

ISO 9004: The Path to Experiencing Sustained Value from Management Review

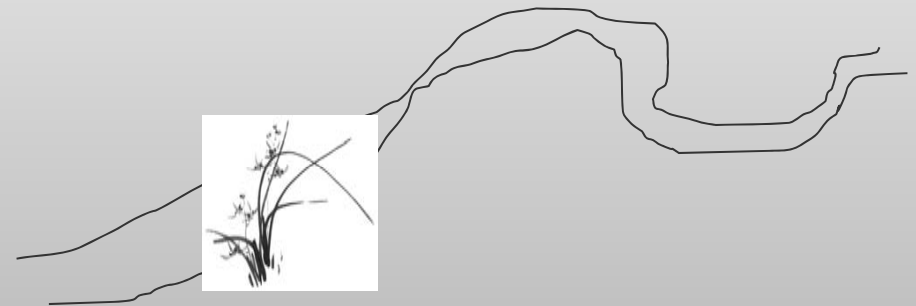
Presented by

Denise Robitaille

Le Chêne et le Roseau

(The Oak Tree and the Reed)

by Jean de LaFontaine




ISO 9001:2008

5.4.2 b Quality management system planning

- “Top management shall ensure that...the integrity of the quality management system is maintained when changes to the quality management system are planned and implemented.”

ISO 9004:2009 4.3

“An *organization's environment* will be *undergoing change continually*, regardless of its size ..., its activities and products, or its type



**Fundamental
premise of
ISO 9004:2009**

ISO 9004:2009

Managing for the sustained success of an organization —
A quality management approach

Getting value from management review

ISO 9001:2008 5.6 Management review

- What are expectations?
- What should we be able to get from the review process?
- What's the usual outcome?

ISO 9001: 2008 5.6.2

Inputs to management review

- Results of audits
- Customer feedback
- Process performance and product conformity
- Status of preventive and corrective actions
- Follow-up actions from previous reviews
- Changes that could affect the quality management system
- Recommendations for improvement

Purpose of 9004 revision

Provide organizations with guidance to achieve sustained benefit from a more broad-based and in-depth QMS implementation.

How do we get from...



This

- Results of audits
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...to this

Provide organizations with guidance to achieve sustained benefit from a more broad-based and in-depth QMS implementation.

The Structure of ISO 9004:2009

- 4 Managing for the sustained success of an organization
- 5 Strategy and policy
- 6 Resource management
- 7 Process management
- 8 Monitoring, measurement, analysis and review
- 9 Improvement, innovation and learning

Key features and concepts

- Sustained success
- Organization's environment
- Interested parties
- Resource management
- Monitoring key performance indicators
- Innovation and learning
- Self-assessment

Sustained success

- Ability to continually meet needs and expectations of customers and interested parties over time
- Balanced approach
- Ensures long term viability

- Results of audits
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Organization's environment

- Internal
- External
- How it affects us and our ability to serve our customers

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Interested parties

Customers	<ul style="list-style-type: none">-- new designs requiring acquisition of new technology-- increase in competitors selling to organization's customers-- demands for faster delivery
Suppliers	<ul style="list-style-type: none">-- relocation off shore-- loss of certification-- global raw material shortages
Financial institutions	<ul style="list-style-type: none">-- tightening of lending policies /changes in rules-- availability of funds to lend
Society	<ul style="list-style-type: none">-- environmental concerns-- changes at the local community level-- revisions to statutory and regulatory requirements
People in the organization	<ul style="list-style-type: none">-- availability of competent staff-- opportunity for learning and advancement-- safe work environment

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- Customer feedback**
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Resource management

- Financial
- People
- Suppliers
- Infrastructure
- Knowledge/information/technology
- Natural resources

- Results of audits
- Customer feedback
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Monitoring key performance indicators

- 1st pass yield
- Time to quote
- Supplier performance
- Design cycle time
- Machine downtime
- Delivery
- Order accuracy
- Etc.

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Innovation

- Plan for the future
- Anticipating technological trends and changes
- Tool for surpassing customer expectations

- Results of audits
- Customer feedback
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Learning

- Distinct from “training”
- Ability for whole organization to learn
- More than just “data”
- Culture to be fostered

- Results of audits
- Customer feedback
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ISO 9004:2009 4.3

“An organization's environment will be undergoing change continually, regardless of its size ..., its activities and products, or its type ... **consequently this should be monitored constantly by the organization.**”

Such monitoring should enable the organization to identify, assess and manage the risks related to interested parties, and their changing needs and expectations”.

Self assessment

- Use to facilitate decision-making
 - Sustainable success
 - Meeting/exceeding customer expectations
 - Addressing concerns of interested parties
 - Mitigation of risk
 - Resource allocation

Self assessment

- Use to facilitate decision-making
 - Decisions relating to organization:
 - strategic planning
 - prioritization of plans
 - acquisition of additional resources (including people)
 - revise/improve processes

Where does information come from?

- Management review
 - Customer feedback
 - Auditing
 - Corrective actions
 - Preventive actions
 - Key performance indicators

Effectiveness of assessment

- Reliant on:
 - Selection of appropriate key performance indicators
 - Planning
 - Monitoring of processes
 - Analysis and understanding of data
 - Integration of additional objective information from:
 - Internal environment
 - External environment

Several assessment tools

- Top management self assessment
 - Performed by top management
 - Quick overview of position in relation to strategy
- Detailed self assessment
 - Performed by cross-functional team
 - Assess capability of business in terms of processes
 - More elaborate

Factual approach to decision making

- Use the data from management review to drive the self-assessment process.
- What do your key performance indicators say about your:
 - Capacity to fulfill/exceed customer requirements
 - Ability to address concerns of interested parties
 - Responsiveness to changes in market
 - Efficient use of resources
 - Organizational ability to learn/innovate

Maturity model

Clause	Level 1	Level 2	Level 3	Level 4	Level 5
7.1	Processes are planned in an informal manner	Key processes are well defined and managed	Process planning is integrated strategic deployment	Agility, innovation, flexibility in process improvements	World-class process performance
8.4	Anecdotal evidence of analysis	Analysis of relevant indicators performed periodically	Systematic analysis supported by statistical tools	Analysis used for evaluation of new resources, etc	Relevant external factors analyzed for risk and opportunities

Factual approach and maturity levels

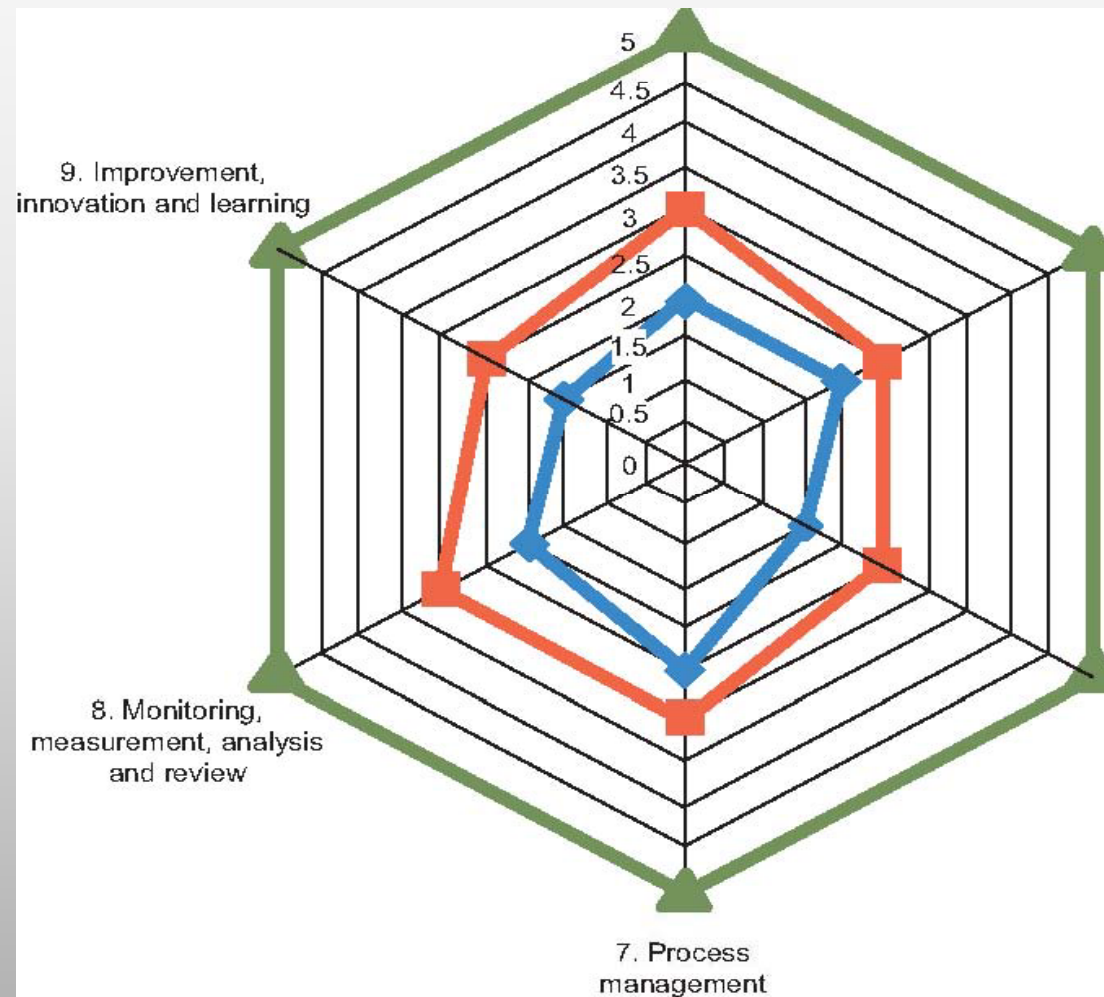
- Based on our key performance indicators, **to what degree** does our organization reflect:
 - Capacity to fulfill/exceed customer requirements
 - Ability to address concerns of interested parties
 - Responsiveness to changes in market
 - Efficient use of resources
 - Organizational ability to learn/innovate

Maturity in relation to 9004

Assess maturity level in relation to ISO 9004:2009

- 4 Managing for the sustained success of an organization
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Diagram of results



ISO 9001: 2008 5.6.3

Outputs from management review

...decisions and actions related to

- Improvement of the effectiveness of the [QMS] and its processes
- Improvement of product related to customer requirements
- Resource needs

Resource management

- Financial
- People
- Suppliers
- Infrastructure
- Knowledge/information/technology
- Natural resources

ISO 9001: 2008

Outputs from **assessment and review**

...decisions and actions related to

- ❑ **Sustaining the success of the organization**



**Identifying changes
that affect your QMS**

ISO 9001:2008

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ISO 9001: 2008 5.6.2

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Relocation

- Challenges related to moving business (either in same city, different part of the country or overseas)
- Applicable ISO 9001:2008 requirements
 - Enough product to continue to serve customers 7.2.2
 - Cost for moving production equipment 6.3
 - Possible changes in local laws related to your industry (several)
 - Replacing personnel who cannot move to new location 6.2.2
 - Recruiting
 - Qualification
 - Training

Relocation (con't)

- Challenges related to moving business (either in same city, different part of the country or overseas)
- Applicable ISO 9001:2008 requirements
 - Infrastructure issues 6.3
 - Telecommunication systems (telephones, internet)
 - New building HVAC (heat, cooling work environment)
 - Re-configuring work cells
 - Setting up production equipment
 - Communicating with customers and suppliers 7.2.3
 - Re-calibrating production and test equipment 7.6

What changes affect your QMS?

Sustained success

- Ability to continually meet needs and expectations of customers and interested parties over time
- Ensures long term viability
- Balanced approach to meeting needs and expectations of customers and other interested parties

Interested parties

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Thanks!!

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