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

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## Foreword

Standards such as the ISO 9000 series evolve and change to meet industry requirements. The introduction of ISO 9001:2000 created a fundamental shift from a set of requirements outlined in the 1994 version to the description of a business model, which provided a set of operating principles rather than a prescriptive list of conditions to cover. The introduction of ISO 9001:2008 reinforces this management approach and clarifies certain minor details that support this approach. All key elements remain unchanged from the 2000 version.

The business model introduced in the 2000 version was underpinned by the 'process-based approach' to management, which was in reality a step change from the 1994 version of the Standard. It introduced the idea that a management system is a living entity; something that can never be fully documented, made up of cross-functional key business processes organized in such a way as to describe the system itself. This system described how the management team managed their business and delivered the business objectives – a system based in the 'real world'.

Whilst some organizations took on board this fundamental shift, far too many, for all sorts of reasons, saw it as a relatively minor change and did little to really update their previous management system. This was exacerbated by many registration bodies not supporting the need to make fundamental adjustments and continuing to register systems that were only marginally different to the 1994 compliant versions. The result is that many systems are not really considered as valuable as they should by senior management within the organizations that use them. If this situation is to change – and it must for belief in the Standard to survive – the intention of the year 2000 update has to be taken on board by all involved in ISO 9001. This means those who use it and those who register these organizations against it.

This book has therefore been revised to include new developments since it was last issued and to re-emphasize the aspects of ISO 9001:2008 that the new version addresses. If you have already created an ISO 9001 or business management system that follows the principles outlined in the previous version of this book, then you will not need to make any changes to address ISO 9001:2008. If you have not, then understanding this approach will give you the tools to make the Standard an indispensible part of your senior management's toolkit, helping them to address the business sustainability challenges all organizations face in 2009 and beyond.

## The world has changed – Important information

It is also worth mentioning that there have been significant changes in belief in the critical importance of having sound systems and processes to deliver effective management; in other words, outcomes that satisfy customers and other stakeholders. The financial meltdown was caused by the complete breakdown in the ability of large multinational organizations and regulators around the world to manage systems and processes effectively. This was despite huge budgets, intelligent people and access to the most senior management.

This obvious example shows us how important properly designed systems and processes are. It equally demonstrates the importance of defining and understanding how they are managed and monitored to ensure delivery of objectives, without detrimental side effects. What has been clearly demonstrated is that it is simply no longer good enough to just check compliance. Although this book is not about auditing the fact remains that the systems and processes you create and manage will need to be audited, not just for compliance but to:

- identify business risks to meeting objectives;
- audit the real world, not just the paper world;
- indicate what will happen not just pictures of the past; and
- audit behaviours that deliver outcomes not just outputs.

A separate book looking at auditing in more detail is part of this updated series and you are encouraged to review this as well. The global issues probably already have affected you and your management system, and if not certainly will, so it is worthwhile making sure you also understand some of the other tools that will help you address them.

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Introduction 1

Outlines how process-based management draws on many theories
of management to provide a holistic and practical approach that
gives real visibility to what is important in the organization. We
also outline why process management is different and why those
who have seen or implemented the approach so far describe it as
'just plain common sense'.

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#### 1. The process-based management system in context

 An overview of where quality management has come from and how the process-based approach advocated by ISO 9001:2008 challenges the principles on which traditional quality management has been built.

#### 2. The process approach

• A practical view of process management that dispels the myths surrounding the subject. We define the subject and look at how the top-level management system, business processes and key performance indicators can be structured to create an effective process-based management system. We also consider the implications of the approach on the softer, but equally important, organizational issues of cultural change and communications.

#### 3. Designing your management system

Designing your management system is a strategic activity that
ultimately defines how your organization will be managed to
deliver its objectives. We explore the key steps necessary to
design the process-based management system and its acceptance
by the organization.

#### 4. Process design (mapping and understanding processes)

Having identified the processes that make up the system the
next stage is to understand them in more detail and particularly
their cross-functional nature. In designing and effectively
implementing a management system we need to understand
the processes, measure them and based on their performance
improve them. This comes from the knowledge that nothing can
be improved if it is not measured and nothing can be effectively
measured unless it is firstly understood.

#### 5. Procedure design – Linking supporting information to processes

• The need for supporting information is based upon the needs of the organization and the business risks that it faces. The supporting information can come in many forms, and this chapter will look at procedures. It is, however, fair to say that unlike the 1994 version of ISO 9001, there is much more to the 'system' than its procedures. Procedures give the detailed 'how-to' information that an organization feels it needs to ensure its people can effectively and consistently carry out the activities allocated to them. They are not written just because we do something, but because we find them useful and they minimize risk to an acceptable level.

#### 6. Linking of processes

• Processes are best designed using individual cross-functional teams. This not only ensures that key steps in the process are not omitted by mistake, but it also ensures that there is, at least, a degree of input from the managers and staff involved in actually delivering and running the processes. This starts to create real ownership by the team. It is, however, vital that even though they have been developed in detail by different teams that they still deliver overall what the organization needs, and that there is no duplication. Linking of processes achieves this.

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#### 7. Key performance indicators (KPIs)

• This aim of ISO 9001:2008 is to generate continuous improvement. The key drivers for this are the measurement of your results and what you have achieved. Identifying measures or key performance indicators is quite straightforward, making sure the organization has the right ones and that they are acted upon is another matter. We look at developing KPIs that truly do reflect the processes within your system, and hence your business performance.

#### 8. Implementing the system

Having designed the system and its processes, and identified
the measures that are going to be used to manage and improve
the system, the next stage is implementation. The key activities
that need to be effectively carried out for success are examined,
so that the management system becomes just 'the way you do
things', not something separate.

#### 9. Selecting an appropriate registration body

• There is no doubt that registration bodies are changing. Like everyone else they have to compete for business and deliver services that meet their customers' needs. With the failure of compliance auditing in the financial sector the wider focus on how audits take place has risen considerably. In this chapter we explore how to select a certification body to help ensure the same failing that affected the systems and processes in the financial sector do not happen to the quality and business processes of your organization.

#### 10. Case studies

• Three real-life case studies are included to show how organizations have used the approach outlined in this book to achieve business improvement. We also look at the pitfalls of trying to implement a system that reflects the clauses of the Standard itself rather than looking first at what their business needs.

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## Introduction

The process-based management system (PBMS) is at the heart of ISO 9001:2008 and is the culmination of a long period of evolution in management thinking. It builds directly on the best developments and, whilst not providing a completely new way of managing an organization, can significantly improve business performance when implemented effectively. In particular, it offers an essential and powerful insight into what really makes organizations tick. It provides real visibility of what is important – the things on which both management attention and organizational activity should focus in order to be successful. It then provides the mechanism to do this as a part of 'business as usual'.

The PBMS brings together ideas from a large number of individual management theories and practices, which have too often in the past been treated as stand-alone initiatives. It provides the 'glue' that brings these initiatives together as a cohesive whole. On their own, many of these individual initiatives fell short of delivering the benefits promised. Taken together as part of the PBMS, the likelihood of successful delivery is greatly increased. This is perhaps not surprising – very few of the initiatives really do stand alone from other equally important issues. Indeed, very often there are high levels of interdependence. You only have to look at the disappointment felt within some organizations when Total Quality Management (TQM) or Investors In People (IIP) did not fully live up to their promise. In both cases there are often cultural, performance measurement and organizational issues that need to be addressed in order for them to succeed – but how often have they been implemented without this being fully tackled or even understood? And what other issues also need thinking about at the same time to facilitate their effective implementation? Very few important ideas about management stand alone.

So why should the PBMS be different? A number of very important reasons spring to mind, the prime one being that the PBMS is not an initiative, but a way of thinking. To this can be added:

- it deals with the 'whole organization' rather than focusing on improving individual parts;
- it starts with strategy and forges links with the rest of the organization's activities;
- it is inclusive, allowing everyone to be involved in both development and delivery;
- it provides the mechanism for true empowerment of both individuals and teams;
- it is not a static system it is alive and moves with changing priorities and needs. Implementation is the start, not the end point;
- it is simple and enables everyone within the organization to understand their role and contribution to success.

Lastly, and perhaps most importantly, those who have so far seen this approach and understood what it is really all about call it 'just plain common sense', which is, as we all know, surprisingly uncommon. This is a management philosophy that is about everyone within the organization, not just the managers and what they do.

If you have read the initial book in this series, this volume will provide a clear insight into how you can translate the principles it describes into a practical and powerful management system, leading to both business benefit and registration against the international standard ISO 9001:2008.

Should you be aiming to obtain formal registration, and you have not yet read the previous book in this series, then we recommend you do so as it provides further useful insight into the Standard itself. Alternatively, you may wish to implement an effective PBMS without obtaining formal accreditation (if so then read on). There is sufficient here to get you going on what will be an exciting and illuminating experience: defining your organization through its key business processes, and then managing and improving them to deliver enhanced business performance over time.

# 1. The process-based management system in context

## The need for change in quality management

If you were in the 'quality industry' during the 1980s and 1990s you will appreciate that the development of the updated international standard on quality management, ISO 9001:2000, now ISO 9001:2008, has been a real step forward. It has brought quality management to the place it always should have been – the very heart of the way an organization is managed. Perhaps surprising to some people, this change has also unsettled many of the quality managers who have been the mainstay of the quality industry in this period. This change of emphasis takes their role into a different level of importance, with a need for different skills and competencies – a challenge that some find difficult to accept. Unfortunately, it is not only some quality managers who have had this difficulty - many of their senior managers, and other people within 'support functions' who now need to become involved, are also finding the change difficult to embrace. To add to the confusion, many of the myriad external 'quality consultants' are also not helping the change, as they provide 'off-the-shelf' systems to their clients, or ones that are delivered without the real involvement of senior management or all functions within the organization. It is no wonder that there is still a real level of confusion about what was really intended by ISO 9001:2000, now ISO 9001:2008, and the PBMS.

These problems often stem from the fact that many people within an organization do not really understand how their jobs and their daily activities should relate to a 'quality management system'. They perhaps know what such a system has been in the past and do not see that they need to part of it. There has been no requirement to be involved up to now, so why should they

suddenly become so? It is after all only an updated version of the 1994 standard. The solution to this real issue is to provide education about what the updated standard really means. 'Quality management' of the future is in reality 'business management'. Once the word 'quality' is replaced by the word 'business', these problems start to clear, and the way in which everyone within the organization should become involved can start to be better understood. This is the first step towards improvement, which is a key principle of the Standard.

History plays a big part in these perceptions. All too often, interpretations of the previous versions of the Standard have said that effective implementation depended upon delegation to a quality manager, who was often a middle manager. They would then work with 'production' or 'service delivery' managers and their staff to create a documented system of 'procedures' that define what they do and how they do it – this became the core of the 'quality manual'. The purpose of creating this manual was to provide a mechanism to manage and monitor these activities, making sure that they deliver the required output. The eventual aim was the consistent application of any essential 'industry' or other 'special requirements' and the consistent delivery of products or services to customers.

It was often a tactical and operational role, which in some cases had little direct or obvious relationship to the strategic direction of the organization. What often made it worse was that in many organizations the prime purpose of having the system was to gain accreditation against the Standard, rather than to deliver business performance.

It is no wonder that in many people's eyes it had become discredited and that a new impetus was needed to get it back on track. This impetus was the reissue of the 2000, now the 2008, version of ISO 9001 – and hence the significantly different requirements it contained. Whilst still placing the delivery of customer satisfaction as the focus of the system, it is much more specific in creating a direct link between the customer and business objectives of the organization and the processes that have been put in place to deliver the products and services they need. A further change was the requirement for measurement that customer satisfaction had actually been achieved. There is also a key requirement to adopt a process approach.

## Process-based management

The PBMS is a management system that is based on simple ideas:

- understand your business processes and what they need to achieve;
- manage their delivery;

- monitor their actual performance against set targets;
- and then improve both the processes themselves and their performance over time.

The aim of doing this is to meet your business objectives.

In line with this approach, ISO 9001:2008 requires users to understand and then effectively manage the process(es) that contribute towards their success. Process management has been placed at the core of this standard for one very good reason – it is considered to be a best-practice approach to the delivery of business performance. In the case of this standard, the processes are primarily focused on the delivery of customer satisfaction, and hence it is the basis of external accreditation.

If only it were this simple to deliver customer satisfaction! Unfortunately, even with ISO 9001:2000, a large number of organizations have not really moved their systems on very far. Many have not fully appreciated the power, importance or full impact of the thinking behind the Standard, but have merely tried to use it in the same way as before. Some have tried to apply it by developing processes that are based upon the various clauses within the Standard itself and not what the organization actually needs in order to be successful. Others have restricted their 'system' to the customer delivery processes only, forgetting that they can still fail to deliver their overall organizational objectives, even if they satisfy their customers. More importantly, they have not recognized the contribution of other business processes to the delivery of the customer experience, or the daily prioritization that goes on between satisfying different stakeholders.

One does wonder if they have ever asked themselves how long they can continue to satisfy customers if they are not also satisfying their other key stakeholders. Even though they may be applying the 'letter of the Standard' and gaining the appropriate accreditation, neither they, nor their customers, are going to benefit fully from their investment in the development and implementation of their management system. In order to be successful, over time, they also need to look at and understand the companion standard, ISO 9004:2000, due itself for update in 2010, which extends this thinking by focusing on performance improvement and including other 'stakeholders' within the management system.

In effect, they have implemented a process-based 'initiative', leaving the management of the rest of their business activities to be covered somewhere else. They will have the same difficulty that has always been the case for organizations that create a multitude of management systems, with separate ones for each of the initiatives they wish to manage. How often have you seen separate management systems for such things as quality management (ISO 9001), Investors in People (IIP), environmental management systems (EMS), health and safety, value-based

management (VBM), business improvement (BI), etc? How often have they had to compete for resource and recognition, sometimes seen to be fighting against each other rather than acting together for the overall benefit of the organization? How often have they been seen as the 'pet initiative' of a particular manager or director, who seems to pursue them without the real support of their colleagues? And how often have these failed to deliver the true value that had been expected? Failure has not normally been because of anything wrong with the ideas behind the initiatives themselves, but because of the way they were implemented.

## So, what is a management system?

A management system is not a set of documents either in paper form or held electronically. Any system is a living entity, something that is always changing and evolving, reacting to the environment in which it sits. In the case of a business it is the business environment in which it operates. As this business environment changes so does the organization; it adapts and the system therefore changes.

Of course describing the organization as a living entity is very conceptual and we need to be able to make this real in some way. People will quite rightly wonder how this relates to them and how something that lives can be managed or described. To help explain this we need an example, so let's use the human.

The human body is a system that is made up of key body parts such as heart, lungs, legs, etc. These body parts are in effect our key processes and are organized in such a way to operate together to make us work. This structure is the system and we/it wouldn't work very well if our legs were organized in such a way that they were stuck to our head!!! Our performance, i.e. the performance of our system, can be measured and assessed as can the performance of our individual body parts or processes. This measurement is against targets such as the number of beats our heart makes or how high our blood pressure is. If there are risks then we need to carry out corrective action or improvements. Organizations act in the same way when it comes to their system and processes. They:

- identify them (key body parts in our example);
- organize them (so the organization works as an overall entity);
- define them to understand how they work as individual elements;
- · measure their performance to identify risks; and
- improve them or manage the risk with preventive action.

We could take the analogy still further by saying that doctors (and we and others do as well) assess the performance of the human body and individual body parts to identify risks and their effectiveness and well-being. They/we

then recommend actions to resolve any issues. Auditors should be fulfilling the same function for organizations by looking at the organization's processes and identifying risks to its effectiveness, but do they? Using the analogy again, do auditors really check that the legs are not connected to the head? Or if the brain is really understanding what the eyes are seeing, or if the eyes are seeing what is really happening around them? However, not all body parts are vital to everyone's success. This of course depends on what you are seeking to achieve, and people often lead successful and fulfilling lives without necessarily having full functionality available to them. However, there are some body parts that we all need to have, such as the brain, heart and lungs, as these are key body parts. In the same way there are processes in organizations that are not vital to success, however, there are others which are and it is these key processes that are critical, need to be identified and form the majority of your management system. Without them being effective, risks lie ahead.

What you must remember is that whatever you document, it is not the real world, just a description of that real world to help you understand it. So when you measure performance, run improvement activity or indeed audit, it needs to be the real world we are considering not the documented one, i.e. what actually happens.

Many quality professionals are involved in certification audits and selecting which registration body to use. If the auditor comes into the organization and asks 'Can I see your management system?' we know instantly that they don't really understand what a management system is, because they are already standing or sitting in it – it is all around them!!!! It is the organization itself, so it is a silly question to ask. Of course it also shows that the auditor doesn't really understand ISO 9001:2008. We do not aim to cover the complexities of auditing this 'living' system in this book, but it is covered in the companion book to this series.

### Where ISO 9001:2008 could be used

The PBMS is equally applicable to every type or size of organization – as indeed is the ISO 9001:2008 standard itself. The Standard was created as an international document, rather than starting life as a single national or industry standard. This means that it has to be capable of being applied across the globe – regardless of the culture of different countries or for that matter the culture of different organizations. It also applies to all sectors. This includes 'for profit' businesses from any commercial or industrial field, whatever type of product or service they sell. It also covers all types of 'not for profit' organizations, such as charities and central and local government bodies. Lastly, it also has to apply to organizations

of any size – from 'one-man-band' to multinational organizations. These requirements were quite a tall order, and virtually impossible for any standard that was to be written in the way that management standards have historically been created. ISO therefore built the Standard by bringing together a range of key business principles rather than to list specific detailed 'things' that organizations need to do. They looked at all of the best-practice approaches that have been developed over recent years, and considered how they work together for the delivery of business benefit.

The ISO 9000:2000 series (ISO 9000/9001/9004:2008) was created from this understanding of best-practice business principles, and deliberately left the interpretation of these principles to individual organizations. They knew that every organization would need to apply them in a way that was specific to their own unique situation – no two organizations would have exactly the same interpretation. There is also the acknowledgement that organizations will develop over time. This will certainly include changing business objectives and will hopefully also be because of their increasing maturity in 'process-thinking'. As this happens, their management system will also need to change, as will the way in which they interpret the principles within the Standard. This movement is the real meaning of business improvement. If the Standard were prescriptive about exactly what organizations need to do in order to comply, then it would be of little use to drive a relevant and useful management system in any organization.

What it does – and does well – is to give a 'best-practice' basis for senior management teams to think about how they need to lead their organization, and how they can focus every part of it on the delivery of business results. Interpreted well, it can be the way in which organizations can transform their performance. Interpreted badly, it will be a millstone around the neck of an organization that will quickly become discredited and disposed of. Those responsible for deciding how to use it have the opportunity, and responsibility, to decide which of these alternatives it should be.

#### The PBMS is the foundation

One key approach prevails across the whole of the ISO 9000 range of standards – process management. It is the foundation upon which all of the other principles are built and applied. It is the mechanism by which any organization can define and manage the way all of its constituent parts work together to jointly deliver their business results – the outcomes that are delivered to their customers and other stakeholders. Applying this principle well is the way organizations can move from a departmental (silo) approach to a cross-functional (process) approach and ensure everyone is focused on what is really key to the organization's success.

Equally important to those who wish to apply other management standards, is the fact that ISO 9001:2008 is now being used as the basis from which they are built – so getting this right is essential for moving forward with any of these other standards in the future.

So, whether you are wishing to develop a PBMS for gaining ISO 9001:2008 accreditation, or you feel it is the approach you wish to use to maximize your organizational performance, the message should be the same. Think business first, standard second. Build the system that reflects your business needs rather than blindly developing a system that follows the individual clauses of the Standard. If you don't, you may well get accreditation, but you will miss out on the big benefit – the opportunity for enhanced and sustainable business performance.