

Quality Management

Your guide to using ISO 9001
for competitive tendering...



Recap

- Quality – what it is
- Quality – what you need to do to provide a service your clients want (resources, systems and processes)

What is ISO 9001?

- World's most recognised standard
- 187,000 organisations are registered
- Framework to manage your business to ensure
 - Customer satisfaction
 - Internal improvement
 - Manage Business Risk

Origins of ISO 9000

- Pre – 1979 - Defence QA Standards
- 1979 - BS 5750 in UK
- 1987 - ISO 9000 rev 1
- 1994 - ISO 9000 rev 2
- 2000 - ISO 9000 rev 3
- 2008 - ISO 9001 rev 4
- 2015 - ISO 9001 rev 5

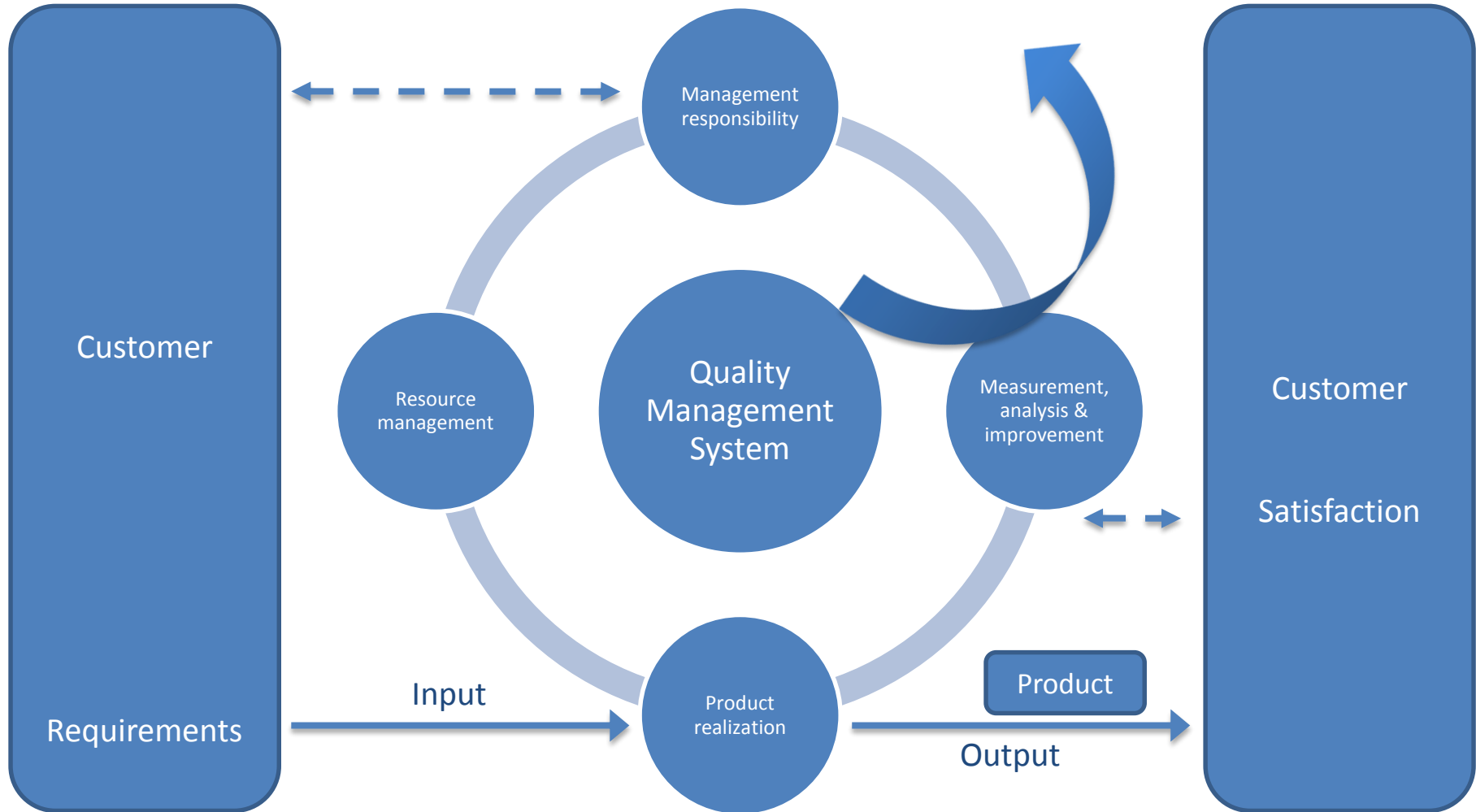
ISO 9001:2008

- Single standard
- Manufacture & service
- Clear language
- All sizes of organisations
- Structure of linked processes
- Measures of improvement and effectiveness
- Alignment with other systems

ISO 9001:2008

- 4. Quality management systems
- 5. Management responsibility
- 6. Resource management
- 7. Product realization
- 8. Measurement analysis & improvement

Continual improvement



BUILDING YOUR SYSTEM

Policy, standards & legislation

- Write a policy that tells people what you do
- Identify what standards and legislation you need
- Commit to standards and applicable legislation in the policy
- Commit to ISO 9001 and continual improvement
- Communicate this to everyone
- Use to set objectives

Task...

What does your company do?

How do you make sure you deliver excellent products or services?

Back at work... Write a policy

My company is the leading provider of my **product or service**.

We are committed to meeting or exceeding our customers expectations by... **insert your main business commitments & key business standards...**

To achieve these commitments we have implemented and maintained a quality management system to meet the requirements of ISO 9001:2008 (**2015**) which is used as a basis for continual improvement.

Documents... you will need

- Quality policy & objectives
- Quality manual
- Documented procedures & records required by ISO 9001
- Documents, procedures & records, determined by you to be necessary to ensure the effective planning, operation and control of processes

By the way...documented means implemented & maintained (i.e. you actually do it!)

Mandatory documented procedures

- Document control
- Control of records
- Internal audit
- Control of nonconforming product
- Corrective action
- Preventive action

Mandatory Records

- Management Reviews
- Training Records
- Planning Records
- Product Requirement Review Records
- Design Input Records
- Design Review Records
- Design Verification & Validation Records
- Design Change Records
- Supplier Evaluation Records
- Validation Records
- Calibration Records
- Internal Audit Records
- Product/Service Monitoring & Inspection Records
- Non conformities
- Concessions
- Corrective Action Records
- Preventive Action Records

Other requirements

- Provision of resources
- Competence of staff
- Systems and procedures in place to deliver the product
- Purchasing controls (suppliers)
- Measuring performance (for decision making and meeting objectives)
- Dealing with non-conformance

The High Level Structure (2015)

- Annex SL is the common framework that is to be used for all management systems (with a few exceptions)
- Will generate consistency through aligning sub-clauses across standards
- Common language across all standards
- Continues to use the Plan-Do-Check-Act approach

The High Level Structure

Annex SL has 11 standard clauses for all standards:

0 – Introduction

1 – Scope

2 – Normative references

3 – Terms and Definitions

4 – Context of the organisation

5 – Leadership

The High Level Structure

11 standard clauses for all standards

(continued):

6 – Planning

7 – Support

8 – Operation

9 – Performance evaluation

10 - Improvement

Next steps to ISO 9001...

- Month 1: Gap analysis – identify what you already have and what you need to do – implement the system into your business! Also set the scope.
- Month 2: Write policy, manual, objectives and other mandatory documents
- Month 3: Agree & launch the documentation
- Month 4-6: Run the system; implement and audit
- Month 4: Awareness training & auditor training
- Month 5-6: Audit your system
- Month 6-7: Management review

The assessment process

- Select only UKAS accredited Certification Body
- Stage 1 Review: Desk top audit to check you have a documented system
- Stage 2 Review: Formal assessment to award certification
- Costs – around £550-£650 per day



ANY QUESTIONS?