John Mason's Plain Text

Quality Management Systems

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Quality Management Systems

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Forward

This is the second book in a series called 'John Mason's Plain Text' and for good reason. When speaking all things quality, I speak quite plainly. No rocket science, no dark art, just plain text. I propose to talk with you, not at you, in these pages. And yes, the book talks nothing but quality management systems. Not environment management systems, not safety management systems, and perhaps just a little bit about integrated management systems, but mostly quality. Why? Because I live and breathe quality.

Many thanks must go to many without whom this book would had never seen the light of day but in particular the following are dear to my heart; Linda Mason, Tegan Mason, Alison Mason and Jessica Mason for giving up their time and opportunities while I hunched over the keyboard. Thanks also to Nicole Baines and Jeff Goodman.

The following are my pecuniary interests. I am the managing consultant of the consulting company quality.com.au. This is one of the trading names of a holding company Oberon NSW Pty Limited of which I am the managing director and shareholder. quality.com.au is certified to ISO 9001, ISO 14001 and AS 4801 (circa 2014) with Global-Mark. I am also a shareholder, subcontractor, nonexecutive chairman of Global-Mark. Does this influence my outlook, recommendations and advice? Probably, but you can make up your own mind.

And lastly, if you like what you have read, send me an email at I.Like@quality.com.au and let me know why. I will publish your kindness on the web. On the flip side, email me at I.Dont.Like@quality.com.au and should your feedback make it to print, I will send you a free copy of the next edition.

Enjoy the read.

John Mason

Introduction

Introduction

The main purpose of this book is to breakdown the International Standard ISO 9001:2008, and provide an outline of the requirements needed to develop a quality management system.

The book comprises three main parts:

1. This introduction;
2. Strategies and
3. Requirements

There is some overlap and none a prerequisite to another.

In the requirements section I follow the order of the clauses and sub clauses of the Standard.

The book draws on my personal experiences in my quality management systems journey over the last 22 years (circa 2014).

What I can say with confidence is each business is unique and what I have set out to do is explore what can be done by a business without a prescription.

Details concerning the certification processes are contained in a previous book, John Mason's Plain Text – Quality Certification. This book, however, does contain some commentary on the essential strategies of certification.

There is no right or wrong answer to the conceiving, planning, implementing and managing of a quality management system.

Ultimately the how and the why is up to you and your business to determine. My own belief is that all companies have some semblance of a working quality management system, thus making the question redundant.

The real question and ultimate answer is (and no, it is not 42!) "Can I improve our quality management system and should I base it on an accepted standard/ model?"

Yes should always be the answer to both questions.

That leaves you to determine what the best organisational fit is for the time and place.

In my consulting business (quality.com.au) it simply makes:

- good policy;
- good practice;
- good, process;
- good productivity and
- good sales and marketing.

You will notice that I didn't use the word best. That certainly doesn't mean we are not close to best. What we really are is fit for purpose which by any definition is what quality is all about.

The demographics of quality.com.au are:

- Small number of employees;
- Large number of subcontractors;
- Small number of clients;
- Small number of suppliers;
- Medium number of complex projects;
- Large number of referrals.

When we talk to a client we do not refer to the quality management system as a quality management system and we do not structure it based on perceived structure requirements for certification purposes.

We can do this because we are experienced consultants who know the nuances of the standard and of the business. But if quality certification isn't your core business, then trade-offs need to be made. Trade-offs don't mean poor practice, they mean tailoring activities to meet an organisational fit for purpose at a given time.

By way of example, this story might assist.

One of the first things I did when I got my first managerial role (in a quality department of a consumer packaging company) was to treat my 'little' department as a discreet, stand alone company. I had a strategic plan, a budget, set policies, documents for internal use and documents for external stakeholders and so on. None of this was a direct requirement of any KPI or management expectation. Our department knew all about it but we never referred to it or promoted it as the quality management system for either our own purposes or the company's.

By default, as we were called the quality department, it was seen as a quality management system, but the ease for others to adopt such processes as and when they saw a need for such systems meant it was, by degree, adopted by many other areas of the business.

The moral of the story is:

- walk the talk of your own systems and strive to make them better for all stakeholders today;
- then, should a need arise to formalise or test the systems to known models or certifications, do so without compromise and
- be just a little bit clever when keeping all stakeholders appraised and appeased.

What are the benefits?

A client's experience

There are many benefits from a quality management system. You need to decide if any of the following fit into your current strategic plans. If they don't, there are probably a multitude of other reasons why you should (and of course, why you should NOT) have a quality management system.

If it fits your strategic plans today, review the fit tomorrow and if circumstance has changed, your benefits may have too.

Here is a list of benefits our clients have gained by implementing a quality management system:

- business rules;
- governance;
- policy setting;
- communication;
- succession planning;
- transitional management;
- marketing;
- government contracts;
- client requirements;
- due diligence;
- business review;
- benchmarking;
- knowledge management;
- documentation management;
- resource management;

- peer recognition;
- point of difference over competition;
- cost reduction;
- gross margin improvement;
- and many, many more.

Remember, a good quality management system is organisationally and culturally seamless within the entire business which must be 'walked and talked' by everyone in the business.

quality.com.au's experience

Without our quality management system, quality.com.au does not have a business. That's right, no business.

Our quality management system is a seamless part of how we do all of our day to day activities, reports and reviews. In fact, it is not even referenced as the quality management system. It just exists.

Imagine a sole trader back in the midst of the 'recession we had to have' (circa 1991) establishing, expanding and managing its growth into Australia's most successful quality management system consultancy.

How? By developing and using a quality management system.

And after 22 short years (circa 2014), some 17 years after the 'death' of quality management systems, our business continues to grow on the back of sound business rules and operational processes that are embedded in all facets of the business.

Decide for yourself what benefits you could gain from a quality management system thoughtfully and professionally infused into every aspect of the business.

Do they deliver better business?

The fundamentals of a well-designed quality management system will:

- ensure more business through sales;
- deliver more business through customer retention, and
- provide more business through cost reduction.

Big claims. But true.

A quality management system will ensure the most effective sales process is in place and will ensure this process is replicated throughout the business. It will ensure the correct pricing is presented and most importantly, that the terms and conditions are understood and delivered consistently. It will also ensure the full sales cycle is being driven to increase sales conversions.

Customer retention can be achieved by addressing customer needs in a timely manner, providing a consistent message, meaningful data gathering, determining satisfaction and early detection and resolution of any logistical issues.

Once you have attracted more business and kept it, it is time to drive margin improvement via cost reduction. This can be achieved through the continual improvement focus of a quality management system.

A quality management system is the systemisation of processes of a business. By documenting, learning, doing and improving, a business can optimise and improve its performance.

If you have time I would suggest you read an excellent book (not quality management system related) called "The E-Myth" which explains how the most successful businesses of all time are actually quality management system based. Simply, once a business owner systematises a business so that they can work

on the business rather than in the business, the sky is the limit to the growth of that business.

This is a practice that I have enthusiastically adopted and as a result, I am recapturing more and more of my time each year while still growing my business.

Do they deliver more sales?

There is no easy answer to this question.

What I can say is that having quality management system certification DOES NOT guarantee you will win government work. If you are establishing a quality management system and then trying to get it certified solely to win government work, DON'T.

I have seen numerous companies who have obtained government work without certification. I have also come across companies that once awarded the work, have been allowed by the government to develop and / or certify a quality management system.

In reality, Government departments are the same as everyone else. They are looking for price, quality and service when they tender. Being certified avoids the risk of not winning business because of the "convenient" excuse of "not being certified."

Strategies

Which quality management system model?

The answer is the one that is right for your company (and then perhaps for your customers and then your suppliers). But at the end of the day, it must be the very best management tool for your company to enable it to achieve your desired business outcomes.

There are many models you can choose to design a quality management system around. In fact there are thousands of templates available as a starting point, but they should only be used as a template to be modified to suit the corporate culture and commercial risk exposure of the market sector within which your company operates.

This book will focus on quality management system models based on ISO 9001:2008.

Platforms and Software?

I have reviewed most Australian based platforms and software products for quality management systems and also some international and online products. I have even used (and would highly recommend if it were possible) an in-house built and supported quality management system.

However, to date, I have not put my name to any of them, nor have I maintained a recommendation of them. It doesn't mean that I haven't recommended a product in the past. In fact, I am currently promoting a document system as I type (circa 2013). I have left the name out of the book as the review is incomplete, but am happy to share with you if you go to my LinkedIn profile.

I have used many systems. I have signed agreements and promoted many systems but only after completely restructuring my own quality management systems onto their platform.

Each promised a panacea of solutions to all quality management systems woes. The majority do most things required by a quality management system. Some do it all.

Most:

- do more than is required;
- require the company to do things differently;
- require you to double handle data;
- will flood you with emails and reminders and try to give responsibilities to people who just don't want it;
- try and replace already established software and platforms required by different disciplines within the company.

All of them are too complex, difficult to understand (remember, this is the dark art of quality management systems) and have too many rules thrust upon non quality

people which, to them, quickly pigeon-holes the system as just another bureaucratic attempt to strangle the business.

I am sorry if I have offended my past and present software colleagues. I don't mean to.

By way of explanation, I have had these discussions with them and will continue to do so. Most empathise with my call for simple, user friendly interfaces and the non-proliferation of information when not needed. They are, of course, restricted by the platform, the development structure, the perceived solutions and the inevitable, trying to be all things for all scopes of quality management systems.

And so, we make no assumptions on platforms or software. We work with what is intrinsically embedded in the company and the culture of knowledge management. If a client is using one, we will work with it. If asked to comment or critique we will do so but only if asked.

The Standard

If you are seeking quality management system certification within Australia, indeed, in the world, there is only one standard - ISO 9001:2008.

There are local derivatives, for example in Australia it is called AS NZS 9001, in the UK it is BS 9001, but these are identical to each other and the ISO version in all aspects other than name.

There are also industry standards, that some industry associations or industry sectors may impose on the market, but these are not generally internationally recognised and cannot be part of a certification, for example; ISO 16949.

Required Procedures

Since 2008, the standard requires 6 documented procedures.

These documented procedures are found in the following clauses:

4.2.3 - control of documents;

4.2.4 - control of records;

8.2.2 - internal audits;

8.3 - nonconforming product;

8.5.2 - corrective action; and

8.5.3 - preventive action.

No other clauses require documented procedures, but they do require established processes that have records to demonstrate effective controls.

You are permitted to merge some of these procedures. For example you can merge:

- control of non-conformity; and
- corrective actions; and
- preventive actions,

in the one documented procedure.

It is critical that you ensure you meet all requirements from the standard for these three very different elements. You just can't give the procedure a tri-name and expect it pass an audit.

You can combine document management and records management into the one procedure but, as described above, make sure you address all aspects of both areas.

I have also seen the internal quality audit procedure merged with other procedures such as management review, compliance monitoring.

I don't recommend this.

Why? Auditing has a very specific set of requirements and if you miss the mark conceptually, you will be punished in third party audits.

I will define the differences between process and procedures later in the book, but I support the incorporation of core processes into documented procedures.

As examples it could include sales, management review, purchasing, operations, test equipment and design control. All other aspects of the business are left up to your desire to capture anything else.

Please keep in mind, that if there is a process and it is uniformly followed by all relevant persons, the proof will be in the records generated as opposed to whether you have or need a clever documented procedure to describe it.

Which management system first?

There are other management systems based on published standards and those other systems have a core focus of risk identification and mitigation.

These systems relate to:

- quality;
- environment;
- safety;
- food safety;
- electronic data security.

There are others but I have restricted this list to only those systems based on standards that can be certified.

The decision to sequence and to design and implement any one or more of these is a very personal and business situational question. As a caveat, please keep in mind the trading name of our consultancy (you know, quality.com.au).

The decision as to which one, in what sequence, or whether to integrate them, is just as personal and so I will not sequence them as a group other than to state that you should always start with a quality management system and add or integrate the others as you see fit or as you need. Of course, this can be done simultaneously, but make sure the core structure and processes are quality management system based.

Integration

There are common elements when integrating quality, environment and safety management systems, and some processes can be merged.

Remember most people only think in silos, so why not keep your management systems in silos as well. Better still, let people 'think' they are in silos.

Use terminology that suits the reader and the reader's frame of mind. If it is known as 'xyz' in environment circles, then call it that in the initial stages. There will always be plenty of time for ownership and true integration once you have stakeholder buy in.

The best resource I have ever used when designing a bespoke integrated management system and or adding additional management systems to a quality management system is a hand book from Standards Australia; "HB 139-2003 - Integrating Quality, Environment and Safety Management".

It contains well thought through cross reference tables and notes on each clause, and sub clause.

Ensure you have a thorough understanding of the ramifications when integrating elements from different standards. Cross reference tables will provide the most effective assistance.

The differences between standards are clearly defined in the hand book. But the requirements for documented procedures are not.

With quality, the standard says, "a documented procedure shall be established".

For the environment it states "the organization shall establish, implement and maintain a procedure(s)."

Safety is the same as environment with the exception of the 'odd' statement such as this "Procedures shall be in place to ensure that…" This doesn't refer to a documented procedure. It means a process (the same as quality) but auditors sometimes interpret the requirements differently, so care is required.

The difference between forms and records

There doesn't have to be a difference, provided those discussing them have the same intent. In fact, the standard doesn't talk about forms, it talks about documents in general. But in the quality world, both forms and records are different and need to be managed very differently.

Here are some simple definitions.

A 'form' is a structured document, either online or offline specifically designed to collect data in a prescribed format.

Normally, a form is used to collect data for a database so that further products or services can be processed.

The form itself is known by its own identifier, its name, its number, its intent.

My favourite example of a form is the annual leave form for my company. Without it there is no annual leave. As we don't use form numbers, it is simply called the 'leave form' because it is also used for sick leave, special leave, etc.

Now a record, by my definition, is a collection of data. Sometimes such data is online, sometimes it is collected on a form, sometimes it is just a discreet unit of measurement.

It is simply a piece of information representing a whole or a part of the required data. The record itself is known for its content and not what is was recorded on or in it.

Therefore my favourite form, the leave form, once I fill it in, is no longer known as a leave form, but John's annual leave record for July 2012.

The most important part of this whole definition, transition story is that you need controls for each part. Such controls are varied and are very different in design and implementation.

Before you head off and put policy and procedure behind each, get your definitions clear and your journey will be far simpler.

Structure your system for certification

During the design process for a quality management system, I like to know who is the proposed certification provider and if possible, who the proposed auditor will be.

Why? Like it or not there are some certification providers, and some auditors who have preconceived ideas about systems and structure.

During the design phase, there are some structural issues that really don't matter what you do, so it makes sense to ask your certification provider or auditor what their expectations are and design accordingly.

Remember, that they are not allowed to 'consult' and will be quite reticent to give you any structure or direction. Similarly, some of them have almost unique outlooks on documentation, so temper their suggestions with an internet search for best practice around any suggestion.

A good thing to do is to keep such things to the time of the document review, when they will necessarily make judgements and by default give you directions as to their interpretation.

At the end of the day, neither you, nor your organisation or customers really need a particular direction in a particular facet. You can always change it later, but if it makes the certification process easier, why not do so.

Implementation Overview

Designing a quality management system is simple. The proof is in the pudding as they say. My questions are, who are 'they' and have 'they' ever tried getting an administration clerk to raise an improvement request?

My best advice is, once you design it implement it. Nothing more, nothing less.

Don't wait to get the process or the procedure perfect before implementation. That just won't happen.

Remember do, review, change, and plan. An over-arching implementation strategy should follow the following steps:

1. Launch;
2. Awareness;
3. Promote;
4. Tool-up;
5. Do;
6. Audit;
7. Correct;
8. Management review;
9. Start again.

Over the next few chapters we will explore each of the above. Personally, I like to get visual with these steps, especially for my own project management.

If you can make a visualisation simple, you can use it in management reports and in launch, awareness and promotional communications within the organisation. It may seem a little glib, but set up a bulletin board (hard copy or virtual) and keep the information simple and relevant.

Have a countdown clock to milestones or to the next milestone, etc. Put the answers to 'pop' quizzes on the board forcing people to visit and so and so on. Why not 'focus' your marketing department and get them involved in the process. It might even be fun.

Communication

There is a clause in the standard that talks about communication. Clause 5.5.3 Internal communication.

To paraphrase; top management must ensure that appropriate communication processes are established within the organisation and that communication takes place regarding the effectiveness of the quality management system.

Did you notice the lack of documentation needed? What is required is appropriate processes of communication. General these are notice boards; emails; newsletters; tool box meetings; management review meetings; sales meetings; etc.

During the design phase, structured communication (that is when, who, records) should be defined. In particular, these should be around quality awareness and management reviews.

In the implementation phase, a really good marketing and sales strategy for rolling out the quality management system is a very important part of any awareness programme.

Not sure how to do this? Why not consult with the marketing department and choose a strategy as with any product or service your company offers. Have a countdown clock. Have competitions. Have a naming workshop for key elements of the system such as getting rid of the old acronyms with something a little more user friendly. And so on.

Make bold announcements in big fonts and colours. Start a 'social network' campaign or even some gorilla marketing with 'walkway art' or car window flyers. The sky is the limit. In short make it fun and involve your staff.

Make sure what you do communicate is truthful, meaningful and of course ratified by top management.

Consultants

Opportunity costs of using consultants

From a consultant's perspective, our projects normally fall into one of three design and involvement categories:

1. Project management only;
2. Project management joint venture; and
3. 'Just do it all'.

Project management is all about…. project management. At quality.com.au we oversee the design of the project plan and then ensure milestones are met using assigned internal resource to do the work.

Nominally, a typical project would require about 5~10 days in total with the internal resource needing to spend at least one day a week for the duration on the documentation and implementation.

The project management joint venture scenario means we will do the project management. We will write the documentation. We will assist in the implementation.

As the business you have to be proactive and share information with your colleagues, aggregate comments, decisions and reviews, attend meetings, ensure implementation milestones are met whilst remaining the management representative for the organisation. This means we will spend 10~20 days on our side of the equation and you will need to dedicate one hour per week for the duration. This is our most common approach and generally our clients' preferred approach.

An even more effective solution involves building the system incorporating quality.com.au as the quality coordinator conducting the implementation of activities including:

- management reviews;
- document control;
- corrective actions; and
- internal audits.

By using this approach we can reduce the number of days for the project, reduce your time to one hour per fortnight, and there is very little ongoing work once you get your certification.

The 'do it all' approach has the least impact on your internal resources. It costs a little bit more, but when combined with ongoing support, it means you can set and forget whilst receiving the accolades for the end result.

It is often as simple as attending some training sessions, a few meetings and your task is completed. Although not our preferred model of execution, it is effective when lead times are tight.

As always, the approach is up to you.

Selection

Engaging external consultants to do a short-term project is common in business. Not so common is hiring a technical expert on an ongoing basis to manage an aspect of your business. Hiring either for the first time can be a little intimidating.

As this is a book on quality management systems I will stick to my knitting and explain how to engage consultants and technical experts in this field. There are whole books and short courses on consultant selection and they may assist to achieve a better understanding.

And since I am a person who:

- Is engaged for such a role; and
- Engages short-term technical experts.

I will look at both sides of the equation.

The reality is that most consultants will do most things for a fee.

Why? They need cash or they think they can do everything. Be wary of both. If they 'need' the contract and I mean are 'desperate for the contract' their judgment can be skewed.

My biggest asset in such a process is 22 years in the quality management systems consulting sector. This means that I know who are my class a, class b type clients and prospects and more importantly, who are my class c and class d type clients and prospects.

I know what I like to do (yes, quality management systems) and I will gladly establish whether I am the person for the job quickly before wasting time and resources on both sides of the discussion. If, during the discovery stage I determine that I am not the right fit, I give the prospect an out, and more importantly, an alternate provider to contact.

Fees

There are many ways in which to charge a client and many providers have found, and are constantly reinventing them. The main factors determining price are supply, demand, technical expertise, track record, costs, fair gross margin, client expectation, client engagement, outputs, etc, etc. The biggest caveat I can give to this chapter is that you DO actually get what you pay for.

Looks like normal business? It is. When outsourcing to consultants, don't expect to get someone full time (or near enough) at a modest hourly rate. If you wanted that, then you should hire someone. If you are truly after a 'teach a person to fish' result, expect to pay a premium.

A warning – don't get the most expensive at the shortest possible involvement and lead time. This is a recipe for throwing good money after over promised outputs.

When it comes to the determining the total fees for a project, here are some of the factors that determine the final amount:

- 1. Who is doing what work;
- 2. Is there a need for a project director, manager, consultant, consultant support, administration, etc? Each have different fee rates, each have different time constraints;
- 3. Remember that most consultants in this field are sole traders. Sure they might have a Pty Ltd but they are just sole operators who fill the function of all the positions listed above. Some will average the hourly / daily fee and charge you the one rate for the entire project, some will bring on resources as needed, and others just take best guess and hope to land the work;
- 4. Be careful and ask for details if you are unsure. There will always be a lump sum. The project will require a certain amount of hours or days within a certain lead time;
- 5. Technical expertise will need to be retained for known milestones;
- 6. Your consultant will need to determine the volume of work based on the resources you will need;

- The more resources you provide, the less you will need from your consultant.

And so the 'mythical' equation is dusted off and a number evolves. The hourly / daily rate is applied and the lump sum appears. Quite often this figure is large and mostly because it has to be.

Expenses

There are also always costs, and expenses. Some are direct, many are indirect. As a guide:

- 1. Your consultant needs to indicate what they are;
- 2. They need to estimate based on known parameters;
- 3. They should agree to anticipate costs within budget constraints and with triggers to highlight those out of their control.

Complicated? Not really. Just make sure they are itemised, estimated, as you would with any expense allocation and that there are 'rules' around what are automatic, what are within budget, and the 'what ifs'.

As an example a good consultant can plan such expenses and costs to within a thousand dollars for a project with interstate travel over the course of a 12 month project. Just make sure that wriggle room estimates are itemised and included for budgeting.

Once you have negotiated the price, the costs, the expenses and to the best of your ability, the unknown, you should be satisfied with the lump sum, the hourly / daily rates, the level / class of travel, etc. If you are not, fix it. Importantly, do all your negotiations before engagement.

There can be some rise and fall in final figures due to contingency, but don't use ignorance or unhappiness to stall payments once payments fall due.

Invoicing and terms

One point of contention with invoicing and payments are the 'agreed' terms of payment. Normally consultants will ask for 7 days.

Why? Basically, most of their costs are wages, if not their own, then their subcontractors. Most expenses will also need to be paid upfront and if there are terms they are generally a maximum of 28 days interest free on a credit card. So expect 7 day terms.

If your company cannot accommodate this, then decide what they can accommodate and communicate. Don't just sign agreements and expect your consultant to be happy when your normal terms are 30 days, extending to 60 days depending on when invoices are lodged and as cash flow permits payment.

It is not good business not to discuss these matters, and then disagree on them after the event. Don't agree to terms you cannot meet.

Once payment terms are agreed, the following will also need to be discussed and agreed;

- formatting of invoices,
- when and where to lodge invoices,
- personnel involved with lodgement, and the process goes on.
-

The most practical and successful course of action is to make the process easy for all stakeholders for transparency, review and processing purposes.

Our current best practice with all projects and ongoing support agreements is to make invoice values as uniform as possible. We start with a commencement fee (normally 20%), then equal payments per month based on the lead time of the project. Whether we turn up or not, the monthly invoice is the same and is lodged on the 15th of each month. There are no surprises. We then invoice for expenses as they are incurred.

Contracts

The main conditions of any contract should be lead time, lump sum, expenses, deliverables, certification, expectations, resources, what ifs, etc. It is important to focus the document on 'intents' rather than the minutia that is a quality management system. Critically define "must have", "would like", "best practices".

Get the terms of the contract right and keep them as plain English as you can.

We have 10 terms in our standard agreement. Below is the first of them.

1. Project modification

Your company is afforded the right to terminate the contract at any time, with your company only liable for fees and expenses incurred up to the termination notice.

The remainder of our terms are really housekeeping and reaffirmation of particulars described in the contract.

Keep your contracts simple, reflective of each party's intentions and vitally maintain open communications. Once you are on the same page and comfortable with the client / consultant you have selected, the remainder is rolling up your sleeves and getting the business done.

DIY Opportunity Costs

When we start down the path of quality management system design and discovery we are usually asked the question 'How much time and money do I need to contribute to the project?'

The answer is never simple. But there are some guidelines based on the deliverables for any given project.

You can design, implement and get a quality management system certified by yourself, it isn't rocket science.

A quality management system is a framework to ensure the 8 principles of quality can be achieved. There is an international standard that provides a structured approach to this endeavour and it is really only a matter of reading the requirements, interpreting them and developing policy, process, procedure and records around what you and the company want to achieve.

Sounds simple? You just need to:

- decide on resources;
- time;
- budget;
- learn any new skills;
- plan the project;
- etc.

And then; if you are internet savvy and if you are clever, you can start from ground zero to certification hero within 12 months. If you can dedicate say one day a week, you'll do it in a shorter lead time. It will take a little longer if less days are committed or if you are doing it by committee, and if will be dramatically shorter if:

1. You bring a 'walk before you run' strategy to the plan;
2. You use a "keep it simple" first, then modify into more elaborate processes as needed;
3. Adopt the biggest time frame shortener in the 'let's not wait until it is perfect' scenario.

All of these scenarios impact the opportunity costs of the entire project.

Plagiarism

Personally, I do not advocate plagiarism and don't do it. I research best practice and glean from what others have tried, but copyright is copyright, so don't do anything illegal. If you want to use something in particular, then seek permission from the owner, and or give credit or links to the source.

Plenty of my original material has been reworked, redeveloped, re-quoted, re-sent and then shown to me over the years but I generally take no action. Why? Because I know that it is not the form or the written procedure that makes a good quality management system, rather it is the intent and the leadership that will make something work.

Procedures -v- Processes

There are no real differences in the real world but in quality management systems there are a number of intents surrounding these two.

Procedures are a set of instructions in a prescribed format and order giving the reader an understanding of how a number of different processes interact.

A process is an implied rule or understanding of a particular activity or set of activities.

In certification, it is normally accepted that procedures are documented in some manner. ISO 9001 requires 6 documented procedures.

However, the standard also asks that 15 types of quality management systems records are generated to verify the effectiveness of a quality management system.

You cannot generate a record of an activity unless there was a process generating that record. Instead of documenting a procedure describing how that record is generated, all a quality management system needs to do is demonstrate the process is understood and applied uniformly in order to generate the desired records demonstrating effectiveness.

In other words, if the process is simple, the staff competent and the records readily retrievable and demonstrable of the desired outcomes, you don't need to write a procedure. But there are other reasons why you would want to document a procedure, including improving knowledge preservation, succession planning and training resources. As always, that is up to you, your business and your risk profiles.

Procedures -v- Work Instructions

To the 'lay' person, there is no difference.

To the partially informed it is a convenient differentiation in an attempt to de-value a document when found by an auditor.

To the expert, any document that has been generated to describe a process, no matter the detail, the prescription or the intent, should be judged by the end-user and subsequently reviewed for accessibility, relevancy and most importantly, its impact on the total system.

What is the difference and when should you have one, the other or both? Once again, the situation is totally up to the client organisation and the end users.

By definition, documentation within a quality management system is broadly broken into a number of categories. These being:

- vision;
- policy;
- procedure;
- instruction.

The structure and format can be determined by the company and or end users with the intent being:

- vision - overall strategy;
- policy - a business rule or ideology as a subset of vision;
- procedure - what has to be done to achieve policy;
- instructions - the minutia to comply with procedure.

As discussed, the standard only requires six documented procedures and records to be generated to verify fifteen

processes (see the applicable chapter), and does not stipulate any requirements for additional documentation.

That is left completely up to the need of the organisation and normally as a consequence of risk management. That means if you want work instructions to explain in detail or to prescribe strict process, use them. The format is up to you including. screen shots, pictograms, photos, etc. It is totally at your discretion.

Make sure that if they are to be valued, you apply the same document control measures as you do for all your quality management system documents, use them in training sessions and include them in internal quality audits.

How to start

Before you start a quality management system, you need to establish a business case to do so. There are significant costs and restructuring around some quality management systems so you need to be prepared.

Don't just get one because you think you will get more government work. Do your research, talk with your suppliers and speak to your peers and customers. Learn from their experience. Your business case can be as complex or as simple as you desire, just make sure there is a return on investment and measure it.

Once you have the business case, sell it to management. Demonstrate the return on investment and what will be in it for them. Say things like; better governance, more profits, less waste, greater succession planning and knowledge preservation.

Once you do this you will have management buy-in. Without it the design and implementation may not necessarily get the desired return. With it, you will get active participation and a better resourced outcome.

Now that management are behind the project, it boils down to typical project management techniques. The first steps are to determine the goals, objectives, desired outcomes, resource availability and time lines. With this data gathered, a simple Gant chart will get you started and you are on your way.

Planning

Planning is a fundamental element for the success of any business and any quality management system. My planning guidelines (no particular order):

- bullet points;
- use brain dumps;
- have a target end date;
- plan at macro level;
- determine resources and shortfalls;
- choose a sponsor;
- obtain a budget;
- be realistic;
- determine review frequency;
- record planning changes and why;
- communicate and promote plans;
- make plans visual;
- give plan priority;
- don't miss deadlines;
- know why deadlines are missed;
- start today (if not today, this afternoon);
- "don't panic" (thanks Douglas Adams);
- chunk up;
- focus.

The following system elements are in order for planning and development of a quality management system:

1. Quality policy;
2. Quality manual;
3. Internal audit procedure;
4. Corrective (and preventive if desired) action procedure;
5. Management review process;
6. Document management procedure;
7. Records management procedure;
8. Control of nonconformance procedure;
9. Training process;
10. Any other elements you feel you require.

As with life and business, failing to plan is a plan to fail. So get on with it. Get a piece of paper or a blank screen and start writing down those bullet points.

Structure

When considering the structure of your quality management system, you need to be aware of the platforms and the environments within which the resultant documentation will be presented to the end user (a topic in itself). From there, you choose whether to structure the system into manuals, discreet files, departmental portals, etc, etc.

Is it on an intranet, internet, cloud, protected drive or directory on a LAN? Is it in hard copy? Yes, there are still cases for quality management systems to be in hard copy. And so the question of structure goes on.

It comes down to organisational, cultural, and personal choices for both the end user and the administrator as to what structure is best suited for readability, control management, version management, navigation, etc.

Do you have single documents, as single electronic files or do you aggregate all documents, including forms into a single file, structured as a manual? And yes, as you guessed, it doesn't matter!

Each choice or option comes with its own pros and cons. Each requires subtle differences in document controls, version controls and the physicality of making sure hard copies are updated and available.

Remember, that a consistent approach is more advantageous (but not mandatory) and that if there are exceptions to your rules, define them and document them.

Forms

By definition - A 'form' is a structured document / medium, either online or offline specifically designed to collect data in a prescribed format.

Normally, a form is used to collect data for a database so that further products or services can be processed. The form itself is known by its own identifier, its name, its number, its intent. My favourite example of a form is the annual leave form for my company. Without it, there is no annual leave. As we don't use form numbers, it is simply called the 'leave form' because it is also used for sick leave, special leave, etc.

There are no rules regarding forms. They need to be purpose built for the job.

Identification protocols are probably the most important aspect of a form and this is really only important so that it can be found.

If the resting place of forms is electronic, and hopefully under controlled access conditions, then version or issue control identifiers are mute. This doesn't mean you can ignore identifiers, version controls etc, it just means that you have to have the relevant controls in place to suit.

What I am saying? Be savvy. Be simple. Don't fog the document with confusing annotations, numbers, amendment histories, signatures and the like unless you absolutely have to.

You will know when your forms are useful and under control, when the people know where to find them, use them completely (no blanks), have the correct attachments and signatories and don't need to be reworked once they hit the next stage of the process. If not, you will need to go back to the drawing board because a good form becoming a great formis just part of the quality journey.

Work Instructions

In the not too distant past, work instructions were an integral part of any detailed or complex quality management system. They were expected to exist. So what are they?

My definition is - A structured, documented set of commands giving direction, describing process in detail.

They are quite specific to the task at hand, to the individual piece of equipment or component currently being operated. They prescribe with no room for interpretation.

The simplest form of work instruction is the '1' and '0' on a switch. On or off - there is no try.

Quite often the user manual of any piece of equipment is a good example of work instruction. They can be in any format; pictogram, flow diagrams, text, electronic, help screens, etc, etc. They should follow the same rules concerning document management but some choose to have them remain outside the quality management system. The main reason for this is the volume of instructions, their frequency of use and the need for frequent changes.

So why have them?

If you are serious about your quality management system and you have robust risk management within the system, your own organisational / risk needs will determine if you should have them or not. Reasons to have them would include succession planning, training resources, technical benchmarks, reference materials for infrequent processes, cross checks, etc.

Don't be misled by the certification or consulting fraternitythat insist all details of all processes should be documented in order to make their jobs easier. Always temper such requests by considering frequency of task, risk, collected data, probability

of errors, etc and once you have an informed judgment, react accordingly.

How to structure procedures

At the risk of repetition, there are no rules!

There are some document management requirements to ensure that you have the most current documentation at the right location, but other than that it is up to the business.

I have seen and or developed some very typical procedure formats. These are very structured, highly stylised, magnificently automated, colour, online, etc. At the end of the day, your users / readers will determine how effective they are in communicating a message, a rule or a structured set of instructions.

No matter what structure I use, the structure is deliberate and purposeful. Quite often it is to de-complicate a requirement of the standard, or an attempt to eliminate the double handling of information.

Try not to add complexity to the structure for cleverness, accuracy or perceived ISO needs. If you do, the reader quite often loses the desire to read and or even start a document. Start with a summary, deliver the content and, should a deliberate structure be needed to conform to the standard, hide it, systematise it, or put it at the end.

The golden rule is that once you have a structure, stick to it. And if you find a better way to communicate the same message, do so and roll it out in a controlled manner over a short lead time. If you can't, then perhaps you should look at your documentation model anyway, because it might not yet be best practice.

Document Control

How you manage your documents should be structured around the risk to the company.

For example, in a law firm, structuring a legal response around an incorrect precedent is high risk. Using the wrong annual leave form is low risk (unless of course you can't go on holidays, then the risk lies with the employee!).

Having a document control system that can manage both scenarios is desirable, but not a necessity. There are some things that are so mission critical, so commercially sensitive, that they deserve the 'extra hard yard' of control to ensure things go right. Therefore putting them on 'Google docs' might not be the best solution, but in so many ways , it might.

It really is a mine field of exposure, mitigation and downright dumb luck, and these are just the documents over which you have complete control.

Then there are external documents. Those things that you need to use and adhere to but you don't publish or control. Forget just having a clever repository for them, you will need a process of review, issue and recall to ensure things go right, especially in the field. A great example of this would be drawings or specifications used at a construction site.

Unfortunately there are no definitive solutions to these complex needs. Some solutions are better than others. Some are just wrong.

Here is a very simple list to review when considering your document management; MS SharePoint, Google Docs, DocuShare, BaseCamp, DropBox, just to name a few. There are so many available via the cloud and some more worthy than others for review. The main selection criteria you should

consider are, single source of data, check in / out capability, version control, distribution control, data backup / recovery and others. Good luck.

Certification

The quality certification processes are described in part two of this book. However, if you have chosen the quality management systems only version, you can purchase all things related to quality certification at the bookstore.

It is important, however that you have some insights into the process.

Certification of a quality management system is a process of rules and requirements. It is perhaps the easiest component of implementing a quality management system. However, I have written an entire book on the process. So as you can imagine, there are plenty of rules and requirements.

Perhaps the best advice I can give, is to ensure you know the minimum requirements, don't wait for best practice within the quality management system and choose your certification provider wisely. Here are some words on these three.

Minimum requirements mean different things to different certification providers (so check their idiosyncratic variances) but at a minimum you must ensure the following has happened; or records are available to demonstrate that you have:

1. The mandatory written procedures available and meet the requirements of the standard;
2. Management reviews (x2) conducted and recorded;
3. Conducted all, or at least most, of your internal audits and they have been conducted and recorded;
4. An effective volume of nonconformances and corrective actions managed and recorded through a full cycle and
5. Made all personnel aware they have an impact on the system.

Don't wait for best practice to materialise via the quality management system. In some companies this may take 3 months, others 24 months and often, never.

Circumstance will dictate the lead time. An effective quality management system will ensure a journey towards it. But the reality is, if you cannot plan it or realise it with projected desired timelines, then ensure the minimum requirements are in place and subject yourself to the certification process. That will help identify a shorter path to your quality management system utopia.

Finally, and not necessarily the least of the three, the selection of your quality management system certification provider will impact the process. There are over 30 providers in Australia, and probably 100 times that globally. Each is different to the other.

Fortunately in Australia we have the Joint Accreditation Scheme Australia New Zealand (JASANZ) which ensures that all providers operate similarly and that each provides a bona vide certificate, normally recognised globally.

Despite this, they are sufficiently different operationally, with a different auditor pool, reporting requirements and interpretations that impact on the project. Treat them the same as any purchase of a key service provider and let them impress you with their customer service, price and quality of work.

Requirements

The Requirements Caveat

This is covered in the previous forward and introduction but for clarification here is another. I have not addressed every clause and sub clause.

Why?

Generally because some are just commentary, some are quite plain in intent. So if I have not covered it specifically, the reader will need to do their own interpretation and management. Sorry, but I am sure you are up to it!

If there is something of interest to you and I have not covered it in this book, please visit the link below and complete the details in the 'Ask us something' online form. I will provide the answer free of charge within 24 hours of receipt.

http://www.quality.com.au/contact.html.

The Standard

Standards for quality management system certification in Australia started sometime before 1987. They were mostly military grade quality assurance specifications for supply of 'materiel' (yes, military speak for inbound stuff).

In 1987, Standards Australia published their three quality assurance standards; AS3901, 3902, 3903. You could be certified to only one of them, depending on the scope of your organisation. The focus for each was based on these capabilities:

1. Design control, manufacturing, inspection; or
2. Manufacturing, inspection; or
3. Inspection only.

I have only ever seen one company with AS3903 certification.

In 1994, the three standards were merged, more closely aligned with the ISO standards and published as ISO AS/NZS 9001.

The 2000 revision was a copy of the international publication, with the final current version being published in 2008.

For historical purposes, the next few pages are my published summary paper about the changes to the standard and certification of the 2008 version. This is then followed by my thoughts on what will change in the 2015 version.

Both are very technical and a very dry read.

ISO 9001:2008 – changes from 2000

Clause 4 Quality management system

Clause 4.1 (General requirements) (a), instead of requiring you to "identify" the processes needed in your system, it now requires that you "determine" them.

This means that provided you know what they are, you don't need to specify them. Clause 4.1, now no longer requires you to define any outsourced processes, but you must define the controls used to control them. A new Note (2) in clause 4.1 now says that clause 7.4 may apply to outsourced processes.

Clause 4.2.3 (control of documents) has been amended slightly. The scope of "documents of external origin" has been clarified to state that it only applies to those external documents which are needed for the planning and operation of the system.

Clause 4.2.4 (control of records) has been extensively rewritten but seems to mean exactly what it did before.

Clause 5 Management responsibility

Clause 5.1 (management commitment) (a) now says "statutory and regulatory" instead of "regulatory".

Clause 5.5.2 (Management representative) clarifies that this must be a member of the organisation's own management, instead of just "of the management".

Clause 6 Resource management

Clause 6.2.1 (Human resources), clarifies that the competence requirements are relevant for any personnel who are involved in the operation of the quality management system.

In clause 6.2.2, training is now only required "where applicable" to achieve the necessary competence. The other changes to this clause are clarifications or changes for consistency with other clauses. Competence still remains a matter of interpretation rather than definition.

Clause 6.3 (Infrastructure) sub-clause (c) now includes "information systems" under the "Infrastructure of the organisation."

Clause 6.4 (Work environment), includes conditions under which work is performed, for example physical, environmental and other factors such as noise, temperature, humidity, lighting, or weather.

Clause 7 Product realisation

Clause 7.2.1 (Customer related processes), provides that post-delivery activities may include; actions under warranty provisions, contractual obligations such as maintenance services, supplementary services such as recycling or final disposal.

Clause 7.3.1 (Design & development planning), provides that design and development review and certification and validation have distinct purposes. These may be conducted and recorded separately or in any combination as suitable for the product and the organization.

Clause 7.3.3 (Design & development outputs), clarifies that information needed for production and service provision includes preservation of the product.

Clause 7.5.2 has always been confusing. In essence, if you can verify your products are correct before they leave the building, you probably don't need to validate your processes. Note 1 implies that the clause probably applies to service industries. Note 2 gives examples of some service industries and manufacturing industries to which this clause probably applies.

Clause 7.5.3 for Identification &traceability has been expanded. Product status must be identified throughout the production process.

Clause 7.5.4 (Customer property), explains that both intellectual property and personal data should be considered as customer property.

Clause 7.5.5 have been "harmonised" with 7.5.4 but their requirements have not altered at all.

Clause 7.6 (Now re-titled Control of Monitoring and measuring equipment), explanatory notes have been added relating to the use of computer software:

"Confirmation of the ability of computer software to satisfy the intended application would typically include its verification and configuration management to maintain its suitability for use."

Clause 8 Improvement

Clause 8.2.1 (Customer satisfaction) is now accepted that customer perception of meeting requirements is just an "indicator", not a measurement of the performance of the system. A Note is added to explain that monitoring of customer perception may include input from sources such as customer satisfaction surveys, customer data on delivered product quality, user opinion surveys, lost business analysis, compliments, and dealer reports.

Clause 8.2.2 (auditing) has been "harmonised" but its requirements have not altered at all.

Clause 8.2.3 (Monitoring / Measurement of process) two words have been added which could have a large impact on your system. The sub-clauses (a) - (d) only apply "where practicable". Also, the last sentence of the 2000 version of the standard has now been moved up to become sub-clause (d). A Note has been added to clarify that when deciding on appropriate methods, the organization should consider impact on the conformity to product requirements and on the effectiveness of the quality management system.

8.5.2 (Corrective action) and clause 8.5.4 will require a review of the effectiveness of the actions taken. (Most assessors and auditors currently assume that it says this already, although it doesn't!).

ISO 9001:2015 – changes from 2008

This is an update on the proposed changes. More changes are likely to follow once more comments and interpretations can be reviewed.

Be aware that the changes are not finalised.

There is an increase from 8 clauses to 10 clauses. There appear to be no more mandatory documented procedures. It will be left up to you to decide if you need something documented.

The current requirement for preventive action has been replaced by a new requirement - to determine and reduce risk. It seems to be semantics.

Much more documented information describing results of activities will be required. At this time precise details are not forthcoming.

Monitoring and measuring devices will go back to being called equipment.

The controls remain the same. Product is now called goods and services, which is an attempt to cover off on service providers and quite helpful.

Some things have moved from one clause to another, for example, document control, control of non-conformance and product realisation.

It does attempt harmonisation with 14001 and 18001 which is desirable, but unfortunately incomplete. What is really needed is one standard covering quality, environment and safety allowing you to select what is relevant to you. It does remove most of the prescription which is good news.

For auditors the bar is raised yet again. It requires them to have even more business acumen, exposure and savvy.

Don't forget that it is still a work in progress. However, from my perspective - bring it on.

Quality management system (4)

General requirements and process maps (4.1)

In this clause, there are a number of things that an organisation must do including identify processes, determine the sequence and interaction of processes, determine criteria and methods of control, ensure resource availability and monitor, measure and take action. Nowhere does the standard then imply that an organisation should then go out and produce flow diagrams, process flows, charts or maps to describe their business.

Although each of these tools is very useful, if they are not part of your culture or documentation, think hard about including them into your management system. Instead, other indicators / records that may demonstrate these requirements including your business plans, organisation charts, list of procedures and the structure and content of your procedures, might be more relevant.

Document control (4.2)

Easily the biggest number of pages in this book is dedicated to actual control or management of documents.

Firstly, some definitions need to be outlined. There is some repetition in these pages to what was covered in the strategies section, but it is vital to get this right. Not just for the standards sake, but mostly for the sake of the effectiveness of your quality management system.

What is a document? Some, if not most, think that a document is a form and that it needs to have some type of version or issue control displayed at the bottom of a piece of paper that you fill in to get annual leave (or similar). This is an example, it is not the definition.

In quality management system terms, a document is a discreet item that contains information relevant to the system. It can be in any format, medium, media (if there is a difference), it can be a description, an interface, a data collection point, etc, etc. And depending on the importance and risk to the system, will depend on the control of the document.

Control? Yes. What version, issue, distribution, status, colour, identifier, review, approval, disposal, archive, amendments, etc, etc.

In previous times this included stamping every single piece of paper with the words 'controlled' or 'uncontrolled'. Thankfully these days are gone. A simple footer note with a page number, issue number or date, file name now satisfies. Documents should have a version control box with author name, reviewers name, dates, version number, issue number, next review, and amendment history.

Online documentation version controls could include amendment histories, check-in / check-out status, read only, intranets, etc, etc. There are some very good proprietary products out there; none we endorse, but many we use.

The standard is quite clear on the requirements, and the beauty of the clause is in its intent without prescription. Read it carefully. I am sure you will identify or develop an appropriate measure of control to suit you.

My best advice is to control all documents in a uniform manner. Don't differentiate between system documents, non-system documents, whatever documents. If it is required by the company, control it.

Last century document control had an inordinate amount of focus from system designers and certifiers alike. There was the 'rule' that every piece of blank paper, form, instruction, procedure, process, policy, etc had to be controlled. And in some awkward systems, this meant that every uncontrolled piece of paper had to be marked as uncontrolled. It was the number one reason why a company was not certified on their first attempt purely by the volume of corrective actions around the controllability of paper.

In one of my 'horror' stories, the auditor asked me for the work instruction for a work station (one of 112 pieces of plant in this factory). The instruction showed issue 4, the register showed issue 5. They then asked for the corresponding drawing for the parts that were made at this station, and it too did not match the register. A 'major' nonconformance was raised. As a by-line, the 100% inspection of all documentation on all 112 work stations found that they were the only two documents misaligned.

Some of the older methodologies used in most paper based systems in the past were document registers, amendment lists and histories, stamped pages of obsolete, uncontrolled and superseded documents, title blocks, version controls, issue controls, signatures on registers, signatures on individual forms, defining authors, defining approvers, defining issuers and sometimes all of this information appeared on every page of every form, record, procedure, manual, etc, etc, etc. It was a nightmare which bogged down change, created barriers and created jobs for document controllers.

One of the defining moments for quality.com.au was the discovery of the formula for meaningful, lawful, certifiable means of document control that did not mean extra work, was

easy to use and was easily adaptable no matter what medium or platform was being used and I will share this with you over the next few pages.

How many procedures? (4.2.1)

Let me repeat this requirement from the previous section in the book. The absolute minimum number of documented procedures required by the standard is only 6 and they cover the following clauses;

- 4.2.3 - control of documents,
- 4.2.4 - control of records,
- 8.2.2 - internal audits,
- 8.3 - nonconforming product,
- 8.5.2 - corrective action; and
- 8.5.3 - preventive action.

All other clauses, while they do not require documented procedures, will require established processes and records that can demonstrate effective controls.

Quality manual (4.2.2)

The standard says; "The organisation has established and will maintain a quality manual that includes;

a) the scope of the quality management system, including details of and justification for any exclusions

b) the documented procedures established for the quality management system, or reference to them, and

c) a description of the interaction between the processes of the quality management system."

This does not mean that you have to have a stand alone 'manual' neatly packaging the standard and or the organisation's system. It can be a collection of documents, manuals, policies, etc. Some certification bodies 'require' you to have a stand alone document called a quality manual addressing each element of the standard.

There are pros and cons in this exercise but it largely up to you to decide if it is a requirement for you. The key issues behind this element are the justification of exclusions. Some will do this in management review minutes, some in defined capabilities statements, others in the ubiquitous quality manual. I recommend the latter so that it readily retrievable during a certification audit.

I also recommend that you take the referencing option with point b). I would also marry it to a cross reference table so that the correlation between the standard and your quality management system is apparent.

Lastly, a 'description' of the interaction between processes does NOT mean you have to have a process flow chart or a swim lane diagram or any form of schematic. These are most often used to keep the certifiers at bay, but provided you are comfortable with the description, your system and certifier should be satisfied.

Last century, a quality manual (especially as a requirement from some of Australia's certification fraternity) was a 're-hash' of the standard itself. Clause for clause, an 'answer' from your organisation as to what your quality management system does to address each element, clause, sub clause, section, etc.

As an exercise whilst developing your quality management system, this is a very good idea. It will ensure you are addressing the relevant sections. This would allow the management representative to demonstrate that they have addressed all facets of the standard. As a comparator in an apples -v- apples exercise, it is a good tool to compare organisations who are vying for your business.

Remember, it is not a requirement and if you are forced to have one just to satisfy a certification body, then its value is diminished significantly.

Document control (4.2.3)

The standard says with [comments from me] in brackets;

"Documents required by the quality management system are controlled" [and therefore by definition, those that aren't, aren't. Previously this meant that every other piece of paper has to be identified as not being part of the system. Today, you can be clever with scope, definition, registers, location, etc.].

"Records are controlled according to the requirements given in 4.2.4." [records demonstrating document control need to be generated, legible and readily retrievable. They can be hard copy, electronic, in a register or embedded in the document itself].

"A documented procedure has been established to define the controls needed" [this means you have to have a procedure and you have to have it documented. There are no exceptions].

"The procedure needs to:

a) approve documents for adequacy prior to issue," [set some rules, set some definitions, name names or titles].

"b) review and update as necessary and re-approve documents," [deem when this is necessary, explain what the triggers are, what mechanisms you use to record the update and then define who re-approves, which is normally the person or title who approved the original document]

"c) ensure that changes and the current revision status of documents are identified," [identified is the key word here. It doesn't mean embedded but it could. It means that either within the procedure, the register, amendment or the document itself. There are just so many options here. Pick the one that suits you, your readers, your organisational culture and stick with it].

"d) ensure that relevant versions of applicable documents are available at points of use."

[There is so much softness in this statement: relevant, applicable. So when you are designing a document control / management process, you will need to define what is relevant, what is applicable and make sure that you can demonstrate how availability is ensured. Recently, the use of an intranet will deal with most of these issues.]

"e) ensure that documents remain legible and readily identifiable," [Legibility is a mute characteristic or perhaps it is intrinsic and therefore not needed to be described. The key in this part is the ready identification. This is not prescriptive. It is left up to you and the system designer to determine who can identify a relevant, applicable, available document. The easiest way is to have a simple identifier, backed up with supplemental information and defined in the procedure.]

"f) ensure that documents of external origin are identified and their distribution controlled, and" [By my definition, an external

document is one which is not 'owned' by the organisation but needed by the quality management system. These can be supplier or client documents, standards, specifications, etc. A good way to control them is to maintain a register and review their relevance at defined intervals. The register should include who is the controller and where they are located.]

"g) prevent the unintended use of obsolete documents, and to apply suitable identification to them if they are retained for any purpose." [This clause requires you to define what you do with obsolete documents, e.g. remove from intranet, file in a specific directory and why they are retained and for how long.]

By keeping documentation electronic, most document control issues are easily managed, with most of the detail described in the mandatory procedure ensuring you are using the right form at the right time.

What is my position regarding external documents? My definition of an external document is; any document, irrespective of format, which your company does NOT have control of the content, but is used/referenced in your management system. Such documents include; standards, legislation, statutes, supplier marketing collateral, etc.

The best way to manage external documents is to treat them as any other document in your quality management system. This might mean scanning a document, registering a document and / or including the document into the document register, intranet or quality manual. There is no need to rename, renumber, etc. Just be specific with the naming conventions as with all other documents and ensure that there are 'triggers' in the system that will ensure external documents are reviewed and or re-issued as needed. This may entail a subscription service, treating them as inventory, ensuring your service

provider/supplier is aware of the importance to your company. The key is to remember NOT to make any extra work and to keep hard copy documents up to date at the various issue points.

Records (4.2.3.e)

The minimum records required by the standard, listed by clause number are:

- 4.2.3 - control of documents;
- 5.6.1 - management review;
- 6.2.2 – training;
- 7.1 - planning of product realisation;
- 7.2.2 - review of requirements related to product;
- 7.3 - design and development;
- 7.4.1 - purchasing process;
- 7.5.2 - validation of processes for production and service provision;
- 7.5.3 - identification and traceability;
- 7.5.4 - customer property;
- 7.6 - control of monitoring and measuring devices;
- 8.2.2 - internal audits;
- 8.3 - nonconforming product;
- 8.5.2 - corrective action; and
- 8.5.3 - preventive action.

You don't need a procedure to describe how these records are generated, just a process. Keep an open mind when designing your quality management system and only document what your business needs to ensure customer focus and profitability.

Records management (4.2.4)

This is not a complex subject but one that is critical to any organisation. Of particular concern is the duration in years that you must retain records to demonstrate conformance to a set of criteria, standard, statute or law. There are some amazing time lines for some very different types of operations.

Here is a sneak peak and some of the legal requirements for the retention of records:

- quality management systems = 3 years;
- tax records = mostly 5 years;
- personnel records = term of employment plus 5 ~ 10 years;
- environmental and remediation records = 30 years;
- some OHS requirements have no defined limitations, therefore some records are to be kept indefinitely.

On the path to legally sound records management, the first thing we should start with is a definition. Here is mine. A record is a single source, or a collection of data that demonstrates conformance to, nonconformance with, and or knowledge of, defined criteria. Regarding the difference between a form and a record, let's say a form is the defined criteria, whilst the data 'written' on to the form is the record.

The standard says; "Records are established and maintained

to provide evidence of conformity to requirements and of the effective operation of the quality management system. Records remain legible, readily identifiable and retrievable. A documented procedure has been established to define the controls needed for the identification, storage, protection, retrieval, retention time and disposition of records."

The first thing you must know for a quality management system is that you must have a documented procedure for this element. If you don't have one or at least have the above requirements addressed in a merged procedure, then you are noncompliant. The procedure must address:

1. Identification;
2. Storage;
3. Protection;
4. Retrieval;
5. Retention time; and
6. Disposition of records.

You will notice there is no prescription behind these requirements. You can address the requirements in each process or procedure or you can develop a matrix or table and describe these controls. There is no right or wrong way to manage records.

The only tricky component is the statement concerning "Records remain legible, readily identifiable and retrievable." This may require some training, some discipline, some practice. Just remember, that 'I can't find them' is no defense in either quality management systems or tax audits. It is worth running dummy runs on retrieval and readability, particularly if you are

relying on computer data. Don't forget how quickly equipment becomes obsolete – do remember 5¼" floppy disks??

Management responsibility (5)

Management commitment (5.1)

The standard requires "Top management to provide evidence of its commitment to the development and implementation of the quality management system and continually improving its effectiveness by:

- communicating to all personnel the importance of meeting customer as well as statutory and regulatory requirements;
- establishing the quality policy;
- ensuring that quality objectives are established;
- conducting management reviews; and
- ensuring the availability of resources."

The standard is quite explicit and it concerns the development, implementation and improvement of the quality management system. If you have a certified quality management system you will have the required evidence to demonstrate such commitment. In fact without that evidence, you wouldn't be certified.

Don't let auditors make you develop specific processes or procedures around the points above. Just make sure that in a cross reference document or quality management system road map, you have direct correlations between the standard and the evidence you will present as demonstrating conformance. Importantly, direct linkages need to be highlighted.

In a nutshell, develop a communication plan and submit it for management review or to a steering committee during the development and implementation of your quality management system. Refer to the quality policy, the goals and objectives

toward quality. Review each during management review and of course, make sure you have the right resources to achieve each.

Notice anything special about this clause yet? That's right, they are each mirrored / cross referenced in the body of the standard. If you get this clause right or the other 5 reference points right, you should self-determine and thus demonstrate the effectiveness. Don't fall into the trap of cross referencing between each element, without actually generating the required records. A rookie mistake made by many, so be aware.

Legal requirements (5.1)

There is only one small paragraph within the standard that talks about legislation. In other standards, there are whole clauses dealing with this. But this is quality and here is an excerpt;

"Top management provides evidence of its commitment to the development and implementation of the quality management system and continually improving its effectiveness by a) communicating to all personnel the importance of meeting customer as well as statutory and regulatory requirements……" and the standard goes on.

The standard just tells us we need to communicate legal obligations. It does not provide a framework or guidance (of course you can get this from "ISO 9004"). You will need to determine to what depth you investigate, and what your legal requirements are. For most companies, the minimum would include; tax law, fair trading law, OHS and if you pollute, some environmental laws. But we digress, as you should retain the services of a good corporate advisor for some of the trickier legalities.

We do have responsibilities to communicate (and if you are clever, review first) the organisation's regulatory and statutory requirements. I would normally do this as part of external documentation and management reviews. How you do it is up to you and the level of risk exposure.

As an aside, when going through the certification phase of your quality management system, your auditor will keep an eye on legal requirements because they are charged with the responsibility not to ignore legal obligations. This means whilst they will not seek legal compliance, they shut down an audit if they discover an illegal operation or environment. Be warned!

Customer focus (5.2)

What are the expectations with customer focus in ISO 9001?

There are three places that specifically reference customer requirements (ISO 9001 clauses).

(5.2.) Customer focus - asks the company to remember who keeps us in business and to look at the next two references.

(7.2.1.) Determination of requirements related to product - this clause really wants us to be sure you know what the customer wants (even if they don't), including protection of goods to the final destination. This nearly equates to the old 'contract review' with a little more emphasis on the customer.

(8.2.1.) Customer satisfaction - asks us to monitor information with regard to the customer's perception of us and whether we have met their requirements. The standard wants us to establish the methods and to review the data. IT DOES NOT mean you have to produce a survey or questionnaire and go through the expense of number crunching and reporting.

Think a little outside the box and see if you aren't already collecting this data through other means?

Quality policy (5.3)

Here are two dictionary definitions:

1. Wise, expedient, or prudent conduct or management;
2. A principle, plan, or course of action, as pursued by a government, organization, individual.

My definition is; a rule for, or intention of a group in a particular function. This not a vision or mission statement. Though mission, vision, value statements, etc are very important documents, they are not the subject of this chapter.

In the standard, the quality policy requirements are that "top management ensures the quality policy:

- is appropriate to the purpose of the organisation;
- includes a commitment to comply with requirements and continually improve the effectiveness of the quality management system;
- provides a framework for establishing and reviewing quality objectives;
- is communicated and understood within the organisation; and
- is reviewed for continuing suitability."

If you are developing a quality management system and thereby a quality policy, the interpretation given to this requirement is wide. If you are developing a policy with certification as an objective, then you need to address each

of the five requirements. Here are my thoughts on these requirements.

As a preamble, the need for top management involvement means that the policy should be signed, authorised, reviewed at the highest level of the organisation, at the highest form of strategic planning meetings, reviews, etc which should include the CEO, MD, etc.

1) "Appropriate to the organisation' - before you can determine appropriateness, you need to define the organisation. You can do this within the policy or in the scope of certification, but you need to do it. Once defined, the words will determine appropriateness.

2) State you will "comply with requirements" of the system (and if it is based on the standard, name the standard, ISO9001). State that you will continually improve the effectiveness. It does not mean you have to define how in the policy, but you can expand if you feel it is necessary.

3) "Provides a framework" does not mean you have to describe it. You can if you wish, but I would rather reference the framework.

4) "Is communicated and understood" - once again, you do not have to explain how, but a reference to the mechanism that ensures understanding is best.

5) "Is reviewed for suitability" - normally left outside the policy itself, but the review process can be nominated (not described) or at least a forward date documented that forces a review.

On the next page is a very simple policy which has a few assumptions outside the document itself.

Quality Policy

quality.com.au is committed to providing exceptional service in management system design, development, implementation and support.

Our quality objectives are satisfied clients and continual improvement. To ensure these objectives can be achieved, we have established and will maintain a quality management system which complies with AS/NZS ISO 9001.

Through our training programs, all employees and consulting associates have gained a sound understanding of this policy, our management system, and have been empowered to deliver service excellence. We will achieve our objectives through our focus, our commitment and our training.

This policy will be reviewed [insert date].

signature

John Mason

managing consultant

[insert date when signed]

The standard does not prescribe structure, the rules for review or the amount of detail. This is up to you. Have the top ranking executive sign it. Provide a date when it was signed. Include a date (or window / period) for when the policy will be reviewed. Remember "Provide a framework" does not mean provide a procedure or process description, it means refer to or just provide.

As a guide to the size required, one page is adequate, in fact, three easy to read paragraphs is ideal.

Put it on letterhead, get it scanned after execution, put it in a frame, put it in the foyer, put it on your web site and intranet. Include it in induction presentations, employee booklets, etc. And most importantly, walk the talk.

Quality objectives (5.4.1)

I will focus a great deal of attention on this requirement. A great deal.

Quality objectives are an integral part of a quality management system. They are often misinterpreted by both the organisation and the certification body.

It is easy to understand why, especially with the frequency of mentions in the standard itself and the lack of prescription around them. This makes them as diverse as the organisations trying to define them.

Before I explore quality objectives, here are the quality objectives mentioned ISO 9001:2008. It is a long list, so persevere.

"4.2 Documentation requirements

4.2.1 General requirements, the quality management system documentation includes a) documented statements of a quality policy and quality objectives,

5.1 Management commitment

Top management provides evidence of its commitment to the development and implementation of the quality management system and continually improving its effectiveness by c) ensuring that quality objectives are established,

5.3 Quality policy,

Top management ensures the quality policy, c) provides a framework for establishing and reviewing quality objectives,

5.4 Planning

5.4.1 Quality objectives,

Top management ensures that quality objectives, including those needed to meet requirements for are established at relevant functions and levels within the Systems. The quality objectives are measurable and consistent with the quality policy.

5.4.2 Quality management system planning,

Top management ensures, a) the planning of the quality management system is carried out in order to meet the requirements given in 4.1, as well as the quality objectives,

5.6 Management review

5.6.1 General,

Top management reviews the organisation's quality management system, at planned intervals, to ensure its

continuing suitability, adequacy and effectiveness. This review includes assessing opportunities for improvement and the need for changes to the quality management system, including the quality policy and quality objectives.

6.2 Human resources

6.2.2 Competence,

awareness and training the organisation will d) ensure that its personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the quality objectives.

7 Product realisation

7.1 Planning of product realisation

The organisation has planned and developed the processes needed for product realisation. Planning of product realisation shall be consistent with the requirements of the other processes of the quality management system. In planning product realisation, the organisation has determined the following, as appropriate: a) quality objectives and requirements for the product;

8.5 Improvement

8.5.1 Continual improvement

The organisation continually improves the effectiveness of the quality management system through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions and management review."

Now you know why I will spend plenty of time on this topic!

The very first question that should be asked is; "do you want to include quality objectives in the general objectives of the organisation?" There are no rules around this. Just choose one or the other and change it if it doesn't work.

There are some quite specific requirements from the standard and if you don't want to include such requirements around company wide objectives, then it is best to leave it at this stage so as not to jeopardise your certification program.

I personally keep them separate in the initial stages of a project so that the machinations have some focus. Once people are used to the objectives process, adopting others become less stressful. For those companies who have fully blown strategic and business plans that have already identified quality objectives, a simple overlay to ensure corrective structure and reporting is the best strategy. For my company, quality is a single objective within the strategic plan, which are then split into key attributes and managed operationally on an ongoing basis. You need to have documented quality objectives. They need to be linked from your quality policy. They need to have targets. They need to have assigned resources. They need to be reviewed. They need to be communicated.

Over the years I have managed this process for many clients and used many tools that address each of the above. The methodology and tool is very dependent on the organisational culture of the client. I never prescribe what they 'have to do'. Only via a process of discovery would we suggest a few models and then agree with the client the most suitable methodology. Of course, we have changed models if the original chosen wasn't quite working (and conversely, if it doesn't align what your auditor 'wants' to see). Don't forget the absolute minimum and remember there is nothing wrong with adding to the

requirements as needed.

So here are just a few ways to manage quality objectives:

- Include them in the strategic business plans;
- Include them as separate standing agenda items in company meetings and or management review meetings;
- Draft and maintain a quality objectives plan which is reviewed at company meetings and or management reviews.

Never have less than two objectives (and preferably have a third). The start-up objectives must be; customer satisfaction, continual improvement (and my add-on, achieve certification).

The standard describes the requirements of quality objectives in one small sub clause, in just two short sentences and it causes so much angst in the design, implementation and certification.

And here are the relevant words, again, "Top management ensures that quality objectives, including those needed to meet requirements for product (see 7.1.a) are established at relevant functions and levels within the organisation. The quality objectives are measurable and consistent with the quality policy."

So as far as I am concerned, the above does not say you have to have objectives stated in your quality policy. It does not say you have to have metrics around product characteristics and it does not say a whole lot more.

What it does require is you have objectives (plural) with at least one concerning product (or service) that are established, are communicated and are relevant to the person / function receiving the information.

Perhaps the most important process is to ensure that what is stated in your quality policy can be then 'converted' into measurable objectives for the organisation. This means that all quality policy components should have a corresponding objective and that there should not be any objectives that are not included in the policy statement.

Let us now look at the mechanics.

We now know what they are (or perhaps more importantly what they are not). Next is to link them from your quality policy, structure them and communicate them. You need all three to be compliant with the standard.

Having your quality objectives buried in your strategic or business plans is OK as long as they are linked from the policy. The questions are then can they be effectively communicated to all levels of the organisation and are they relevant to the person / function to which they are being delivered?

They must be communicated, and if they are in a commercially sensitive document then they won't be. You may need different tiers of documentation, and or accessibility. Remember to keep the reader in mind.

As yet we haven't spelt out what the objectives are. Once you have your objectives, you need to structure them along the above guidelines.

Clearly state the objective. Develop a program or process to manage the objective. Assign a measurable target or set of targets. And last and by no means least, assign resources to ensure that objectives can be met. It is no good having an objective that says 100% inspection of all 300,000 welds per year if you don't have the means, the people, and the know-how to do such a thing. But if you can keep these four things in

focus (objective, program, target, resource) when developing quality objectives, you might make things certifiable, perhaps even useful!

Now, I am finally going to tell you the minimum quality objectives needed for certification or at least to meet the requirements of the standard.

We have explored quality objectives from the standard and then the mechanics and the metrics, now we need to go to the requirements of the standard for 'quality policy'.

The standard says "top management ensures the quality policy:

- is appropriate to the purpose of the organisation;
- includes a commitment to comply with requirements and continually improve the effectiveness of the quality management system;
- provides a framework for establishing and reviewing quality objectives;
- is communicated and understood within the organisation; and
- is reviewed for continuing suitability.

From this we can distil two quality objectives:

- comply with the quality management system; and
- continually improve the quality management system.

Both can be measured via internal quality audit results and the corrective / preventive action processes. You can also use the certification process to measure compliance.

Have you noticed there has not been any mention of the customer or even focus on the customer or satisfaction? There

is none. There is an expectation that at least one quality objective will be structured around the customer, so have one and you won't have to debate it with the certification fraternity.

Now that you have your objectives you just need to word them correctly, set a target for each, measure them, report them, resource them and demonstrate that you can do all that and still react to any adverse trends within them.

Last words (promise). If I have designed your system, these will be hard wired into the management review environment. Not as an operational agenda item, but one of reviewing results, targets, resources and remedial actions.

Goals and objectives don't happen without an executive sponsor and they should sit at the stratospheric level of the company.

Once this happens, it will be up to senior managers and operational staff to make such objectives relevant to the operational needs and KPIs. If you can't do that, then you have the wrong goals and they are misaligned.

In the implementation phase of a quality management system, make sure at least one of your objectives is certification of your management system. This is a great way to demonstrate that objectifying a KPI is a journey, not just a stab in the dark.

Objectives or importantly achieving objectives is just a project. A project needs a timeline, resources, funding and results. Your objectives can last forever, especially if they holistically say to 'continually improve forever' but most should centre around tangible results, like double sales , halve costs, etc, etc.

Taking smaller steps first will give more impetus on the mechanism and keep morale at the right pace. Objectives can

be as simple as reducing rework costs of returned goods by 5%.

Bite sized chunks will let you practice before addressing the elephant in the room.

Keeping them focused on the elements of the quality policy will also ensure you are addressing multiple certification elements simultaneously and hence making the implementation phase run just a little bit more smoothly. Happy objectifying!

Responsibility and authority (5.5.1)

So much can go wrong with this requirement. The interpretations, or should I say misinterpretations, have caused so much grief for the uninitiated. So let's cut through the chaff.

The standard requires "top management ensures that responsibilities and authorities are defined and communicated within the organisation."

And that is it. Nothing more! So how can you do this?

Firstly look at the complexity, expectations, risk exposures and communications of your company. Is there something you already do that meets this one sentence? Does 'definition' mean documentation? The short answer is no, but the level of understanding once communicated, may require 'ensure-ance' via something that is documented.

Policies, responsibilities sections in procedures, published delegated authority lists, job descriptions, training records can be used either singularly, or in combination with each other.

To what extent? Here is an example from our own certified quality management system that maps out exactly who is who in the zoo at quality.com.au. We have an organisation

chart, job descriptions, 7 documented procedures (each with a responsibilities section), 18 policies (which are predominantly only a paragraph long) and training records.

Quality management representative (5.5.2)

The standard requires "top management has appointed a person who, irrespective of other responsibilities, has the following responsibilities and authorities:

a) ensuring that the processes needed for the quality management system are established, implemented and maintained;

b) reporting to top management on the performance of the quality management system and any need for improvement; and

c) ensuring the promotion of awareness of customer requirements throughout the organisation."

The specific duties of a Management Representative are; coordinate, conduct or facilitate that the above and the six mandatory procedures of the standard are documented, the required records are generated and most likely have a leading role in management review, document management, internal quality audits, corrective actions, preventive actions, quality objectives.

Nominally the Quality Management Representative will report to senior management and / or participate in senior management meetings in order to determine the performance of the quality management system and possible improvements.

The promotion of awareness of customer requirements means ensuring that the product realisation, sales, and or customer service processes are in place. Internal audits and subsequent corrective actions will ensure continuous improvement of these processes.

It can also mean a bit of creativity in communications to ensure all stakeholders within the company are aware of the quality policy, how to use the quality management system and how to report opportunities for improvement.

In the 2008 version of the standard, there is an explanatory note that says the Quality Management Representative could also have responsibility for liaison with external parties on matters relating to the quality management system. If you wade through the quality speak, that means that you are your contact with your certification body but this is not a prerequisite.

Internal communication (5.5.3)

The standard requires "top management ensures that appropriate communication processes are established within the organisation and that communication takes place regarding the effectiveness of the quality management system."

Did you notice the lack of documentation needed? However, you do need appropriate processes of communication. So what are these? They are; notice boards, emails, newsletters, tool box meetings, management review meetings, sales meetings, etc.

Do you need to document that you do this? No. Should you point to these processes in some fashion to make the auditor's life a bit easier? You don't, but you should be aware. I like to include specific examples in the quality management system

road map. Then there is the second half of requirement which directly relates to communicating the effectiveness of the quality management system. I like to include such a statement / minute in the minutes of management review. Once you do this the first half of the equation is met.

Then, decide how appropriately this communicates to the relevant levels of the organisation. If the minutes are freely available via notice boards, emails, shared drives, then do no more. If these are secret documents for senior management only, then you need to identify how you are going to communicate the relevant content to the troops. Just decide on the mechanism and do it. Be sure you include that mechanism in your road map!

Management review (5.6)

The requirements of management review for a quality management system is simple. The standard has its own clause. The standard defines the inputs and outputs. The standard then leaves it up to the organisation to define who, when, where and what format.

Just be careful. Some certification service providers have expectations. If you have already chosen a certification provider, why not ask them about their expectations concerning frequency, format or forum, etc. Don't ask them what to do but rather seek a clarification to ensure you are prepared. Don't be surprised if they are non-committal.

Although the standard does not require a procedure, I always write one. It should not be more than a page in length and should focus on; who attends, the minimum attendance, the frequency (no longer than annual is the expectation), define

the use of a checklist, a standing agenda, the minutes, reports, attachments, and responsibilities. Try and externalise the data submissions and review before a meeting occurs so as to minimise the time needed for the actual meeting. You can try and combine the requirements within other meetings, so long as they are relevant / complimentary.

Generate the minutes on the same day if possible. Always include reference to, and or, actual tabled documents. Always have an action list / summary and ensure that they are assigned to people with deadlines.

The rest is best practice in good meeting mechanics and corporate governance which will in turn ensure your management reviews, determine the effectiveness of your quality management system.

So let's implement the management review. You now know the rules and the structure. It is time to expose the process to senior managers. Sometimes this is not for the feint hearted, but if all things are going to plan, it is a wonderful time to shine!

In preparation for your certification audit, I recommend you conduct at least two management reviews meetings ensuring the meeting's minutes record all required 7 inputs and all 3 required outputs. Your management review meetings should also include any exclusions, any defaults (for example, external documentation or legislation), etc and of course the ubiquitous statement of effectiveness of the quality management system and whether it is meeting your company's goals and objectives.

The really good part of the implementation is the communication and focus. It will streamline senior management input and reduce the need for resource gulping reviews during project plan meetings. Keep the inputs to the

meeting external, gather and collate the relevant data and supply to all participants well before the meeting.

What is most important during these meetings is to proffer solutions to any gaps or bottle necks during this data sharing stage so that stakeholders can vote on solutions rather than discuss and think tank more work for you.

This is a very powerful and empowering phase. Enjoy it.

Resource management (6)

Resources (6.1)

There is a whole clause within the standard relating to resources, with this sub clause being an overview.

The organization shall determine and provide the resources needed; a) to implement and maintain the quality management system and continually improve its effectiveness, and b) to enhance customer satisfaction by meeting customer requirements. I don't know why this couldn't be lumped under some general category or sub clause but it is not. Therefore you need to address it and audit it. If you have the intent of continual improvement and customer satisfaction, then the very fabric of your system can validate this clause. And if it does, a simple reference within your quality management system cross reference table (road map) will suffice with such examples as management review and quality policy, just to name a few.

If not? Make sure there is ample description in your quality manual about how you will address the resource needs of your quality management system.

Human resources, competence, awareness and training (6.2, 6.2.2)

Personnel performing work affecting product quality are competent on the basis of appropriate education, training, skills and experience. This leads very nicely into the sub clause of competence, awareness and training.

The standard requires the company will:

- determine the necessary competence for personnel performing work affecting product quality;

- provide training or take other actions to satisfy these needs;
- evaluate the effectiveness of the actions taken;
- ensure that its personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the quality objectives; and
- maintain appropriate records of education, training, skills and experience.

On reflection, this is pretty self-evident. Simply break them down into their components and develop something to fit your company organisational and structural parameters. Don't invent anything here. If your training need identification is ad hoc, then let it be. Don't invent a performance appraisal system if there is no need or more importantly, no desire.

Over the next few pages, I will address 6.2.2 in more detail and provide some tips on creating evidence for your quality management system certifications.

Did you notice the terminology from the above five points? 'The company will; a)…. It doesn't say you need a documented procedure, but in my mind it is an advantage especially when framing the process to achieve certification. A simple procedure outlining the five bullet points would suffice.

For the first three do you have competencies (skills, training, awareness, certified, licensed, etc) that are needed to be able to operate equipment, to satisfy regulatory needs or as the standard asks, that impact on quality? If yes, list them and list the people who can.

We will deal with how later. A list of competencies can be attributes as well, just be careful. If such information is included

in job descriptions or position specifications, then 'listing' them will enable an overview but this is purely voluntary.

Next, review any gaps between desired or needed competencies and actual competencies. You can do this by 'deeming', appraisals, interviews, etc. Nothing is mandated here other than that you identify them and then deliver the necessary actions so that personnel can be considered competent.

Records of such reviews, delivery and results need to be kept. Either in the list, the person's employee file or some form of spreadsheet or database. Make sure you are not duplicating records that are already controlled.

Then, evaluate the actions. Can they now do the job to the level of expertise you want or need? Do they have a certificate or license? Can you observe their performance and deem them competent. It is always up to you, just make sure there are records.

As you can read above, the standard is very specific concerning the requirements of training. Now as the project manager for the design and implementation of your quality management system, it is time to walk the talk based on the requirements of the procedure or process you have determined, designed for the company.

When determining training needs, here are some assumptions; everyone will need to be made aware of the quality management system and the impact they have on it, the management representative will require specific training, internal auditors must demonstrate competence (and independence), personnel named in the relevant procedures must demonstrate competence, operational processes are conducted by competent personnel.

The rest of the training needs can be deemed, identified during appraisals, customer feedback, management reviews, new product, process, materials, equipment acquisitions and so on. Use the relevant tools to capture such needs, then plan and deliver making sure at every step that appropriate records are reviewed and generated. Get copies of qualifications, licences, permits, etc and group them by employee or discipline. There are no rules, just make sure you define and adhere to your own organisational requirements.

One of the best tools for mentoring, observation, deemed experience, internal training, etc is to test the individual and to keep a record of it. As an example, a 30 minute training video / presentation should have a five question pop quiz at the end keeping it to either a multiple choice or true / false format. This will determine a rudimentary understanding of the person and provide you with a record of effectiveness. Make sure you communicate with the person if they get any answers incorrect.

Infrastructure and work environment (6.3, 6.4)

Personally, I just don't know why these clauses are in the standard. It begs the question why don't we have the other one million company attributes in the standard that we need for product, service conformance or even that nasty little thing called customer service??

The infrastructure clause (6.3) requires that a company has determined, provided and will maintain the infrastructure needed to achieve conformity to product requirements.

Infrastructure includes, as applicable; a) buildings, workspace and associated utilities, b) process equipment (both hardware and software), and c) supporting services (such as transport or communication).

The work environment requirement (6.4) is that a company has determined and will manage the work environment needed to achieve conformity to product requirements.

Some auditors have grabbed on to the word 'maintain' in the first paragraph of 6.3 to mean maintenance programs, service records etc, but have you noticed there are no requirements for process, procedure or records? Let's assume that every facet of a company will in some way impact on the quality of your product and service and that during the planning and continuous cycles, any 'weakness' will be identified and rectified and preventatively planned for in the future.

For mine, a checklist item in management review for these two clauses should cover these requirements.

Product and service provision (7)

Clause 7 is the only clause in the standard that allows you to seek exclusions. When seeking exclusions for a quality management system or a certification, you cannot just pick and choose to suit. If your company designs, then you need to include design. If they purchase, you need to include purchasing. Some say, that if it does not have a direct impact on the product or service then you can exclude it.

However, I believe that any aspect of your business will have an impact on your product or service so don't seek exclusions unless it is absolutely necessary. In fact, if you are implementing a quality management system for continuous improvement and customer focus, then include all of your business aspects so there is not a 'rule for some and not for others' mentality.

My thoughts are that the only real exclusions that should ever be sought are design control or test equipment and I will deal with each in forthcoming chapters. Just remember, if you seek an exclusion, you will need to provide evidence and a justification for seeking an exclusion. To ensure transparency, such justifications should be clearly stated in prominent documentation such as the quality manual or even the quality policy. Just make sure it is readily available when requested.

Planning of product realisation (7.1)

The standard says; Your company has planned and developed the processes needed for product or service realisation. Planning of product or service realisation shall be consistent with the requirements of the other processes of the quality management system.

In planning product or service realisation, your company has determined the following, as appropriate:

- quality objectives and requirements for the product;
- the need to establish processes, documents, and provide resources specific to the product or service;
- required verification, validation, monitoring, inspection and test activities specific to the product and the criteria for product acceptance;
- records needed to provide evidence that the realisation processes and resulting product or service meet requirements. The output of this planning is in a form suitable for your company's method of operations.

It all seems 'much ado about nothing'. No procedures are needed. No specific process is needed. No specific records are needed. It really is alluding to something, but not really specifying what. I struggle with this clause. The auditing fraternity generally struggles with this clause. The desired outputs are covered by other clauses and required records, yet not cross referenced here

Consultants and auditors do make some assumptions here as to what is best practice and what should be in the system.

As always, my recommendation is to stick with the intent. This means; have a process for the review of your product or service offering. This can be done in management review, strategic plans, customer forums, etc. Then have a process for taking a new or modified product or service off the drawing board and getting it into the product or service offering. Depending on your product or service type, it will then depend on the risk mitigation and controls that are needed to do this. In some

organisations this can take years, involve hundreds of persons and regulators. For others, it could be the result of a long lunch, a web site tweak and before you know it, you are an environmental expert leveraging off your quality management system knowledge.

Make sure you have a process and generate the required records as your systems sees fit.

Customer related processes (7.2)

In all matters relating to this clause, product means service as well.

What we are trying to achieve from this clause and sub clauses is to establish how we interact with that most troublesome of all beasts – the customer. The sub clauses set it out pretty well.

Find out what the customer wants, check that they really want it and then tell them about the first two steps. There are a number of points to each of the sub clauses that you need to address, but if you get the intent right, you should do well.

Determination of requirements related to the product (7.2.1)

The standard wants "the company must determine;

a) requirements specified by the customer, including the requirements for delivery and post-delivery activities;

b) requirements not stated by the customer but necessary for specified or intended use, where known;

c) statutory and regulatory requirements related to the

product, and

d) any additional requirements determined by the company."

a) and c) are self-explanatory and if you have been in business for any length of time, you probably have these down pat.

b) is more problematic. You have to try and anticipate what they want, even when they don't know what they want, but because you are the product / service expert, you need to inform them of what they want. A bit like explaining terms, technical specs and so forth. Thank goodness for the 'where known' at the end of b). Because if you do not know what the customer doesn't know or won't tell you, then how can you be expected to deal with it? I suppose it is a bit like when you buy a computer from the US; there is always a list of warnings to clarify that you are only going to use the machine for good and not evil.

First, a quick note on d) - the additional requirements as determined by you, not the customer. Overall it attempts to have you trying to outguess the customer with any particular needs or conditions. I think this point could have been merged into a).

Review of requirements related to the product (7.2.2)

The standard wants "the Company to review the requirements related to the product. This review is conducted prior to commitment to supply a product to the customer (eg. submission of tenders, acceptance of contracts or orders, acceptance of changes to contracts or orders) and ensures that:

a) product requirements are defined;

b) contract or order requirements differing from those previously expressed are resolved; and

c) the Company has the ability to meet the defined requirements."

Records of the results of the review and actions arising from the review shall be maintained. Where the customer provides no documented statement of requirement, the customer

requirements shall be confirmed by the Company before acceptance. Where product requirements are changed, the Company shall ensure that relevant documents are amended and that relevant personnel are made aware of the changed requirements.

Customer communication (7.2.3)

"The Company has determined and will implement effective arrangements for communicating with customers in relation to:

a) product information;

b) enquiries, contracts or order handling, including amendments; and

c) customer feedback, including customer complaints."

This is wordy and complicated. On reflection, the above, is very prescriptive and self-evident. A simple procedure should suffice, addressing each of the above elements. You don't need a documented procedure but I would rather have one, especially around authority limits for go / no go for tenders, quotes and proposals, and very much so when concerning communications, escalations, feedback and complaints.

If you intend not to use a procedure, just make sure there are

ample records to demonstrate your processes are robust and of course meet the requirements of the clauses above.

Design and development (7.3)

This clause and its sub clauses is what I regard as the 'elephant in the room', primarily because of the complexity and prescription. Why there are so many requirements and so much baggage is beyond me. I know that design is one of THE very most important aspects of products and service. It is justthat it is normally left up to experts, qualified persons, and academics that need to be meticulous, in order to keep people and property safe and functioning for the planned duration.

So why have so much prescription in the standard? There are just so many important things to business, to customer focus, to continuous improvement that are glibly single sentenced in the standard. Why not this one as well? I don't know.

The good news is that you can get an exclusion. The bad news if you do design, you can't get an exclusion. So the proof is in the core business activities and what you are contracted to do. Nine out of ten times, you are doing 'development' and when I say development, I mean modifying known models within know parameters to suit an application. If you are doing this, then I would recommend an exclusion. Anything more, no. Now read on.

The seven topics we will cover in these pages are; Design and development planning; Design and development inputs; Design and development outputs; Design and development verification; Design and development validation; and Control of design and development changes.

On reflection, these sections should only apply to 5% of all companies seeking certification.

We will start the discussion with; Design and development planning; Design and development inputs; Design and development outputs.

Design and development planning (7.3.1)

You must plan and control the design and development of

product through staging, review, verification and validation of each stage, assign responsibilities, manage the interface between responsibilities and groups, with any resultant design plan being updated as needed, concerning the process.

I have seen one page plans, 200 page plans, simple Gantt charts and very complex MS Project examples. Just consider and reference the above elements and have a plan.

Design and development inputs (7.3.2)

Inputs include functional and performance requirements, applicable statutory and regulatory requirements and where applicable, information derived from previous similar designs, and other requirements essential for design and development. These inputs are to be reviewed for adequacy, completeness, unambiguity and must not be in conflict with each other. Keep the above in mind when developing your plan.

Design and development outputs (7.3.3)

Design and development outputs are to be provided in a form that enables verification against the design and development input, and approved prior to release.

These outputs should meet the input requirements for design and development, provide appropriate information for purchasing, production and for service provision, contain or reference product acceptance criteria, and specify the characteristics of the product that are essential for its safe and proper use. Keep these as components in your plan and all should be good.

Design and development review (7.2.4)

At suitable stages, systematic reviews of design and development are performed in accordance with planned arrangements; a) to evaluate the ability of the results of design and development to meet requirements, and b) to identify any problems and propose necessary actions.

Participants in such reviews include representatives of functions concerned with the design and development stage(s) being reviewed. Records of the results of the reviews and any necessary actions need to be maintained.

Simply the intent is to update your design plan. To do this you need to conduct a review meeting and ensure the right people are there. Generate minutes or an action plan and follow them up next review. Remember that some clients have quite specific requirements concerning such reviews and reporting, so make sure you know them and if you want to change those requirements, get their approval.

Design and development verification (7.3.5)

Verification is performed in accordance with planned arrangements to ensure that the design and development

outputs have met the design and development input requirements. Records of the results of the verification and any necessary actions are maintained.

I use a roadmap / cross reference type document to demonstrate that outputs equal inputs, and when they don't, there is an action plan to fix them.

Design and development validation (7.3.6)

Design and development validation is performed in accordance with planned arrangements to ensure that the resulting product is capable of meeting the requirements for the specified application or intended use, where known. Wherever practicable, validation is completed prior to the delivery or implementation of the product. Records of the results of validation and any necessary actions are maintained.

Validity, is by definition, proof that the design works. Get it tested, seek peer evaluation, trial, etc. Get the results, check the results, and compare results to the previous five elements. Is it OK? If not, record what isn't and fix it. Redo all previous steps.

Design and development changes (7.3.7)

Design and development changes are identified and records maintained. The changes are reviewed, verified and validated, as appropriate, and approved before implementation. The review of design and development changes includes evaluation of the effect of the changes on constituent parts and product already delivered. Records of the results of the review of changes and any necessary actions must be maintained.

The last thing is to make sure that if you change anything, you record it. Record it on the design documentation, in test results, in meeting minutes, etc and when you change it, do the previous six steps again, review it again, change it again and record it again.

Purchasing (7.4)

This clause is a mixed bag of good business practice with a throwback to the prescriptive past. It is a three part clause; purchasing process (the good bit), purchasing information and verification of purchased product (being the throwbacks).

The process is very open ended and enables an organisation to deal with purchasing decisions as they see fit. The standard reads: "an organisation will ensure that purchased product conforms to specified purchase requirements." The type and extent of control applied to the supplier and the purchased product is dependent on the effect of the purchased product on subsequent product realisation or the final product.

Rather simple really. Whilst a documented procedure is not required, I would always have one to ensure authority levels are defined or referenced, and to give an overview of the process involved.

More important is the review of suppliers. In a previous version of the standard, this had its own sub element and was the fixation of many auditors trying to get companies to rate suppliers on some sort of convoluted machination. Thankfully, no more! Just good business practices are all that are required. I wouldn't have a stand alone procedure (unless warranted by the complexity) but if you have a purchasing procedure (or at least a process), the review and acceptance of suppliers should be an integral component.

The standard talks about; "a company evaluates and selects suppliers based on their ability to supply product in accordance with company requirements. Criteria for selection, evaluation and re-evaluation are established. Records of the results of evaluations and any necessary actions arising from the evaluation are maintained." The sting being, records must be generated. Don't get hung up on questionnaires, audits reports, etc (of course, unless warranted) but at least identify the records that are generated that verify the review activities. These can include minutes of meetings, emails, etc. I also like (not mandatory) a supplier list and reviewing it in management review meetings.

The rest of this element is trite. Make sure you address the requirements in your process or procedure, but if you have robust purchasing processes, you will cover them as a matter of course.

The standard says; "purchasing information describes the product to be purchased, including where appropriate:

a) requirements for approval of product, procedures, processes and equipment;

b) requirements for qualification of personnel; and

c) quality management system requirements. A company ensures the adequacy of specified purchase requirements prior to their communication to the supplier.

The standard wants the verification of purchased product. A company has established and will implement the inspection or other activities necessary for ensuring that purchased product meets specified purchase requirements. Where a company or its customer intends to perform verification at the supplier's premises, the company will state the intended verification

arrangements and method of product release in the purchasing information.

Simply create a reference to these requirements or ignore this part, dependent on business needs.

Production and service provision (7.5)

The sub clauses of the above clause are:

- control of production and service provision;
- validation of processes for production and service provision;
- identification and traceability;
- customer property and;
- preservation of product.

In a previous version of the standard, each one of these had their own clause and sub clauses. I am glad that they were rationalised to those outlined above but I feel that they are still a little too prescriptive.

However, they are all effective and if your aim is for your quality management system to be best practice, they are a very good starting point to manage how you deliver product or service to market.

Start with a process description or even a procedure with the key bullet points of how you 'make' your product or service. Next, add in the following controls; description of product characteristics, work instructions, equipment, monitoring and measuring devices, monitoring and measurement, and release, delivery and post-delivery activities.

Most of us already do this, we just need to break down the quality speak and put it your own terms based on product, service, regulation, industry, market.

The standard is quite specific; you must carry out production and service provision under controlled conditions. You actually get to pick these conditions.

However, they have suggested some under the ubiquitous phrase 'as applicable'. Some auditors will ignore this and assume you will have listed controls. Don't be fooled! You get to pick applicability.

So here are the conditions with some suggested measures. It is your choice and you get to put in place what needs risk

mitigation. This isn't a long list. You can make it as long or as short as you need.

"Controlled conditions include, as applicable:

- the availability of information that describes the characteristics of the product [drawings, specifications, ingredients, scope of work, terms and conditions, etc];
- the availability of work instructions, as necessary [these can be in any format, any media and you should only use them if they contribute to the end users capability of delivering a conforming product or service at any stage of the cycle];
- the use of suitable equipment [the right tool for the right job];
- the availability and use of monitoring and measuring devices;
- the implementation of monitoring and measurement

[if you sell by a unit of measure, you need to meet legal obligations for measuring equipment and if it is to a specification, you had

- better make sure you get this right]; and
- the implementation of release, delivery and post-delivery activities [see below]."

This is perhaps the most important part of any product or service realisation and these aspects get a combined, single bullet point. Are there Inspection and Test Plans involved? Can you rework slightly off specification products and services? Is delivery 'Free on Base'? Are there charges, methodology and so on? Are there warranty issues, maintenance and service requirements and so much more? Define them and then determine the need for controls. Make them yours and not what is perceived as the norm.

Validation of production and service provision (7.5.2)

Last century, this was called 'special processes'. The standard now says; "The company validates any processes for production and service provision where the resulting output cannot be verified by subsequent monitoring or measurement.

This includes any processes where deficiencies become apparent only after the product is in use or the service has been delivered. Validation demonstrates the ability of these processes to achieve planned results. The company has established arrangements for these processes including, as applicable:

a) defined criteria for review and approval of the processes;

b) approval of equipment and qualification of personnel;

c) use of specific methods and procedures;

d) requirements for records; and

e) re-validation."

The intent is, that if you make something and the only way of testing it or ensuring that it meets specification is to do destructive testing, then put in the above requirements. I don't mean to trivialise this, it is a fundamental set of criteria for any manufacturer or service provider. In my twenty two plus years of consulting, even when I have come across a potential client who knows little about quality, they have these measures in place. No, really! There are not too many businesses in existence that want to make bad product or deliver bad service. So they don't. They may not know the quality speak behind the above requirements but they sure know how and why.

When you reach this part of your quality management system development, use the requirements as a guideline, identify how you already do these things, document them if it is of benefit, and point to records that demonstrate your process and move on to the next clause.

Here is a simple example. Your company supplies two pieces of steel welded together in a bracket. No protective coating. Weld strength of 150 KPa. There are approximately 1,097,123 ways of describing this process to ensure the specification is met. Here are just a few. Bill of Material, drawing, sample plan for destructive testing for weld failure, purchase orders, material specifications for metal and welding rods, non-destructive testing of all welds, prototype evaluations, test jigs for squareness, thickness, width, standard operating procedure for assembly and welding, welding ticket of operator, quarantine area, retesting procedures, concessions processes and so on.

Try a little risk management analysis. Try communication with your suppliers and customers. Have pride in your workmanship and get on with it.

Identification and traceability (7.5.3)

The standard wants you to consider the following. And when I say consider, I mean have a response in a quality manual, have operational procedures if they are applicable or at least have a review point, say annually, in a management review or as part of planning for realisation reviews.

The standard continues with "where appropriate, your company identifies the product by suitable means throughout product realisation. The company identifies the product status with respect to monitoring and measurement requirements. Where traceability is a requirement, the company controls and records the unique identification of the product."

Be aware that the clause does not say that you have to have a procedure. It doesn't even need to have a process. It doesn't even need to have records (unless of course you do require traceability)! So why is it even mentioned at all? I don't really know.

Identification can be by name, number, location, colour, picture, barcode, or any unique qualifier that stops inadvertent misidentification. The same rules apply for the status of a product or service. Can it be readily examined and determined if it passes, fails, hold, concession, reject, etc?

The only really tricky paragraph is that 'when it is a requirement', you need to keep records of components, testing, use-by, delivery and even recycling for life cycle requirements. If there

is a need for this, there is much review, much operational controlling, much complexity, which at the end of the day, will be determined by your risk exposure of the product or services.

Customer property (7.5.4)

What is customer property? It could be perfume samples in a magazine, coil aluminium for painting, your favourite photo for framing, soil samples for analysis, etc.

The standard implies you wouldn't know how to control such things if in fact you did control such things as part of your product / service offerings. It is a throwback to the manufacturing origins of the standard.

However, it is very important if you in fact do manage materials, products, records, etc on behalf of your customer, especially if they are to be incorporated into the final product / service.

My thinking is that if you do (and I would say almost a whole 1% of you might!), that you in fact you would already be doing what the standard requires.

The requirement of the standard is that your company exercises care with customer property while it is under your control or being used by you. Your company identifies, verifies, protects and safeguards customer property provided for use or incorporation into the product. If any customer property is lost, damaged or otherwise found to be unsuitable for use, it is reported to the customer and records maintained.

Just break it down into the components and describe them. I would draft a procedure or at least a work instruction to manage these. Make sure such processes are married to your control of nonconformance processes and as a best practice,

treat all such items as you would any other inventory / bill of material item to ensure the integrity of the controls.

Preservation of product (7.5.5)

Last century and in a previous version of the standard, this topic was a whole sub clause, very structured, very prescriptive, but it was useful.

Now you get one paragraph. However, it is one of my favourite sub clauses as it demonstrates just how the standard can be useful and 'guide-like' without over complicated jargon.

Unfortunately, the last sentence will trip some up or be seen to be duplication but as always, remember, it is the intent that matters.

The requirement is that "your Company preserves the conformity of product during internal processing and delivery to the intended destination. This preservation includes identification, handling, packaging, storage and protection. Preservation also applies to the constituent parts of a product."

There are no requirements for a procedure. No requirement for records. Just a requirement that processes are in place to meet your needs and those of your customer when it comes to making sure your product / services meet expectations concerning the right item, protection in transit, condition on arrival, readiness for use and shelf life.

It also makes you consider applying the same controls to the product at all stages of receipt, processing and delivery and that the same applies to all materials and components of the final product / service as well.

When it comes to designing systems, make sure you are doing this, record it as an internal quality audit and or split up the requirements into other documented procedures as needed and then make sure your 'road map' keeps a track of it.

Control of monitoring and measuring devices (7.6)

Entire books have been written about calibration of test equipment. In ISO 9001 it is clause 7.6 - control of monitoring and measuring devices.

In many cases the control of such devices is critical to both product specification and contract specification. In some cases if you don't control such devices carefully and within risk parameters, the only way to verify that a product is meeting contractual requirements is to conduct destructive testing. This is not a good protocol or commercial outcome since you cannot sell a product (or service) that has been

destroyed in a test to prove it is working properly. But on the flip side, we don't test or calibrate every little piece of equipment in the business just to be on the safe side. The cost alone of such outsourced services could send you broke or at least dent your gross margins. Be smart about what you 'need' to calibrate, what you need to monitor and what is just a good guideline to know.

Sometimes, the device is only used as an aid to manufacture, an indicator that things are within defined limits but their measurements are not used to define final contractual obligations.

A great example of this is the humble viscosity measurement device called the 'love cup'. In the printing industry, the

viscosity of certain coatings and inks is imperative to usage, colour, texture, etc. But in nearly all instances, the controlling factor is colour. So whilst you can get the viscosity right based on the calibrated measurement device (Love cup), it doesn't mean 'jot' to the customer if it results in the wrong colour. So why calibrate it? Well, that becomes a personal decision; a risk decision that has interpretation. The final outcome cannot be guaranteed when final approval is as subjective as colour!

So, be innovative with your test equipment regime. Link calibrations and tests guidelines with risk. Keep good records of decisions as to why, and focus on core contractual requirements.

Measurement, analysis and improvement (8)

This is the last clause of the standard and it is perhaps the most important clause of the standard. It is one of the four pillars of any quality management system. It is the improvement phase.

Remember if you are not moving forward with improvements, you are actually going backwards as your competition will be moving forward. Change is inevitable, so embrace it and have systems in place to manage it.

General (8.1)

The standard wants "your Company to plan and implement the monitoring, measurement, analysis and improvement processes needed:

a) to demonstrate conformity of the product;

b) to ensure conformity of the quality management system; and

c) to continually improve the effectiveness of the quality management system. This includes determination of applicable methods, including statistical techniques, and the extent of their use."

The last sentence niggles me and it is only included so that there is a link to the previous version of the standard, which gave statistical techniques its own sub clause. I would love to be that fly on the wall in technical committees and standing committees for the standard as the 'technocraty' debate endlessly over how to educate the great 'unquality' and the importance of stats.

In reality, this introductory clause is pretty self-explanatory and so enough is said.

Customer satisfaction (8.2.1)

From the standard we have covered customer focus, customer feedback, even customer owned property. Now, just 8 clauses in, we are dealing with satisfied customers.

It is quite often the butt of jokes when talking about quality management systems, and in particular about certification of quality management systems, that you can be a quality company, even if your 'quality' is not quality. Just do poor quality consistently and certification is yours. From 2008 the standard finally began talking about the satisfaction (as a verb) of customers.

The standard says; "as one of the measurements of the performance of the quality management system, your company monitors information relating to customer perception as to whether your company has met customer requirements. The methods for obtaining and using this information has been determined."

Be careful here. It is not just actual satisfaction but perceived satisfaction that is being sought. Did you notice there was no prescription in the above paragraphs? No mention of surveys, CRMs, etc.

Determine the methodology and have records available to demonstrate effectiveness. For the quality management systems we design, this is always a quality objective for customer satisfaction. This means you need to set targets, develop programs to achieve them, assign resources and review the results to determine effectiveness. A great PDCA (Plan, Do, Check, Act) cycle! It is up to the organisational culture of the client as to what methodologies you would use to gather the data.

Yes, surveys are a good tool. Yes, exit interviews, experience interviews, contract reviews, scheduled review meetings, social media, and so many more are good tools.

Pick one. See if it fits. If not, pick another. But never stop. May I repeat this? Never stop seeking the opinions of your wonderful clients, because if they won't tell you, who will?

Internal audit (8.2.2)

This is the most important part of the standard. For emphasis I will repeat that - This is the most important part of the standard.

The requirements are listed below.

Your company will conduct internal audits at planned intervals to determine whether the quality management system;

a) conforms to the planned arrangements,

I. to the requirements of the International standard and

II. to the quality management system requirements established by your company , and

b) is effectively implemented and maintained.

An audit program is planned, taking into consideration the status and importance of the processes and areas to be audited, as well as the results of previous audits. The audit criteria, scope, frequency and methods are defined. Selection of auditors and conduct of audits ensure objectivity and impartiality of the audit process.

Auditors do not audit their own work. The responsibilities and requirements for planning and conducting audits, and for reporting results and maintaining records are defined in a documented procedure.

The management responsible for the area being audited ensures that actions are taken without undue delay to eliminate detected non-conformance and their causes. Follow-up activities include the verification of the actions taken and the reporting of verification results."

Yes, the most important clause for any quality management system.

Why?

When done properly, it is the communication catalyst for review, for change and for improvement. Isn't that what quality is all about?

The key points are:

- planning;
- independence;
- defined criteria;
- a documented procedure;
- defined responsibilities;
- effective records;
- management commitment;
- follow up.

You can do what you please with the procedure, just make sure that you cover all requirements.

I recommend external training of your audit manager / facilitator and your auditors. Yes, it is that important. But

before you go off and get too many auditors trained, be aware of the following pitfalls / common mistakes:

- audits are not reviews, or management reviews, or desktop reviews, or stocktakes, quality assurance, etc;
- improvement auditing should not come before compliance auditing;
- lack of independence;
- too many auditors;
- not knowing the difference between process auditing, procedural auditing system auditing;
- complex audit plans, complex reporting, complex or unique corrective actions;
- not having a documented procedure;
- lumping, batching audits into major events.

There are many pitfalls and I am regularly asked to come in and streamline this process to take away the hurt.

My core recommendations are, firstly:

- write a procedure

Then:

- develop a plan;
- train two auditors;
- keep audits to less than 30 minutes;
- draft simple reports;
- agree on corrective actions with the right people;
- record, record, record.

Audits provide a three pronged impact. A)communication, b) status, c) opportunity for change (if needed, change is usually needed during implementation).

As a communication exercise, especially with process / procedure owners and stakeholders, the internal audit is a marvelous tool to talk through a documented procedure or step through a process.

Quite often, the 'ah hah' moment is realised when the auditor and auditee profess their interpretation of a paragraph or stage. The realisation of clarity or lack of it, will drive either a need to up skill a person or modify the document. Testing of new aspects specifically developed to meet the quality standard will / should bring questions to the fore and so on.

At the end of the audit, the participants will have a good understanding of the preparedness / status of department or person under review. Examples include whether you will need to modify anything, determining if these are enough records or if effectiveness is evident and more. The most important outcome is knowing where you are.

Once known, change can be planned, implemented and reviewed again. Better now than when the external auditor comes knocking.

Monitoring and measuring of processes (8.2.3)

The standard wants "your company to apply suitable methods for monitoring and, where applicable, measurement of the quality management system processes. These methods demonstrate the ability of the processes to achieve planned results. When planned results are not achieved, correction and corrective action is taken, as appropriate, to ensure conformity of the product."

There are many 'key' words in the above; suitable, where applicable, as appropriate, planned and the most important, 'the quality management system processes'. Not machinery, not inventory management, not anything other than the procedures and processes identified within the scope of the quality management system.

These include; internal audits, trend analyses, planned maintenance scheduling, etc. Some monitoring processes are a requirement of license conditions, so you need to keep on top of them. Others are defined in KPIs or quality objectives.

No need to go big here. No need to re-invent or develop tricky stuff. The important thing is to keep it simple and make sure you close loop this monitoring back to your own corrective action procedures.

Make sure that normal monitoring has fail-safes, hold points and the ability to approve concession.

If you have adequately described this in your Control of Nonconforming Product

Procedure, your Corrective Action Procedure and your Preventive Action Procedure, then all you need do is 'road-map' it and you're done.

One last comment - I always include this as a management review item to be sure, and to give auditors the ability to tick the box when they cannot get their head around your particular industry.

Monitoring and measuring of product (8.2.4)

Your company is to monitor and measure the characteristics of the product to verify that product requirements have been met.

This is to be carried out at appropriate stages of the product realisation process in accordance with the planned arrangements. Evidence of conformity with the acceptance criteria is maintained. Records indicate the person(s) authorising release of product. Product release and service delivery does not proceed until the planned arrangements have been satisfactorily completed, unless otherwise approved by a relevant authority and, where applicable, by the customer.

Remember that product / service are interchangeable. All in all it is a great balance of prescription and applicability.

Prescription - make sure what you make meets specification.

Then you choose when and by what method, frequency, etc. Base applicability on your historical data or by when the characteristics can be measured, but most importantly, when they are supposed to happen based on a predetermined plan. I have goose bumps. This is true quality assurance.

Prescription. Keep evidence. Keep records. Make sure such records demonstrate conformance and who did what when under what delegated authority.

Prescription. Do not proceed with the next stage until the defined plan has been met, even if such a plan includes overriding by either higher authorities or that absolute being, the customer.

No procedure is needed here. No inspection and test plan is needed. The only requirements are process and the records to back it up. However, unless it is absolutely apparent, a simple

flow chart, or procedure or inspection and test plan would benefit the company. Don't get hung up on the structure, just generate something that is useful, clear and concise so that the 'plan' can be achieved.

Control of nonconforming product (8.3)

This clause requires a documented procedure. This clause requires records. It is also one of the last non generic references that may confuse a reader, especially if they are in the service sector.

There is a definition in the front of the standard that qualifies product so that product can mean service. It is the only specific definition in 9001 with all other definitions deferred to 9000. Yet it is still confusing.

What about a nonconforming process, policy, competency, price? I propose that the heading of the clause should read, control of non-conformance, full stop. That way any nonconformance, variation, deviation can be 'captured' and dealt with.

What are the requirements? Identification and control from unintended use. Once done, then you need to:

1. Eliminate nonconformance;
2. Use, accept or release the nonconformance;
3. Preclude the nonconformance from being used;
4. Determine effects after use or delivery;
5. Subject the corrected nonconformance to the same verification processes as before.

Can you merge these requirements into other procedures? In a word, yes.

It may be merged with the corrective action procedure or the credits procedure or the post production inspection procedure, etc. The choice is yours. Just make sure you address all of the above elements and your quality management system will do well.

Breaking the clause down into parts provides more clarity.

"Your company ensures that product which does not conform to product requirements is identified and controlled to prevent its unintended use or delivery. The controls and related responsibilities and authorities for dealing with nonconforming product (and of course, or service) are defined in a documented procedure."

This is one of the mandatory requirements for a procedure and a good one too. It is so important that you have this clause under control and to have this process under control. The standard is quite prescriptive as to what you have to do. You must do one or more of the following:

"1. take action to eliminate the detected nonconformity;

2. authorise its use, release or acceptance under concession by a relevant authority and, where applicable, by the customer; and lastly,

3. take action to preclude its original intended use or application."

This provides a clear hierarchy of control. Eliminate the problem, accept the problem or stop the problem by either of the first two.

Once you have done this, you need to demonstrate via appropriate records that anything that you have done has been done as per the procedure.

The standard goes on to say that if you fix a problem, then the 'fixed' product or service is again tested and verified to the requirements and of course, all the while keeping records to show it now conforms.

The quirkiest part of this clause is to describe what you have to do if the problem is detected after delivery or use has started.

You need to define what you do with the 'knock on' ramifications of the problem. Do you recall? Do you compensate, replace, credit, etc? How far back do you go? When do you deem remaining stock is OK? This is a very large 'piece of string' scenario and can only be truly reviewed and controlled by thoughtful risk assessment, management and mitigation.

For high risk industries, such as automotive, this is often described in legislation, codes, and best practices. For the rest of us, listen to your customers and develop policy and process from their feedback.

Because of the importance of this clause, I like to keep this procedure as a separate, stand alone procedure just to make sure that you are giving the importance to each of the aspects of this clause. This does not mean you cannot merge this procedure with others, such as corrective action. Just make sure that you address every aspect, even if not applicable to your company.

Analysis of data (8.4)

Analysis of data is probably the most ignored clause of the standard.

Why?

It is often regarded as bit fluffy by certifiers and many times is simply left alone, but when they do give it some focus, they are like a dog with a bone.

"Your company determines, collects and analyses appropriate data to demonstrate the suitability and effectiveness of the quality management system to evaluate where continual improvement of the effectiveness of the quality management system can be made.

This includes data generated as a result of monitoring and measurement and from other relevant sources. The analysis of data provides information relating to; customer satisfaction, conformity to product requirements, characteristics and trends of processes and products including opportunities for preventive action, and suppliers."

As always it has the very big caveat of 'appropriate data' with the intent only to demonstrate suitability, effectiveness of the quality management system and to evaluate

continuous improvement. They list a number of aspects of the business that contain 'relevant data' for analysis but nowhere does it prescribe what and how. So don't be bullied and or go overboard in satisfying this requirement.

Always start with data that is generated now, especially data that is relevant to the owners and shareholders.

Financial data is a good starting point. Then look at what other data is collected and reported on.

Next, look at the fuzzy stuff. I won't define what is fuzzy and what isn't. Just remember, if you have to invent tools to gather data just for the sake of the quality management system, then it is probably fuzzy.

This doesn't mean fuzzy is bad. Some companies need to move fuzzy to core, because without it you probably can't demonstrate appropriate, relevant data and analysis. If you can't, then you probably won't get certified either.

So define what data is core to the business, describe when it is gathered, when it is analysed and even describe how it is analysed to demonstrate that you do it. I would normally put this in both the quality manual and a management review procedure, because at the end of the day, it needs to have a quality focus to meet the requirements of a quality management system.

Continual improvement (8.5.1)

The critical thing is that these words, continual improvement, should be in your quality policy.

Next they should be in your quality objectives. Once in there, you need to determine targets, resources and reviews of the metrics and machinations. And when all this is in place, it will be a KPI for the implementation phase of your new quality management system.

It is all part of the implementation phase and as I like to call it, 'walking the talk.'

It is the PDCA (Plan, Do, Check, Act) cycle of any quality assurance program.

Quality management systems are a tool of quality assurance and the foundation of quality assurance is continual improvement.

The standard and the clause is all about improvement.

The standard wants continual improvement. Not 'sometimes improvement'.

Your manual and system should say something like this:

'Your company continually improves (remember, not continuously, see later in the chapter) the effectiveness of the quality management system, through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions and management review.'

Your quality policy therefore must refer to continual improvement.

By definition within the standard, it means your quality objectives need to be hard wired to it, with the standard then going on to refer to some of the improvement tools already mandated in the standard; audits, data, corrective action, preventive action and management reviews.

Each of these aspects has a requirement for planning and closed loop actions to ensure they are continual. For example, one of the inputs of management review is the follow up of previous actions / reviews.

There are no requirements for documentation other than the above references and tie-ins. I generally default to the 'road map' / cross reference table and move onto the next clause.

Before I do, let's finish off with some definitions and intents. There is much debate around the word 'continual' and some of us less educated, interchange it with the word continuous.

Here are my thoughts on this controversy. Yes, they are different words, with different meaning but the split is; continuous means uninterrupted (without end), whilst continual means frequently (without pause). As always, it is the intent that counts, and the fact that the standard wants continual, give it continual and get on with it.

Corrective action (8.5.2)

The standard says "your company must take action to eliminate the cause of non-conformance in order to prevent recurrence.

Corrective actions are to be appropriate to the effects of the nonconformance encountered. A documented procedure is established to define requirements for:

a) reviewing nonconformance (including customer complaints);

b) determining the causes of nonconformance;

c) evaluating the need for action to ensure that nonconformance do not recur;

d) determining and implementing action needed;

e) records of the results of action taken; and

f) reviewing corrective action taken."

This is pretty self-explanatory, but did you notice the two really big elephants in this room?

You must have a documented procedure.

Of course, as always, it can be a part of another procedure with whatever title you like, but ALL (yes capitals) the elements of the above must be included.

The second is that it does not ask for preventive (or preventative) actions or processes. It asks for actions or to be more accurate, the need for actions to stop a nonconformance from recurring. So please do not make preventive action review as part of this process, procedure, form, spreadsheet, etc. I will discuss preventive actions next chapter.

Another important aspect is that you need to deal with customer complaints and dissatisfaction in this procedure, or at least refer to another documented procedure that does.

The methodology and data capture for this clause of the standard is completely left up to you. Make sure whatever you use covers off all the elements.

I have seen and used many different proprietary products to manage this process. Some include intranets, spreadsheets, stand alone forms, registers, databases and so much more.

I have seen the grading of incidents, matters, nonconformances on target areas such as systems, customers, vendors, employees with emphasis on fixing wrongs, suggesting improvements, risk avoidance and so very much more. I have seen systems that make you start a corrective action for everything and those that only use it as an escalation. Each and every one of them has pros and cons and could easily be the sole topic of this book.

The best thing to do is start. Then review. Then modify if needed, and then act accordingly. Eventually you will find a fit for your company and its risks.

I have never conducted an internal audit of my own system and not discovered or desired a change to either the documentation or the process. Never. Once you identify the change, use your corrective action process to manage the change. Don't worry about the size of change or the volume

of change, let the platform and the process tell you how good or bad it is whilst you are using it.

Remember, make sure you don't have preventive action as part of the corrective action process. Also ensure you label and implement an effectiveness review in the corrective action process to ensure that a problem is not repeated. This is not preventive. It might prevent recurrence, but as written before it didn't actually stop the problem from occurring in the first place. And this is what the intent of the standard really wants? The answer is pro-active prevention of a problem ever occurring.

The great thing about this is that you are generating records to demonstrate the implementation and effectiveness of the quality management system. It won't be easy, but it will serve multiple purposes.

Preventive action (8.5.3)

Whole books, white papers, conference key notes, etc have been generated on what is a preventive action.

Before we go on, let's answer this question first. What is the difference between preventive and preventative. The short answer is none.

The short definition of preventive (according to http://www.yourdictionary.com/) is 'anything that prevents'. And when you search on preventative it says 'variant of preventive.' And so in the real world they are just a variant of each other with the focus on prevention.

What is the relationship with corrective action? The standard gives each one their own sub element. The majority of non-quality-expert people simply merge the two with the intent of having one precede the other in a continuous improvement cycle. I think this is a good thing. But it cannot be an exclusive use of the preventive sub element.

In an effective quality management system, a proactive review of 'what if' questions should be addressed or at least discussed and recorded in an attempt to totally prevent an occurrence that could be detrimental to the quality management system and or the company in general.

Why not record such a discussion in management review? Why not make it a standing management review agenda item? Or why not even program a quarterly review of data trying to identify possible trends, possible emergence, etc? Then either record it in the minutes of your management review or start a NCR, CAR, CAPA, or whatever you call your corrective action / continuous improvement mechanisms and record your findings there.

Don't forget, the standard does require a documented procedure on this sub element, so draft one and either keep it stand alone or merge it with your corrective action procedure or management review procedure (if you have one).

One interesting fact or helpful hint about this clause is that it is completely separate from corrective action. When I was first

introduced to this concept I was to read clause 8.5.2 and replace the word corrective with preventive. Now this is not completely accurate but it does give you a sense of the difference and why you should have a separate procedure.

The standards wants you to "determine action to eliminate the causes of potential non-conformance in order to prevent their occurrence.

Preventive actions are appropriate to the effects of the potential problems. A documented procedure has been established to define requirements for:

a) determining potential non-conformance and their causes;

b)evaluating the need for action to prevent occurrence of non-conformance,

c) determining and implementing action needed,

d) records of results of action taken, and

e) reviewing preventive action taken."

Yes it is very similar. The intent? It is not meant as an adjunct to corrective action to prevent re-occurrence, but to stop occurrence.

When I design systems, I either write a separate procedure and include a review for trends of corrective actions and/or include in the management review process to ensure a proactive review of potential impacts is recorded in the minutes.

By doing such an analysis you can stop a problem by anticipation, because a trend is showing you potential. It is a tad confusing but if used wisely, you might just head-off potential issues before they occur.

John Mason

John Mason is founder, managing director, managing consultant and managing auditor of Oberon NSW Pty Limited, trading as quality.com.au and Quality Certifications, a specialist management consultancy designing, developing, implementing, supporting and auditing quality management systems based on ISO 9001.

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