GUIDANCE ON CONFORMING TO ISO 9001:2015

ADVICE AND EXAMPLES FROM AN AUDITOR
About Milt Dentch

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- Conducted over 500 audits for large and small companies
- Diverse client background from a floating oil rig in the Gulf of Mexico to a 4,000 employee electronics manufacturer in the Ukraine
- Past roles include being an engineer for the paper industry, and a manager at both the Polaroid Corporation and the Furon Corporation
- BS in mechanical engineering from Worcester Polytechnic Institute
- MS in Total Quality Systems from the National Graduate School of Quality Management
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Agenda

- ISO 9001 History
- Plan-Do-Check-Act and the QMS
- The QMS as a Process
- New Requirements of ISO 9001:2015
- Documentation
- Transition Timetable
- ISO 9001:2015 Transition Program
ISO 9001 History

1987  ISO 9001 International Standard
1994  ISO 9001 Revision International Standard
2000  ISO 9001 Revision International Standard
2008  ISO 9001 Amendment International Standard
2015  ISO 9001 Revision International Standard
Plan-Do-Check-Act
PDCA: **PLAN**

- Top management establishes the context, scope, boundaries and quality policy of the QMS
- Quality objectives are selected and programs established to achieve the objectives
- The core processes of the QMS and their interactions are determined
- Performance indicators for the core processes are established
PDCA: **DO**

- Production and/or service processes are implemented with controls maintained to ensure customer requirements are met.
- Processes supporting the core processes are implemented.
PDCA: **CHECK**

- The quality management system is monitored and audited to measure performance against the organization’s objectives and customer requirements.
- The performance and results of the quality management system are reported to top management.
PDCA: **ACT**

- Actions are initiated to correct deficiencies and improve the quality performance as indicated by the monitoring and measurement of the quality management system results.
- Resources and employee training are provided as appropriate to ensure improvement of the quality management system.
The QMS as a Process

Management establishes the context, scope and boundaries of the QMS

Management establishes the Quality Policy of the QMS

Quality Objectives are selected with programs established to achieve the objectives

The core processes of the QMS and their interactions are determined

Performance Indicators are established for the core processes

Controls are established to ensure customer requirements are met
Support Processes

Documentation
Training
Quality Assurance
Calibration
Maintenance
Corrective Actions

Internal Audit
Communication
Risk Assessment
Monitoring & Measurement
Management responsibilities
Management Review
New Requirements of ISO 9001:2015

• Context and expectations of interested parties;
• Actions to address risks and opportunities;
• Expanded top management commitment & integration of the QMS into the business;
• Organizational knowledge;
• Programs to achieve quality objectives;
• Documentation
Clause 4.1: Understanding the organization and its context

“The organization shall determine external and internal issues that are relevant to its purpose and its strategic direction and that affect its ability to achieve the intended results of its quality management system.”

Organizations are now required to consider the external issues such as new technology, potential market forces, social and economic environments, international competition that could impact the organization’s business strategy.
Examples: External Issues

• Product related regulations
• New technology
• New competition
• Outsourced suppliers
• Supplier vulnerability
• Supplier costs
• Material restrictions
• Energy costs
• Employee benefit costs
• Employee organizations
• Export tariffs
Examples: Internal Issues

• Employee turnover
• Retiring employees
• Employee costs
• Aging equipment/ facilities
• Employee morale
Clause 4.2: Understanding the needs and expectations of interested parties

“Due to their effect or potential effect on the organization's ability to consistently provide products and services that meet customer and applicable statutory and regulatory requirements, the organization shall determine:

a) the interested parties that are relevant to the quality management system;
b) the requirements of these interested parties that are relevant to the quality management system.”

The organization needs to determine the interested parties that may be relevant to the quality management system.
Examples: Interested Parties

- Regulatory bodies
- Market sectors
- Neighbors
- Community

Note: Organizations may consider some details on external, internal issues and the needs of interested parties as “company confidential.”

External auditors should expect to review only the process used to develop the business strategy.
Clause 6.1: Actions to address risks and opportunities

“The organization shall determine the risks and opportunities that need to be addressed to give assurance that the quality management system can: achieve its intended results; enhance desirable effects; prevent, or reduce undesired effects; achieve improvement.”

How the organization assesses the risks and opportunities related to its purpose, business strategy and expectations of interested parties to ensure the quality management system meets its objectives is (could be) a requirement
Overview: Risk Based Thinking (RBT)

The Annex to ISO 9001:2015 makes RBT optional:

A.4 Risk-based thinking:

Although (6.1) specifies that the organization shall plan actions to address risks, there is no requirement for formal methods for risk management or a documented risk management process.

_I suggest organizations establish RBT or risk analysis as appropriate to the context of their business._
RBT and the Business Model

**Machine Shop:**

SWOT analysis (strength, weakness, opportunities, threats) as part of annual business review.

**Multi-site international contract manufacturer:**
Continual application of: FMEA (failure mode and effects analysis); or PPAP (production part approval process)
Risk Analysis as Part of Change Control

All organizations can benefit from risk analysis and management as part of their change control process within the context of ISO 9001:2015:

- Process or equipment changes
- Raw material specifications and changes
- Document control
- Design
- Regulatory revisions
- Outsourced processes
- Effectiveness of corrective actions
- Internal audit planning
Process or Equipment Changes

When production equipment or processes are changed, the implementation plan should include the potential risk for product quality.

Testing prior to release of “new” product to customers is a common technique employed, along with the application of FMEA (Failure Mode and Effects Analysis).
Any change in materials used in production should be tested before release to customers. The organization should ensure their suppliers are aware of the need to maintain control and communication of any changes in their specifications or processes.
Document Control and Review

The organization should ensure documents used by employees are maintained and controlled to avoid mistakes. Work instructions should be reviewed at some frequency to ensure employees are not by-passing operating instructions.
Design

During the design process, a robust verification and validation plan should be employed to eliminate risks related to new designs. The new design process should also include the risk analysis related to the impact the new design process may have on employee safety and the organization’s environmental impact, including end of life disposal issues.
Regulatory Updates

The organization should maintain a process to be aware of changes to statutory and regulatory obligations related to its products to eliminate risks related to non-compliance.
Outsourced Processes

Processes performed by external parties can create a risk for the organization in meeting its commitment.

External supplier selection should include controls related to the impact the supplier can have on producing acceptable product or services. Inspection of externally supplied products should be based on inspection cost vs. risk related to supplier errors.
Effectiveness of Corrective Actions

An important part of the corrective action process is how effective the correction was to reduce the risk of a recurrence of the same issue.

Time and resources allocated to measuring the effectiveness of the correction should be commensurate with the risk of recurrence.
Internal Audits

The internal audit plan should be based on the impact a process may have on quality performance as well as the history the particular process has in generating nonconformances.

By focusing on the history and impact of each process, the organization can allocate auditing resources to reduce risk of errors.
ISO 9001:2015 does not have a requirement for “preventive action”. The thought is the entire quality management system is preventive in nature and the risk analysis approach is also preventive.

Note: the use of preventive actions as a risk analysis approach can be an effective technique, provided the actions will reduce or eliminate the probability of specific undesirable events from happening in the future - and not just prevent a corrective action situation from reoccurring. I would encourage the organization to avail themselves of other options for risk analysis depending on their business model.
Is top management committed to the QMS?

- Do members of top management attend Management Reviews?
- Is the “management representative” a member of the senior staff?
- Does management provide support for resources necessary to maintain and improve the QMS?
Integrating QMS into Business Processes

• The KPIs (key performance indicators) are assigned to quality and business parameters as well as the safety and environmental metrics.
• Quality driven waste reduction projects include improved environmental performance.
• “Best-in-class” organizations have established a Business Management System (BMS) incorporating their financial, quality, safety and environmental systems into a cohesive operational model.
Clause 7.1.6: Organizational knowledge

“The organization shall determine the knowledge necessary for the operation of its processes and to achieve conformity of products and services.”

The organization needs to determine and manage the knowledge necessary to safeguard the organization from loss of expertise through staff turnover and changes in outsourced providers. The organization needs to maintain awareness of the latest technology related to its products, services and processes.
Organizational Knowledge examples

- Secession planning: process to replace key employees
- Supplier contingency planning: single sourced & sole sourced suppliers present a risk.
- Technology updating: Who is the CTO? (chief technology officer)

Note: Organization knowledge as part of the organization’s business strategy may be confidential. External auditors should expect to review only the process used to develop the planning related to organizational knowledge.
Clause: 6.2 Quality objectives and planning to achieve them

“When planning how to achieve its quality objectives, the organization shall determine: what will be done; what resources will be required; who will be responsible; when it will be completed and how the results will be evaluated.”

The organization will need to have a defined program on how to achieve each of its quality objectives. This requirement is consistent with ISO 14001:2015 for environmental objectives programs and should reduce auditing inconsistencies- and enhance quality improvements.
Documentation and ISO 9001:2015

• “New” requirements
• Documented information
• The quality manual
Clause 7.5.2: Creating and Updating

“When creating and updating documented information, the organization shall ensure appropriate: identification and description (e.g. a title, date, author, or reference number); format (e.g. language, software version, graphics) and media (e.g. paper, electronic); review and approval for suitability and adequacy.”

ISO 9001:2015 is more prescriptive in document control than prior revisions. The organization is now required to define how the organization formats their documented information.
Documentation and ISO 9001:2015

• “Documented Information” now describes documents and records;
• A quality manual is not required;

I suggest maintaining the current “documents” and “records” terminology.

I suggest organizations continue to use a quality manual as a high level consolidation of the key elements- or roadmap, of their quality documentation- BUT streamlined to eliminate non-value verbiage and paraphrasing.
Suggested Contents of a Quality Manual

- A description of the context of the organization and expectations of interested parties.
- The scope of the quality management system.
- The description of the ISO 9001:2015 requirements, which are not applicable to the quality management system,
- The documented procedures established for the quality management system, or reference to them.
- A description of the processes and their interaction between the processes of the quality management system.
- The Quality Policy
- Responsibilities/ Authorities
ISO 9001:2015 Summary

- “Verifiable” requirements
- “Subjective” requirements
“Verifiable” Requirements

• Programs for achieving objectives

• Creating documentation
“Subjective” Requirements

• Context and expectations of interested parties
• Actions to address risks and opportunities
  (I suggest risk analysis be “verifiable”)
• Expanded top management commitment & integration of the QMS into the business
• Organizational knowledge
ISO 9001:2015 Transition Timetable

• The standard ISO 9001:2015 was published on October 25, 2015

• Companies presently certified to ISO 9001:2008 will have three years to bring their quality management systems up to date with ISO 9001: 2015

• ISO 9001:2008 certificates will become invalid and will be withdrawn as of October 25, 2018
ISO 9001:2015 Transition Program

- Review and revise “scope” of QMS to include context of business; internal/external issues and interested parties;
- Update quality manual and documentation procedure;
- Develop “Risk Analysis” process
- Develop “Organizational Knowledge” process
- Formalize planning to achieve quality objectives
- Conduct Management Review:
  - Demonstrate “integration” of QMS with business
  - Review risk analysis and organizational knowledge
  - Review quality objectives programs
- Conduct Internal Audit to ISO 9001:2015
- Corrections from Internal Audit
To learn more…

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