is a statement in your policy that shows that management and the organization are committed to continually improving the organization's performance.			
	c. provides a framework for establishing and reviewing quality objectives	c. The aim of the policy is to provide a structure, a form of words, against which the (business) objectives can be set. This does not mean the objectives have to be in the policy; it is more likely these are in the business plan.			
	d. is communicated and understood within the organization	d. The policy needs to be communicated to all managers and staff, which includes those who join the organization after the launch of the system. This needs to be understood by all managers and staff. It does not mean it has to be quotable or repeated 'parrot fashion', just understood and applied to what people do.			
	e. is reviewed for continuing suitability	e. The policy needs to be reviewed periodically (it is your choice how often) to ensure that it remains suitable for your organization.			

Planning

Clause No	What it says	What it means	Currently do this and in the system	Currently do this but not in the system	New to the organization
5.4.1	*Quality Objectives* Top management shall ensure that quality objectives … are established at relevant levels within the organization. The quality objectives shall be measurable and consistent with the quality policy	You will recall from previous chapters that ISO 9001:2008 is really concerned with business objectives. Therefore your most senior management team are responsible for setting the business objectives for the organization, which may be in the form of a business plan. These need to be based on the information gained from the customer focus section. These high-level business objectives need to be broken down to ensure that all relevant functions/processes are aligned. In turn these objectives need to be broken down into individual objectives. You therefore need to create a hierarchy of objectives, all aligned to each other. This ensures that everything anyone does is aimed at delivering the overall aims and objectives of the business. Objectives need to be measurable and aimed at delivering the intention outlined in the Quality Policy, perhaps making them SMART (Specific, Measurable, Achievable, Realistic, Timely).			

Clause No	What it says	What it means	Currently do this and in the system	Currently do this but not in the system	New to the organization
5.4.2	*Quality management system planning* a. the planning of the system is carried out to meet the requirements of 4.1 as well as the quality objective b. the integrity of the quality management system is maintained when changes are planned and implemented	a. Senior management must ensure the process-based management system meets the requirements of Subclause 4.1, i.e. it is a complete system based on Plan, Do, Check, Act and describes the continuous improvement cycle. b. The system must also be designed to deliver the organization's objectives, which, of course, means that if the objectives change then so might the processes. Because the management system may change (either because the objectives have changed or there are improvements being made) the integrity of the system must be maintained so that it continues to support the organization. It can't be left to fall into disrepair during the change process.			
5.5.1	Top management shall ensure that responsibilities and authorities are defined and communicated within the organization	Senior management need to show who is responsible for what. Often this is shown on the process map but can be in other documents as well, such as organization charts, job descriptions, etc. These would also cover key control points and levels of authority. To ensure that they are actioned correctly these controls, responsibilities and levels of authority need to be communicated throughout the organization.			

Clause No	What it says	What it means	Currently do this and in the system	Currently do this but not in the system	New to the organization
5.5.2	Top management shall appoint a member of management who … shall have the responsibility and authority that includes: a. ensuring that the processes … are established, implemented and maintained b. reporting to top management on the performance of the system and need for improvement c. ensuring the promotion of awareness of customer requirements throughout the organization	a. Someone needs to take responsibility for making sure that the system actually exists and is being maintained. b. This individual needs to ensure that the performance of the system is reported to the management team along with any needs for improvement. Often this performance is based on trends, with the actual task of collecting and collating the results being left to others as required. c. This requires that the person appointed as the management representative adopts one or more methods to ensure that everyone in the organization is aware of the importance of meeting and focusing on customer requirements.			
5.5.3	Top management shall ensure that appropriate communication processes are established … and communication takes place regarding the effectiveness of the management system	Senior management need to make sure that the results of running the system and individual processes, together with other issues that may affect performance of the system, are communicated throughout the organization. To do this you can use any method: electronic, intranet, face-to-face meetings or on noticeboards. The auditor will be concerned with how effective the method(s) you choose are.			

Clause No	What it says	What it means	Currently do this and in the system	Currently do this but not in the system	New to the organization
5.6.1	Top management shall review the management system at planned intervals to ensure its continued suitability, adequacy and effectiveness	Senior management must review the performance of the organization and therefore the system. This needs to be at planned intervals. The review is likely to be an existing management meeting, like a board meeting, operational meeting or team video conference, and take place each week, month or every six months. You decide how often the management need to review performance of the business and how this will be achieved.			
5.6.2	Review inputs	The standard lists the information that needs to go into the review. You don't necessarily need to have agenda points for each but they must be covered in some form. This is not an exhaustive list and your management team may well cover other areas that are outside the scope of ISO 9001:2008.			
5.6.3	Review outputs	Having considered and reviewed the information and results presented to the review, ISO 9001:2008 lists the outputs. These are essentially the decisions on resources that need to be made, i.e. restructure/reassignment, and what improvements are required to either the processes or the product or service to meet the requirements of the customer established through Subclause 5.2.			

Clause 6 – Resource management

Having set the organization's objectives the main purpose this clause is to ensure that the right resources (people, physical assets such as buildings, equipment, IT, etc.) are procured/obtained and managed whilst they are in use. Because the aim of this clause is to make sure that the resources are capable of meeting customer requirements, any processes in this area are also likely to include how assets, people, equipment, etc., are adjusted as the organization learns and adapts and its customers and its business environment change.

Clause No	What it says	What it means	Currently do this and in the system	Currently do this but not in the system	New to the organization
6.1	The organization shall determine and provide resources needed:				
	a. to implement and maintain the system and continually improve its effectiveness	a. Senior management need to make sure that the necessary resources have been procured and allocated to allow the processes to operate effectively. It requires management to manage and use the resources available to them with the aim of optimizing the performance of the organization. Few organizations have perfect resources and the auditor cannot say you have the right or wrong resources, but you will need to demonstrate that you are optimizing their use.			
	b. to enhance customer satisfaction by meeting customer requirements in the best possible way	b. As well as optimizing resources to meet the needs of the system and the organization's objectives, senior management also need to ensure that they are used with the aim of meeting/improving customer satisfaction.			

Human resources

Clause No	What it says	What it means	Currently do this and in the system	Currently do this but not in the system	New to the organization
6.2.1	Personnel performing work … shall be competent on the basis of appropriate education, training, skills and experience	People who carry out work that affects the quality or performance of the products and services you supply need to be competent to carry out their jobs. This doesn't just mean the people who actually make and deliver the product or service but other support areas, as they have a fundamental part to play in the overall performance of the organization. How people develop the necessary competence is down to them and your organization. People learn in different ways and ISO 9001:2008 does not prescribe any one method. The question is how effective is your organization in developing the skills and knowledge of its people?			
6.2.2	The organization shall: a. determine the necessary competence for personnel …	a. There are many different ways to determine the competence required to carry out a particular job. ISO 9001:2008 is looking for evidence that this has been completed. Competences can be captured in any form: inclusion in job descriptions, personnel specifications, database IT solutions, simple charts, tailored documents, etc. The auditor will assess the effectiveness of your method to support the organization and its objectives, not the method you choose.			

Clause No	What it says	What it means	Currently do this and in the system	Currently do this but not in the system	New to the organization
	b. provide training and other actions to satisfy these needs	b. Having defined the competences required the organization needs to provide training and other learning experiences that ensure that its people are indeed competent. Inevitably this will involve some form of competence review at some stage to identify the training and development gap that needs to be filled. This all needs to be an appropriate process.			
	c. evaluate the effectiveness of the actions taken	c. Having provided training and development interventions, the next stage is to evaluate how effective these were in addressing the competence gap identified. The evaluation needs a demonstration of some form of the new skills or knowledge (i.e. competence) in a working or simulated environment, not just a 'chat'.			
	d. ensure that its personnel are aware of the importance of their activities and how they contribute to the achievement of the objectives	d. How the organization goes about achieving these objectives depends on its own methods. Again the auditor will assess how effective the method is. Some examples may include team meetings, one-to-one meetings, intranet information, performance or appraisal reviews, etc. You have to ensure that people understand what the impact of their activity is on the performance of the organization. People cannot			

Clause No	What it says	What it means	Currently do this and in the system	Currently do this but not in the system	New to the organization
		work effectively in a vacuum without knowing how they fit into the bigger picture of the whole organization. This clause addresses this point. In many instances individual personnel will have their own objectives to achieve; these need to be aligned with the overall organizational objectives.			
	e. maintain records of education, training, skills and experience	e. You need to keep records of the training that people have received. This is for all sorts of legal and regulatory reasons as well as business reasons. Just ask yourself when these records might be needed! These records need to be kept in accordance with Subclause 4.2.4.			

Infrastructure

Clause No	What it says	What it means	Currently do this and in the system	Currently do this but not in the system	New to the organization
6.3	The organization shall determine, provide and maintain the infrastructure needed to achieve conformity to product requirements	Your organization needs to identify what buildings, plant, equipment, hardware, software and other assets it needs to manage its business effectively and deliver the organization's objectives.			

Clause No	What it says	What it means	Currently do this and in the system	Currently do this but not in the system	New to the organization
		Having defined what it needs to manage, your organization then needs to procure these assets and commission them into the business, making sure any regulatory or legal requirements are complied with. Having commissioned the assets these then need to be maintained so that they are capable of continually delivering the set objectives. Once they have 'outlived' their usefulness, the assets need to be disposed of or replaced to ensure continuity of effective delivery. All these are areas that need to be in the appropriate processes.			
	Infrastructure includes as applicable:	What the processes need to cover depends on your organization and whether or not it uses these resources to deliver its product and services. For example, if your scope takes into account the whole business then it is more than likely that these areas will affect you and will therefore have to be included in the system. Alternatively you may be part of a larger organization where some of these activities are outside your direct control. In this case they would not be included in your system.			

Clause No	What it says	What it means	Currently do this and in the system	Currently do this but not in the system	New to the organization
	a. buildings, workspace and associated utilities	a. This covers buildings and facilities management as well as the provision and management of utilities such as electricity, gas, energy, water, etc. as appropriate to your organization's objectives and the products and services you supply.			
	b. process equipment (both hardware and software)	b. This covers any equipment your organization needs to deliver its objectives.			
	c. supporting services (such as transport or communication)	c. Any other infrastructure resources you use such as vehicles, telephone systems, etc.			

Work environment

Clause No	What it says	What it means	Currently do this and in the system	Currently do this but not in the system	New to the organization
6.4	The organization shall determine and manage the work environment needed to achieve conformity of product requirements	In order to deliver your products and services effectively the environment in which they are made and delivered needs to be considered. The aim here is to manage the working environment in such a way that it enables the product or service to be delivered.			

Clause No	What it says	What it means	Currently do this and in the system	Currently do this but not in the system	New to the organization
		This will be different for every organization but could include manufacturing areas, offices, shops, specialist research and development areas and controlled environments. This may address such issues as light, heat, airflow and facilitating social interaction such as in a shop, etc.			

Clause 7 – Product realization

Having procured the necessary resources needed to deliver your products and services and put in place processes to maintain these assets, the next step is to actually deliver the products and services themselves. ISO 9001:2008 covers all eventualities here, so there may be parts that do not apply to your organization. Provided they do not affect the quality of the products or services they can be excluded. The elements required for the effective delivery of the product realization clause of ISO 9001:2008 come from many parts of the organization and diverse business activities, so it is highly unlikely that this can be effectively covered within a single business process, any management system that suggests this is missing the whole point of the standard.

Planning of product realization

Clause No	What it says	What it means	Currently do this and in the system	Currently do this but not in the system	New to the organization
7.1	The organization shall plan and develop the processes needed for product realization. Planning of product realization shall be consistent with the requirements of the other	As part of your management system you need to identify processes that describe how your organization:			

Clause No	What it says	What it means	Currently do this and in the system	Currently do this but not in the system	New to the organization
	processes of the quality management system (see 4.1)	• interacts and communicates with customers, identifying what their needs are and whether or not you are capable of meeting them; • designs any products or services to meet your objectives, the market and customer needs; • makes and provides the product or service to the customer; • purchases the consumables and materials it needs; • keeps track of the products and services it provides;			
	In planning product realization, the organization shall determine the following, as appropriate:	in other words how you 'do' what your organization has set out to achieve. You need to show how you deliver your products and services. The necessary activities will depend on the nature of your organization.			
	a. quality objectives and requirements for the product	a. What are the product or service objectives that need to be met/achieved and what are the customer and market requirements for the product?			
	b. the need to establish processes, documents, and provide resources specific to the product	b. What processes and documents do you need that will enable the product or service to be delivered consistently, meeting the customer requirements?			
	c. required verification, validation, monitoring and test activities specific to the product and the criteria for product acceptance	c. What tests and monitoring activity needs to be carried out as the product or service is created or delivered? Who does this, when and against what criteria, so that only acceptable products and services are delivered to the customer?			

Clause No	What it says	What it means	Currently do this and in the system	Currently do this but not in the system	New to the organization
	d. records needed to provide evidence that the realization processes and resulting product meet requirements (see 4.2.4)	d. What records do you keep that demonstrate that the processes you are using are, in fact, being run and that the product or service you deliver meets requirements?			

Customer-related processes

Determination of requirements related to the product

Clause No	What it says	What it means	Currently do this and in the system	Currently do this but not in the system	New to the organization
7.2.1	The organization shall determine: a. requirements specified by the customer, including the requirements for delivery and post-delivery activities	a. As part of your system and therefore your processes you need to show how your organization identifies and understands the stated customer requirements, i.e. what the customer expects/requires from your organization in terms of product or service delivery. This could be verbal as well as documented, based upon how your organization operates and the products and services it delivers.			

Clause No	What it says	What it means	Currently do this and in the system	Currently do this but not in the system	New to the organization
	b. requirements not stated by the customer but necessary for specified or intended use, where known	b. Often there will be unstated customer requirements that need to be considered and understood. For example, if I were buying a car I may request (state) that it drives fast, I wouldn't necessarily state that it needs to stop and specify the braking system required. I would expect the car company to build this 'unstated' need into the product and fit a braking system based on the type of car.			
	c. statutory and regulatory requirements related to the product	c. In determining the requirements of the product or service you also need to consider any related regulatory issues, i.e. you wouldn't want to deliver a product or service that broke the law or failed to meet regulatory requirements. This could include export issues, health and safety legislation, etc. Obviously these requirements are based on what products and services your organization provides, but the onus is on you to find out.			
	d. any additional requirements determined by the organization	d. Anything else that your organization feels it needs to find out about before progressing an order.			

Review of requirements related to the product

Clause No	What it says	What it means	Currently do this and in the system	Currently do this but not in the system	New to the organization
7.2.2	The organization shall review the requirements related to the product	Having determined what the customer requires based on their stated and unstated needs, as well as taking into account any legal or regulatory issues, the next stage is to review these to confirm that your organization is capable of delivering what is required.			
	This review shall be carried out prior to the organization's commitment to supply a product to the customer (e.g. submission of tenders, acceptance of contracts or orders …) and ensure that:	This review of capability needs to take place before your organization commits to delivery. You need to ensure that:			
	a. product requirements are defined	a. the product or service being requested is defined;			
	b. contract or order requirements differing from those previously expressed are resolved	b. any differences between what has previously been requested and this request are clarified or resolved;			
	c. the organization has the ability to meet the defined requirements	c. you have the capability of delivering what is required.			
	Records …	Records need to be kept. Organizations vary in size, scope and the market sectors they serve as well as the type of products and services they deliver. How you demonstrate this review is based on these factors.			

Clause No	What it says	What it means	Currently do this and in the system	Currently do this but not in the system	New to the organization
	Where the customer provides no documented statement of requirement, the customer requirements shall be confirmed by the organization before acceptance	In some organizations the customer does not provide or need to provide a documented statement of requirements. This could apply where verbal requests are made for products or services. Even though a documented statement is not made, you must still confirm the requirements before committing to supply or deliver the product or service.			
	Where product requirements are changed, the organization shall ensure that relevant documents are amended and that relevant personnel are made aware of the changed requirements	If the customer changes the requirements then you must ensure that any relevant documents are changed and that people affected are informed of these changes.			

Customer communication

Clause No	What it says	What it means	Currently do this and in the system	Currently do this but not in the system	New to the organization
7.2.3	The organization shall determine and implement effective arrangements for communicating with customers in relation to:	As part of your system and its processes you will, if it effects your organization, need to include areas that cover how you communicate with your customers. For many organizations this may fall under the 'marketing' banner but even those organizations that do not have a marketing function will often:			

Clause No	What it says	What it means	Currently do this and in the system	Currently do this but not in the system	New to the organization
	a. product information	a. communicate product-related information to their customers including any instructions on how to use the product or service such as operating details;			
	b. enquiries, contracts or order handling, including amendments	b. explain to customers how the organization can be contacted should they have an enquiry or questions over how their order or request is being progressed;			
	c. customer feedback, including customer complaints	c. communicate to customers how they can complain and provide feedback on performance or the standard of service, etc. Of course, the methods you use are based on your needs and those of your customers but approaches could include the use of websites and/or intranets.			

Design and development

From time to time your organization may identify products and services that either the general market or individual customers require. Where this is the case your organization needs to have defined processes that describe how these new or enhanced products and services are designed and/or developed.

Design and development planning

Clause No	What it says	What it means	Currently do this and in the system	Currently do this but not in the system	New to the organization
7.3.1	The organization shall plan and control the design and development of product	The first stage in designing and developing a new or enhanced product or service is to plan how this will be achieved and the steps involved. How this is demonstrated and what methods you use are up to you and your organization. Typically these processes tend to be project-based and consequently project management or new product development methodologies are often used.			
	During the design and development planning, the organization shall determine:	Any plan (or project plan) needs to contain information that shows:			
	a. the design and development stages	a. each stage or phase of the project, design or development;			
	b. the review, verification and validation that are appropriate to each design and development stage	b. when pilots, prototypes, mock-ups or service examples will be tested and the results reviewed to ensure that the product or service meets any technical specification and the needs specified by an individual customer or the market generally. These are, in effect, design 'milestones' that need to be met before work can continue;			

Clause No	What it says	What it means	Currently do this and in the system	Currently do this but not in the system	New to the organization
	c. the responsibilities and authorities for design and development	c. who is responsible for doing what in the plan. This includes responsibilities for managing the design and development and management approvals needed to progress the design or development activity.			
	The organization shall manage the interfaces between different groups involved in design and development to ensure effective communication and clear assignment of responsibility	Rarely is a new or enhanced product or service planned and created by one department or one particular group of people without affecting other parts of the organization. This part of the subclause requires you to manage the interfaces with other parts of the organization as the new product or service is being developed. Therefore in many organizations design and development are undertaken by a cross-disciplinary group drawn from across the organization so that those who need to be involved are involved at this stage. Often those who actually deliver the product or service (see Subclause 7.5) are not involved in its design or development, with the inevitable results.			
	Planning output shall be updated, as appropriate, as the design and development progresses	Plans are just that, plans – forecasts of what we want to do. Often in the light of experience the plan needs to change, as individual tasks are performed and progress is made. The impact of completing one task will typically have a positive or negative impact on the			

Clause No	What it says	What it means	Currently do this and in the system	Currently do this but not in the system	New to the organization
		next. If the design or development is 'on plan' then the plan stands as it is correct. 'Positive' or 'negative' impacts will mean that the plan will need to be adjusted and therefore updated to show what will happen, resulting in a new estimate or forecast. Plans must be managed. When and how this is done will form part of the overall design process or project methodology.			

Design and development inputs

Clause No	What it says	What it means	Currently do this and in the system	Currently do this but not in the system	New to the organization
7.3.2	Inputs relating to product requirements shall be determined and records maintained (4.2.4). These inputs shall include:	When creating a document that describes what the technical specification is for the new or enhanced product or service, a number of areas need to be considered. If this is not done at the start then there is a danger that the delivered product or service will not meet the customer requirements. Therefore when designing or developing a product or service you need to understand and use information related to the following:			

Clause No	What it says	What it means	Currently do this and in the system	Currently do this but not in the system	New to the organization
	a. functional and performance requirements	a. What the product or service is actually to achieve. What level of performance it is meant to have, what sort of features and characteristics make up the product or service, what sort of functionality it possesses. How have the customer's needs and requirements been understood and interpreted into your 'technical speak'? This subclause is concerned with collecting relevant information that allows you to make an informed decision about what your product or service should look like. Assessing risks of product failure/service breakdown would be a key part of this activity.			
	b. applicable statutory and regulatory requirements	b. This includes making sure that you have identified any legal or regulatory requirements in designing and developing the product or service. Failure do this may lead you to delivering products and services to your customer that contain aspects that could lead to a regulation or law being broken.			
	c. where applicable, information derived from previous similar designs	c. Use information from past activity when other products and services were designed, if you feel it is appropriate.			

Clause No	What it says	What it means	Currently do this and in the system	Currently do this but not in the system	New to the organization
	d. other requirements essential for design and development These inputs shall be reviewed for adequacy. Requirements shall be complete, unambiguous and not in conflict with each other	d. Anything else that is important such as ethical or environment issues that do not come under statutory regulation. The information that you gather to help you design and develop your product or service needs to be reviewed for adequacy, i.e. are the individual items of information correct, are they complete or are there 'holes': has anything been missed? Typically you would expect the customer to be involved in the latter stages of defining the inputs. This can form the basis/criteria to demonstrate that the design output meets the design inputs, see Subclause 7.3.3 below. Who does this and how they do it would be part of the process of your design. In addition, as part of this review the information must not contradict itself; for example, a performance requirement that breaks the law or uses a similar past design that has different functions.			

Design and development outputs

Clause No	What it says	What it means	Currently do this and in the system	Currently do this but not in the system	New to the organization
7.3.3	The outputs of design and development shall be provided in a form that enables verification against the design and development input and shall be approved prior to release	Having considered/analysed the inputs to the design or development, the next stage is to produce a document or some other output that describes what is to be created. This output can be in any form based on your needs and requirements but must be in such a form that it can be used at a later date to test (verify) that the designed product or service actually meets the need.			
	Design and development outputs shall:	When producing the output documents they must:			
	a. meet the input requirements for design and development	a. show how the design inputs from Subclause 7.3.2 have been met or covered;			
	b. provide appropriate information for purchasing, production and for service provision	b. provide sufficient information and detail to business areas such as purchasing and operational areas that allow them to carry out their tasks effectively;			
	c. contain or reference product acceptance criteria	c. these outputs should also describe what criteria need to be applied that demonstrate an acceptable product or service;			
	d. specify the characteristics of the product that are essential for its safe and proper use	d. show what features or characteristics of the product or service are critical if it is to be used safely and properly.			

Design and development review

Clause No	What it says	What it means	Currently do this and in the system	Currently do this but not in the system	New to the organization
7.3.4	At suitable stages, systematic reviews of design and development shall be performed in accordance with planned arrangements (see 7.3.1):	As part of the planning phase you will have identified particular times and events at which progress and results will be reviewed and decisions taken on further activity.			
	a. to evaluate the ability of the results of design and development to meet requirements	a. These planned reviews need to cover the ability of the product or service to meet the design and development requirements mentioned in Subclause 7.3.3, i.e. whether the new or enhanced product or service will deliver what is required.			
	b. to identify any problems and propose necessary actions	b. If not then appropriate action needs to be taken.			
	Participants in such reviews shall include representatives of functions concerned with the design and development stage(s) being reviewed. Records of the results of the reviews and any necessary actions shall be maintained (see 4.2.4)	The people who carry out the reviews need to include those, or their representatives, who were involved in the design and development stages so that they are able to communicate results and findings and be party to any decision. Records of these reviews need to be kept along with details of any resulting action.			

Design and development verification

Clause No	What it says	What it means	Currently do this and in the system	Currently do this but not in the system	New to the organization
7.3.5	Verification shall be performed in accordance with planned arrangements (see 7.3.1) to ensure that the design and development outputs have met design and development input requirements	There is often some confusion regarding verification and validation. Verification is concerned with testing/checking the new or enhanced product or service against the output documents (or other outputs) that will have been produced as part of Subclause 7.3.3. In other words, have we created what we said we would produce? These tests or checks will typically have been included as tasks or events when you planned the design and development activities in Subclause 7.3.1. The results of these tests need to be kept as records and fed into design review activities.			

Design and development validation

Clause No	What it says	What it means	Currently do this and in the system	Currently do this but not in the system	New to the organization
7.3.6	Design and development validation shall be performed in accordance with planned arrangements (see 7.3.1) to ensure that the resulting product is capable of meeting the requirements for the specified application or intended use, where known	While verification is concerned with checking/confirming that the product or service meets your internally produced design and development requirements, validation is concerned with making sure that the new or enhanced product or service is capable of meeting what the customer or your market requires in the 'real world'. Will the product or service actually deliver what is required for its intended use? There is no point in delivering a product or service that doesn't meet market or customer requirements. This step puts in place a check, at the design and development stage, that is intended to manage this risk. So verification is concerned with internal issues and is therefore internally focused, while validation is concerned with external issues and is therefore externally focused.			
	Wherever practicable, validation shall be completed prior to the delivery or implementation of the product	You need to carry out validation activities prior to the new or enhanced product or service going into the delivery stage, wherever possible.			
	Records of results … shall be maintained	As before, results of these tests or checks need to be maintained as records and fed into planned review activities for consideration.			

Control of design and development changes

Clause No	What it says	What it means	Currently do this and in the system	Currently do this but not in the system	New to the organization
7.3.7	Design and development changes shall be identified and records maintained	As a result of verification, validation and review, changes may be needed. Where this is the case any output documents (or other methods) need to be updated with the change and controlled. This is to ensure that everyone knows the current specification and that everyone is working with the same information.			
	The changes shall be reviewed, verified and validated, as appropriate, and approved before implementation	This step is in place to ensure that any changes are themselves verified, validated, reviewed and approved before the new or enhanced product or service is implemented.			
	The review of design and development changes shall include evaluation of the effect of the changes in constituent parts and product already delivered	Sometimes you may make a change that could have an effect on something that has already been created. This clause requires that if you carry out a change you need to go back to what has already been developed and check that the change has not adversely affected past work.			
	Records …	Records of the review of changes need to be kept. Typically, in many organizations, the review of changes is included as part of the general review.			

Purchasing

Purchasing process

Clause No	What it says	What it means	Currently do this and in the system	Currently do this but not in the system	New to the organization
7.4.1	The organization shall ensure that purchased product conforms to specified purchase requirements	Although the title of this subclause is 'purchasing process', that does not mean that the activities of the purchasing function cannot be included in one or more business processes. To meet the requirements of this subclause you need to demonstrate that what you actually get or purchase from suppliers is what you want and that it meets your requirements and, if it isn't, what you do about it. The important point here is that we are talking about consumables, things you use when producing your product or service – not assets, which are covered under Clause 6.			
	The type and extent of control applied to the supplier and the purchased product shall be dependent upon the effect of the purchased product on subsequent product realization or the final product	The methods and approaches you use to control your suppliers are based upon the importance of the purchased materials they supply to your final product or service. Low impact may mean less control; high impact will probably require a more robust system to be in place.			
	The organization shall evaluate suppliers based on their ability to supply the product …	Before you purchase a product or service from a supplier you need to be satisfied that they are capable of delivering what is required. Therefore you will need			

Clause No	What it says	What it means	Currently do this and in the system	Currently do this but not in the system	New to the organization
		to show how this evaluation and selection take place. Just because a supplier meets the criteria your organization establishes the first time, does not mean it will continue to do so. Therefore you need to re-evaluate the supplier's ability from time to time to satisfy yourself that they will continue to meet your requirements. The frequency and depth of the re-evaluation is dependent upon the importance and impact of the product or service they supply to your final product or service. Throughout, records need to be maintained.			

Purchasing information

Clause No	What it says	What it means	Currently do this and in the system	Currently do this but not in the system	New to the organization
7.4.2	Purchasing information shall describe the product to be purchased, including where appropriate …	Of course, different organizations have different requirements when they are placing orders with their suppliers. As before, the level of detail included on the order document depends on the importance and impact of the product or service being supplied on your final product or service.			

Clause No	What it says	What it means	Currently do this and in the system	Currently do this but not in the system	New to the organization
		The Standard gives some areas to consider, which are applied where appropriate: a. any approvals required for the product or service itself, any particular processes that need to be applied and procedures that need to be followed as well as any equipment that needs to be used; b. any qualifications or training the suppliers producing the product or service need to have; c. any quality management system requirements the supplier needs to be operating to.			
	The organization shall ensure the adequacy of specified purchase requirements prior to their communication to the supplier	The orders and the information they contain need to be adequate before they are sent to the supplier, so that the supplier is clear on what is expected or required.			

Verification of purchased product

Clause No	What it says	What it means	Currently do this and in the system	Currently do this but not in the system	New to the organization
7.4.3	The organization shall establish and implement the inspection or other activities necessary for ensuring that purchased product meets specified purchase requirements	Before implementation your organization must have a method in place to check that the products or services you have purchased are correct and fit for use prior to them actually being used. This will very much depend upon the impact of the product or service but could take the form of a formal test in a laboratory, a quick visual check or no check at all as this is managed by the supplier guaranteeing the quality and the fact that it meets the specification, through the use of batch certificates. Sometimes you or indeed your customer may need to test the product or service on your suppliers' premises before it is dispatched to you. Where this is the case you need to specify what the arrangements are and the method used to approve the release on the order or purchasing information.			

Production and service provision

Control of production and service provision

Clause No	What it says	What it means	Currently do this and in the system	Currently do this but not in the system	New to the organization
7.5.1	The organization shall plan and carry out production and service provision under controlled conditions. Controlled conditions shall include:	When you are producing or delivering your product or service you need to monitor the conditions under which this is carried out. Don't forget this will be in your process(es). The intention is that anyone can deliver a product or service but to deliver it to the customer to a consistent level of performance, time and time again, requires the conditions in which it is delivered to be controlled.			
	a. the availability of information that describes the characteristics of the product	a. People providing the product or service need to have the correct information about the product or service they are delivering.			
	b. the availability of work instructions, as necessary	b. Sometimes, to achieve a consistent delivery of a product or service, people need instructions on how to do it. This may be the case where consistency is important or where something is done rarely and people cannot remember what to do. Some organizations call these instructions 'procedures' on the basis that they describe 'how' a task is completed.			

Clause No	What it says	What it means	Currently do this and in the system	Currently do this but not in the system	New to the organization
	c. the use of suitable equipment	c. People carrying out the tasks of creating and delivering the product or service need to have the equipment necessary to complete the task effectively. There is clear a connection here with the resource management clause.			
	d. the availability and use of monitoring and measuring devices	d. People who are involved in producing or delivering the product or service need to have the use of equipment that enables them to test the product as it is produced. Sometimes, in a manufacturing environment, the testing would be carried out by a laboratory but is nonetheless an activity that is part of this delivery/ production process.			
	e. the implementation of monitoring and measurement	e. Carry out the monitoring and measurement of the product or service as it is created/delivered as planned, using the equipment provided.			
	f. the implementation of release, delivery and post-delivery activities	f. In your processes you need to show how products or services are released to the customer, how these are delivered and by whom, and details of post-delivery activities such as after-sales services, enquiry lines, etc.			

Validation of processes for production and service provision

Clause No	What it says	What it means	Currently do this and in the system	Currently do this but not in the system	New to the organization
7.5.2	The organization shall validate any processes for production and service provision where the resulting output cannot be verified by subsequent monitoring or measurement. This includes any processes where deficiencies become apparent only after the product is in use or the service has been delivered	Not everything you do can be tested to see if it meets your and the customer's requirements prior to its release and subsequent use. This is typically something where only by using the product or service will you and your customer see if it actually works. In these cases you need to show that the processes have been tested or validated to prove or demonstrate that they have the ability to deliver what is required. These processes may be performed by a subcontractor or on another site, and delivered direct to the customer.			
	The organization shall establish arrangements for these processes including, as applicable:	Because the product or service cannot be proven to work until it is in use, there are a number of areas you need to consider, based on the product or service you are actually delivering:			
	a. defined criteria for review and approval of the processes	a. What criteria you use to review the validity of these processes, the results of which are used to approve them.			
	b. approval of equipment and qualification of personnel	b. Who approves the use of which equipment to be used and how qualified the people carrying out the tasks have to be and how you know who they are.			

Clause No	What it says	What it means	Currently do this and in the system	Currently do this but not in the system	New to the organization
	c. use of specific methods and procedures	c. These types of processes may require methods and/or procedures to produce and deliver the product or service that differ from those normally used. If this is the case then these need to be identified and used.			
	d. requirements for records	d. You may need to keep records that demonstrate that the processes have been run as planned. If this is the case these need to be retained securely, following Subclause 4.2.4.			
	e. revalidation	e. Just because the process has been validated once and then used does not mean that it will work a second time. Therefore there may be a case for retesting the process at some later date to validate that it is still operating correctly. The need for revalidation is based on your business needs and those of the product or service being produced or delivered.			

Identification and traceability

Clause No	What it says	What it means	Currently do this and in the system	Currently do this but not in the system	New to the organization
7.5.3	Where appropriate, the organization shall identify the product by suitable means throughout product realization	You need to show how the individual batches, projects, orders or accounts are uniquely identified throughout your business, to ensure that they are traceable from inception to delivery and use by the customer. Where traceability is required by either your organization and/or your customer, records are required that show this unique identification. You should be able to trace a product or service throughout the system and its processes including inputs from suppliers, although continuous production could preclude this to some extent.			
	The organization shall identify the product status with respect to monitoring and measurement requirements	As the individual product or service is produced it may well go through various stages of creation before it is delivered to the customer. Where this is the case you need to show the 'status' (this could be in many forms such as pass/fail, approvals, results of tests, configuration management or control points, etc.) as it progresses through the production steps. This ensures that only products and services that have successfully passed the previous steps are worked on, i.e. quality assurance.			

Customer property

Clause No	What it says	What it means	Currently do this and in the system	Currently do this but not in the system	New to the organization
7.5.4	The organization shall exercise care with customer property while it is under the organization's control or being used by the organization. The organization shall identify, verify, protect and safeguard customer property …	There may be occasions when you take or use property that is owned by the customer and use or include it in the products or services you are producing. This could apply to physical items such as components or non-physical items such as ideas, the content of documents and intellectual property. If any of this material is lost, damaged or is found to be unsuitable for use, then records of this need to be kept and the customer informed.			

Preservation of product

Clause No	What it says	What it means	Currently do this and in the system	Currently do this but not in the system	New to the organization
7.5.5	The organization shall preserve the conformity of product during internal processing and delivery to the intended destination. This preservation shall include identification, handling, packaging, storage and protection	When you are producing a product or service you need to include in your processes how your organization protects and stores it to ensure it reaches the customer still intact and fit for use. This clause also covers the actual delivery of the product or service.			

Control of monitoring and measuring devices

Clause No	What it says	What it means	Currently do this and in the system	Currently do this but not in the system	New to the organization
7.6	The organization shall determine the monitoring and measurement to be undertaken and the monitoring and measuring devices needed to provide evidence of conformity of product to determined requirements (see 7.2.1)	This requires you to state and include in your processes where you measure the performance of the product or service (as it is produced) and the methods you use. Records of this measurement need to be kept but what you measure, when and how is up to you, as long as the decision you make is based on what you are trying to produce or deliver.			
	Where necessary to ensure valid results, measuring equipment shall be:	When you use any equipment to carry out the measurement, you need to ensure that this equipment is:			
	a. calibrated	a. calibrated, to ensure that the readings the equipment is showing are correct;			
	b. adjusted or re-adjusted as necessary	b. adjusted, if the equipment is out of calibration, so that readings will once again be accurate;			
	c. identified to enable the calibration status to be determined	c. identified so that everyone knows it is 'calibrated equipment'. This could be simply using a unique number traceable to a calibration record. In addition, its status needs to be shown, i.e. whether it is calibrated, or out of calibration and also, typically, the last time it was tested and when testing is due next;			

Clause No	What it says	What it means	Currently do this and in the system	Currently do this but not in the system	New to the organization
	d. safeguarded from adjustments that would invalidate the measurement result	d. protected whilst in use and treated accordingly to ensure that it is not damaged so that subsequent results are not invalidated;			
	e. protected from damage during handling, maintenance and storage	e. protected so that it cannot be damaged whilst it is handled, maintained or stored when it is not in use.			
	The organization shall take action on the equipment and any product affected	You need to include in your processes what you do with equipment that is out of calibration. You also need to show what you do with any product that has been tested with the 'out of calibration' equipment, to ensure that it meets customer requirements and product or service specifications. This may even include product recall and retest activities.			
	Records of the results of calibration and verification shall be maintained	Records of calibration need to be kept.			
	When used in the monitoring and measurement of specified requirements, the ability of computer software to satisfy the intended application shall be confirmed. This shall be undertaken prior to initial use and reconfirmed	Many pieces of equipment in use are self-calibrating and have software programs built in for this purpose. Where this is the case, or where any additional software is used, you need to satisfy yourself that the program itself has the ability to carry out the calibration tests prior to using the equipment and then periodically check to make sure it continues to do so.			

Clause 8 – Measurement, analysis and improvement

With the products and services delivered, the last stage is to measure your organization's performance against the planned objectives and carry out improvements to your organization that will:

- allow the planned objectives to be achieved in the future;
- enable enhanced objectives to be achieved in the future; or
- a combination of both.

This clause is all about learning from your activities through analysing results and then putting in place short-term corrective actions to stop any problems or issues from getting any worse, and then carrying out longer-term preventive action to improve the organization. Of course, improvements do not have to be carried out just as a result of problems but could be initiated simply to improve business performance. The important point as far as ISO 9001:2008 is concerned is that you demonstrate you are measuring results and acting on the information to complete the improvement loop, and therefore achieving continuous improvement. Such improvement needs to be applied to the overall management system itself, as well as the individual processes it contains, so there will be a need to demonstrate how competing improvement opportunities and requirements are prioritized.

Clause No	What it says	What it means	Currently do this and in the system	Currently do this but not in the system	New to the organization
8.1	The organization shall plan and implement the monitoring, measurement, analysis and improvement processes needed:	All the activities covered in this clause need to be in one or more defined processes; see Subclause 4.1. Traditionally in many organizations these processes have not been structured or transparent and from experience this area requires the greatest attention.			
	a. to demonstrate conformity of product	a. Are we delivering what we said we would deliver?			
	b. to ensure conformity of the quality management system	b. Are the processes and working practices we have in place being applied?			
	c. to continually improve the effectiveness of the quality management system	c. Are the processes and working practices we have in place effective in delivering what is required and are the results used to improve performance?			

Customer satisfaction

Clause No	What it says	What it means	Currently do this and in the system	Currently do this but not in the system	New to the organization
8.2.1	As one of the measures of the performance of the quality management system, the organization shall monitor information relating to customer perception as to whether the organization has met customer requirements	Your organization needs to collect and collate information that relates to how customers perceive whether or not you have met their requirements. The key word here is 'perception'. These are not 'hard indicators'. For example, your organization may well be achieving high repeat sales, low complaints and low product or service failures but that does not mean that the customer is happy with what you are doing. It is a measure of perception – what they think or feel. Measuring customer perception provides information on *future customer intentions*. All the hard data above is a *reflection of the past*. One has already happened, the other is yet to come.			
	The methods for obtaining and using this information shall be determined	The methods you use to collect this information are up to you but they need to be defined. Of course, there may be a number of methods depending on your organization and the business it is in. The information you are seeking is often subjective and the methods you use will need careful consideration. Often the most useful information can be gained from the people who actually deal with customers and this can supplement any more formal methods for information capture.			

Internal audit

Clause No	What it says	What it means	Currently do this and in the system	Currently do this but not in the system	New to the organization
8.2.2	The organization shall conduct internal audits at planned intervals to determine whether or not the quality management system: a. conforms to planned arrangements … b. is effectively implemented and maintained An audit programme shall be planned taking into consideration the status and importance of the processes and areas to be audited …	Each process or sub-process needs to be audited at planned intervals. Therefore you need a schedule that shows this. What method you use is up to you: your auditor will assess how effective your chosen methods are. a. Are we doing what we said we would do? b. Are the processes effective? There are two aspects to audits. It is not good enough just to check that we are doing what we say we are doing. We need to audit/assess how effective the system and its processes are, and where it can be improved. In the past there has been too much 'reliance on compliance' auditing. The audit schedule/programme needs to be based on the level of importance your organization places on the individual processes and areas being audited. In deciding how often an audit is required, past audit results need to be considered. Therefore it is very unlikely that every process or area will be audited to the same frequency.			

Clause No	What it says	What it means	Currently do this and in the system	Currently do this but not in the system	New to the organization
	The audit criteria, scope, frequency and methods shall be defined	Although the scope and frequency of the audits can be described on the programme or schedule, it is very difficult to describe the methods at this stage because there are many different methods in use. The methods used will depend on what is being audited, so this is more likely to be defined when you carry out the individual audit as part of the internal auditor's planning and preparation. Methods include one-to-one interviews, email, videoconference, group interviewing, self-assessment, etc.			
	Selection of auditors and conduct of audits shall ensure objectivity and impartiality of the audit process	Auditors need to be allocated based on their impartiality in relation to the process or area being audited, and their independence of the work involved.			
	... shall be defined in a procedure … and maintain records	How you carry out audits needs to be defined in a procedure and you need to keep records to demonstrate that audits have been carried out.			
	The management responsible for the area being audited shall ensure that actions are taken without undue delay	The manager responsible for the area or process being audited needs to take action on any findings in a timely fashion based upon the risk to the organization of the issue raised.			

Clause No	What it says	What it means	Currently do this and in the system	Currently do this but not in the system	New to the organization
	Follow-up activities shall include verification of the actions taken …	Review or follow-up audits need to be carried out to confirm that the action taken as a result of an initial finding has, indeed, been carried out and has been effective.			

Monitoring and measurement of processes

Clause No	What it says	What it means	Currently do this and in the system	Currently do this but not in the system	New to the organization
8.2.3	The organization shall apply suitable methods for monitoring and, where applicable, measurement of the quality management system processes These methods shall demonstrate the ability of the processes to achieve planned results	You need to identify what measures or key performance indicators you will use to measure the performance of individual processes, with the appropriate targets or objectives. Not all processes or sub-processes will have measures but where there are measures these should link to your organization's objectives and to the purpose of the process. There are no requirements as to how many you need, so stay focused on the purpose of the process and the objectives of the organization. Other measures may exist that measure the performance of the system as a whole rather than an individual process. Unlike the process measures that tend to be more tactical in nature, these are more strategic and longer term.			

Clause No	What it says	What it means	Currently do this and in the system	Currently do this but not in the system	New to the organization
	When planned results are not achieved, correction and corrective action shall be taken, as appropriate to ensure conformity of the product	When these indicators or measures show that the process is not delivering what is required, action needs to be taken to correct the defective product or service involved, and corrective action taken to ensure that the situation does not occur again.			

Monitoring and measurement of product

Clause No	What it says	What it means	Currently do this and in the system	Currently do this but not in the system	New to the organization
8.2.4	The organization shall monitor and measure the characteristics of the product to verify that product requirements have been met	As the product or service is being manufactured/delivered through the product realization processes, the specification or characteristics that make up the product or service need to be measured and monitored to identify any problem areas. There is a requirement to maintain records of these monitoring activities, checks or tests that have been carried out, along with details as to who authorized the release of the product or service. Your organization may well already carry out such checks but not recognize them as such; for instance, reading and signing a letter to a customer.			

Clause No	What it says	What it means	Currently do this and in the system	Currently do this but not in the system	New to the organization
		The product or service cannot be released to the customer until everything that is supposed to have happened has happened, i.e. the manufacture or delivery of the service has been achieved following the processes, procedures and controls that have been put in place as part of the system. The only exception to this is when an authorized person or, where applicable, the customer approves delivery of the product or service.			

Control of nonconforming product

Clause No	What it says	What it means	Currently do this and in the system	Currently do this but not in the system	New to the organization
8.3	The organization shall ensure that product which does not conform to product requirements is identified and controlled to prevent its unintended use or delivery. The controls … shall be defined in a documented procedure	This requires you to have a documented procedure that shows how your organization manages and controls products and services that are not up to standard or that do not meet the required specification. This extends to how you prevent the defective product or service from reaching the customer or being used unintentionally. Records showing what action you take to deal with any of these products or services need to be kept along with details of any concessions from customers.			

Clause No	What it says	What it means	Currently do this and in the system	Currently do this but not in the system	New to the organization
		After a product or service has been reworked it needs to be tested to ensure it meets requirements before it is released to the customer.			
	When nonconforming product is detected after delivery or use has started, the organization shall take action appropriate to the effects or potential effects of the nonconformity	After the product or service has been delivered a defect may come to light. Where this is the case, processes need to be in place that describe how your organization handles this situation. Records of the action you take need to be kept with any action being based on the nature/effect of the nonconformity. The Standard therefore places a requirement to provide after-delivery services.			

Analysis of data

Clause No	What it says	What it means	Currently do this and in the system	Currently do this but not in the system	New to the organization
8.4	The organization shall determine, collect and analyse appropriate data to demonstrate the suitability and effectiveness of the quality management system and …	Your organization is required to collect data related to the process and product measures described earlier and analyse this data in some way that is appropriate to you. This could include control charts, Six Sigma analysis or a simple spreadsheet. In addition, as part of the analysis, information relating to customer satisfaction and supplier performance should be included. Collectively this could			

Clause No	What it says	What it means	Currently do this and in the system	Currently do this but not in the system	New to the organization
		be known as your management information system.			
	… to evaluate where continual improvement of the effectiveness of the quality management system can be made. This shall include data generated as a result of monitoring and measurement and from other relevant sources	Whichever methods you use, the analysis should enable you to identify trends and other improvement opportunities that, when implemented, will enhance the effectiveness of the organization.			

Continual improvement

Clause No	What it says	What it means	Currently do this and in the system	Currently do this but not in the system	New to the organization
8.5.1	The organization shall continually improve the effectiveness of the quality management system through the use of the quality policy, objectives, audit results, analysis of data, corrective and preventive actions and management review	In other words, use all the monitoring information discussed under this clause to improve the performance and effectiveness of your organization on a continual basis. This is a small clause in ISO 9001: 2008 and easily overlooked, but its impact (see Subclause 4.1) is that you must include this in your process-based management system. There is, therefore, likely to be a process in your system that describes how structured change or improvement is achieved following a review of performance at a management review.			

Corrective action

Clause No	What it says	What it means	Currently do this and in the system	Currently do this but not in the system	New to the organization
8.5.2	The organization shall take action to eliminate the cause of nonconformities in order to prevent recurrence A documented procedure shall be established to define requirements for …	As your organization undertakes its day-to-day business, on occasions things will go wrong or at least not quite right. When this happens corrective action must be taken to find out what went wrong and to prevent it happening again. This could happen in any one of your processes. Where this does happen you need a procedure that describes how you handle the situation. This needs to cover reviewing the issue, determining the cause, evaluating the need for action, implementing the action and reviewing its effectiveness. Records need to be kept.			

Preventive action

Clause No	What it says	What it means	Currently do this and in the system	Currently do this but not in the system	New to the organization
8.5.3	The organization shall determine action to eliminate the causes of potential nonconformities in order prevent their occurrence	If corrective actions are necessary as a result of an activity not going quite right, preventive action is called for to stop them happening in the first place. This shouldn't be confused with improvement activity mentioned in Subclause 8.5.1, which is carried			

Clause No	What it says	What it means	Currently do this and in the system	Currently do this but not in the system	New to the organization
		out as a result of measuring performance. These are 'mini improvements' that don't really need the full rigour of a formal improvement process and occur as part of day-to-day operations, perhaps as a part of risk assessment or FMEA activity that will identify potential problems and determine how to handle them. (Failure Mode Effect Analysis – FMEA – is a technique for analysing the significance of the failure of a given component or factor in a process.) Again you will need a procedure that describes this activity covering how potential problems are identified and their causes, evaluating the need for action, determining and implementing the action and evaluating the action taken to see if it has been effective. Throughout, records need to be kept. Many organizations combine corrective and preventive procedures, as the activity often happens at the same time.			

This concludes our detailed look at ISO 9001:2008. As you can tell sometimes there are small clauses with few words, which are almost hidden amongst bigger clauses that appear to have a more significant impact. A good example of this is the need for a continual improvement process, looked at in Clause 8. The clause doesn't actually say it requires a process until you go back to the requirements of Subclause 4.1, when it becomes obvious that one is actually required. To understand ISO 9001:2008 you need to continually make the links between the different parts; it is not just a case of reading it and applying each clause and subclause in isolation.

What follows is an overview of the differences between the 2000 and 2008 versions of ISO 9001. It is included for those people who already have their organization registered and need to ensure that any additional requirements are added into their system. As outlined in the foreword to this book, the changes are minor in nature, so those that are very minor have been omitted to ensure focus on what really matters.

Section	Ref	Change	What it means
0.1	Para 1	The design of the organization's quality management system is defined by the environment in which the organization sits including the risks it faces.	The management system is not designed in isolation from the outside world. As explained in this book the system and therefore the organization is driven by the business environment in which it finds itself. Care needs to be taken to interpret the word 'environment' as 'business environment' – i.e. everything outside of the business that will affect what it does and how it does it.
0.3	–	The description of the relationship between ISO 9001 and ISO 9004 has changed. They continue to complement each other.	ISO 9001 sets the baseline and ISO 9004 outlines guidance on improving the system to gain maximum business benefit from it.
0.4	Para 1	A comment has been added that the development of ISO 9001:2008 made due consideration to ISO 14001:2004.	ISO 9001 is the baseline for a business management system. As ISO 14001:2004 was written after the 2000 version of ISO 9001 a degree of catching-up was required to bring both Standards into line and ensure they are fully consistent.
1.1	Bullets a) & b)	Again, statutory requirements have been added (as in Section 0.1).	Clarification that the system must meet statutory requirements that effect the organization and that these should be built into the system.
	Notes	Note 1 clarifies that the Standard covers the products customers purchase and that have been produced from the realization processes. Note 2 has been added to explain that statutory and regulatory requirements may be expressed as legal requirements.	Make sure that all products that customers buy have been included, and all processes that define, create and deliver these products have been included in the system. If the system has been created following the guidance in this book then this wouldn't be a problem as you should have automatically applied all requirements, from whatever source.

Section	Ref	Change	What it means
4.1	Bullets	a) The word 'identify' has been replaced with 'determine'. e) Where 'applicable' has been added to 'measure'.	This means that the processes needed to be defined within the system rather just identified Not all processes should be measured although it may be good practice to do so. This change allows the organization to make this choice, but any measurement should be linked to provide better understanding of the effectiveness of delivery of customer/ stakeholder needs and the organization's business objectives.
	Para 4	The statement regarding outsourced processes emphasizes that those that have been outsourced must be controlled from within the system.	Organizations often manage costs and effectiveness by outsourcing specialist processes to other organizations. Where this takes place, the management system must show how this outsourced activity is managed and controlled. You simply cannot abdicate responsibility even though the activity is managed and delivered elsewhere. The level of management needed should reflect the level of risk to the effective delivery of what the organization does.
	Notes	Note 1 'analysis and improvement' added. Note 2 has been added giving a definition of an outsourced process. Note 3 expands on the type of control that may be applied to outsourced processes.	This clarifies that processes are needed to show how analysis and improvement take place within the system. See above comment. This is a useful list to ensure that outsourced processes are managed. See above comment.
4.2.1	Notes	Note 1 has been added to clarify that a single document may include the requirements for one or more procedures.	This is obvious really, just use your common sense. There are no prizes for the amount of documentation created, only for having an effective system.

Section	Ref	Change	What it means
5.5.2	Para 1	The requirement that the management representative needs to be a member of the organization's management	The management system is the organization, and the organization exists to deliver objectives so it makes sense for ownership to exist at the highest level. It does not say that it has to be, for example, ' … a fully employed member of staff or director of the business', but they do need to have demonstrable responsibility within and input at the senior management level. Providing this is the case, it could be, for example, a specialist consultant, especially where there is a small organization that needs this additional expertise.
6.2.1	a)	In the 2000 version people have to be competent where what they do affects 'product quality'. The 2008 version states that people need to be competent where they 'affect conformity to product requirements'.	They both really mean the same in the real world: be sure that people who can effect what is produced and delivered to customers are competent in their job.
6.2.2	b)	This states that 'where applicable' training needs to be provided 'to achieve the necessary competence'.	Therefore there needs to be a direct link in applying training where there is a need to develop competence.
6.3	c)	Now includes information systems rather than just states communication.	Clarifies that the processes in the management system need to cover how IT and other information systems are managed, measured and improved.
6.4		New note added to clarify what work environment means and gives examples such as noise, temperature and humidity.	No further explanation needed.
7.2.1	d)	The word 'determined' has changed to 'considered necessary'.	No further explanation needed.
	Notes	Note added to explain what the phrase 'post delivery activities' may include, i.e. warranty provisions, etc.	No further explanation needed.
7.3	Notes	A note has been added to say that design and development review, verification and validation have distinct purposes. They can be conducted and recorded separately or in any combination, as suitable for the product and the organization.	It is up to you as to how these activities are performed and the results recorded. Therefore design a process that meets your needs and manages your risks. Providing you can be sure all elements that are needed are included then that is OK.

Section	Ref	Change	What it means
7.3.3	Notes	New note added to say that the design must include how the product will be preserved.	Make sure this element is included in your design process. 'Preserved' means that it will still be fit for purpose when it is needed, so this can apply to both physical and information types of products.
7.5.3	Para 2	An added requirement to clarify that inspection and test status must be identified 'throughout product realization'.	It must be clear throughout production what the status of the product is.
7.5.4	Notes	The phrase 'and personal data' has been added to the note about intellectual property.	Clarification that personal data is included and that processes or supporting procedures need to show how this is protected as much as all other intellectual property used in the process.
7.6	Notes	This explains that where computer software is used to measure the acceptability of products and services it must contain verification and configuration management to ensure its ongoing suitability.	If you use computer software to test a product, the software/hardware system itself must be maintained, changes managed and, typically, there would be some method for checking it works as it should.
8.2.1		A note has been added giving some examples as to how customer perception can be measured.	No further explanation needed.
8.2.2	Para 5	Management responsible for the area audited must ensure that 'necessary corrections and corrective actions' are taken following audit results.	This means that it is the line manager's responsibility not the quality manager's to implement changes.
8.4	f)	Clarification that checking the effectiveness of any corrective action made needs to be carried out	The corrective action needs to be effective, so the procedure needs to show how this checking takes place.
8.5.2	e)	Clarification that checking the effectiveness of any preventive action made needs to be carried out	The preventive action needs to be effective, so the procedure needs to show this checking takes place.

5. Where next – The 'implementation plan'

Getting started

When considering implementing a process-based management system it is critical to create a plan that describes the steps involved. This plan really needs to start with building an awareness among senior management of ISO 9001:2008, process-based management and the impact it will have on the organization. Our experience shows that this awareness needs to focus on its effect on business results and improving business performance, rather than the detail of the Standard. You have to make sure they understand 'what's in it for them' – the more there is the more they will engage.

Imagine that when you are preparing to present the case to your senior management team for implementing and/or registering to ISO 9001:2008, you will have only 20 to 30 minutes to communicate the critical points, so there will be little room for the detail of the Standard. By all means use the figures and examples in this book.

An example presentation may include:

- an overview of ISO 9001:2008;
- an introduction to process-based management systems;
- examples of other management systems;
- benefits others have found;
- outline project plan.

Once awareness and interest have been created, the next step is to define what processes make up the system. This needs to be completed and agreed before any mapping of processes or any other activity takes place. This activity should

include the senior management team and is a logical extension to the awareness briefing. It is very difficult to build a system without this initial step, and early on in this book we emphasized the need to define the system effectively to begin with. Many organizations are tempted to skip this, but experience shows that this is the most important step. Even if you can't get the senior management involved as much as you would like, this stage should still be your first step – we can't emphasize this enough. If you start to build your system from anything else, you will be heading in the wrong direction.

An example implementation plan

Steps	Tips
Senior management awareness	Keep it short and to the point. Focus on the organization and results rather than the detail of the Standard.
Identify key business processes and the sequence	First key step. Don't move on until this is agreed by the management team. Involve the management team as much as possible.
Define process owners/leaders and how processes will be defined	Process owners are normally senior managers.
Define cross-functional processes and sub-processes	Keep this 'pacy' to maintain momentum in the project and map to a consistent level of detail. Separate the 'what' from the 'how'. Use cross-functional teams as required.
Gain agreement to the processes	This confirms the sequence of the processes and the system itself.
Add in procedures and agree	
Create a short policy document	Outline the scope of the system, policy, process framework and a description of the system. This does not need to be a long document and we suggest it is positioned as a publicity piece that you would be pleased to hand to a customer or new staff member. Include colour and pictures as required. The design for this could follow any corporate branding.

Steps	Tips
Create manual	The structure of ISO 9001:2008 and the way it is implemented 'lends' itself to a software-based solution rather than a paper-based one. The important point for the manual is that you can show the links between the system, the processes and supporting documents and procedures.
Define process and product measures or key performance indicators (KPIs) with targets	These need to include 'metrics', i.e. something as a percentage of something else. Targets indicate the level of performance required. Most processes and sub-processes have KPIs.
Train internal auditors to audit for compliance and effectiveness	Make sure any training you purchase follows the advice in 'Getting help', below.
Carry out awareness training for managers and staff to launch the system	Keep this short, to the point and relevant to the audience.
Operate the system	Carry on 'business as normal'. Keep track of the areas and processes that are new to your organization to make sure they are being implemented.
Collect and collate KPI information and carry out audits	Measure performance. Carry out audits and close them down by carrying out any corrective action. Audit both compliance and effectiveness.
Identify improvement project(s)	Run your management review as part of normal business, making sure that the senior management team review KPI results, audit results, customer satisfaction information, etc. to identify improvements and resource needs. Keep records.
Deliver improvement projects	Pick a simple, straightforward improvement to start with so that everyone can see the link between the process, the results, the change and the improved results.

Steps	Tips
Keep going for three months at least	To create the necessary evidence for the assessment and more importantly to give the system time to 'bed down' in the organization.
IF YOU REQUIRE THIRD PARTY REGISTRATION – Arrange pre-assessment from your registration body	This is not offered by all registration bodies but is a useful tool to help introduce the system. This allows you to get to know your auditor and to identify any large gaps or points you may have missed.
IF YOU REQUIRE THIRD PARTY REGISTRATION – The registration assessment itself	There is no need to panic over the actual assessment. Your registration body wants you to be successful, so treat them as colleagues with the same aim and you will benefit from the assessment and its findings. However, make sure that you select a registration body that is following the principles outlined in this book and applies them to their own business, otherwise there may be a mismatch in understanding.
Have a party	Celebrate success.

How long the plan takes to implement is up to you and the resources available. Keep the implementation moving at speed and remember, as with any change, some people will like it, others won't and some will simply not care; but that is up to them. You are presumably reading this because you are either interested in the subject or need to put in place a management system that will improve your organization and its performance, so:

- stay focused on the end goal;
- seek support from the management team when you need it;
- involve as many people as you can throughout the plan;
- act as the facilitator rather than the 'doer' supporting others;

and you will have a successful implementation.

How do I go about auditing my processes?

Apart from the implementation of process-based management, which usually brings about a significant change to the way organizations operate, another big change is caused by the need to look at both compliance and effectiveness. This is likely to be how systems and processes are audited. It is worth briefly discussing their impact, as every organization needs to audit what it does as one of the requirements for ISO 9001:2008. How to audit is covered in detail in the auditing book that forms part of this series, but in overview the need for change is being highlighted and further driven by the impact of the 2008/2009 financial meltdown, where traditional practices, including auditing, as much as others, completely failed to prevent what actually took place – a failure of systems, processes, measurement and risk management.

What is important is that these lessons are learnt, so that the same failure does not occur to your system and its supporting processes. As a result, auditing practice is evolving as follows, and your auditing techniques need to address this changing requirement, in order to fully support your organization's business objectives.

Traditional approach	For the future this includes
Focuses on producing pictures of the past	Looks at what is likely to happen in the future
Focuses on looking at outputs	Focuses on behaviours that produce outcomes
Focuses on compliance	Focuses on risk and effectiveness
Produces tactical information	Produces strategic information reporting against objectives
Focuses on the paper world	Focuses on the real world, not just what people say or write down

What if I already have existing processes and other documents?

Many organizations already have documented processes, procedures or other documents they use to manage their business. Some organizations may already have documentation as a result of implementing ISO 9001:2000. If you still want them and they add value to your organization, all these can be included in your new process-based management system. So to start with don't throw

them away but build your system using the approach described and incorporate what you need from your existing business information and documents at the appropriate place in the system.

Getting help

There are many places where you can get help and support. Inevitably the 'quality' of this help and support can vary between suppliers. A good source is to contact other organizations that have implemented a process-based management system and learn from them. Ask what they learnt and what they would or wouldn't do next time. If you do need external support or facilitation, points to consider are as follows:

- Do they understand process management?
- How many process-based management systems have they put in place?
- Do they have a view of what the future looks like or how your system may be developed?
- Are they willing to include areas that are obviously not covered by ISO 9001:2008 but are part of your organization?
- Do they understand better, or as well as, your senior management team how an organization or business works?
- Are they 'all-rounders' able to speak to and work with people from across your organization and at any level?

There are, of course, many other questions you could ask a supplier. Just make sure you are getting the right information and approach for your organization.

And finally

We hope you have enjoyed reading this short book and that it has given you an insight into ISO 9001:2008 and how it is implemented. Process-based management is a very large subject that, in theory, knows no boundaries. New management disciplines and methods are being created all the time. The chances are that they will be included in your management system as the system itself and your organization matures. Any one of these may have a positive impact on the performance of your organization or business, so make sure they are considered for inclusion to support effective delivery of your business objectives.

Our website at www.the-hpo.com provides more information and examples that you can use to help understand and implement ISO 9001:2008. It also contains a knowledge hub that you can use to keep up to date with latest developments.

References

International standards

ISO 9000:2000, *Quality management systems – Fundamentals and vocabulary*
ISO 9001:2008, *Quality management systems – Requirements*
ISO 9004:2000, *Quality management systems – Guidelines for performance improvements*

Other books in the series

BIP 2014 (2009) *Creating a process-based management system for ISO 9001:2008 and beyond,* London, BSI (ISBN 978 0 580 67657 4)
BIP 2015 (2009) *Process Management Auditing for ISO 9001:2008,* London, BSI (ISBN 978 0 580 67658 1)

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ISO 9001 and quality management systems are widely used, but in order to recognize the full benefit of these powerful tools an organization needs to know exactly what they mean for them in practice.

Understanding ISO 9001:2008 and Process-based Management Systems decodes the standard, explaining it in clear business terms and linking it closely to how an organization operates in the real world. By focusing on identifying and delivering the organization's business objectives, this user-friendly guide shows how the requirements of ISO 9001:2008 can be met – not the other way around.

This book examines the impact of process-based management, outlines what is required to achieve certification, and advises how to build the foundations for business improvement beyond ISO 9001:2008. It shows how to maximize the benefits of a quality management system by applying it appropriately, and how overall business performance can be enhanced.

The interpretations in this guide are based on the 'real world' experience of facilitating the creation, implementation and improvement of process-based management systems that meet the requirements of ISO 9001:2008.

About the Authors

Ian Rosam and Rob Peddle are directors of the HPO (High Performance Organisation Group) and between them have a wealth of management experience. They have developed new and innovative approaches to 'management by process' and helped organizations of all sizes, from all sectors, improve their business performance. At the heart of this is the effective identification and management of their business processes. They have a deep-seated belief that the management of business processes is fundamental to an organization's business success.

ISBN 978-0-580-67656-7

9 780580 676567

BSI ref: BIP 2013