



NSAI

ISO 9001:2015 Draft.

Fergal O'Byrne,
Head of Business Excellence Certification.

John Tighe
ISO 9001 Lead Auditor & Scheme Champion.

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ISO/CD1 9001:2015

- Alongside CD1, the ballot for 3 specific questions agreed in Sept 2013.
 - Maintain **exclusions** – ballot lost.
 - “**Goods and Services**” v. “Products”, ballot won.
 - “**Improvement**” instead of “continual improvement” ballot won.

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- Annex to CD1: QMP – approved
 - No comments needed
- QMP – Quality Management Principles

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7 QMP

- Customer focus
- Leadership
- Engagement of people
- Process Approach
- Improvement
- Evidence based Decision Making
- Relationship Management

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ISO/CD1 9001:2015

High level structure and common text

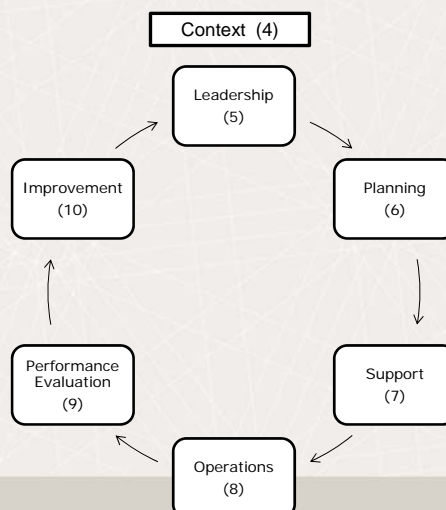
- Annex SL of ISO Directives
 - Structure and common text **not supposed to change** - justified comments will be sent to SC2 that will decide to send to TMB
 - **Additions** to common text allowed (and were done) for:
 - Specific essential quality requirements
 - Essential to reflect QMP
 - Requirements and notes that enhance or clarify common text

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High level structure (1).



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High Level Structure (2).

1. **Scope**
2. **Normative references**
3. **Terms and definitions**
4. **Context of the organization**
 - Understanding the organization and its context
 - Needs and requirements
 - Scope
 - Management System
5. **Leadership**
 - General
 - Management commitment
 - Policy
 - Roles, responsibility and authority
6. **Planning**
 - Actions to address risks & opportunities
 - Objectives and plans to achieve them

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High Level Structure (3).

7. **Support**
 - Resources
 - Competence
 - Awareness
 - Communication
 - Documented information
8. **Operation**
 - Operational planning and control
9. **Performance evaluation**
 - Monitoring, measurement, analysis & evaluation
 - Internal audit
 - Management review
10. **Improvement**
 - Non conformity and corrective action
 - Improvement

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ISO/CD1 9001:2015 Significant Changes

a) Redrafting to make the standard more generic and more easily applicable by service industries.

- Explicit reference to goods and services
- Revision on measurement equipment and design and development

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ISO/CD1 9001:2015 Significant Changes

b) Context of the organisation

- HLS introduced
- 4.1 Understanding the organization and its context and 4.2 Understanding the needs and expectations of interested parties
- Identify impacts on planning the quality system
- In 9001:2015 the scope is unchanged

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ISO/CD1 9001:2015 Significant Changes

c) Process approach

- Process approach is more explicit than in 2008 edition
- 4.4.2 (in 4.4 Quality management system) specifies essential requirements

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ISO/CD1 9001:2015 Significant Changes

d) Risk and Preventive Action

- HLS first part of 6. Planning
- “determine the risks and opportunities that need to be addressed to: assure the quality management system can achieve its intended outcome(s); prevent, or reduce, undesired effects; achieve improvement”
- **Relation with context and interested parties**

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ISO/CD1 9001:2015 Significant Changes

e) Documented information

- HLS adopted without significant change and addition
- Document and record replaced by documented information

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ISO/CD1 9001:2015 Significant Changes

f) Control of external provision of goods and services

- Addresses all forms of external provision
- Risk based approach to determine type and extent of control

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Context of the organisation (4)

4.1

Understanding the organisation and its context

4.1

– 9001 specific text:
Relevant to strategic direction

Consider:

Changes and trends
Relations and Perceptions
of relevant IP Governance,
strategic priorities,
Resources

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Context of the organisation (4)

4.2

Understanding the needs
and expectations of
interested parties

Understand and
anticipate needs of
expectations affecting
customer

Requirements and
customer satisfaction

Identifies relevant IP to
be considered

Note on Innovation
Opportunities

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Context of the organisation (4)

4.3

Determining the scope of the quality management system

Scope stated in terms of goods and services, the main processes to deliver them and the sites of the organisation included.

Need to maintain exclusions to be balloted

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Context of the organisation (4)

4.4

Quality management system

The organisation shall apply a process approach to its quality management system

4.4.2

Process approach

Text a) to f) reinforce process approach

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Leadership (5)

5.1

Leadership and
commitment

With respect to the
quality management
system

and

5.2

Quality Policy

With respect to the needs
and expectations of
customers

Quality policy unchanged

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Leadership (5)

5.3

Organisational roles,
responsibilities and
authorities

Top management **shall be
accountable for the
effectiveness of the quality
management system** and shall
assign the responsibility and
authority for

QMS effectiveness,

Outputs of products,

Reporting and

Promoting awareness of customer
requirements

No management representative

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Planning (6)

6.1

Actions to address risks and opportunities

Consider outputs from 4.1 and 4.2 to identify risks and opportunities that need to be addressed:

6.2

Quality Objectives (HLS)

assure that the organisation can consistently achieve conformity of goods and services and customer satisfaction

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Planning (6)

6.3

Planning of changes

Identify need and opportunity for change

Take change in a planned manner

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Support (7)

7.1 Resources

Infrastructure,
Process Environment;
Monitoring and
Measurement devices and
Knowledge

Less prescriptive on
calibration

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Support (7)

7.1 Competence

7.2 Awareness

7.3 Communication

7.4 Documented Information

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Product Realisation (8)

- 8.1 Operational planning and control (HLS)
- 8.2 Determination of market needs and interactions with customers
- 8.3 Operational planning process
- 8.4 **Control of external provision of goods and services**
- 8.5 Development of goods and services
- 8.6 Production of goods and provision of services
- 8.7 Release of goods and services
- 8.8 Nonconforming goods and services

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Performance Evaluation (9)

- 9.1 Monitoring, measurement, analysis and evaluation
- 9.2 Internal Audit
- 9.3 Management Review
 - Clarified text on measurement (valid results)
Requirement for performance indicators of the quality management system
 - Analysis of data reinforced and clarified

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Improvement (10)

10.1 Non conformity and corrective action

10.2 Improvement

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Improvement (10)

The organisation shall improve the quality management system, processes and goods and services, as appropriate, through responding to:

- Results of analysis of data;
Changes in the context of the organisation;
- Changes in identified risk (6.1): and new opportunities.

The organisation shall evaluate, prioritise and determine the improvement to be implemented.

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