## Brian Hunt

Brian Hunt is a freelance consultant who specialises in business process improvement and simplification. His experience includes working with public, private and voluntary organisations.

He believes that achieving simplicity in business processes is the best way to reduce waste and to enable an agile response to market opportunities or threats. He applies experience from a wide range of industries and from knowledge areas including 6 Sigma, business analysis and quality systems.

His qualifications include 6 Sigma Black Belt, CBAP™ and F.Inst.L.M.

His website is:

*www.businessprocessagility.com*

**The international quality management standard, ISO 9001, started life as UK standard, BS5750, itself based on the existing Ministry of Defence standard MoD 05/21. It was published as an international standard in 1987.**

Since then it has gained a reputation for adding bureaucracy but little business benefit. Companies often felt that they had to have ISO9001 certification to satisfy buyers in government or in large organizations.

The original standard focussed on compliance with documented procedures. Process interaction and customer satisfaction was ignored.

However, the standard was radically changed in the year 2000 revision when it switched its focus from compliance to continuous improvement and a process led approach.

The latest version, ISO9001:2008 provides a framework, a Quality Management System (QMS) which identifies and controls those activities that contribute to successful business operation and customer satisfaction.

This white paper describes the standard and why the author believes that it should be used as a first step towards effective business process management and improvement.
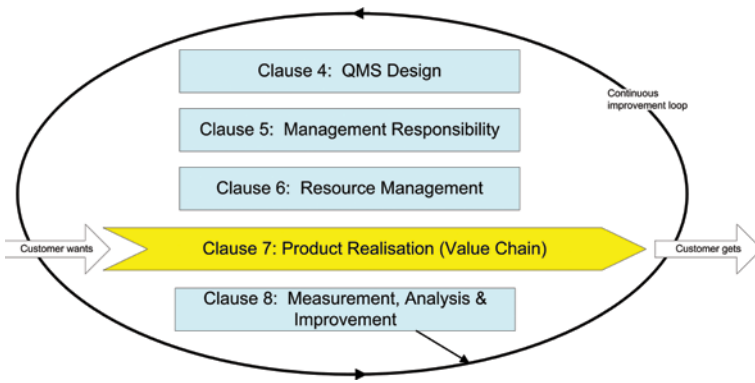
As the standard has been produced by an international committee, some of the wording of it is complex and needs interpretation. However, the basic principles of it are simple and outlined in the following pages.

Figure 1: Operational structure of ISO 9001:2008 (authors simplified version of the process based quality management system diagram in the ISO standard).

# The Eight Clauses of the ISO 9001 Standard

**Introduction and background information on the standard:**

1. Scope
2. Normative Reference
3. Terms and definitions

**Control requirements. These must be implemented:**

4. QMS Design
5. Management Responsibility
6. Resource Management
7. Product Realisation (Value Chain)
8. Measurement, analysis and improvement

Note that the continuous improvement loop applies to all operations. In practice, if continuous improvement and increasing customer satisfaction can be demonstrated, then the majority of the requirements of the standard will be met.

# ISO 9001 Clause 4
## Quality Management System

| Requirement | Comment |
|---|---|
| Establish, document, maintain and continually improve a quality management system that complies with the standard. | Requires the organization to define the required processes, their interactions and the resources required so that customer satisfaction and continual improvement can be achieved. |
| Define and implement supporting documents and controls | Documents required include quality policy, objectives, manual, procedures and records. There are six mandatory procedures:"<br>• Internal audit<br>• Record control.<br>• Document control.<br>• Corrective action.<br>• Preventive action.<br>• Control of faulty product. (Products include services)<br><br>Additional procedures and records as required for effective control of business processes and customer satisfaction. |

# ISO 9001 Clause 5
## Management Responsibility

| Requirement | Comment |
|---|---|
| Management commitment | This must be communicated and demonstrated. Commitment must be shown by providing adequate resources e.g. people, training, IT resources, information etc. This may require a change in organizational culture. |
| Customer focus | Know what customers want and meet or exceed these requirements. All activities should be contributing towards customer recognized value. |
| Quality policy | An effective quality policy is a visible and believable commitment to meeting or exceeding the requirements of the standard. |
| Quality objectives and planning | The quality policy has to be supported by measurable and relevant objectives. Without these, the quality policy is worthless. |
| Responsibility, authority and communication | Who does what should be clearly defined and communicated. Providing RACI charts on the company Intranet is one simple approach. |
| Management review | The management system needs to be reviewed and improved to meet changing requirements of the organization and to resolve any problems such as low customer satisfaction, warranty claims and change requests. |

# ISO 9001 Clause 6
## Resource Management

| Requirement | Comment |
|---|---|
| Determine and provide resources | Define the resources required to support processes and operations and ensure that they have the capability and capacity to meet customer requirements. |
| Human resources | Everyone in the organization must have the appropriate competences to ensure that the work they do will not negatively affect the services or products produced by the company.<br>Training requirements need to be identified and met. |
| Infrastructure & Work Environment | Define and provide the tools, equipment, and facilities needed to ensure that products or services can be provided to consistent quality.<br>These include data backup, building requirements (workshops, offices, clean rooms etc.) and test equipment. |

# ISO 9001 Clause 7
## Product Realization (Value Chain)

| Requirement | Comment |
|---|---|
| Planning | Identify, create and develop the processes needed to deliver products and services to customers. |
| Customer related processes | Ensure that any additional requirements from customers are known and met. These may include product or service modifications, additional tests or special delivery requirements. |
| Design | Manage the design life cycle from agreement on specification, design review, change management, through to verification and handover. |
| Purchasing | Ensure that requirements for products or services are clearly defined and assured so that they cannot have a negative effect on the quality of the delivered products or services. |
| Production and service provision | Ensure the effective control of processes required for production of products and services. Although this is one sub clause, it covers the whole area of manufacturing and operations management. |

# ISO 9001 Clause 8
## Measurement, Analysis and Improvement

| Requirement | Comment |
|---|---|
| Measurement, analysis and improvement | The key processes and how these are measured, analyzed and then improved must be defined and documented. |
| Customer satisfaction | Customer satisfaction must be measured and managed by taking appropriate analysis and improvement action. |
| Internal audit | A procedure for internal audit must be documented and audits performed to assess the performance of the quality management system. |
| Measurement and monitoring of products and processes | This requires sufficient measurement and monitoring to ensure that the production of products and services is under control and meeting requirements. |
| Control of  monitoring and measuring equipment | As decisions will be made based on the output of monitoring and measuring equipment, this equipment must provide accurate and repeatable results. |
| Control of nonconforming product | Any products or services that do not meet requirements must be controlled and prevented from reaching customers. This procedure must be documented. |
| Data analysis | Management information required to ensure consistent management of products or services must be identified, collected and analyzed. |
| Continual improvement | Provide training and leadership to make continual improvement part of the way your organization operates. |
| Corrective and preventive action | Ensure that the causes, or potential causes, of product or service failures or inadequacies are identified and resolved. |

# The 8 Quality Management Principles

The management guidance within the standard is based upon the eight principles below:

### Principle 1: Customer Focus
Organizations exist to provide a service to customers and therefore should understand their customer's current and future needs and expectations and strive to achieve or exceed these.

### Principle 2: Leadership
Leaders establish unity of purpose and direction of the organization. They are responsible for creating and maintaining the environment and culture in which people can become fully involved in achieving the organization's objectives.

### Principle 3: Involvement of People
Everyone in the organization, at whatever level, needs to be fully involved so their abilities can be recognized and used for organizations benefit.

### Principle 4: Process Approach
All interdependent activities within the organization are known and managed to ensure effective internal and external customer/supplier handovers and alignment of process capability and capacity to customer requirements

### Principle 5: System Approach to Management
Identifying, understanding and managing interrelated processes as a system reduces siloed working and improves organizational effectiveness and efficiency.  Everyone is able to see how their activities contribute to the delivery of products or services.

### Principle 6: Continual Improvement
With global competition and financial pressures, no organization can afford to accept that what satisfies customers today will satisfy them tomorrow. Therefore continual improvement should be a permanent objective of the organization.

### Principle 7: Factual Approach to Decision Making
Quick and accurate decision making is supported by facts, data, information and knowledge

### Principle 8: Mutually Beneficial Supplier Relationships
Rather than trying to get the lowest prices from suppliers, organizations and their suppliers work in partnership and build mutually beneficial relationships so that both improve their ability to create value.
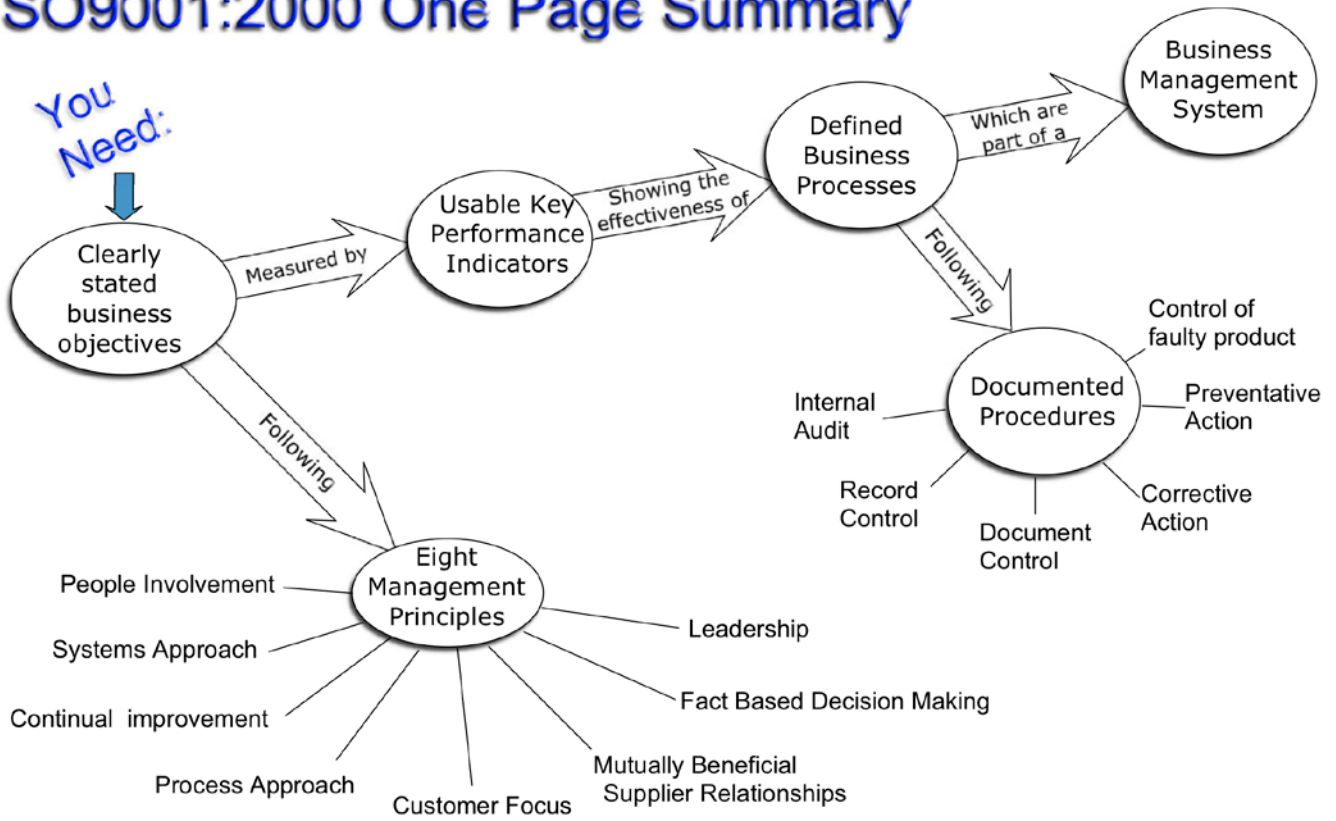
# ISO9001:2000 One Page Summary



You Need:

Clearly stated business objectives

Measured by

Usable Key Performance Indicators

Showing the effectiveness of

Defined Business Processes

Which are part of a

Business Management System

Following

Documented Procedures

Internal Audit
Record Control
Document Control
Control of faulty product
Preventative Action
Corrective Action

Following

Eight Management Principles

People Involvement
Systems Approach
Continual improvement
Process Approach
Customer Focus
Leadership
Fact Based Decision Making
Mutually Beneficial Supplier Relationships

**Figure 2: ISO9001:2008 Summary**

## Summary

ISO9001:2008 makes good business sense in establishing and developing business process management. The requirements of the standard are summarized in *Figure 2*.

ISO 9001:2008 can be used to guide the review and development of an effective business management system. The results depend on the skill, knowledge and understanding of quality systems applied by the user. A 'fundamentalist' approach to interpreting and applying the standard can be damaging and must be avoided. The purpose of ISO9001:2008 is to support and guide business process management, not stifle it.

The standard provides the basic level of control. Once compliance to it has been achieved, it can be used as a stepping stone for further development. The CMM diagram below shows where ISO9001:2008 aligns to levels of process maturity.
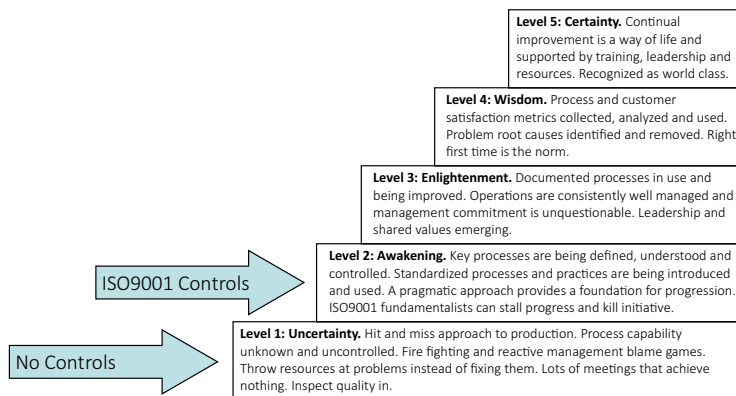


**Level 5: Certainty.** Continual improvement is a way of life and supported by training, leadership and resources. Recognized as world class.

**Level 4: Wisdom.** Process and customer satisfaction metrics collected, analyzed and used. Problem root causes identified and removed. Right first time is the norm.

**Level 3: Enlightenment.** Documented processes in use and being improved. Operations are consistently well managed and management commitment is unquestionable. Leadership and shared values emerging.

**Level 2: Awakening.** Key processes are being defined, understood and controlled. Standardized processes and practices are being introduced and used. A pragmatic approach provides a foundation for progression. ISO9001 fundamentalists can stall progress and kill initiative.

ISO9001 Controls

**Level 1: Uncertainty.** Hit and miss approach to production. Process capability unknown and uncontrolled. Fire fighting and reactive management blame games. Throw resources at problems instead of fixing them. Lots of meetings that achieve nothing. Inspect quality in.

No Controls

**Figure 3: ISO9001 and the CMM (Based on Crosby's 1979 Capability Maturity Model. Quality is Free ISBN 0-07-014512-1)**

**Figure 4: IDEF0 Example. The business operation is the value chain that produces customer recognized value.**
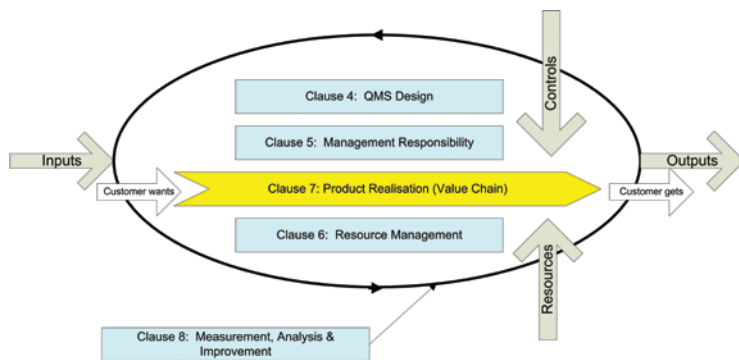


**Figure 5: ISO9001 mapped to ISO9001**

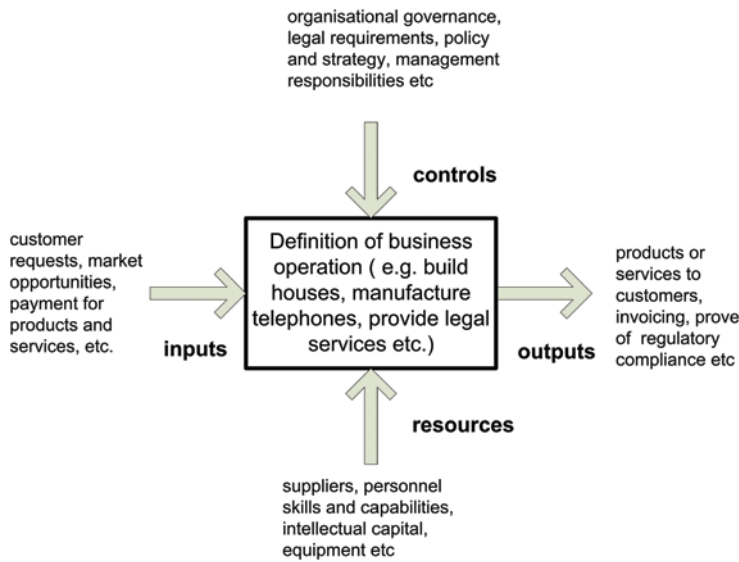# Applying ISO 9001:2008 to your organisation

Understand and define the key processes in your organization. The simplest way to do this is to use the IDEF0 notation as described in *Figure 4*. This can then be mapped onto ISO9001 as in *Figure 5*.

From this top level understanding of the organization, a gap analysis can be performed using the ISO 9001 summary diagram shown on *Figure 2*.

*Figure 5* is from a national company that had stopped using ISO 9001 some years previously.

The gap analysis can then be used to create an improvement action plan to get the basic ISO9001 requirements in place.

As this action plan progresses, progress towards ISO 9001 compliance will be made and can be continued to achieve either a management system which is compliant to the standard or is also certified against it by an external assessment body such as LRQA, BSI or DNV.



**Figure 6: ISO9001:2008 Example Gap Analysis**

# Conclusion

Although ISO9001 has gained a bad reputation over the last couple of decades, I suggest the new version, ISO9001:2008, is now reappraised as a proven approach to managing and improving business processes, for achieving improved operational efficiently and customer satisfaction.

While some of the terminology used in the standard may be unfamiliar, the basic principles of defining and managing value chain and supporting processes, customer satisfaction and continual improvement are fundamental requirements for a competitive business.

It also clearly defines the processes that must be controlled and the records to be kept. This helps avoid the ad-hoc growth of confused, duplicated and uncontrolled processes. I see frequent examples of organizations trying to implement process automation where complexity and duplication within the process landscape results in confusion and wasted time deciding where to start. This can result in project delivery dates being rescheduled and promises to customers and suppliers broken.

ISO9001:2008 can be used to self assess and develop business processes and to determine how these interconnect as part of an organizational system. It makes clear who does what, how and where. It should be regarded as a tool for business process management and meeting its requirements as a milestone on the journey to recognized business excellence.

Please contact the author for any further information on how ISO9001:2008 can deliver business benefits for your organization.

*This white paper contains a simplified summary of ISO 9001:2008. This is provided only to introduce ISO9001:2008 as a business improvement tool.*

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