Welcome

NSAI Workshop

ISO 9001:2015 / ISO 14001:2015

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Welcome & aims of the Workshop

1. **Completing the Questionnaire 9K and/or 14k**
2. **Continue and test back at your organisation**
3. **Options to:**

(i) Maintain manuals and update

(ii) Maintain manuals and address additional requirements elsewhere

(iii) Integrate totally within your business management system but address documented information

4. **Deadline for old certification:**

   15.09.2018

5. **Upgrade at your next audit**

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ISO 9001:2015 High Level Structure

1. **Scope**
2. **Normative references**
3. **Terms and definitions**
4. **Context of the organization**
   - Understanding the organization and its context
   - Understanding the needs and expectations of interested parties
   - Determining the scope Of QMS/EMS
   - Quality/Env management system and its processes
5. **Leadership**
   - Leadership and commitment
   - Quality/Env Policy
   - Organizational roles, responsibilities and authorities
6. **Planning**
   - Actions to address risks and opportunities
   - Quality/Env. objectives and planning to achieve them
   - Planning of changes
   - Compliance obligations (Env)

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ISO 9001:2015 High Level Structure

7. Support

- Resources
- Competence
- Awareness
- Communication
- Documented information

8. Operation

- Operational planning and control
- Requirements for products and services (Quality)
- Design and development of products and services (Quality)
- Control of externally provided processes, products and services Production and service provision
- Release of products and services
- Control of nonconforming outputs (Quality)
- Emergency preparedness (Env)

9. Performance evaluation

- Monitoring, measurement, analysis and evaluation
- Internal audit
- Management review

10. Improvement

- General
- Nonconformity and corrective action
- Continual improvement

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CONTENT

Clause 4 - Context of the Organisation

- Context
- Interested Parties
- Scope of the Management system
- Process Approach

Clause 5 – Leadership

- The emphasis on Leadership

Clause 6 – Planning

- The focus on risk-based thinking
- Management system objectives
- How change is addressed

Clause 7, 8, 9 and 10

- QMS / EMS Questionnaires
- Process Clause Matrix

ISO 9001:2015 Contents

1. **Scope**
2. **Normative references**
3. **Terms and definitions**
4. **Context of the organization**
   - Understanding the organization and its context
   - Understanding the needs and expectations of interested parties
   - Determining the scope Of QMS
   - Quality management system and its processes
5. **Leadership**
   - Leadership and commitment
   - Quality Policy
   - Organizational roles, responsibilities and authorities
6. **Planning**
   - Actions to address risks and opportunities
   - Quality objectives and planning to achieve them
   - Planning of changes
7. **Support**
   - Resources
     - Organizational knowledge
   - Competence
   - Awareness
   - Communication
   - Documented information
8. **Operation**
   - Operational planning and control
   - Requirements for products and services
   - Design and development of products and services
   - Control of externally provided processes, products and services
   - Production and service provision
     - Post Delivery, Control of change
   - Release of products and services
   - Control of nonconforming outputs
9. **Performance evaluation**
   - Monitoring, measurement, analysis and evaluation
   - Internal audit
   - Management review
10. **Improvement**
    - General
    - Nonconformity and corrective action
    - Continual improvement

Black: core MS requirements **Red: new MS requirements**
Green: ISO 9001 specific

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ISO 14001:2015 Contents

1. **Scope**
2. **Normative references**
3. **Terms and definitions**
4. **Context of the organization**
   - Understanding the organization and its context
   - Understanding the needs and expectations of interested parties
   - Determining the scope of the environmental management system
   - Environmental management system
5. **Leadership**
   - Leadership and commitment
   - Environmental policy
   - Organizational roles, responsibilities and authorities
6. **Planning**
   - Actions to address risks and opportunities
     - General
     - Environmental aspects
     - Compliance obligations
     - Planning action
   - Environmental objectives and planning to achieve them
     - Environmental objectives
     - Planning actions to achieve
7. **Support**
   - Resources
   - Competence
   - Awareness
   - Communication
     - General
     - Internal communication
     - External communication
   - Documented information
8. **Operation**
   - Operational planning and control
     - Lifecycle perspective
   - Emergency preparedness and response
9. **Performance evaluation**
   - Monitoring, measurement, analysis and evaluation
     - General
     - Evaluation of compliance
   - Internal audit
   - Management review
10. **Improvement**
    - General
    - Nonconformity and corrective action
    - Continual improvement

Black: core MS requirements **Red: new MS requirements**
Green: ISO 14001 specific

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Clause 4.1 - Context of the organisation

- This is a new requirement and a very important one, because it is necessary to obtain an overview of the organisation to understand the quality challenges of the organisation, and the risk inherent in their sector.
- An organisations context is influenced by its business environment that characterises each sector or industry; the customers and their needs, the required knowledge and technologies, the materials, services and systems that are required for producing the product or service, legal, regulatory, cultural constraints and the application and interfaces between them.
- To determine context means to identify the **internal** and **external** factors that can impact the organisations strategic objectives and the planning of the quality management system.
- Focus on factors that can affect **customer satisfaction** and **delivery** of quality products and/or service.
- The context will influence the type and complexity of the quality management system needed.

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Context of the Organisation

Internal context:

- **Performance factors:** products and service offerings, financial results, regulatory requirements
- **Resource factors:** including infrastructure, environment for the operation of the processes, organizational knowledge, assets, capabilities, information systems
- **Human factors:** such as competence of personnel, organizational behaviour & culture, relationships with unions, suppliers & partners
- **Operational factors:** such as process or production and service provision capabilities, performance of the quality management system, monitoring customer satisfaction
- **Factors** in the governance of the organization, such as its rules and procedures for decision making or organization's structure

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Context of the Organisation

External context:

- **Economic factors:** such as money exchange rate, 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
- **Market factors:** such as competition**,** including the organization's market share, similar or substitute products or services, market leader trends, customer growth trends, market stability, supply chain relationships
- **Statutory and regulatory factors:** which affect the work environment such as trade union regulations, legal and statutory requirements (e.g. environmental legislation and codes)

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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 / PESTLE** analysis (political, economic, social technological, legal and environmental) this analysis determines which factors can influence how the organisation operates.
- The PESTLE 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

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Context Analysis Process

- **Analyse and Evaluate Internal and External Issues.** Use model of choice to identify compliance obligations, interested parties, environmental and market factors, (create a matrix of identification, evaluation and prioritization based on positive and negative impact (risk and opportunity)).
- **SWOT analysis**. Classify external factors into Strengths, Weaknesses, Opportunities and Threats (Risks and Opportunities).
- **Key Issues:** From the SWOT, identify the key issues facing the organisation, i.e. the high priority issues that must be addressed in strategy, policy and objectives.
- **Create Policy.** Document, communicate and make available a policy that addresses the key issues and commits the organization to continual improvement.
- **Set Objectives.** Set objectives consistent with policy that are measurable, monitored and communicated. SMART objectives, quality objectives, environmental objectives etc.

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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

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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

Legal Factors	Environmental Factors
Anti-trust law	Weather
Discrimination law	Climate change
Copyright, patents, intellectual property law	Laws regarding environmental pollution
Employment law	Air and water pollution
Consumer protection and e-commerce	Attitudes towards and support for renewable energy
Health and safety law	Waste management
Data Protection	Attitudes towards green or ecological products
Regional legislation	Recycling
Foreign trade	Energy consumption

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

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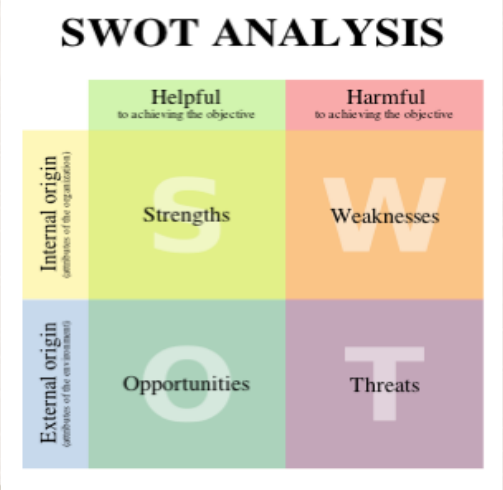
Context of the Organisation

- **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**



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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?

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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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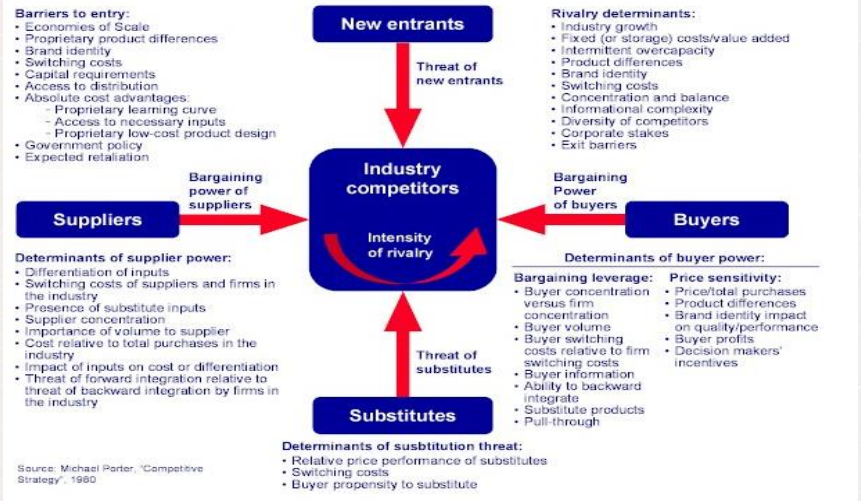
SWOT Analysis Questions

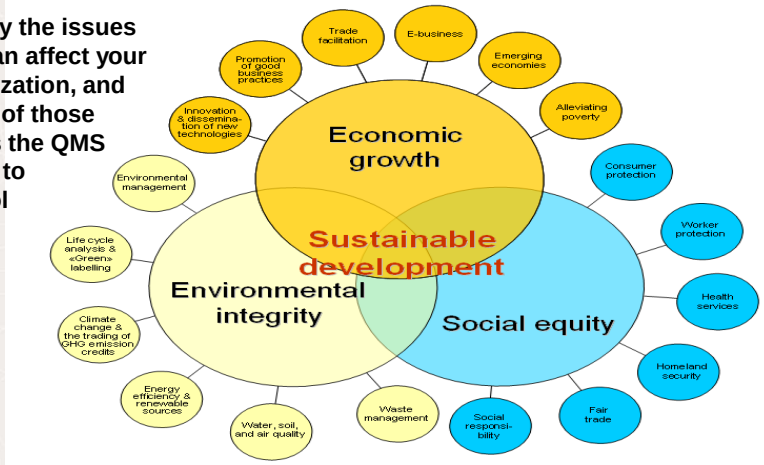
Opportunities	Threats
What good opportunities can you spot?	What obstacles do you face?
What interesting trends are you aware of?	What are your competitors doing?
Are there changes in government policy related to your field?	Are quality standards or specifications for your products or services changing?
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



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EMS Organisational Context

Clause 4.1

New requirement to understand the organisation's context to identify opportunities for the benefit of both the organisation and the environment

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EMS Organisational Context

4.1 Context – External issues

Cultural	Economic
Social	Natural
Political	Technological
Legal	Supply chain
Financial	Competition

EMS Organisational Context

4.1 Context – Internal issues

Organisational structure
Legal compliance
Policy, objectives and strategies
Capability and capacity
Information systems
Internal relationships
Management standards
Organisation style and culture
Contractual relationship

EMS Organisational Context

Examples of internal and external which can be relevant to the organisation include environmental conditions related to air and water quality, land use, existing contamination, natural resources availability and biodiversity that can affect the organisation or be affected by the organisations aspects.

Context of the Organisation

For example:

- A small distribution business of imported goods could find out what **external issues** could affect the achievement of its quality management system's intended results**:** its government policy for import-export activities, the type and quantity of its competitors, the culture of local consumers, or its credit availability.
- **internal issues** that could affect its intended results include: its infrastructure, organizational knowledge, delivery capabilities and the competence of people working on its behalf.
- Internal and external issues can change, and therefore its context should be monitored and reviewed on a regular basis.

Context Of the Organisation

Complete Questionnaire

- QMS Question A1 & A2
- EMS Question 4.1

Later

- Develop PESTEL / SWOT analysis

Clause 4.2 - 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 **relevant** interested parties which can have an impact on your ability to provide products and services that meet requirements.
- There will be those **external** interested parties that impose specific legal, regulatory or contractual requirements.
- There may be also requirements specified by **internal** interested parties, such as : management, staff, shareholders, trade unions, etc.

Identifying Interested Parties

The list of relevant interested parties can be unique to your organisation. You can develop criteria for determining relevant interested parties by considering their:

- possible influence or impact on the organisations performance or decisions
- ability to create risks and opportunities
- possible influences or impact on the market
- ability to affect the organisation through their decisions or activities

Need to understand the needs, expectations, and requirements of your interested parties / stakeholders.

Determine which of these needs and expectations become the organization's 'requirements

These are critical to ensuring that your products or services meet requirements which is the reason for having QMS.

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Classifying Interested Parties

Group interested parties based on their relationship with the organisation by their:

- **Responsibility** – investors, etc.
- **Influence** – pressure groups, etc.
- **Proximity** – neighbours, etc.
- **Dependency** – employees, etc.
- **Representation** – trade unions, etc.
- **Authority** – regulators, etc.

Different groups may require a different management approach, relevance, needs and expectations

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Power and Interest Matrix

Useful tool for helping you decide how to manage a particular Interested party

How much **interest** do they have in your decisions and activities – interpreted as the strength of their relevance

How much **power** or influence do they have over your decisions and activities – interpreted as their significance or risk

Plotting helps to prioritise the effort required to meet their needs and expectations

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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

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Interested party	QMS requires from Interested Parties	Needs and expectations of Interested Parties
Customers, Retailers, Distributors	Specifications for design, manufacture, delivery, support	Design, quality, price, quick response & on-time delivery of products and services
Owners Share Holders Board	Financial investment, Decisions & support Improvements	Sustained profitability, Return on investment, Transparency, Legal compliance
People in the organization	Leadership, Motivation, Direction Involvement. Products & Services. Follow QMS requirements.	Good work environment, Health & safety, Job security, Professional development, Recognition and reward, Training, Working relationships
External Providers Partners	Products, Services or Raw Materials. On-time delivery. Reliability.	Mutual benefit and continuity, Prompt payment, Good working relationship
Society Regulatory Authorities	Legal & regulatory requirements. Certainty of law	Environmental protection Ethical behaviour Compliance with statutory and regulatory requirements Conformity to industry codes & standards

Interested party	QMS requires from Interested Parties	Needs and expectations of Interested Parties
Local residents	Workforce, Good relations	Safe working conditions, environmentally friendly operations
Bank / Finance	Good Governance, Stability, Credit	Financial performance Cash flow
Trade Unions	Realistic expectations Co-operation	Employment law compliance, Good working relationship with management
Insurers	Guidance on risk, identification, treatment, avoidance	No claims Risk management Prompt payment
End Users	Details of their needs, expectations and requirements	Performance, ease of use, safety, reliability, maintainability, disposability

Interested Parties

Interested Parties (IP)	QMS requires from IP	IP Needs & Expectations	Issues / Risks	Objectives	Risk Analysis Treatment Plan	Priority
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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EMS Internal interested parties

- Employees
- Unions
- Worker representatives
- Managers
- Parent organisation
- Investors or donors
- Board of directors
- Shareholders

EMS External interested parties.

- Customers & clients
- Neighbouring community members
- Suppliers & subcontractors
- Government agencies
- Local, national authorities
- Trade associations

EMS External Interested parties

- Legal advisors
- Competitors
- Insurers
- Regulatory bodies
    - 1. EPA
    - 2. HAS
    - 3. SEAI

EMS External interested parties

- Sub-consultants
- External suppliers
- Members of the public
- Accreditation bodies
- Professional institutions
- Financial institutions

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.

Interested Parties

Complete Questionnaire

- QMS Question A3
- EMS Question 4.2

Later

- Develop an interested parties matrix

Clause 4.3 - Scope of the QMS

- The scope is a vital part of the QMS as it defines how far the QMS extends within the company's operations (**boundaries**),
- The scope shall state the types of **products and services** covered, and provide justification for any requirement of ISO 9001:2015 that the organization determines is not applicable to the scope of its QMS.
- The organization's scope shall be maintained as documented information, e.g.:- quality manual; marketing materials; website; etc. must be clear on the scope of its QMS certification to avoid confusing or misleading customers.

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Scope of the QMS

The scope of the QMS, should be established based on the:

- **context-related external and internal issues**
- **relevant requirements from relevant interested parties**
- **products and services of the organization**

In determining the scope, you should also establish the **boundaries** of your QMS by considering such issues as:

- infrastructure of the organisation
- organisations different sites and activities
- commercial policies and strategies
- centralised or external provided activities, processes, products and services
- organizational knowledge

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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.

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 belonging to their customers or external providers
- there is only one site for its operations that it needs to consider in the context-related issues, and sterilisation process is outsourced
- The scope may be: **Import and commercialization of glass bottles for cosmetics in the Technology Park facility for the European market, with the sterilisation process outsourced.**
- 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
- **NOTE:** Be aware that the "scope of the quality management system" may differ from "the scope of certification to ISO 9001:2015".

Scope of the QMS

Complete Questionnaire

- QMS Questions A4, A5
- EMS Question 4.3

Later

- Discuss and document scope with management

Clause 4.4 - QMS Process

All organisations use processes to achieve their objectives

- is a set of interrelated or interacting activities that 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)

The process approach includes establishing the organisations processes needed to operate as an integrated and complete system

- The management system integrates processes and measures to meet objectives
- Processes define interrelated activities and checks, to deliver intended outputs
- Details planning and controls can be defined and documented as needed, depending on the organisations context

Risk-based thinking, PDCA & the process approach

- The **process approach** enables an organisation to plan its processes and their interactions.
- The **PDCA** cycle enables an organisation to ensure that its processes are adequately resourced and managed, and that opportunities for improvement are determined and acted upon.
- **Risk-based thinking** enables an organisation to determine the factors that could cause its processes and its quality management system to deviate from the planned results, to put in place preventive controls to minimise negative effects and to make maximum use of opportunities as they arise.

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Risk-based thinking, PDCA & the process approach

These three concepts together form an integral part of ISO 9001:2015 standard. Risks that may impact on objectives and results must be addressed by the management system. Risk-based thinking is used throughout the process approach to:

- Decide how risk is addressed in establishing the processes to improve process outputs and prevent undesirable results.
- Define the extent of process planning and controls needed (based on risk).
- Improve the effectiveness of the quality management system
- Maintain and manage a system that inherently addresses risk and meets objectives.

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PDCA Tool

PDCA is a tool that can be used to manage processes and systems:-

- **P** Plan: set the objectives of the system and processes to deliver results ("What to do" and "How to do it")
- **D** Do: implement and control what was planned
- **C** Check: monitor and measure processes and results against policies, objectives and requirement ,and report results
- **A** Act: take action to improve the performance of processes

PDCA operates as a cycle of continual improvement, with risk-based thinking at each stage

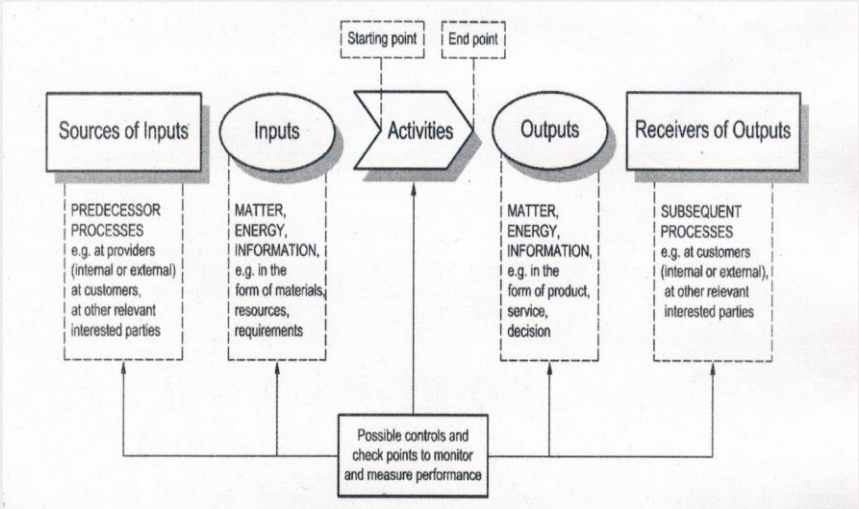
Process approach

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



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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.

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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			

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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%

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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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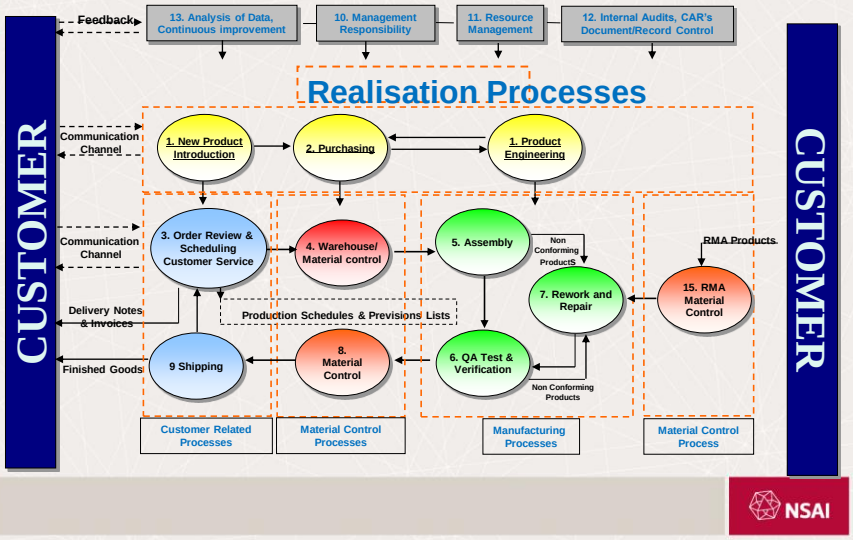
Process Interaction



QMS Processes

Complete Questionnaire

- QMS Question A6
- EMS Question 4.4

Later

- Develop your processes, identify the inputs and outputs, identify the risks in each process, and define your measurements and targets

Clause 5 - Leadership and commitment

- **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.
- The intent of this requirement is to ensure that top management, demonstrate leadership and commitment by taking an active role in engaging, promoting, and ensuring, communicating and monitoring the performance and effectiveness of the quality management system.
- If you want your quality management systems to be successful you need management support. Without this support the QMS will be overtaken by other priorities and the benefits from using continual improvement to focus on customer needs will be lost.
- The role of top management is to **inspire** by leading by example.
- Top management is expected to be "**hands on**" and to ensure that the quality policy and quality objectives are consistent with the overall strategy and context.

Leadership

Clause 5.2 – Quality Policy

- Quality policy basically unchanged, emphasis on communication.

Clause 5.3 – Organisational roles, responsibilities and authorities

- No requirement for a management representative, yet the responsibilities and authorities still remain.

- including:
  - that processes are delivering their intended outputs,
  - promotion of customer focus,
  - reporting on the performance of the QMS
  - ensuring the integrity of the QMS is maintained during changes.

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How to show commitment

- QMS effectiveness is measured, & management is involved in assessing this, (Management Reviews).
- The Quality Policy and objectives are in place per management direction, communicated in the organization, and tracked for progress.
- Ensuring the integration of the quality management system requirements into the business processes (not a side project).
- Resource needs are reviewed and addressed by management.
- Continual improvement is promoted and supported by management.
- Ensuring that recommendations from audits, corrective actions, management reviews, etc. are implemented.

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How to show commitment

- There is a way to ensure customer, statutory and regulatory requirements are understood and met, and people understand why this is important.
- Management focus on customer satisfaction.
- Organizational roles, responsibilities, and authorities are assigned, understood by the person who is assigned, and known to all employees.
- 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.

Leadership

Complete Questionnaire

- QMS Question B1 to B9
- EMS Question 5.1 to 5.3

Later

- Organisation Chart
- Ensure that all management attend the management review, ensure that they are aware of the management system requirements and their responsibility for implementing the management system

Clause 6.1 - Risk-based thinking

- One of the key changes in the 2015 revision of ISO 9001 is to establish a systematic approach to considering risk, by using **risk-based thinking** the QMS becomes proactive rather than reactive in preventing or reducing undesired effects through early identification and action. Preventive action is built-in when a management system is risk-based

- In establishing and operating the QMS, your organization should identify what it wants to achieve, i.e. objectives and intended results. Risk is the effect of uncertainty on these objectives and intended results

- You should consider the external and internal issues and relevant interested parties that can have an impact on achieving these objectives and 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.

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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 systems, 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.

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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

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Risk Management Process

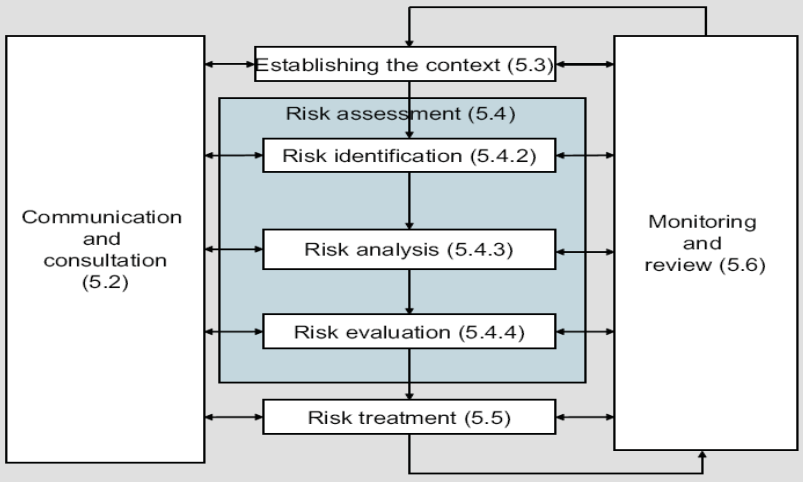

Figure 3 — Risk management process

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Risk identification

Identify what your risks are –

- Determining the factors that could cause a process or the entire QMS to deviate from the planned results
- it depends on context, interested parties
- prioritize the way you manage your processes
- balance risks and opportunities

Example:

- *If I cross a busy road with numerous fast-moving cars the risks are not the same as if the road is small with only a few slow-moving cars. It is also necessary to consider such things as weather, visibility, personal mobility and specific personal objectives (context).*

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Risk analysis

Prioritise the risk in order based on frequency, likelihood, severity, impact on objectives, monetary consequences, loss of customers, legal exposure, impact on interested parties. Identify what is acceptable and what is unacceptable.

***Example**: Objective: I need to safely cross a road to reach a meeting at a given time.*

- *It is **UNACCEPTABLE** to be injured. It is **UNACCEPTABLE** to be late.*
- *Reaching my goal more quickly must be balanced against the likelihood of injury. It is more important that I reach my meeting uninjured than it is for me to reach my meeting on time.*
- *It may be **ACCEPTABLE** to delay arriving at the other side of the road by using a footbridge if the likelihood of being injured by crossing the road directly is high.*
- *I analyse the situation. The footbridge is 200 metres away and will add time to my journey. The weather is good, the visibility is good and I can see that the road does not have many cars at this time.*
- *I decide that walking directly across the road carries an acceptably low level of risk of injury and will help me reach my meeting on time.*

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Risk evaluation

Plan actions to address the risks

how can I avoid, eliminate or mitigate risks?

Example:

- *I could eliminate risk of injury caused by being hit by a vehicle if I use the footbridge but I have already decided that the risk involved in crossing the road is acceptable.*
- *Now I plan how to reduce either the likelihood or the impact of injury. I cannot reasonably expect to control the impact of a car hitting me. I can reduce the probability of being hit by a car.*
- *I plan to cross at a time when there are no cars moving near me and so reduce the likelihood of an accident. I also plan to cross the road at a place where I have good visibility.*

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Risk treatment

Implement the plan – take action

- **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

Example:

- *I move to the side of the road, check there are no barriers to crossing. I check there are no cars coming. I continue to look for cars whilst crossing the road.*

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Risk monitoring & review

Check the effectiveness of the action – *does it work?*
Periodically reviewing identified risks, identifying new risks (internal/external), ensuring proper execution of planned risk treatments

- ***Example:*** *I arrive at the other side of the road unharmed and on time: this plan worked and undesired effects have been avoided.*

Learn from experience – improve

- ***Example:*** *I repeat the plan over several days, at different times and in different weather conditions.*
- *This gives me data to understand that changing context (time, weather, quantity of cars) directly affects the effectiveness of the plan and increases the probability that I will not achieve my objectives (being on time and avoiding injury).*
- *Experience teaches me that crossing the road at certain times of day is very difficult because there are too many cars. To limit the risk I revise and improve my process by using the footbridge at these times.*
- *I continue to analyse the effectiveness of the processes and revise them when the context changes.*

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Risk monitoring & review

Also continue to consider innovative opportunities:

- *can I move the meeting place so that the road does not have to be crossed?*
- *can I change the time of the meeting so that I cross the road when it is quiet?*
- *can we meet electronically?*

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Risk Assessment Techniques

- There is no requirement in **ISO 9001:2015** to use formal risk management in the identification of risks and opportunities. You can choose the methods that suit your needs.
- **ISO 31000 Risk Management** – more formal approach, not obligatory
- The standard **IEC 31010** ***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 Assessment Techniques

- 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.

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?

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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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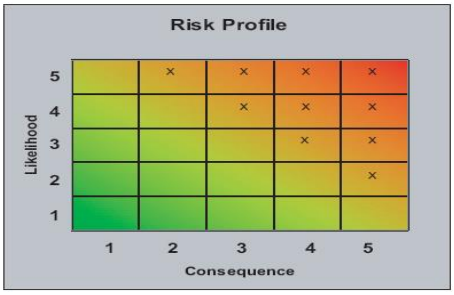
Risk Evaluation



Key:

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

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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															

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										

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EMS Risks & Opportunities

Areas of focus

- Other risks and opportunities
- Significant environmental impacts
- Compliance obligations
- Planning action
- Environmental objectives

Significant aspects can result in risks and opportunities associated with adverse impacts (threats) or beneficial impacts (opportunities)

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Risk & Opportunity

Complete Questionnaire

- QMS Questions C1, C2, C3
- EMS Question 6.1

Later

- Develop a risk register and treatment plan

Clause 6.2 - 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 quality management system
- Quality objectives can be technical, strategic or operational.
- 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

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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

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Quality Objectives

Quality objectives shall:-

- Consistent with quality policy
- Relevant to products & services and enhance customer satisfaction
- Measurable
- Monitored
- Updated

Organisation shall determine:-

- What will be done
- Resources required
- Responsibility
- Timeframe
- How results will be evaluated

Quality Objectives

Complete Questionnaire

- QMS Question C5
- EMS Question 6.2

Later

- Discuss quality / environmental objectives with management , and develop a plan for each objective

Clause 6.3 – Planning of Changes

- One of the goals of the ISO 9001:2015 is to enhance the requirements for addressing changes at system and operational levels. Once an organisation has identified its context and interested parties and then identified the processes that support this linkage, addressing changes becomes an increasing important component of continued success.
- Once processes are determined, an organisation will need to identify the risks and opportunities associated with these processes. To achieve the benefits associated with the determination of risks and opportunities, changes may be needed.
- Changes are intended to be beneficial to the organisation and need to be carried out as determined by the organisation (change control) to prevent undesirable effects during and after a change.
- 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-work, segregation of nonconforming products, or cancellation or postponement of a service.
- Triggers that can cause a change to QMS:- Customer feedback, innovation, product nonconformity, determining risk, employee feedback, etc.

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Examples of Change

1. Extensive repairs are planned on a major route. A bus company recognises that this will affect the companies ability to meet customer requirements and reliably deliver its usual service. To plan changes they consider:
   a revised route to avoid the road works and excessive delays, revising its timetable to take into account the extra time needed, if extra buses need to be put onto the route during this period, appointing a named person to deal with enquiries and complaints about the changes.

2. As part of its annual planning a business can identify specific times in the year where a high peak of demand will occur due to regular events. The management can make provisions to be prepared and get more business due this opportunity. On the other hand, there may be an irregular events. The management 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 management can pre-arrange to have some local vendors ready to react to requests for additional supplies, and also to have additional staff on standby.

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Steps to implement changes

- 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.

Types of changes

- Process changes (inputs, activities, outputs, controls, etc.)
- Communication with customers
- Communication with supply chain
- Inspection, Equipment
- Employee training / competence
- Introducing a new process
- Provide / change documented information
- Outsource a process
- Many others

NOTE

Prior to making a change, consider unintended consequences
After making a change, monitor the change for effectiveness

Planning of Changes

Complete Questionnaire

- QMS Question C4

Later

- Implement a change control method within your organisation, and educate management /employees

Clause 7 – Support

Clause 7.1 Resources

Clause 7.1.1 General

- Organisation to consider capabilities and constraints of existing internal resources and what needs to be obtained from external resources.

Clause 7.1.2 People

- The term people replaces human resources.

Clause 7.1.3 Infrastructure

- No changes.

Clause 7.1.4 Environment for the operation of processes

- Used to be "Work environment".
- Need to identify and maintain the environment that your organisation needs in order to support process operations and to achieve conformity of products and services.

Clause 7 – Support

Clause 7.1.5 – Monitoring and measuring resources

- "Equipment" has been replaced by "resources",
- Resources include work tools, human resources, test methods, software, etc. This may have a big impact for service organisations, which may have previously excluded Clause 7.6 Control of monitoring and measuring equipment.
- Organisations need to determine the suitability of the resources and retain documentary evidence of fitness for their purpose.
- Acknowledgement that professional judgement ,software, etc. may also be a measuring resource
- Less descriptive on calibration.

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Clause 7 – Support

Clause 7.1.6 – Organisational knowledge (new sub-clause)

- Organisations have to determine the knowledge it needs for the operation of its processes and to achieve conformity of products and services.
- Has to obtain and maintain that knowledge, and make available as necessary (internal or external).
- When addressing changing needs or trends, the organisation shall consider current knowledge and determine how to obtain necessary additional knowledge.
- Knowledge is gained by experience, its information that is used and shared, intellectual, lessons learnt from past experience.
- External sources: obtained from customers, external providers, conferences, academia.

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Clause 7 – Support

Clause 7.2 – Competence

- "Competence" replaces "Competence, training and awareness".
- Extension of competence from those whose "work affecting conformity to product requirements" to "affects its quality performance". Includes external resources.
- A note is included to explain applicable actions can include:- provision of training, mentoring, hiring or contracting of competent persons.

Clause 7.3 – Awareness

- Awareness now includes the quality policy, quality objectives, contribution to effectiveness of QMS, benefits of improved quality performance and implications of non-conforming with the QMS requirements.
- There is an increased emphasis on awareness to ensure that everyone knows the implications of not conforming to the QMS.
- An employee who is not aware or untrained represents a potential risk.

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Clause 7 – Support

Clause 7.4 – Communication

- "Communication" replaces "Internal communication", and includes internal and external communications relevant to the QMS.
- Develop a communications plan, which can include a variety of mediums including: briefings, seminars, newsletters, noticeboards, conferences.
- Requires the organisation to determine the what, when, with whom, how, and who communicates.
- Customer communication is addressed in Clause 8.2.1, as it determines the requirements for products and services.

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Clause 7 – Support

Clause 7.5 – Documented information

- The term "documented information" replaces "documentation", "documented procedure" and "records".
- Fewer prescriptive requirements, no requirement for quality manual or documented procedures.
- But documented procedures could be seen as one form of risk control.
- The QMS shall include documented information determined by the organisation as being necessary for the effectiveness of the QMS.
- It does require "documented information to be either maintained (procedure) or retained (record), documented information is mandatory on clauses 4.3, 4.4, 5.2.2, 6.2.1, 7.1.6, 7.2, 7.5.1, 8.1, 8.2.3, 8.3.2, 8.3.3, 8.3.4, 8.3.5, 8.3.6, 8.4.1, 8.5.1, 8.5.2, 8.5.6, 8.6, 8.7, 9.1.1, 9.2, 9.3, 10.2.
- More flexibility on the type of documents, format must be appropriate, can be in any format and on any medium and can come from any source. Documented information must be controlled, as before.

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Support

Complete Questionnaire

- QMS Question D1 to D10
- EMS Question 7.1 to 7.5

Later

- Identify key resources
- Required knowledge
- Key competencies
- Communications plan
- Documented Information

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Clause 8 – Operation

- "Products and services" replaces "product".
- The term "products and services" includes all output categories, hardware, services, software and processed materials.
- Deals with the execution of the plans and processes.

Clause 8.1 – Operation planning and control

- "Product realisation" has been replaced with "operation".
- There are a number of new requirements:-
  - inclusion of action to address risk and opportunity,
  - addressing control of planned changes,
  - reviewing consequences of unintended changes,
  - taking action to diminish adverse effects.

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Clause 8 – Operation

Clause 8.2 Requirements for products and services

Clause 8.2.1 - Customer communication

- Includes the handling and treatment of customer property, if applicable.

Clause 8.2.2 Determination the requirements for products and services

- Rewording.
- Organisation has the ability to meet the claims for the product and services it offers.

Clause 8.2.3 - Review of the requirements for products an services

- Rewording.
- New note: Requirements can also include those arising from relevant interested parties.

Clause 8.2.4 - Changes to requirements for products and services

- Organisation shall ensure that relevant documented information is amended, and that relevant persons are made aware of the changed requirements, when the requirements for products and services are changed.

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Clause 8 – Operation

Clause 8.3 – Design and development of products and services

- "Design and development" changed to "Design and development of products and services".

Clause 8.3.1 – General (New sub clause)

- The organisation shall establish, implement and maintain a design and development process that is appropriate to ensure the subsequent provision of products and services.

Clause 8 – Operation

Clause 8.3.2 – Design and development planning

- There are a number of new items to be considered:-

- the nature, duration and complexity of the activities,
- Internal and external resources needed,
- The requirements for subsequent provision of products and services
- the need for involvement of customer and user groups,
- the necessary documented information to confirm that requirements have been met.

Clause 8.3.3 – Design and development inputs

- There are a number of new items to be determined:-

- standards or codes of practice that the organisation has committed to implement,
- Information derived from previous similar design and development activities,
- Internal and external resources needed,
- Potential consequences of failure due to the nature of the product or service,

Clause 8 – Operation

Clause 8.3.4 – Design and development controls

- Combines three clauses of ISO 9001:2008, "Design and development review", "Design and development verification" and "Design and development validation".

Clause 8.3.5 – Design and development outputs

- Includes or reference monitoring and measurement requirement.
- Shall retain documented information resulting from the design and development process.

Clause 8.3.6 – Design and development changes

- "Control of design and development changes" replaced by "Design and development changes".
- Shall review and control changes made to design inputs and outputs, to the extent that there is no adverse impact on conformity to requirements.

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Clause 8 – Operation

Clause 8.4
Control of externally provided processes, products and services

- Externally provided / provider replaces purchasing, purchased and suppliers.
- Acknowledges the trend towards greater use of subcontractors and outsourcing

Clause 8.4.1 – General

- Controls are to be provided for the following:-
  - products and services that are provided by external providers for incorporation into the organisation's own products and services,
  - products and services that are provided directly to the customer by the external provider on behalf of the organisation,
  - outsourcing a process or function or part of a process or function to an external provider.
- External provision, includes associated companies

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Clause 8 – Operation

8.4.2 – Type and extent of control

- Organisations shall:-
- Ensure that externally provided processes remain within the control of its QMS
- Define both the controls that it intends to apply to an external provider and those it intends to apply to the resulting output,
- Consider the potential impact of the externally provided processes, products and services on its ability to consistently meet customer and statutory and regulatory requirements,
- Consider the effectiveness of the controls applied by the external provider,
- Determine the verification, or other activities, necessary to ensure that the externally provided processes, products and services meet requirements.

8.4.3 – Information for external providers

- Replaces "Purchasing information".
- Includes :- Communicating the control and monitoring of the external provider's performance to be applied by the organisation.

Clause 8.4 –
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 & services

An outsourced process is any value-adding or conversion activity related to your product or service, that is performed by an external organisation (subcontractor, sister facility, etc.). The external organisation may perform the outsourced activity at their facility or yours.

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

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Externally provided processes, products & services

You must be able to demonstrate sufficient controls over outsourced processes to ensure that such processes are performed according to the relevant requirements of ISO 9001:2015.

The nature and scope of such control will depend on the nature of the outsourced or subcontracted process and the risk involved.

Outsourced processes may be controlled in any number of ways, e.g., providing the vendor with product specifications; your supplier quality manual that they must meet; asking for inspection and test results or certificates of compliance; validation of outsourced process; conducting product and QMS audits of your vendor; etc.

The expectation here is that you flow down to your vendor, the relevant ISO 9001:2015 requirements that you would have to implement, had you performed the process at your own facility.

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Clause 8 – Operation

8.5 Production and service provision

8.5.1 – Control of production and service provision

- Includes the requirements of ISO 9001:2008 Clauses "7.5.1 Control of production and service provision" and "7.5.2 Validation of processes for production and service provision".
- The requirement for work instructions has been replaced by Documented information.

8.5.2 – Identification and traceability

- No new requirements.

8.5.3 – Property belonging to customers or external providers

- Replaces "Customer property".
- Requires organisations to take care of property from external providers as well as customers.

Clause 8 – Operation

8.5.4 – Preservation

- Replaces Preservation of product.
- Now includes transmission (information, software).

8.5.5 – Post-delivery activities (New sub clause)

- Identify the activities that must be carried out after product or service delivery, such as: warranty, maintenance services, recycling, final disposal.

8.5.6 – Control of changes (New sub clause)

- The organisation shall review and control unplanned changes essential for production or service provision.
- Document: results review, actions taken, and who authorised the change.

Clause 8 – Operation

Clause 8.6 – Release of products and services

- Replaces "Monitoring and measurement of product".
- No new requirements.

Clause 8.7 - Control of nonconforming outputs

- Replaces "Control of nonconforming product".
- No requirement for a documented procedure. But there is a requirement to maintain documented information.
- When dealing with nonconforming product or service, the organisation needs to consider:-
  - segregation, containment, return or suspension,
  - informing the customer,
  - authorise re-provision of the products and services.

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EMS Operations

8.1 Operation planning and control

- Lifecycle perspective requirement added

8.2 Emergency preparedness and response

- Requirement to periodically review after test

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EMS Life Cycle definition

Consecutive and interlinked stages of a product (or service) system, from raw material acquisition or generation from natural resources to final disposal.

(ISO 14001:2015)

EMS Life Cycle definition

The life cycle stages include:

- acquisition of raw materials
- design
- production
- transportation & delivery use
- end-of-life treatment
- final disposal.

EMS Life Cycle Stages

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EMS Life Cycle Perspective

- When determining environmental aspects, the organization considers a life cycle perspective.
- This does not require a detailed life cycle assessment; thinking carefully about the life cycle stages that can be controlled or influenced by the organization is sufficient.

(ISO 14001:2015)

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EMS Life Cycle Perspective

Life Cycle Stage	Considerations
Pre-Manufacture	Land-use in production of raw materials and vulnerability; logistics – package, transport, etc - of delivery to factory; supply route vulnerability
Product Manufacture	Energy & water consumption; waste; litter, vibration, noise, odours, lighting
Product delivery	Packaging; routes to market; interim warehousing
Product Use	Energy consumption; components & servicing
Refurbishment, Recycling, Disposal	Ease of recovery of product; dismantlability/separation of components and recovery of valuable materials; safe disposal

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

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 14004:2015** does mention **life cycle perspective** with respect to the requirement relating to **context** as outlined in section 4.1.

EMS Life cycle perspective

When determining environmental aspects and associated impacts consideration to be given to a life cycle perspective where relevant

EMS Life cycle perspective

Consistent with a life cycle perspective environmental requirements will be considered in:

- Design and development processes
- Procurement of products and services
- Communication with external provider including contractors
- With respect to transportation, delivery, end of life and disposal of its products & services

Operations

Complete Questionnaire

- QMS Question E1 to E11
- EMS Question 8.1 & 8.2

Later

- Change control process / procedure
- External Providers controls
- Identify Process Risk
- Update design process / procedure
- service industry to address design & development if applicable.
- Address post-delivery activities

Clause 9 – Performance Evaluation

Clause 9.1 – Monitoring, measurement, analysis and evaluation

- More emphasis on monitoring and measurement.
- Requirement for performance indicators for the QMS.
- Organisations need to plan, how and when they're going to monitor, measure, analyse, and evaluate their QMS.
- And then implement their monitoring and measurement activities.
- Organisations must show how the analysis and evaluation of data is used, with regards to the need for improvements to QMS.
- A key tool in driving the QMS is to enhance customer satisfaction.

Clause 9.2 – Internal audit

- No requirement for documented procedure.
- Some slight modifications to the requirements.
- Take into consideration changes to the organisation.

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Clause 9 – Performance Evaluation

Clause 9.3 – Management Review

Looks at whether the management system is suitable, adequate and effective, items to be reviewed under management review include:-

- Take into consideration strategic direction of the organisation,
- Changes in external and internal issues relevant to QMS,
- Trends and indicators for: customer satisfaction, issues concerning external providers and other relevant interested parties, adequacy of resources, process performance and conformity of products and services,
- Effectiveness of action taken to address risk and opportunities,
- New potential opportunities for continual improvement.

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EMS Performance Evaluation

9.1.2 Evaluation of compliance

- Frequency
- Evaluation
- Maintain knowledge

Performance Evaluation

Complete Questionnaire

- QMS Question F1 to F7
- EMS Question 9.1 to 9.3

Later

- Set performance indicators for QMS
- Monitor, measure, analyse & evaluate QMS
- Update management review requirements

Clause 10 – Improvement

Clause 10.1 – General (New sub clause)

- Contains requirements from clause 8 of 9001:2008, pays more attention to improvement, includes improvement to processes, product or service and QMS.
- Select opportunities for improvement – meet customer requirements and enhance customer satisfaction.

Clause 10.2 – Nonconformity and corrective action

- Does not include a clause on Preventive action as an emphasis on risk-based thinking throughout the standard supersedes a single clause on preventive action.
- Additional requirements include, taking action to control and correct nonconformity and address the consequences, determining if similar nonconformities exist or could happen, making changes to QMS if necessary.
- Need a proactive corrective action process.

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Clause 10 – Improvement

Clause 10.3 – Continual improvement

- The organisation shall continually improve the suitability, adequacy and effectiveness of the QMS.
- Determine opportunities for improvement and implement actions to achieve intended outcomes
- Areas of underperformance or opportunities shall be addressed as part of continual improvement.
- The organisation shall select and utilise applicable tools and methodologies for investigation of the causes of underperformance and for supporting continual improvement.
- Need to be able to demonstrate that outputs from analysis & evaluation processes are used to make changes to the QMS if necessary

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Improvement

Complete Questionnaire

- QMS Question G1 to G4
- EMS Question 10.1 to 10.3

Later

- Select opportunities for improvement
- Address areas of underperformance
- Make changes to management system if necessary

Section H QMS Questionnaire
Section 11 EMS Questionnaire

- Complete only if you are already registered to ISO 9001:2008 / ISO 14001:2004, and you are upgrading to ISO 9001:2015 / ISO 14001:2015

- If for any reason you are not approved for upgrade at a reassessment audit then you need to maintain registration to ISO 9001:2008 / ISO 14001:2004

Guidance

- ISO 9000:2015 Quality management systems -Fundamentals and vocabulary
- ISO 9001:2015 Quality management systems –Requirements
- ISO/TS 9002:2016 Quality management systems – Guidelines for the application of ISO 9001:2015
- ISO 9001:2015 for Small Enterprises (What to do?)
- Correlation matrices between ISO 9001:2008 and ISO 9001:2015

  (This is available along with other information from the link below)

  www.iso.org/tc176/sc02/public.

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Guidance

I.S. EN ISO 14001:2015

-Annex A – Guidance on use
-Annex B – X-reference 2004 /2015

I.S. EN ISO 14004:2016
Practical guide

ISO 14001:2015 - A Practical Guide

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Guidance

Here is a link to the ISO/TC 207 site which will give you information on ISO 14001:2015 and related issues.

- https://committee.iso.org/sites/tc207sc1/home/projects/published/iso-14001---environmental-manage/iso-14001-interpretation.html

Standard related to ISO 14001 which is being revised:

- ISO/14005 Environmental management systems -- Guidelines for the phased implementation of an environmental management system, including the use of environmental performance evaluation

In relation to EMS, the following new standards are being developed:

- ISO/14006 Environmental management systems -- Guidelines for incorporating eco-design
- ISO/14007 Environmental management -- Determining environmental costs and benefits – Guidance
- ISO/CD 14008 Monetary valuation of environmental impacts from specific emissions and use of natural resources -- Principles, requirements and guidelines

EMS standard published in 2016

- ISO 14004:2016 Environmental management systems -- General guidelines on implementation

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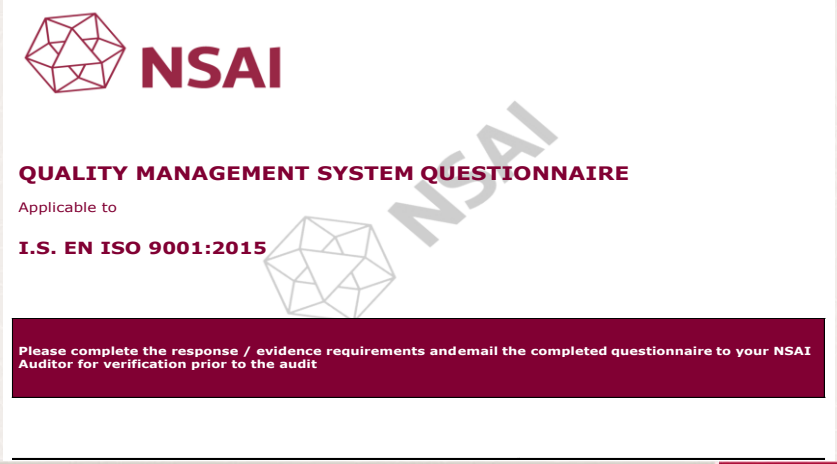
QMS Questionnaire



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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

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EMS Questionnaire

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ENVIRONMENTAL MANAGEMENT SYSTEM QUESTIONNAIRE

Applicable to

I.S. EN ISO 14001:2015

Return completed:

Section 1: EMS Technical Questionnaire
For completion prior to registration or upgrade to 14001:2015.

(To be reviewed for accuracy and updated as appropriate at reassessment.)

Section 2: EMS Requirements Checklist
For completion by all clients.

Section 3: EMS Three Year Summary
For completion when the audit is a three year re-assessment

with any other relevant information to:

Certification Services
NSAI
1 Swift Square
Northwood
Santry
Dublin 9

For North American Applications:

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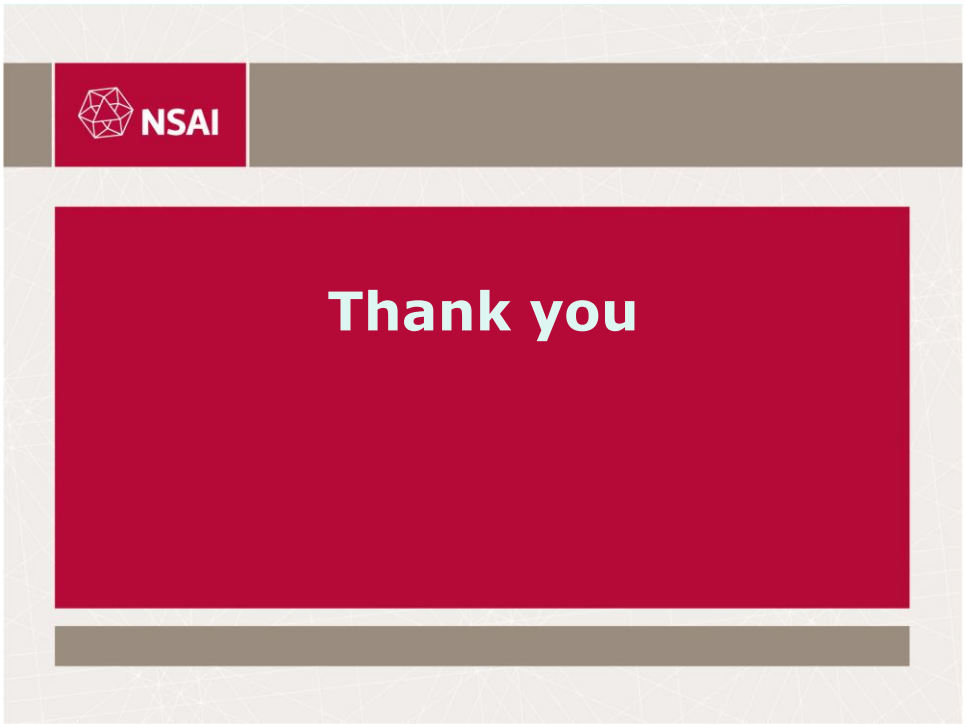
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Thank you