

# ISO9001:2015 Quality Manual

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Power Conversion, Control and Data  
Renewables and Industry

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# 1 Introduction

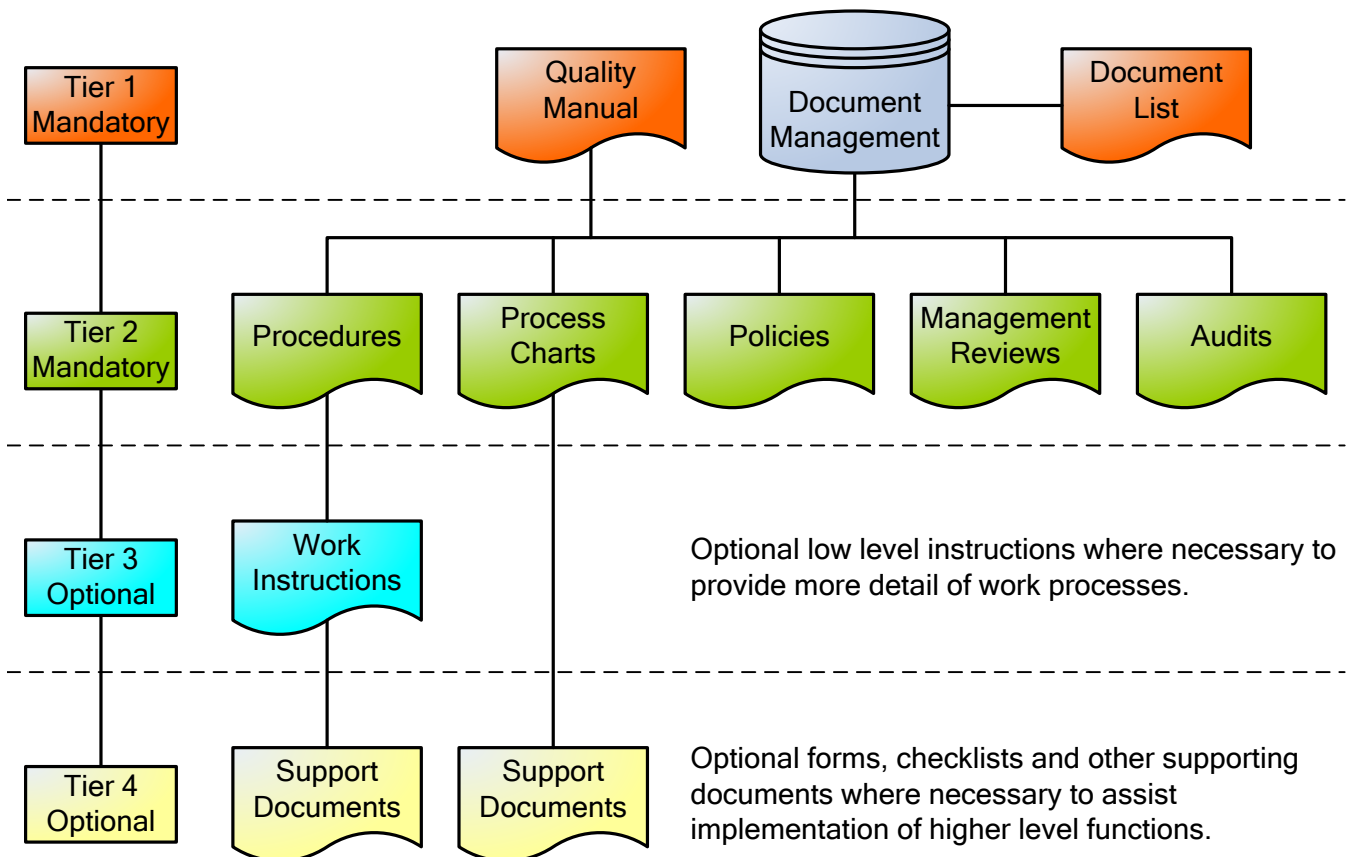
This Quality Manual details how Opus Design Services Limited (“The Company”) has implemented and continues to improve a Quality Management System (QMS) that is compliant with the requirements of the International Standard BS EN ISO 9001:2015, the Low Voltage Directive (LVD) (2014/35/EU) and the Electromagnetic Compatibility (EMC) Directive 2014/30/EU.


The Quality Manual is the first-tier document in a series of documented systems used within the company that define and communicate the business flows and procedures for the purposes of:

- a) Consistently providing products that meet the customers agreed specification and the relevant industry standards. Providing control of risks with mitigating controls.
- b) Enhancing customer satisfaction through effective use of the Quality Management System, including processes for continual improvement throughout the company.

## 1.1 Document structure

The Quality Management System consists of a hierarchical set of linked documents organised in different tiers as shown in the example below. All quality system documents shall be controlled using an in-house custom designed, database driven document management system.



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## 2 Company information

### 2.1 Company profile, history and scope

Opus Design Services Ltd is located in Whalley Lancashire. The company was established in 2017 and specialises in the Design and Value Engineering of various electrical systems including but not limited to industrial power conversion and variable speed drive systems, control equipment software and engineering.

Contract Electrical Engineering design services including written specifications, electrical design, operational software, equipment supply, system test, commissioning and consulting services to the industrial, renewable and other market sectors. Related services include computer modelling of complex control systems to allow algorithms to be developed and tested prior to commissioning.

Specialities include the advanced application of variable speed drives, Siemens PLC and TIA Portal programming environments.

External and internal issues are accommodated within the detailed procedures, as are the requirements of relevant interested parties, products and services of the company.

The client base includes:

- Siemens AG. Erlangen. Germany
- Siemens Energy Inc (Dresser Rand). Houston. USA.
- 4Navitas (Green Energy Solutions) Ltd. Blackpool. UK.
- Optima Control Solutions Ltd. Blackburn. UK.

### 2.2 Control and distribution


The Quality Manual is issued with the authority of the Managing Director who reviews changes prior to issue.

Controlled distribution in electronic form only to two locations:

- File copy for development use: Managing Director.
- Quality web site read only copy: All company staff as authorised by the Managing Director.

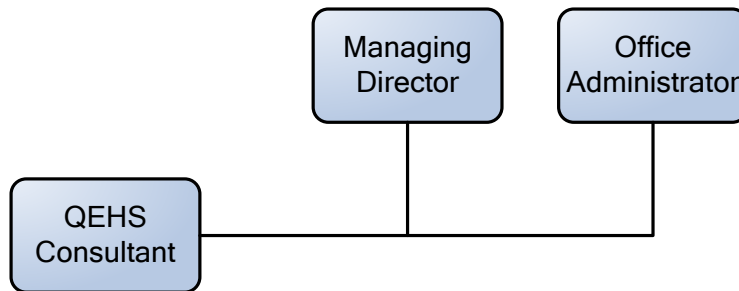
Note: Other Quality Manual printouts and copies of any form will be classed as uncontrolled.


- ❖ Procedure reference: QP001: Control of Documented Information.

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## 2.3 Organisational chart

The company has the following organisational structure:



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### 3 Quality policy statement



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Opus Design Services Limited's management are committed to the establishment and continuous improvement of market leading process-based system solutions, aimed at satisfying our customers' evolving needs. The performance standard within the company for every task we do is zero defects. Hazard and Risk Analysis to reduce uncertainty is established.

Everyone in the company is aware that they are both a supplier and a customer in the "Customer Supplier Chain" of quality that links our external suppliers with our Internal and external customers.

The company are committed to meeting customer and applicable statutory and regulatory requirements including: BS EN ISO 9001 2015 Quality System, Low Voltage Directive (LVD) (2014/35/EU) and the Electromagnetic Compatibility (EMC) Directive 2014/30/EU, where applicable, through the use of applicable standards.


Everyone recognises the need to do his or her job "Right First Time Every Time".

We focus on quality through technology, excellence in product quality, outstanding reliability, customer-centred service and cost focus, to make innovative and appropriate solutions available to our customers.

Signed *Adrian W. West* Dated 1st August 2019

Dr Adrian West

Managing Director

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## 4 Context of the organisation

### 4.1 Understanding the organisation and its context


The company has established, documented, implemented and subsequently continuously develops a Quality Management System that is intended to conform to the requirements of International Standard BS EN ISO 9001:2015, the Low Voltage Directive (LVD) (2014/35/EU) and the Electromagnetic Compatibility (EMC) Directive 2014/30/EU.

In establishing the Quality Management System, the company has taken due account of the following needs:

- Determination of the processes required for the Quality Management System and their application throughout the company including external and internal issues.
- Determination of the sequence and interfaces of the processes.
- Determination of the criteria and methods required to ensure the effective operation and control of the processes.
- Availability of resources and information needed to support the operation and monitoring of the processes.
- Monitoring, measurement where applicable and analysis of the processes.
- Implementation of actions to achieve planned results and continuous improvement.
- All legal, technological, competitive, market, cultural, social and economic issues (whether international, national, regional or local) shall be closely examined with the overall aim of enhancing the company QMS continued ability to produce quality products and services.

❖ [Procedure reference: QM003: Appendix A Process Sequence and Interactions.](#)

Note: Any outsourced products or services are controlled by the assessment, approval and monitoring of approved suppliers / contractors.

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## 4.2 Understanding the needs and expectations of interested parties

The company shall determine the interested parties that are relevant to the company Quality Management System.

To meet the requirements of customers and regulatory authorities the company shall establish the relevant requirements, monitor and review as necessary.

## 4.3 Determining the scope of the quality system

The company determines the types of product and services that it will cover and provide justification for any requirement of the standard that the organisation determines is not applicable to the scope of the quality system.

External and internal issues are accommodated within the detailed procedures, as are the requirements of relevant interested parties, products and services of the company.

## 4.4 Quality management system and its processes


The processes including inputs and outputs are determined and managed to ensure that all contract deliverables conform to customer requirements.

- ❖ Procedure reference: QM003: Appendix A Process Sequence and Interactions.

The company shall ensure the resources, information responsibilities, risks, opportunities for improvement, monitoring, measurement controls and subsequent analysis are covered in the quality procedures to ensure that the processes achieve the intended results.

Opportunities for improvement are noted and action taken.

Documented information is maintained.

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## 5 Leadership

### 5.1 Leadership and commitment

#### 5.1.1 General

Top management will demonstrate leadership and commitment by:

- Ensuring accountability for the quality system.
- Ensuring that quality policy and objectives are established and reviewed, including regular management reviews.
- Using a process approach.
- Using risk-based analysis.
- Ensuring adequate resources are available.
- Communicating awareness of the quality system.
- Achieving intended results.
- Directing and supporting personnel.
- Promoting improvements.
- Ensuring that customer statutory and regulatory requirements are met.

#### 5.1.2 Customer focus

The top management will ensure that:

- Customer needs and expectations are determined and converted into requirements.
- Customer and all relevant statutory and regulatory requirements are identified and met.
- Risks and opportunities for improvement that could affect the company's ability to supply conforming products and services have been identified and addressed.
- Customer satisfaction is enhanced.

### 5.2 Policy

#### 5.2.1 The company quality policy


The company shall establish a quality policy that will be:

- Relevant to the company's organisational goals and considers the expectations and needs of customers.
- Provide a framework for reviewing objectives.
- Include a commitment to meeting customer and applicable statutory and regulatory requirements.

#### 5.2.2 Quality manual details coverage

The quality manual shall provide details concerning responsibilities, training and resources required for each activity that will be:

- Communicated, understood and implemented throughout the company.
- Efficient, comprehensive and effective in ensuring that the organisation delivers the right product on time to the agreed specifications and is within budget;
- Regularly reviewed for continuing suitability.


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### 5.3 Organisational roles and responsibilities

The company shall continually review the resources to ensure that adequate staff and equipment are available to meet customer requirements.

The company shall:

- Define the roles and their inter-relations, responsibilities and authorities in order to facilitate effective quality management, ensuring that the QMS conforms to the requirements of the international standard and ensuring this information is communicated throughout the company.
- Establish the inter-relationship of personnel involved in managing, performing and/or assessing all work that affects the quality of deliverables, providing independence and authority as necessary.
- Ensure the processes can deliver the intended outputs.
- Ensure that everyone and everything in the organisation has a part to play in quality.
- The Managing Director will have overall responsibility for the QMS. This includes:
  - Ensuring that all processes are established, implemented and maintained.
  - Reporting to top management any need for improvement.
  - Ensuring the quality manual policies, procedures, related work instructions and other relevant documentation are up-to-date.
  - Ensuring compliance with statutory and regulatory legislation.

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## 6 Planning

### 6.1 Actions to address risks and opportunities

The company shall:

- Consider the QMS within the context of the organisation (4.1).
- Consider customer requirements (4.2).
- Determine risks and opportunities that need to be addressed.
- Give assurance that the QMS can achieve the intended results.
- Enhance desirable effects
- Prevent or reduce undesired effects.
- Achieve improvement.

- ❖ Procedure reference: QP004: Order Processing.
- ❖ Procedure reference: QP005: Design and Development.
- ❖ Procedure reference: QP006: Project Management.

### 6.2 Quality objectives and planning to achieve them

#### 6.2.1 Quality objectives

The company shall establish objectives. The objectives shall:


- Be measurable and reviewed.
- Be consistent with the quality policy.
- Include a commitment to continual improvement.
- Cover the applicable requirements of deliverables.
- Be relevant to conformity of products and services, and enhancement of customer satisfaction.
- Be monitored.
- Be communicated to relevant staff.
- Be updated as required.

#### 6.2.2 Planning

The company shall establish:

- What will be done.
- Processes required.
- Resources required.
- Who will be responsible.
- When will the work be completed.
- How results are evaluated and realisation processes.
- Change control.
- Verification activities criteria for acceptability.
- Documentation required.

- ❖ Procedure reference: QP005: Design and Development.
- ❖ Procedure reference: QP006: Project Management.


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## 6.3 Planning of changes

When there is a requirement for change, this shall be carried out in a planned controlled manner.

All changes are reviewed by top management considering:

- The proposal for change and consequences.
  - Current and future requirements.
  - The markets served and expectations of customers.
  - Availability of resources.
  - The integrity of the QMS.
  - Allocation or de-allocation of responsibilities and authorities.
  - Risk assessment.
  - Improvement opportunities.
- 
- ❖ Procedure reference: QP004: Order Processing.
  - ❖ Procedure reference: QP005: Design and Development.
  - ❖ Procedure reference: QP006: Project Management.
  - ❖ Procedure reference: QM005: Appendix C Management of Change.

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## 7 Support

### 7.1 Resources

#### 7.1.1 General

The company shall identify and make available the resources (e.g. people, materials, equipment, infrastructure), training, induction, responsibilities, working environment, maintenance required to establish, maintain and improve the quality management system. The company shall consider:

- The capabilities and restraints on existing internal resources.
- Requirements from external suppliers.
- Documented information including control, change control and retention.
- Monitoring and measurement resources and traceability are in place.

#### 7.1.2 People

The company are responsible for ensuring that all personnel are trained, competent and sufficiently experienced to undertake their assigned activities and responsibilities effectively for implementing and approving the company QMS so that it complies efficiently with contract and statutory/regulatory requirements.

- ❖ Procedure reference: QP009: Competence Awareness and Training.

#### 7.1.3 Infrastructure

The company shall determine, provide and maintain the infrastructure required to achieve product and service conformity regarding (but not limited to) the following:


- Workspace and associated activities.
- Buildings and utilities.
- Hardware and software.
- Tools and equipment.
- Information technology and communications facilities.
- Support services e.g. transport, communication or information systems.

#### 7.1.4 Environment for the operation of processes

The company's work environment is a combination of human (e.g. social and psychological), physical and environmental factors (e.g. air flow, cleanliness, heat, hygiene, humidity, lighting, noise, pollution, temperature, vibration and weather). All of these factors influence motivation, satisfaction and performance of people and, as they have the potential for enhancing the performance of the company, they shall be taken into consideration when considering how to achieve conformity of products and services.

The company shall provide and maintain those human and physical factors of the work environment required to achieve output conformity. The company has overall responsibility for establishing, implementing and maintaining this activity and shall include:

- Health & safety conditions.
- Work methods.
- Work ethics.
- Ambient working conditions.

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## 7.1.5 Monitoring and measuring resources

### 7.1.5.1 General

Not applicable to the company.

### 7.1.5.2 Measurement traceability

Not applicable to the company.

## 7.1.6 Organisational knowledge

The company systematically capture and preserve knowledge and learning gained with regard to the company's products, supplies and documented information. The company are responsible for maintaining this "organisational knowledge" as documented information.

Knowledge can be gained from:

- Internal sources (e.g. knowledge gained from experience, lessons learned from failures and successful projects).
- The results of improvements in products and services.
- External sources (e.g. customer feedback, suppliers, sub-contractors, academia, industry advisory bodies, industry standards and conferences).

## 7.2 Competence

The company shall identify and make available personnel who are competent through education, training and/or experience to complete assigned tasks to end user requirements, to company standards and to comply with regulatory statutory legislation.


- ❖ Procedure reference: QP009: Competence Awareness & Training.

### 7.2.1 Training

The company shall establish procedures to:

- Identify training needs.
- Provide appropriate training.
- Evaluate the effectiveness of the training provided.
- Maintain documented information and records concerning all training.
- Ensure the relevant levels of skill and expertise is available to handle the expected workload.

- ❖ Procedure reference: QP009: Competence Awareness & Training.

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### 7.3 Awareness

The company shall establish and maintain procedures to make its employees, at each relevant function, aware of the quality policy, any quality objectives which are relevant to them, and how they contribute to the effectiveness of the QMS including the benefits of improved performance.

All personnel associated with a product or service shall be made aware of the importance of:

- Conformance with the quality policy.
- The significant impact of their work activities on quality (actual or potential).
- The benefits of improved personal performance.
- Their roles and responsibilities in achieving conformance with the policy and procedures and the requirements of the QMS.
- The potential consequences of departure from specified procedures.

❖ Procedure reference: QP009: Competence Awareness & Training.

### 7.4 Communication

Top management shall ensure that suitable communication processes are established within the organisation for all internal and external (including sub-contractors) communication concerning or relating to the company QMS and statutory/regulatory obligations.

Methods used include:

- Team briefing.
- E-information.
- Company meetings.

### 7.5 Documented information

#### 7.5.1 General

The company shall establish an agreed method for controlling all documented information associated with the international standard and quality policy necessary for the effectiveness of the QMS.


❖ Procedure reference: QP001: Control of Documented Information.

#### 7.5.2 Creating and updating

Documentation associated with the company's QMS shall include:

- Identification and description e.g. title, date, author, and reference number.
- Revision level.
- Statements regarding policy and objectives.
- Approval and reviews.
- Procedures that clearly describe the sequence of processes necessary to ensure conformance with ISO 9001:2015.
- Instructions to ensure the effective planning, operation and control of processes and quality of all documented information.
- Effective document control including distribution, access, retrieval and use.
- Change control e.g. version control, retention and disposition.

The Managing Director shall establish and maintain the Quality Manual which shall be regularly reviewed and audited to ensure continued acceptability, validity and effectiveness.

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### 7.5.3 Control of documented information


The company shall establish a documented procedure for the control of all documents.

The procedure shall ensure that:

- Documents are approved for adequacy prior to release and available for use.
- Distribution of all users is established.
- Documents are reviewed, updated as necessary and re-approved.
- Documents remain legible, readily identifiable and retrievable.
- Documents of external origin can be identified, controlled and recorded.
- Only relevant versions of documents are in use.
- Obsolete documents are removed from the point of issue or otherwise controlled to prevent unintended use.
- Any obsolete documents retained for legal or knowledge preservation purposes are identified.
- A master list of documents is established.
- Documents are suitably stored and preserved to prevent damage or deterioration.
- Electronic copies are issued when appropriate.
- The procedure shall address change control to the relevant version, issue or revision level.

❖ Procedure reference: QP001: Control of Documented Information.

❖ Procedure reference: QP002: Control of Records.

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## 8 Operation

The company shall ensure that customer's requirements, including delivery and post-delivery activities are fully understood, documented and implemented.

### 8.1 Operation planning and control

The company shall ensure that:


- Processes to realise the required deliverables and their sequence and interactions are planned, developed, and controlled.
  - Resources needed to achieve conformity to the product and service requirements are determined.
  - Requirements for products and services are determined.
  - Criteria for processes are established.
  - Criteria for the acceptance of products and services are established, including the amount of verification, validation, monitoring, measurement, inspection and test activities that will be required.
  - There is communication with customers.
  - All contracts /orders are reviewed.
  - Any changes are communicated to interested parties including customers and suppliers.
  - Documented information is determined, maintained and retained.
- 
- ❖ Procedure reference: QP001: Control of Documented Information.
  - ❖ Procedure reference: QP002: Control of Records.
  - ❖ Procedure reference: QP004: Order Processing.
  - ❖ Procedure reference: QP005: Design and Development.
  - ❖ Procedure reference: QP006: Project Management.

### 8.2 Requirements for products and services

#### 8.2.1 Customer communication

The company shall ensure that the customer is kept up-to-date with the progress of their enquiries, deliverable contracts/orders. All feedback/comments and complaints are dealt with in a speedy and effective manner. The company shall define communication requirements relating to:

- Product and service information.
  - Progress of enquiries/contracts/orders.
  - Action on complaints and non-conformances.
  - Storage of customer property.
  - Action on changes/amendments.
- 
- ❖ Procedure reference: QP004: Order Processing.
  - ❖ Procedure reference: QP008: Non-Conformance.

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## 8.2.2 Determining the requirements of products and services

The company shall identify customer requirements and review the requirements.

The company shall establish a process for identifying customer requirements that determine:

- Completeness of the customer and/or service requirement.
- Statutory and regulatory requirements.
- Specific customer requirements for availability, delivery and support of the product or service.
- Assurance that the company can meet the claims for products and services.

## 8.2.3 Review of the requirements for products and services

### 8.2.3.1 Review before commitment

The company shall complete a thorough assessment and review of all requirements specified by the customer including changes, to ensure it can meet the requirements of products and services, including the requirements for delivery and post-delivery.

The assessment/review shall ensure that:

- Product and service requirements are clearly defined.
- Statutory and regulatory requirements are included.
- Requirements not specified by the customer are included as necessary for fitness for purpose.
- Contract or order requirements differing from those previously defined are resolved.
- The company has the resources, expertise and financial stability to meet the requirements.

❖ Procedure reference: QP004: Order Processing.

### 8.2.3.2 Retained documents


The company shall retain documented information, as applicable:

- On the results of contract review.
- On any new requirements for the service.

## 8.2.4 Changes to requirements of products and services

If there are any changes that either the customer or the company wish to make to a contract or a product or service, then these changes and the results of changes will be retained as documented information and the relevant parties notified.

❖ Procedure reference: QP005: Appendix C, Management of Change.

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## 8.3 Design and development of products and services

### 8.3.1 General

The company shall plan and control the design and development of its products and services. The company shall design, develop and implement a process which will be subject to control and analysis.

- ❖ Procedure reference: QP005: Design and Development.

### 8.3.2 Design and development planning

The company shall plan and control the design and development of products and services which shall include:

- Process stages and reviews.
- Nature, duration and complexity for design and development activities.
- Verification and validation activities.
- Identification of responsibilities and authorities.
- Effective communication and involvement of customers and users.
- Internal and external resource needs.
- Control of interfaces.
- Level of controls.
- Documented information.

### 8.3.3 Design and development inputs

The company shall review for (adequacy and approval) all design and development inputs. The Company shall maintain procedures to ensure that the functions of the design development and planning activities are in line with the customer's specified requirements. Procedures shall be defined and documented and shall consider:


- Functional and performance requirements from the customer.
- Applicable statutory, regulatory and legal requirements.
- Environmental requirements.
- Information from previous designs.
- Industrial standard codes of practice.
- Potential consequence of failure.
- Conflicting design inputs to be resolved.

### 8.3.4 Design and development controls

The company shall ensure that design and development inputs are adequate, complete and unambiguous and if there are variations of conflicts between design inputs, they must be resolved.

At suitable stages, systematic reviews of design and development shall be carried out in order to:

- Evaluate the ability of the design and development to meet requirements.
- Evaluate the ability of deliverable to meet requirements for quality.
- Identify problems.
- Propose follow-up actions.
- Ensure adherence to contractual and statutory requirements have been met.
- Ensure all alternatives design concepts have been considered.
- Ensure all potential design problems have been identified and evaluated.
- Ensure all calculations have been correctly performed and re-checked.
- Ensure that the deliverable continues to meet customer and other statutory requirements.

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#### 8.3.4.1 Design and development verification

The company shall ensure that verification processes are planned and implemented to ensure that the design and development output meets the design and development input. Procedures shall be available to complete periodic evaluations of the design output against the design input using one of the following methods:

- Comparison with other designs.
- Alternative calculations to verify the precision of the original calculations and their analysis.
- Third party evaluation.
- Feedback from previous designs.
- Customer feedback.

#### 8.3.4.2 Design and development validation

Prior to the delivery or implementation of the design and development, validation shall be performed to confirm the resultant deliverable is capable of meeting customer requirements.

The company shall ensure that:

- Records of all validations are maintained.
- Design and development validation is completed in line with planned arrangements, to ensure that the resulting deliverable is capable of meeting customer requirements.
- Ensure that records are maintained.

#### 8.3.5 Design and development outputs

The company shall ensure that the design and development outputs:


- Meet the input requirements.
- Identify critical characteristics.
- Use available procedures.
- Are approved by the customer.
- Include reference monitoring, measuring requirements and acceptance criteria as appropriate.
- Include documented information that is retained.

#### 8.3.6 Design and development changes

All changes to the design criteria (input and output) shall be subject to strict documentation control and be reviewed by the designer and the customer. Records shall be retained.

All changes shall be authorised by a responsible authority. Actions necessary to prevent adverse impacts shall be taken.

❖ [Procedure reference: QP005: Design and Development.](#)

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## 8.4 Control of externally provided processes, products and services.

### 8.4.1 General

The company shall establish documented procedures to ensure that all purchased products and services conform to the specified purchase requirements. A list of approved suppliers shall be maintained. The company shall establish controls to be applied to externally supplied products and services e.g. when

- Products or services supplied are to be incorporated into the company's products or service.
- A process or part of a process is provided by an external source.

The company shall apply a process for the selection, evaluation, monitoring of performance and re-evaluation of external providers. Documented information shall be maintained.

### 8.4.2 Type and extent of control

The company shall ensure procedures are implemented to ensure that all purchasing documents contain information clearly describing the product and / or service ordered and will include the company requirements including qualifications and competence of sub-contractors. The company shall ensure the adequacy of specified purchase requirements prior to release.


- ❖ Procedure reference: QP007: Purchasing.

### 8.4.3 Information for external providers

The company shall ensure that there is a procedure to ensure that all products and services received are checked to confirm that:

- They are those that were ordered.
- The delivery is on time.
- They are of good quality.
- They meet statutory and regulatory requirements.

- ❖ Procedure reference: QP007: Purchasing.

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## 8.5 Production and service provision

### 8.5.1 Control of production and service provision

To meet output targets (and at the same time, to prevent defects), the company shall plan and carry out production and service provision under controlled conditions which shall be documented.

The company shall identify requirements and ensure, as applicable:

- There is an ability to comply with contractual requirements.
  - Hazards and risks are identified and mitigated.
  - Actions are put in place to prevent human error.
  - The availability of suitable monitoring equipment and procedure.
  - Documented information defines the results to be achieved.
  - The availability of documented work instructions and drawings.
  - Validation and re-validation.
  - Suitably trained and competent staff are available.
  - Suitable environment conditions.
  - Suitable infrastructure.
  - There is a communication system.
  - There is a process for problem intervention.
  - The deliverable and post-delivery activities.
- ❖ Procedure reference: QP004: Order processing.
- ❖ Procedure reference: QP006: Project management.

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### 8.5.2 Identification and traceability

Where traceability is required, the company shall have procedures in place for identifying the status of deliverables. The company shall be capable of controlling and recording:

- The identification of the product or service.
- The status of the deliverable.
- The traceability of the deliverable.

❖ Procedure reference: QP005: Design and Development.

### 8.5.3 Property belonging to the customer or external providers

The company shall ensure that all property belonging to customers is identified, verified, protected, stored and maintained. Any customer property that is lost or damaged or otherwise found to be unsuitable for use shall be reported to the customer. Records shall be maintained.

### 8.5.4 Preservation

The company shall preserve all outputs during service provision to ensure conformity to requirements to the destination, including identification, packaging, storage transport, installation, commissioning, handling and maintenance.

### 8.5.5 Post-Delivery activities

Following the delivery of a product or service, the company shall monitor post-delivery activities including, warranty obligations, contractual obligations, concerning. Consideration shall be given to:

- Statutory and legal obligations.
- Potential undesired consequences of product or service.
- Customer feedback.


### 8.5.6 Control of changes

The company shall review and control changes for design production or service to ensure continuing conformance with requirements.

## 8.6 Release of products and services

The company shall ensure that the characteristics of all products and services at all stages meet customer's specified requirements.

❖ Procedure reference: QP005: Design and Development.

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## 8.7 Control of non-conforming outputs

### 8.7.1 Applicable actions

The company shall establish a procedure for the control of non-conforming outputs and shall ensure that any processes, products and services that do not conform to requirements are controlled, identified in order to prevent unintended use or delivery. The company shall ensure that non-conforming products or services:


- That do not conform are prevented from unintended use or delivery.
- Have been corrected and are verified to demonstrate conformity.
- Are only accepted by concession following authorisation if all regulatory requirements are met and the identity of the person(s) authorising the concession is recorded.
- That need to be reworked shall be subject to the same authorisation and approval procedure as the original work.
- Are segregated and identified.
- That the customer is informed if applicable.

### 8.7.2 Documentation

The company shall retain documentation describing the non-conformity including:

- Description of the non-conformity.
- Actions taken.
- Concessions obtained.
- Identification of the authority deciding any actions.

❖ Procedure reference: QP008: Non-conformance.

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## 9 Performance Evaluation

### 9.1 Monitoring, measurement, analysis, evaluation

#### 9.1.1 General

The company shall plan and implement measurement, monitoring, analysis and improvement of all QMS processes, conduct audits and management reviews to determine:

- What needs to be monitored and frequency.
- Methods of monitoring, measurement analysis and evaluation.
- Timing of analysis and evaluation of results.
- Type of documentation to be retained.

❖ Procedure reference: QP006: Project Management.

#### 9.1.2 Customer satisfaction

The company shall monitor customer perceptions of the degree to which their needs have been fulfilled. Typically, customer feedback and compliments shall be recorded to gauge the level of compliance.

#### 9.1.3 Analysis and Evaluation

The company shall establish documented procedures to determine, collect, collate, analyse and evaluate appropriate data to demonstrate and confirm to the customer that the company is capable of continuing to produce quality products and services. Top management shall establish documented procedures to collect data for the analysis of:


- Effective planning.
- Customer feedback.
- Customer satisfaction and/or dissatisfaction.
- Conformance to requirements.
- Processes and procedures used to produce deliverables.
- Characteristics and effectiveness taken to address risks and opportunities for improvement.
- The performance and effectiveness of the QMS.
- The performance of suppliers and sub-contractors.

❖ Procedure reference: QP003: Management Review.

❖ Procedure reference: QP004: Order Processing.

❖ Procedure reference: QP006: Project Management.

❖ Procedure reference: QP007: Purchasing.

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## 9.2 Internal audit

### 9.2.1 Implementation

The company shall establish an internal audit process at planned intervals to assess the strengths and weaknesses of the QMS, to ensure it conforms to the QMS and conforms to the international standard. The process will assess whether the QMS is effectively implemented.

### 9.2.2 Audit planning

The company shall plan maintain and implement an audit programme considering the important status of each process, any changes and the results of previous audits. The audit shall consider the efficiency and effectiveness of all processes. The company shall establish a documented audit procedure including:

- The responsibilities and requirements for the audit.
- The criteria, scope, frequency and methodologies used.
- Selection of auditors who are objective to the process.
- Confirmation that audit results are reported to management.
- Confirmation that appropriate corrective actions are taken without delay.
- Methods for identifying opportunities for improvement.
- Methods for recording results.

❖ Procedure reference: QP010: Internal Audit.

## 9.3 Management review


### 9.3.1 General

The company shall carry out a review of the QMS at regular planned intervals, to ensure its continued suitability, adequacy, effectiveness and alignment to with the strategic objectives and direction of the company.

### 9.3.2 Management review inputs

The company shall review (but not limited to):

- Results and follow-up from previous reviews.
- Quality objectives and policy.
- Results of internal and external audits.
- Customer satisfaction and feedback.
- Process performance.
- Product and service performance.
- Monitoring and measurement results.
- Status of non-conformance and corrective actions.
- Supplier and sub-contractor performance.
- Adequacy of resources.
- Changes that could affect the QMS.
- Recommendations for improvement.
- Actions taken to reduce hazards and risks.
- New or revised statutory requirements.


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### 9.3.3 Management review outputs

The output of the management review shall include (but not limited to):

- Opportunities for improvement.
- Change control.
- Resource needs.
- Documented records.
- Risk management.
- Compliance with regulatory and statutory requirements, In particular ISO 9001 2015.

❖ Procedure reference: QP003: Management Review.

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## 10 Improvement

### 10.1 General

The company shall ensure that they continually evaluate opportunities for improvement and implement any actions needed to meet and exceed customer requirements thus enhancing customer satisfaction. This shall include:

- Improving products and services to meet current needs and future expectations.
- Correcting or preventing undesired effects.
- Improving the performance and effectiveness of the QMS.

### 10.2 Non-conformity and corrective action

The company shall ensure they have the necessary processes and procedures to:

- Prevent the use or delivery of non-conforming products (including storage and disposal)
- Determine how corrective actions are controlled
- Determine how actions to prevent re-occurrence are controlled
- Establish how the company ensures continual improvement of its products and services.

#### 10.2.1 Occurrence of a non-conformity


When a non-conformity occurs including customer complaints and is identified, the company shall take whatever action is necessary to:

- Control and correct the non-conformity.
- Deal with any resultant consequences.
- Find out the cause of the non-conformity.
- Consider whether there is potential for similar problems arising.
- Take whatever actions are required.
- Review and analyse the non-conformity.
- Review the effectiveness of corrective action taken.
- Make changes to the QMS if necessary.
- Update hazards, risks and opportunities for improvement.

#### 10.2.2 Documentation

The company shall retain documented information including establishing a procedure for identifying and preventing nonconforming or hazardous products and services being delivered to a customer. All parts and products shall be capable of being traced and recalled if necessary. Documented information shall provide evidence of the non-conformity and resultant actions taken.

- ❖ Procedure reference: QP008: Non-Conformance.

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## 10.3 Continual improvement

The company shall constantly seek to improve the suitability, adequacy and effectiveness of its QMS and processes and procedures to attain overall customer satisfaction including consideration of:

- The results of analysis and evaluation.
- Outputs of management reviews.
- Identification of changes.
- A review of objectives.
- A review of the quality policy.
- Customer complaints follow-up reviews.


❖ Procedure reference: QP003: Management Review.

❖ Procedure reference: QP006: Project Management.

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## 11 Appendices

- ❖ Reference: QM003: Process Sequence and Interactions.
- ❖ Reference: QM004: Hazards, Risks and Mitigation.
- ❖ Reference: QM005: Management of Change.

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