



# Demystifying ISO 9001:2015

## ISO 9001:2015

---

### Presented by Geoff Gray

- » Cert IV in Training & Assessment
- » Registered Lead Auditor (IRCA)
- » Fellow Australian Institute of Company Directors

A Certificate of Attendance will be issued at the completion of this training course.

**GRAY**  
MANAGEMENT SYSTEMS

03 9876 5152  
[www.grayms.com.au](http://www.grayms.com.au)

## CONTENTS

	Page no.
Course Objectives	3
History of Quality Standards	4
The Process Model	6
Who is ISO?	7
Intent of the Standard and why change?	8
The ISO Family of Standards	8
THE HB Guides	8
JAS-ANZ	11
Quality Management Principles	13
Quality Management System	14
QMS – Requirements	15
0.3 Process Approach	16
PDCA	16
0.3.3 Risk Based Thinking	17
QMS requirements	18
4 Context of the organisation	19
4.2 Needs and expectations of interested parties	20
4.3 Determining the scope	20
4.4 QMS and its processes	21
5 Leadership	22
5.3 Organisational roles, responsibilities & authorities	23
6 Planning	23
6.2 Quality objectives	24
7 Support	24
7.2 Competence	26
7.3 Awareness	27
7.5 Documented information	27
8 Operation	28
8.1 Operational planning & control	28
8.2 Requirements for products & services	29
8.3 Design & development	30
8.4 Control of externally provided processes, products & services	31
8.5 Production & service provision	32
8.6 Release of products & services	33
8.7 Control of nonconforming outputs	34
9 Performance evaluation	35
9.2 Internal audit	36
9.3 Management review	37
10 Improvement	38
10.2 Nonconformity & corrective action	38
10.3 Continual improvement	38
Certification process	39
Alteration status	40

## **COURSE OBJECTIVES**

By the end of the course, participants should have gained:

- An understanding of the history of Quality System Standards
- An understanding of process-based approach to management systems
- Knowledge about the ISO & JAS-ANZ organisations
- An understanding of Quality Management Principles
- Knowledge regarding the documentation requirements of ISO 9001:2015
- Confidence in being able to apply the intent of the Standard to their workplace
- An understanding of the content of the ISO 9001:2015 Standard
- An understanding of the audit and certification requirements



## **Student Notes:**

## **HISTORY OF QUALITY STANDARDS**

As defined by ISO 8402, quality is "The totality of features and characteristics of a product or service that bear on its ability to satisfy stated or implied needs".

Within this definition, we can identify concepts of fitness for purpose, value for money, customer satisfaction and conformance to requirements. These concepts of quality are not new, nor are they restricted to any age or culture.

In 1987, a committee of the International Organisation for Standardisation (ISO), under the chairmanship of Canada, worked to produce an international quality standard.

They considered many national inputs and produced a standard, which was largely based on BS 5750, its notes and commentaries. This series of standards is the ISO 9000 series, which embraces ISO 9001, 9002, 9003 and 9004.

The ISO 9000 Family of Standards has grown since 1987 with the addition of guidelines for particular industries (eg. services), activities (eg. developing quality manuals) and system auditing (eg. management of audit programs).

In Australia they were known as the AS 3900 series embracing AS 3901, AS 3902 and AS 3903. These standards were revised in 1994 and were known as AS/NZS ISO 9001, 9002 and 9003 Standards.

Within Australia, the AS 1821, AS 1822, AS 1823 Standards were used to prior to 1987.

### **ISO 9000:2000**

During the years 1998 - 2000 the Standards for Quality Systems were reviewed and after much consultation with user groups and industry bodies were revised and reissued in December 2000. The 2000 standards contain a number of changes based on an extensive customer survey. Some of the changes were as follows:

- The structure of the standard was altered to be more in line with business processes
- The jargon used was altered to make it easier to align with service based organisations
- Continual improvement included a measurable requirement
- Closer compatibility with ISO 14001 was a key theme
- Measurement of customer satisfaction was introduced
- The scope was broadened to include efficiencies for all interested parties,
- Exclusions of requirements in clause 7 became allowable, and
- The 9002 and 9003 standards were eliminated.

The main clauses of the standard are shown on the next page and were maintained in the 9001:2008 update.

## ISO 9001:2008

This upgrade of the 2000 version contained no new requirements, just clarifications to existing requirements based on eight years of experience. It also introduces changes to further improve consistency with ISO 14001:2004 (EMS).

### CONTENT OF THE ISO 9001:2008 STANDARD

Clause 1	Scope
Clause 2	Reference
Clause 3	Terms & Definitions
Clause 4	Quality Management System
Clause 5	Management Responsibility
Clause 6	Resource Management
Clause 7	Product Realisation
Clause 8	Measurement, analysis and improvement

This update included the 2000 'Process Model' that graphically displays how each of the sections relates.

The latest standard (ISO 9001:2015) builds on this Process Model and is shown on the next page.

## ISO 9001:2015

This latest upgrade is considered to be a major change to the previous versions, and quality and audit professionals will have to revise their current thinking and work in different ways in order to maintain compliance.

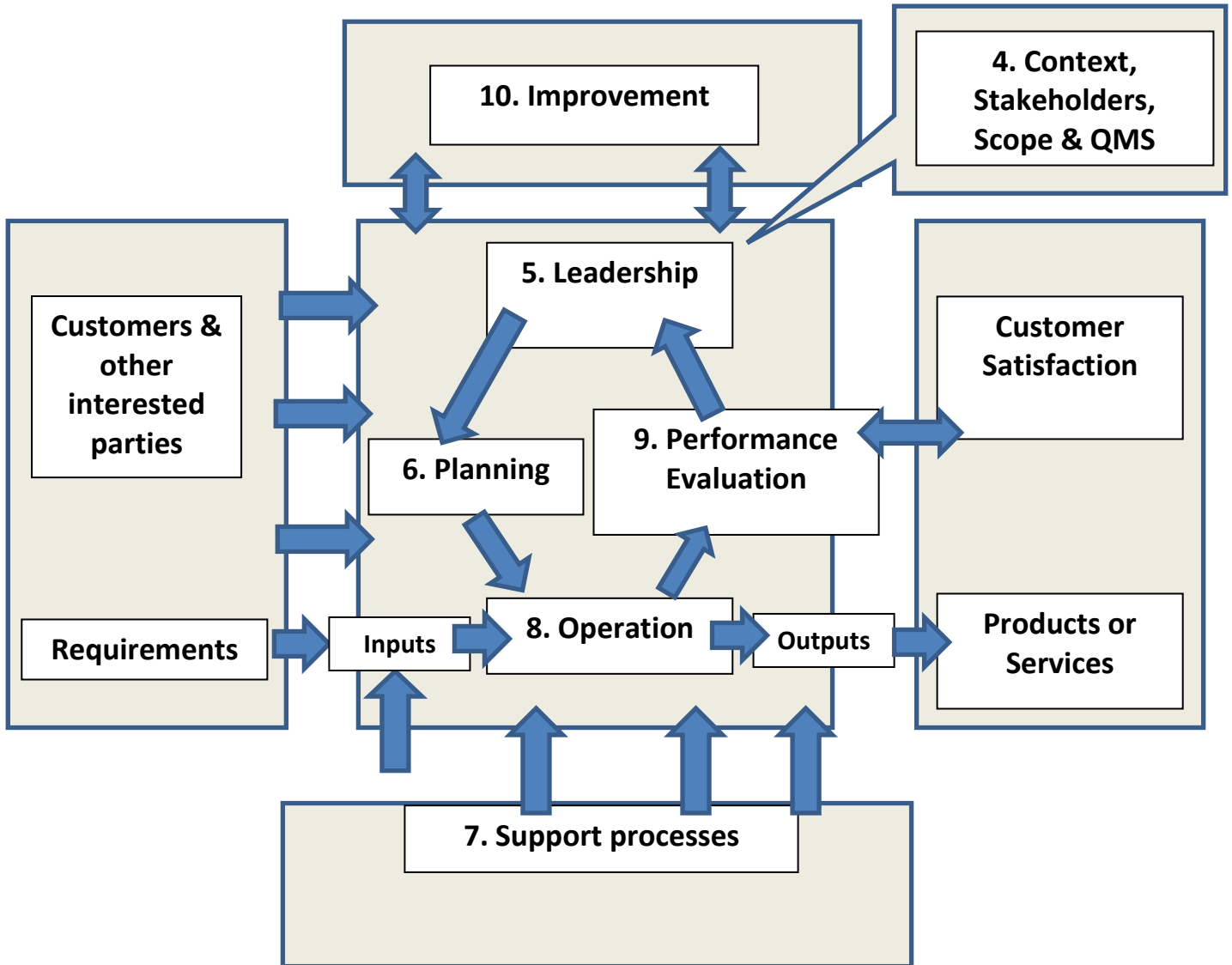
This major change has been caused by the introduction by ISO of Annex SL (previously known as ISO Guide 83). Annex SL provides a 10 clause structure that all management system standards will have to follow at the time of their next revision. This will make it easier for organisations to integrate other management system standards such as environmental (ISO 14001), food safety (ISO 22000), energy (ISO 50001), etc... as they will all follow the same 10 clause structure.

The 10 clauses are as follows:

1. Scope
2. References
3. Terms & Definitions
4. Context of the Organisation
5. Leadership
6. Planning
7. Support
8. Operation
9. Performance evaluation
10. Improvement

It is hoped that standards committees will in the future concentrate their efforts developing sector specific requirements that will be focused on clauses 6 and 8. The other clauses will basically remain unchanged, hopefully speeding up the standard revision process.

## ISO 9001:15 Process Model



Later today we will discuss the content of the various clauses in greater detail.

ORGANISATION  
INTERNATIONALE DE  
NORMALISATION



INTERNATIONAL  
ORGANIZATION FOR  
STANDARDIZATION

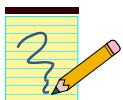
## WHO IS ISO?

ISO, (derived from the Greek word “*ISOS*” meaning the same or level), is a worldwide federation of national standards bodies from some 175 countries. Based in Geneva, Switzerland, the International Organisation for Standardisation is a non-governmental organisation established in 1947. The mission of ISO is to promote the development of standardisation and related activities in the world with a view to facilitating the international exchange of goods and services, and to developing cooperation in the spheres of intellectual, scientific technological and economic activity.

(Ref: ISO website at [www.iso.org](http://www.iso.org))

## Examples of ISO Achievements

ISO Film speed code  
Telephone and Banking card dimensions  
Sea freight container sizes  
The SI system of measurement  
Symbols for Automobile controls  
Wire ropes  
ISO metric screw threads  
ISBN (Book Numbers)  
Quality Management Standards (ISO 9000)  
Environmental Management Standards (ISO 14000)  
Auditing Standards (ISO 19011 & ISO 17021)  
Food Safety Management (ISO 22000)  
Risk Management (ISO 31000)  
Etc.



## Student Notes

## **INTENT OF THE STANDARDS**

When these Standards were first released, companies designed their quality systems around the “order of appearance” of the elements of the Standards. Included in their systems were only those aspects required as a minimum in order to achieve certification with the least effort. System design was largely driven by marketing pressures and a prescriptive audit process.

Today, a more popular approach is to use the standard as a guide on which to base the system, and include other aspects such as Health, Safety, Risk and Environmental requirements.

The new standard encourages businesses to design their systems in such a way that best reflects the way their business processes flow. Adopting this approach ensures that employees will more readily follow its content as it is easily related to the business in which they work. Using this logic the system will be easier to abide by and easier to audit, which should then make it easier to find improvements.

Your system should be regarded as the ‘street directory’ or ‘story’ of your company.

## **WHY CHANGE THE STANDARDS?**

Extensive surveys have been carried out on a worldwide basis in order to understand better the needs of all user groups of the ISO 9000 standards. The new revisions consider previous experience with quality management systems and emerging insights into generic management systems.

ISO has a policy of reviewing international standards at least every five years.

## **The ISO 9000 Family of Standards**

There has been a vast reduction in the quantity of standards contained within the ISO 9000 series. There previously existed about 20 documents covering a range of options depending on the industry sector that applied. Now there are 3 main documents:

ISO 9000:2015	Quality Management Systems – Fundamentals & Vocabulary
ISO 9001:2015	Quality Management Systems – Requirements
ISO 9004:2009	Managing for the sustained success of an organization -- A quality management approach

## **Handbooks (HB Guides)**

Within Australia, Standards Australia has published a series of guidance documents to assist with the understanding of ISO 9001 and other standards with respect to certain Industry sectors. These are listed on the following page.



## **HB Guides to ISO 9001** (always under revision)

The following guidebooks have been produced by industry groups to provide some guidance as to how the ISO 9001 standard may be interpreted for that industry sector. All these publications are available from [www.saiglobal.com](http://www.saiglobal.com) Note: These are constantly changing due to the frequency of the changes that occur.

It is recommended that you check with the SAI Global website. ([www.saiglobal.com](http://www.saiglobal.com))

Subjects covered include:

### **HB 90.1 The Small Business Handbook**

This Handbook provides guidance for small business on quality management systems based on ISO 9001. It explains what quality management systems are and gives examples of how to interpret and implement the requirements of ISO 9001. The auditing process for certification is briefly described.

### **HB 90.2 The Service Industry Handbook**

This Handbook is written about the way a service industry operates. It provides a competency-based approach to service development and delivery that recognizes that both the point of contact with the customer is critical, and back-of-house activities are needed to deliver the service to achieve customer satisfaction. It will provide both a sound approach to ISO 9001 for service industries, and a better understanding of the benefits that service organizations implementing the Standard can achieve.

### **HB 90.3 The Construction Industry Guide**

This Guide explains the requirements of ISO 9001 in terms relevant to the construction industry. Guidance focuses on each Clause of ISO 9001 as it applies to the key processes within a construction industry organization, with additional notes on applications relevant to engineering and building projects of any kind.

### **HB 90.4 The Food Processing Industry Guide**

Provides guidelines for those involved in the Food Processing industry on establishing quality management systems complying with the requirements of ISO 9001. The requirements and application of each clause of the Standard is explained in terms understood by food industry participants. Typical examples are included to assist in understanding these requirements.

### **HB 90.5 Correlation between ISO 9001 and HACCP Principles**

This Handbook provides a correlation between the requirements listed in the clauses of ISO 9001 and the requirements which are implicit in the HACCP Principles, and brings out the complimentary nature of the two sets of requirements. The Handbook provides a guide for those who have a system based on either of these approaches and wish to implement the other or integrate both systems.

### **HB 90.6 The Legal Profession Guide**

Provides guidance for the legal profession on quality management systems that comply with the requirements of ISO 9001. The requirements of the Standard are described in terms common to the legal profession, and the application of various requirements and typical examples in the legal environment are included.

### **HB 90.7 Education and Training Guide**

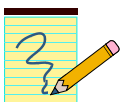
Provides guidelines for those involved in education and training on establishing quality management systems complying with the requirements of ISO 9001. The requirements and application of each clause of the Standard is explained in terms understood by educationalists and trainers. Typical examples are included to assist in understanding these requirements.

### **HB 90.8 Healthcare Services Guide**

Provides guidance to organizations that provide health services, and to those involved in the health services sector, on the development and implementation of quality management systems based on ISO 9001. The application of each requirement is described in terms relevant to health services, and examples are included to assist in understanding their application.

### **HB 90.9 Software Development Guide**

Provides guidance for the software industry on quality management systems complying with ISO 9001. It relates particularly to the development of software and explains the application of the quality management systems requirements in this field. Guidance is given on the process model and design and development as they may apply to the software developer. The terminology used and the examples given are relevant to the software industry.



## **Student Notes**

## JAS-ANZ (Joint Accreditation System Australia New Zealand)

([www.jas-anz.com.au](http://www.jas-anz.com.au))



### Accreditation/Certification

These words are often mixed up. Within Australia & New Zealand, JAS-ANZ is the regulator that accredits certification bodies to allow them to certify organisations. Hence a certification body goes through an **accreditation** (or approval) process to be able to audit companies for compliance to standards. This allows certification bodies to then audit organisations for compliance to management standards which is called the **certification** process.

### A brief history (taken from their website)

JAS-ANZ is an independent, third-party accreditation body established in 1991.

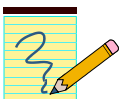
To perform at a high standard, we operate under the JAS-ANZ Treaty Agreement between Australia and New Zealand establishing the Governing Board, Technical Advisory Council and Accreditation Review Board of the Joint Accreditation System of Australia and New Zealand.

JAS-ANZ is a not for profit international organisation funded from our commercial activities.

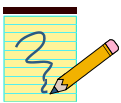
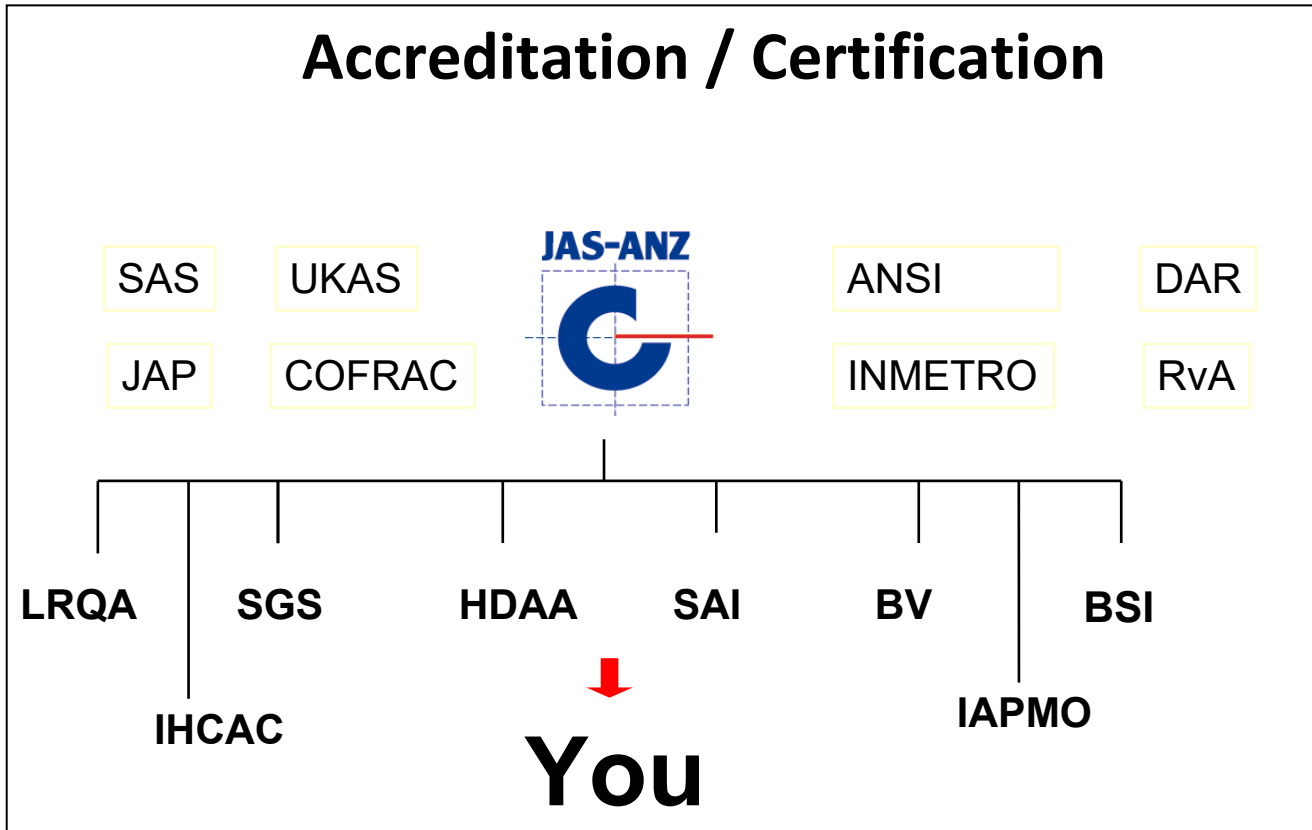
JAS-ANZ accepts applications from certification or inspection bodies operating anywhere in the world, irrespective of their size, location or affiliation.

JAS-ANZ operations are overseen by a Governing Board. Our Technical Advisory Council and Accreditation Review Board allow us to bring technical expertise and stakeholder involvement to the development of accreditation programs and accreditation decisions.

Our Secretariat, located in Canberra, Australia, and Wellington, New Zealand, is the administrative arm of the Governing Board. The Secretariat administers the accreditation process, coordinates the work of technical committees, provides input into national and international committees and working groups, and develops new accreditation programs.



### Student Notes:



### Student Notes:

## QUALITY MANAGEMENT PRINCIPLES

The latest revision of ISO9001 has been based on seven quality management principles, which reflect best management practices developed by international quality experts and endorsed by the ISO/TC 176/SC2 committee.

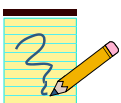
When revising the ISO 9000 standards the committee consulted all the quality awards programs around the world and found they had based their programs on the following principles. In order to not present an ambiguous approach, the new standard embraces these principles, and more.

These seven principles are:

- 1. Customer focused**
- 2. Leadership**
- 3. Engagement of people**
- 4. Process approach**
- 5. Improvement**
- 6. Evidence based decision-making**
- 7. Relationship Management**

These principles are described further in ISO 9000:2015 which we mentioned earlier and is the document that explains all the terms & definitions used. The explanation covers the rationale of why the principle is important, some examples of benefits, and examples of typical actions to improve the organisation's performance when applying the principle.

The terms and definitions can also be located at [www.iso.org/obp](http://www.iso.org/obp). This is an online browsing platform provided free by ISO.



### Student Notes:

## **QUALITY MANAGEMENT SYSTEM** (the 'road map' or 'story')

The system should be documented in such a way that it is easily understood by the users and need only be as comprehensive as required to achieve the desired control. Keep in mind the fact that what is written must be complied with and it is the extent of this compliance that is audited by certification bodies, so, ***keep it simple!***

If the system is documented and implemented effectively, then the benefits will be numerous. Customers will be more assured of your ability to supply. Employees will be happier working within a well-defined and managed system. Management will be able to spend more time managing rather than "fire fighting".

These factors should all contribute to a more financially stable organisation and enhance its ability to control change.

Previous versions of the standard prescribed manuals, procedures, records and work instructions or similar. Progressively, the standard has been reducing the prescription regarding what documentation and records must be maintained and retained. This latest standard takes a bold approach by not specifying any procedures or records. The onus is on the organisation to determine, implement, maintain and retain '**documented information**'. This new term replaces the previous requirements for a quality manual, procedures and records.

It is quite a new approach by the standard writers and will cause some difficulties with auditors and practitioners who fail to be open-minded when determining what a functioning management system is.

For those students reading this and wanting to know what to do with your current system, take heart, the Annex A at the rear of the 9001:2015 standard provides the following advice.

There is no requirement in this standard for its structure or terminology to be applied to the documented information of an organisation's quality management system.

There is no requirement for the terms used by an organisation to be replaced by the terms used in this international standard. Organisations can choose to use terms which suit their operations e.g. documents, records or protocols instead of documented information: or supplier, partner or vendor rather than external provider.

Remember, whatever approach you take, the design of the system must suit the organisation. Do not let external auditors dictate their preferences.

On the following pages you will find a summary of all the ISO 9001:2015 clauses. Because of copyright we are not permitted to reproduce the exact wording. However, on our public courses we make available the latest copy of the standard for your personal use only. (We pay a copyright fee for this service)

# ISO 9001:2015

## Quality Management Systems - Requirements

### Introduction

#### 0.1 General

The adoption of a quality management system should be a strategic decision of an organisation which can help to improve the organisation's performance.

The quality management system requirements specified in this International Standard are complementary to requirements for products.

The standard also mentions here that it is not trying to make all systems the same. Every business has different ways of working and as such, the systems need to reflect the way you want your organisation to function.

The main benefits of having a system based on the ISO 9001 standard is to:

- Assist organisations to consistently meets their customer and regulatory requirements
- improve the ability of an organisation to enhance customer satisfaction, and
- assist to identify risks and opportunities in line with the business context

The standard is not trying to enforce uniformity of management systems.

There is no need to align the clausal structure of the standard with that of an organisation's systems.

There is no need to use the terminology that is found within the standard.

The standard aims to compliment other criteria that organisations have to meet.

The meaning of the following words used within the standard means the following:

**Shall** means mandatory

**Should** means a recommendation

**May** indicates a permission

**Can** indicates a possibility or a capability

**Notes** are guidance only.

#### 0.2 Quality management principles

These have been described previously in this manual.

### 0.3 Process approach

This International Standard promotes the adoption of a process approach when developing, implementing and improving the effectiveness of a quality management system, to enhance customer satisfaction by meeting customer requirements.

For an organisation to function effectively, it must identify and manage numerous linked activities. An activity using resources and managed in order to enable the transformation of inputs into outputs, can be considered as a process. Often the output from one process directly forms the input to the next.

The application of a system of processes within an organisation, together with the identification and interactions of these processes, and their management, can be referred to as the “process approach”.

An advantage of the process approach is the ongoing control that it provides over the linkage between the individual processes within the system of processes, as well as their combination and interaction.

The standard encourages this process-based thinking using the Plan, Do Check, Act improvement methodology. There is a diagram located on page viii in the standard.

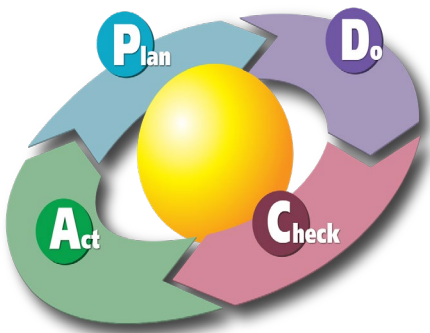
Utilising this process-based approach allows an organisation to manage systems more effectively and efficiently from start to finish.

When used with a quality management system, such an approach emphasizes the importance of:

- a) understanding and consistency in meeting requirements,
- b) the need to consider processes in terms of added value,
- c) obtaining results of process performance and effectiveness, and
- d) continual improvement of processes based on objective measurement.

#### Plan-Do-Check-Act Cycle (PDCA)

This is a philosophical approach on which to base the rationale for business improvement. Made popular by Dr. Edwards Deming, it was a technique for analysing and solving problems.



Using this technique, it helps to view all processes within an organisation as a whole.

It is not mandatory as the standard says it *can* be used rather than *shall*.

Figure 2, in the standard explains how it fits within the standard.



### 0.3.3 Risk Based Thinking

In this latest revision, the standard has introduced risk-based thinking and removed requirements for preventive action as they have been deemed to be of the same intent.

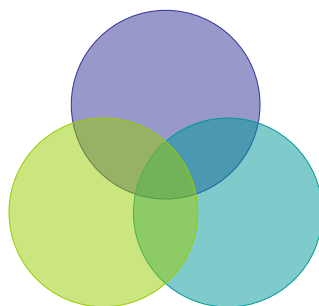
Risks can be seen as opportunities and/or threats to the business. Anything we do in business today needs to be evaluated to ensure that any threats are avoided or minimised and any opportunities are exploited. Risk based thinking is a way of preventing problems before they eventuate and to capitalise on any advantages that may be taken with respect to the operation of the management system.

The ISO Risk Management standard ISO 31000 may be consulted as to approaches that may be taken to manage risk. It is emphasised in Annex A of the current standard that there is no requirement for organisations to implement a formal Risk Management system.



### 0.4 Relationship with other management system standards

As mentioned earlier, the introduction of Annex SL is forcing all management system standards to harmonise their structure to enhance the ability of organisations to integrate two or more standards. In the following years you will see a convergence of system structures as Annex XL has an increasing effect.



## Quality Management System Requirements

### 1. Scope

This International Standard Specifies requirements for a quality management system where an organisation:

- a) needs to demonstrate its ability to consistently provide product that meets customer and applicable regulatory requirements, and
- b) aims to enhance customer satisfaction through the effective application of the system, including processes for continual improvement of the system and the assurance of conformity to customer and applicable statutory and regulatory requirements.

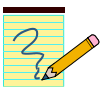
The standard can be applied to any organisation, big or small, whether they be a manufacturer, Government department, service provider or whatever. The words product or service are interchangeable.

### 2 Normative references

ISO 9000:2015, *Quality management system – Fundamentals and vocabulary*. This standard may be consulted for explanations of the various terms and definitions used within the standards.

### 3 Terms and Definitions

See above



### Student Notes:

## **4 Context of the organisation**

### **4.1 Understanding the organisation and its context**

This is a new clause. In the previous editions of the standard, organisations would decide to prepare a quality manual and tell a story about the various subject matter explaining how they would comply, without any rhyme or reason. Referenced here were procedures and all sorts of documentation for staff to follow.

Now the standard is asking organisations to document considerations made regarding internal and external factors that can affect the organisation's processes, products & services provided, the content of the quality management system, the strategic direction in which the organisation wishes to head, cultural, legal, industry requirements and much more. These factors may change over time and are to be reviewed on a regular basis.

These factors could arise from internal or external sources and may include the following:

- risks
- opportunities
- changes in Government
- cultural,
- financial
- introduction of new technology
- market demands & market share
- strategic
- company values etc...

Good organisations do this anyway as part of the planning process when developing a quality management system. It would be logical if top management could document their rationale as to why the quality management systems exists and include an explanation regarding the content.

From this point onwards, the clause relating to Management Review (9.3) could be used to continually review the above factors to address any changes that need to be made.

The intent here is to ensure that the quality management system is integral to the functioning of the organisation on a day by day basis.

## 4.2 Understanding the needs and expectations of interested parties

In line with 4.1 above, it is critical that all relevant stakeholder interests, wants and needs are determined to ensure that the organisation's strategy, direction, planning and activities are harmonized. This is critical to ensure the origination is relevant and focused on the things that matter.

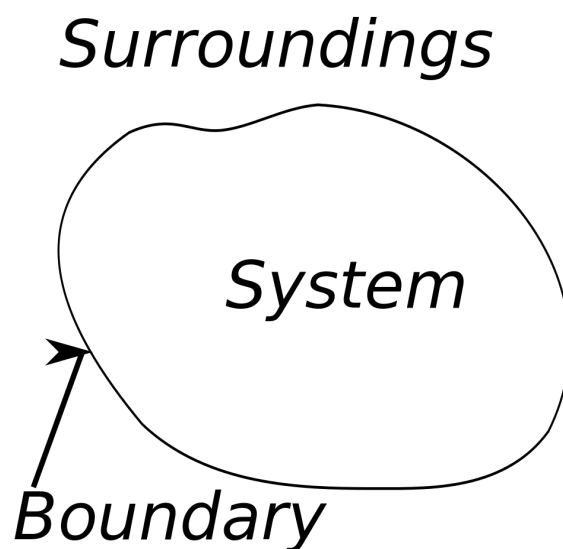
A formal stakeholder analysis conducted initially, and then at regular intervals is a technique an organisation can use to ensure all relevant needs and expectations of all stakeholders are continually being monitored and considered.

Part of this process is to initially identify who are the stakeholders?

## 4.3 Determining the scope of the quality management system

Only after the evaluation of the above factors (4.1 & 4.2) can the scope of the quality management system be determined. The scope is like a fence that borders the activities of the organisation. This is relevant for certification purposes as it defines what's in and what's out, which dictates the time taken to conduct an audit. As an example an organisation may be a registered training organisation that also provides disability services and runs a workshop for clients at three different locations. They may choose to certify all or part of the business operations. The scope statement would articulate what is to be certified or within scope and what is not.

Normally an organisation would address all requirements of the standard. However, if the organisation deems that a part of the standard is not applicable to the scope of work then the organisation must document justification for this non applicability. As an example, clause 7.1.5.2 requires measurement traceability. If the organisation is a service provider and does not make use of, or need, any measuring equipment, then justification for non-applicability may be justified.



## 4.4 Quality management system and its processes

This standard continues the trend of its predecessors to further reduce the prescription regarding how an organisation goes about creating their documented information to be used by staff to ensure clarity and appropriate control of work activities.

There is no requirement for manuals, procedures, work instructions or records. The standard is very open and asks for 'documented information' which is the new term that replaces the quality manual, control of documents, and records.

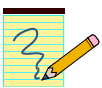
Subtly, the standard requires organisations to **maintain** documented information to support the operations of its processes, (policies, procedures, instructions, manuals etc) and, to **retain** documented information to have confidence that the processes are being carried out as planned (records).

It is completely up to the organisation to design their systems in such a way that best suits their needs, as long as the following has been defined for the processes:

- inputs and outputs
- sequencing and interaction
- responsibilities & authorities
- applicable criteria determined
- applicable resources
- risks & opportunities
- regular evaluation & change process controlled
- mechanisms to capture improvement

All the above can be overseen as part of the internal audit process.

For those who have existing well-functioning and organized systems based on the previous versions of the standard, Annex A on page 21 of the standard states that there is no need to change your existing systems, methods or jargon to line up with the latest standard.



### Student Notes:



## 5 Leadership

### 5.1 Leadership and commitment

#### 5.1.1 General

In this section the writers of the standard continue with their upward push towards top management. For too long the responsibility of developing, documenting, implementing and managing the quality management system has been left to those other than top management. This filters down in the organisation as a sign of lack of commitment.

The standard requires top management to demonstrate leadership and commitment by:

- being accountable for the effectiveness of the QMS.
- Ensuring that policy and objectives are in line with the context and strategic direction
- Ensuring that the QMS is fully integrated into day to day tasks (It's what we do)
- Promoting the process approach and risk-based thinking
- Providing resources to make it happen
- Communicating the importance of the QMS
- Engaging, directing and supporting staff to contribute to the effectiveness of the QMS
- Promoting improvement and supporting other managers in their roles.

What more can the standard say about leadership? External auditors should interview the CEO and request to see evidence of the above.

As usual, top management shall demonstrate leadership when it comes to being customer focused. Risks and opportunities with respect to meeting or not meeting customer expectations need to be evidenced.

## 5.2 Policy

### 5.2.1 Establishing the quality policy.

The standard requires that management publish a 'Quality Policy'. The standard is quite clear as to what it should contain. The policy is a powerful statement of intent by top management and such should be articulated carefully to all employees. It is usually very visible and signed off by the CEO. Care should be taken when documenting a policy to ensure that any stated imperatives are fulfilled, measurable, meaningful, and relevant to the organisation. In some organisations a *customer charter*, *mission* and/or *vision* statement may be used to meet this requirement. Consider how employees will embrace the content of the policy.

### 5.2.2 Communicating the quality policy

Complimenting 5.2.1 above, the policy needs to have a high profile and be readily available.

### 5.3 Organisational roles, responsibilities and authorities

This clause is a combination of the old clause for responsibility and authority blended with the previous requirement for a management representative. To ensure top management take a leadership role, these former split requirements rest right at the foot of top management. It also shows that quality management is a top management responsibility, not a department on its own.

Top management shall ensure that the responsibilities and authorities are defined and communicated within the organisation.

A large proportion of avoidable errors and waste in business occurs because employees are not clearly aware of what they are responsible for and what authority they have to make decisions alone. Responsibilities and authorities for all personnel should be clearly defined and made known to each employee. Some companies will develop role descriptions covering the above and have the employee sign off as a means of ensuring comprehension. An organisation chart also helps to define reporting lines within an organisation. If you decide to include responsibilities and authorities within procedures, care must be taken to ensure that they do not contradict the content of position descriptions.

The standard prescribes the outcome not the method to be used.

## 6 Planning

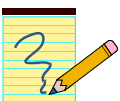
### 6.1 Actions to address risks and opportunities

This requirement is a new addition to the standard. In line with the new approach to risk based thinking, top management need to have considered risks and opportunities when first developing a QMS.

If your organisation decides to go down this path, you need to be aware of the pitfalls or errors to avoid? What opportunities exist whereby your QMS can actually make your processes better and improve the way work is done, or to help you exploit opportunities to sustain the organisation?

In almost every case it is more effective to prevent an unwanted situation from occurring as opposed to fixing an error after it has been made!

6.1.2 If risks or opportunities are identified, then proportionate actions need to be taken as an integral part of the process.



### Student Notes:

## 6.2 Quality objectives and planning to achieve them

Objectives for how quality is to be achieved are also required. Objectives are measurable goals, targets or KPIs (Key Performance Indicators). These must be established at relevant functions, levels and processes needed for the QMS. (Which could also include external processes)

Consider establishing objectives for each group, site or process within your organisation. Rather than high-level static objectives, establish meaningful, realistic, measurable short and long-term objectives.

After all, what is the point of having business objectives that are unachievable or unrealistic? As objectives are monitored and reached, others must be developed, monitored and achieved and so on.

To make these objectives meaningful, in addition to their establishment, organisations have to ensure that the following is stated:

- What will be done
- What resources are required
- Who is responsible
- When will it be completed
- How will the results be evaluated



The management review function (9.3) is a popular way to monitor the effectiveness of objectives.

## 6.3 Planning of changes

Just like other management system standards, the control of change can cause an unwanted consequence if not managed effectively.

For this to be avoided there needs to be a process that controls changes and modifications to the QMS.

## 7. Support

### 7.1 Resources

This clause of the standard is the main support act. All those aspects that are needed to support the conduct of business; people, tools, infrastructure, a proper work environment, knowledge, communication, documented information (documents & records) and more. Without these resources, a business will not function.

Most who attend my training courses complain about the lack of, or reduction in, resources available to do the work. May be this is a result of the excesses of the past and the need to reduce excessive costs?

The following is an overview of resource requirements.



The organisation shall determine and provide the resources needed. The organisation must consider internal capabilities and restraints. Any extra resources are usually sourced from external providers.

Evidence must be available for auditors to see that resource determination has taken place and that it is happening on an ongoing basis. Management Review is a good mechanism for conducting this review.

A lack of resource provision is often identified as a cause of audit non-conformance.

### 7.1.2 People

The most important resource in any organisation is people. It is appropriate to have a mature recruitment strategy and process supported by a comprehensive induction process. A training matrix can also work to list staff against competencies and positions and/or roles. Job descriptions are also a popular way to document staff competencies as well as authorities and responsibilities. (see 5.3 above)

### 7.1.3 Infrastructure

This requirement first appeared in the previous version of the standard. I call it the 'what if' clause. What would happen if you lost your:

- power supply
- gas supply
- water supply
- internet connection
- only transport contractor
- phone system
- data back-up system
- sole subcontracted resource etc...



This blends in well with risk based thinking. The loss of any of the above applicable resources is going to cause a risk to your organisation. Think about adding the above to your risk profile or risk matrix/register.

### 7.1.4 Environment for the operation of processes

Often an organisation's work environment may cause a detrimental effect on the products or services you deliver.

As an example, a food company must ensure that food storage is clean, pest free, and at the correct temperature. This example would contrast with an electrical workshop where a pest free and clean environment would have less of an impact on the product? Whatever the potential environmental effect, evidence must be available about the determination of the various issues and their ongoing monitoring.

Do not forget to consider other issues such as bullying, discrimination, cultural issues, stress, heat, personal hygiene, light, airflow, noise etc..

### **7.1.5 Monitoring & measuring resources**

For those organisations that rely on calibrated equipment or software to gauge the outcome of product conformance, documented information must be available to show that suitable controls are in place to ensure calibration status is known.

Documented information (instructions) must be in place to describe how this equipment is used and for what purpose.

As per the previous version, processes need to be in place to describe what actions are required when this equipment is found to be out of calibration.

### **7.1.6 Organisational knowledge**

This clause is new to the standard. Often, a staff member departs from an organisation and takes a lot of workplace knowledge with them. This can cause problems for some organisations as that knowledge has to be re-collected and restored to the level as it was before that knowledge walked out the door. Knowledge is accumulated over time and can be quite valuable to an organisation. Knowledge can also be collected from lessons learnt, seminars, conferences or similar.

Intellectual knowledge can be commercially sensitive and is to be tightly guarded. What controls should be in place to protect this?

As an example, what if a new person was recruited to an organisation to perform a specific function. What documented information is available and in what form, so that this knowledge is readily transferred to the new recruit? One of the great benefits of having a documented QMS is to make knowledge sharing so much easier.

Organisations must show that the determination of this knowledge has taken place and as mentioned several times before, reviewed on an ongoing basis as knowledge needed, will change continually.

## **7.2 Competence**

Often the understanding of the differences between knowledge and competence is not always clearly known.

Simply put, knowledge is knowing how to perform a task, whereas competence is having the knowledge and skill to be able to perform the task.

Not much has changed here from the previous version of the standard. An organisation must determine what competencies are needed by staff to perform their duties. This competence can be attained by appropriate education, training and/or past experience. Records are to be maintained to show that staff have acquired appropriate competence. As above, things change over time, so ongoing monitoring of competency is required. If a competency gap emerges the organisation may sub-contract to obtain the competence or train up existing staff.

## 7.3 & 7.4 Awareness & Communication

These requirements are similar to the previous version except that communication has gone one step further and included external communication in addition to internal communication.

It is well and good to have all this documented information contained within your QMS, however, if the stakeholders do not know of its existence then the QMS is of little value.

Staff need to know what they should refer to obtain information about their role. They also need to know what the consequences will be should they not follow or perform required activities as communicated within the QMS.

Websites are a popular way in which organisations communicate to external stakeholders. Depending on the nature of the communication, it may be necessary to designate certain personnel to be responsible to perform this communication to avoid mixed messages or confusion.

## 7.5 Documented information

This is a new term that replaces the previous subjects of Control of Documents & Control of Records.

For those familiar with the previous version, you can maintain your existing systems if they will continue to manage these subjects effectively. The same can be said about the Quality Manual as required by the previous version. If the manual continues to serve its purpose effectively, then it can continue to be used in its current format if it addresses all requirements.

Guidance from ISO has advised that where the term '**maintain documented information**' appears within the standard, then this means a procedure, instruction, plan, manual, SOP or similar may be used to control activities. Where the term '**retain documented information**' appears within the standard, then this means a record of a current and/or prior event must be kept.

Controls are required here to ensure that staff are made aware of how to:

- Create and update documents
- Use appropriate headings and footers
- Follow a process for review and approval of documented information
- Use appropriate media
- Distribute and retract new and old documentation
- Protect documentation and company information
- Care for records
- Control changes to documented information
- Disseminate new documented information



## 8. **Operation** (Doing the Work, making the product, delivering services)

Within the previous versions over the past 28 years, various terms have been used to describe how work is controlled. Terms such as Production Control, Product Realisation and Process Control have all be tried and cast aside. These terms did not seem appropriate for a service provider or Government agency. The latest version has used the term 'Operation'. Will this be successful? Time will tell.

Clause 8 of the standard has a logical flow and describes sequentially:

- Planning
- Communication with customers
- Determining what the customer wants
- Understanding what the customer wants and determining capability
- Documenting the agreement by both parties
- Controlling any agreed changes between the parties
- Design of the product or service
- Controlling inputs from external suppliers and customers
- Communication with external providers
- Doing the work /providing the service
- Identification & traceability of products or services
- Looking after customer's or supplier's property
- Care & delivery of products & services
- Release of products or services
- Controlling any problems

As per clause 7 in the previous standard, the standard is trying to present a logical sequence. Some organisations can cover this whole sequence by the use of a process map or similar. Other may have a manual that describes the business flow from start to finish. There is no prescription on how it should be documented as long as it gives support to the process and presents in a logical easy to understand manner for the users.

Terminology that you use might be called: Service Delivery, Manufacturing Control, Training Programs, Food Services, Aged Care Program Monitoring, Property Management, or a similar term that appropriately describes what you do and how you control it.

### 8.1 **Operational planning and control**

Way back at clause 4.4 it is a requirement to determine how the processes are going to be controlled. Here, there is a requirement to plan and implement the systems as determined previously.

A decision needs to be made at this stage as to what activities for planning and control need to be established. Construction companies often develop a project specific plan which is a mini system designed specifically for each project. Our training organisation uses a Training & Assessment Strategy manual for each course offering. Other businesses may utilise a software based system that controls the flow of work from start to finish?

Like all business if you fail to plan then you can plan to fail! Within your management system you need to describe what activities are performed to ensure that adequate planning takes place so that when you come to perform what you are good at, there will be no wasted effort. Other techniques employed include a collection of recipes, a lab manual, a budgeting process or a resource plan or similar.

You need to answer questions such as: What are we trying to achieve? What targets or objectives have been set? What resources will we need? When it's done how are we going to check it and against what?

What records will we have to keep? Who is responsible for the outcome and what competencies are needed?

Your planning processes might be an integral part of a process that includes design development.

Part or all of the planning and control processes might be outsourced, in which case controls are needed to control the providers of these outsourced aspects. This is mentioned in more detail when we discuss control of externally provided processes, products and services coming up at clause 8.4.

## **8.2 Requirements for products & services**

### **8.2.1 Customer communication**

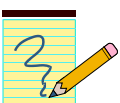
Organisations must determine how they are to interface with customers. Organisations must make it easy for customers both existing and potential to communicate their requirements using whatever medium is to be used. Most organisations will have a website that allows customers to find out what products and services are on offer. In some sectors the effort placed on website design and functionality is critical for business success.

### **8.2.2 Determining requirements for products & services**

Before work is commenced, organisations must find out exactly what the customer wants. Are there any applicable requirements or legislation? Can the products and services advertised be delivered as promised? Does the customer know what they want? Often a quotation process is used to ensure there is no ambiguity between what is offered and what is wanted.

### **8.2.3 Review of requirements as mentioned above.**

Care must be taken to ensure that your organisation does not promise what they cannot deliver! All the agreed requirements from both organisation and customer need to be documented.



## **Student Notes:**

## 8.2.4 Changes to requirements for products & services

This requirement means that anyone can change their mind at any time, as long as the change is agreed to by all parties and documented in the form of a record. For example, when building a house there are always changes that occur because of unavailability of certain products, or new products that emerge during construction. These are agreed and documented as amendments.

Aged care organisation may have care plans for their clients. Due to changes in circumstances, these plans are often amended with the agreement of all parties.

The Weather Bureau may provide an amended weather forecast due to sudden changes in weather.

## 8.3 Design & development of products & services

In general there has been little change to this part of the standard compared to the previous version. As discussed earlier, any clause in the standard may be considered for non-applicability. Those aspects that are deemed to be non-applicable must be justified, documented and excluded from the scope of the QMS as mentioned earlier.

In the past Design, has often been excluded because it was not relevant to the organisation. As an example, a stockist, a document storage company, a bus company, or similar does not have a design function. Therefore it would be permissible to deem design as non-applicable.

The layout of this clause is easy to follow and it must be remembered that you do not have to have a separate procedure or process defined that follows the sequence exactly unless you choose to. If you are a design company and every order requires some design, then a lot of these clauses will probably be addressed in the previous clause on 8.1 Operational planning & control and/or the following clause 8.5 on production and service provision.

In order to ensure that the desired output is achieved, it is advisable to have a procedure or design plan, or some step by step process defined for the various steps for your design activities. It is crucial for long term success that the design output is right. Often design output is expressed in the form of a drawing, a plan, a recipe, a project specification, a pilot training course or the finished article as a 'first off sample'.

The standard begins with ***design and development planning (8.3.2)*** which covers such things as resources required, design stages, allocation of responsibilities, cross communication within your organisation, complexity, verification and validation activities, inputs from all parties and a record of requirements.

The next step involves collecting all information required as ***input (8.3.3)*** so that design can occur. Information such as functional requirements, laws, standards and regulations, failure consequences, efficiency or similar must be collected and analysed for ambiguity or conflict. ***Design and development controls (8.3.4)*** requires that documented results are to be retained to record results to be achieved, results of design reviews, verification and validation activities, to ensure all steps are covered.

When completed, the **output (8.3.5)** of the design process must meet the input criteria including conformance to any necessary safe operating requirements. The design output must reference any acceptance criteria. Records shall be maintained of design outputs.

If any **changes (8.3.6)** occur throughout or after the design process, then these changes must be recorded and maintained. Also, if changes occur after completion you may have to be repeat verifications and validations performed on products or services already in use.

## **8.4 Control of externally provided processes, products and services**

### **8.4.1 General**

Most organisations have to purchase goods and services, then add value and on sell to customers. Sometimes goods and services are provided by our customers, and other times our suppliers may deliver directly to our customers without any involvement by your organisation. Definitions of these goods, services and processes may include the following.

- Tangible materials purchased from suppliers, wholesalers or retailers
- Intangible services received from consultants or advisors
- Sub contracted activities such as, HR, data storage, transport
- Pest control services
- X-rays provided by patients
- Project work provided by students
- Joint venture and/or partnership arrangements

### **8.4.2 Type and extent of control**

Controls must be considered to manage the above to ensure the consistent supply of conforming products and/or services to customers. Controls such as the following may be used.

- Purchase orders with clear descriptions
- Proposals and matching contracts
- Joint venture agreements
- Policies, procedures
- Signed consent forms
- Supplier audits.
- Inspections
- On-site inspections
- Incoming goods inspections
- Certifications

Whatever controls are used, organisations must have proof that these controls are in place and there is recorded information to evidence its implementation.

### 8.4.3 Information for external providers

To enable the organisations' external providers to understand what is expected from them, the organisation needs to determine and clearly communicate what is expected. This shall be determined prior to communication to the provider. This may be a simple sign off on a purchase order or contract or some other authorisation process. All provisions of supply need to be covered as appropriate.

## 8.5 Production and service provision

### 8.5.1 Control of production and service provision

#### How do you control the way work is done?

Whatever business you conduct, the standard requires that your product or service is generated and provided in a controlled way to ensure that whatever is made or delivered is in accordance with your customers' wishes.

The standard then proceeds to give an array of control mechanisms from which to choose. In short, it might be an instruction manual, a suite of instructions, a drawing, specification, a series of photographs or procedures for inspection and testing or similar.



#### How do you validate the processes you employ?

If you have processes that you cannot tell if the outcome has been met until after completion, then there is a higher degree of probable error and waste.

Such processes must come under tighter control. A welding process for a critical job is usually controlled by having weld procedures and the use of a qualified welder. A cooked food product has a recipe. A training program has a course plan and uses a qualified teacher.

A critical medical process is controlled by a qualified practitioner, A gas detection procedure prior to entry into a confined space.

These are all examples where the process employed needs to be validated prior to execution to eliminate error.



## **8.5.2 Identification and traceability**

This clause ensures that your products can be differentiated from each other by suitable means and that if required or specified, traced at some time in the future. Part numbers, serial numbers, student ID, batch lots etc. are some of the techniques used. (Traceability is only required when specified)

## **8.5.3 Property belonging to customers or external providers**

Care must be taken when organisations receive items from customers or suppliers to ensure that these items are protected from damage and identified appropriately. These items range from materials, components, tools and equipment, premises, intellectual property and personal data.

If any of these items are lost, damaged or unsuitable for use, they must be identified, controlled to prevent inadvertent use, recorded and reported to the customer or external supplier.

Examples may be medications provided by patients, student course work, sites provided to a developer, cars for repair etc..

## **8.5.4 Preservation**

In short you should have controls in place to ensure that any product at whatever stage within your business is protected from damage or spoilage, even up to the point of delivery if agreed with your customer. This could mean protection of data under the Privacy Act, maintenance of food products prior to and during delivery, controls over shelf life, vermin controls in a dairy or weather proofing of products exposed to the elements.

## **8.5.5 Post-Delivery activities**

Organisations must determine all relevant obligations such as warranty, legal requirements, after sales service, agreed goods return policies, issues with non-conformance, customer feedback, and contract agreements and have in place suitable systems to manage to above situations.

## **8.5.6 Control of changes**

This requirement must be addressed by organisations to ensure that all changes to the systems relating to product and service processes are controlled, recorded and reviewed.

## **8.6 Release of products and services**

This requirement is unchanged from the previous standard and requires organisation to have in place 'final inspection' processes to ensure that the customer will receive what is expected. Evidence must be retained to prove that all agreed requirements have been met and that records of this approval has been kept.

Inspection reports, test results, sign off by an approved authority or similar is used to affect this step in the process.

## 8.7 Control of nonconforming outputs

I call this clause the 'just in case clause', because hopefully there will be no need for it.

However, mistakes are made within the supply chain and it is your responsibility to have controls in place to ensure that any incorrect product or service that is provided is identified and controlled.

The Cranfield University in the UK has conducted studies that show that if we eliminate preventable problems, waste, shrinkage, leakage, credit notes, customer returns, and any other mistakes from our area of responsibility there will be an improvement of up to 15% in productivity in manufacturing companies and up to 30% in service companies!

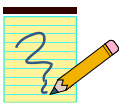
Just imagine that for a minute. That's more than what we make in profit! There is money to be saved and resources should be devoted to eliminate it. A lot of employees state that they haven't got time or enough resources to do audits or improve processes, yet, they devote up to a quarter of their time on wasted activities or fixing mistakes! Enough of the soap box.

The key to this clause is the way in which non-conformances are captured and recorded. Often there will be an NCR (non-conformance report form), or a simple entry in a computer system. Internal problems are usually found by the employees as a result of inspections, maintenance activities or audits, whereas external problems arise in the form of warranty claims, product returns and customer complaints.

A procedure would be helpful that describes how the problem products or services are captured and identified, how they are dealt with, who is responsible for deciding what to do, whether to claim a concession from the customer and what records to keep.

It is important to not treat all problems the same. You may have a formal process for dealing with a major issue. However, this formal process may be a disincentive for someone who finds a smaller problem. The standard lets you take different actions based on the risk of what has been found.

In some companies I have seen them combine this clause with some of the following clauses and call it 'Problem Solving'. In this way you may need only one procedure or process instead of three.



### Student Notes:

## 9 Performance evaluation

### 9.1 Monitoring, measurement, analysis and evaluation

#### 9.1.1 General

To borrow a well-worn phrase *'You can't manage what you can't measure'* is not a bad starting point for this part of the standard.

In order to determine the financial success of business entities, the monitoring, measurement and analysis of financial information has been occurring for 2000 years.

The same should apply to the effectiveness and efficiency of your management systems. If you have good monitoring systems in place that produce meaningful information or data, then you can demonstrate conformance and identify where improvements are required.

The methods and techniques to be used are up to you.

#### 9.1.2 Customer satisfaction

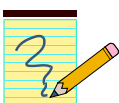
The basic fundamental of any business entity is to satisfy customers. Customers are the reason for your existence.

They provide your revenue, so it is important to gain some knowledge of how satisfied they are with your products or services. A lot of companies send out surveys to their customers, however, this may displease customers and the return rate is usually low.

The standard is very subtle and so should you be when determining the best way. The standard requires you to monitor information relating to customer perception. It doesn't say to collect it directly from them. You may determine this from information you have within your company.

Techniques to consider may include reduction in credit notes, reduction in returns, increase of referrals or repeat business, minutes from client focus meetings, increased share price, a courtesy call after delivery, information collected from sales staff, letters received from happy customers or awards received.

Whatever you decide, ensure that staff are made aware of the methods and that there is consistent application.



#### Student Notes:



### 9.1.3 Analysis and evaluation

By analysing selected data carefully, trends may be detected to allow actions to be taken to take advantages of positive trends and to also allow for action should negative trends be detected.

The standard mentions four areas as a minimum where data can be analysed, but don't restrict your thinking to just these areas. You may want to analyse data relating to market trends, rise and falls in customer complaints, credit notes, warranty claims, increased funding, product yield, throughput, earnings per employee, market share, business from referrals, share price, waste, or anywhere trends can be picked up to indicate the effectiveness of your management systems.

The result of this analysis provides a valuable input to your management review process.

***Comment:***

One of the real keys to a management system is the availability of data to provide objective information as a measure of conformity to policies, objectives, goals, key performance indicators (KPIs) and customer satisfaction. You can't manage what you can't measure.

## 9.2 Internal Audit

For those that know me well this is my pet subject. It's the glue that keeps it all together.

Ask yourself how much effort is required to develop and implement management systems within businesses? No volunteers for writing procedures, criticism for those that have, lots of compromise to eventually get them nearly right, a bit of after-hours work and not to mention the time and resources required.

How easy would it be to let loose inappropriate auditors and undo all that good work. A DuPont site I worked at took 7 person years to implement their management system. The techniques used and the staff selected to perform internal audits need to be chosen carefully.

Internal audit is one of the tools you can use to ensure that your system is kept up to date with what happens in your business today. A street directory is updated every so often as new streets and features are added. If it wasn't updated it would become less useful over time.

As your business processes and techniques change so should your management systems. Auditing is a way to ensure that your systems match your processes and that you lock in new and improved techniques to ensure they become the norm.

You are moving along the right path when employees welcome an internal audit on their processes. Unfortunately because of ignorance, some managers use the audit process as a policing tool rather than an information gathering exercise.

All audits should be conducted in a positive manner. Otherwise they are a waste of time. Audits should be conducted to help companies improve their management systems not just to please a certification process.

There are a lot of past mindsets that influence the way in which audits have been conducted; however, the standard does not specify the techniques to be used. Unlike certification audits, internal audits can be less formal events scheduled according to your business demands, available resources and risks associated with your business operations. Its helpful to have a procedure that simply explains the way you wish to conduct audits as guidance for your staff.

All aspects of your systems need to be audited eventually. Job descriptions, procedures, instructions, policies, plans, organisation charts, flow charts, etc including the linkage between these documents. Don't just audit procedures individually. Ensure that several linked procedures are audited as a process to ensure no gaps or excessive overlaps exists between them.

Establish a flexible schedule of audit activity based on value to your business and any associated risk or past knowledge. Use auditing as a communication & educational tool so that staff can learn across the organisation rather than just in their own area.

If you get behind in your audits compared to your established schedule, don't do some hurried audits to get back on track. It is better to select the most important processes and do it properly and re-schedule the other audits for a later date.

Ensure that your auditors engage the auditees (process owners) to ensure that the audit process is a joint effort rather than just the auditor's view of things.

To maximise your efforts, integrate your audit process to cover other compliance requirements such as OH&S, or environmental obligations.

### **9.3 Management review**

This requirement ensures that management take time out to reflect on the efficiency and effectiveness of the management system. This provides an opportunity to analyse the data flagged up from the system. e.g. audit results, customer feedback, improvements, changes, complaints, waste, supplier performance etc.

As an outcome of this process actions should be determined and followed up at the next review. Top management must be involved in this process. The frequency of such reviews is determined by need.

These reviews may also be a part of an existing management meeting process.



## 10 Improvement

### 10.1 General

The intent here is to ensure that you are making progress with regard to the effectiveness of your management system. Are we doing things better this year than last, or are we going backwards? Are we using less of our resources to maintain our management system? Are we making good use of our system indicators such as audits, management review and data analysis?

All businesses must improve over time or face losing market share, so it makes sense to ensure that measures are in place to provide this information.

### 10.2 Nonconformity and corrective action

This is one of those 'what if' clauses that sits there just in case it is needed. Like 8.7 it is hoped that it will never be needed.

As we all know, problems sometimes occur, and a process is required to capture the problem and fix it. Historically a special form is often used but this is not always necessary. Filling out a form is sometimes overkill and is often a disincentive for solving a minor problem.

The standard requires that actions are to be taken appropriate to the effects of the problem, which might be a correction by an operator or a major event using a lot of resources. It all depends on the risk of what you are correcting.

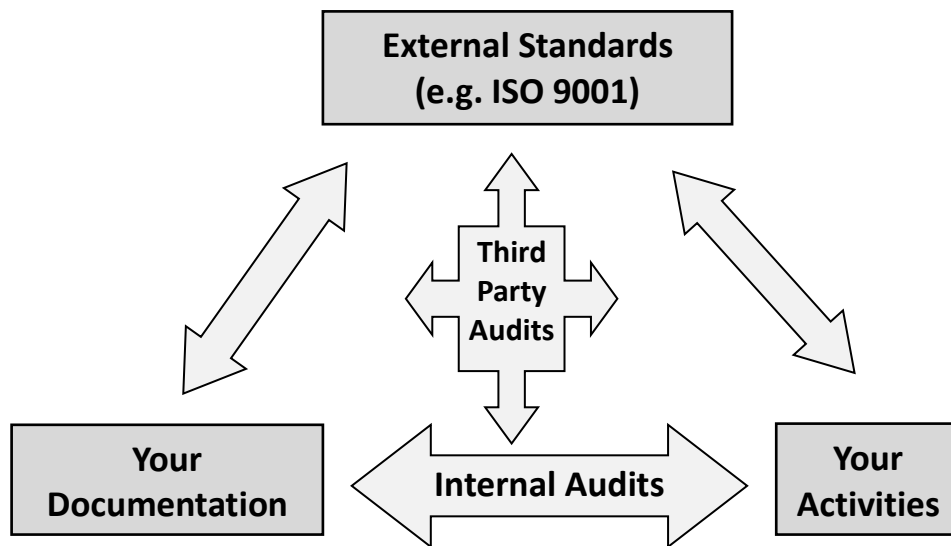
A procedure is helpful here to define the action to be taken to solve the problem. It may be short term or long term, but it still costs money to fix things.

***Comment:***

Correction is action taken to correct a nonconformity.  
Corrective action is defined as action taken to eliminate the causes of an **actual** nonconformity to prevent recurrence.

### 10.3 Continual improvement

Evidence must be available to show that the QMS has improved from year to year and that good use is made of data analysis and the output from management review.



### Certification Process

For a complete list of accredited certification providers, go to the JAS-ANZ website at [www.jas-anz.com.au](http://www.jas-anz.com.au). There are approximately 120 certification companies to choose from within Australia and essentially, they all follow a similar process.

The protocols for the third-party process are found in ISO 17021, Conformity Assessment—Requirements for bodies providing audit and certification of management systems.

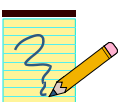
Most certification companies will provide a brochure and/or kit which explain the whole process in detail.

### Sources of Information?

Australian and International Standards can also be found on the SAI-Global web site at [www.sai-global.com](http://www.sai-global.com).

For a free download of 'Frequently Asked Questions' about the new Standards go to the ISO website at [www.iso.org](http://www.iso.org)

Another useful reference website is [www.bsi.org.uk/iso-tc176-sc2](http://www.bsi.org.uk/iso-tc176-sc2)



### Student Notes:

## ALTERATIONS STATUS

Initial Release of original version	10 February 2000
Update for ISO 9001:2000 Standard (Changeover)	14 February 2001
Corrected minor typos	10 December 2001
Addition of HB Guides	28 August 2002
New issue-ISO 9001:2000 Demystified	1 January 2004
Updates re RABQSA, ISO members to 150	20 June 2005
New issue – ISO 9001:2008	15 December 2008
Minor updates and improvements	1 January 2011
New issue of ISO 9001:2015	1 <sup>st</sup> November 2015
Modification for online delivery	1 <sup>st</sup> April 2020

**The Presenter:** **Geoff Gray** (Certificate IV in Assessment & Workplace Training)

Geoff has been running quality management and auditing courses for over 25 years. Geoff brings to his courses a wealth of knowledge gained from client companies that have implemented systems to conform to ISO 9001 ISO 14001, HACCP, SafetyMAP & AS 4801. During the course, examples are provided to assist with a streamlined and simple approach to implementation. Geoff has been involved with the presentation of Lead Auditor training courses within Australia, Japan, Hong Kong, Indonesia, Singapore, Taiwan, Vanuatu, Fiji and China. Geoff is also a registered Lead Auditor, and a Fellow of the Australian Institute of Company Directors.

For Further Information contact:

Geoff Gray, Director  
 Gray Management Systems Pty Ltd  
 ACN 073 631 268  
 ABN 15 073 631 268

PO Box 2355  
 Ringwood North, Victoria 3134

Phone: 03 9876 5152  
 Mobile: 0417 353 182  
 email: geoff@grayms.com.au

**[www.grayms.com.au](http://www.grayms.com.au)**

*NOTE: If you require training for staff in the future, in-house, online and public courses options are available, enquire as above.*

**LAST PAGE**