



ISO 9001:2015

Transition to ISO 9001:2015

Sys**EX**pert

Goal	Goal #1: To put greater emphasis on leadership engagement
Goal	Goal #2: To help address organizational risks and opportunities in a structured manner
Goal	Goal #3: To use simplified language and a common structure
Goal	Goal #4: To be more user-friendly for service and knowledge-based organizations

Goals of New Standard (ISO 9001:2015)

01

Top management's involvement has never been achieved at the intended level of the standard with the old version

02

The unwanted result was that too often the QMS was operating in a "silo" and top management's involvement was kept at a minimum

03

Wording of the new version in terms of Leadership responsibilities is much more forceful and encompassing

04

One of the main responsibilities refers to the **integration of the organization's business processes, strategic direction and risk-based thinking**

Leadership Engagement – Goal #1

In the old version, “preventive action” was described as an action to curtail non-conformities by applying risk mitigation strategies

The concept of preventative action was too often misunderstood and consequently not used at the intended level of the standard

Business processes, products and services were not systematically the object of risk-based thinking and there was no formal linkage with business management issues to accurately identify risks and opportunities

The intent is to analyse the risk and opportunities considering external and internal issues, as well as needs of interested parties identified in the context of the organisation

Risks and Opportunities in a Structured Manner – Goal #2

Each certifiable ISO standard had its own structure. It created a problem for companies having more than one certification (ex. ISO 9001 and 14001) for integration of management systems

New version of the same standard had a different structure which complicated transition to the new version

Adoption of a high-level structure makes integration of management system much easier

The structure is more in line with the way business operates

Use of Simplified Language and a Common Structure – Goal #3



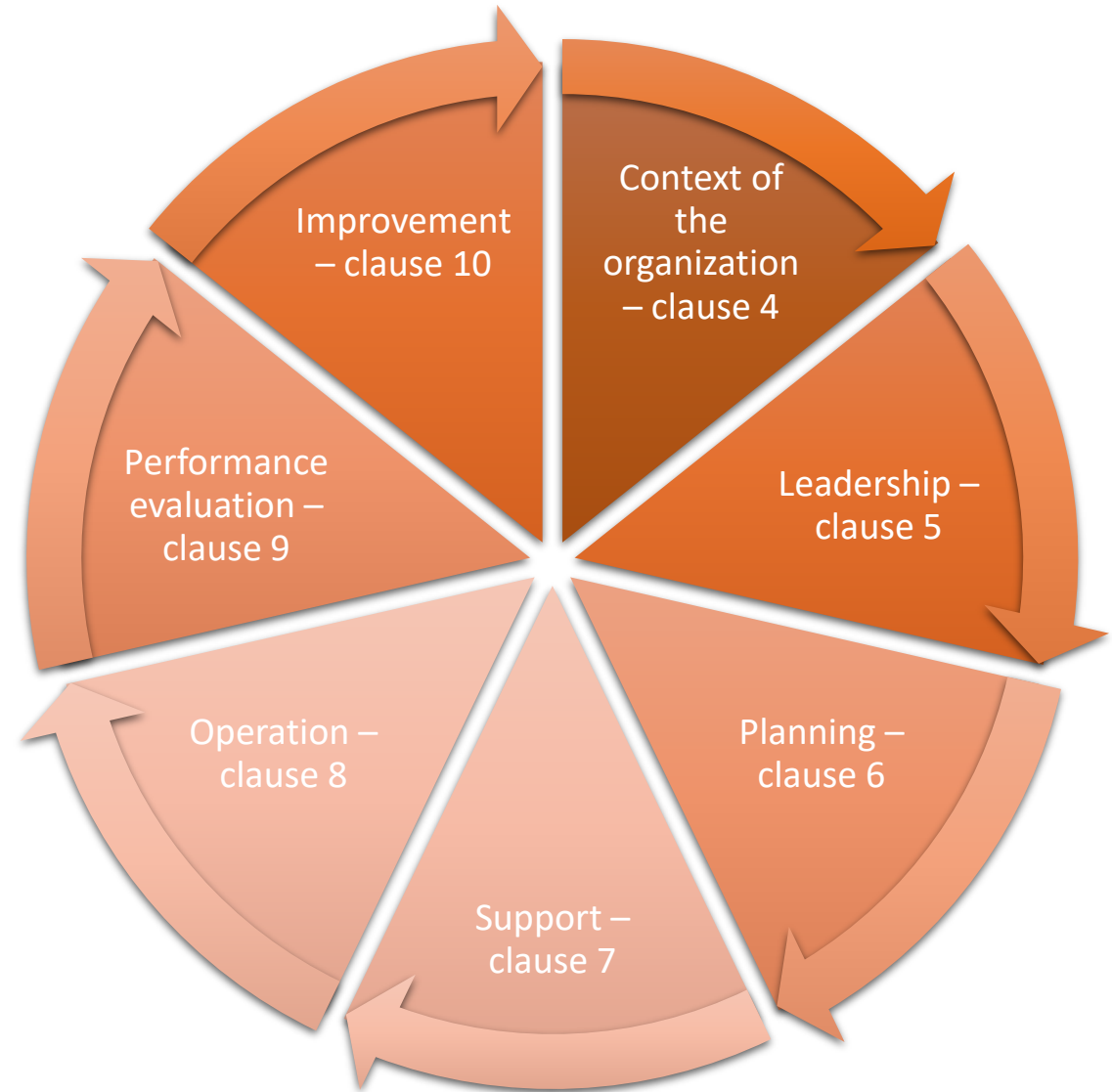
High Level
Structure

ISO 9001:2008	ISO 9001:2015
0. Introduction	0. Introduction
1. Scope	1. Scope
2. Normative References	2. Normative References
3. Terms and Definitions	3. Terms and Definitions
4. Quality Management System	4. Context of the Organization
5. Management Responsibility	5. Leadership
6. Resource Management	6. Planning
7. Product Realization	7. Support
8. Measurement, Analysis and Improvement	8. Operations
	9. Performance Evaluations
	10.Improvement

User-friendly Service and Knowledge- based Organizations – Goal #4

- The old version only used the term, product, in all of the requirements of the standard. The omission of the term, service, made the standard harder and less friendly to comprehend for service and knowledge-based organizations
- The new version consistently refers to “products and services” in all requirements and outputs of processes
- The new version will be easier to understand and its applicability to the security industry will be more evident

ISO 9001:2015 – clauses' view



Context of the organisation – clause 4

- QMS does not operate in isolation; it is impacted by different forces (marketplace, regulatory environment, technology, demographics, economy)
- Must determine what are:
 - the external / internal issues (SWOT analysis, environmental scan)
 - Expectations / constraints of interested parties
 - Strategic direction – mission – vision – policy
- Importance of processes (clause 4.4)
 - Risk-based thinking was added
 - Actions to address risks and opportunities (clause 6.1) must be incorporated in processes

More encompassing than previous version

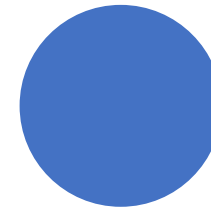
Top Management must demonstrate leadership by fulfilling numerous requirements

Among those requirements are:

- Accountability for effectiveness of QMS
- Communications of policy, objectives, requirements of the standard
- Ensuring resources needs for implementation of QMS (ex. roles and responsibilities in job description)

Expect auditors to spend much more time with CEOs / COOs

Leadership – Clause 5



| Planning – Clause 6

Determination of risks and opportunities based on external / internal issues and needs / expectations of interested parties

Plan actions to address risks and opportunities

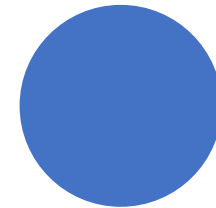
Incorporate actions in processes

About resources to support QMS

Pay particular interest in

- Competence – necessary competence of persons doing work
- Awareness – policy, objectives, contributions to QMS, nonconformity implications
- Communications – development of a communication plan is a “must”
- Org knowledge – how do you capture it and how is it maintained and made available

Support – Clause 7



Operation – Clause 8

Similar to previous version of standard

Emphasis on operational controls

Development of controls (work instructions, procedures, inspections, targeted audits) to make sure processes achieved the desired outcomes

Determination of product / service requirements and review of these requirements (contract requirements including statutory requirements and others)

Performance Evaluation – Clause 9

Similar to previous version of standard

Determination of what needs to be measured and monitored

Emphasis on internal audit to cover all requirements

Emphasis on management review with clear inputs and outputs (decisions based on inputs)

Improvement – clause 10

Improvement of services (broad concept) – part of management reviews inputs and outputs – how to improve the QMS ?

Analysis is required

Improvement through nonconformity corrective actions