Bridging Leadership from ISO 9001:2015 to Performance Excellence

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ASQ 1208
About IMEC

Who we are:
IMEC is a private, public partnership that operates through the National Institute of Standards and Technology (NIST)

What we do:
IMEC delivers customized training, hands on technical assistance, and leadership advisement to help manufacturers improve bottom line results
CONTINUOUS IMPROVEMENT
- Lean Enterprise
- Quality Management
- ERP/ERP
- Six Sigma
- Safety and Health
- Quick Response Manufacturing

PROBE
- Promoting Business Excellence

STRATEGY
- Strategic Planning
- Business Transition

ILPEx
- Baldrige Criteria for Performance Excellence

TOP LINE
- Marketing & Sales
- Market Insights
- Product Innovation & Technology
- Exporting

SUPPLY CHAIN
- Top Tier Engagement
- Supplier Engagement
- Risk Management
- Total Cost of Ownership

WORKFORCE DEVELOPMENT
- Leadership Development
- Supervisor Effectiveness (TWI)
- Change Management

GREEN MANUFACTURING
- Energy Management (ISO 50001)
- E3: Economy, Energy, Environment
- Waste Reduction
ISO 9001:2015 Elements that are Heading in the right direction for Performance Excellence
ISO 9001:2008 to ISO 9001:2015 Key Changes

Process approach, coupled with the PDCA methodology and risk-based thinking to align or integrate its quality management system with the requirements of other management system standards as it sees fit.

• Standard Format/ ##
• Safety Requirements
• Environmental Requirements
ISO 9001:2008 to ISO 9001:2015 Key Changes

Local Level
Plan
Do
Check
Act

System Level
PDCA
Systemic Evaluation more than just compliance

Systemic Evaluation more than just compliance
ISO 9001:2008 to ISO 9001:2015 Key Changes

Focus
- Meeting your requirements

- Prescribed Documents
- ISO 9001:2008 required (6) key documents

Focus
- Define your context
- Documented Information (e.g. Database entry)

ISO 9001:2015
Context of the Organization

Business Plan
- Leadership
- Stakeholders
- Suppliers
- Risk Plan

Steps to fulfill requirements
- Auditing
- Competence
- Performance
- Continuous Improvement

Deliver requirements

Customer Satisfaction

Customer Requirements
ISO 9001:2008 to ISO 9001:2015 Key Changes

**Increased Leadership** requirements

- What does increased Leadership look like?
  - KPI / Metrics
  - Accountability
  - Improvement

Was the Quality Manager or Director responsible for the entire Quality Management System?

- Evidence of Leadership must be present....
ISO 9001:2008 to ISO 9001:2015 Key Changes

**Improvement Efforts** to increase *customer satisfaction*

- Continuous Improvement results driven

- Key Process Metrics instilled by Leadership to monitor customer satisfaction

- Internal Customer satisfaction? Stakeholders?
ISO 9001:2008 to ISO 9001:2015 Key Changes

Risk-based thinking

Elements of Risk, adopted from FMEA
1. Severity
2. Occurrence
3. Detection

Are you required to complete an FMEA?
Risk-Based Thinking

Using Risk-Based Thinking in ISO 9001:2015:

- **Clause 4 (Context)** the organization is required to determine the risks which may affect this.
- **Clause 5 (Leadership)** top management are required to commit to ensuring Clause 4 is followed.
- **Clause 6 (Planning)** the organization is required to take action to identify risks and opportunities.
- **Clause 8 (Operation)** the organization is required to implement processes to address risks and opportunities.
- **Clause 9 (Performance evaluation)** the organization is required to monitor, measure, analyse and evaluate the risks and opportunities.
- **Clause 10 (Improvement)** the organization is required to improve by responding to changes in risk.
ISO 9001:2015 Context

Quality Management System (4)

Supports & Operation (7,8)

Plan (P)

Do (D)

Check (C)

Act (A)

Leadership (5)

Performance evaluation (9)

Improvement (10)

Planning (6)

Organization and its context (4)

Customer requirements

Needs and expectations of relevant interested parties (4)

Customer satisfaction

Results of the QMS

Products and services
ISO 9001 vs. Performance Excellence


ISO 9001:2015 vs. Performance Excellence

ISO 9001:2015
- Systems Approach
- Product and Service Quality for the Customer
- Minimal Health/Safety
- No Financial
- Minimal Innovation

Malcolm Baldrige/Performance Excellence
- Yes
- Yes
- Yes
- Yes
ISO 9001:2015 Limitations

• **Context** (communication requirements force re-evaluation of the QMS)
• Engaging **Leadership** in the **Context** of the Organization
• Foundation for **Strategic Planning**
• ISO = **Compliance**; Performance Excellence = **Improvement**
• **Environmental** (Competitive Pressures force re-evaluation of the Innovation Process)
• **Commoditization** (need to simplify product and/or streamline process)
Technical Specialist, IMEC

Over 20 years focusing on Continuous Improvement

- Lean
- Six Sigma
- ISO 9001 Lead Auditor
- ISO 13485 (Medical) Lead Auditor
- TS16949 Lead Auditor
- HACCP Certified
- B.S. Industrial Technology, NIU
- M.S. Industrial Management, NIU
- M.S. Information Systems, DePaul

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