
Ian Rosam and Rob Peddle
(The High Performance Organisation Group Ltd)
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 than 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.
# Contents

1. **Businesses first/standards second – The context**  
   - A short overview of the past, what ISO 9001:2008 is really about and how to understand it without looking at the standard at all.  

2. **ISO 9001:2008 in overview – The ‘what’**  
   - A manager’s view of ISO 9001:2008, its principles and how it impacts on the business – The ‘what’ we have to achieve.

3. **Business process management – The ‘how’**  
   - If ISO 9001:2008 describes the ‘what’ we have to achieve, this chapter covers the ‘how’ by introducing business management by process. This chapter describes the business as a system and includes the structure of a process-based management system, using good practice, that meets the needs of both the business and ISO 9001:2008.

4. **ISO 9001:2008 in more detail – The ‘gap’**  
   - Having covered what the standard is and how it is implemented this chapter covers the clauses of ISO 9001:2008 in more detail. This chapter has been constructed to allow you to carry out a short gap analysis giving you a ‘picture’ of what you need to do.

5. **Where next – The ‘implementation plan’**  
   - Based on experience this chapter covers how to implement business process management, the pitfalls to avoid as well as finding help and selecting a registration body.

References
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 to 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 seriously.

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 organization’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.

![Diagram: Living the business performance cycle](image)

**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

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<td>A reliance on compliance</td>
<td>Effectiveness is critical</td>
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<td>Procedure and detail driven</td>
<td>Business performance driven</td>
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<td>Concentrates on doing things right</td>
<td>Concentrates on doing the right things in the first place</td>
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<td>Focuses on what you do</td>
<td>Focuses on why you do it</td>
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<td>Internally focused</td>
<td>Externally driven</td>
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<td>Based on consistency of delivery</td>
<td>Based on improving customer satisfaction</td>
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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 it 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 future. 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 9001 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 huge 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.
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.