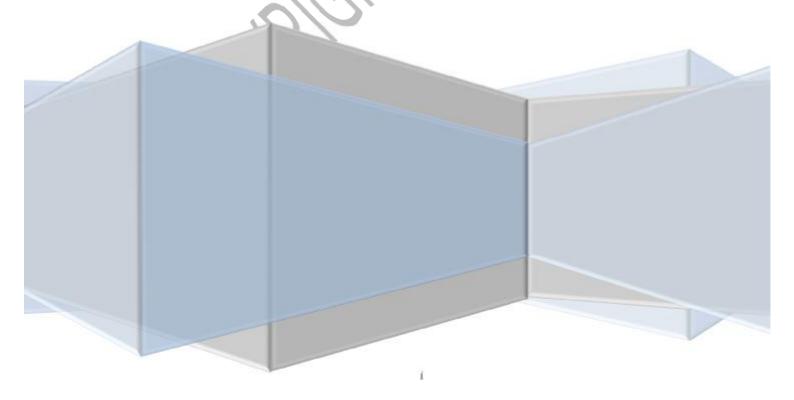
# Mapwright P/L

# The Guide – How to Get ISO 9001

Jane Bennett (Mapwright)



#### How to do ISO 9001 and get a simple, practical and effective system

Congratulations on purchasing the DIY ISO 9001 Kit.

This Guide explains how to use my simple, practical *and* effective method to improve your management of quality and to get certification if you choose. My method and approach has been developed, used, tested, refined, improved and proven over many years in many different organisations and businesses across diverse fields.

The Guide sets out what to do, how and when to do it. It's the heart of the DIY ISO 9001 Kit. Use it with the examples, tools and templates supplied in the Guide, Toolbox and CD, to develop the best system for you.

But don't just adopt anything without further thought, believing 'we have to do it exactly like this'. That's just not so. Modify or adapt anything when and how you want, so it becomes your system and works well *for you*. Because every organisation really is unique – even two organisations in exactly the same field won't do things the same. And you definitely want it to be *your* system, never mine.

You may not want to use every template in DIY Toolbox, for example. Perhaps you already have some things that work for you, and would meet requirements with only a little change. Great – build on what you have. Where something is necessary but missing right now, you could use mine, or take the idea but apply it differently. For example, anyone with in-house IT expertise usually far prefers automated / online solutions such as databases, applications, websites, wikis or an intranet instead of paper/manual logs or forms. I think it's a very intelligent path, but not everyone has access to those resources.

Always remember, it's your system. Aim for a quality management system that supports and enables you to do whatever it is that you do effectively, keeping your clients happy and things humming along.

I suggest you keep the following in front of you, as a frequent reminder:

This is *our* quality system.

It must work for us.

May your journey be interesting and successful. I look forward to helping. Regards, Jane Bennett

Director of Mapwright, BA, DipEd, Grad Dip Bus Info Technology, Principal Quality Management Consultant, qualified Auditor and certified Coach

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#### And a note about the word 'business'

I have used the word business (or company) often because it is shorter and quicker to read and write than the correct, but longer one: *organisation*. If you aren't a business, please substitute *organisation* wherever you see 'business' or 'company'. And please also be reassured that ISO 9001 and the DIY Kit are equally applicable to all organisations, whether commercial businesses or not.

#### Dear 'Chief'

Congratulations on your decision to go for ISO 9001.

There are many benefits to be gained from a quality management system that meets the requirements of this international Standard. All my clients and customers (*all* of them) report the value and the very many benefits they got from it. Some expected, others not anticipated, but all very welcome.

But while ISO 9001 can be beneficial, whether it will be (or not) is up to you.

Because it is you who is the leader: the quality sponsor or champion, regardless of your title. Titles vary but the need for leadership in quality does not. You see, the Standard says what must be done, but it does not dictate how. The how is up to you and your people of course. Led, coached and helped by you.

Customer Focus and Leadership are the first two principles of quality management that the Standard is based on. The Standard itself sets many requirements that top management\* are specifically accountable for.

That's you.

ISO 9001 is internationally known and respected; using it as the model for your system can result in a robust and highly effective management system. But to get that and the results you want, you must:

- Set a clear policy on quality; something that summarises your position
- Put that policy into action: say how things are to be done by setting clear criteria for your services (or products) and your business processes
- · Make sure everyone is held personally accountable for quality, and finally
- Insist and make sure that everyone works this way, so that your system really is just 'the way we do things around here'.

Yes, of course you can delegate much of the work to others to implement, co-ordinate and manage. But you must tell them and everyone what you want out of your quality system. Lead the way. Make sure it happens.

Because if **you** don't make your quality management system real, champion it and care about it, you can be very sure of one thing. No one else will.

It's your company and your system - not mine and definitely not any auditor's. Joseph Juran, a quality expert, said 'every successful quality revolution has included the participation of upper management. We know of no exceptions'. Me neither.

It is you who sets the goal, makes the plans, guides, coaches and oversees, takes the risks, pays the bills and (I hope) reaps the rewards. And all good quality professionals, including auditors, know that.

I do wish you every success and fortune in your journey along the ISO 9001 quality road. I hope that you make it a rewarding and valuable one for you and your people, your company and last, but definitely not least, your customers. I look forward to helping you get there.

Jane Bennett, Director, Mapwright Pty Ltd

u're the head person (or people): the decision-maker and leader: the one who makes key decisions and makes ngs happen, regardless of your title, whether business owner, MD, CEO, Director, President, Head Honcho, Grand obah or anything else. The 9001 Standard uses the term 'top management'.

# 1 Getting It Before You Start

This chapter provides important background theory with some basic concepts and terms.

You need a foundation, in order to work more efficiently and smoothly. Many clients have said they had difficulty until they really 'got' some of the stuff in this section, and wished they'd understood it earlier. So bear with me through a little theory, because it'll be helpful.

## 1.1 About the DIY Approach

The approach I use in my DIY Kit and consulting practice is Intelligent Quality (IQ). It is based on three key principles.

The purpose is to have a quality management system that is:

- Simple
- · Practical, and
- Effective.

Simple: A system that is as simple as it can be. Not convoluted or heavy on rules, bureaucracy, forms and paperwork. Who needs that? Or has the time?

Practical: A system that works in practice, not just theory. And one that suits your organisation, your customers, and your operations, services and/or products. As easy to work with as you can make it, with flexibility built in.

Effective: You get results. The system works. It enables your business or organisation to do what you do, delivering the results you require and want.

Simple, practical and effective.

Some systems only achieve one of these: others can achieve two out of the three. But effective quality management systems have all three characteristics working together.

Possibly not all the time and in every situation, but you should always aim for it. Accepting that, at times, you may have to weigh up the pros and cons of one principle against another, and decide which is more important in *that* particular situation.

A simple example to illustrate: following problems with incorrect sales, someone creates The Form. From now on, every sale must be entered onto Form 39B and given to the salespeople who must enter it before any delivery will be processed. At first glance, looks like a simple solution. But what happens if, for example, you get a new customer in a tearing hurry, throwing a cheque or cash at you and wanting the goods right then and there? Or the courier is already at the door, and you really need to get the goods on board?

Unless this is a very rare event – once in a blue moon – your system needs to be flexible and practical enough to accommodate such events. And the *No Sales Can Happen Without a Form 39B* rule won't.

If you adopt *simple, practical and effective* as guiding principles, I am confident you'll achieve a robust system that works for you *and* gets you certification if you choose that.

Also, putting together the parts of your system is very much like putting together a jigsaw puzzle. It isn't a linear do this, then that and then that. You will do bits and pieces simultaneously or close together, others will have certain prerequisites that must be in place. My aim is to offer a sensible approach and roadmap that will minimise backtracking or rework as far as is possible.

#### 1.2 A Few Basics

#### 1.2.1 About Management Systems

What is a 'management system'?

It's a type of system: one that is used to *manage* in the sense of to run, organise and direct an organisation. It doesn't matter what type of an organisation, whether a commercial business or a non-profit such as a charity, school or government department.

Without any kind of management system, each organisation would have to start from scratch pretty much every day and figure out what to do, and then how to do it. That definitely isn't something you want to do daily, so we develop and use management systems. I say we develop but often management systems sort of grow in a patchwork, ad hoc way over time, not unlike a garden perhaps, where different gardeners have different ideas of what it should look like.

Think of it as the system that operates the business (or whatever organisation) every day; whether or not you recognise it as a management system, that's what it is. It may be a good one or very average, or not very good at all, but there is a system already.

#### 1.2.2 About Systems Thinking

Which is where thinking in terms of *systems* comes in: this will help you to think about and interpret the activities and events in your company or organisation from that different perspective. Systems thinking recognises that every organisation is comprised not just of various functional parts (teams, departments, divisions and so forth) but also of systems and even subsystems.

Typically, business owners or managers would pick one aspect to focus on (say, 'low sales') and give all their attention to Sales to try and solve this. Then, when they'd got higher sales, they would switch attention to the next problematic area, say 'on time delivery, without errors'.

However, this approach is limited to thinking about *individual parts* of an organisation, rather than the whole. Suppose the company Sales Manager decides to pay and reward their sales staff purely on the numbers of sales they get. And doesn't think about the other possible consequences, especially if they make errors entering customer details, including their name and delivery address. Only higher sales matter.

But any problems in capturing essential information accurately would then land on the poor delivery department. And if you've ever had the frustrating experience of being told *sorry*, *we're Sales and we don't handle that, you'll have to contact our Delivery Centre*, you know the weakness of that approach.

Any company may have some or even all very good departments which operate very well individually, but which are isolated from each other and effectively operate in silos. They aren't integrated into a harmonious whole. That almost invariably means problems for the customer, and thus for the company, sooner or later.

Making the shift from thinking only about parts or departments to thinking systems and processes is a big change of mind-set. And immensely valuable.

Most businesses at an absolute minimum will need these management systems:

- financial to make sure the business (and people!) get paid and tax obligations are met
- safety to avoid injuries and keep people safe
- quality to make sure what they do (services or goods) meet the requirements so that customers get what they want and expect.

All of them interact to some degree, and together help the organisation to stay in business, operate and fulfil its legal obligations.

#### 1.2.3 What Is a Quality Management System?

The term *quality management system*, frequently shortened to QMS or just *quality system*, is often used to mean different things. And because of this, people often interpret it differently. For some reason, once that Quality word crops up, people seem to have very different views. Aim for a shared understanding in your company so that everyone has the same one.

So, what *is* a quality management system? And does a company with a quality management system have something that your company doesn't?

Tip: Remember, if you're a non-profit, charity, government department, foundation or similar, just substitute organisation when you see 'business' or 'company'.

Probably not. In fact, you almost certainly *already have* a quality management system. (Even if you think you don't.)

- Have you been operating for at least a year or two?
- Are you successful?
- If a business, are you making a profit? If non-profit, are you meeting the terms of your charter (the reason you exist)?
- Are customers or clients returning or referring others to you? Giving you positive feedback?
- Are you getting new business? Referrals? New customers/clients?

If you answer yes to some or most of these, then you do already have a quality management system. Which isn't really surprising.

You see, any successful organisation needs some kind of system, so that customers get what was agreed. You don't want to start making things up on an hourly or daily basis! And if customers don't get what they want or the product/service isn't what you said it was, or isn't done/delivered/made when or how you said it would be, or doesn't do what you said it would, then bad things happen, from losing customers to going out of business.

Yes, you may want to improve how some things are done, become more profitable, effective or efficient, expand your market, increase your customer base or a host of other things, but you do already have some kind of system for quality management – the system that gets your services and/or products to into the hands of your customers.

But at this point, it isn't an 'ISO 9001 system'.

Some important things to keep in mind when thinking of systems:

- 1. When thinking of your quality system, focus on the outcomes you want, and then organise and manage your processes and structures to achieve them.
- 2. You need to understand how the parts of your system interact or affect each other. For example, sales with service delivery, service or product design with sales and production, and so on. It's one reason why processes are so important.
- 3. Then if problems arise, or you need to change something, you respond by looking at the larger patterns of interactions (the *processes*) rather than only at individual components, such as a department or a particular person.
  Processes are very important and we'll look further at them later in this Guide.
- 4. The DIY Kit (and ISO 9001) is focussed on the system that manages quality.

I have consulted to many, many different organisations with a huge variety of internal cultures. In doing this, I've noticed what an enormous difference it makes when a company has an open, positive and healthy culture: how powerful that is and how much it works to the company's advantage. It's one reason why I suggest having a set of values.

The opposite is also true. The hardest companies to make headway in are those with a toxic culture: one with a culture of blame and/or punishing mistakes. To learn more about this, I strongly recommend the work of Steve Simpson – see Resources for more information.

#### Watchpoints

- Don't drive lead by example. Encourage and coach, not dictate. If you just impose changes as 'the new order around here' or something we have to do 'because ISO says', you'll probably encounter resistance, resentment, even sabotage.
- If your company is accustomed to blame and punishes mistakes, start working on that now. Because almost nothing will kill a quality project more quickly.

#### Tasks - Communicating

- Review how you communicate internally, including about your QMS processes, changes, performance. Do you have sound ways to do that? Some methods include scheduled meetings, staff get-togethers or similar events, or posting information on noticeboards or intranets. Emails are often the least successful. If yours aren't working well now, improve them.
- Think about what issues might arise in connection with *people* change management? Will there be a need for major changes, or not? How do you plan to tackle them? And how will you avoid or manage possible problems?

# 1.3 Understanding ISO 9001

An overview of the structure and main clauses (sections):

Clause	Heading	Contains	Comments	
0	Introduction	Background information and context	Do read this – many don't. Some useful information.	
1	Scope & application	What it applies to and its intent.		
2	Normative References	Lists any document indispensable to understanding this one: just ISO 9000		
3	Terms and definitions	Just points you back to ISO 9000, which defines terms and vocabulary.		
4	Context	Requirements to consider relevant context, issues & parties, determine the QMS scope ensure it meets all applicable requirements.		
5	Leadership	Requirements for the top level		
6	Planning	Requirements to plan for the QMS itself (planning for products/services is in clause 8)	These are the 'meat' of the Standard. They contain the requirements – the things you must have or do, and be able to demonstrate for auditors (if you want certification)	
7	Support	Requirements for all the resources needed to support operations & the QMS itself		
8	Operations	Requirements for 'doing what you do'; core requirements for services or products		
9	Performance evaluation	Requirements to evaluate and review performance; includes internal audit		
10	Improvement	Requirements to improve, including for corrective action		
Annexes	A - C.	You can mostly ignore		

# 1.4 ISO 9001 in a Nutshell – What It Requires

There's no getting around it: yes, you need an understanding of the Standard itself. Not having this is somewhat like going for a driver's licence but not reading the road rules.

The Standard places the focus very firmly on the customer (hooray!) and what needs to be done, exist or happen in order to have a business whose processes ensure customer needs are understood and met consistently, and which constantly strives to do things better.

The clauses to focus on are 4-10. They contain the actual requirements – the things you must do or have, shown as unshaded rows in the table on p 18. While some of the sections in the shaded rows are useful, they are for information and don't contain any actual requirements. (That's what 'Informative' means under the relevant headings.)

This section has a succinct, plain English summary of what the Standard requires. Of course, more information on the requirements and how to meet them is given in other parts of this Guide.

#### 4. Requirements for the Organisational Context

Think about:

- your company 'environment' and any relevant issues for your management system; this includes any legislation applying to your products/services, statutory requirements, etc.
- any parties who have a relevant interest: clients/customers, of course, but there may also be others; know what they require and expect
- the products or services the management system will apply to.

Decide on the scope of your system and write it down, taking the results of thinking about these things into account. Identify the processes and documented information you need for the quality system. Operate, maintain and improve your system.

#### 5. Requirements for Top Management to Demonstrate Leadership and Commitment

Top management must lead the way, and demonstrate their leadership and commitment.

They must be fully accountable for their QMS, its effectiveness and for achieving the results wanted. They must ensure the system and its processes are fully integrated into the business (not a thing apart). They must ensure all applicable requirements are consistently met, and maintain the focus on enhancing customer satisfaction.

They must have a suitable written quality policy, and ensure it is understood and used.

They must ensure responsibilities and authorities are assigned and understood. This includes those for making sure processes achieve the results planned, the system is maintained (even when things change), suitable reporting on performance is done (see clause 10) and that the system itself meets the requirements of ISO 9001.

#### 6. Requirements for Planning

Do suitable planning, including risks and opportunities. Taking context, interested parties and scope into account (clause 4), identify which risks and opportunities need addressing in order to achieve the outcomes you want, for the business, and its processes, services or products. Plan how to manage these, depending on their nature, importance and risk,

Write a set of quality objectives, aligned to what you said in your quality policy. Make sure they're measurable and relevant, and that they suit your business and what it does.

Plan how to achieve them: who will do what when, and how the results will be evaluated. Use them (see clause 10). Note: further planning for your services / products is required in clause 8.

#### 7. Requirements for Support

Decide what resources and support you need for the QMS to operate and for services/products to meet all applicable requirements and provide it. This includes having:

- competent people, and ensuring they know what your QMS requires.
- the necessary infrastructure and environment.

If your system includes monitoring/measuring to get valid results, provide the necessary resources (equipment, devices, tools, etc.). If measurement traceability is required, calibrate your measuring equipment. Keep evidence that shows you do this.

Documented information: decide what you need, create it, have it available as needed, and manage it. Control the written information that you need to operate, both internal and external information. Maintain the knowledge in your business and make it available.

#### 8. Requirements for Operations

Plan and use the processes you need to achieve your objectives and make sure your services /products meet all the applicable requirements.

Have suitable ways to communicate with your customers, so they get accurate information from you, and you respond to their enquiries, orders or feedback.

Make sure you have requirements clear (whether customers, yours, any legislative/statutory ones, etc), and can fulfil the order, before you agree to supply. If things change, manage that.

If design applies: have a process to ensure it is done under suitably controlled conditions and the required result is produced. Have suitable documentation for and of the process, including planning, inputs, outputs, as well as controlling any changes that may occur.

#### 9. Requirements for Evaluating Performance

Evaluation how your QMS performs and whether it is effective, with evidence showing you do it. Includes decide what to monitor and measure, the data needed for that, analysis and evaluation of the data, and monitoring customer perceptions of how well you have done.

Have a program of internal audit that informs management whether you're meeting requirements (yours and 9001's), and if the QMS is effective and maintained. Have evidence to show this.

Top management must review all aspects of their QMS at suitable planned intervals, to make sure it remains suitable and aligns with their strategy. Includes review of various mandatory inputs and having information to demonstrate this and records of decisions and improvement opportunities.

#### 10. Requirements for Improvement

Continually improve. Pick things to improve (products/services/processes/the QMS) and improve them, to meet the requirements of your customer's and 'enhance' their satisfaction.

Manage nonconformity. Take corrective action that is suitable and appropriate for the type of NC and its impact. Do this by analysing the NC, determining the cause/s, taking action if required, including changes to QMS if needed, and reviewing the outcome to see if it was effective.

#### 1.4.1 Don't overlook this bit

In doing all of this (and it may sound a lot, but it will become clearer), don't overlook this important statement very early in the Introduction to ISO 9001: 2015, about a quality management system: