Context of the Organization and Interested parties

An Implementation Approach
What’s Hard About Transitioning? Top 5 Responses – Hundreds of Webinar Registrants

5. Changing documentation / new format
4. Finding time to get it done
3. Training and organizational understanding
2. Risk Based Thinking
1. Leadership

Leadership establishes context of the organization and interested parties’ needs and expectations.
Agenda: Context of the Organization and Interested Parties

Overview: ISO 9001:2015 Clause 4
- Clause 4.1 – Understanding the Organization and its Context
- Clause 4.2 – Understanding the Needs and Expectations of Interested Parties
- Why did ISO 9001:2015 add these requirements?

IMEC’s approach to address these requirements
- Use Performance Excellence model guidance
- Getting it done – 3 methods
- Q&A
Overview: ISO 9001:2015 Clauses 4.1 and 4.2
Context of the Organization Drives QMS
Leadership Monitors and Reviews for Improvement

The Business
Purpose, Strategic Direction, Issues Affecting Success,
Interested Parties and Their Requirements

Clause 4 – Context

Scope
Policy
Objectives
Plans
Resources
People
Methods

Clause 4 – Context
Clause 5 - Leadership
Clause 6 - Planning
Clause 7 - Support
Clause 8 - Operation

Feedback
Clauses 9 and 10
Performance Evaluation and Improvement
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 result(s) of its quality management system.

The organization shall monitor and review information about these external and internal issues.

What is the organization’s purpose and strategic direction?
What results does the organization intend to achieve through its QMS?
What are the relevant internal and external issues?
How does the organization monitor and review issues?
Purpose and Strategic Direction: Examples of Some Factors to Consider

- Complex versus simple product or service
- Multiple regulated customer type vs single unregulated customer type
  - Military AND Automotive AND Medical Device vs. Consumer products
- Contract manufacturer versus end-to-end integrated organization
- High end specialized niche market vs. mass market copycat
- Grow by acquisition? Intend to be acquired?
- Growing versus shrinking market?
- Part of a broader corporate structure that defines overall objectives and is the sole customer of your output?
**What are the intended results of your quality management system”?**

**Think: Quality, Cost, Speed**

*(Note: measurable objectives could come from some of these)*

<table>
<thead>
<tr>
<th>Reduced waste, less rework/scrap</th>
<th>Faster on-boarding</th>
<th>Faster service / OTD</th>
<th>Improved profits</th>
</tr>
</thead>
<tbody>
<tr>
<td>Better product designs</td>
<td>Work force flexibility</td>
<td>Meet Regulations</td>
<td>Easier to sell</td>
</tr>
<tr>
<td>Consistent customer experience</td>
<td>Job stability, growth, satisfaction/morale</td>
<td>Smooth new product intro, time to market</td>
<td>First to market, bigger market share</td>
</tr>
<tr>
<td>Improved incoming parts, supplier quality</td>
<td>Clear roles, communication</td>
<td>Customer loyalty (not shopping)</td>
<td>Less unplanned O/T</td>
</tr>
<tr>
<td>Capacity utilization</td>
<td>Employee safety</td>
<td>Fewer failed products</td>
<td>Lower warranty costs</td>
</tr>
</tbody>
</table>
Identifying Relevant External and Internal Issues

• What is relevant?
  • Issues that can: ___positively or negatively_______________
    the organization’s ability to: ___achieve results______________

• Examples of relevant internal issues
  • Organizational performance including financial, e.g. ___new products___
  • Resource factors, e.g. ___IT capabilities, facility, location, ___________
  • Human aspects, e.g. ___competencies, culture, age, experience_______
  • Management-related, e.g. ___organizational structure, corporate issues___

• Examples of relevant external issues
  • Economic issues, e.g. ___exchange rates, inflation, credit availability___
  • Social factors, e.g. ___unemployment rate, public perception__________
  • Political/legal, e.g. ___regulatory, government stability, trade agreements
  • Technological, e.g. ___new materials, equipment; patent expirations___
  • Competition, e.g. ___market share, competitive advantage/disadvantage
How can an organization identify, monitor, and review the relevant issues?

- Define systematic methods
- Repeat the process at reasonable intervals – verify assumptions, add new information, update original facts
- Take actions appropriate to analysis:
  - Update risk assessments and plans
  - Update processes
  - Apply resources
  - Inform the right people
- Typically done for financial and legal objectives – why not quality?
- What evidence would you look for as an auditor that this is done?
4.2 Understanding the Needs and Expectations of Interested Parties

Due to their effect or potential effect on the organisation’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 shall monitor and review information about these interested parties and their relevant requirements.

Who are the relevant interested parties?

What do they require?

How does the organization monitor and review information about interested parties and their requirements?
...So who should we count as “relevant” within the context of your organization

“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…”

(ISO 9001:2015 Clause 4.2)

3.2.3
interested party
stakeholder
person or organization (3.2.1) that can affect, be affected by, or perceive itself to be affected by a decision or activity

EXAMPLE Customers (3.2.4), owners, people in an organization, providers (3.2.5), bankers, regulators, unions, partners or society that can include competitors or opposing pressure groups.

(ISO 9000:2015)
Why did ISO 9001:2015 add these requirements?

• Feedback from users – business relevance of ISO 9001

• Learnings from Business Excellence Models
  • *These definitions, agreed by Leadership and communicated, guide the organization to greater achievements*

• ISO 9001 gives flexibility in how to define context, issues, interested parties, and requirements, but makes it clear they are to be used:
  • *Scope, 6.1 Planning, and all requirements related to risk*

• An advancement from the concept of a quality manual that outlines approaches to ISO 9001 requirements.
  • *Instead, 4.1 and 4.2 ask for an outline of the approach to achieving results*
IMEC Approach:
Performance Excellence Model
Capturing 4.1 and 4.2: Some alternatives, continued

Baldrige Organizational Profile

- Typically 5 pages
- Concise but thorough statement
- May address more than ISO minimum; organizations discretion
- Structured, systematic approach to create and revise
Benefits to using the Organizational Profile

• Engages leadership in important discussion about the organization’s key characteristics
• Promotes conversation about the organization’s strategic situation
• Provides a snapshot of the organization, how you operate, and the challenges you face
• Beyond compliance and focused upon performance excellence and improvement
• Organizations can receive expert feedback and recognition from many state based Performance Excellence programs on completion of their Organizational Profile
4 Context of the organization

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 result(s) of its quality management system. The organization shall monitor and review information about these external and internal issues.

P.1 Organizational Description: key organizational characteristics

a. Organizational Environment
(1) Product Offerings
(2) Mission, Vision, and Values
(3) Workforce Profile
(4) Assets
(5) Regulatory Requirements

Source: ISO 9001:2015

Source: Organizational Profile
ISO 9001 and the Organizational Profile Alignment

4 Context of the organization

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 result(s) of its quality management system.

The organization shall monitor and review information about these external and internal issues.

Source: ISO 9001:2015

P.2 Organizational Situation: strategic situation

a. Competitive Environment
   (1) Competitive Position
   (2) Competitiveness Changes
   (3) Comparative Data

b. Strategic Context

c. Performance Improvement System

Source: Organizational Profile
4 Context of the Organization
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 shall monitor and review information about these interested parties and their relevant requirements.

Source: ISO 9001:2015

b. Organizational Relationships
(1) Organizational Structure
(2) Customers and Stakeholders
(3) Suppliers and Partners

Source: Organizational Profile
The Baldrige Organizational Profile provides questions guide a thorough description of your organization. Additional guidance is in the Notes section.
Getting it done:
3 Methods of Implementation
Method 1
Straw Document

- Leader (Quality Director, for example)
  - Draft a document
  - Circulated for comments
  - Refine
  - Publish with management approval
- Fastest method
- Least amount of discussion and learning from team
- May work well for:
  - Mature organizations – well understood by all
  - Small, informal organizations
  - Resistant teams – this is at least a starting point

Caveat:
Don’t outsource! The benefit is in the learning from doing it yourselves!
Method 2
Input Gathering, then Straw Document

• Leader facilitates input gathering (Quality Director, for example)
  • Written surveys – ratings or short answers
  • Interviews – team meetings or 1-1
  • People or groups are assigned questions to answer
•Leader drafts straw document for review and approval
• Potentially slowest method
  • Major effort on facilitator
  • Raises awareness and may lead to strong buy-in and discussion
• May work well for:
  • Resistant teams where Leader is strong
  • Teams who work remotely or are hard to assemble
  • High functioning teams who take their homework seriously
Method 3
Facilitated Workshop

- 1-2 full group sessions
  - *Pre-work and homework: Information gathering and refinement*
- Facilitator guides discussion
  - *Asks the hard questions and challenges answers*
- Potentially fastest method, but highest involvement and impact
  - *Major effort to get people together*
  - *Provides education and team building*
  - *Leads to strongest buy-in and discussion*
  - *Prepares team for ongoing monitoring, review, and improvement*
- May work well for:
  - *Committed teams who are open to learning and growth*
  - *Strong personalities who can benefit from outside facilitation*
  - *Busy teams who need to commit time all together to get it done*
  - *Resistant teams who need to develop buy-in through group interaction and strong leadership*
Let’s take some Questions!