

Detailed Contents

1. 'GETTING IT' – BEFORE YOU START	1
1.1 About the IQ Approach	1
1.2 About Management Systems and Models	2
1.2.1 Management systems and systems thinking.....	2
1.2.2 Management models.....	3
1.2.3 What is a quality management system?.....	3
1.3 Some Basics of Quality	7
1.3.1 Eight Principles of Quality.....	7
1.3.2 An Essential Quality Tool.....	8
1.4 Managing Change	11
1.4.1 People and Change.....	11
1.4.2 Company Culture.....	12
2. SETTING IT UP: PROJECT PLANNING	13
2.1 Treat it as a Project	13
2.2 Answer the Key Questions	13
2.2.1 Why do ISO 9001?.....	13
2.2.2 What will it look like?.....	15
2.3 Understanding the Standard	16
2.3.1 ISO 9001 Management System Model.....	17
2.3.2 Structure of ISO 9001 Standard.....	18
2.3.3 More Models.....	19
2.4 Getting Started	21
2.4.1 Project Launch (optional).....	21
2.5.1 Where are we now? the Gap Analysis.....	22
2.5.2 Typical Gap Analysis Findings.....	23
2.5.3 Creating a Baseline Plan.....	25
2.5.4 Indicative Project Schedule.....	26
2.5.5 How long 'should' it take?.....	26
3. DOING IT: PHASE 1	27
3.1 Defining the What: Policy and Objectives	27
3.1.1 What and why policy matters.....	28
3.1.2 Planning: Setting Objectives.....	31
3.1.3 How to Set Objectives.....	32
3.1.4 How to Write Good Objectives.....	35
3.1.5 Objectives: Using Them.....	38
3.2 About Documentation	41
3.2.1 Why Document?.....	41
3.2.2 Documentation Required by ISO 9001.....	41
3.2.3 Typical Document Patterns.....	42
3.2.4 Do We Document Everything?.....	44
3.3 Controlling Documents	45
3.3.1 What needs control?.....	45
3.3.2 How to do identification.....	47
3.3.3 How to distribute/release documents.....	48
3.3.4 How to do version control.....	49
3.3.5 How to control external documents.....	50
3.3.6 How to do approval or sign-off.....	50
3.3.7 Controlling data.....	52
3.4 Don't Start Writing Until You Know this	52
3.5 The Quality Manual	53
3.5.1 Writing the Manual.....	53
4. DOING IT: PHASE II	57
4.1 Managing Resources	57
4.1.1 Human – Your People.....	57
4.1.2 Other Resources: Infrastructure & Environment.....	62
4.2 Defining the 'How To' – Processes & Procedures	63
4.2.1 What <i>Is</i> a Process?.....	63

4.2.2	Why processes are important	64
4.2.3	Grouping Processes.....	65
4.3	Your Business Processes	66
4.3.1	Identifying and Mapping Processes	67
4.3.2	About Design	70
4.3.3	Measurement and monitoring – processes and product.....	73
4.3.4	Process Relationships.....	75
4.3.5	Process vs Procedure.....	76
4.4	Documenting the ‘How To’	78
4.4.1	Why Document Processes or Procedures?	78
4.4.2	Guidelines for Writing ‘How to’	79
4.4.3	Checklist for Reviewing.....	85
4.5	Supporting Processes	86
4.6	Other Requirements	86
4.6.1	Equipment used to monitor or measure	86
4.6.2	Infrastructure and maintenance.....	87
4.6.3	Invoicing and billing.....	87
4.7	Suppliers & Purchases.....	88
5.	DOING IT: PHASE II CONTINUED.....	91
5.1	Progress Review.....	91
5.2	Selecting the Certifier.....	91
5.3	The ‘Management Review’ stuff.....	93
5.3.1	How <i>Not</i> to Do It.....	93
5.3.2	Management Review – the real stuff.....	94
5.4	Those Mandatory Procedures.....	98
5.5	The Problem Stuff.....	98
5.5.1	What is it?	98
5.5.2	Understanding the terms	99
5.5.3	The procedures.....	101
5.5.4	Two simple and systematic approaches.....	102
5.5.5	Was action effective?.....	105
5.6	Improvement Tools and Techniques	105
6.	PROVING IT: PHASE III	109
6.1	What about customers?	109
6.2	Managing Your Records.....	110
6.2.1	What’s a Record?.....	110
6.3	Internal Audit	113
6.3.1	About Internal Audit.....	113
6.3.2	What Quality Audits Are Supposed to Do.....	113
6.3.3	Audit Guidelines	115
6.3.4	How to write up actions (corrective/preventive action)	116
6.3.5	Sanity check – is there a trail?.....	118
7.	PROVING IT: CERTIFICATION.....	119
7.1	What will the auditor look for?.....	119
7.2	Stage 1 Audit	120
7.3	Final Preparation.....	121
7.3.1	The ‘Big Three’ that Auditors Scrutinise Closely	122
7.3.2	Help! THE Audit is next week & we just changed something	122
7.4	Stage 2 Audit	123
7.4.1	What to Expect.....	123
7.4.2	During the Audit.....	124
7.4.3	Do We Get It?	125
7.4.4	Certifiers are service providers.....	126
7.4.5	Problem audit (very rare).....	127
7.5	Are We There Yet?.....	128
	APPENDIX A: TASKS LIST	129
	APPENDIX B: RESOURCES LIST	130

1. 'Getting It' – Before You Start

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

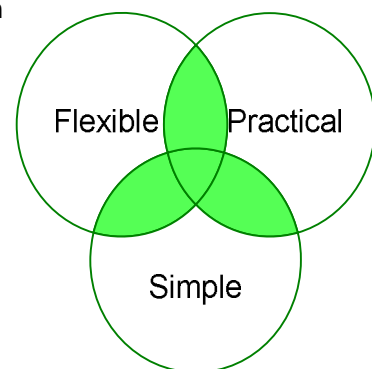
If you understand these, you'll work more efficiently and run your project more easily. Many past clients have said they had difficulty until they really 'got' this stuff, and wished they'd understood it earlier. So bear with me, even if some of it seems a bit theoretical, because plunging ahead without it is a bit like trying to drive without reading the road rules.

1.1 About the IQ Approach

The Intelligent Quality (IQ) approach is based on three key principles.

The aim is to achieve a quality management system that is:

- ♦ Simple
- ♦ Practical, *and*
- ♦ Flexible.



Simple: A system should be as simple as it can be, as simple as it's possible for it to be.

Practical: It should be pragmatic and as easy as you can make it: a system that suits your organisation, its particular context and customers. You definitely don't want something that's fine in theory but which simply doesn't work in practice.

Flexible: The system can accommodate changes and exceptions and 'special cases'. Because these happen, and a system should be able to handle them, rather than being dogmatic or unyielding. The system can be changed when something changes in your world, and also can be adapted and scaled up or down when needed.

Simple, practical **and** flexible.

Some systems achieve one of these; some may achieve two out of the three. But the most effective quality management systems have all these three characteristics working together harmoniously.

At times, you may have to weigh up the pros and cons of one principle against another, to decide what is more important in that particular situation.

For example, one so-called solution to a problem is for someone to create a new form. "*From now on, every sale must be entered onto Form 123 and given to the salespeople to enter*". At first glance, this looks 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?

Unless this is a 'once in a blue moon' event, and unlikely to ever happen again, your system should be flexible enough to accommodate such events. And the '*No Sale without a Form 123 Rule*' won't.

If you adopt *Simple, Practical and Flexible* as a guideline from the IQ approach, I am confident you'll achieve a robust system that works for you *and* gets you certification.

1.2 About Management Systems and Models

This section briefly explains what a 'management system' is and a quality management system. If you need some basic understanding about systems, see 'What is a system?' in the website customers-only section.

1.2.1 Management systems and systems thinking

A 'management system' is a particular type of system: one that is used to manage and direct an organisation such as a commercial business or a non-profit like a charity or a school.

Thinking in terms of **systems** helps you to take a broader perspective, and then to consider and interpret patterns and events in an organisation from that perspective.

Applying systems thinking to management and organisations is a comparatively recent development. Once, managers would typically take a single aspect (say, 'low sales') and put all their attention on the Sales Department. Once they'd got better sales happening, they would then switch attention to another aspect, such as 'delivery'. The problem was that this approach was limited to parts: it didn't take into account the system as a whole. If you've ever had the frustrating experience of being told 'the Accounts Department does it this way' or 'oh, you'll have to contact Delivery about that', then you've had first-hand experience of the weakness of that approach.

Because any company may have some or even all very good departments which operate very well – good sales force, good delivery systems – but which are isolated from each other and effectively operate alone. They aren't integrated into a harmonious whole. Which usually means that the company as a whole suffers, and often the customer as well. (As a customer, if I get a supplier like that – "no, DepartmentName doesn't do it that way" then I transfer my custom to a better one.)

Systems thinking recognises that every organisation is comprised not just of various functional parts (teams, departments or divisions) but also of **systems** and even subsystems. For example, there's a quality management system to make sure customers get what they want, a financial management system to manage the money side of things, a safety management system to make sure the workplace and its people are safe; there may also be an environmental management system. Or you can think of all of these systems as making up one large entity (the enterprise-wide system) of which the various components are subsystems.

As systems thinking and its importance has become better understood, it's become more common to be aware of the need to understand how the parts of a system interact or affect each other, for example, sales with service delivery, service or product design with sales and production, and so on.

Also, to be proactive rather than reactive: to focus on the **outcomes** wanted, and then deliberately create the processes and structures needed to achieve them. Then if problems arise, you diagnose and respond to them by looking at the larger patterns of interactions (the processes) rather than just looking only at individual components, such as a department or a person.

Making the shift from thinking individual components or departments to thinking about a system is a big change of mind-set. And immensely valuable.

1.2.2 Management models

We use models frequently to make sense of our world. Models help us to find or give meaning by recognising patterns we've seen before, or perhaps by creating new ones. Models are created internally – 'in our heads'. And in the same situation, different people may form different models, and will thus see things very differently.

Models shape thinking and behaviour. They may cause us to expect certain outcomes from activities. For example, a manager with the mental model of how recruitment worked in a previous company illustrated below would probably expect it to operate much the same in their new organisation.



Models are how we represent the reality we perceive, so they are *always* simplifications of the situation or thing itself. And models change and evolve with new experience, values, beliefs and priorities; they also may change when challenged by new information.

Imagine how it must have been to be a sailor setting out on a long voyage to the unknown, when people still believed the earth was flat. Moving from a model of the Sun revolving around the Earth to one where the Earth revolved around the Sun caused enormous upheavals. Which illustrates the conflicts that can arise when people are convinced that *their* model (or version) of reality is a truer or better representation of reality than that of others.

Why are we talking models? Because you probably already have a mental model of your business. And the ISO 9001 Standard uses a particular model of a quality management system, which we'll look at shortly.

Systems need management

Another thing to understand is that systems themselves **need** to be managed and maintained. No organisational system can be just left to 'manage itself'. They don't and won't. If left to themselves, individual system components will become selfish and compete; the situation will deteriorate.

There are two paths that any management system takes. If attention is paid to it and effort is put in to structure, manage and it, it will evolve and become stronger and better. If it is ignored or neglected, it will deteriorate and gradually fall apart.

The choice is yours.

1.2.3 What is a quality management system?

The term *quality management system*, often shortened to 'QMS' or just *quality system*, is often used to mean different things. And because people may interpret it differently, you need a clear understanding in your company of what is meant, so everyone operates from a shared understanding.

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

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 couple of years? Are you successful? If you're a business, are you making a profit? Are customers returning? Are you getting new ones? Is business expanding? If a non-profit, are you meeting the terms of your charter, the reason you exist?

Tip: I've mostly used the term 'business' or 'company' throughout this Guide for brevity. If you're a trust, foundation, non-profit, charity, government department, instead, please just swap that term where needed.

If you answer yes, 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, delivered 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 – a quality management system that gets your services and/or products to customers.

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

Typical small business pre-ISO 9001

Over many years of consulting to companies wanting to get ISO 9001, and many, many reviews and assessments of their current status against the requirements (a gap analysis, of which more soon), there's one almost universal feature:

Pre-ISO 9001 organisations usually don't have a robust and well-developed **system** as much as they have some **people** who are quite invaluable.

These people are essential. They know the important things. Usually it's because they've been there for quite a while, and accumulated a store of knowledge. Usually kept between their ears.

Very little is codified or captured, ie, written down. Things are usually passed on by word of mouth. If things are written down, usually it's only a few essential bits and pieces – perhaps because they found not having it written down caused mistakes, lost time/money and unhappy customers. Or Jenny went on holiday and the boss realised before she went that no one else knew how to do her job. Or they brought in a lot more people, and then found that those new people just didn't seem to know what to do. Because of course, they hadn't been round long enough to find out.

Can you see that this isn't much of a 'system'? And definitely not one that would meet ISO 9001.

While the picture is most frequent in small businesses, surprisingly often it's the case in medium and even larger ones as well.

Businesses can grow and become quite successful, but still struggle from a lack of good systems, because they are still trying to operate using the ad hoc 'growing like Topsy', people-dependent methods and processes that worked up to now, more or less. And without effort to maintain and develop your system, it won't keep pace.

Do you have a system or critical people?

- ♦ Your customers get what was agreed some, or even a lot of the time, but at times there's a great deal of frantic effort behind the scenes to make it happen.
- ♦ Customers get the right products or services provided that Fred or Francesca is there; if they're away things fall apart.
- ♦ Tony leaves. His replacement keeps asking questions that no one knows the answers to, and there's nothing written down which says how things should be done. And no one knows where Tony kept certain things that someone else depends upon to do *their* work.
- ♦ You know different people are doing things in different ways. "Why don't those new people know it's done this way? Didn't anyone tell them?"
- ♦ Things start to 'fall between the cracks'. Things work OK sometimes, but not others. The same or similar problems or failures keep cropping up. And when you have any stress on the system (a sudden increase in business or a big turnover of staff) it gets much worse.
- ♦ Business is expanding, you're growing very fast but some things are starting to fall apart, or you think they may do.
- ♦ You're the owner but you're working most if not all the time. You just can't afford to take time away for a holiday, even though you'd love to.

Sound familiar to you? If so, you probably don't have a system as much as you have some critical people. But don't worry, because we're going to improve the situation.

Why are you in business?

Most businesses answer *to make money*, and that's a just fine answer. To do that, you:

- ♦ Supply a service or product
- ♦ Give the market what it wants (deliver to your customers' requirements)
- ♦ Supply products/services when they are wanted (deliver on time).

The system you use to do that is a *quality management system*.

You will also add in something that prevents you from going broke (because there's no point in that):

- ♦ Supply your service or product at a price the market is willing to pay and which suitably compensates you.

So at its most basic, you could describe quality as producing what is wanted, when it is wanted, so that you achieve your aims. For a profit-making business, that is most often making a profit and staying in business. For a non-profit, it will mean fulfilling the mission or objectives of your organisation (and not going broke).

What the term means

When I use the term 'quality management system', I mean:
it's the system you use to manage your organisation, to ensure requirements are met consistently and customers get what they want and was agreed.

Note that 'requirements' includes both *explicitly* stated customer requirements (those that are detailed on a purchase order or a proposal or a website or a phone call) and *implied* ones – normal, reasonably expected or even demanded by legislation.

The system itself consists of various components, including management (whether that's one person or several or more), resources (people, tools, equipment), processes (how things are done), documents (policies, procedures, checklists, forms etc also IT systems) and records (evidence that shows things were done).

Some examples of quality management systems

Consulting firm	System ensures that individual consultants use a consistent, agreed approach to understand client requirements, document them in a proposal, and deliver them as agreed. Implied requirements include a professional approach, courteous staff, adhering to all relevant legislation.
Training company	System ensures that students are taught what they wanted to learn, and the content of the course matches what was described. Implied requirements include qualified staff, having the right information about courses, receiving good course materials, a suitable environment and resources for learning.
Security firm	System ensures that suitable personnel maintain security at the venues they are booked to attend, and follow the company's code of conduct, including dress and behaviour requirements. Implied requirements as per consulting firm.
Manufacturer	System makes sure products meet specifications, that customers get the right products which will suit their requirements, and are delivered on time at the agreed price. Implied requirements include meeting any Standards and legislation applicable to the product.
Restaurant	System ensures customers receive what they ordered and their meals match the description. Implied requirements include pleasant staff and environment, meals received in reasonable time, a clean kitchen and all health regulations met.
Construction	System makes sure customers get a building that is built according to the detailed specifications and plans, to the price and timeline agreed, and that the building is fit purpose. Other requirements include meeting all relevant codes, standards and regulations and passing all required inspections.
Non-profit counselling organisation	System ensures that clients see qualified, registered and experienced counsellors, and are provided with advice and help appropriate for their situation. Implied requirements would include confidentiality, respect and support for clients, non-discrimination, etc.
Real estate company (realtor, property sales),	System ensures there is a similar approach by sales personnel to listing and selling properties to the price agreed with client. Implied requirements would include complying with all relevant legislative or regulatory requirements.
Distributor	System ensures that suitable products are sourced from suitable suppliers, and delivered to the customers. Delivery could be direct from supplier to customer, or the distributor might warehouse, store and deliver the items themselves. Implied requirements could include products meeting safety and other standards demanded by the particular state or country.

5.3 The 'Management Review' stuff

The term 'management review' is often misunderstood. Many people believe the Standard says you 'must' have a regular Management Review Meeting and that you 'must' have a documented management review procedure.

By now you should know that if you hear something like this, you should go back & read what it actually says. In fact it doesn't say either of these things. It *does* say that you (senior management) must review what is going on in your business at 'planned intervals' – that is, not ad hoc or reactive reviews. And that you should be checking to see that things are going as you planned, and doing something about it if they aren't. It also expects you to consider if you can do things better (improve), and to make changes when and if necessary. Which is what **any** good business manager would be doing anyway, surely?

Again, it's simply good basic business sense. In fact, it's so basic to what people do in business, that they often overlook the fact that they are doing it. And then think they have to do something more, or have a special kind of meeting for 'management review'. You don't.

What you do have to do is to decide how you will best meet the requirements of the clause, and be able to show the records to demonstrate you are.

Management review falls into both the Plan and Study phases of the PDSA cycle. It closely relates to your goals and objectives, because you need those in place (Plan) before you can review whether you are on target, study the results and decide what to do next (Act).

5.3.1 How *Not* to Do It

One way of doing this (which I *don't* recommend), is to set up a completely new meeting, held quarterly or biannually, say, and to write up a formal 'Management Review' procedure, and have an agenda which lists all the things from clause 5.6.2:

- ♦ Audit results
- ♦ Customer feedback
- ♦ Process performance and product conformity
- ♦ Status of preventive and corrective actions
- ♦ Follow-up actions
- ♦ Changes
- ♦ Recommendations for improvement.

The result? Usually you end up with a few people sitting in a room (if you can actually get them there) in a meeting they don't want to be at but think they have to have, with an agenda they don't really understand. Wondering what on earth they are supposed to be doing and how they should be doing it.

And probably thinking very rude thoughts about 'quality'.

I don't know about you, but if I was an MD heading into a meeting with an agenda that started with Audit Results and then moved on through items called 'Process performance and product conformity', followed by 'Status of preventive and corrective actions', I might start wondering why I ever thought I wanted ISO 9001.

'Surely these people understand I have a real business to run! This stuff just takes up valuable time and I really can't see the value... I suppose this means we'll have to cut short our usual management meeting, but that's really important today.

We just **have** to decide how we're going to implement our new marketing strategy ... and I really want to know what the response has been to that new service we tried out with Ashtons. Hmm, wonder if we'll get that Barnes & Borne job? We must have a pretty good chance. If we do, it's probably time to think about putting another person on because we'll then have enough forward work lined up to make it worthwhile. Maybe also we should bring forward the due dates on our training & development plan ...'

Hold it right there.

That **is** management review.

The *real* stuff.

5.3.2 Management Review – the real stuff

The 'real stuff' of management review includes the meetings and discussions you have with key managers and/or team members. It's the thinking and planning you do about new services, improving existing ones, changing things to make them better, do things cheaper or faster, do more for your customers, or find new customers.

It's the reflecting you do on things that went wrong, and how you could avoid that in future. It's taking customer feedback and channelling that feedback into your business, making alterations and fine-tuning. And it's also the planning for new services or products, for opening new locations, new business growth ... the working **on** your business, not working *in* your business (Michael Gerber again).

The Standard says you have to do this management review stuff, but again, it doesn't say how. The how is up to you, remember, because it's your business. So make what the Standard calls management review work for you. Yes, you have to show you do it to meet clause 5.6, but make sure that what you do is valuable to you, that it reflects what you actually do and works well for you.

It is not possible or advisable to be prescriptive here, because it depends on issues such as the size of your business, the number of managers, how you are organised, how you do this stuff now, and what will work *for you*.

Management review is *not* a single meeting, let alone a single activity. In fact, contrary to misinformed popular opinion, the Standard doesn't even stipulate meetings. It's entirely possible to do it without meetings.

Review by management is a collection of activities that can take place in a number of different ways, venues or forums. But this area can be tricky, because owners/MDs are often the people who least like to follow a system. That's another reason why it needs to be their system, one that supports rather than hampers them.

Tasks – Management Review

- Identify how or if you do 'management review' currently.
 - Identify the various ways in which management performs its review functions currently; how do you monitor what is going on now?
 - If you have meetings, identify what key meetings or discussion forums you have. What issues are considered and discussed in which forum? What is decided where? Except in a very small and simple company, consider a matrix of meetings, such as the examples below.
 - Check what records you keep of your 'management review' activities.
- Check your findings against the inputs required in clause 5.6.2. Are they all covered? If any are missing, make whatever changes are needed to ensure they are all covered.

Note that an agenda doesn't need to list all items from 5.6.2 by name: **do** call things by the names that **you** use and that make sense in your company. You then just explain to the auditor, for example, that an 'Action Request' or a 'QI' or a 'Red Flag' is the way that your company deals with nonconformity or corrective action.

- Make sure you have records to demonstrate the outputs required by 5.6.3. If there are none and it's just verbal, or doesn't cover minimum requirements, you *must* make changes. Various of your *DIY Milestone Plans* (page 25) and your notes on those (or an equivalent) can serve as records of your planning, review and progress through to certification.

Examples can include: minutes, action items, summary reports, even diary notes, emails. The owner of one company has offices around the country and a total staff of 18. He sends out a weekly 'email roundup' of news, status, issues, etc. to keep them all informed.

Another example: You have travelling sales people or interstate staff who send in a weekly report by email. Instead of deleting them, create an email folder and use it to store them (for say 3 – 6 months). They can be used as records of your 'management review' activity: you do look over them, don't you? (If not, why get them written?)

- Include the status of your quality management system project in *at least one* of the forums for management review, as an agenda or action item or a circulated report.
- If you described management review in your quality manual, review what you said. You may need to update it if you made changes.
- Keep doing management review and reviewing how you are performing (both *system and organisation*) *against your objectives*, not solely sales or product/service.

Watchpoints

- ✘ Don't overlook the need for management to consider the results of audits. Sometimes people forget about this because you probably aren't at the audit point yet. But you will be.
- ✘ Avoid the trap of having the special 'ISO 9001 only' meeting. Make systematic review of performance part of the fabric of your management system.