



ISO 9001 - the past and present 借古喻今 – ISO 9001的蛻變

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Where are we?

- **ISO 9001:2015** published in September 2015
 - Earlier versions: 1987; 1994; 2000 and 2008
- **ISO official survey 2014**
 - 1.609 million ISO management system certificates issued worldwide
 - 1.138 million in ISO 9001
 - China 342,800 (337,033 in 2013)
 - Hong Kong 2295 (2563 in 2013)
 - Macau 115 (100 in 2013)
 - Taiwan 10,328 (11,118 in 2013)
- Previous number of certificates
 - 1994 (70,384); 2000 (408K) and 2008 (980K)

A twenty-eight (28) year journey

- 1 **QUALITY MANAGEMENT**
- 2 **TOP MANAGEMENT COMMITMENT**
- 3 **RISK BASED THINKING**
- 4 **IMPROVEMENT**
- 5 **DOCUMENTATION**

From QA to QM (1/5)

- 1987** QUALITY SYSTEMS –
MODEL FOR QUALITY ASSURANCE
- 1994** QUALITY SYSTEMS –
MODEL FOR QUALITY ASSURANCE
- 2000** QMS – REQUIREMENTS (8 QMP)
- 2008** QMS – REQUIREMENTS (8 QMP)
- 2015** QMS – REQUIREMENTS (7 QMP)

Process approach, process auditing

Top management commitment (2/5)

- 1987** NOT MENTIONED
- 1994** NOT MENTIONED
- 2000** REQUIRED
- 2008** REQUIRED
- 2015** TAKE ACCOUNTABILITY,
ENGAGE PEOPLE,
EMBED QMS INTO BUSINESS

Risk based thinking (3/5)

- Not explicit in previous versions
 - 1987 Clause 4.14 corrective action
 - c) initiating preventative actions to deal with problems to a level corresponding to the risks encountered;
 - 1994 Clause 4.14 corrective action
 - 4.14.2 corrective action
 - 4.14.3 preventive action
 - 2000/2008 Clause
 - 8.5.2 Corrective action/8.5.3 Preventive action
- 2015: Context and internal/external factors
 - Risk based thinking
 - Term of 'Preventive action' disappeared

Improvement (4/5)

- 1987 and 1994
 - improvement not part of the requirements
- 2000 and 2008
 - Requirement on continual improvement
 - 'small step improvement' (kaizen 改善)
 - Adopted from ISO 14001:1996
 - Continual means 'one after the other'; 'recur'
 - Continuous means 'non-stop', 'never ending';
- 2015
 - Improvement includes all types of improvement
 - continual improvement

No of (mandatory) documented procedures (5/5)

1987	2
1994	20
2000	6
2008	6
2015	0

What we are having?

- Annex SL
- Enhanced requirements on top management (embed QMS)
- Risk based thinking
 - Context, interested party requirements, risks and opportunities
- Organizational knowledge
- Revised terminologies
 - Products and services
 - External provision (outsourcing, purchasing)
- Less mandatory documentation
 - No manual, no documented procedures
 - Maintain and retain
- Concept of Improvement (including continual improvement)

Output Matters !!!
