Welcome
Mr. Fergal O’Byrne
Head, Business Excellence
NSAI
Aims of the day

• NSAI Transition policies
• NSAI Roadshow presentations
• NSAI Questionnaires or ‘Self Assessment’ tools
• ISO Transition documents – *suite of documents published by ISO to aid in the transition*
• Case studies from NSAI Clients who have made the upgrade

As they are released these documents can be downloaded from the NSAI website: [www.nsai.ie/management-systems.aspx](http://www.nsai.ie/management-systems.aspx)

*(Copy of link will be available at the end of the seminar)*
ISO 9001:2015
September/October 2016
John Tighe
Certification Services
CONTENT

• Context Of the Organisation
• Interested Parties
• Scope of the QMS
• Process Approach
• The emphasis on Leadership
• The focus on Risk-based thinking
• Quality Objectives
• How Change is addressed
• Externally provided Processes, Products, Services
• QMS Questionnaire
• Process Clause Matrix
Context

• An organisation's context involves its operational environment.

• The context must be determined both within the organisation and external to the organisation.

• To determine context means to identify the internal and external factors that the organisation must consider when they manage risks.

• Internal context includes: internal stakeholders, vision, mission, objectives, governance, resources, contractual relationships, capabilities and culture.

• External context includes: external stakeholders, legal, social, political regulatory, financial, economic, and competitive environment are external factors that influence the selection of objectives or its ability to achieve its goals.
Context of the Organisation

Internal context:

- Overall performance of the organization, products & service offerings, financial results, regulatory requirements
- Resource factors, including infrastructure, environment for the operation of the processes, organizational knowledge, assets, capabilities, information systems
- Human aspects such as competence of personnel, organizational culture, relationships with unions, suppliers and partners
- Operational factors such as process, production or delivery capabilities, performance of the QMS, customer evaluations
- Factors in the governance of the organization, such as its rules and procedures for decision making or the organization’s structure
Context of the Organisation

External context:

• Macro-economic factors such as money exchange rate predictions, the general economic situation, inflation forecasts, credit availability
• Social factors such as local unemployment rates, safety perceptions, educational levels, public holidays and working days
• Political factors such as political stability, public investments, local infrastructure, international trade agreements
• Technological factors such as new sector technology, materials and equipment, patent expirations, professional codes of ethics
• Competition, including the organization’s market share, similar or substitute products or services, market leader trends, customer growth trends, market stability
• Factors which affect the work environment such as trade union regulations, legal and statutory requirements (e.g. environmental legislation and codes)
Context of the Organisation

• ISO 9001:2015 provides no suggested methods to analyse the context of an organisation, but there are many models that can help an organisation to understand the strategic nature of their industry and how they fit into that environment.

• Such as PEST analysis (political, economic, social and technological) this analysis determines which factors can influence how the organisation operates.

• The PEST factors can be classified as opportunities and threats in a SWOT analysis (strengths, weaknesses, opportunities and threats).

• another method is Porter’s five force model.
# PEST Analysis Template

<table>
<thead>
<tr>
<th><strong>Political Factors</strong></th>
<th><strong>Economic Factors</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>Ecological/Environmental Issues</td>
<td>National economic policies and trends</td>
</tr>
<tr>
<td>National &amp; international: current &amp; anticipated future Legislation</td>
<td>Taxation issues</td>
</tr>
<tr>
<td>Regulatory bodies</td>
<td>Seasonal / weather issues</td>
</tr>
<tr>
<td>Government policy’s</td>
<td>Trade &amp; monetary conditions</td>
</tr>
<tr>
<td>Funding, grants, initiatives</td>
<td>Specific sector conditions</td>
</tr>
<tr>
<td>Market &amp; political lobbying groups</td>
<td>Interest &amp; exchange rates</td>
</tr>
<tr>
<td>Wars / conflicts</td>
<td>International trade &amp; monetary issues</td>
</tr>
<tr>
<td>Social Factors</td>
<td>Technology Factors</td>
</tr>
<tr>
<td>---------------------------------------------------</td>
<td>---------------------------------------------------------</td>
</tr>
<tr>
<td>Demographics &amp; Lifestyle trends</td>
<td>Competing technology development</td>
</tr>
<tr>
<td>Attitudes &amp; opinions</td>
<td>Associated / dependent technologies</td>
</tr>
<tr>
<td>Consumer attitudes, opinions, &amp; buying patterns</td>
<td>Replacement technology / solutions</td>
</tr>
<tr>
<td>Media views, advertising, publicity</td>
<td>Maturity of technology / organisations products/ services</td>
</tr>
<tr>
<td>Law changes affecting social behaviour</td>
<td>Information &amp; communications, Social media use</td>
</tr>
<tr>
<td>Image of the organisation</td>
<td>Technology legislation</td>
</tr>
<tr>
<td>Major events &amp; influences</td>
<td>Innovation potential</td>
</tr>
<tr>
<td>Buying access &amp; trends</td>
<td>Technology access, licensing, patents</td>
</tr>
<tr>
<td>Ethnic / religious issues</td>
<td>Intellectual property issues</td>
</tr>
<tr>
<td>Marketing Factors</td>
<td></td>
</tr>
<tr>
<td>-----------------------------------------</td>
<td></td>
</tr>
<tr>
<td>Total market size &amp; market penetration</td>
<td></td>
</tr>
<tr>
<td>Barriers to entry</td>
<td></td>
</tr>
<tr>
<td>Trends &amp; indicators</td>
<td></td>
</tr>
<tr>
<td>State of maturity</td>
<td></td>
</tr>
<tr>
<td>Knowledge of customers</td>
<td></td>
</tr>
<tr>
<td>Competitors</td>
<td></td>
</tr>
<tr>
<td>Channels of distribution</td>
<td></td>
</tr>
<tr>
<td>Branding &amp; packaging</td>
<td></td>
</tr>
</tbody>
</table>
Context of the Organisation

• SWOT analysis is a useful technique for understanding your strengths and weaknesses, and for identifying both the opportunities open to you and the threats you face.
## SWOT Analysis Strategy

<table>
<thead>
<tr>
<th></th>
<th><strong>Opportunities</strong> (external, positive)</th>
<th><strong>Threats</strong> (external, negative)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Strengths</strong> (internal, positive)</td>
<td><strong>Strength-Oppportunity strategies</strong>&lt;br&gt;Which of the company’s strengths can be used to maximise the opportunities you identifies?</td>
<td><strong>Strength-Threats strategies</strong>&lt;br&gt;How can you use the company’s strengths to minimise the threats you identified?</td>
</tr>
<tr>
<td><strong>Weaknesses</strong> (internal, negative)</td>
<td><strong>Weakness-Oppportunity strategies</strong>&lt;br&gt;What actions can you take to minimise the company’s weaknesses using the opportunities you identified?</td>
<td><strong>Weakness-Threats strategies</strong>&lt;br&gt;How can you minimise the company’s weaknesses to avoid the threats you identified?</td>
</tr>
<tr>
<td>Strengths</td>
<td>Weaknesses</td>
<td></td>
</tr>
<tr>
<td>--------------------------------------------------------------------------</td>
<td>---------------------------------------------------------------------------</td>
<td></td>
</tr>
<tr>
<td>What advantage does your organisation have?</td>
<td>What could you improve?</td>
<td></td>
</tr>
<tr>
<td>What do you do better than anyone else?</td>
<td>What should you avoid?</td>
<td></td>
</tr>
<tr>
<td>What unique or lowest cost resources can you draw upon that others can't</td>
<td>What are people in your market likely to see as weaknesses?</td>
<td></td>
</tr>
<tr>
<td>What do people in your market see as your strengths?</td>
<td>What factors loose you sales?</td>
<td></td>
</tr>
<tr>
<td>What factors mean that you get the sale?</td>
<td>What do your competitors provide that you don't?</td>
<td></td>
</tr>
</tbody>
</table>
## SWOT Analysis Questions

<table>
<thead>
<tr>
<th>Opportunities</th>
<th>Threats</th>
</tr>
</thead>
<tbody>
<tr>
<td>What good opportunities can you spot?</td>
<td>What obstacles do you face?</td>
</tr>
<tr>
<td>What interesting trends are you aware of?</td>
<td>What are your competitors doing?</td>
</tr>
<tr>
<td>Are there changes in government policy related to your field?</td>
<td>Are quality standards or specifications for your products or services changing?</td>
</tr>
<tr>
<td>Are there changes in technology or markets?</td>
<td>Is changing technology threatening your position?</td>
</tr>
<tr>
<td>Are there changes in social patterns, population profiles, lifestyle changes?</td>
<td>Could any of your weaknesses seriously threaten your business?</td>
</tr>
<tr>
<td>Local events?</td>
<td>Do you have bad debt or cash flow problems?</td>
</tr>
</tbody>
</table>
Porter Five Forces Model

**Barriers to entry:**
- Economies of Scale
- Proprietary product differences
- Brand identity
- Switching costs
- Capital requirements
- Access to distribution
- Absolute cost advantages:
  - Proprietary learning curve
  - Access to necessary inputs
  - Proprietary low-cost product design
- Government policy
- Expected retaliation

**Rivalry determinants:**
- Industry growth
- Fixed (or storage) costs/value added
- Intermittent overcapacity
- Product differences
- Brand identity
- Switching costs
- Concentration and balance
- Informational complexity
- Diversity of competitors
- Corporate stakes
- Exit barriers

**Suppliers**

**Determinants of supplier power:**
- Differentiation of inputs
- Switching costs of suppliers and firms in the industry
- Presence of substitute inputs
- Supplier concentration
- Importance of volume to supplier
- Cost relative to total purchases in the industry
- Impact of inputs on cost or differentiation
- Threat of forward integration relative to threat of backward integration by firms in the industry

**Buyers**

**Determinants of buyer power:**
- Buyer concentration versus firm concentration
- Buyer volume
- Buyer switching costs relative to firm switching costs
- Buyer information
- Ability to backward integrate
- Substitute products
- Pull-through

**Intensity of rivalry**

**Substitutes**

**Determinants of substitution threat:**
- Relative price performance of substitutes
- Switching costs
- Buyer propensity to substitute

**New entrants**

**Threat of new entrants**

**Bargaining power of suppliers**

**Bargaining Power of buyers**

*Source: Michael Porter, "Competitive Strategy", 1980*
Context of the Organisation

Identify the issues that can affect your organization, and which of those issues the QMS needs to control.
Context

For example:

• A small distribution business of imported goods could find out that its government policy for import-export activities, the type and quantity of competitors, the culture of local consumers, or credit availability, are external issues that can affect the achievement of its planned results.

• As internal issues, it may find out information about its infrastructure, organizational knowledge, delivery capabilities and personnel competences.

• Internal and external issues can change, and therefore should be monitored and reviewed on a regular basis.
Interested Parties

• The definition of “interested party” states that it is a “person or organization that can affect, be affected by, or perceive itself to be affected by, a decision or activity”.

• The intent of this requirement is to ensure that you consider the requirements of relevant interested parties, beyond just those of the customer and end user. However, you only need to focus on those interested parties which are relevant to your QMS.

• There will be those external interested parties that impose specific legal, regulatory or contractual requirements on an organisation

• There may be also requirements specified by internal interested parties, such as : management, staff, shareholders, trade unions, etc.
# Interested Parties

## Interested Parties List

<table>
<thead>
<tr>
<th>Interested Party</th>
<th>Int. / Ext</th>
<th>Reason for Inclusion</th>
</tr>
</thead>
<tbody>
<tr>
<td>Certification Body</td>
<td>External</td>
<td>Audit for ISO compliance, issue certifications</td>
</tr>
<tr>
<td>Customers</td>
<td>External</td>
<td>Purchase our products and services</td>
</tr>
<tr>
<td>People in the organisation</td>
<td>Internal</td>
<td>Directly responsible for manufacture of products, delivery of service</td>
</tr>
<tr>
<td>End User</td>
<td>External</td>
<td>End user of our products and services</td>
</tr>
<tr>
<td>Investors</td>
<td>Internal</td>
<td>Have direct concern over the financial health of the company</td>
</tr>
<tr>
<td>Labour Union Representatives</td>
<td>Internal</td>
<td>Concerned with compliance to labor contract, represent workers</td>
</tr>
<tr>
<td>Local Community</td>
<td>External</td>
<td>Impacted by our activities in the region</td>
</tr>
<tr>
<td>Partners</td>
<td>Internal</td>
<td>Assist in financial support and management guidance of the company</td>
</tr>
<tr>
<td>Public</td>
<td>External</td>
<td>Concerned with compliance to labour contract, represent workers</td>
</tr>
<tr>
<td>Regulatory Body</td>
<td>External</td>
<td>Mandate regulatory requirements</td>
</tr>
<tr>
<td>Supplier</td>
<td>External</td>
<td>Provides our raw materials and critical support services</td>
</tr>
<tr>
<td>Top Management</td>
<td>Internal</td>
<td>Has direct responsibility for management of the company</td>
</tr>
</tbody>
</table>
# Interested Parties

<table>
<thead>
<tr>
<th>Interested party</th>
<th>Needs and expectations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Customers</td>
<td>Design, quality, price, quick response &amp; on-time delivery of products and services</td>
</tr>
<tr>
<td>Owners/Share Holders, Board</td>
<td>Sustained profitability, Transparency, Legal compliance</td>
</tr>
<tr>
<td>People in the organization</td>
<td>Good work environment, Health &amp; safety, Job security, Professional development, Recognition and reward, Working relationships</td>
</tr>
<tr>
<td>External Providers/Partners</td>
<td>Mutual benefit and continuity, Prompt payment, Good working relationship</td>
</tr>
<tr>
<td>Society/Regulatory Authorities</td>
<td>Environmental protection, Ethical behaviour, Compliance with statutory and regulatory requirements, Conformity to industry codes &amp; standards</td>
</tr>
</tbody>
</table>
## Interested Parties

<table>
<thead>
<tr>
<th>Interested party</th>
<th>Needs and expectations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Local residents</td>
<td>No complaints relating to noise, parking, waste, health &amp; safety, pollution</td>
</tr>
</tbody>
</table>
| Bank / Finance    | Financial performance  
                   | Cash flow                                                        |
| Trade Unions      | Employment law compliance, Good working relationship with management |
| Insurers          | No claims  
                   | Risk management  
                   | Prompt payment                                                 |
## Interested Parties

<table>
<thead>
<tr>
<th>Interested Parties</th>
<th>Needs/Expectations</th>
<th>Issues/Risks</th>
<th>Opportunity</th>
<th>Risk Analysis Treatment Plan</th>
<th>Communication</th>
</tr>
</thead>
<tbody>
<tr>
<td>Board</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Customers</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Competitors</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Regulators</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Neighbours/Society</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Staff</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Financial Institutions</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Shareholders/Owners</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Suppliers</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
### Issues

<table>
<thead>
<tr>
<th>Ln</th>
<th>Interested Party</th>
<th>Issue of Concern</th>
<th>Bias</th>
<th>Processes Affected</th>
<th>Priority</th>
<th>Treatment Method</th>
<th>Record Reference / Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Certification Body</td>
<td>Level of compliance to ISO 9001.</td>
<td>Mixed</td>
<td>Process 1</td>
<td>Low</td>
<td>Internal Auditing</td>
<td>See audit records</td>
</tr>
<tr>
<td>2</td>
<td>Employee / Staff</td>
<td>Expect to be compensated</td>
<td>Risk</td>
<td>QMS Management</td>
<td>Medium</td>
<td>Manage company finances appropriately</td>
<td>Financials (confidential)</td>
</tr>
<tr>
<td>3</td>
<td>Employee / Staff</td>
<td>Expect satisfactory equipment, facilities</td>
<td>Risk</td>
<td>QMS Management</td>
<td>Medium</td>
<td>Internal Auditing</td>
<td>See audit records</td>
</tr>
<tr>
<td>4</td>
<td>Employee / Staff</td>
<td>Require appropriate training</td>
<td>Risk</td>
<td>QMS Management</td>
<td>Low</td>
<td>Training provided, assessed through audits</td>
<td>See training records</td>
</tr>
<tr>
<td>5</td>
<td>Management</td>
<td>Company must remain financially healthy</td>
<td>Risk</td>
<td>QMS Management</td>
<td>Medium</td>
<td>Manage company finances appropriately</td>
<td>Financials (confidential)</td>
</tr>
<tr>
<td>6</td>
<td>Management</td>
<td>QMS processes must be efficient</td>
<td>Risk</td>
<td>QMS Management</td>
<td>Medium</td>
<td>Internal Auditing</td>
<td>See audit records</td>
</tr>
<tr>
<td>7</td>
<td>Management</td>
<td>Concerned with growth of company</td>
<td>Opportunity</td>
<td>QMS Management</td>
<td>Medium</td>
<td>Management Review Activity</td>
<td>See Opportunity Register</td>
</tr>
<tr>
<td>8</td>
<td>Direct Customer</td>
<td>Expect high quality products</td>
<td>Risk</td>
<td>Manufacturing</td>
<td>Medium</td>
<td>Risk Register / FMEA</td>
<td>See Risk Register Line 4, 7, 15</td>
</tr>
<tr>
<td>9</td>
<td>Direct Customer</td>
<td>Expect on time delivery</td>
<td>Risk</td>
<td>Manufacturing</td>
<td>Medium</td>
<td>Risk Register / FMEA</td>
<td>See Risk Register</td>
</tr>
<tr>
<td>10</td>
<td>Direct Customer</td>
<td>Could be source of referrals to new customers</td>
<td>Opportunity</td>
<td>Quoting and Orders</td>
<td>Medium</td>
<td>Marketing Enhancement</td>
<td>See Mgmt Review records</td>
</tr>
<tr>
<td>11</td>
<td>Direct Customer</td>
<td>Flows down QMS requirements</td>
<td>Risk</td>
<td>Quoting and Orders</td>
<td>Medium</td>
<td>Internal Auditing</td>
<td>Internal audit records</td>
</tr>
<tr>
<td>12</td>
<td>Local Community</td>
<td>Expect us not to pollute environment</td>
<td>Risk</td>
<td>QMS Management</td>
<td>Low</td>
<td>Other</td>
<td>Good management practices</td>
</tr>
<tr>
<td>13</td>
<td>Local Community</td>
<td>Expect us to be a “good citizen” locally</td>
<td>Risk</td>
<td>QMS Management</td>
<td>Medium</td>
<td>Other</td>
<td>We do this naturally</td>
</tr>
<tr>
<td>14</td>
<td>Local Community</td>
<td>Can provide positive press</td>
<td>Opportunity</td>
<td>QMS Management</td>
<td>Low</td>
<td>No action, proceed normally for now</td>
<td>Maintain good relations locally</td>
</tr>
<tr>
<td>15</td>
<td>Regulatory Body</td>
<td>Must comply with all regulations and statutes</td>
<td>Risk</td>
<td>QMS Management</td>
<td>High</td>
<td>No Action: Accept Risk per Mgmt Decision</td>
<td>Do this as normal part of business</td>
</tr>
<tr>
<td>16</td>
<td>Supplier</td>
<td>Expect to be paid promptly</td>
<td>Risk</td>
<td>Purchasing</td>
<td>Medium</td>
<td>Manage company finances appropriately</td>
<td>Financials (confidential)</td>
</tr>
<tr>
<td>17</td>
<td>Supplier</td>
<td>Require clearly defined requirements</td>
<td>Risk</td>
<td>Purchasing</td>
<td>Medium</td>
<td>Risk Register / FMEA</td>
<td>See Risk Register</td>
</tr>
<tr>
<td>18</td>
<td>Supplier</td>
<td>Require adequate notice of rush jobs</td>
<td>Risk</td>
<td>Purchasing</td>
<td>Medium</td>
<td>Risk Register / FMEA</td>
<td>See Risk Register</td>
</tr>
<tr>
<td>19</td>
<td>Supplier</td>
<td>Vendor performance impacts on our reputation</td>
<td>Mixed</td>
<td>Purchasing</td>
<td>Medium</td>
<td>Vendor Auditing</td>
<td>Flow down of requirements on POs; auditing if needed</td>
</tr>
</tbody>
</table>
Interested Parties

For example:

• A small distribution business of imported goods could find out that regulations requires it to obtain permits, licences or other forms of authorizations; the local community expects it to provide safe working conditions and have environmentally friendly operations; its shareholders demand a reasonable profit.

• The intent of this requirement is to ensure that you consider the requirements of relevant interested parties, beyond just those of the customer and end user. However, you only need to focus on those interested parties which are relevant to your quality management system.
Scope of the QMS

In determining the scope of the QMS, you need to address context-related issues, relevant requirements from relevant interested parties, and the products and services of the organization.

The scope should take into account your organization’s products and services, considering such issues as:

- infrastructure of the quality management system, including different sites and activities
- which processes are externally provided (outsourcing)
- commercial policies and strategies
- centralized/external provided activities, processes, products and services
- organizational knowledge
Scope of the QMS

Some examples of activities that you may perform to process the collected information, in order to determine the QMS scope, should include:

- assessment of the applicability of the ISO 9001 requirements
- justification of any non-applicable requirement, taking into account that non-applicable requirements should not affect the ability of your QMS to achieve conformity of products and services
- analysis of collected information based on the identified impacts of your organization’s capabilities, customers, other relevant interested parties and legal requirements
- determination of the processes, products and services needed to ensure the conformity of your products and services and the enhancement of customer satisfaction
Scope of the QMS

For example, in determining the scope for a small distribution business of imported goods, after analysing the collected information, it can find that:

- the requirements in clauses 8.3 and 8.5.3 are not applicable because it does not carry out design and development, and does not have any property of their customers or their suppliers
- there is only one site for its operations that it needs to consider in the context-related issues
- The scope may be: Import and commercialization of glass bottles for cosmetics in the Technology Park facility
- The outputs of the activities listed above should be available in a documented scope, including the justification of the non-applicable requirements, and any outsourced processes
Process approach

Remember, a process:

• is a set of interrelated or interacting activities
• uses inputs to deliver an intended result
• has built-in controls and checks of performance and promotes improvement.
• The inputs and outputs may be tangible (e.g. materials, components or equipment) or intangible (e.g. data, information or knowledge)
Process approach

In order to determine the processes you need, you should consider the following:

• the defined scope of the quality management system
• list of products and services
• list of sites and production lines processes
• capabilities
• performance indicators such as:
  - service response time; service outage trends, throughput rates, defect rates; re-work costs; warranty costs
  - risks and opportunities identified (see 6.1)
• organization charts
Process approach

For example:

The processes needed for a small distribution business of import goods may be:

- Strategic planning process
- Commercial process
- Procurement and import process
- Distribution process
- Administration process
- IT support process
- QMS process
Process

**Sources of Inputs**
- PREDECESSOR PROCESSES
  - e.g. at providers (internal or external)
  - at customers,
  - at other relevant interested parties

**Inputs**
- MATTER, ENERGY, INFORMATION,
  - e.g. in the form of materials, resources, requirements

**Activities**

**Outputs**
- MATTER, ENERGY, INFORMATION,
  - e.g. in the form of product, service, decision

**Receivers of Outputs**
- SUBSEQUENT PROCESSES
  - e.g. at customers (internal or external), at other relevant interested parties

**Possible controls and checkpoints to monitor and measure performance**
Assembly Process Model

A different example is shown below for an assembly process; this would be repeated for all the other processes in the organisation.

<table>
<thead>
<tr>
<th>Assembly Process Owners</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Position</strong></td>
</tr>
<tr>
<td>Production Manager</td>
</tr>
<tr>
<td>Production Supervisors</td>
</tr>
<tr>
<td>Process Engineer</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>QMS Procedures / Documents</th>
</tr>
</thead>
<tbody>
<tr>
<td>QP08</td>
</tr>
<tr>
<td>OP09</td>
</tr>
<tr>
<td>OP11</td>
</tr>
<tr>
<td>OP12</td>
</tr>
<tr>
<td>OP15</td>
</tr>
<tr>
<td>CM01</td>
</tr>
<tr>
<td>ETC.</td>
</tr>
</tbody>
</table>
## Assembly Process Model

<table>
<thead>
<tr>
<th>From Process</th>
<th>Inputs</th>
<th>Assembly Process</th>
<th>Outputs</th>
<th>To Process</th>
</tr>
</thead>
<tbody>
<tr>
<td>QA Test</td>
<td>Quality Plan Records</td>
<td></td>
<td>Assembled Products</td>
<td>QA Test</td>
</tr>
<tr>
<td>Material Control</td>
<td>Materials</td>
<td></td>
<td>Quality Plan Records</td>
<td>QA Test</td>
</tr>
<tr>
<td>Product Engineering</td>
<td>Drawings</td>
<td></td>
<td>Completed Control Charts</td>
<td>Data Analysis</td>
</tr>
<tr>
<td>Product Engineering</td>
<td>Machine Programs</td>
<td></td>
<td>Non-conforming products</td>
<td>Rework &amp; Repair</td>
</tr>
<tr>
<td>Order Review &amp; Scheduling</td>
<td>Production Schedule</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Product Engineering</td>
<td>Control Charts</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Resource Management</td>
<td>Manpower</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
# Assembly Process Model

<table>
<thead>
<tr>
<th><strong>Measurement</strong></th>
<th><strong>Target</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>First Pass Yield</td>
<td>≥ 98%</td>
</tr>
<tr>
<td>RMA</td>
<td>≤ 500 DPPM</td>
</tr>
<tr>
<td>Machine Utilisation</td>
<td>86%</td>
</tr>
<tr>
<td>On time delivery to customer</td>
<td>≤ 3 days</td>
</tr>
<tr>
<td>Absenteeism</td>
<td>3.5%</td>
</tr>
</tbody>
</table>
# Application and Quotation Process

<table>
<thead>
<tr>
<th>Suppliers</th>
<th>Inputs</th>
<th>Process</th>
<th>Outputs</th>
<th>Customers</th>
</tr>
</thead>
<tbody>
<tr>
<td>Client</td>
<td>Phone Call / Email</td>
<td>1. Client Inquiry</td>
<td>Send RFQ</td>
<td>Marketing</td>
</tr>
<tr>
<td>Marketing</td>
<td>Client Request</td>
<td>2. Send out RFQ</td>
<td>Email</td>
<td>Client</td>
</tr>
<tr>
<td>Client</td>
<td>Completed RFQ</td>
<td>3. Review RFQ (not offered)</td>
<td>Decision - No</td>
<td>Client /Marketing</td>
</tr>
<tr>
<td>Client</td>
<td>Completed RFQ</td>
<td>3.2 Review RFQ (offered)</td>
<td>Decision - Yes</td>
<td>Marketing</td>
</tr>
<tr>
<td>Client</td>
<td>Completed RFQ</td>
<td>4 Log Data</td>
<td>Update Goldmine</td>
<td>Marketing</td>
</tr>
<tr>
<td>Client</td>
<td>Completed RFQ</td>
<td>5. RFQ Complete (no)</td>
<td>Return RFQ to Client</td>
<td>Client</td>
</tr>
<tr>
<td>Client</td>
<td>Completed RFQ</td>
<td>6. RFQ Complete (yes)</td>
<td>RFQ to Manager</td>
<td>Operation Manager</td>
</tr>
<tr>
<td>Operation Manager</td>
<td>Complete RFQ</td>
<td>7. Complete Quote + Manday Sheet</td>
<td>Quote / Manday Sheet</td>
<td>Marketing</td>
</tr>
</tbody>
</table>

*NSAI*
Process Interaction

1. New Product Introduction
2. Purchasing
3. Order Review & Scheduling
4. Warehouse/Material Control
5. Assembly
6. QA Test & Verification
7. Rework and Repair
8. Material Control
9. Shipping
10. Management Responsibility
11. Resource Management
12. Internal Audits, CAR's
13. Analysis of Data, Continuous improvement
15. RMA Material Control

Realisation Processes

Communication Channel

Customer Related Processes
Material Control Processes
Manufacturing Processes
Material Control Process

Customer
Finished Goods
Delivery Notes & Invoices
Feedback

NSAI
Emphasis on Leadership

- Top management is defined in ISO 9001:2015 as the “person or group of people who directs and controls an organization at the highest level”. In a small organization this may include the owner or partners and a few key people who report directly to them.

- In terms of providing evidence, your top management will be expected to not only ensure that its commitment is well known throughout your organization, but also to keep appropriate records to show how this was achieved. Reports of management meetings can be used to provide such evidence.

- Ensuring the integration of the QMS requirements into the business processes

- The intent of this requirement is to establish the roles, authorities and responsibilities of top management in relation to the effectiveness of the quality management system, and the achievement of planned results.
Leadership

Top management can demonstrate fulfilment of their authorities and responsibilities by ensuring the achievement of the planned results, and:

a) ensuring that the quality management system continues to be suitable and effective in fulfilling your objectives, through continual performance monitoring or measurement and periodic management reviews (see 9.1 and 9.3)

b) taking account of your context, in regards to both internal and external issues, and strategic direction, when developing and updating the quality policies and objectives, to ensure that they are aligned with, and supportive of, the overall business processes.
Leadership

c) ensuring that the quality management system processes interface with the processes of other functions (e.g. finance, design, testing, customer support, etc.) within your organization.

d) ensuring there is effective liaison between departments and functions, with a systematic approach designed to achieve effective flow of inputs and outputs between processes and co-operation in assessing and mitigating risks.

e) monitoring the current and projected workload and schedules and ensuring that adequate quality management system resources (human, tools, equipment etc.) are provided, when and where needed.
Leadership

f) frequently communicating, via internal information meetings, e-mail, personal discussions, organizational intranet, etc., the value and benefits of the quality management system and adherence to its requirements.

g) monitoring the outputs of the quality management system, and ensuring that the relevant persons or groups are assigned responsibility and authority for corrective actions when intended results are not achieved.

h) communicating (see 7.4) the value, with factual evidence, of the benefits of improvements (see clause 10) in areas of customer retention, increased market share, reduction of costs, etc.
Leadership

i) ensuring that information and recommendations from internal, second and third-party audits (see 9.2) and management reviews (see 9.3) are communicated to responsible parties within your organization, demonstrating the value and benefits of improvements.

j) providing support and guidance to other management functions (e.g. finance, design, testing, customer support, etc.) in the interpretation and understanding of customer, statutory and regulatory requirements, customer feedback, etc.
Risk-based thinking

• Risk is the effect of uncertainty on objectives.
• In establishing and operating the QMS, your organization should identify what it wants to achieve, i.e. objectives and intended results.
• In planning the system your organization should assess what can impact on achieving these objectives and the intended results; this includes identifying associated risks and opportunities.
• You should consider the external and internal issues and relevant interested parties that can have an impact on the QMS achieving its intended results. In identifying the needs of these interested parties, the risks and opportunities for the QMS that need to be addressed should be determined.
• In identifying risks and opportunities the organization should plan actions to mitigate risks and leverage opportunities. This is adopting a "risk-based approach"
• ISO 9001:2015 does not require formal risk management
• ISO 31000 Risk management — more formal approach not obligatory
Risk-based thinking

Having identified the risks and opportunities that can impact the QMS, you should plan actions to address these. The determined actions need to be incorporated into the processes of both the quality management system and the wider business, and the effectiveness of these actions evaluated.

Actions to address risk include developing appropriate process controls, for example:

• the inspection, monitoring and measuring of processes, products and services;
• calibration;
• product and process design;
• corrective actions, and in particular making sure that these are extended to other relevant areas of the organization;
• specified methods and work instructions;
• the training and use of competent persons.
Risk-based thinking

- is not new
- is something you probably do already
- is ongoing
- ensures greater knowledge of risks and improves preparedness
- increases the probability of reaching objectives
- reduces the probability of negative results
- makes prevention a habit
- is a systematic approach to risk management
Risk-based thinking

**Identify** what your risks are – it depends on context, interested parties prioritize the way you manage your processes balance risks and opportunities

**Analyse** and prioritize your risks

*what is acceptable? what is unacceptable?*

**Evaluate** - Plan actions to address the risks

*how can I avoid, eliminate or mitigate risks?*

**Treat / Address** - Implement the plan; *take action*

*reduce the probability*

**Monitor / Review**

check the effectiveness; *does it work?*
learn from experience; *improve*
Risk-based thinking

• There is no requirement in ISO 9001 to use formal risk management in the identification of risks and opportunities. You can choose the methods that suit your needs.

• The standard IEC 31000 *Risk management – Risk assessment techniques* provides a long list of risk assessment methodologies, some of which may be appropriate, depending on what your organization does and its context.
Risk-based thinking

- At the strategic level, tools such as Strengths, Weaknesses, Opportunities and Threats analysis (SWOT); Political, Economic, Social, Technological, Legal, Environmental analysis (PESTLE); and Porter’s 5 Forces industrial analysis, can be used. A simple approach can include asking "what if" questions. Application of Brainstorming techniques can be used as one of the effective tools for application of risk based thinking.

- Some techniques can be more popular in certain sectors, e.g. Failure, Mode and Effects Analysis (FMEA) in the automotive sector; Failure, Mode, Effects and Criticality Analysis (FMECA) in for the medical devices sector; Hazard, Analysis and Critical Control Points (HACCP) for the food sector. It is for you to decide which methods or tools to use.
Risk Management Process

Communication and consultation (5.2)

Establishing the context (5.3)

Risk assessment (5.4)

Risk identification (5.4.2)

Risk analysis (5.4.3)

Risk evaluation (5.4.4)

Risk treatment (5.5)

Monitoring and review (5.6)

Figure 3 — Risk management process
1. **Risk Identification:** Determining the factors that could cause a process or the entire QMS to deviate from the planned results (risk register, risk log, software)

2. **Risk Ranking:** Placing the risk in order based on frequency, likelihood, severity, impact on objectives, monetary consequences, loss of customers, legal exposure, impact on interested parties.
3. Risk Treatment:
- **Avoidance**: Eliminate causes, changing plans, discontinuing activities, etc.
- **Mitigation**: Reduce event probability, limiting exposure, reducing impacts, etc.
- **Acceptance**: Taking no action and accepting consequences
- **Transference**: Removing impact / consequences by reassigning responsibility
- **Exploitation**: Increasing probability while maximising possible effects

4. Risk Monitoring:
- Periodically reviewing identified risks, identifying new risks (internal/external), ensuring proper execution of planned risk treatments, and evaluating effectiveness of action taken.
## SWOT Analysis Strategy

<table>
<thead>
<tr>
<th></th>
<th><strong>Opportunities (external, positive)</strong></th>
<th><strong>Threats (external, negative)</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Strengths</strong></td>
<td><strong>Strength-Opportunity strategies</strong>&lt;br&gt;Which of the company’s strengths can be used to maximise the opportunities you identifies?</td>
<td><strong>Strength-Threats strategies</strong>&lt;br&gt;How can you use the company’s strengths to minimise the threats you identified?</td>
</tr>
<tr>
<td><strong>Weaknesses</strong></td>
<td><strong>Weakness-Opportunity strategies</strong>&lt;br&gt;What actions can you take to minimise the company’s weaknesses using the opportunities you identified?</td>
<td><strong>Weakness-Threats strategies</strong>&lt;br&gt;How can you minimise the company’s weaknesses to avoid the threats you identified?</td>
</tr>
</tbody>
</table>
## SWOT Analysis for computer store

<table>
<thead>
<tr>
<th>Strengths</th>
<th>Weaknesses</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Knowledge:</strong> our competitors are pushing boxes, but we know systems, networks, programming, and data management</td>
<td><strong>Price &amp; Volume:</strong> The major stores are pushing boxes and can afford to sell for less.</td>
</tr>
<tr>
<td><strong>Relationship selling:</strong> we get to know our customers, one by one</td>
<td><strong>Brand power:</strong> We can't match the competitors full-page advertising in the Sunday papers. We don't have the national brand name.</td>
</tr>
<tr>
<td><strong>History:</strong> we've been in our town forever. We have the loyalty of customers and vendors</td>
<td><strong>Service:</strong> We are not open the same hours as the major stores.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Opportunities</th>
<th>Threats</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Training:</strong> The major stores don't provide training, but as systems become more complex, training is in greater demand</td>
<td><strong>The larger price-oriented store:</strong> When they advertise low prices in the newspaper, our customers think we are not giving them good value.</td>
</tr>
<tr>
<td><strong>Service:</strong> As our target market needs more service, our competitors are less likely than ever to provide it.</td>
<td><strong>The computer as appliance:</strong> Volume buying of computers as products in boxes. People think they need our services less.</td>
</tr>
</tbody>
</table>
## Risk Register

<table>
<thead>
<tr>
<th>No.</th>
<th>Category</th>
<th>Risks</th>
<th>Objectives</th>
<th>Owner</th>
<th>Risk Treatment in place</th>
<th>Likelihood</th>
<th>Consequences</th>
<th>Level</th>
<th>Actions</th>
<th>Due Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Technology</td>
<td>Confidential information being disclosed to unauthorised parties</td>
<td>- Clear policy on access control in place&lt;br&gt;- Data in transit is always encrypted&lt;br&gt;- Audit logs record access to sensitive information</td>
<td>AB</td>
<td></td>
<td>4</td>
<td>5</td>
<td>20</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>Supply</td>
<td>Supplier failing to deliver service as per the SAL - Telecom Co.</td>
<td>- Formal contract in place&lt;br&gt;- Clear communications channels established&lt;br&gt;- contract subject to Formal regular review</td>
<td>CD</td>
<td></td>
<td>4</td>
<td>4</td>
<td>16</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>Environment</td>
<td>Loss of a key facility through fire</td>
<td>- Smoking is not allowed in the building&lt;br&gt;- Work on electrical installation is subject to a Work permit&lt;br&gt;- Flammable liquids and combustible materials are strictly controlled&lt;br&gt;- Fire protection is installed throughout the building&lt;br&gt;- building and contents are insured</td>
<td>IL</td>
<td></td>
<td>3</td>
<td>4</td>
<td>12</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>People</td>
<td>Lack of expertise of employees</td>
<td>- All employees receive induction training&lt;br&gt;- Structured training program in place</td>
<td>EF</td>
<td></td>
<td>3</td>
<td>3</td>
<td>9</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
## Risk Register

<table>
<thead>
<tr>
<th>#</th>
<th>Process</th>
<th>Risk</th>
<th>Probability (of risk occurring)</th>
<th>Consequence (if risk is encountered)</th>
<th>Cons. Rating</th>
<th>Risk Factor (Probability x Consequence)</th>
<th>Mitigation Plan (required for risk factors &gt;8)</th>
<th>Risk Factor after Mitigation</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td></td>
<td></td>
<td></td>
<td>Potential Loss of Contracts</td>
<td></td>
<td></td>
<td>May reference external plan document</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td></td>
<td></td>
<td></td>
<td>Potential Harm to User</td>
<td></td>
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</tr>
<tr>
<td>3</td>
<td></td>
<td></td>
<td></td>
<td>Inability to Meet Contract Terms / Requirements</td>
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<td></td>
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<tr>
<td>4</td>
<td></td>
<td></td>
<td></td>
<td>Potential Violation of Regulations</td>
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<td></td>
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<td></td>
<td></td>
<td>Impact on Company Reputation</td>
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<td></td>
<td></td>
<td></td>
<td>Estimated Cost of Correction</td>
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</tbody>
</table>
Risk Evaluation

Key:

<table>
<thead>
<tr>
<th>Likelihood</th>
<th>Consequence</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 Rare</td>
<td>1 Negligible</td>
</tr>
<tr>
<td>2 Low</td>
<td>2 Minor</td>
</tr>
<tr>
<td>3 Medium</td>
<td>3 Moderate</td>
</tr>
<tr>
<td>4 High</td>
<td>4 Significant</td>
</tr>
<tr>
<td>5 Very High</td>
<td>5 Substantial</td>
</tr>
</tbody>
</table>

Risk Profile

Consequence

Likelihood
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
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<tr>
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<td>5</td>
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<td>6</td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>OPP RATING:</td>
<td>RISK RATING LIMIT:</td>
<td>Type</td>
<td>Priority</td>
<td>Treatment</td>
<td>Bias</td>
<td>Processes</td>
<td>Likelihood</td>
<td>Occurrences</td>
<td>Potential</td>
</tr>
<tr>
<td>------------</td>
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<td>-----------</td>
<td>------</td>
<td>-----------</td>
<td>------------</td>
<td>-------------</td>
<td>-----------</td>
</tr>
<tr>
<td>8.0</td>
<td>8.0</td>
<td>External</td>
<td>Emergency</td>
<td>No Action: Accept Risk per Mgmt Decision</td>
<td>Opportunity</td>
<td>All Processes</td>
<td>Cannot occur / not applicable</td>
<td>Has never occurred.</td>
<td>None / NA</td>
</tr>
<tr>
<td>Internal</td>
<td>High</td>
<td>Risk Register / FMEA Style</td>
<td>Risk</td>
<td>Process 1</td>
<td>Unlikely to Occur</td>
<td>Has not occurred in past 10 years.</td>
<td>Minor</td>
<td>Possible</td>
<td>&lt; €100,000</td>
</tr>
<tr>
<td>Medium</td>
<td>Root Cause Analysis</td>
<td>Neutral</td>
<td>Process 2</td>
<td>Somewhat likely to occur</td>
<td>Has occurred in past 10 years.</td>
<td>Moderate</td>
<td>Definite</td>
<td>&lt; €500,000</td>
<td>Moderate</td>
</tr>
<tr>
<td>Low</td>
<td>Internal Auditing</td>
<td>Mixed</td>
<td>Process 3</td>
<td>Likely to occur</td>
<td>Has occurred in past 5 years.</td>
<td>High</td>
<td>High</td>
<td>&gt; €500,000</td>
<td>Severe</td>
</tr>
<tr>
<td>Root Cause Analysis</td>
<td>Process 4</td>
<td>Very likely to occur</td>
<td>Has occurred in past year.</td>
<td>Very High</td>
<td>Legal Risk</td>
<td>&gt; €1,000,000</td>
<td>Very severe</td>
<td>€0 or N/A</td>
<td>Great impact</td>
</tr>
<tr>
<td>Corrective Action (CA)</td>
<td>Process 5</td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Vendor Auditing</td>
<td>Process 6</td>
<td></td>
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</tr>
<tr>
<td>Other Auditing</td>
<td>Process 7</td>
<td></td>
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</tr>
<tr>
<td>Management Review Activity</td>
<td>Process 8</td>
<td></td>
<td></td>
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<td></td>
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Quality Objectives

• Establishing objectives and planning how to achieve them can help your organization to accomplish its business goals.

• The quality objectives take the goal(s) stated in the quality policy and turn these into statements for improvement against which plans can be made.

• Quality objectives may be established to measure the performance of products, processes, customer satisfaction, suppliers, use of resources, and the overall performance and effectiveness of the QMS.

• If you state in your policy that you will “meet customer requirements”, then you might set customer focused objectives for: product defects, customer complaints and returns, on-time delivery, etc.
Quality Objectives

Examples of quality objectives:

• **Product**: reduction in defect rates, PPM, scrap rates, on-time delivery

• **Process**: improving productivity, reduction of waste, set-up times or rework, improved cycle times

• **Customer**: product returns, reduction in complaints, improvement in customer satisfaction scores, improved on-time delivery.

• **Suppliers**: reduction of complaints or defects, improved on-time delivery

• **Resources**: availability, capability, personnel, competency, efficiency, absenteeism
Quality Objectives

• The objectives should be designed to be **SMART** (setting objectives that are Specific, Measurable, Achievable, Realistic and Time-based).

• **Specific**: Clear and concise

• **Measurable**: If you can't measure, how do you know it has been achieved.

• **Achievable**: Personnel need to agree that the objective is achievable

• **Realistic**: Do not set unrealistic goals

• **Time-based**: Need to set a due by date to focus attention and to monitor achievement to your goals
How Change is addressed

• One of the goals of the ISO 9001:2015 revision is to prevent undesirable effects during and after a change and to ensure that changes are introduced and implemented in a controlled manner.

• In day-to-day business, many changes can impact on the QMS. In some cases, a change can lead to a reactive action such as re-working, segregation of nonconforming products, or cancellation or postponement of a service. Monitoring such incidents can help identify trends or opportunities for improvement, to reduce the likelihood or frequency of such events.

• Examples

1. With the introduction of new software for order handling you might plan performance tests and validation, and run both the old and new systems concurrently to ensure the new system operates as intended before being fully adopted

2. In deciding to establish a new office for service provision in a new territory, you might choose to apply formal project management techniques
How Change is addressed

1. As part of its annual planning a restaurant/pub can identify specific times in the year where a high peak of demand will occur due to a regular event such as a tournament in town or a concert. The manager can make provisions to be prepared and get more business due this opportunity. On the other hand, there may be an irregular event, such as a weekend trip of college students. The manager could not be expected to be aware that this would happen and will need to react to this unexpected demand. This is where a process for dealing with unplanned changes is valuable. The manager can pre-arrange to have some local vendors ready to react to requests for additional supplies, and also to have additional staff on standby.
How Change is addressed

• Define the specifics of what is to be changed
• Have a plan (tasks, timeline, responsibilities, authorities, budget, resources, needed information, others)
• Engage other people as appropriate in the change process
• Develop a communication plan (appropriate people within the organization, customers, suppliers, interested parties, etc. may need to be informed)
• Use a cross functional team review the plan to provide feedback related to the plan and associated risks
• Train people
• In implementing changes, you should also consider the impact on the current scope of the QMS.
• Measure the effectiveness and identify any additional problems, update QMS if necessary
• The organization shall retain documented information describing the results of the review of the changes, the person authorizing the change, and any necessary action arising from the review.
Externally provided processes, products and services

An important requirement in this clause is that when you outsource any process that affects conformity to product and service requirements, you need to decide how you are going to control that process.

There are two situations that frequently need to be considered when deciding the appropriate level of control of an outsourced process:

When you have the competence and ability to carry out a process, but choose to outsource that process (for commercial or other reasons). In this situation the process control criteria should already have been defined, and can be transposed into requirements for the external provider of the outsourced process, if necessary.

When you do not have the competence to carry out the process yourself, and choose to outsource it. In this situation you have to ensure that the controls proposed by the external provider of the outsourced process are adequate. In some cases it may be necessary to involve external specialists in making this evaluation.
Externally provided processes, products and services

- Outsourcing is an important external source activity.
- Outsourcing can be defined as making an arrangement where an external organisation performs part of the organisation's role, function or process.
- Outsourced products and services may be:
  1. intended for incorporation into the organisation’s products or services,
  2. external provider provides products and services directly to your customer,
  3. external provider provides a process or part of a process to your organisation,
  4. external provider provides its property for use or incorporation into your product or service
Externally provided processes, products and services

Consider:

1. Potential impact of externally provided processes, products and services on your organisations ability to meet requirements.
2. Effectiveness of the controls applied by external provider

Determine

1. Controls to be applied to externally provided processes, products and services.
2. Criteria for the evaluation, selection, performance monitoring and re-evaluation of external providers.
3. Verification and other activities to ensure that externally provided processes, products and services meet requirements.
Externally provided processes, products and services

Ensure:
1. Externally provided processes, products and services conform to requirements.
2. Externally provided processes, products and services remain within the organisation's control.
3. Adequacy of requirements to be communicated to the external providers.

Define controls to be applies to:
1. Externally providers, and
2. Resulting output
Externally provided processes, products and services

Communicate to the external providers your requirements for the:

1. Processes, products and services
2. Approval of products and services
3. Approval of methods, processes and equipment
4. Release of products and services
5. Required competence
6. External providers interactions with your organisation
7. Control and monitoring of the external provider’s performance to be applied
8. Verification and validation activities to be performed at the external provider’s premises

Apply
1. Determined controls, criteria and other activities.
QUALITY MANAGEMENT SYSTEM QUESTIONNAIRE

Applicable to

I.S. EN ISO 9001:2015

Please complete the response / evidence requirements and email the completed questionnaire to your NSAI Auditor for verification prior to the audit.
## 9001:2015 Process Clause Matrix

### I.S. EN ISO 9001:2015 PROCESS APPROACH MATRIX: PROCESS v CLAUSE

**COMPANY NAME:**

Enter the processes in this column and indicate the clauses that apply by placing an "X" in the relevant cell in the matrix

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<th>4.3</th>
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Show requirements relevant to a process by placing an "X" in the intersection
Thank you

Questions later
I.S. EN ISO 14001:2015
Mr. Ronan Bairead
Lead Auditor, NSAI
ISO 14001:2015

What have we seen?

What are we looking for?
Key Changes

- High Level Structure
- Context of the organisation
- Interested parties
- Risk Assessment Focus
- Life Cycle Perspective
- Documented information
High Level Structure

1 Scope
2 Normative references
3 Terms definitions
4 Context of the organization
5 Leadership
6 Planning
7 Support
8 Operation
9 Performance evaluation
10 Improvement
Terms and definitions

• Terms related to organisation and leadership (3.1.1. – 3.1.6.)

• Terms related to planning (3.2.1. – 3.2.11)

• Terms related to support and operation (3.3.1. – 3.3.5.)

• Terms related to performance evaluation and improvement (3.4.1. – 3.4.11)
EMS Questionnaire 14001:2015

• Replaces EMS Project Plan & Technical Questionnaire

• To be issued to NSAI clients before ISO 14001:2015 assessment

• 3 distinct sections - explanation of when sections need completing on page 1 of the form
EMS Questionnaire 2015

Section 1: Technical Questionnaire

• For completion prior to registration or upgrade to 14001:2015

• To be reviewed for accuracy and updated as necessary at re-assessment
Section 2: Requirements Checklist

• For completion at Registrations, Upgrades to ISO 14001:2015 and Re-Assessments
Section 3: 3 Year Summary

• For completion when the audit is a 3 year Re-Assessment
Documented Information

4.3 Scope of the EMS

5.3 Environmental Policy

6.1.1 Risks and opportunities

6.1.2 Environmental Aspects

6.1.3 Compliance obligations
Documented Information

6.2.1 Environmental Objectives

7.2 Competence

7.4.1 Communication

8.1 Operational planning and control

8.2 Emergency preparedness & response
Documented Information

9.1.1 Monitoring, measurement, analysis and evaluation

9.1.2 Evaluation of compliance

9.2.2 Internal audit programme

9.3 Management Review

10.2 Nonconformity and corrective action
4.3. **Scope of the EMS**

Scope to be maintained as documented information giving consideration to external and internal issues, compliance obligations, organisational set up, activities, products and services & authority and ability to exercise control and influence.
4.3. Scope of the EMS

Context Register

• Internal issues
• HR, processes, culture, values
• Potential threats, controls in place
• Associated risk or opportunity
4.3. Scope of the EMS

Context Register

- External issues
- Political, regulatory, economic, technological, climatic
- Potential threats, controls in place
- Associated risk or opportunity
4.3. **Scope of the EMS**

**Interested Parties Register**

- Internal parties
- Needs & expectations
- Associate risk or opportunity
4.3. Scope of the EMS

Interested Parties Register

• External parties
• Needs & expectations
• Associated risk or opportunity
5.3. Environmental Policy

Environmental Policy Statement

• Addresses requirements (a) to (e)
• Approved by appropriate authority
• Evidence of appropriate distribution
6.1.1 Risks & Opportunities

Risks and opportunities that need to be addressed

Processes needed for:

- Environmental Aspects
- Compliance obligations
- Planning action
6.1.2 Environmental Aspects

- Aspects/impacts Register including aspects, associated impacts, significance rating & criteria for rating

- Evidence to demonstrate that a life cycle perspective has been considered in the impacts analysis process

- Significant environmental aspects can result in risks and opportunities
6.1.3 Compliance Obligations

- Register of compliance obligations
- Environmental Legislation
- Other requirements
6.2.2 Environmental Objectives

Environmental objectives register detailing for each objective:

- What will be done
- Resources required
- Responsibility
- Completion time scale
- Progress evaluation mechanisms
7.2 Competence

- Competence required
- Training plan
- Training records
7.4.1 Communication

What, when, with whom and how to communicate defined:

• Internal communications
• External communications
• Communications matrix
8.1. Operational planning and control

Controls can include engineering controls & procedures

- Waste management processes
- Subcontractor control processes
- SDS Control process
- Life cycle perspective to be considered
8.2. Emergency preparedness and response

- Emergency Plan
- Site plans
- ERT Training records
- Emergency test records
- Equipment maintenance records
9.1.1 Monitoring, measurement, analysis and evaluation

Monitoring matrix detailing:

- What to be monitored
- Method for monitoring
- Monitoring frequency
- Who is to complete monitoring
- Monitoring evaluation
- Records to be maintained
9.1.2 Evaluation of compliance

Record demonstrating compliance evaluation has taken place:

• Who completed the evaluation
• When the evaluation took place
9.2.2 Internal Audit

- Annual audit programme
- Audit Reports
- Corrective action records
- Audit records
9.3. Management Review

• Agenda
• Attendance & frequency
• Presentations
• Minutes
10.2 Nonconformity and corrective action

- Corrective action register
- Non-conformance records
- Corrective action records and forms
Life cycle perspective requirements appear in two requirements of I.S. EN ISO 14001:2015

- 6.1.2 - Environmental aspects
- 8.1 - Operational planning and control
6.1.2. Life cycle perspective

Annex A states that a detailed life cycle analysis is not required... **thinking carefully about life cycle stages that can be controlled or influenced by the organisation is sufficient**

Current guidance in **ISO 14001:2015** does mention **life cycle perspective** with respect to the requirement relating to **context** as outlined in section 4.1.

Regarding environmental aspects three elements that have to work together are control, influence & life cycle
8.1 Life cycle perspective

To be considered in:

• Design & development processes
• Procurement of products & services processes
• Processes related to provider & contractors
• Processes related to transportation, delivery, use, end-of-life treatment & final disposal
Manual Requirement

For all 2015 re-assessment/upgrade audits completed to date, Manual in place

For all 2015 registration audits completed to date, Manual in place

Some manuals in different format such as System Contents sheet, X-ref Matrix etc.
Thank you