

Integrating Multiple Quality System Standards under One Business Management System

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Business Management Systems

BQMS definition:

- The **Business Quality Management System** is the set of business processes and activities needed to drive an organization to achieve exceptionally high levels of performance as determined by their stakeholders.

Integrating Business Systems

- Quality and related standards
 - ISO 9000, ISO 9001 and ISO 9004
 - ISO 13485 (medical devices)
 - ISO/TS 16949 (automotive)
 - ISO 14000 (environmental)
 - OSHAS 18000 (health, safety, ...)
 - ISO 19011 (audit process)
 - ISO 31000 (risk management)

New requirements for all management system standards

- ISO have decreed that all management system requirement standards (MSS) shall use a common structure, core text etc.
- This is stated in Annex SL of the ISO Directives
- The aim is to facilitate integration and to avoid multiple approaches for similar elements of management

Annex SL Structure

- Clause 4 – Context of the organization
- Clause 5 – Leadership
- Clause 6 – Planning
- Clause 7 – Support
- Clause 8 – Operation
- Clause 9 – Performance evaluation
- Clause 10 - Improvement

Clause 4.1

Understanding the organization and its context :

- The organization shall determine external and internal issues that are relevant to its purpose and that affect its ability to achieve the intended outcome(s) of its XXX management system.

Clause 4.2

Understanding the needs and expectations of interested parties:

- The organization shall determine
 - the interested parties that are relevant to the XXX management system, and
 - the requirements of these interested parties.

Clause 4.4

XXX Management system

- The organization shall establish, implement, maintain and continually improve an XXX management system, including the processes needed and their interactions, in accordance with the requirements of this International Standard.

Leadership and commitment 5.1

- Top management shall demonstrate leadership and commitment with respect to the XXX management system by:
 - ensuring that the XXX **policy and XXX objectives are established and are compatible with the strategic direction of the organization**
 - ensuring the integration of the XXX **management system requirements into the organization's business processes**

Actions to address risks and opportunities - Clause 6.1

- determine the risks and opportunities that need to be addressed to:
- assure the XXX management system can achieve its intended outcome(s)
 - prevent, or reduce, undesired effects
 - achieve continual improvement.

So what does this mean?

- It means those with ISO 9001 (quality systems), ISO 14001 (environmental management systems), all industry-specific standards and (eventually) ISO 45001 will all have to ensure they reflect:
 - Context
 - Needs of interested parties
 - Integrate into overall management system etc
 - Risk and opportunities

Many common core elements

- Process documentation
- Organizational roles and responsibilities
- Support
 - Resources
 - Communication
 - Documentation
 - Competency
 - Awareness
- Audit, review, improvement

What is PAS 99

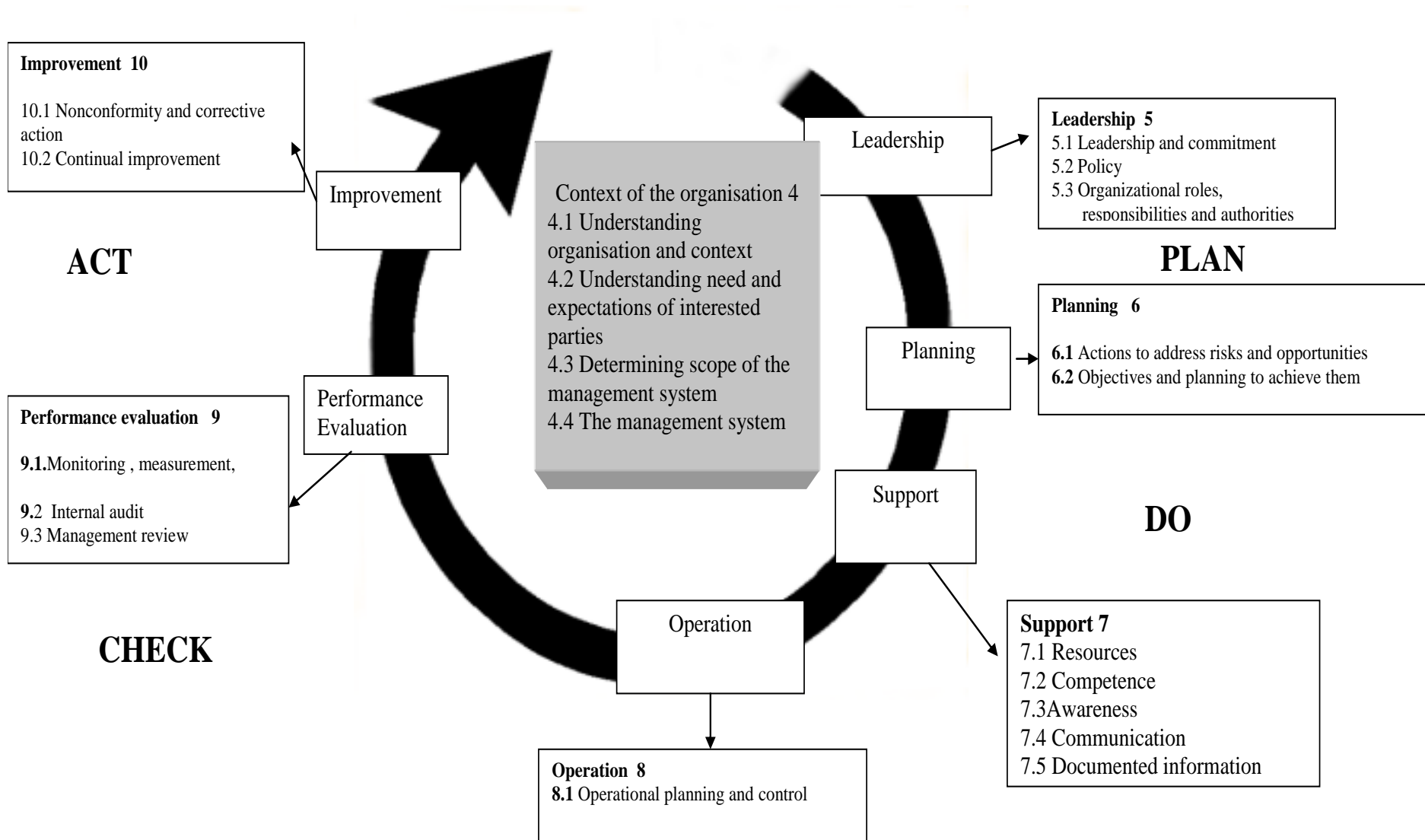
- Specification issued by BSI
- 'Recognised' by Certification Bodies
- Framework by which you can manage all elements of your business
 - ISO 9001
 - ISO 14001
 - OHSAS 18001
 - Sector Standards: ISO/TS 16949, ISO 13485 etc
 - Specialist Standards: Organic Food, Fair Trade, Lexcel, Sarbanes Oxley

Structure of PAS 99

6 common requirements:

- Policy
- Planning
- Implementation & Operation
- Performance Assessment
- Improvement
- Management Review

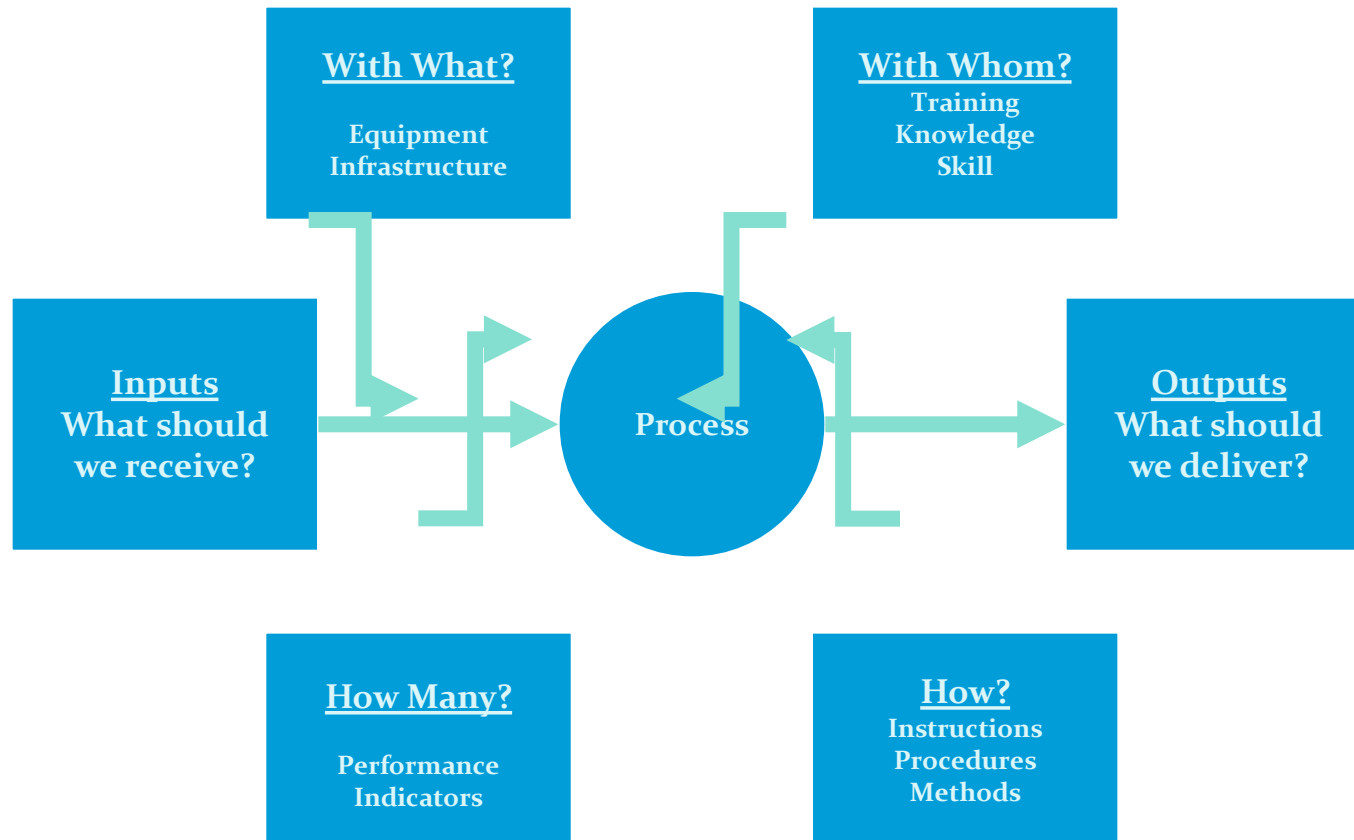
PAS 99:2012 Framework



integrating business systems

- PAS 99 takes account of the six common requirements for management systems standards outlined in ISO Guide 72; guidance document and also follows the Plan, Do, Check, Act approach of all the major ISO management systems requirements standards.
 - **Policy**
 - **Planning**
 - **Implementation & Operation**
 - **Performance Assessment**
 - **Improvement**
 - **Management Review**

Process Map



integrating business systems

- Where and how does the systems integration actually take place?
 - Integration results from consolidating **management reviews** as operating performance (including conformance to values, policies and principles) from each management (sub-)system is discussed, including their interactions.

integrating business systems

- Where and how does the systems integration actually take place?
 - Integration fostered by consolidating **internal process audits** across the various segments of the operating systems.
 - Consolidated audits allow the organization to assess the impact of each sub-system on the others.

Risk Based Approach

Evaluation of Aspects & Impacts : evaluate the significant business issues & the associated risk

- Quality: Preventive Action?
- Automotive: FMEA
- Food: HACCP
- Medical Devices: Product Risk Assessment
- Environmental: Aspects & Impacts
- OH&S: Risk Assessment, HAZOP
- Corporate Governance: Corporate Risk

Goal: Establish a common frame work to identify, evaluate and control business risks of any type.

Legal & Other Requirements

4.3.2 Identification of legal & other requirements

- Environmental: licences, waste, water, WEE etc
- OH&S: HASAW, Manual Handling, PUWER, Consultation
- Human Resource: Working time directive, equality, disability etc
- Data Protection: Do you hold customer information?
- Products: CE Marking, design requirements
- Import/Export: Legal requirements, product specifics
- Software: Are you licensed correctly?
- Corporate Governance: New companies act & director liability

Documenting Working Procedures

Operational Planning & Control - for example machine maintenance:

- OH&S: Wear your PPE, Use the permit to work, isolate the machine
- Product: Ensure machine is cleaned, set up for quality critical to quality parameters
- Environmental: Don't throw the oil down the drain etc.

Goal: One stop shop document for each process and task.

IMS Audit

Internal Audits

- Saves time
- Must focus on processes (not system elements)
- Use auditors & specialists to achieve competency
- Carefully define the scope of the audit & criteria

Goal: Common vision, goals and priorities for the business as a whole

Some Barriers to Integration

- Perception:
 - *Can a good Environmental/Quality/H&S Manager cut it running an IMS?*
- Fear:
 - *Is this a clever way to 'right size' the organisation?*
- Too Hard:
 - *Sound fantastic Mike but...*
- Lack of Control:
 - Nice try Mike but I've just spent the last 5 years trying to get everyone to follow the Q/E/H&S procedures – we need to maintain the focus not dilute it!

Implementing an IMS

- Write a policy for the IMS
- Define the system – write a well structured manual to act as your ‘instruction book’
- Make sure you have well developed process understanding
- Install common system elements

What the Certification Bodies tell you!

- Still need to be certified 3 times
(i.e. ISO 9001, ISO 14001 & OHSAS 18001)
- Probably will not make any kind of cost saving
- Not all auditors are multi skilled (you may get 2-3 auditors) – so it will cost more!

Thank You!

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