

## ISO 9001:2015 – Has now been released

This information is provided for the many clients of Gray Management Systems as a contribution towards the loyalty shown to us.

The following is designed to help organisations transition to the new ISO 9001 standard which was released in late September 2015.

### Background

ISO (International Organisation for Standardisation) has a policy of reviewing all standards on a regular basis to ensure that ISO standards remain relevant and current to meet the changing needs of businesses. This update is the fifth upgrade since the first edition in 1987.

From the outset, the Quality Management Standards have been about helping businesses to improve and to continually meet their customer and regulatory requirements. The latest versions have emphasised the need to manage a business from start to finish using a process based approach. In parallel, other management standards such as environmental (14001), IT service management (20000), food safety (22000), business continuity (22301), information security management (27001) and energy management systems (50001) have been implemented along with ISO 9001. Each standard has their own technical committee who each have a different opinion as to the structure and content of their particular standard. This is logical and understandable, however if a business has to implement several of these standards concurrently it can be difficult to integrate varying requirements covering the same subject matter. Currently these standards are all structured differently which can also cause difficulties.

Increasingly there has been a convergence of thoughts amongst the technical committees regarding the structure of the various management systems standards. This convergence is intended to enhance the alignment among the ISO management system standards to facilitate their implementation. This latest version of ISO 9001 represents a 'Technical Revision'

What impact will this update have on organisations, trainers, consultants, certification bodies, accreditation bodies, auditors and management systems writers? The publication of Annex SL (previously ISO Guide 83) which defines the framework for a generic management system, has caused this change. All new ISO management system standards will adhere to this framework and all current management system standards will migrate to the framework at their next revision. (ISO 9001 & ISO 14001 were released late September 2015)

In future, all ISO management system standards should be consistent and compatible - they will all have the same look and feel. This could be the beginning of the end of the conflicts, duplication, confusion and misunderstanding arising from subtly different requirements across the various management systems standards.

Certified businesses will have until September 2018 to make the transition. Certification bodies will be responsible to assist their clients with this transition process.

Ultimately, if the implementation of a management system closely reflects the way the organisation functions then there should be minor changes only. All the *favourite* clause requirements will be there but probably in a different place.

## What Has Changed?

### Change in Structure

As mentioned above, all future management system standards will follow a ten clause layout as determined by Annex SL. The clause structure will be as follows:

#### Introduction

1. Scope
2. Normative references
3. Terms and definitions
4. Context of the organisation
5. Leadership
6. Planning for the quality management system
7. Support
8. Operation
9. Performance evaluation
10. Improvement

The following is an analysis and identification of each of the new clauses with respect to the current version of the standard.

#### Introduction

In the Introduction before the clauses, the standard subtly introduces new language such as 'context of the organisation', 'risk based thinking', 'strategic direction' and 'documented information'. These points will be discussed in greater detail later.

A risk based approach has always been implicit in the previous versions of the standard; however there is greater emphasis on this new requirement. As seen later, this approach has replaced Preventive Action which has been deleted.

The process-based model incorporating the PDCA improvement cycle remains but expanded to include the extra clauses. Mention has been made that it is not mandatory for organisations to follow the identical clause by clause sequence when defining a management system.

The current requirement for six mandated procedures has been deleted and a new requirement for organisations to maintain "*documented information*" to the extent necessary to support the operation of processes to have confidence that the processes are being carried out as planned. Documented information is a broad term that covers policies, plans, procedures and records. The requirement for a quality manual has been removed.

## 1. Scope

The main change here is that the current specific requirements regarding exclusions have been deleted. The new requirements for exclusions have been relaxed and are covered later.

## 2. Normative references

No change here except the reference to the latest Fundamentals & Vocabulary Standard (ISO 9000:2005)

## 3. Terms and definitions

No change except for the reference to the latest Fundamentals & Vocabulary Standard (ISO 9000:2005)

## 4. Context of the Organisation

This clause introduces a new requirement that the organisation has determined and aligned the internal and external issues that are relevant to the purpose and strategic direction of the organisation. The intent here is that the organisation understands issues such as legal, technological, competition, market conditions, social, economic, values, culture, knowledge and performance. The needs and expectations of interested parties (stakeholders) need to be included in this determination. Mature organisations can address these requirements via their current strategic and business planning processes and their stakeholder engagement processes.

Once the above are determined, the scope of the management system can also be determined. Although not overtly mentioned here, documented information must be available to show what has been included and what has not (a scope statement). There is no longer a specific requirement about exclusion coming from just a single clause, (currently clause 7).

Risks and opportunities must be determined and a plan in place to show that appropriate actions are being taken to address them. The adoption of a risk management approach that includes a risk matrix and risk register should address this requirement. The new standard also mentions that there is no requirement for a *formal* risk management or documented risk management process. Additionally risks and opportunities could also be made agenda items to be covered during the management review process.

## 5. Leadership

Compared to the current Responsibility and Authority requirements not a lot has changed here. Objectives have been shifted to Clause 6, Management Review has been shifted to clause 9 and there is no longer a specific requirement for a Management Representative, although the current responsibilities are still a requirement.

## 6. Planning for the management system

There is a new requirement here that requires organisations to integrate into the QMS the actions taken to address the risks and opportunities mentioned above in clause 4. The requirement for quality objectives has been expanded slightly to be more explicit regarding what will be done, what resources will be required, who will be responsible, when will it be completed and evaluation of results. The new standard is not only focussing on improvement of the system but improvement of business performance.

## 7. Support

This clause incorporates the current clauses on resource management, control of monitoring and measuring equipment, control of documents and records (now merged into documented information) and includes a new requirement for external communication similar to the current requirements of the ISO 14001 EMS and AS 4801 OHS standards. The current clause on Human resources (6.2), has been split into Organisational Knowledge and Competence and includes extra emphasis on intellectual knowledge, and identification of knowledge gaps.

## 8. Operation

This clause covers the majority of the current clause 7 (product realisation). Greater clarity is provided regarding the definition of design which is useful. The current purchasing clause has been reworded to 'Control of externally provided processes, products and services'. A new requirement has been included here to cover unplanned changes that can affect production or service provision. Included in this clause is the current requirement that deals with non-conforming products and services.

## 9. Performance evaluation

This clause contains part of the similar requirements of the current clause on Monitoring, analysis and improvement, together with the current Management review requirements.

## 10. Improvement

The remainder of the current clause 8 is included here with little change except that Preventive action has been deleted in favour of numerous mentions of Risk Management as discussed previously.

## Where to now?

What should your organisation do now that the standard has been released? Well, as I always say during my training courses, organisations fall into two categories as follows:

### The Enlightened

Enlightened organisations plan ahead and make changes in a controlled manner which is less stressful and ensures a better result.

### The Desperate

Desperate organisations leave it to the last minute and make a mess of the changeover process which is inefficient, ineffective and stressful.

Now is a good time to re-assess where you are with your management systems structure and how it is communicated and utilised throughout your organisation. Have you got too much documentation? Is the system embraced by your colleagues? Is it user friendly? Does it look and sound like your organisation? Is it possible to integrate other compliance criteria into the one manageable system? Has the system been designed to pass an external audit rather than to help run your organisation?

## Conduct a 'Gap Analysis'

The first step is to purchase a copy of the standard and conduct a gap analysis to determine what gaps in your current system may exist with respect to the new standard. You can do this by photocopying clauses 4.0 to 10.3 onto A3 and cross check between the new requirements and your existing system requirements. As you go, write down what is currently compliant and in a different colour write down what is missing (the gap). You will now have a 'to do' list of what you have to do to close any existing gaps.

Do not be concerned at this stage with where the new requirements are located within the standard.

It is important to re-visit a comment I made earlier that you do not have to replicate the clause by clause numbering sequence in your own management system. The important thing here is that the new requirements are covered somewhere.

It may also be an opportune time to conduct a Gap Analysis against the new EMS standard (ISO 14001) should that be a requirement, and integrate the requirements of both standards in the one system.

## Systems Structure

I have always said during my training courses that management system design must reflect the organisation it supports. If not done already, now is the time to ensure that the structure of your management system matches the structure of how your organisation actually operates. Collectively, your policies, procedures, instructions, plans, work flows, records and support systems tell the *story* about how your organisation works from start to finish. This helps to ensure clarity, reduced risk and improved compliance.

## Your Current Management System

If your current system works for your organisation then there is no need to change it, just enhance it with the new requirements. As usual, there will be some certification body auditors who have their pet likes and dislikes. Remember, this is all about running an efficient organisation that meets its regulatory and client requirements.

There is no need to dispense with the current management representative/Quality Manager/Compliance Manager/ Quality Manual/ Document Control and Records Management procedures just because they are no longer required.

## Talk to your Certification Body Auditor

All certification bodies are starting to upskill their auditors regarding the approach to be taken to help you make the transition. Your auditor should be familiar with your system and be able to guide you in the right direction regarding the changeover timetable.

## Educate your staff

Involve your staff with the changeover process. Let them know what the changes are and what effect they will have on your management system. Seek their advice and input as to how they would like to see the changes integrated into the organisation.

## **Internal Audit**

After the changes have been made it would be a good idea to use your internal audit process to validate the changes made to ensure all is well.

## **Further Information**

If you need any help with the new changes please ask or send us an email.

Regards

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