QUALITY SYSTEM

FOR

ESTATE INSURANCE GROUP

CONTENTS

1.0 QUALITY POLICY

ESTATE INSURANCE GROUP provides a professional insurance broking service. To include provision of UK property, commercial insurance and personal lines.

This goal will be achieved through the creation of a total quality culture that underpins all our activities on a day-to-day basis.

To achieve this objective, the organisation has adopted:

BS EN ISO9001: 2015 – Quality Management Systems Requirements

The following will be fundamental to the achievement of our quality culture:

- The quality policy will be appropriate to the purpose and contextual issues faced by the organisation
- Will assist with promoting our strategic objectives (set out within our objectives presentation)
- Provides a framework for setting measurable quality objectives
- The organisation will ensure that applicable requirements where required are addressed within our QMS
- The Company will promote and foster continual improvement and improvement of the quality system
- This quality policy shall be made available on our portal and as documented information
- The Directors will ensure adequate communication of this policy to staff, customers, and contractors and where appropriate stakeholders. As a minimum staff and contractors will be appraised and understand this policy
- The quality policy will be available to interested parties and stakeholders

This policy will be reviewed at the Company's scheduled management review forums.

Jeremy Stephen

Managing Director

2.0 Scope of Quality System

The scope of the quality management system includes all activities carried out by the Company at its operating address: -

The scope to include:

Provision of UK property, commercial insurance and personal lines policies.

3.0 Scope not applicable.

As per section 4.3 of ISO9001 2015. The following activities are not within scope:
Design 8.3

7.1.5.2 Measurement traceability. The aforementioned is not identified with the organisation's quality management system.

QUALITY MANUAL DISTRIBUTION

See Listing

5.0 CONFIDENTIALITY

The quality systems manual is restricted to a list of holders approved by the Management Representative and detailed as such in the distribution list set out in this section.

No part of the manual may be copied or passed to other persons or organisations without the express approval of the Management Representative. Controlled copies may be issued to external bodies subject to prior approval. A record of such issue in maintained in the external distribution list.

Maintenance of externally issued copy is limited to the life cycle of any contract and should be returned on completion of such contract or stipulated period.

Uncontrolled copies of the quality manual, where issued under the authority of the Managing Director, are current at the date of issue but will not be subsequently maintained.

6.0 RESPONSIBILITY OF MANUAL HOLDERS (CONTROLLED COPIES)

All revisions of the manual are conditional on the approval of the Management Representative prior to introduction. The Management Representative, who will ensure that holders of controlled copies receive all approved amendments, controls revision or amendment to any part of the manual.

The manual holder is responsible for updating their copy of the manual and in the event of re-issue the obsolete copy will be returned to the Management Representative.

The Management Representative will, from time to time, conduct an audit as part of document control to verify the status of all issued copies of the quality manual - against the master copy, which is held under the direct control of the Management Representative.

CONTROLLED COPIES

Holder	Date Issued	Copy No	Signature
		01	
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		-	

**** Denotes master copy**

External

Holder	Date Issued	Copy No	Signature
Certification Body			
-			
Any other external holders – listed			

7.0 QUALITY SYSTEM REVISION

Changes to the quality manual will be the responsibility of the Management Representative who acts as the Management Representative.

Except where it is necessary to issue a section as a whole, only revised pages are issued. A record of all amendments and issues to the quality manual is maintained.

The quality systems manual is continuously reviewed by the Management Representative to reflect any amendments to the international standard ISO9001 2015.

Where major system changes are required, in line with improvements, or when the number of amendments becomes unwieldy, the manual will be re-issued.

A controlled copy of the manual is submitted to the chosen certification body for approval, prior to assessment. A master copy is securely maintained by the appointed Management Representative, who acts as custodian of the quality system that operates within the organisation

Changes to the manual will be formally recorded in the revision index of this section, with the master manual acting as a reference to all other manuals with regard to status.

In the instance of major or significant change or upgrade to the quality manual the Management Representative will inform the appointed certification body to determine any requirement with regard to continued assessment. In the case of minor amendment of the manual the details will be recorded in the manual revision process and the certification body advised at the time of their next visit to the organisation.

8.0 REVISION INDEX

DATE	SECTION	DETAILS	AUTHORISED BY

9.0 STRUCTURE OF QA SYSTEM

		How Addressed
4.1	Under the organisation and it's context	
	The organization shall determine external and internal issues that are relevant to its purpose and its strategic direction and that affect its ability to achieve the intended result(s) of its quality management system.	Refer to context of organization presentation.
	The organization shall monitor and review information about these external and internal issues	Monitored at QMS Management Reviews and at regular changes planned throughout the year.
	NOTE 1 Issues can include positive and negative factors or conditions for consideration.	
	NOTE 2 Understanding the technological, competitive, market, cultural, social and economic environments, whether international, national, regional or local. external context can be facilitated by considering issues arising from legal,	Facilitated through PESTEL analysis, linking context with external and internal factors. Use of ISO31000 2009 – Risk Management.
	NOTE 3 Understanding the internal context can be facilitated by considering issues related to values, culture, knowledge and performance of the organization	
4.2	Understanding the needs and expectations of interested parties	PESTEL analysis linked to stakeholder analysis. Documented information held within
	Due to their effect or potential effect on the organisation's ability to consistently provide products and services that meet customer and applicable statutory and regulatory requirements, the organization shall determine:	Needs and expectations of interested parties defined within presentation on context and process for handling enquiries / agreements.
	a) the interested parties that are relevant to the quality management system;	The interested parties are defined within the context presentation.
	b) the requirements of these interested parties that are relevant to the quality management system.	Requirements are addressed within the context presentation. Documented information.
	The organization shall monitor and review information about these interested parties and their relevant requirements.	Top management shall gather information about interested parties at Board Meetings, Management Reviews, feedback, media statements etc.
4.3	Determining the scope of the quality management system	
	The organization shall determine the boundaries and applicability of the quality management system to establish its scope.	The organization will prepare a documented scope. This will be held within this quality system.
	When determining this scope, the organization shall consider:	
	a) the external and internal issues referred to in 4.1;	External issues will be considered in scope plus internal. This will be documented information.
	b) the requirements of relevant interested parties referred to in 4.2;	Requirements of interested parties will be retained & documented within scope.
	c) the products and services of the organization.	The products & services are defined within the documented scope.
	The organization shall apply all the requirements of this International Standard if they are applicable within the determined scope of its quality management system.	Exclusion: design & development
	The scope of the organization's quality management system shall be available and be maintained as documented information. The scope shall state the types of products and services covered, and provide justification for any requirement of this International Standard that the organization determines is not applicable to the scope of its quality management system.	Scope detailed within this quality system document.
	Conformity to this International Standard may only be claimed if the requirements determined as not being applicable do not affect the organization's ability or responsibility to	

	ensure the conformity of its products and services and the enhancement of customer satisfaction.	
4.4	**Quality management system and its processes**	
4.4.1	**The organization shall establish, implement, maintain and continually improve a quality management system, including the processes needed and their interactions, in accordance with the requirements of this International Standard.**	**Demonstrated through processes of audits & outputs. Opportunities for improvement may be highlighted at QMS Management Review.**
	The organization shall determine the processes needed for the quality management system and their application throughout the organization, and shall:	**The organization has created a high level interaction of processes diagram. This will link to the required processes within the organization.**
	a) determine the inputs required and the outputs expected from these processes;	**The organization has highlighted these within the interactions of processes diagram.**
	b) determine the sequence and interaction of these processes;	**The organization will highlight within the interactions of processes table.**
	c) determine and apply the criteria and methods (including monitoring, measurements and related performance indicators) needed to ensure the effective operation and control of these processes;	**Key processes within the organization, will have suitable monitors and measures deployed. These will be highlighted within the core business process charts.**
	d) determine the resources needed for these processes and ensure their availability;	**The organization will determine resource needs at the management review meetings & within the context presentation.**
	e) assign the responsibilities and authorities for these processes;	**Process diagrams will identify the owner within the organization.**
	f) address the risks and opportunities as determined in accordance with the requirements of 6.1;	**The organization has developed a risk management process, predicated upon ISO31000.**
	g) evaluate these processes and implement any changes needed to ensure that these processes achieve their intended results;	**Processes & their ability to achieve desired results will be evaluated through audit & measurement.**
	h) improve the processes and the quality management system.	**Improvements will be planned & agreed at the QMS management review.**
4.4.2	**To the extent necessary, the organization shall:**	
	a) maintain documented information to support the operation of its processes;	**Process flows describing operations & support functions will be documented & made available.**
	b) retain documented information to have confidence that the processes are being carried out as planned.	**Process diagrams will be retained describing the operations of the organization.**
5	**Leadership**	
5.1	**Leadership and commitment**	
5.1.1	**General**	
	Top management shall demonstrate leadership and commitment with respect to the quality management system by:	
	a) taking accountability for the effectiveness of the quality management system;	**Can be demonstrated in the context presentation.**
	b) ensuring that the quality policy and quality objectives are established for the quality management system and are compatible with the context and strategic direction of the organization;	**The quality policy will take cognizance of the International Standard for quality. It will take into consideration the context of the business & its strategic direction.**
	c) ensuring the integration of the quality management system requirements into the organization's business processes;	**The QMS is intended to detail the organization's operational activities.**
	d) promoting the use of the process approach and risk-based thinking;	**Key operations within the business will be process based.**
	e) ensuring that the resources needed for the quality management system are available;	**Resource needs will be established at the QMS management review & within the context presentation.**
	f) communicating the importance of effective quality management and of conforming to the quality management system requirements;	**The organization has created a process for communication of the QMS.**
	g) ensuring that the quality management system achieves its intended results;	**Audits & reviews of monitors and measures will ensure that the QMS is delivering its intended results.**
	h) engaging, directing and supporting persons to contribute to the effectiveness of the quality management system;	**The context presentation & quality policy will be communicated to all staff within the organization.**

	i) promoting improvement;	**Improvement opportunities will be derived from stakeholder feedback. Audits etc.**
	j) supporting other relevant management roles to demonstrate their leadership as it applies to their areas of responsibility.	**Senior Management will assist process owners to maximize the potential of the QMS.**
	NOTE Reference to "business" in this International Standard can be interpreted broadly to mean those activities that are core to the purposes of the organization's existence, whether the organization is public, private, for profit or not for profit.	
5.1.2	**Customer focus**	
	Top management shall demonstrate leadership and commitment with respect to customer focus by ensuring that:	
	a) customer and applicable statutory and regulatory requirements are determined, understood and consistently met;	**Customer requirements, together with statutory & regulatory requirements are determined. See process for 'enquiry handling'.**
	b) the risks and opportunities that can affect conformity of products and services and the ability to enhance customer satisfaction are determined and addressed;	**Risks associated with the organization's ability to supply are determined within the context presentation & the risk assessment process.**
	c) the focus on enhancing customer satisfaction is maintained.	**Refer to process for customer satisfaction.**
5.2	**Policy**	
5.2.1	**Establishing the quality policy**	
	Top management shall establish, implement and maintain a quality policy that:	**Quality Policy prepared and authorized by the MD.**
	a) is appropriate to the purpose and context of the organization and supports its strategic direction;	**Takes cognizance of the contextual issues highlighted within the presentation.**
	b) provides a framework for setting quality objectives;	**Quality objectives will be clearly established to support the organization's aims & objectives.**
	c) includes a commitment to satisfy applicable requirements;	
	d) includes a commitment to continual improvement of the quality management system.	**Continual improvement will be highlighted & discussed at regular management review meetings.**
5.2.2	**Communicating the quality policy**	
	The quality policy shall:	
	a) be available and be maintained as documented information;	**The Quality Policy will be displayed within the organization, and on the portal. It will be retained as documented information.**
	b) be communicated, understood and applied within the organization;	**The policy will be communicated to staff. It will be made available on the portal.**
	c) be available to relevant interested parties, as appropriate.	**The policy will be made available to relevant interested parties upon request.**
5.3	**Organizational roles, responsibilities and authorities**	
	Top management shall ensure that the responsibilities and authorities for relevant roles are assigned, communicated and understood within the organization.	**The organization will ensure that organizational roles & responsibilities are defined within process charts, job authority matrix etc.**
	Top management shall assign the responsibility and authority for:	
	a) ensuring that the quality management system conforms to the requirements of this International Standard;	**Relevant responsibilities shall be assigned to staff within the organization to ensure that all relevant requirements of this Standard are addressed.**
	b) ensuring that the processes are delivering their intended outputs;	**Each key process within the organization shall have a process owner clearly identified.**
	c) reporting on the performance of the quality management system and on opportunities for improvement (see 10.1), in particular to top management;	**A nominated person within the organization shall be appointed to report on the effectiveness of the quality system.**
	d) ensuring the promotion of customer focus throughout the organization;	**The Managing Director will promote customer focus throughout the organization. This is highlighted within the context of organization presentation.**
	e) ensuring that the integrity of the quality management system is maintained when changes to the quality management system are planned and implemented.	**When the organization makes planned changes to the quality system, these will be recorded for purpose of review and clarity.**
6	**Planning**	

6.1	**Actions to address risks and opportunities**	
6.1.1	**When planning for the quality management system, the organization shall consider the issues referred to in 4.1 and the requirements referred to in 4.2 and determine the risks and opportunities that need to be addressed to:**	**The organization has created a risk process based upon ISO31000, This addresses issues within 4.1 & 4.2 of the Standard.**
	a) give assurance that the quality management system can achieve its intended result(s);	**The quality system will be designed to achieve its intended results.**
	b) enhance desirable effects;	**Through continual improvement**
	c) prevent, or reduce, undesired effects;	**Through the risk assessment model.**
	d) achieve improvement.	**Continual improvement mechanisms.**
6.1.2	**The organization shall plan:**	
	a) actions to address these risks and opportunities;	**Risks & opportunities will be highlighted within the ISO31000 Risk Assessment model.**
	b) how to:	
	1) integrate and implement the actions into its quality management system processes (see 4.4);	**The organization will integrate the QMS within a management system identifying inputs & outputs.**
	2) evaluate the effectiveness of these actions.	**Actions taken will be evaluated at management reviews.**
	Actions taken to address risks and opportunities shall be proportionate to the potential impact on the conformity of products and services.	**The risk assessment model used based upon ISO3100 2009 will define risk and impact with a score system.**
	NOTE 1 Options to address risks can include avoiding risk, taking risk in order to pursue an opportunity, eliminating the risk source, changing the likelihood or consequences, sharing the risk, or retaining risk by informed decision.	**Refer to risk assessment methodology.**
	NOTE 2 Opportunities can lead to the adoption of new practices, launching new products, opening new markets, addressing new customers, building partnerships, using new technology and other desirable and viable possibilities to address the organization's or its customers' needs.	
6.2	**Quality objectives and planning to achieve them**	**The organization shall create and communicate a range of quality objectives. These shall be documented within**
6.2.1	**The organization shall establish quality objectives at relevant functions, levels and processes needed for the quality management system.**	
	The quality objectives shall:	
	a) be consistent with the quality policy;	**Objectives will be SMART based and will be available within the context presentation.**
	b) be measurable;	**Objectives will be measurable and defined within presentation and QMS management review**
	c) take into account applicable requirements;	**See above**
	d) be relevant to conformity of products and services and to enhancement of customer satisfaction;	**Objectives selected will consider relevance to service / product offered.**
	e) be monitored;	**Process areas & objectives set will be monitored to ensure results can be achieved.**
	f) be communicated;	**The objectives are clearly communicated on the portal.**
	g) be updated as appropriate.	**When required objectives will be updated at the QMS management review meetings.**
	The organization shall maintain documented information on the quality objectives.	**Quality objectives will be documented within the context / objectives presentation.**
6.2.2	**When planning how to achieve its quality objectives, the organization shall determine:**	
	a) what will be done;	**Identified within the QMS management review**
	b) what resources will be required;	
	c) who will be responsible;	
	d) when it will be completed;	

	e) how the results will be evaluated.	
6.3	**Planning of changes**	
	When the organization determines the need for changes to the quality management system, the changes shall be carried out in a planned manner (see 4.4).	
	The organization shall consider:	
	a) the purpose of the changes and their potential consequences;	**Changes will be considered and recorded within the QMS management review.**
	b) the integrity of the quality management system;	**Integrity issues will be discussed at the management review.**
	c) the availability of resources;	**Resource issues required will be discussed at the management review.**
	d) the allocation or reallocation of responsibilities and authorities.	**Allocation or re-allocation will be discussed at the management review meetings.**
7	**Support**	
7.1	**Resources**	
7.1.1	**General**	
	The organization shall determine and provide the resources needed for the establishment, implementation, maintenance and continual improvement of the quality management system.	**Resource needed will be established within the context presentation.**
	The organization shall consider:	
	a) the capabilities of, and constraints on, existing internal resources;	**This area will be considered for input data into resources management.**
	b) what needs to be obtained from external providers.	**Requirements from external parties will be considered.**
7.1.2	**People**	
	The organization shall determine and provide the persons necessary for the effective implementation of its quality management system and for the operation and control of its processes.	**The organization shall define people related issues within the context presentation and the QMS management review meetings.**
7.1.3	**Infrastructure**	
	The organization shall determine, provide and maintain the infrastructure necessary for the operation of its processes and to achieve conformity of products and services.	**Infrastructure process deployed.**
	NOTE Infrastructure can include:	
	a) buildings and associated utilities;	**Refer to process**
	b) equipment, including hardware and software;	**Refer to infrastructure log.**
	c) transportation resources;	**Refer to infrastructure log**
	d) information and communication technology.	
7.1.4	**Environment for the operation of processes**	
	The organization shall determine, provide and maintain the environment necessary for the operation of its processes and to achieve conformity of products and services.	**Refer to infrastructure log and any required health and safety audits.**
	NOTE A suitable environment can be a combination of human and physical factors, such as:	
	a) social (e.g. non-discriminatory, calm, non-confrontational);	
	b) psychological (e.g. stress-reducing, burnout prevention, emotionally protective);	
	c) physical (e.g. temperature, heat, humidity, light, airflow, hygiene, noise).	
	These factors can differ substantially depending on the products and services provided.	**Refer to outputs of any health and safety audits.**
7.1.5	**Monitoring and measuring resources**	
7.1.5.1	**General**	

	The organization shall determine and provide the resources needed to ensure valid and reliable results when monitoring or measuring is used to verify the conformity of products and services to requirements.	**Monitoring & measuring will be defined within process charts. Where defined this will be maintained & assessed.**
	The organization shall ensure that the resources provided:	
	a) are suitable for the specific type of monitoring and measurement activities being undertaken;	**Reviewed by top management & discussed with MD**
	b) are maintained to ensure their continuing fitness for their purpose.	**Items are reviewed during audits & monitoring reviews.**
	The organization shall retain appropriate documented information as evidence of fitness for purpose of the monitoring and measurement resources.	**Appropriate information will be retained as required.**
7.1.5.2	**Measurement traceability**	
	When measurement traceability is a requirement, or is considered by the organization to be an essential part of providing confidence in the validity of measurement results, measuring equipment shall be:	
	a) calibrated or verified, or both, at specified intervals, or prior to use, against measurement standards traceable to international or national measurement standards; when no such standards exist, the basis used for calibration or verification shall be retained as documented information;	~~**Where calibrated equipment is used a process / instruction will be developed. It will be tested & certified to national standards.**~~
	b) identified in order to determine their status;	**Items will be identified as to their status.**
	c) safeguarded from adjustments, damage or deterioration that would invalidate the calibration status and subsequent measurement results.	**Items will be safeguarded from adjustments, damage or deterioration.**
	The organization shall determine if the validity of previous measurement results has been adversely affected when measuring equipment is found to be unfit for its intended purpose, and shall take appropriate action as necessary.	**Further checks will be undertaken to assess the capability of testing equipment, when it is found to be unfit.**
7.1.6	**Organizational knowledge**	
	The organization shall determine the knowledge necessary for the operation of its processes and to achieve conformity of products and services.	**The organization has developed a knowledge process.**
	This knowledge shall be maintained and be made available to the extent necessary.	**Knowledge will be defined that is relevant to the tasks required.**
	When addressing changing needs and trends, the organization shall consider its current knowledge and determine how to acquire or access any necessary additional knowledge and required updates.	**Further knowledge needs will be reviewed at the QMS management review meetings.**
	NOTE 1 Organizational knowledge is knowledge specific to the organization; it is generally gained by experience. It is information that is used and shared to achieve the organization's objectives.	
	NOTE 2 Organizational knowledge can be based on:	
	a) internal sources (e.g. intellectual property; knowledge gained from experience; lessons learned from failures and successful projects; capturing and sharing undocumented knowledge and experience; the results of improvements in processes, products and services);	
	b) external sources (e.g. standards; academia; conferences; gathering knowledge from customers or external providers).	
7.2	**Competence**	
	The organization shall:	
	a) determine the necessary competence of person(s) doing work under its control that affects the performance and effectiveness of the quality management system;	**The organization has developed a competence process. All staff have a competence grid breaking down their work functions to assess: application of skills & knowledge.**
	b) ensure that these persons are competent on the basis of appropriate education, training, or experience;	**Refer to competence process.**

	c) where applicable, take actions to acquire the necessary competence, and evaluate the effectiveness of the actions taken;	
	d) retain appropriate documented information as evidence of competence.	
	NOTE Applicable actions can include, for example, the provision of training to, the mentoring of, or the reassignment of currently employed persons; or the hiring or contracting of competent persons.	
7.3	**Awareness**	
	The organization shall ensure that persons doing work under the organization's control are aware of:	**The context presentation, policy and contents of the portal are communicated to all staff as required.**
	a) the quality policy;	**Quality policy is communicated**
	b) relevant quality objectives;	**Quality objectives are communicated.**
	c) their contribution to the effectiveness of the quality management system, including the benefits of improved performance;	**Defined within context presentation**
	d) the implications of not conforming with the quality management system requirements.	**Defined within communication process**
7.4	**Communication**	
	The organization shall determine the internal and external communications relevant to the quality management system, including:	**The organization has created a communications process.**
	a) on what it will communicate;	**Refer to communications process**
	b) when to communicate;	**Refer to communications process**
	c) with whom to communicate;	**Refer to communications process**
	d) how to communicate;	**Refer to communications process**
	e) who communicates.	**Refer to communications process**
7.5	**Documented information**	
7.5.1	**General**	
	The organization's quality management system shall include:	
	a) documented information required by this International Standard;	**The organization will create a documented management system & maintain documented records as required.**
	b) documented information determined by the organization as being necessary for the effectiveness of the quality management system.	**The information will be retained within a quality manual and portal structure where applicable.**
	NOTE The extent of documented information for a quality management system can differ from one organization to another due to:	
	— the size of organization and its type of activities, processes, products and services;	**Processes and interactions will be described within the interactions of processes diagram.**
	— the complexity of processes and their interactions;	**The interaction of processes will detail the diagrammatic of the quality system**
	— the competence of persons.	
7.5.2	**Creating and updating**	**New process charts are controlled & updated by the version and date & author section on each process.**
	When creating and updating documented information, the organization shall ensure appropriate:	
	a) identification and description (e.g. a title, date, author, or reference number);	**New process charts are controlled & updated by the version and date & author section on each process.**
	b) format (e.g. language, software version, graphics) and media (e.g. paper, electronic);	**Format will be either: hard copy or soft copy. Retention periods will be defined.**
	c) review and approval for suitability and adequacy.	**Documents will be reviewed for adequacy & suitability prior to issue.**

7.5.3	Control of documented information	
7.5.3.1	Documented information required by the quality management system and by this International Standard shall be controlled to ensure:	
	a) it is available and suitable for use, where and when it is needed;	Refer to document control process
	b) it is adequately protected (e.g. from loss of confidentiality, improper use, or loss of integrity).	Refer to document control process
7.5.3.2	For the control of documented information, the organization shall address the following activities, as applicable:	
	a) distribution, access, retrieval and use;	Refer to document control process
	b) storage and preservation, including preservation of legibility;	Refer to document control process
	c) control of changes (e.g. version control);	Refer to document control process
	d) retention and disposition.	Refer to document control process
	Documented information of external origin determined by the organization to be necessary for the planning and operation of the quality management system shall be identified as appropriate, and be controlled.	Refer to document control process
	Documented information retained as evidence of conformity shall be protected from unintended alterations.	Refer to document control process
	NOTE Access can imply a decision regarding the permission to view the documented information only, or the permission and authority to view and change the documented information.	
8	Operation	
8.1	Operational planning and control	
	The organization shall plan, implement and control the processes (see 4.4) needed to meet the requirements for the provision of products and services, and to implement the actions determined in Clause 6, by:	Processes will be controlled within either a portal or hard copy system. The processes will be defined by the PDCA model and identify inputs and outputs.
	a) determining the requirements for the products and services;	The organization has developed a process to handle enquiries & orders.
	b) establishing criteria for:	
	1) the processes;	Processes are established on the input output model
	2) the acceptance of products and services;	Defined within process maps
	c) determining the resources needed to achieve conformity to the product and service requirements;	Resources will be determined within process & context presentation.
	d) implementing control of the processes in accordance with the criteria;	Processes are implemented to address criteria.
	e) determining, maintaining and retaining documented information to the extent necessary:	The process diagrams will be retained as per documentation control.
	1) to have confidence that the processes have been carried out as planned;	Processes will be tested for effectiveness prior to approval.
	2) to demonstrate the conformity of products and services to their requirements.	Processes will be tested & evaluated to ensure service / product meets requirements.
	The output of this planning shall be suitable for the organization's operations.	Processes will be agreed & authorized prior to loading to portal.
	The organization shall control planned changes and review the consequences of unintended changes, taking action to mitigate any adverse effects, as necessary.	Refer to changes process.
	The organization shall ensure that outsourced processes are controlled (see 8.4).	Outsourced processes will be controlled
8.2	Requirements for products and services	
8.2.1	Customer communication	Refer to communications process.
	Communication with customers shall include:	Refer to communications process.
	a) providing information relating to products and services;	Refer to communications process
	b) handling enquiries, contracts or orders, including changes;	Refer to communications process

	c) obtaining customer feedback relating to products and services, including customer complaints;	**Refer to communications process**
	d) handling or controlling customer property;	**Refer to communications process**
	e) establishing specific requirements for contingency actions, when relevant.	**Refer to communications process**
8.2.2	**Determining the requirements for products and services**	
	When determining the requirements for the products and services to be offered to customers, the organization shall ensure that:	
	a) the requirements for the products and services are defined, including:	**Refer to enquires and sales process**
	1) any applicable statutory and regulatory requirements;	**The organization will maintain a listing of associated statutory & regulatory requirements**
	2) those considered necessary by the organization;	**See above.**
	b) the organization can meet the claims for the products and services it offers.	**Refer to enquiries & orders process.**
8.2.3	**Review of the requirements for products and services**	**Refer to enquiries & order process.**
8.2.3.1	**The organization shall ensure that it has the ability to meet the requirements for products and services to be offered to customers. The organization shall conduct a review before committing to supply products and services to a customer, to include:**	**Refer to enquiries & order process**
	a) requirements specified by the customer, including the requirements for delivery and post-delivery activities;	**Refer to enquiries & orders process**
	b) requirements not stated by the customer, but necessary for the specified or intended use, when known;	**Refer to enquiries & orders process**
	c) requirements specified by the organization;	**Refer to enquiries & orders process**
	d) statutory and regulatory requirements applicable to the products and services;	**Refer to legal register**
	e) contract or order requirements differing from those previously expressed.	**Refer to enquiries & orders process**
	The organization shall ensure that contract or order requirements differing from those previously defined are resolved.	**Refer to enquiries & orders process**
	The customer's requirements shall be confirmed by the organization before acceptance, when the customer does not provide a documented statement of their requirements.	**Refer to enquiries & orders process**
	NOTE in some situations, such as internet sales, a formal review is impractical for each order. Instead, the review can cover relevant product information, such as catalogues.	**If internet ordering is established a process will be formulated.**
8.2.3.2	**The organization shall retain documented information, as applicable:**	**Documents relevant to handling enquiries & orders will be retained.**
	a) on the results of the review;	**Refer to process & associated records**
	b) on any new requirements for the products and services.	**Refer to process & associated records**
8.2.4	**Changes to requirements for products and services**	**Refer to enquiries & orders process**
	The organization shall ensure that relevant documented information is amended, and that relevant persons are made aware of the changed requirements, when the requirements for products and services are changed.	**Refer to enquiries & orders process**
8.3	**Design and development of products and services**	**If identified within scope, see design checklists**
8.3.1	**General**	
	The organization shall establish, implement and maintain a design and development process that is appropriate to ensure the subsequent provision of products and services.	**Applies for all of design section.**
8.3.2	**Design and development planning**	
	In determining the stages and controls for design and development, the organization shall consider:	
	a) the nature, duration and complexity of the design and development activities;	

	b) the required process stages, including applicable design and development reviews;	
	c) the required design and development verification and validation activities;	
	d) the responsibilities and authorities involved in the design and development process;	
	e) the internal and external resource needs for the design and development of products and services;	
	f) the need to control interfaces between persons involved in the design and development process;	
	g) the need for involvement of customers and users in the design and development process;	
	h) the requirements for subsequent provision of products and services;	
	i) the level of control expected for the design and development process by customers and other relevant interested parties;	
	j) the documented information needed to demonstrate that design and development requirements have been met.	
8.3.3	**Design and development inputs**	
	The organization shall determine the requirements essential for the specific types of products and services to be designed and developed. The organization shall consider:	
	a) functional and performance requirements;	
	b) information derived from previous similar design and development activities;	
	c) statutory and regulatory requirements;	
	d) standards or codes of practice that the organization has committed to implement;	
	e) potential consequences of failure due to the nature of the products and services.	
	Inputs shall be adequate for design and development purposes, complete and unambiguous.	
	Conflicting design and development inputs shall be resolved.	
	The organization shall retain documented information on design and development inputs.	
8.3.4	**Design and development controls**	
	The organization shall apply controls to the design and development process to ensure that:	
	a) the results to be achieved are defined;	
	b) reviews are conducted to evaluate the ability of the results of design and development to meet requirements;	
	c) verification activities are conducted to ensure that the design and development outputs meet the input requirements;	
	d) validation activities are conducted to ensure that the resulting products and services meet the requirements for the specified application or intended use;	
	e) any necessary actions are taken on problems determined during the reviews, or verification and validation activities;	
	f) documented information of these activities is retained.	
	NOTE Design and development reviews, verification and validation have distinct purposes. They can be conducted separately or in any combination, as is suitable for the products and services of the organization.	
8.3.5	**Design and development outputs**	
	The organization shall ensure that design and development outputs:	
	a) meet the input requirements;	
	b) are adequate for the subsequent processes for the provision of products and services;	

	c) include or reference monitoring and measuring requirements, as appropriate, and acceptance criteria;	
	d) specify the characteristics of the products and services that are essential for their intended purpose and their safe and proper provision.	
	The organization shall retain documented information on design and development outputs.	
8.3.6	**Design and development changes**	
	The organization shall identify, review and control changes made during, or subsequent to, the design and development of products and services, to the extent necessary to ensure that there is no adverse impact on conformity to requirements.	
	The organization shall retain documented information on:	
	a) design and development changes;	
	b) the results of reviews;	
	c) the authorization of the changes;	
	d) the actions taken to prevent adverse impacts.	
8.4	**Control of externally provided processes, products and services**	**Refer to process.**
8.4.1	**General**	
	The organization shall ensure that externally provided processes, products and services conform to requirements.	**Refer to control of externally provided processes.**
	The organization shall determine the controls to be applied to externally provided processes, products and services when:	**As above.**
	a) products and services from external providers are intended for incorporation into the organization's own products and services;	
	b) products and services are provided directly to the customer(s) by external providers on behalf of the organization;	
	c) a process, or part of a process, is provided by an external provider as a result of a decision by the organization.	
	The organization shall determine and apply criteria for the evaluation, selection, monitoring of performance, and re-evaluation of external providers, based on their ability to provide processes or products and services in accordance with requirements. The organization shall retain documented information of these activities and any necessary actions arising from the evaluations.	
8.4.2	**Type and extent of control**	
	The organization shall ensure that externally provided processes, products and services do not adversely affect the organization's ability to consistently deliver conforming products and services to its customers.	
	The organization shall:	
	a) ensure that externally provided processes remain within the control of its quality management system;	
	b) define both the controls that it intends to apply to an external provider and those it intends to apply to the resulting output;	
	c) take into consideration:	
	1) the potential impact of the externally provided processes, products and services on the organization's ability to consistently meet customer and applicable statutory and regulatory requirements;	
	2) the effectiveness of the controls applied by the external provider;	

	d) determine the verification, or other activities, necessary to ensure that the externally provided processes, products and services meet requirements.	
8.4.3	**Information for external providers**	**Refer to process.**
	The organization shall ensure the adequacy of requirements prior to their communication to the external provider.	
	The organization shall communicate to external providers its requirements for:	
	a) the processes, products and services to be provided;	
	b) the approval of:	
	1) products and services;	
	2) methods, processes and equipment;	
	3) the release of products and services;	
	c) competence, including any required qualification of persons;	
	d) the external providers' interactions with the organization;	
	e) control and monitoring of the external providers' performance to be applied by the organization;	
	f) verification or validation activities that the organization, or its customer, intends to perform at the external providers' premises.	
8.5	**Production and service provision**	
8.5.1	**Control of production and service provision**	**Core operating processes will be established.**
	The organization shall implement production and service provision under controlled conditions.	
	Controlled conditions shall include, as applicable:	
	a) the availability of documented information that defines:	
	1) the characteristics of the products to be produced, the services to be provided, or the activities to be performed;	**Defined within process.**
	2) the results to be achieved;	**Defined within process**
	b) the availability and use of suitable monitoring and measuring resources;	**Refer to resources process / infrastructure**
	c) the implementation of monitoring and measurement activities at appropriate stages to verify that criteria for control of processes or outputs, and acceptance criteria for products and services, have been met;	**Refer to resources process / infrastructure**
	d) the use of suitable infrastructure and environment for the operation of processes;	**Refer to resources process / infrastructure**
	e) the appointment of competent persons, including any required qualification;	**Refer to training & competence process**
	f) the validation, and periodic revalidation, of the ability to achieve planned results of the processes for production and service provision, where the resulting output cannot be verified by subsequent monitoring or measurement;	**Refer to process**
	g) the implementation of actions to prevent human error;	**Refer to process**
	h) the implementation of release, delivery and post-delivery activities.	**Refer to process**
8.5.2	**Identification and traceability**	**Refer to core process.**
	The organization shall use suitable means to identify outputs when it is necessary to ensure the conformity of products and services.	**This is detailed within the core process**
	The organization shall identify the status of outputs with respect to monitoring and measurement requirements throughout production and service provision.	**This is detailed within core process**
	The organization shall control the unique identification of the outputs when traceability is a requirement, and shall retain the documented information necessary to enable traceability.	**Identification shall be detailed within the process.**

8.5.3	**Property belonging to customers or external providers**	**Property belonging to customers defined within core processes.**
	The organization shall exercise care with property belonging to customers or external providers while it is under the organization's control or being used by the organization.	
	The organization shall identify, verify, protect and safeguard customers' or external providers' property provided for use or incorporation into the products and services.	
	When the property of a customer or external provider is lost, damaged or otherwise found to be unsuitable for use, the organization shall report this to the customer or external provider and retain documented information on what has occurred.	
	NOTE A customer's or external provider's property can include materials, components, tools and equipment, premises, intellectual property and personal data.	
8.5.4	**Preservation**	
	The organization shall preserve the outputs during production and service provision, to the extent necessary to ensure conformity to requirements.	**Preservation shall be identified within core processes.**
	NOTE Preservation can include identification, handling, contamination control, packaging, storage, transmission or transportation, and protection.	
8.5.5	**Post-delivery activities**	
	The organization shall meet requirements for post-delivery activities associated with the products and services.	**Post-delivery activities are identified within core operational processes.**
	In determining the extent of post-delivery activities that are required, the organization shall consider:	**Post-delivery activities are identified within core operational processes.**
	a) statutory and regulatory requirements;	**Review of requirements with regards statutory requirements is defined within the core processes**
	b) the potential undesired consequences associated with its products and services;	**If applicable defined within the core processes**
	c) the nature, use and intended lifetime of its products and services;	**Defined within the process.**
	d) customer requirements;	
	e) customer feedback.	**See customer satisfaction process.**
	NOTE Post-delivery activities can include actions under warranty provisions, contractual obligations such as maintenance services, and supplementary services such as recycling or final disposal.	
8.5.6	**Control of changes**	
	The organization shall review and control changes for production or service provision, to the extent necessary to ensure continuing conformity with requirements.	**Refer to change control process**
	The organization shall retain documented information describing the results of the review of changes, the person(s) authorizing the change, and any necessary actions arising from the review.	
8.6	**Release of products and services**	
	The organization shall implement planned arrangements, at appropriate stages, to verify that the product and service requirements have been met.	**Refer to core operations process.**
	The release of products and services to the customer shall not proceed until the planned arrangements have been satisfactorily completed, unless otherwise approved by a relevant authority and, as applicable, by the customer.	**Refer to core operations process**
	The organization shall retain documented information on the release of products and services. The documented information shall include:	**Refer to core operations process**
	a) evidence of conformity with the acceptance criteria;	

	b) traceability to the person(s) authorizing the release.	**Refer to core operating process**
8.7	**Control of nonconforming outputs**	
8.7.1	**The organization shall ensure that outputs that do not conform to their requirements are identified and controlled to prevent their unintended use or delivery.**	**Refer to control of non-conforming outputs and noncompliance process**
	The organization shall take appropriate action based on the nature of the nonconformity and its effect on the conformity of products and services. This shall also apply to nonconforming products and services detected after delivery of products, during or after the provision of services.	**Refer to above**
	The organization shall deal with nonconforming outputs in one or more of the following ways:	
	a) correction;	
	b) segregation, containment, return or suspension of provision of products and services;	
	c) informing the customer;	
	d) obtaining authorization for acceptance under concession.	
	Conformity to the requirements shall be verified when nonconforming outputs are corrected.	
8.7.2	**The organization shall retain documented information that:**	
	a) describes the nonconformity;	
	b) describes the actions taken;	
	c) describes any concessions obtained;	
	d) identifies the authority deciding the action in respect of the nonconformity.	
9	**Performance evaluation**	
9.1	**Monitoring, measurement, analysis and evaluation**	**Refer to resources / monitoring & measuring process**
9.1.1	**General**	
	The organization shall determine:	
	a) what needs to be monitored and measured;	
	b) the methods for monitoring, measurement, analysis and evaluation needed to ensure valid results;	
	c) when the monitoring and measuring shall be performed;	
	d) when the results from monitoring and measurement shall be analysed and evaluated.	
	The organization shall evaluate the performance and the effectiveness of the quality management system.	
	The organization shall retain appropriate documented information as evidence of the results.	
9.1.2	**Customer satisfaction**	**Refer to customer satisfaction process**
	The organization shall monitor customers' perceptions of the degree to which their needs and expectations have been fulfilled. The organization shall determine the methods for obtaining, monitoring and reviewing this information.	
	NOTE Examples of monitoring customer perceptions can include customer surveys, customer feedback on delivered products and services, meetings with customers, market-share analysis, compliments, warranty claims and dealer reports.	
9.1.3	**Analysis and evaluation**	**Refer to management review process**
	The organization shall analyse and evaluate appropriate data and information arising from monitoring and measurement.	
	The results of analysis shall be used to evaluate:	
	a) conformity of products and services;	
	b) the degree of customer satisfaction;	

	c) the performance and effectiveness of the quality management system;	
	d) if planning has been implemented effectively;	
	e) the effectiveness of actions taken to address risks and opportunities;	
	f) the performance of external providers;	
	g) the need for improvements to the quality management system.	
	NOTE Methods to analyse data can include statistical techniques.	
9.2	**Internal audit**	**Refer to audit process**
9.2.1	**The organization shall conduct internal audits at planned intervals to provide information on whether the quality management system:**	
	a) conforms to:	
	1) the organization's own requirements for its quality management system;	
	2) the requirements of this International Standard;	
	b) is effectively implemented and maintained.	
9.2.2	**The organization shall:**	
	a) plan, establish, implement and maintain an audit programme(s) including the frequency, methods, responsibilities, planning requirements and reporting, which shall take into consideration the importance of the processes concerned, changes affecting the organization, and the results of previous audits;	
	b) define the audit criteria and scope for each audit;	
	c) select auditors and conduct audits to ensure objectivity and the impartiality of the audit process;	
	d) ensure that the results of the audits are reported to relevant management;	
	e) take appropriate correction and corrective actions without undue delay;	
	f) retain documented information as evidence of the implementation of the audit programme and the audit results.	
	NOTE See ISO 19011 for guidance.	
9.3	**Management review**	**Refer to management review process**
9.3.1	**General**	
	Top management shall review the organization's quality management system, at planned intervals, to ensure its continuing suitability, adequacy, effectiveness and alignment with the strategic direction of the organization.	
9.3.2	**Management review inputs**	
	The management review shall be planned and carried out taking into consideration:	
	a) the status of actions from previous management reviews;	
	b) changes in external and internal issues that are relevant to the quality management system;	
	c) information on the performance and effectiveness of the quality management system, including trends in:	
	1) customer satisfaction and feedback from relevant interested parties;	
	2) the extent to which quality objectives have been met;	
	3) process performance and conformity of products and services;	
	4) nonconformities and corrective actions;	
	5) monitoring and measurement results;	

	6) audit results;	
	7) the performance of external providers;	
	d) the adequacy of resources;	
	e) the effectiveness of actions taken to address risks and opportunities (see 6.1);	
	f) opportunities for improvement.	
9.3.3	**Management review outputs**	
	The outputs of the management review shall include decisions and actions related to:	
	a) opportunities for improvement;	
	b) any need for changes to the quality management system;	
	c) resource needs.	
	The organization shall retain documented information as evidence of the results of management reviews.	
10	**Improvement**	**Refer to continual improvement process**
10.1	**General**	
	The organization shall determine and select opportunities for improvement and implement any necessary actions to meet customer requirements and enhance customer satisfaction.	
	These shall include:	
	a) improving products and services to meet requirements as well as to address future needs and expectations;	
	b) correcting, preventing or reducing undesired effects;	
	c) improving the performance and effectiveness of the quality management system.	
	NOTE Examples of improvement can include correction, corrective action, continual improvement, breakthrough change, innovation and re-organization.	
10.2	**Nonconformity and corrective action**	**Refer to Non Conformity Process / Risk**
10.2.1	**When a nonconformity occurs, including any arising from complaints, the organization shall:**	
	a) react to the nonconformity and, as applicable:	
	1) take action to control and correct it;	
	2) deal with the consequences;	
	b) evaluate the need for action to eliminate the cause(s) of the nonconformity, in order that it does not recur or occur elsewhere, by:	
	1) reviewing and analysing the nonconformity;	
	2) determining the causes of the nonconformity;	
	3) determining if similar nonconformities exist, or could potentially occur;	
	c) implement any action needed;	
	d) review the effectiveness of any corrective action taken;	
	e) update risks and opportunities determined during planning, if necessary;	
	f) make changes to the quality management system, if necessary.	
	Corrective actions shall be appropriate to the effects of the nonconformities encountered.	
10.2.2	**The organization shall retain documented information as evidence of:**	
	a) the nature of the nonconformities and any subsequent actions taken;	
	b) the results of any corrective action.	

10.3	**Continual improvement**	**Refer to continual improvement process.**
	The organization shall continually improve the suitability, adequacy and effectiveness of the quality management system.	
	The organization shall consider the results of analysis and evaluation, and the outputs from management review, to determine if there are needs or opportunities that shall be addressed as part of continual improvement.	