



ISO 9001:2015 – BACK TO BASICS

Martin Graham

Principal Assessor - QMS

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IS TO HELP
CUSTOMERS
DELIVER PRODUCTS
THE WORLD CAN
TRUST

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- 5 day Lead Auditor – NQA or IRCA

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KEY INFO

- 60 minute webinar
- Questions in the chat box
- Q&A at the end
- Recording of webinar circulated shortly

YOUR PRESENTER



Martin Graham

ISO 9001, ISO 14001, ISO 45001,
ISO 50001, SSIP

NQA Principal Assessor for Quality



Martin is an experienced lead auditor, with 20 years' exposure to the certification industry covering sectors including retail, manufacturing and assembly, construction, engineering, testing, mechanical & electrical installations, transport logistics, communication, education and training providers. Having knowledge of managing each step of the certification process, he is well positioned to understand clients' needs and support them through the certification process.

WHAT WILL BE DISCUSSED?

- What is quality?
- What is a Quality Management System?
- Why not just control? Control v Assurance
- Intended outcomes
- PDCA



WHAT WILL BE DISCUSSED?

- Process approach
 - Principles
 - Key requirements
 - Often missed or misunderstood
 - Make it a system!
-

WHAT IS QUALITY?

‘Degree to which a set of inherent characteristics of an object fulfils requirements’.

CHARACTERISTICS

Distinguishing feature

A characteristic can be inherent or assigned

A characteristic can be qualitative or quantitative

CHARACTERISTICS

There are various classes of characteristic, such as the following:

- a) Physical (e.g. mechanical, electrical, chemical or biological characteristics);
 - b) Sensory (e.g. related to smell, touch, taste, sight, hearing);
 - c) Behavioural (e.g. courtesy, honesty, veracity);
 - d) Temporal (e.g. punctuality, reliability, availability, continuity);
 - e) Ergonomic (e.g. physiological characteristic, or related to human safety);
 - f) Functional (e.g. maximum speed of an aircraft).
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OBJECT

Entity, item, anything perceivable or conceivable

EXAMPLE Product, service, process, person, organization, system, resource

Objects can be material (e.g. an engine, a sheet of paper, a diamond), non-material (e.g. conversion ratio, a project plan) or imagined (e.g. the future state of the organization).



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REQUIREMENTS

Need or expectation that is stated, generally implied or obligatory.

“Generally implied” means that it is custom or common practice for the organization and interested parties that the need or expectation under consideration is implied.

A specified requirement is one that is stated, for example in documented information.

A qualifier can be used to denote a specific type of requirement, e.g. product requirement, quality management requirement, customer requirement, quality requirement.

Requirements can be generated by different interested parties or by the organization itself.

It can be necessary for achieving high customer satisfaction to fulfil an expectation of a customer even if it is neither stated nor generally implied or obligatory.

This constitutes one of the common terms and core definitions for ISO management system standards given in Annex SL.

WHAT IS A QUALITY MANAGEMENT SYSTEM?

WHAT IS A QUALITY MANAGEMENT SYSTEM?

Set of interrelated or interacting elements of an organization to establish policies and objectives and processes to achieve those objectives.

A management system can address a single discipline or several disciplines, e.g. quality management, financial management or environmental management.

The management system elements establish the organization's structure, roles and responsibilities, planning, operation, policies, practices, rules, beliefs, objectives and processes to achieve those objectives.

The scope of a management system can include the whole of the organization, specific and identified functions of the organization, specific and identified sections of the organization, or one or more functions across a group of organizations.

This constitutes one of the common terms and core definitions for ISO management system standards given in Annex SL.

CONTROL V ASSURANCE

CONTROL V ASSURANCE?

Quality assurance - part of quality management focused on providing confidence that quality requirements will be fulfilled.

Quality control - part of quality management focused on fulfilling quality requirements.

The main difference – Confidence

Confidence in intended outcomes – Prevention not Defect Detection

INTENDED OUTCOMES



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INTENDED OUTCOMES / RESULTS

- Achieving Policy
 - Fulfilling Objectives
 - Customer Focus
 - Satisfaction
 - Compliance
 - Improvement
 - Enhanced Performance
 - Efficiency
 - Communication
 - Consistency
 - Commercial
 - Reduced Risks
-

PDCA

PDCA

4.1 Context
4.2 Interested parties
4.3 Determine the scope
5.0 Leadership / Policy
6.0 Plan/Risks/Hazards/Compliance
7.0 Resources

8.0 Operational planning
and control
Emergency preparedness



10.0 Improvement
Non-conformances
Corrective action

9.0 Performance evaluation
Compliance / Audits / Man
review

➤ **PLAN**

Establish what needs to be achieved and organise resources

➤ **DO**

Implement the processes

➤ **CHECK**

Monitor and measure the processes and their outputs

➤ **ACT**

Respond to findings from the checking activities in order to improve

PROCESS APPROACH

PROCESS APPROACH

“Any activity which receives inputs and converts them to outputs can be considered as a process.”

Set of interrelated or interacting activities that use inputs to deliver an intended result.





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PROCESS APPROACH

- Consistent and predictable results are achieved more effectively and efficiently when activities are understood and managed as interrelated processes that function as a coherent system.
 - The QMS consists of interrelated processes. Understanding how results are produced by this system enables an organization to optimize the system and its performance.
-

Possible actions include:

- ✓ Define objectives of the system and processes necessary to achieve them;
 - ✓ Establish authority, responsibility and accountability for managing processes;
 - ✓ Understand the organization's capabilities and determine resource constraints prior to action;
 - ✓ Determine process interdependencies and analyse the effect of modifications to individual processes on the system as a whole
-

Possible actions include:

- ✓ Manage processes and their interrelations as a system to achieve the organization's quality objectives effectively and efficiently;
 - ✓ Ensure the necessary information is available to operate and improve the processes and to monitor, analyse and evaluate the performance of the overall system;
 - ✓ Manage risks which can affect outputs of the processes and overall outcomes of the QMS.
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SUPPORTING

Typically include:

- Quality assurance
- Documented information control
- Internal audits
- Management review
- Non-conformance management
- Corrective action

ORGANISATIONAL

Typically include:

- Human resources/training
 - Security
 - Facilities management
 - Accounts
 - IT
 - Business development/marketing
-

PRINCIPLES



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PRINCIPLES

1. Customer Focus

The primary focus of quality management is to meet customer requirements and to strive to exceed customer expectations.

2. Leadership

Leaders at all levels establish unity of purpose and direction and create conditions in which people are engaged in achieving the organization's quality objectives.



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PRINCIPLES

3. Engagement of People

It is essential for the organisation that all people are competent, empowered and engaged in delivering value.

Competent, empowered and engaged people throughout the organisation enhance its capability to create value.

4. Process Approach

Consistent and predictable results are achieved more effectively and efficiently when activities are understood and managed as interrelated processes that function as a coherent system.

5. Improvement

Successful organisations have an ongoing focus on improvement.

6. Evidence-based Decision Making

Decisions based on the analysis and evaluation of data and information are more likely to produce desired results.

7. Relationship Management

For sustained success, organisations manage their relationships with interested parties, such as suppliers.

KEY REQUIREMENTS



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KEY REQUIREMENTS

- Context
 - Interested parties
 - Risk
 - Customer focus
 - Leadership
 - Process approach
 - Improvement
-

MISSED / MISUNDERSTOOD

Context

The intent of this subclause is to **understand the external and internal issues** that are relevant to the organization's purpose and strategic direction and that can affect, either positively or negatively, the organization's ability to achieve the intended results of its quality management system.

The organization should be aware that **external and internal issues can change**, and therefore, **should be monitored and reviewed**.

An organization might conduct reviews of its context at planned intervals and through activities such as management review.

Interested Parties

The intent of this subclause is to ensure that the organization **considers the relevant requirements** of relevant interested parties, beyond just those of its direct customers.

The intention is to focus on only those relevant **interested parties which can have an impact** on the organization's ability to provide products and services that meet requirements.



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MISSED / MISUNDERSTOOD

Leadership

The intent of this subclause is to ensure that **top management** demonstrate leadership and commitment by **taking an active role** in engaging, promoting, and ensuring, communicating and monitoring the performance and effectiveness of the quality management system. The ways it can be applied are based on various factors, such as the size and complexity of an organization, management style and organizational culture.

For an organization, ‘top management’ may include, for example, the chief executive officer, managing director, general manager, chairman, board of directors, executive directors, managing partner(s), single owner, partner(s) and senior executives/managers.

Top management has the power to delegate authority and provide resources within the organization. If the scope of the management system covers only part of an organization, then top management refers to those who direct and control that part of the organization.

Each organization has different needs and its own specific solution that will be decided by top management. **It is important for top management to ensure that the organization’s quality management system processes are integrated with its business processes.**

MISSED / MISUNDERSTOOD

Risks and Opportunities

The intent of this subclause is to ensure that when planning the quality management system processes, the organization **determines its risks and opportunities and plans actions to address them.**

Its purpose is **to prevent nonconformities**, including nonconforming outputs, and to determine opportunities that might enhance customer satisfaction or achieve an organization's quality objectives.

When determining the risks and opportunities for the quality management system, the external and internal issues (see ISO 9001:2015, 4.1) as well as relevant interested parties' requirements should be considered.

Examples of the risks that the quality management system will not achieve its objectives include the failure of processes, products and services to meet their requirements, or the organization not achieving customer satisfaction.

Examples of opportunities include the potential to identify new customers, to determine the need for new products or services and to bring them to market, or to determine the need for revising or replacing a process by the introduction of new technology in order for it to become more efficient.

Design

The intent of this subclause is to ensure that the organization **establishes, implements, and maintains a design and development process**, in order to ensure that its products and services meet requirements, and which defines the characteristics of the products and services.

The organization shall establish, implement and maintain a design and development process that is appropriate to ensure the subsequent provision of products and services.

It is necessary to note that for service organizations, the approach to design and development may be different from 'traditional' manufacturing organisations.

ISO 9001, clause 8.3, refers only to design and development of products and services. In some organizations it can be beneficial, but not required, to apply the same methodology to design and development of processes.

To be continued in a further webinar...

MISSED / MISUNDERSTOOD

Control of externally provided processes, products and services (Purchasing)

The intent of this subclause is to **control processes, products and services that are provided by an external provider**. External providers could include the organization's corporate headquarters, associate companies, suppliers, or someone to whom the organization has outsourced a process.

The organization is responsible for ensuring that externally provided processes, products and services conform to requirements (e.g. through incoming goods inspection, or surveillance of an outsourced service provider).

You cannot outsource your liability or responsibility.

Internal Audits

The intent of the clause is **to obtain information through internal audits about the performance and effectiveness** of the quality management system from an impartial view.

To ensure that planned arrangements have been completed and that the QMS is **effectively implemented and maintained**.

The audit programme should indicate how frequently the organization will conduct audits (e.g. monthly, quarterly, annually, or according to a schedule that differs for areas or processes over the course of a year).

When determining the frequency, the organization should apply risk-based thinking and consider how often the process is performed, how mature or how complex the process is, any changes in the process, and the objectives of the audit programme. For example, more mature processes are likely to require less frequent internal audits. **More complex processes can require more frequent internal audits.**

Management Review Outputs

The intent of this subclause is to ensure that **management reviews provide outputs** and information about the performance and effectiveness of the quality management system, and on any decisions and actions needed.

The outputs of management reviews **should include decisions and actions relating to opportunities for improvement** (see ISO 9001:2015, 10.1), changes needed to the quality management system.

Not just a set of minutes...

KEEP IT SIMPLE

KEEP IT SIMPLE

- ✓ Decide what you are trying to achieve within your organisation
 - ✓ Policy, Objectives, Improvement, Efficiency, Profit!
 - ✓ Determine what you do, how you do it, the communication and sticking points, the 'go – no go' stages, interactions, communication, risks, known issues
 - ✓ Plan how you will address these points and then implement
 - ✓ Check on how you are doing – is what you planned to do effective? Are you getting what you want from the system, processes, people and equipment?
 - ✓ Act and make changes – it's allowed.
-

KEEP IT SIMPLE

- ✓ Engage and involve people – get their views and opinions
 - ✓ Don't create a system to please an auditor
 - ✓ Reverse engineer – look at what you are doing (good / bad / ugly) and see how this fits with the standard
 - ✓ Remember, it's a *system*. A means of achieving an end
 - ✓ Keep it simple and ensure it adds value, controls and informs
-



QUALITY MANAGEMENT

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place here!**

Q&A



THANK YOU

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