ISO 9001 Quality Manual

ISO 9001

COMPANY NAME

Authored by: Your Name

Online ISO

Revision History

Revision	Date	Record of Changes	Approved by

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1. Introduction

<Short Name> has developed, implemented and maintains a quality management system (QMS), which allows us to:

- document and improve our operations in order to better satisfy the needs and expectations of our customers, stakeholders and interested parties
- demonstrate our ability to consistently provide products and services that meet both the needs of our customers and our compliance obligations
- drive improvement and thereby enhance the satisfaction of our customers

This manual describes our QMS and sets out the authorities and responsibilities of staff operating within it, as well as referencing those procedures and activities that fall within its scope.

1.1 ISO 9001:2015

Our QMS has been developed in compliance with the ISO 9001:2015 standard and adopts a process approach to enhancing customer satisfaction by meeting customer requirements.

Understanding and managing our interrelated processes as a system enables us to control the interrelationships and associated interdependencies so that our overall performance is enhanced.

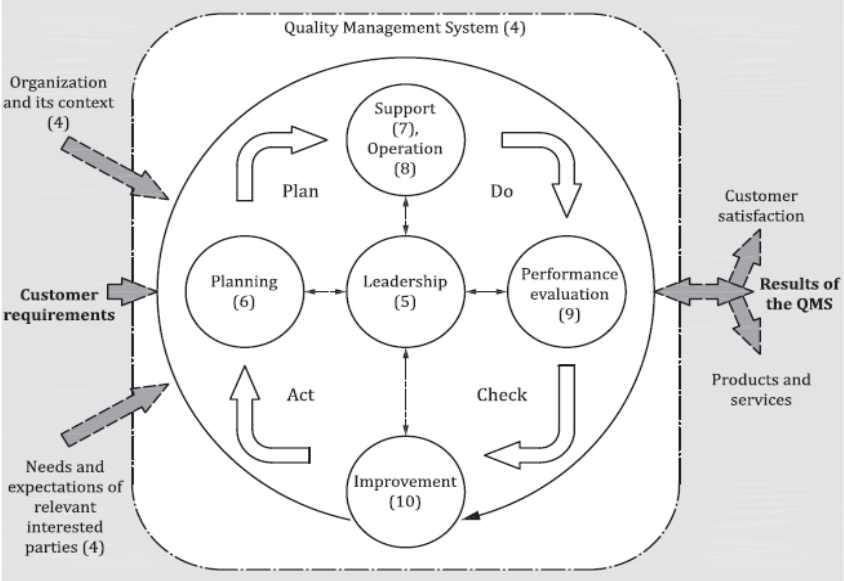
The process approach involves the systematic definition and management of processes, and their interactions, so that we achieve our intended results in accordance with our Quality Policy and strategic direction.

1.2 Plan-Do-Check-Act (PDCA) cycle

Management of the processes and the system as a whole is achieved using the Plan-Do-Check-Act (PDCA) cycle with an overall focus on using risk-based-thinking to take advantage of opportunities and prevent undesirable results.

The application of the process approach in a quality management system enables:

- understanding and consistency in meeting requirements
- the consideration of processes in terms of added value
- the achievement of effective process performance, and
- improvement of processes based on evaluation of data and information



Note: Numbers in brackets refer to the ISO9001:2015 clauses.

2. References

Standard	Title	Description
ISO 9000:2015	Quality Management Systems	Fundamentals and Vocabulary
ISO 9001:2015	Quality Management Systems	Requirements
ISO 9004:2000	Quality Management Systems	Guidelines for Performance Improvements
ISO 19011:2011	Auditing Management Systems	Guidelines for Auditing

3. Terms and Definitions

The terminology used in our QMS reflects both that used in ISO 9001:2015 and:

- standard business/quality terminology
- terms and vocabulary typically used within our scope of activity
- terms typically used in standards and regulations as they relate to our scope of activity

Definitions:

- “compliance obligations” means both those laws and other requirements, be they national or international, that apply to us as an organisation plus any other commitments we enter into, or apply voluntarily, such as contracts, agreements, codes, and standards
- “Top Management”, as referred to by ISO, is represented in <Short Name> by the <Senior Management Team>
- “staff” are all those working under our control
- “we” and “our” refer to <Short Name>

4. Business Context

4.1 Understanding our business, and understanding the needs and expectations of interested parties

To fully understand our business we identify all key internal and external issues that are relevant to our operations and which affect our ability to achieve the intended outcomes of our quality management system.

This involves:

- understanding our core products/services
- understanding the scope of our QMS
- identifying those interested parties ("stakeholders") who receive our products/services, or who may be impacted by them, or who may otherwise have a significant interest in our business
- Identifying and understanding those internal and external issues of concern that impact on our activities/stakeholders

Many such issues are identified through an analysis of risks facing either ourselves or our stakeholders.

Our stakeholders and relevant internal and external issues are identified and monitored as part of quality management reviews and updated as necessary.

The methodology we employ to achieve this understanding is set out in our **QMS Identification of Quality Context Procedure** and the results are recorded in our **Quality Context Log**.

4.2 Scope of our quality management system

4.2.1 Scope

Our QMS satisfies the requirements of ISO 9001:2015 and addresses and supports our processes for the design, development, manufacturing, installation and servicing of our products.

Insert your scope statement above. This should summarise your products/services in a single sentence. If you intend to subject your system to independent third party certification in due course, this summary will be shown your ISO 9001:2015 certificate.

When determining this scope, we have considered:

- our organisation and its context (both internal and external issues)
- the needs and expectations of interested parties (the requirements), and
- our products and services

4.2.2 Exclusions

The following table identifies any ISO 9001:2015 Section 8 requirements that we have excluded from the scope of our QMS, as they are not applicable to our organisation:

Clause	Reason for Exclusion
8.3	As a contract manufacturer, we do not undertake the design of products

Insert any section 8.0 requirements that don't apply to your organisation in the above table. If you don't exclude any Section 8 requirements, specifically state that, in the first line of the table, "The company claims no exclusions from the ISO 9001 standard".

4.2.3 Business locations within the scope

Our QMS applies to our business activities at:

Address Line 1

Address Line 2

Address Line 3

Address Line 4

Insert the address of your organisation above. If you have multiple sites which are covered by this QMS, then you need to list each site to clarify the scope of the application of the QMS.

4.3 Quality management system and processes

4.3.1 Key Processes

The <Senior Management team> have identified those key high-level processes, which properly monitored and controlled, reduce the potential for us delivering non-conforming products/services.

These key high-level processes are identified, monitored and controlled in such a way that any supporting tasks and/or sub-processes are also effectively implemented and controlled.

As part of our QMS, the following key high-level processes have been identified:

- List process here
- List process here
- List process here

Each key high-level process is documented in a Process Definition Document which includes:

- inputs required and outputs expected
- sequence and interaction of activities
- criteria and methods employed to ensure the effectiveness and control of the process
- resources required and the availability of those resources
- responsibilities and authorities
- risks and opportunities

These processes are regularly reviewed, and consequential changes made, both to achieve improvements and to ensure that they continue to achieve their intended results. Process reviews are recorded and retained.

Include here a process map showing your top level processes and how they interact.

4.3.2 Process documents and records

Each Process has a designated Process Owner, who ensures that Process Definition Documents are maintained in accordance with our **Control of Management System Documentation Procedure**.

We operate and maintain arrangements to ensure that process measurement data is retained as set out in our **Control of Management System Records Procedure**.

5. Leadership

5.1 Leadership and commitment

5.1. General

Our <Senior Management Team> demonstrates leadership and commitment to achieving the objectives of our QMS by taking accountability for the effectiveness of our QMS and ensuring that:

- A Quality Policy and Quality Objectives are established for the management system and that they are compatible with our strategic direction and context
- our QMS requirements are integrated into our business processes as appropriate
- staff are aware of the process approach and risk-based thinking
- our QMS is suitably resourced
- the importance of effective quality management and of conforming to the management system requirements are clearly communicated
- our QMS achieves its intended results
- all staff are encouraged to contribute to the effectiveness of the management system
- continual improvement is actively promoted
- individual performance objectives reflect our policies, objectives and targets

5.1.2 Customer focus

Our <Senior Management Team> adopts a customer-first approach by ensuring that:

- customer and applicable compliance obligations are determined, understood and consistently met
- the risks and opportunities that can affect conformity of products and services and the ability to enhance customer satisfaction are determined and addressed
- customer complaints and other customer feedback are continually monitored and measured to identify opportunities for improvement
- we continually look for ways to interact directly with our customers to ensure that we focus on their unique needs and expectations.

5.2 Quality Policy

The <Senior Management Team> has developed our Quality Policy, which is to:

Add Quality Policy here, for examples just google 'example Quality Policy'

The policy must:

- *be appropriate to the purpose and context of your organisation and support its strategic direction*
- *provide the framework for setting Quality Objectives*
- *include a commitment to satisfy applicable requirements*
- *Include a commitment to continual improvement*

This Quality Policy governs our day-to-day operations to ensure quality and is communicated and implemented throughout our organisation. Our Quality Policy is made available as a stand-alone document and widely distributed, including during induction.

Our Quality Policy is typically reviewed annually, as part of the quality management review programme, or as required to recognise the changing needs and expectations of relevant interested parties or the risks and opportunities identified by the risk management process.

5.3 Organisational roles, responsibilities & authorities

Our <Senior Management Team> has assigned responsibilities and authorities for all roles relevant to the full and proper implementation, operation and maintenance of our QMS. These are communicated through the combination of our Organisation Chart and internal Job Titles.

The <Senior Management Team> has assigned responsibility and authority for:

- ensuring that our QMS conforms to applicable standards
- ensuring that QMS processes are delivering their intended outputs
- reporting on the performance of the management system
- ensuring the promotion of customer focus throughout the organisation
- ensuring that the integrity of our QMS is maintained when changes are planned and implemented

All managers are expected to demonstrate their commitment to the development and improvement of our QMS through:

- the provision of necessary resources
- their involvement in the internal audit process
- their proactive involvement in continual improvement activities
- focusing on the improvement of key system processes

All managers are responsible for the implementation of the policies, processes and systems described in this manual and for planning, controlling and resourcing our QMS processes within their area of responsibility.

All staff are responsible for the quality of their work and implementation of the policies and procedures applicable to processes they perform and are encouraged to identify and report any known or potential problems and to recommend related solutions.

All staff responsible for product quality have the authority to stop production to correct quality problems.

6. Planning

6.1 Addressing risks and opportunities

In creating our QMS, we have identified the risks and opportunities that need to be addressed, based particularly on: *4.1 Understanding our business*, and *4.2 Understanding the needs and expectations of our stakeholders* but also including all other aspects of our QMS. Those risks and opportunities have been addressed to:

- ensure that our QMS can achieve its intended outcomes
- enhance desirable effects
- prevent, or reduce, undesirable effects
- achieve continual improvement

When managing risks and opportunities:

- we consider risks and opportunities when taking actions within our QMS, as well as when implementing or improving our QMS
- formal risk management may not be utilised in all circumstances and the level of risk assessment, analysis, actions and recording will be to a level appropriate to each circumstance
- the actions we take to address risks and opportunities are proportionate to the potential impact on the conformity of products/services
- we follow our **QMS Control of Risks and Opportunities Procedure**

6.2 Establishing and achieving Quality Objectives

Each process has at least one Quality Objective; a statement of the intent of the process. Where required by the nature of the process, it's associated risks and their potential impact on the conformity of products/services, then processes may have multiple objectives.

Each process Quality Objective is supported by at least one "metric" or key performance indicator (KPI) which is measured to determine the process' ability to meet the Quality Objective.

In this context, each "Quality Objective" is also a "process measurement" in ISO 9001 terms.

We may use additional process objectives which do not measure quality and these will also be used to measure process effectiveness.

Metrics data is regularly measured and gathered by process owners or other delegated managers. That data is then presented to, and analysed by, <Senior Management Team> who may change or adjust processes, objectives and/or metrics in order to improve outcomes.

The specific Quality Objectives for each process are defined in the appropriate Process Definition Document.

Quality Objectives and their associated metrics and measurements are presented at each quality management review.

When a process does not meet its objective(s), or an unexpected problem is encountered with a process, our **QMS Control of Corrective and Preventive Actions Procedure** is employed to research and resolve the issue and, wherever possible, improve the process.

6.3 Change management

This manual constitutes our overall plan for establishing, maintaining and improving our QMS.

Whenever changes are to be made to processes, or our QMS, those changes are planned, implemented, and then verified for effectiveness as set out in our **Control of Management System Documentation Procedure**.

The quality management review and the internal audit processes ensure the continuing integrity of our QMS when significant changes are planned.

7. Support

7.1 Resources

7.1. General

The <Senior Management Team> ensures that all necessary resources are available to:

- implement and maintain our QMS
- continually improve its effectiveness
- enhance customer satisfaction through meeting or exceeding customer requirements

Resources and resource allocation are assessed and monitored during quality management reviews.

7.1.1 Human resources

The <Senior Management Team> ensures the provision of sufficient staffing for the effective operation of our QMS and its identified processes.

7.1.2 Infrastructure

The <Senior Management Team> ensures that the infrastructure necessary for the operation of processes and to achieve conformity of our products/services is provided and maintained, including preventative maintenance where appropriate.

Infrastructure includes, as applicable:

- buildings, workplace and associated facilities
- process equipment, including both hardware and software
- supporting services, such as transportation
- information and communication technology

Edit the above list to match your circumstances

The <Facilities Manager> has overall responsibility for managing our facilities and equipment maintenance programmes which include:

- transportation and material handling equipment management, maintenance and repair
- process and production equipment management, maintenance and repair
- facilities management, maintenance and repair

We operate and maintain arrangements to ensure the provision and maintenance of infrastructure as set out in our **QMS Control of Equipment Validation and Maintenance Procedure**.

Edit the above list to match your circumstances

7.1.4 Work environment

The <Senior Management Team> ensures an environment suitable for the operation of its processes, and which achieves conformity of products and services, is provided and properly maintained.

Specific environmental requirements for products and processes are determined and documented during quality planning.

Human factors of the work environment, such as social, psychological and safety aspects are only managed through our QMS where they can directly affect process efficiency or product and service quality.

7.1.5 Monitoring and measuring resources

The <Senior Management Team> ensures the provision of the necessary resources to ensure valid and reliable results whenever monitoring or measuring is used to verify the conformity of products/services to requirements.

The <Quality Manager> determines which equipment will be subject to calibration or verification based on:

- the processes, products and services
- the importance of a measurement
- considerations of risk
- the need to comply with specifications or requirements

We operate and maintain arrangements for calibration and/or verification as set out in our **Control of Calibration and Verification Procedure**.

7.1.6 Organisational knowledge

The <Senior Management Team> ensures the availability of the necessary knowledge for the operation of its processes and to achieve conformity of products/services. This may include knowledge and information obtained from:

- internal sources, such as: experience, lessons learned from both failures and successes, advice from subject matter experts and intellectual property
- external sources such as: standards, academia, conferences, and information gathered from customers or suppliers

To ensure that organisational knowledge is retained and transferred, organisational knowledge is recorded in documented information, and is embedded in our processes, products and services.

Examples include:

- documented information regarding processes, products or services
- previous specifications and work instructions
- our experience and knowledge of the technologies and infrastructure we employ
- the experience of skilled people

When addressing changing needs and trends, we consider our current knowledge and determine how to acquire or access any necessary additional knowledge.

7.2 Competence, Awareness, and Communication

We operate and maintain arrangements to ensure competency, awareness and communication as set out in our **Competency Communication and Awareness Procedure**.

These arrangements ensure that:

- all staff are competent to undertake their tasks
- all staff are aware of:
  - our management system(s) and their related policies and objectives
  - their roles and responsibilities
  - their contribution to the effectiveness of our management system(s)
  - the benefits of improved personal performance
  - the importance of complying with our management systems, policies and procedures
  - the consequences of any departure from our management systems, policies and procedures
  - emergency preparedness and response requirements
  - any management system changes the results of the <Senior Management Team>'s annual review of management system(s) compared to their objectives
- training needs are identified
- appropriate training plans are developed and implemented (with the <HR Manager>)
- each role affecting management system outcomes is recorded in the **Role Profile Register**

In addition to our staff, awareness programmes are also provided for contractors, temporary workers and visitors etc. as appropriate.

7.3 Documentation & records

7.3.1 General

Our QMS documentation includes both documents and records.

The <Senior Management Team> has determined the extent of documented information:

- required by ISO 9001:2015
- necessary for the effectiveness of our QMS

Based on the following criteria:

- the size of our business
- the scope, complexity and interaction of our processes, products/services
- the need to demonstrate fulfilment of our compliance obligations
- the competence of our staff

7.3.2 Control of documents

We operate and maintain arrangements for the control of our QMS documentation as set out in our **Control of Management System Documentation Procedure**.

By means of this procedure we ensure that staff have access to the latest, approved information, and that the use of obsolete information is restricted.

Once established, all documented procedures are implemented and maintained.

7.3.3 Control of records

We operate and maintain arrangements for the identification, storage, retrieval, protection, retention, and disposition of quality records as set out in our **Control of Management System Records Procedure**.

This procedure also defines the methods for controlling records that are created by and/or retained by suppliers. These controls are applicable to all those records which provide evidence of conformance to requirements, such as:

- product/service requirements
- contractual requirements
- procedural requirements
- compliance obligations
- the effective operation of the management system

8. Operations

8.1 Operational planning and control

The <Senior Management Team> ensures that the processes needed to deliver products/services are properly planned and controlled.

Planning includes:

- the determination of requirements
- establishing criteria for processes and the acceptance of products/services
- determining the resources required to achieve conformity to requirements
- identifying and implementing process controls
- determining the necessary documentation to ensure confidence in the process and demonstrate conformity to requirements
- the appropriate control of outsourced processes
- ensuring plans are appropriate for our operational environment

We operate and maintain arrangements to ensure that changes to operational processes are planned and implemented as set out in our **Control of Management System Documentation Procedure**,

8.2 Requirements for products and services

8.2.1 Customer communication

We undertake effective communication with our customers, including:

- providing information relating to products and services
- handling enquiries, contracts or orders, including changes
- obtaining customer feedback relating to products and services, including customer complaints
- handling or controlling customer property
- establishing specific requirements for contingency actions, when relevant

8.2.2 Determining customer requirements

In determining the requirements for the products/services that we offer our customers, we take into account:

- requirements specified by the customer, including any requirements for delivery and/or post-delivery
- requirements not stated by the customer but known to be necessary for the specified or intended use
- relevant compliance obligations
- any additional requirements we determine to be relevant

This process requires clear, and often repeated, customer interaction to fully and properly understand the customer's needs.

8.2.3 Review and acceptance of customer requirements

Once customer product/service requirements are fully defined, the <Sales and Marketing Manager> ensures that customer requirements are reviewed prior to commitment to supply. This review ensures that:

a) product requirements are fully defined

b) contract or order requirements differing from those previously expressed are resolved,

c) the organisation has the ability to meet the defined requirements, and/or the claims for the products and services it offers

d) risks have been identified and considered

Managers may decide that a formal risk assessment is required. Any such risk assessment is recorded and where managers decide to accept certain risks as a function of doing business, this is also recorded.

When a risk assessment is conducted, this is filed with the appropriate requirements information.

If a formal quotation is prepared for the customer this is developed with input from all interested parties and approved as directed by the <Sales and Marketing Manager> before being released to the customer.

Purchase orders and related contracts issued in response to quotations are reviewed as required by the <Sales and Marketing Manager> to ensure that there are no differences between them and the related quotation. If there are differences, those differences are resolved with the customer before acceptance.

8.2.4 Changes to Requirements

Where the customer requests changes to work in progress, the changes are ascertained, reviewed and approved prior to our committing to the change.

All relevant documented information relating to changes in product or service requirements is authorised and amended where necessary, and all relevant personnel are made aware of the changes to documented requirements.

Where difficulties in addressing the change are identified they are shared with the customer and, where necessary, contractual changes sought, agreed and recorded.

8.3 Design and development of products and services

For new products/services or significant changes to products/services we operate and maintain arrangements to ensure an accurate translation of customer needs and requirements into detailed design outputs as set out in our **QMS Control of Design and Design Changes Procedure**.

By means of this procedure we address performance, reliability, maintainability, testability, and safety issues, as well as our compliance obligations, and ensure that:

- planning is properly undertaken
- Inputs are clearly and comprehensively defined
- controls are applied as necessary
- outputs meet input requirements and are adequate for process definition
- reviews, verification and validation are conducted
- changes are made in a controlled manner

8.4 Control of externally provided processes, products and services

8.4.1 Externally provided processes

Any process performed for us by a third party is classified as an 'outsourced process'.

The type and extent of control we apply to the outsourced process takes into consideration:

- the potential impact of the outsourced process on the company's capability to provide product that conforms to requirements,
- the degree to which the control for the process is shared,
- the capability of achieving the necessary control through the purchasing contract requirements.
- our understanding and experience regarding the capabilities and competencies of the supplier

In addition, to ensure that the outsourced process meets our requirements we:

- clearly communicate the roles and responsibilities of the outsourcing supplier
- clearly define the quality requirements for the outsourced process
- establish, in advance, our criteria for acceptance and the frequency of any inspections and audits

8.4.2 Externally provided products and services

We operate and maintain arrangements evaluating, selecting and monitoring suppliers as set out in our **QMS Control of Purchasing and Supply Procedure**.

By means of this procedure we ensure that:

- suppliers are evaluated and selected based on their ability to supply products/services in accordance with our requirements and establish clear criteria for selection, evaluation and re-evaluation
- purchases are made using formal purchase orders and/or contracts containing clear descriptions of our requirements
- products/services received from suppliers are verified against the requirements we supplied and suppliers who do not providing conforming products/services may be requested to undertake formal corrective action

8.5 Provision of products and services

8.5.1 Control of provision of products/services

We implement production/service provision under controlled conditions. Those controlled conditions include, as applicable;

- the availability of documents or records that define the characteristics of the products/and/services as well as the results to be achieved
- the availability and use of suitable monitoring and measuring resources
- the implementation of monitoring and measurement activities
- the use of suitable infrastructure and environment
- the appointment of competent persons, including any required qualifications
- the implementation of actions to prevent human error
- the implementation of release, delivery and post-delivery activities

'special processes' are those processes where the results of the process cannot easily be checked, including any processes where deficiencies become apparent only after the product is in use. The outputs of a special process can typically only be verified by destructive testing or through a method outside of our capability. It is possible that the output of a special process cannot be verified at all.

Should we do require such special processes, we employ validation to demonstrate the ability of these processes to achieve planned results by:

- defining qualification criteria and approval of special processes prior to use
- defining criteria for review and approval of the special processes
- approval of equipment and qualification of personnel
- use of specific methods and procedures
- requirements for records
- statistical sampling and revalidation

8.5.2 Identification and traceability

Where appropriate, we identify our products/services or other critical process outputs by suitable means, including:

- identification that includes the status of the product/service as regards monitoring and measurement requirements
- all products/services are considered conforming unless identified as non-conforming, pending inspection or disposition, or similar
- stored equipment and materials are identified as to type, description and inspection status
- unique identification is provided where required by contract, regulatory, or other requirement
- enquiries are identified with a unique estimate number
- orders are identified by contract number

8.5.3 Property belonging to customers or external providers

We exercise care with customer or supplier property while it is under our control.

Once received, such property, including intellectual property such as data or design, is identified, verified, protected and safeguarded. If any such property is lost, damaged or otherwise found to be unsuitable for use, this is immediately reported to the customer or supplier and records maintained.

In cases where the customer provides drawings, specifications, etc. they are managed as documented information.

If the property requires calibration/preventive maintenance, the responsibilities and methods for such are agreed with the owner and documented.

Where managers deem it appropriate, or the owner requests it, such property shall be physically secured in locked, limited-access areas.

8.5.4 Preservation

We ensure that all products and materials are handled and stored appropriately at all stages of the production cycle to prevent damage or deterioration:

- components and products are handled and stored in a manner that prevents damage or deterioration, pending use or delivery
- controls are implemented to prevent the mixing of conforming and non-conforming materials
- specified or original manufacturing packaging is utilised
- age sensitive material is controlled both before and after issue
- all products are suitably packed to prevent deterioration or damage during storage and delivery

8.5.5 Post-Delivery activities

We establish any post-delivery customer requirements before accepting an order.

Post-delivery customer requirements may include:

- customer requirements previously determined to pertain to a particular product/service
- requirements not stated by the customer but known by us to be necessary for the specified use or intended use
- any compliance obligations related to the product/service
- known requirements for post-delivery activities such as training or product/service support
- any additional requirements determined by <Short Name>

All post-delivery activities are provided in accordance with our QMS.

8.5.6 Control of changes

We operate and maintain arrangements for process change management as set out in our **Control of Management System Documentation Procedure**, and for design change management as set out in our **QMS Control of Design and Design Changes Procedure**.

By means of these procedures we review and control both planned and unplanned changes to processes to the extent necessary to ensure continuing conformity with requirements.

8.6 Release of products and services

The acceptance criteria for each of our products/services are properly documented.

Reviews, inspections and tests are conducted at appropriate stages to verify that all product and service requirements have been met before those products/services are released to the customer.

Each of the processes required for the delivery of our products/services may require different methods of measuring and releasing. These methods are set out in each Process Definition Document.

8.7 Control of non-conforming outputs

We operate and maintain arrangements for managing non-conformances as set out in our **QMS Control of Non-conforming Products Procedure** and **QMS Control of Non-conforming Services Procedure**.

By means of these procedures, we ensure that our products/services, or other process outputs that do not conform to requirements, are identified and controlled to prevent their unintended use or delivery.

If you produce only products or only services then edit this paragraph accordingly.

9. Performance Evaluation

9.1 Monitoring, measurement, analysis and evaluation

9.1. General

In order to evaluate the performance of our QMS, we determine:

- what needs to be monitored and measured
- the methods of monitoring, measurement, analysis and evaluation needed to ensure valid results
- the criteria against which we evaluate our quality performance and various indicators
- when such monitoring, measurement, analysis and evaluation should be undertaken
- when the results from monitoring and measurement are to be analysed and evaluated

These activities are used to evaluate:

- the performance and effectiveness of our QMS
- the effectiveness of actions taken to address risks and opportunities
- the effectiveness of planning
- the performance of external providers
- other improvements to the management system

Measurements, analyses and evaluations are appropriately recorded and communicated.

We operate and maintain arrangements to ensure that all calibrated or verified monitoring equipment and validated software is appropriately used and maintained as set out in our **Control of Calibration, Verification and Validation Procedure**.

9.1.2 Customer Satisfaction

We operate and maintain arrangements to ensure customer satisfaction as set out in our **QMS Control of Customer Satisfaction Procedure**.

In accordance with this procedure we employ a range of techniques to monitor our customer's perceptions of the degree to which their needs and expectations have been fulfilled.

The methods for monitoring include:

- product returns and warranty claims
- repeat customers and market share
- analysis of customer complaints and customer satisfaction surveys
- recommendations, recognition and awards
- growth of key accounts
- analysis of credit notes
- on-time delivery

Our corrective and preventive action system is used to develop and implement plans for customer satisfaction improvement to address any deficiencies identified by this monitoring.

9.1.3 Analysis and evaluation

We analyse a range of appropriate data and information arising from measurement and monitoring.

That analysis is used to evaluate:

- conformity of products and services
- the effectiveness of actions taken to address risks and opportunities
- the degree of customer satisfaction
- the performance and effectiveness of our QMS
- the effectiveness of planning
- the performance of external providers
- other improvements to the management system

9.2 Internal audit

We operate and maintain arrangements for internal auditing at planned intervals as set out in our **Control of Internal Auditing Procedure**.

By means of these audits, we provide information to management and determine whether our QMS:

- conforms to our own requirements
- conforms to the requirements of the ISO 9001
- is effectively implemented and maintained
- is effective in achieving our management system's policies and objectives

9.3 Management review

We operate and maintain arrangements for management review of the suitability, adequacy and effectiveness of our QMS, at planned intervals, as set out in our **QMS Control of Quality Management Reviews Procedure**.

These reviews include assessing our QMS's continuing alignment to our strategic direction, opportunities for improvement, and the need for changes.

10. Improvement

10.1 General

We use our QMS, and other inputs, to continuously improve our processes, products and services. The improvement opportunities we seek include:

- addressing evolving and future needs and expectations
- correcting, preventing and reducing undesired effects
- improving the performance and effectiveness of our QMS

10.2 Non-conformity and corrective action

We operate and maintain arrangements to take corrective action to eliminate and further prevent the cause of any non-conformity, and preventive action so as to eliminate the causes of potential similar non-conformities, as set out in our **Control of Corrective and Preventative Action Reporting (CPAR) Procedure**.

10.3 Continual improvement

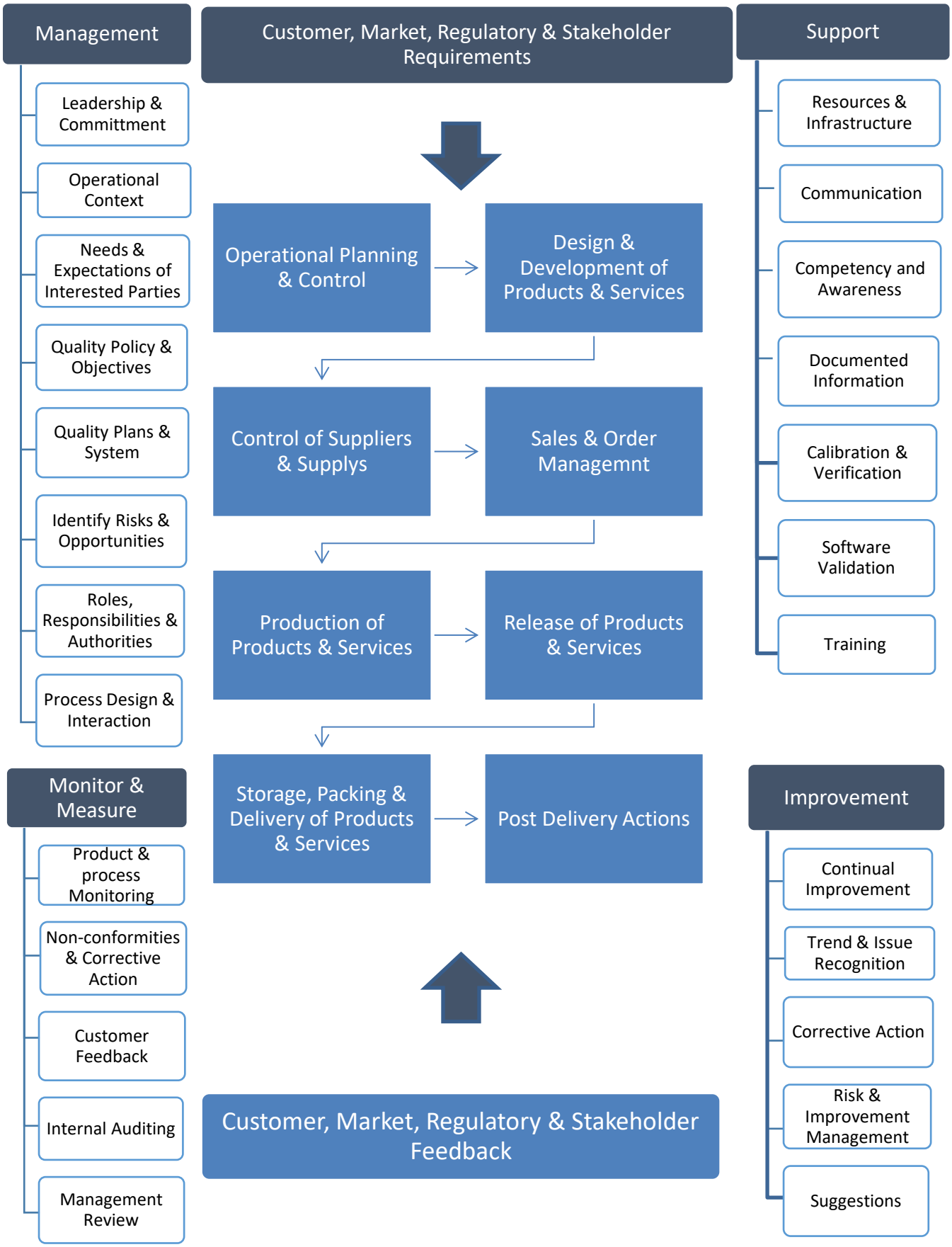
We seek to continually improve the suitability, adequacy and effectiveness of our QMS.

We use the results of analysis and evaluation, and the outputs from quality management review, to identify needs and opportunities for such improvement.

The overall effectiveness of our programme of continual improvement, including both corrective actions and our wider progress in achieving corporate level improvement objectives, is monitored and assessed through our quality management review process.

11. Appendix 1 - QMS Process Map

Modify this QMS process map (which is constructed using Word SmartArt) as necessary:


Management
Leadership & Committment
Operational Context
Needs & Expectations of Interested Parties
Quality Policy & Objectives
Quality Plans & System
Identify Risks & Opportunities
Roles, Responsibilities & Authorities
Process Design & Interaction
Customer, Market, Regulatory & Stakeholder Requirements
Operational Planning & Control
Design & Development of Products & Services
Control of Suppliers & Supplys
Sales & Order Managemnt
Production of Products & Services
Release of Products & Services
Storage, Packing & Delivery of Products & Services
Post Delivery Actions
Support
Resources & Infrastructure
Communication
Competency and Awareness
Documented Information
Calibration & Verification
Software Validation
Training
Monitor & Measure
Product & process Monitoring
Non-conformities & Corrective Action
Customer Feedback
Internal Auditing
Management Review
Improvement
Continual Improvement
Trend & Issue Recognition
Corrective Action
Risk & Improvement Management
Suggestions
Customer, Market, Regulatory & Stakeholder Feedback

12. Appendix 2 - Organisation Chart

Add your organisation chart here to demonstrate who is responsible for what.

13. Appendix 3 - Organisational High Level Process Map

Add your high-level process map here, it should feature all of the processes you have identified above and show how those processes interact.