ISO 9001:2015 Auditing to

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Certification Services

QMS Questionnaire

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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

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9001:2015 Process Clause Matrix

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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

CONTENT

- High Level Structure (HLS)
- Context Of the Organisation
- Process approach
- The emphasis on Leadership
- The focus on Risk-based thinking
- Quality objectives
- How Change is addressed
- Communication
- Documented information
- Design and Development
- Externally provided Processes, Products, Services
- Post-delivery activities
- Performance evaluation

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High Level Structure

The High Level Structure (HLS) is a standardized way of drafting future ISO management system standards

All new standards should respect and share a common consistent core:

- A common framework (table of contents, chapters, etc.)
- Standardised text
- Shared clauses and titles
- Common terms and definitions

Whilst the high level structure cannot be changed, sub-clauses and discipline-specific text can be added.

With the new structure applicable to all new ISO management systems standards it will be much easier to implement multiple, integrated management systems

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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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Context of the Organisation

- Understanding the context of the organisation:-
  - Shareholders / Interested Parties needs and expectations
  - Risk Criteria – avoid, take, treat, tolerate, eliminate, transfer, share
  - Establish Objectives – customer, internal, statutory, profit level, etc.
  - Strategic planning – strategy, direction, decision making, resources

- There are relevant internal and external issues that can affect, either positively or negatively, your organization on its ability to achieve the intended results of your QMS.

- The intention of this clause is to highlight the importance of determining which internal and external issues could have a major impact and therefore should be monitored and reviewed on a regular basis, as the issues can change

- The understanding of these issues is necessary to provide the foundation for determining key QMS elements such as the scope of the quality management system (see 4.3), the processes (see 4.4), the policy (see 5.2), planning, objectives, risks and opportunities (see 6.1).

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Context of the Organisation

Internal issues:

- Overall performance of the organization, including financial results
- Resource factors, including infrastructure, environment for the operation of the processes, organizational knowledge
- Human aspects such as competence of persons, organizational culture, relationships with unions
- 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 issues:

- 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

Need to identify / demonstrate:-

- Evidence of strategic planning, market research, benchmarking
- Does it drive your vision, mission, quality policy, strategic planning, business objectives, etc.
- Can you demonstrate how you are monitoring and reviewing information about these external and internal issues
- Who sets the policies and strategic directions?
- Who co-ordinates and manages the operations?
- Who is involved in production, service and support?
- Is the structure of the organisation defined?
- Have the outsourced functions been identified

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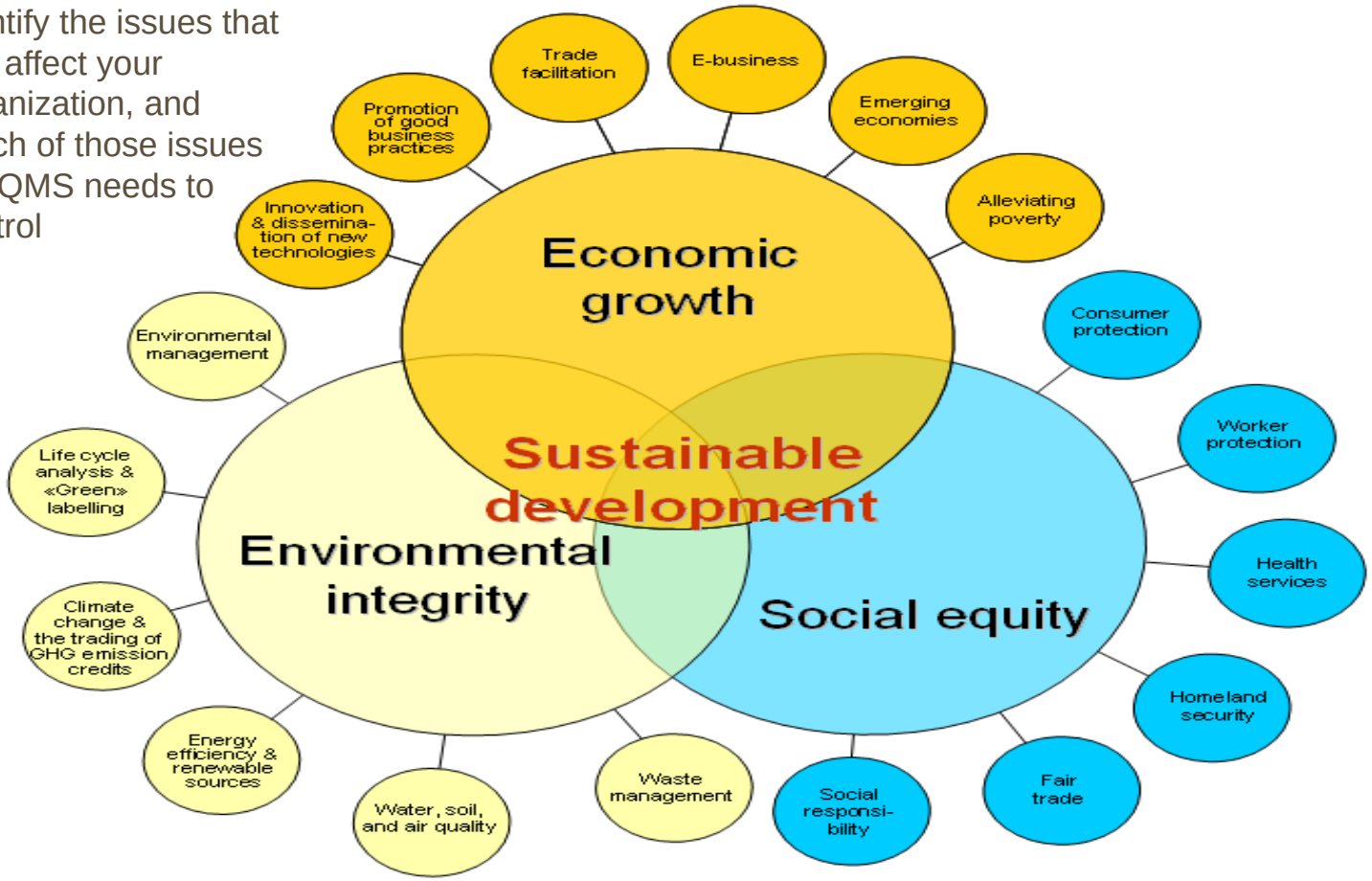
Context of the Organisation

- 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 SWOT

Context of the Organisation

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



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.

- You should be aware that the relevant interested parties and their relevant requirements may be dynamic, and that you should monitor and review them on a regular basis.

Interested Parties

Examples of such interested parties include:

- customers
- end users or beneficiaries
- owners, shareholders
- bankers
- external providers
- employees and others working on behalf of the organization
- legal and regulatory authorities (local, regional, state/provincial, national or international)
- parent and subsidiary organizations
- trade and professional associations
- local community groups
- non-governmental organizations
- local neighbouring organizations/activities in the locality
- competitors

Interested Parties

Some examples of interested party requirements include:

- customer requirements regarding things such as conformity, price,
- contracts with customers or external providers
- conformity to industry codes and standards
- agreements with community groups or non-governmental organizations
- legislation
- memoranda of understanding
- permits, licences or other forms of authorization
- orders issued by regulatory agencies
- treaties, conventions and protocols
- agreements with public authorities and customers
- organizational requirements
- voluntary principles or codes of practice
- voluntary labelling or environmental commitments
- obligations arising under contractual arrangements.

Interested Parties

Interested party	Needs and expectations
Customers	Quality, price, & delivery of products and services
Owners/Share Holders	Sustained profitability Transparency
People in the organization	Good work environment Job security Recognition and reward
Suppliers & partners	Mutual benefit and continuity
Society	Environmental protection Ethical behaviour Compliance with statutory and regulatory requirements

Interested Parties

Need to identify / demonstrate:-

- Relevant interested parties
- Requirements of interested parties (needs & expectations)
- Interested parties requirements addressed in the QMS
- Relevant requirements of interested parties are monitored and reviewed

Scope of the QMS

In determining the scope of the QMS, you need to addresses context-related issues (see 4.1), relevant requirements from relevant interested parties (see 4.2), 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 clause 8.5.3 are not applicable because it 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
- 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

Need to identify / consider / demonstrate:-

The scope of the organisation's QMS shall be available and be maintained as documented information

The scope shall state the types of products and services

Identify any significant process that is outsourced

Consider the requirements of external and internal issues (4.1), interested parties (4.2)

Provide justification for any requirement that is has determined is not applicable to the scope of QMS

Identifies all applicable sites / locations

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 in the 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 approach

When addressing risks and opportunities, you should use risk-based thinking to establish, implement, maintain and improve the QMS and its associated processes, to:

- decide how risk (positive or negative) is addressed in the design of processes to improve process outputs and prevent undesirable results
- improve the effectiveness of the management system
- maintain and manage a system that inherently addresses risk and delivers objectives
- The outputs of the activities listed above may include process flow maps (sequences, interrelationships and authorities or responsibilities, risks and defined criteria) and quality management system performance data, variation control, indicators.

Process approach

Need to identify / demonstrate:-

- Processes
- Inputs requires and outputs expected
- Determine sequence and interaction
- Resources needed
- Monitoring and measurement
- Identify process risk and opportunities
- Evaluate and implement changes as necessary
- Improve the processes
- Documented information to support processes

Assembly Process Model

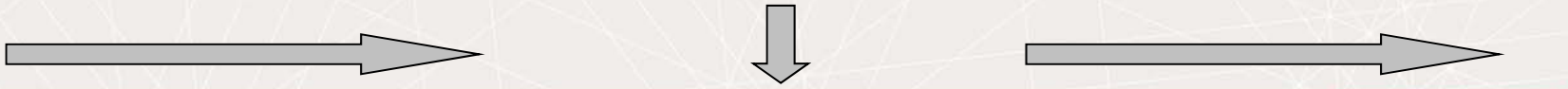
A different example is shown below for an assembly process; this would be repeated for all the other processes in the organisation.

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

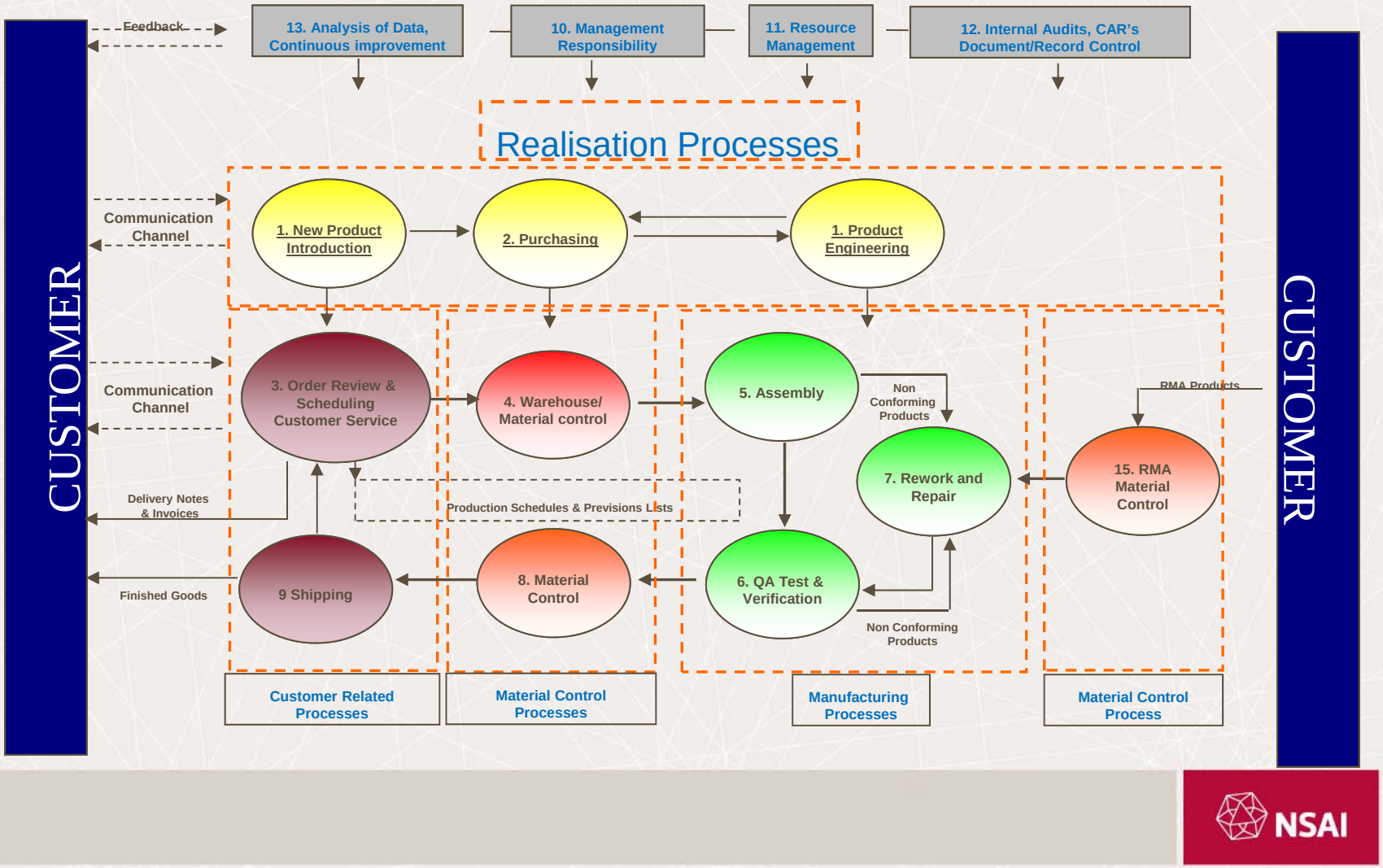
From Process	Inputs	Assembly Process	Outputs	To Process
QA Test	Quality Plan Records		Assembled Products	QA Test
Material Control	Materials		Quality Plan Records	QA Test
Product Engineering	Drawings		Completed Control Charts	Data Analysis
Product Engineering	Machine Programs		Non-conforming products	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%

Process Interaction



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Emphasis on Leadership

- Top management is defined in ISO 9000:2015 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.

Customer Focus

- This clause emphasizes where the inputs to your QMS should come from. It also makes it clear that, irrespective of who actually undertakes the interactions with customers, it is the responsibility of top management to make certain that these requirements are understood and that the necessary resources are available.

- The intent of the requirement is to ensure that top management visibly demonstrates leadership and commitment (e.g. leading by example) in maintaining focus on meeting customers' requirements and enhancing customer satisfaction.

Emphasis on Leadership

Need to identify / demonstrate:-

- To what extent are quality management responsibilities delegated to management representative / quality manager.
- Quality policy and quality objectives are compatible with the context and strategic direction of the organisation
- Ensuring that the QMS and the BMS are integrated
- Greater involvement of top management in the QMS
- Adequate resources provided
- Promoting improvements
- Leadership and commitment with respect to customer and statutory and regulatory requirements, risk and opportunities
- All managers including senior managers and MD must have involvement and understand their roles and responsibilities in line with quality

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*

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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 (see 5.1.1), 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

Need to identify / demonstrate:-

- **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*

Quality objectives

Establishing objectives and planning how to achieve them can help your organization to accomplish its business goals. You should set quality objectives at process or function levels, as appropriate, to ensure implementation of the strategic direction and the quality policy.

The objectives should:

- be consistent with the quality policy
- be measurable, for example specifying a period of time or a defined quantity that needs to be achieved.

You should:

- identify who is responsible for achieving specific objectives
- ensure sufficient resources are made available
- decide how the results will be evaluated.

Quality objectives

Need to identify / demonstrate:-

Objectives:

- are monitored and/or reviewed for progress being made in achieving the objective:
- address applicable requirements and be relevant to conformity of products and services and enhanced customer satisfaction
- are communicated as necessary;
- are updated as appropriate;
- are set and measured using suitable techniques, such as SMART (setting objectives that are Specific, Measurable, Achievable, Relevant and Time-bound), balanced score cards, or dashboards.
- Maintain documentary information on the quality objectives

You and your organization are required to maintain documented information on quality objectives. It is good practice to evaluate performance in order to determine if they are being achieved. Objectives should be updated or added to as necessary, to reflect any changes implemented.

How Change is addressed

New requirements for Change are referenced in:-

- 6.3 *Planning of changes*,
- 8.1 *Operational planning and control*,
- 8.3.6 *Design and development changes*
- 8.5.6 *Control of changes*.

Other references to change are in clauses; 4.4, 5.3, 9.2, 9.3, 10.2

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.

These changes can be related to any element of the process, such as inputs, resources, persons, activities, controls, measurements, outputs, etc.

How Change is addressed

To achieve the benefits associated with changes, the organization should consider all types of changes that can impact your QMS and its ability to consistently provide products and services that meet customer and other requirements or its aims to enhance customer satisfaction.

Changes can include, for example:

- Processes (inputs, activities, outputs, controls, etc.)
- Documented information
- Tooling / Equipment / Inspection
- Employee training / improving competence
- Supplier selection / Supplier management / Outsourcing
- The transfer of new production lines from one site to another
- Changing process methods to improve trends in non- conforming outputs
- Using new computer software systems for a service / process
- Moving to online ordering.

How Change is addressed

- There are many reasons that can cause a change to the QMS:
  - Customer complaint
  - Product failure
  - Employee feedback
  - Innovation
  - External provider (e.g. delivery delays or quality issues)
  - Internal issue (e.g. critical equipment failure, recurrent nonconforming outputs)
  - external issue (e.g. new or modified customer or regulatory requirements).
  - Determined risk / opportunity
  - Internal audit results
  - Management review results

How Change is addressed

Need to identify / demonstrate:-

- 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
- 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.

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Communication

You have to decide what to communicate. Some things are mandatory e.g. the quality policy (see 5.2.2) and organizational roles, responsibilities and authorities (see 5.3.3) others are suggested e.g. the needs and expectations of interested parties (see 4.2) quality objectives (see 6.2) and customer satisfaction (see 9.1.2).

You should think carefully who you communicate with. Obvious are your staff, suppliers and customers; but you should also consider what are called "relevant interested parties" e.g. regulators, your local community, trade associations, local government, competitors.

There are many communication channels available: the traditional (department meetings, round table meetings, lunch and learn sessions, newsletters, posters, flyers, advertising) and the new (emails, texts, websites, blogs, social media).

You should also pay particular attention to any documented information such as advertising, blogs, or websites that relate to claims for the products and services you offer

Communication

Need to identify / communicate / demonstrate:-

- That the following have been communicated to relevant people: the quality policy (see 5.2.2) and organizational roles, responsibilities and authorities (see 5.3.3),
  others are suggested e.g. the needs and expectations of interested parties (see 4.2) quality objectives (see 6.2) and customer satisfaction (see 9.1.2).

- Establish a communication process – Covering what, when, with whom, how and who will communicate, internally & externally

- Retain records, *as appropriate*

Documented information

Previously ISO 9001:2008 differentiated between documents and records. Now, the requirements are to "maintain documented information" and to "retain documented information". The term "documented information" covers the entire range of different types of information that you create, use and keep regardless of the purpose or the media.

Fewer prescriptive requirements, no specific requirement for quality manual or documented procedures. The QMS shall include documented information determined by the organisation as being necessary for the effectiveness of the QMS.

Your existing documented information might be adequate. How you identify and describe your documented information is up to you. If someone looks at a piece of documented information and knows that it is correct, complete and current, then it is probably sufficient.

The important issue is that your people have the information they need to do their job.

Documented information

The following list is not exhaustive or inclusive, but indicates some of the many different forms documented information may take:

- plans, schedules and agendas
- contracts, test results, meeting minutes
- procedures
- work/operating instructions
- user manuals
- statutory/regulatory requirements
- industry standards
- CAD/CAM files
- computer programs/mobile apps
- preferred external provider lists
- specifications, designs, drawings.

Documented information

Need to identify / demonstrate

Documented information needed to be ***maintained*** by the organization for the purposes of establishing a QMS these include:

- The scope of the quality management system (clause 4.3).
- Documented information necessary to support the operation of processes (clause 4.4).
- The quality policy (clause 5.).
- The quality objectives (clause 6.2).
- Document information of external origin necessary for operation of QMS
- This documented information is subject to the requirements of clause 7.5. (creating, updating, control)
- documented information determined by the organization as being necessary for the effectiveness of the quality management system

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Documented information

Documented information needed to be ***retained*** by the organization for the purpose of providing evidence of result achieved (records). These include:

- Documented information to the extent necessary to have confidence that the processes are being carried out as planned (clause 4.4).
- Evidence of fitness for purpose of monitoring and measuring resources (clause 7.1.5.1).
- Evidence of the basis used for calibration of the monitoring and measurement resources (when no international or national standards exist) (clause 7.1.5.2).
- Evidence of competence of person(s) doing work under the control of the organization that affects the performance and effectiveness of the QMS (clause 7.2).
- Results of the review and new requirements for the products and services (clause 8.2.3).

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Documented information

- Records needed to demonstrate that design and development requirements have been met (clause 8.3.2)
- Records on design and development inputs (clause 8.3.3).
- Records of the activities of design and development controls (clause 8.3.4).
- Records of design and development outputs (clause 8.3.5).
- Design and development changes, including the results of the review and the authorization of the changes and necessary actions (clause 8.3.6).
- Records of the evaluation, selection, monitoring of performance and re-evaluation of external providers and any and actions arising from these activities (clause 8.4.1)
- Evidence of the unique identification of the outputs when traceability is a requirement (clause 8.5.2).

Documented information

- Records of property of the customer or external provider that is lost, damaged or otherwise found to be unsuitable for use and of its communication to the owner (clause 8.5.3).
- Results of the review of changes for production or service provision, the persons authorizing the change, and necessary actions taken (clause 8.5.6).
- Records of the authorized release of products and services for delivery to the customer including acceptance criteria and traceability to the authorizing person(s) (clause 8.6).
- Records of nonconformities, the actions taken, concessions obtained and the identification of the authority deciding the action in respect of the nonconformity (clause 8.7).
- Results of the evaluation of the performance and the effectiveness of the QMS (clause 911)

Documented information

- Evidence of the implementation of the audit program and the audit results (clause 9.2.2).
- Evidence of the results of management reviews (clause 9.3.3).
- Evidence of the nature of the nonconformities and any subsequent actions taken (clause 10.2.2).;
- Results of any corrective action (clause 10.2.2).
- documented information determined by the organization as being necessary for the effectiveness of the QMS

Design and development

It is important for you to analyse and determine if this clause is applicable to your organization. If your organization does not perform design and development, and it is not responsible for these processes, you need to carefully review all the requirements in clause 8.3 and identify which are not applicable. You will need to prepare a justification for any that are not applicable and provide details of them in the scope of your QMS

It is important to realize that service organizations have to design their services, and that this may overlap with the development of their service delivery processes. For example, a financial institution might design and develop the services it offers its clients in relation to managing their stock portfolios, or educational institutions design and develop their curricula.

Design and development

Need to identify / demonstrate

- Need to identify if design and development is applicable, if not you need to clearly justify that decision.
- Design and Development outputs include or reference monitoring and measurement requirements, and acceptable criteria.
- Retain documented information resulting from the design and development process, including:- to be able to demonstrate that the D & D requirements have been met, inputs, controls, outputs, and changes.

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

Need to identify / demonstrate

- Have you decided on the appropriate level of control of an outsourced process.
- Outsourced processes will interact with other processes from your QMS. Have these internal processes been identified and are these interactions managed.
- You need also to monitor the performance of your external providers, to ensure that they still meet the original evaluation and selection criteria or any new/revised criteria.
- Retain documented information on criteria for evaluation, selection, monitoring of performance and re-evaluation of external providers.

Post-delivery activities

The intent of this clause is to ensure the organization fulfils relevant requirements after a product or service is delivered, recognizing that delivery does not end an organization's responsibility.

Many products and services are sold with a commitment to provide post-delivery maintenance and support as part of the overall contract. This clause applies in such instances.

You should be aware that commitments made as part of a warranty also form part of the contract and again this clause is relevant.

One example of post delivery service activities is a computer retailer who provides a technical support service by telephone.

Another example can be an electronic equipment distributor that provides a complimentary service to support their customers for managing guarantees.

Also, an insurance agent can establish a process to aid and support his/her customers when they need to apply insurance (e.g. car accident, medical emergency).

Post-delivery activities

Need to identify / demonstrate post-delivery activities:-

- engagement with customers to confirm if the products or services were to their satisfaction;
- on-site installation of equipment and disposal of a customer's old equipment;
- contractual arrangements such as warranties or technical support;
- customer access to on-line information related to the delivery of a product or service, e.g. status of flights; frequently asked questions (FAQs).

Performance evaluation

This clause requires the organization to determine what needs to be monitored and measured and the methods to be used to analyse and evaluate the performance and effectiveness of the quality management system.

When determining what needs to be monitored and/or measured, the organization should consider the actions required in other clauses, such as for establishing the quality management system and its processes (see 4.4), operational planning and control (see 8.1), customer satisfaction (see 9.1.2), analysis and evaluation (see 9.1.3), internal audits (see 9.2) and management review (see 9.3).

The organization should also determine how the monitoring, measurement, analysis and evaluation will be carried out, and the resources (see 7.1.5) that will be needed. The organization should decide on what documented information will need to be retained as evidence of the results.

Performance evaluation

Need to identify / demonstrate

- What the organisation has determined what is needed to be monitored and measured and the frequency of monitoring and measurement.
- The methods to be used to analyse and evaluate the performance and effectiveness of the QMS.
- That adequate resources are available for monitoring and measurement
- to determine the performance and effectiveness of the QMS and any action needed to improve the QMS.
- Obtaining customer satisfaction feedback, analyse and evaluate results, and take action based on feedback.
- Maintain documented information needed to be retained as evidence of results

Thank you

Questions later