Welcome

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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

(Copy of link will be available at the end of the seminar)

ISO 9001:2015

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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 organisations 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

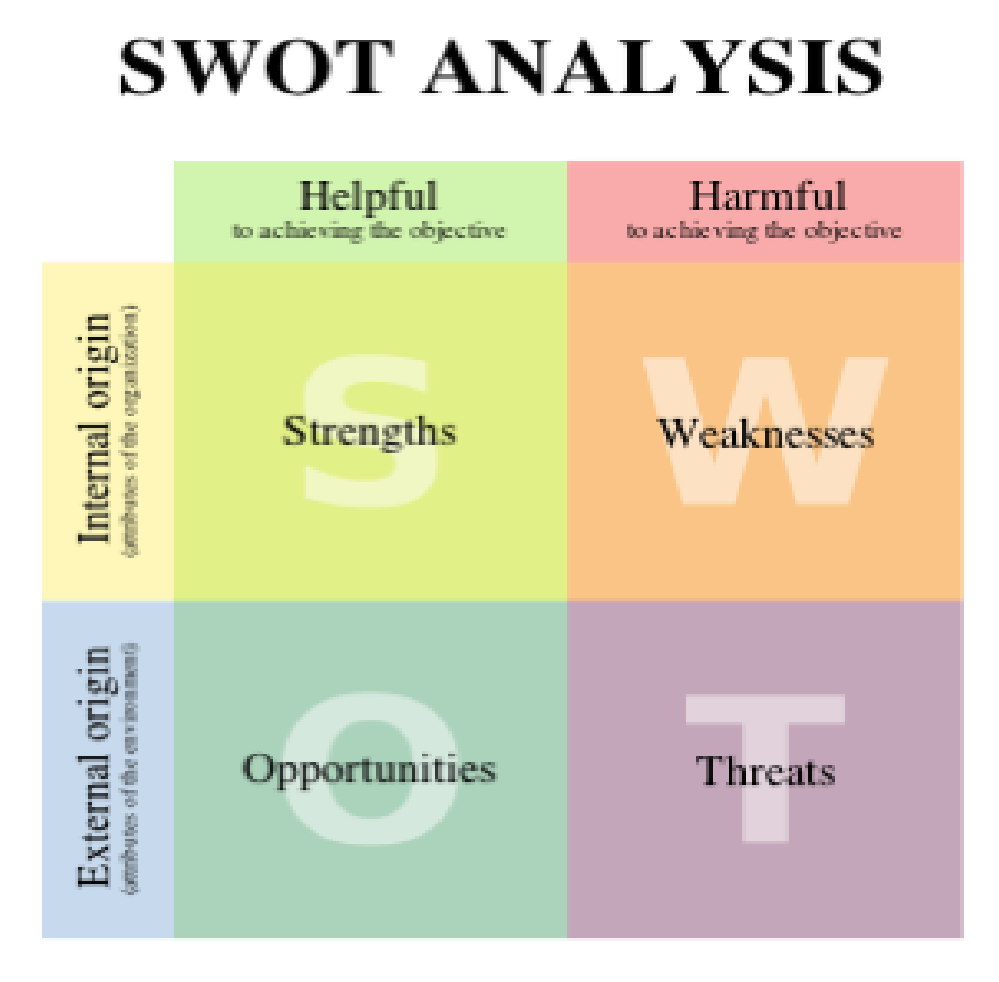
Political Factors	Economic Factors
Ecological/Environmental Issues	National economic policies and trends
National & international: current & anticipated future Legislation	Taxation issues
Regulatory bodies	Seasonal / weather issues
Government policy's	Trade & monetary conditions
Funding, grants, initiatives	Specific sector conditions
Market & political lobbying groups	Interest & exchange rates
Wars / conflicts	International trade & monetary issues

Social Factors	Technology Factors
Demographics & Lifestyle trends	Competing technology development
Attitudes & opinions	Associated / dependent technologies
Consumer attitudes, opinions, & buying patterns	Replacement technology / solutions
Media views, advertising, publicity	Maturity of technology / organisations products/ services
Law changes affecting social behaviour	Information & communications, Social media use
Image of the organisation	Technology legislation
Major events & influences	Innovation potential
Buying access & trends	Technology access, licensing, patents
Ethnic / religious issues	Intellectual property issues

Marketing Factors	
Total market size & market penetration	
Barriers to entry	
Trends & indicators	
State of maturity	
Knowledge of customers	
Competitors	
Channels of distribution	
Branding & packaging	

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

	Opportunities (external, positive)	**Threats** (external, negative)
Strengths (internal, positive)	**Strength-Opportunity strategies** Which of the company's strengths can be used to maximise the opportunities you identifies?	**Strength-Threats strategies** How can you use the company's strengths to minimise the threats you identified?
Weaknesses (internal, negative)	**Weakness-Opportunity strategies** What actions can you take to minimise the company's weaknesses using the opportunities you identified?	**Weakness-Threats strategies** How can you minimise the company's weaknesses to avoid the threats you identified?

SWOT Analysis Questions

Strengths	Weaknesses
What advantage does your organisation have?	What could you improve?
What do you do better than anyone else?	What should you avoid?
What unique or lowest cost resources can you draw upon that others cant?	What are people in your market likely to see as weaknesses?
What do people in your market see as your strengths?	What factors loose you sales?
What factors mean that you get the sale?	What do your competitors provide that you don't?

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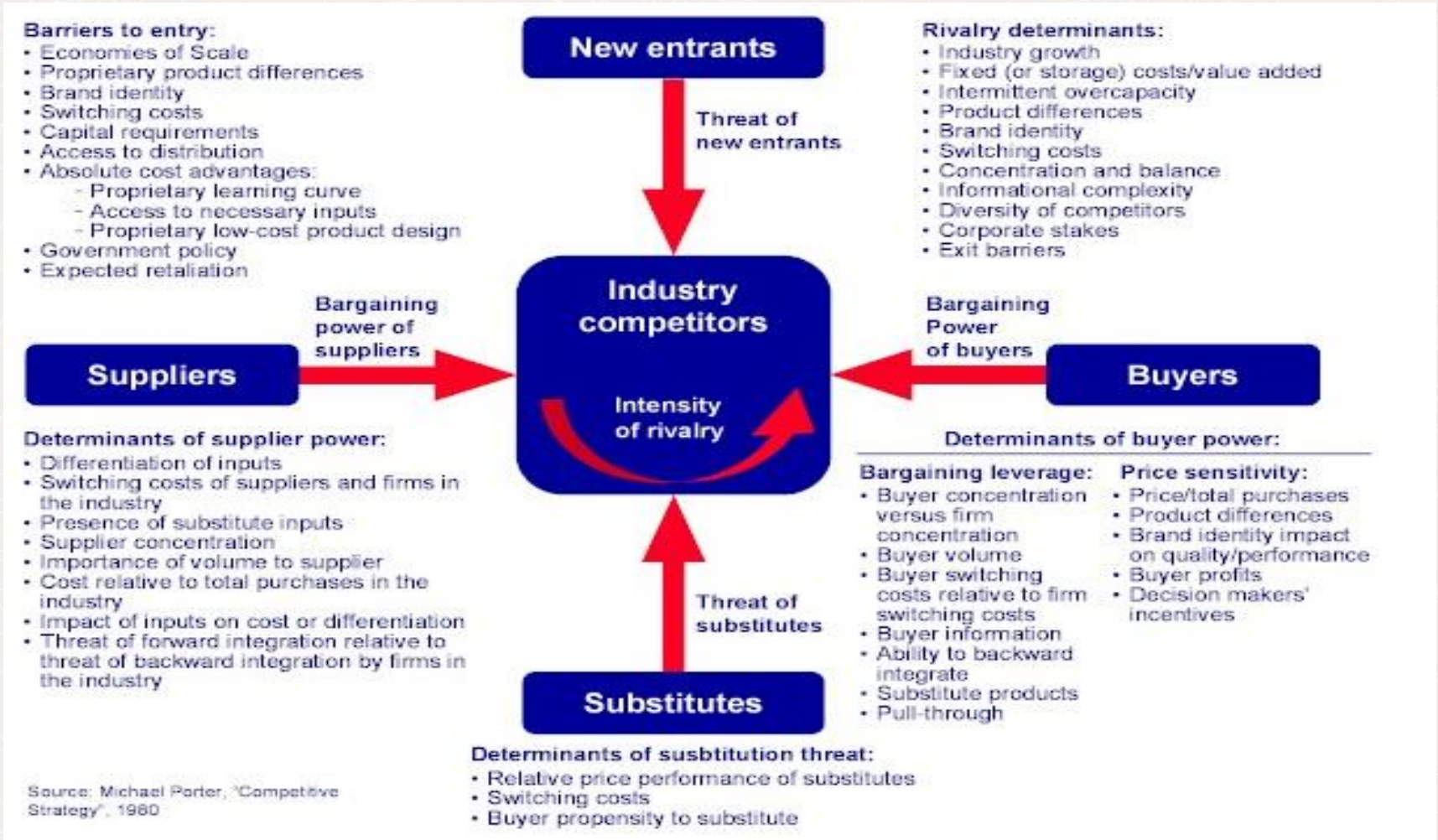
SWOT Analysis Questions

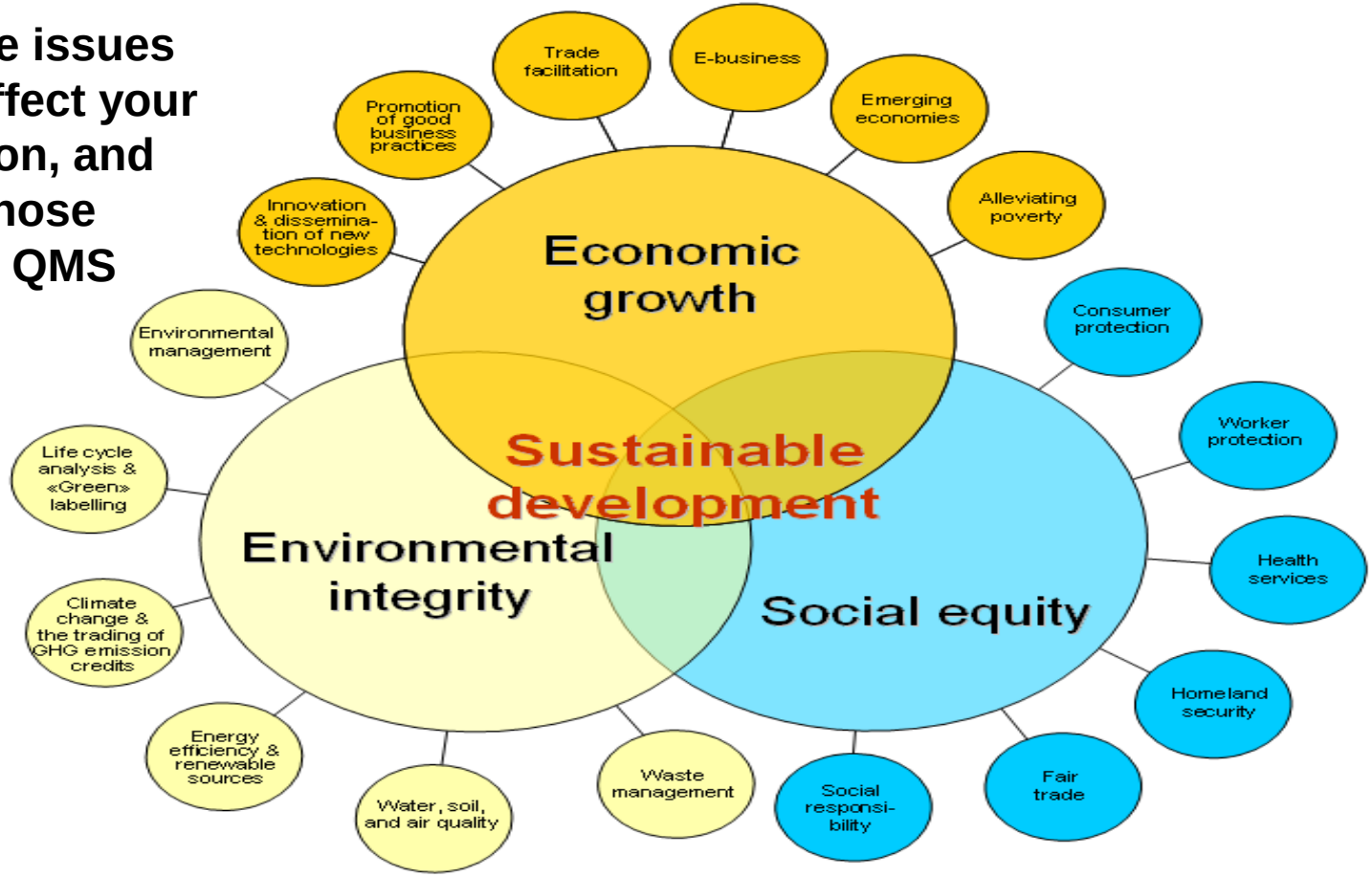
Opportunities	Threats
What good opportunities can you spot?	What obstacles do you face?
What interesting trends are you aware of?	What are your competitors doing?
Are there changes in government policy related to your field?	Are quality standards or specifications for your products or services changing?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

Porter Five Forces Model



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

Interested Parties

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

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Interested Parties

Interested party	Needs and expectations
Local residents	No complaints relating to noise, parking, waste, health & safety, pollution
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

Interested Parties	Needs/ Expectations	Issues / Risks	Opportunity	Risk Analysis Treatment Plan	Communication
Board					
Customers					
Competitors					
Regulators					
Neighbours / Society					
Staff					
Financial Institutions					
Shareholders / Owners					
Suppliers					

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Issues

			Issues List				
Ln	**Interested Party**	**Issue of Concern**	**Bias**	**Processes Affected**	**Priority**	**Treatment Method**	**Record Reference / Notes**
1	Certification Body	Level of compliance to ISO 9001.	Mixed	Process 1	Low	Internal Auditing	See audit records
2							
3	Employee / Staff	Expect to be compensated	Risk	QMS Management	Medium	Manage company finances appropriately	Financials (confidential)
4	Employee / Staff	Expect satisfactory equipment, facilities	Risk	QMS Management	Medium	Internal Auditing	See audit records
5	Employee / Staff	Require appropriate training	Risk	QMS Management	Low	Training provided, assessed through audits	See training records
6							
7	Management	Company must remain financially healthy	Risk	QMS Management	Medium	Manage company finances appropriately	Financials (confidential)
8	Management	QMS processes must be efficient	Risk	QMS Management	Medium	Internal Auditing	See audit records
9	Management	Concerned with growth of company	Opportunity	QMS Management	Medium	Management Review Activity	See Opportunity Register
10							
11	Direct Customer	Expect high quality products	Risk	Manufacturing	Medium	Risk Register / FMEA	See Risk Register Line 4, 7, 15
12	Direct Customer	Expect on time delivery	Risk	Manufacturing	Medium	Risk Register / FMEA	See Risk Register
13	Direct Customer	Could be source of referrals to new customers	Opportunity	Quoting and Orders	Medium	Marketing Enhancement	See Mgmt Review records
14	Direct Customer	Flows down QMS requirements	Risk	Quoting and Orders	Medium	Internal Auditing	Internal audit records
15							
16	Local Community	Expect us not to pollute environment	Risk	QMS Management	Low	Other	
17	Local Community	Expect us to be a "good citizen" locally	Risk	QMS Management	Medium	Other	Good management practices
18	Local Community	Hope us will hire and retain local workers	Mixed	QMS Management	Low	No Action: Accept Risk per Mgmt Decision	We do this naturally
19	Local Community	Can provide positive press	Opportunity	QMS Management	Low	No action, proceed normally for now	Maintain good relations locally
20							
21	Regulatory Body	Must comply with all regulations and statutes	Risk	QMS Management	High	No Action: Accept Risk per Mgmt Decision	Do this as normal part of business
22							
23	Supplier	Expect to be paid promptly	Risk	Purchasing	Medium	Manage company finances appropriately	Financials (confidential)
24	Supplier	Require clearly defined requirements	Risk	Purchasing	Medium	Risk Register / FMEA	See Risk Register
25	Supplier	Require adequate notice of rush jobs	Risk	Purchasing	Medium	Risk Register / FMEA	See Risk Register
26	Supplier	Vendor performance impacts on our reputation	Mixed	Purchasing	Medium	Vendor Auditing	Flow down of requirements on POs; auditing if needed

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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 addresses 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

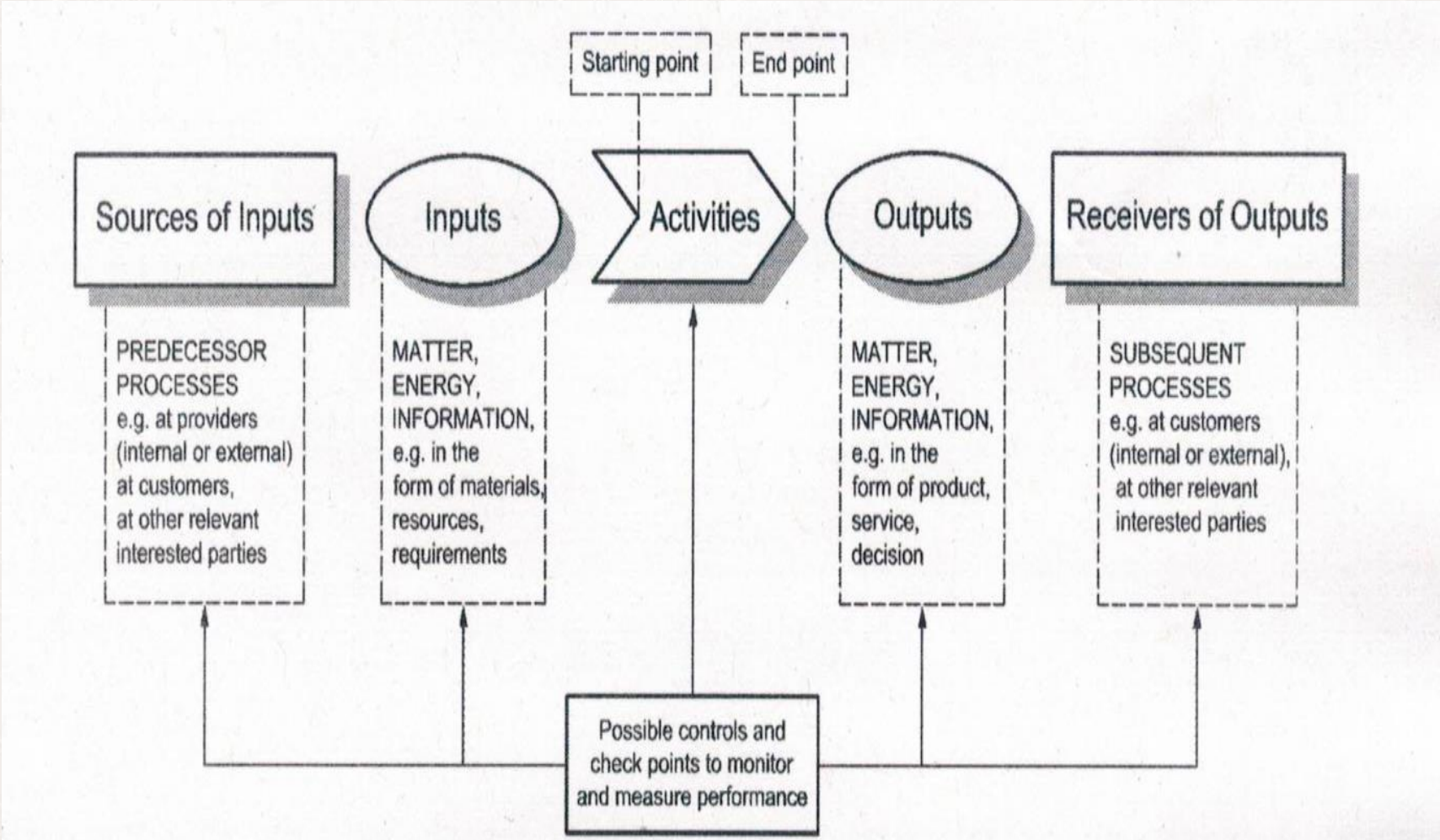
Process approach

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


Starting point
End point
Sources of Inputs
Inputs
Activities
Outputs
Receivers of Outputs
PREDECESSOR PROCESSES e.g. at providers (internal or external) at customers, at other relevant interested parties
MATTER, ENERGY, INFORMATION, e.g. in the form of materials, resources, requirements
MATTER, ENERGY, INFORMATION, e.g. in the form of product, service, decision
SUBSEQUENT PROCESSES e.g. at customers (internal or external), at other relevant interested parties
Possible controls and check points 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.

Assembly Process Owners
Position
Production Manager
Production Supervisors
Process Engineer

QMS Procedures / Documents	
QP08	Control of Non-Conformance
OP09	In process Inspection of Product
OP11	Packaging of Product
OP12	Scheduling
OP15	Assembly Work Instruction
CM01	Competency Matrix
	ETC.

Assembly Process Model

From Process	Inputs	Assembly Process	Outputs	To Process
QA Test	Quality Plan Records		Assembled Products	QA Test
Material Control	Materials		Quality Plan Records	QA Test
Product Engineering	Drawings		Completed Control Charts	Data Analysis
Product Engineering	Machine Programs		Non-conforming products	Rework & Repair
Order Review & Scheduling	Production Schedule			
Product Engineering	Control Charts			
Resource Management	Manpower			

Assembly Process Model

Measurement	Target
First Pass Yield	≥ 98%
RMA	≤ 500 DPPM
Machine Utilisation	86%
On time delivery to customer	≤ 3 days
Absenteeism	3.5%

Application and Quotation

Application → **Application and Quotation Process** → **Quotation**

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

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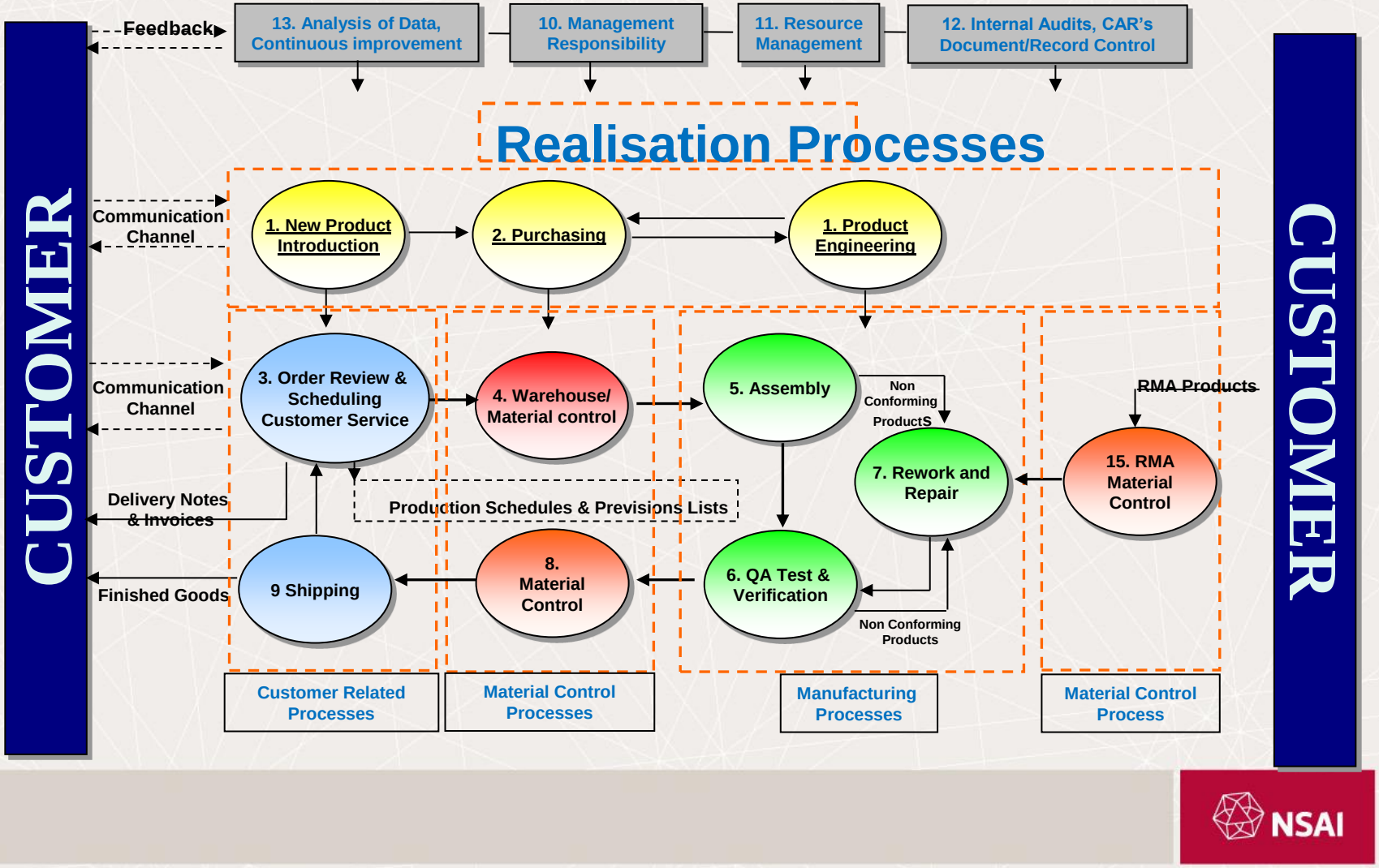
Process Interaction



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.

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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

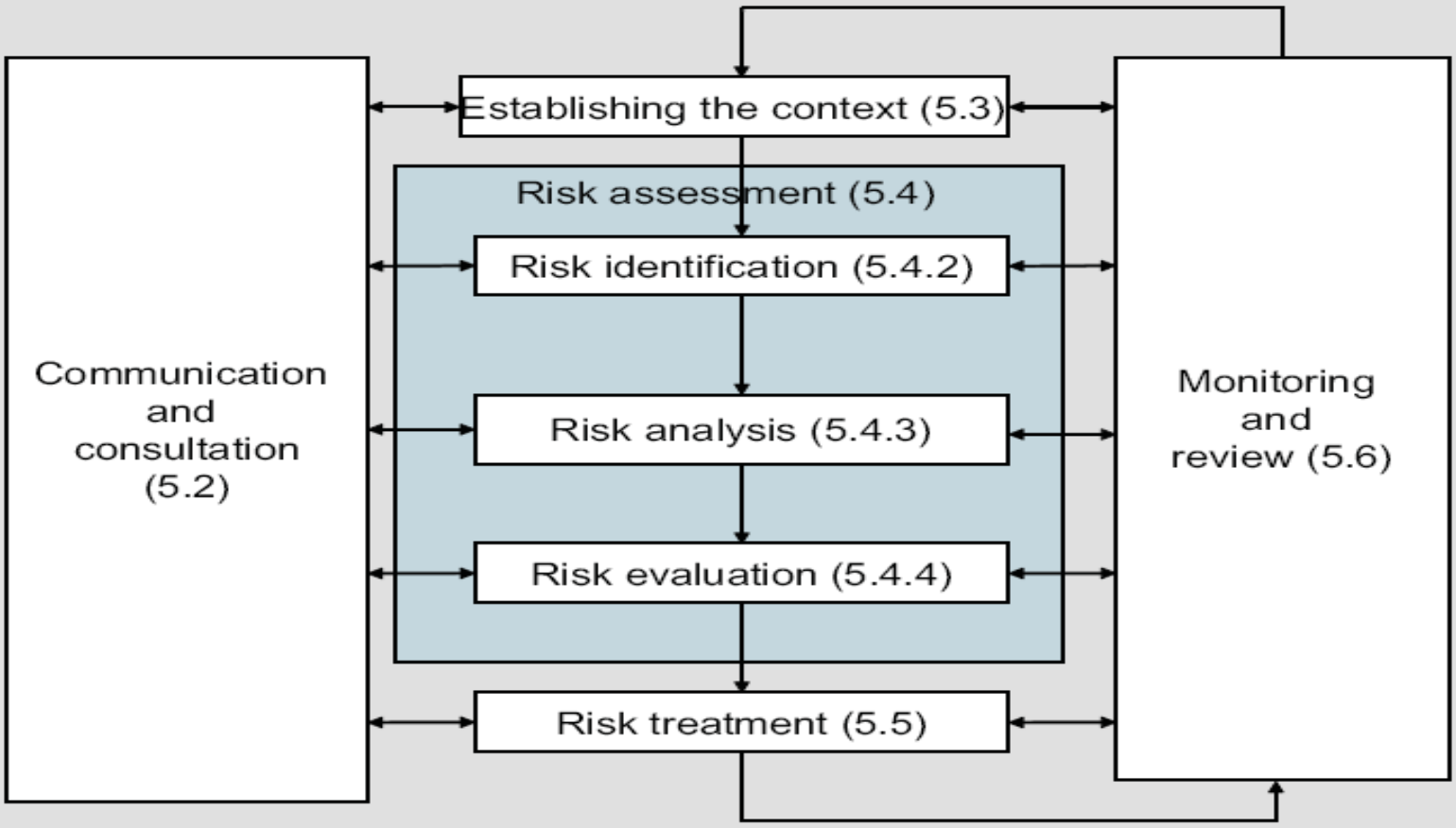

Figure 3 — Risk management process

Risk Management Strategy

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.

Risk Management Strategy

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.

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SWOT Analysis Strategy

	Opportunities (external, positive)	**Threats** (external, negative)
Strengths (internal, positive)	**Strength-Opportunity strategies** Which of the company's strengths can be used to maximise the opportunities you identifies?	**Strength-Threats strategies** How can you use the company's strengths to minimise the threats you identified?
Weaknesses (internal, negative)	**Weakness-Opportunity strategies** What actions can you take to minimise the company's weaknesses using the opportunities you identified?	**Weakness-Threats strategies** How can you minimise the company's weaknesses to avoid the threats you identified?

SWOT Analysis for computer store

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

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

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Risk Register

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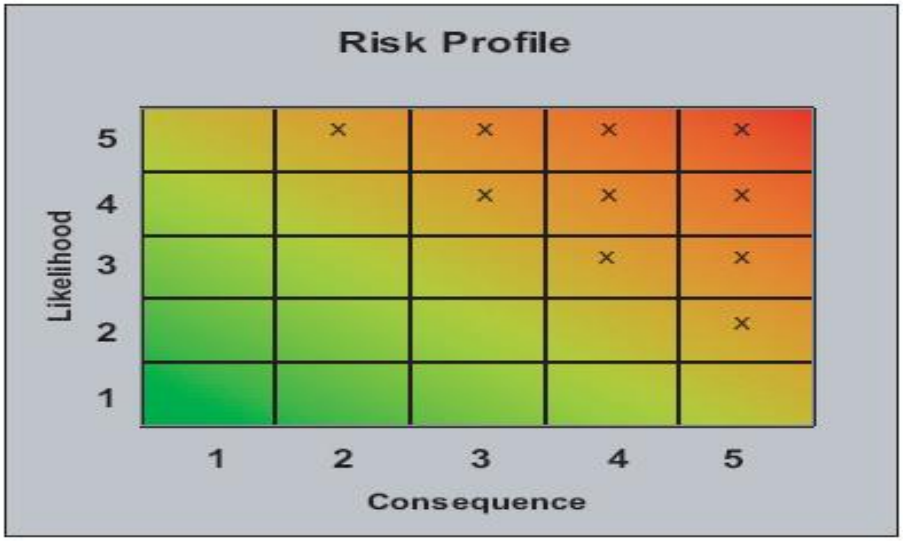
Risk Register

			Risk Register												
#	Process	Risk	Probability (of risk occurring)		Prob. Rating	Consequence (if risk is encountered)						Cons. Rating	Risk Factor (Probability x Consequence	Mitigation Plan (required for risk factors >8) May reference external plan document	Risk Factor after Mitigation
			Likelihood	Previous Occurrences		Potential Loss of Contracts	Potential Harm to User	Inability to Meet Contract Terms / Requirements	Potential Violation of Regulations	Impact on Company Reputation	Estimated Cost of Correction				
1															
2															
3															
4															

Risk Evaluation



Key:

Likelihood	Consequence
1 Rare	1 Negligible
2 Low	2 Minor
3 Medium	3 Moderate
4 High	4 Significant
5 Very High	5 Substantial

Opportunity Register

			Opportunity Register											Number of active improvement activities		
#	Process	Opportunity	Probability (of achieving the opportunity)		Prob. Rating	Benefit (if opportunity is encountered)						Ben. Rating	Opp. Factor (Prob. x Benefit)	Opportunity Pursuit Plan (suggested for Opp. Factors >8)	Post-Implementation Success?	Status
			Likelihood	Previous Occurrences		Potential for New Business	Potential Expansion of Current Business	Potential improvement in satisfying regulations	Potential improvement to internal QMS processes	Improvement to Company Reputation	Potential Cost of Implementation					
1																
2																
3																
4																
5																
6																

Lists

OPP RATING:	RISK RATING LIMIT:	Type	Priority	Treatment	Bias	Processes	Likelihood	Occurrences	Potential	Violation	correction	reputation	cost	reputation	score	Success
8.0	8.0	External	Emergency	No Action: Accept Risk per Mgmt Decision	Opportunity	All Processes	Cannot occur / not applicable	Has never occurred.	None / NA	None / NA	€ 0	None	> €1,000,000	No impact / NA	1	Opportunity Failed
		Internal	High	Risk Register / FMEA Style	Risk	Process 1	Unlikely to Occur	Has not occurred in past 10 years.	Minor	Possible	< €100,000	Minimal	> €500,000	Minimal impact	2	Opportunity Abandoned
			Medium	Root Cause Analysis	Neutral	Process 2	Somewhat likely to occur	Has occurred in past 10 years.	Moderate	Definite	< €500,000	Moderate	< €500,000	Moderate impact	3	Met some expectations
			Low	Internal Auditing	Mixed	Process 3	Likely to occur	Has occurred in past 5 years.	High	High	> €500,000	Severe	< €100,000	Good impact	4	Met all expectations
				Root Cause Analysis		Process 4	Very likely to occur	Has occurred in past year.	Very High	Legal Risk	> €1,000,000	Very severe	€0 or N/A	Great impact	5	Exceeded expectations
				Corrective Action (CA)		Process 5										
				Vendor Auditing		Process 6										
				Other Auditing		Process 7										
				Management Review Activity		Process 8										
				Marketing Enhancement		Process 9										
				Other		Process 10 Other										

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 cant 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 organisations 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 organisations 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.

QMS Questionnaire

NSAI

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

NSAI

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

COMPANY NAME:	**Date:**	**File ref:**

Enter the processes in this column and indicate the clauses that apply by placing an "X" in the relevant cell in the matrix	4.2, 4.3, Context	QMS Processes	Leadership	Policy	Roles, responsibility, authorities	Risk and Opportunities	Quality Objectives	Planning of changes	Resources	Competence	Awareness	Communication	Documented Information	Operation Planning	Requirements Poducts/services	Design & development	Externally provided processes	Production / Service provision	Release of products / services	Nonconforming outputs	Monitoring & measurement	Internal audit	Management Review	Improvement	Nonconformity/corrective action	Continual improvement
Clause No.	4.1	4.4	5.1	5.2	5.3	6.1	6.2	6.3	7.1	7.2	7.3	7.4	7.5	8.1	8.2	8.3	8.4	8.5	8.6	8.7	9.1	9.2	9.3	10.1	10.2	10.3
EXCLUSIONS >>																										

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

EMS Questionnaire 2015

Section 2: Requirements Checklist

- For completion at Registrations, Upgrades to ISO 14001:2015 and Re-Assessments

EMS Questionnaire 2015

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

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