Evolution of quality management

Versions before 1994
- Focus on control of final product
- Specialists singularly responsible
- Integrated quality assurance
- QM is everyone’s responsibility
- Focus on procedure manuals

ISO 9000:1994
- Key leadership responsibility
- Stakeholder perspectives
- Viewing customers in a new way

ISO 9001:2008
- Continual improvement
- Meeting customer requirements
- Conforming to regulatory requirements

ISO 9001:2008
- Integrated quality assurance
- QM is everyone’s responsibility
- Focus on procedure manuals

ISO 9001:2015
- Risk-oriented
- Process-oriented
- High-level structure

ISO 9001:2015
- Continual improvement
- Meeting customer requirements
- Conforming to regulatory requirements

The ISO 9001:2015 provides a stable framework of requirements for the next ten years. The generic approach provides the necessary relevance for all enterprises regardless of their size, organizational structure, industry or sector.

Changes and their impact

ADDED
- New high-level structure
- Risk management
- Harmonization with other management systems

AMENDED
- QM manual
- Documentation requirements
- Representative appointed by top management

What does the new structure look like?

ISO 9001:2008
1 Scope
2 Normative Reference
3 Terms and Definitions
4 Quality Management System
5 Management Responsibility
6 Resource Management
7 Product Realization
8 Measurement, Analysis and Improvement

ISO 9001:2015
1 Scope
2 Normative Reference
3 Terms and Definitions
4 Context of the Organization
5 Leadership
6 Planning
7 Support
8 Operation
9 Performance Evaluation
10 Improvement

What to do next?

Complimentary informational events
Initial project meeting
GAP analysis audit
ISO 9001:2015 training courses
Certification

Need more information?
www.tuv.com/iso-9001-2015

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