Quality Revolution …or Evolution?

ISO 9001:2015
An overview of the Draft International Standard
Based on published information.

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Quality Revolution …or Evolution

Goal of this presentation

- Outline the major changes to the Standard
- No discussion of TC 176 or subcommittees
- Knowledge of ISO 9001:2008 is assumed
- Many unchanged clauses are not addressed
- Commentary: Hopefully kept to a minimum
Based on results of international ballots the described changes will provide support that has been missing for 50+ years!

- **Maintain relevance** in a changing world;
- **Integrate more readily** with other management systems;
- Provide an **integrated approach** to organizational management;
- Provide a **consistent foundation** for the next 10 years;
- Reflect the increasingly **complex environments** in which organizations operate;
- Ensure the new standard reflects the needs of **all potential user groups** (Stakeholders);
- **Enhance** an organization’s **ability** to satisfy its customers.
The requirements regarding following items are removed:

- Quality manual
- Six obligatory documented procedures
- Preventive actions
- Management representative
Major changes - 2.

The “replaced” requirement category is included:

- the term ‘documented information’ instead of the terms ‘document’ and ‘record’;

- the term ‘external provision’ instead of the terms ‘purchasing’ and ‘outsourcing’
Major changes - 3.

The “introduced” requirements are below:

- Context of the organization
- Relevant interested parties
- Actions to address risks and opportunities
- Quality objectives shall determine what will be done, resources, responsibility, timing and evaluation method
- Planning of changes
- Organizational knowledge
- Management reviews shall take into consideration strategic direction(s) of the organization
Major changes - 4.

The requirements regarding the following points are strengthened:

- Process approach
- Added value
- Leadership
- Achievement by the quality management processes conformity to product and service requirements in order to enhance customer satisfaction
In addition, the upcoming ISO 9001:2015 has some **new features**:

- Increased flexibility of documentation usage
- Greater applicability for “service-providing” organizations.
Unchanged

Implementation of the customer focus principle remains the same as the basis for the development of the quality management system.
It should be pointed out that the new structure of the standard does not connect in any way with the expected structure of quality management system documentation, quite the reverse!

This is an issue for Consultants and Auditors alike, forget the past ideas / practices and embrace the total business structure.
0. Introduction.
1. Scope.
2. Normative references.
3. Terms and definitions.
4. Context of the organization.
5. Leadership.
6. Planning for the quality management systems.
7. Support.
8. Operation.
10. Improvement.
# Evolutionary changes

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The structure of the ISO 9001:2015 is

- 4.1, 4.2, 4.3 Establish context, define relevant interested parties and scope of QMS
- 5. Leadership
- 6. Planning for the QMS
- 7. Support
- 8. Operation
- 9. Performance evaluation
- 10. Improvement

Output

Inputs

Customer satisfaction

Products and services

Requirements

Customer and relevant interested parties

Resources, competence, awareness, communication, documented information
Please note

the fact that developers of ISO 9001:2015 have been doing everything possible to ensure that organizations which are already implementing the current standard or are certified, can upgrade their systems to the new version of the standard without making any significant efforts immediately. Some systems will need to change however over the next three years.
Organizations have the full right to use terms already familiar to them such as a ‘document’, ‘record’ or ‘documented procedure’ instead of ‘documented information’ or, for example, may continue to use the terms ‘purchasing’ and ‘outsourcing’ instead of ‘external provision’.

Not forgetting that these may be electron trails!
An Organization should

- **not** change the structure of its quality management system – unless it is not working!

- **not** follow the section numbering of the ‘high level structure’.

- Clarify all Business Processes that are used from start to finish
The Context

------ of the organization is the complex external and internal issues that are relevant to its purpose and its strategic direction and that affect its ability to achieve the intended result of its quality management system.

This is where we need to consider all the Business Processes from end to end---Marketing, Sales, Procurement, Planning, Scheduling-------- through to after sales service
4.1 Understanding the Organization and its Context

- Determine internal and external issues that are relevant to its purpose and strategic direction
- Update such determinations when needed.
- Consider issues arising from
  - Changes, trends that can have an impact on objectives
  - Relationships with & perceptions/vales of interested parties
  - Governance issues, strategic priorities, internal policies
  - Resource availability, priorities, technological change

[Consider an Organizational Profile]
Relevant interested parties

In most situations the interested parties will be:

- The owners of the business / shareholders / trustees
- Goods and service providers to you
- Staff members
- Customers
- Local community
- Government / Local / State / Federal

The stakeholders
4.2 Understanding the Needs and Expectations of Interested Parties

Determine the interested parties that are relevant to the QMS and the requirements of those parties

- Update such determinations when needed.
- Consider the following relevant interested parties:
  - Direct Customers
  - End Users
  - Suppliers, distributors, retailers or others involved in the supply chain
  - Regulators and others
Term ‘products and services’

….is used instead of the term ‘product’ applied in ISO 9001:2008. Term ‘products and services’ includes all categories of process results such as hardware, software, processed materials, components and of course the process outcomes associated with Health Care, Call Centres, Hospitality, Insurance, Banking, Government that make up the 70% of service based industries -- etc
4.4.2 Process Approach - 1

The organization shall apply a process approach
a) **Determine the processes**…
b) Determine the inputs & outputs from each process
c) **Determine their sequence and interaction**
d) **Determine the risks** to conformity and customer satisfaction if unintended outputs are delivered or process interaction is ineffective
e) **Determine criteria, methods, measurements and related performance indicators needed to ensure that both the operation and control of these processes are effective**

Process map by all means!
4.4.2 Process Approach - 2

The organization shall apply a process approach

f). Determine the resources and ensure availability

g). Assign responsibilities and authorities

h). Implement actions required to achieve results

i). Monitor, analyze……these processes ensuring they continue to deliver the intended outputs

j). Ensure improvement of these processes.
Process model considering risks

Interaction with other processes

Provider (external or internal)

Act

Plan

Extent of planning depends on risks

Do

Process (interrelated activities)

Monitoring and measurement

Check

Interaction with other processes

Customer (internal or external)
Actions to address risks and opportunities

In the new version the requirement to perform actions to address risk and opportunities is formulated explicitly and is closely linked with the concept of a process approach.
5.1 Leadership and Commitment

Top Management shall demonstrate leadership and commitment with respect to customer focus by ensuring that

a.) the risks which can affect conformity if goods and services and customer satisfaction are identified and addressed [PFMEA]

[Note – Technically Risk is preceded by one or more Hazards]
Risk and Preventive Action

- Risk Analysis concepts are introduced
- Preventive Action **is no longer a clause** (8.5.3)
- Preventive Action concepts are deployed throughout the Standard (e.g. New clauses 4.1 and 6.1)
- Section 0.5 is very clear about dealing with Risk based thinking and measures
Further thoughts on Risk

- A risk should be understood not only as a negative feature, but also as an opportunity to find possibilities for improvement within processes.

- ISO 9001:2015 does not require a formal risk assessment by developing any kind of documented ‘risk registers’. ISO 31000 ‘Risk management – Principles and guidelines’ can be used as a useful reference (not mandatory) for risk control methods. However why not use the concept?
<table>
<thead>
<tr>
<th>Terms and Definitions (These may be included in ISO 9001 or in ISO 9000)</th>
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<td>21. Corrective Action</td>
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<td>22. Continual Improvement</td>
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5.1 Leadership and Commitment

a.) Ensure Policies, Goals and Objectives are compatible with the Strategic Direction of the organization.

c.) Ensuring the integration of QMS requirements into the organization’s business processes.

d.) Promoting awareness of the Process Approach

h.) Engaging, directing, supporting persons to contribute to the effectiveness of the QMS

i.) Promoting improvement and innovation

j.) Supporting other managers to demonstrate leadership in their areas of responsibility.
5.3 Organizational 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...

*Note that a defined “Management Representative” has been removed.*
*(although the tasks remain)*

*Now we have the opportunity to involve all managers in “quality issues, the buck cannot be passed any more to the QM!*
6.1 Address Risks and Opportunities

Determine Risks and opportunities that need to be addressed to: \[SWOT\]

a) Be assured that the QMS can achieve its intended outcomes
b) ...achieve conformity & customer satisfaction
c) Prevent or reduce undesired effects

The organization shall plan actions to address these \textcolor{red}{R&O} and integrate actions into the QMS and evaluating the effective of actions \textcolor{red}{[PFMEA]}
6.2 Quality Objectives and Planning

When planning how to achieve quality objectives (in each part of the business), the organization shall determine

a.) What will be done
b.) What resources are required
c.) Who will be responsible
d.) When it will be completed
e.) How results will be evaluated

[SMART goals]
In its attempt to make “calibration” requirements less manufacturing-centric, many of the requirements of ISO 9001:2008 have been removed.

Auditors will have to have a higher level of understanding of calibration and metrology rather than relying on the Standard’s requirements e.g. Customer surveys can now be considered as a monitoring device, Market Research organisations -------
7.1.5 Knowledge

*Competency Requirements remain, but “Knowledge” is new.*

Determine the knowledge necessary for the operation of the QMS and its processes.

This will apply to Consultants and auditors alike.
7.3 Awareness

Persons doing work under the organization’s control shall be aware of

a.) The Quality Policy
b.) Relevant Quality Objectives (KPI’s)
c.) Their (personal) contribution to the effectiveness of the QMS, including the benefits of improved quality performance
d.) The implications of not conforming with QMS requirements (e.g. Product / Service Recall)
The organization shall ensure:

a.) Identification and description (e.g., Title, date, author, or reference number)

b.) Format (language, software version, graphics) and media (paper, electronic)

c.) Review and approval for suitability and adequacy

Permissions and version control are addressed to also cover electronic documents
8.3 Operational Planning Process

Implement a process to determine the following:

b.) Actions to identify and address the risks related to achieving conformity of goods and services to requirements. [PFMEA]

Note: This can be referred to as a Quality Plan, a Business Plan and other names.
8.4 Control of External Provision of Goods and Services

No longer “Purchasing” and language extends to the realm of outsourcing and partnerships, managed services etc.

Exercise appropriate controls based on risks. The Organization shall monitor their performance and keep documented information. This is an appropriate point to stress the need for all stakeholders to think about Licensing and Franchise operations.
8.5 Development of Goods and Services

8.5.1 Development Processes
Consistent with the Process Approach and taking into account risks, opportunities
[DPFMEA, DVP&R]

8.5.2 Development Controls

8.5.3 Development Transfer (to production etc.)
Verification and Validation and Design Review requirements are de-emphasized (perhaps as service design is considered)
8.6 Production of Goods, Provision of Services

- 8.6.1 Control of production of goods and provision of services
  - i.) prevention of nonconformity due to human error, such as unintentional mistakes and intentional rule violations [*Poke Yoke*]

- 8.6.2 Identification and Traceability

- 8.6.3 Property belonging to customers or external providers

- 8.6.4 Preservation of Goods and Services including the supply chain

- 8.6.5 Post Delivery Activities (e.g. After sales)

- 8.6.6 Control of Changes
9 Performance Evaluation

9.1.1 Evaluate the performance of processes (4.4) Evaluate the performance and effectiveness of the Quality Management System [KPI’s]

9.1.2 As appropriate, shall obtain data relating to customer feedback and customer views and perceptions of the organization, its processes and its goods and services.
9.2 INTERNAL AUDIT

“status and importance of processes” is replaced with consideration of quality objectives, the importance of the processes concerned and the related risks
d.) Ensure that the results of the audit are reported to relevant management for evaluation
e.) Take appropriate action without undue delay

“Corrections and corrective actions….to eliminate detected nonconformities and their causes” is removed. There is no reference to nonconformance's

Internal Auditors should be as good as External Auditors – if not better!
9.3 Management Review (MR)

M.R. shall be planned and carried out taking into account the changing business environment and in alignment with the strategic direction of the organization.

Information on the performance of the QMS including trends and indicators for:

1.) Nonconformities and Corrective Actions
2.) Monitoring and measurement results \([KPIs]\)
3.) Audit results
4.) Customer feedback
5.) Supplier and external provider issues
6.) Process Performance, product conformity \([KPIs]\)

They may be a separate process or an integral part of other Management meetings.
10.1 Nonconformity and Corrective Action

When a nonconformity occurs

a.) React to it, and as applicable
   • take action to control and correct it,
   • deal with the consequences [containment actions]

b.) Evaluate the need for action to eliminate the causes of the non-conformity in order that it does not recur or occur elsewhere …. …. Determine if similar nonconformities exist or could potentially occur. [System-wide C.A.]
10.2 Improvement

The organization shall improve the QMS, processes and goods and services… through
a.) results of the analysis of data
b.) changes in the context of the organization
c.) changes in identified risk (6.1)
d.) new opportunities

The organization shall evaluate, prioritize and determine the improvement to be implemented

*Note that this is not Continuous Improvement*
Annex A – Quality Management Principles - and other issues - a valuable summary

- Customer Focus
- Leadership
- Engagement of People
- Process Approach
- Improvement
- Evidence-based Decision Making
- Relationship Management
ISO 9001:2015 is a **total rewrite**

- New concepts and format
- Risk assessment throughout
- Process Approach is Mandatory
- More performance measurement – KPI
- Strategic Planning
Conclusions and commentary - 2

- Documents & Records - documented information
- Leadership replaces Management Responsibility
- Goods & Services – less manufacturing language
- More on outsourcing and partnerships
- Include the QMS principles in ISO 9001
Risk Assessment is very good

- Strategic Planning - Integration with the business
- Keep the definitions in ISO 9001
- Continuous Improvement is replaced

- A Risk: More service-friendly wording leads to a loss of specificity around manufacturing
Conclusions and commentary - 4

Need to understand more quality tools and the Business of Business – Baldrige here we come!

- FMEA
- SWOT
- KPI’s
- Hoshin Planning
- Poke Yoke
- Six Sigma and Lean Tools
- Customer / Staff Surveys

What will be the impact on Auditors and Consultants?
My sincere thanks to the many people who helped me put this presentation together:

Toni Pilli AOQ and DQS AusNZ P/L
Dr Chris Brendon DQS AusNZ P/L
Alex Ezrakhovich AOQ
Diane Baguley NZOQ
Ian Dalling CQI Integrated Standards SIG
Thanks for the attention

Thank you for your participation.

Any Questions?

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