James Walker

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Quality Manual

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JAMES WALKER & CO. LTD

Gote Brow

Cockermouth

Cumbria CA13 0NH

UNITED KINGDOM

REASON FOR LAST UPDATE:

Clause 1.1 and 4.3 - Scope amended to make more reflective of PEAR's

Current 4.3 – Scope amended to reflect current site manufacturing capability (removal of compression packing)

Clause 8.5.2 – Reference to OPI47 removed

Author:

Matthew Wilson

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0. Introduction

0.1 General

James Walker & Co. Ltd have developed and implemented a management system in order to document the company's best business practices and to better satisfy the requirements and expectations of our customers. The management system has been developed to continually improve and to sustain the overall performance of our business, products, services, and provide the necessary instructions that create an empowered workforce.

The Quality Manual is considered the normative basis of reference to the International Standard and shall be used internally to provide an overview of BS EN9100:2018 and ISO9001:2015 requirements and how they apply at James Walker & Co. Ltd. The Quality Manual is used externally to introduce the elements of our management system to our customers and other external organizations to the extent necessary.

When an update to the manual is issued additional attention is drawn to Customer Specific Quality Manual Requirements (AREVA, Rolls Royce, MOD as examples):- such as informing the customer of any significant updates which may affect form, fit and function of products and/or services provided.

0.2 Quality Management Principles

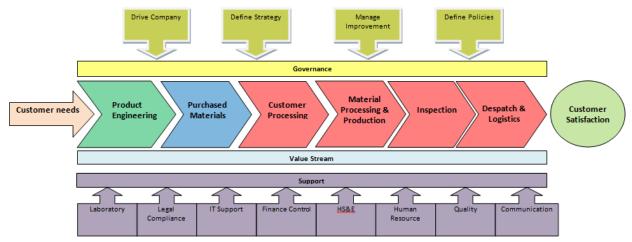
James Walker & Co. Ltd has adopted and realizes the benefits of Quality Management Principles into our daily activities. The intent of the Quality Management Principles is to provide a foundation to continually improve upon the Company's performance. Subsequent sections of the QMS Manual will provide our commitments of the following elements:

- customer focus
- leadership
- communications and the engagement of our people
- process approach
- improvement
- risk & opportunity as well as evidence-based decision making
- Relationship management

0.3 Process Approach

0.3.1 General

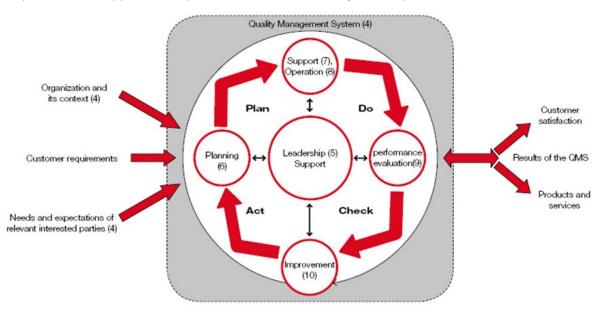
The process approach integrates processes into an all-inclusive system in order to achieve strategic and operational objectives.



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0.3.2 Plan-Do-Check-Act Cycle

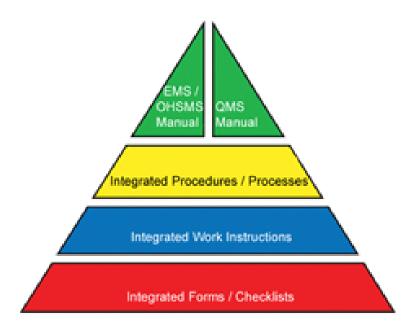
The PDCA cycle has been applied to all processes and to the management system as a whole.



0.3.3 Risk-Based Thinking

James Walker & Co. Ltd has utilized the risk-based thinking philosophy when developing, implementing, and improving the effectiveness of our management system. This approach will enable James Walker & Co. Ltd to effectively plan and implement actions to address risks and opportunities including; but not limited to achieving improved results and preventing negative effects of our products and services.

0.4 Relationship with Other Management System Standards



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1. Scope

1.1 General

James Walker & Co. Ltd has implemented a Quality Management System in compliance with BS EN9100:2018 and ISO9001:2015. This reflects the company's best business practices to surpass the requirements and expectations of our customers. The management system has been developed to continually improve and to sustain the overall performance of our business, products, services, and provide the necessary instructions that create an empowered workforce.

Locations:	Scope:
James Walker & Co. Ltd (BS EN9100)	PEAR 1 – Design & Development
Gote Brow	PEAR 2 – Purchasing
Cockermouth	PEAR 3 – Product Realisation
Cumbria	
CA13 0NH	

1.2 Application / Exclusions

James Walker & Co. Ltd, Cockermouth has determined that there are no exclusions against this standard: BS EN9100:2018.

2. Normative References

The following documents were used as reference points during the preparation of this quality manual:

- 1. ISO 9001:2015 Quality Management Systems Requirements.
- 2. BS EN9100: 2018 Quality Management Systems Requirements
- 3. ISO 9000:2015 Quality Management Systems Fundamentals and Vocabulary.
- 4. AS9102 Aerospace First Article Inspection Requirement.
- 5. QN100_{generic} (NSQ100) (where applicable only)
- 6. 06QPN01 (where applicable only)
- 7. 10CFR50 App B/NQA1-10CFR21 (where applicable only)

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3. Terms and Definitions

The quality management system uses the same internationally recognised terms, vocabulary and definitions given in EN ISO 9000:2015 and the following:

3.1 Counterfeit Part

An unauthorised copy, imitation, substitute, or modified part (e.g. material, part, component), which is knowingly misrepresented as a specified genuine part of an original or authorized manufacturer.

3.2 Critical Items

Those items (e.g. functions, parts, software, characteristics, processes) having significant effect on the product and services; including safety, performance, form, fit, function, producibility, service life etc; that require specific actions to ensure they are adequately managed. Examples of critical items include safety critical items, fracture critical items, mission critical items and key characteristics, etc.

3.3 Key Characteristic:

An attribute or feature whose variation has a significant effect on product, form, fit, function, performance, service life or producibility that requires specific actions for the purpose of controlling variation.

3.4 Product Safety:

The state in which a product is able to perform to its designed or intended purpose without causing unacceptable risk of harm to persons or damage to property.

3.5 Special Requirements:

Those requirements identified by the customer, or determined by James Walker and Co. Ltd, which have high risks of not being met, thus requiring their inclusion in the operational risk management process. Factors used by James Walker and Co. Ltd in the determination of special requirements include product or process complexity, past experiences and product or process maturity.

4. Context of the Organisation

4.1 Understanding the Organisation and Its Context

James Walker & Co. Ltd has determined relevant external and internal issues and items that may become relevant to the company's purpose and strategic direction, and may affect our ability to achieve the intended results of the Management System.

(Refer to A1 PESTLE & A2 SWOT)

4.2 Understanding the needs and expectations of Interested Parties

The effect or potential effect on our organisations ability to consistently provide products and services that meet our customer and applicable statutory and regulatory requirements, James Walker & Co. Ltd has determined the following:

- the interested parties relevant to the Management System
- the requirements of the identified interested parties relevant to the Management System

James Walker & Co. Ltd is committed to continually monitoring, reviewing and analyzing information and relevant requirements of the interested parties to assure their requirements are effectively managed in the Management System.

(Refer to B Interested Parties)

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4.3 Determining the Scope of the Quality Management System

To determine and establish the scope of the QMS, James Walker & Co. Ltd has determined the boundaries and applicability of the QMS and considered the external and internal issues, the requirements of relevant interested parties, and the products and services of the company.

The scope is available and maintained as documented information stating the products and services covered by the QMS. James Walker & Co. Ltd applies all the requirements of BS EN9100:2018 and ISO9001:2015 within the determined scope of the QMS.

James Walker & Co. Ltd has determined, designed and implemented a management system to cover and support the following Scope:

The design and manufacture of packings, seals, gaskets and jointing's, as precision natural and synthetic rubber mouldings, extrusions and sheeting's, rubberised fabric mouldings, sheeting and joints, hydraulic seals. O Rings, lip seals, diaphragms, injection moulded, thermo-plastic components, expanded graphite sheets and gaskets cut in all materials including natural and synthetic rubber, rubber bonded asbestos-free fibre, elastomer bonded cork and PTFE. This includes a system to provide lot traceability to raw materials/components. Stockholding and supply of sealing products.

4.4 Quality Management System and Its Processes

4.4.1 James Walker & Co. Ltd has designed, documented and implemented a quality management system in accordance with the requirements of BS EN9100:2018. This is maintained and continually improved through the use of the Quality Policy, Manufacturing Business Unit Priority Targets (MBU), audit results, analysis of data, corrective and preventative action, management review and customer satisfaction surveys.

The quality management system of James Walker & Co. Ltd also addresses customer and applicable statutory and regulatory quality management system requirements.

In order to design and implement the quality management system, James Walker & Co. Ltd has/does:

- determined the inputs required and the outputs expected from these processes
- (Refer to F392 key process diagrams)
- determined the sequence and interaction of these processes

(Refer to QSM01 – Process Interactions)

- determined and applied the criteria and methods needed to ensure the effective operation and control of these processes
- ensured the availability of the resources needed for these processes
- assigned the responsibilities and authorities for these processes
- addressed the risks and opportunities as determined in the requirements of BS EN9100:2018 clause 6.1
- continually evaluate these processes and implement any changes needed to ensure that these processes achieve their intended results
- continually improve the processes and the quality management system

4.4.2 To the extent necessary, James Walker & Co. Ltd will:

- maintain documented information to support the operation of its processes;
- retain documented information to have confidence that the processes are being carried out as planned

(Refer to QPD 77 Document Control and QPD 77A Control of Records)

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5. Leadership

5.1 Leadership and Commitment

5.1.1 General

The senior management team at James Walker & Co. Ltd is committed to the development and implementation of the quality management system and will continually improve its effectiveness by:

- taking accountability for the effectiveness of the quality management system
- ensuring that the quality policy and quality objectives, including appropriate nuclear safety considerations, are established for the quality management system and are compatible with the context and strategic direction of the organisation
- ensuring the integration of the quality management system requirements into the organisation's business processes
- promoting the use of the process approach and risk-based thinking
- ensuring that the resources needed for the quality management system are available
- communicating the importance of effective quality management and of conforming to the quality system requirements
- ensuring that the quality management system achieves its intended results
- engaging, directing and supporting persons to contribute to the effectiveness of the quality management system
- promoting improvement
- supporting other relevant management roles to demonstrate their leadership as it applies to their areas of responsibility
- ensuring that nuclear safety and other industry safety considerations are taken into account in decision making and are not compromised by any decisions taken.

5.1.2 Customer Focus

The senior management team at James Walker & Co. Ltd will demonstrate leadership and commitment with respect to customer focus by ensuring that:

- customer and applicable statutory and regulatory requirements are determined, understood and consistently met
- the risks and opportunities that can affect conformity of products and services and the ability to enhance customer satisfaction are determined and addressed
- the focus on enhancing customer satisfaction is maintained
- product and service conformity and on-time delivery performance are measured and appropriate action is taken if planned results are not met, or will not be met, achieved

(Refer to SHEP029 Legal and Other Requirements Register)

5.2 Quality Policy

5.2.1 Establishing the quality policy

The senior management team has established, implemented and maintains a quality policy that:

- is appropriate to the purpose and context of James Walker & Co. Ltd and supports its strategic direction
- provides a framework for setting quality objectives
- provides a commitment to satisfy all applicable requirements
- includes a commitment to continual improvement of the QMS

(Refer to Quality Policy Statement)

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5.2.2 Communicating

That the policy is:

- available and maintained as documented information;
- is communicated, understood, and applied within the organisation
- is available to relevant interested parties, as appropriate.

5.3 Organisational Roles, Responsibilities and Authorities

The senior management team at James Walker & Co. Ltd ensures that responsibilities and authorities are defined and communicated within James Walker & Co. Ltd. A management Organisational chart and Organisational chart specific to the Quality department are maintained accordingly and held by the PA to the Site Director.

(Refer to Management and Operations Org Chart)

The senior management team at James Walker & Co. Ltd has appointed a member of the management who, irrespective of other responsibilities, has responsibility and authority that includes:

- ensuring the QMS conforms to the requirements of BS EN9100:2018 and ISO 9001:2015
- ensuring that the processes are delivering their intended outputs
- reporting on the performance of the QMS and on opportunities for improvement, in particular to senior management
- ensuring the promotion of customer focus throughout the organisation
- ensuring the integrity of the quality management system is maintained when changes to the QMS are planned and implemented

The management representative has the organisational freedom and unrestricted access to top management to resolve quality management issues.

6.0 Planning

6.1 Actions to Address Risks and Opportunities

6.1.1 When planning the QMS, James Walker & Co. Ltd has taken into consideration the issues referred to in 4.1 and the requirements referred to in 4.2 and have determined the risks and opportunities that need to be addressed to:

- give assurance that the QMS can achieve its intended results
- enhance desirable effects
- prevent, or reduce, undesired effects
- achieve improvement
- **6.1.2** James Walker & Co. Ltd has planned actions to:
 - address these risks and opportunities
 - and how to;
 - 1) integrate and implement appropriate actions into our QMS processes (see 4.4);
 - 2) including an evaluation of the effectiveness our QMS processes.

Any actions taken to address risks and opportunities shall be proportionate to the potential impact on the conformity of products and services.

(Refer to QPD87 Risk Mitigation, QPD164 Product Risk Register and QPD165 PFMEA)

6.2 Quality Objectives and Planning to Achieve Them

6.2.1 Quality objectives have been established at relevant functions, levels, and processes for the quality

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management system to:

- be consistent with the Quality Policy;
- be measurable;
- take into account applicable requirements;
- be relevant to conformity of products, services and to enhancement of customer satisfaction;
- be monitored;
- be communicated;
- be updated, as appropriate.

James Walker & Co. Ltd maintains documented information on the quality objectives.

- **6.2.2** Planning to achieve quality objectives has been determined by:
 - what will be done;
 - what resources will be required;
 - who will be responsible;
 - when it will be completed;
 - how the results will be evaluated.

6.3 Planning of Changes

When changes to the QMS are deemed necessary, James Walker & Co. Ltd shall ensure the change will comply with the requirements of BS EN9100:2018 and ISO 9001:2015 and shall consider:

- the purpose of the changes and their potential consequences
- the integrity of QMS
- the availability of resources
- the allocation or reallocation of responsibilities and authorities

(Refer to QPD 06 Approved Signatories and QPD 101 Control of Product and Process Change)

7.0 Support

7.1 Resources

7.1.1 General

James Walker & Co. Ltd has determined and provided the resources necessary to establish, implement, maintain and continually improve its QMS and has considered:

- the capabilities of, and constraints on, existing internal resources;
- what needs to be obtained from external providers.

(Refer to QPD 50 Training and QPD 49 Purchasing)

7.1.2 People

James Walker & Co. Ltd has determined and provides the persons necessary for the effective implementation of its QMS and for the operation and control of its processes.

(Refer to QPD 50 Training and QPD 06 Approved Signatories)

7.1.3 Infrastructure

James Walker and Co. Ltd determines, provides and maintains the infrastructure needed to achieve conformity to

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product requirements. Infrastructure includes:

- buildings and associated utilities;
- equipment, including hardware and software;
- transportation resources;
- information and communication technology.

(Refer to QPD 91 Maintenance)

7.1.4 Environment for the operation of processes

James Walker & Co. Ltd has determined, provides and maintains the environment necessary for the operation of its processes and to achieve conformity of products and services.

The environment is a combination of both human and physical factors, such as:

- social (e.g., non-discriminatory, calm, non-confrontational);
- psychological (e.g., stress-reducing, burnout prevention, emotionally protective);
- physical (e.g., temperature, heat, humidity, light, airflow, hygiene, noise).

(Refer to QPD 91 Maintenance and relevant HR policies)

7.1.5 Monitoring and Measuring Resources

7.1.5.1 General

James Walker & Co. Ltd has determined and provided the necessary resources needed to ensure valid and reliable results when monitoring or measuring is used to verify conformity of products and services to requirements.

James Walker & Co. Ltd has ensured that the necessary resources provided:

- are suitable for the specific type of monitoring and measurement activities being undertaken;
- are maintained to ensure their continuing fitness for purpose.

James Walker & Co. Ltd will retain appropriate documented information as evidence of fitness for purpose of the monitoring and measurement resources.

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:

- 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;
- identified in order to determine their status;
- safeguarded from adjustments, damage or deterioration that would invalidate the calibration status and subsequent measurement results.

Where the validity of previous measurement results has been adversely affected when measuring equipment is found to be unfit for its intended purpose, appropriate action shall be taken.

(Refer to QPD 21 Calibration of onsite measuring equipment)

7.1.6 Organisational Knowledge

James Walker & Co. Ltd has determined the knowledge necessary for the operation of its processes and to achieve conformity of products and services.

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This knowledge shall be maintained and be made available to the extent necessary. 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. (Refer to QPD 50 Training)

7.2 Competence

The senior management team at James Walker & Co. Ltd:

- determines the necessary competence of person(s) doing work under its control that affects the performance and effectiveness of the QMS;
- ensures that these persons are competent on the basis of appropriate education, training, or experience;
- where applicable, take actions to acquire the necessary competence, and evaluate the effectiveness of the actions taken;
- retain appropriate documented information as evidence of competence.

(Refer to QPD 50 Training)

7.3 Awareness

James Walker & Co. Ltd has ensured persons doing work under our control are aware of:

- the Quality Policy;
- relevant quality objectives;
- their contribution to the effectiveness of the QMS, including the benefits of improved performance;
- the implications of not conforming with the QMS requirements;
- relevant QMS documented information and changes thereto;
- their contribution to products or service conformity;
- their contribution to product safety;
- their importance of ethical behaviour.

(Refer to QPD 50 Training)

7.4 Communication

The senior management team at James Walker & Co. Ltd has determined the internal and external communications relevant to the QMS, including:

- On what it will communicate;
- When to communicate;
- With whom it will communicate;
- How to communicate;
- Who communicates.

7.5 Documented information

7.5.1 General

James Walker & Co. Ltd's quality management system includes:

- documented information required by BS EN9100:2018 and ISO 9001;
- documented information determined by James Walker (UK) Ltd as being necessary for the effectiveness of the quality management system.

(Refer to QPD 77 Document Control and QPD 77A Control of Records)

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7.5.2 Creating and updating

When creating and updating documented information James Walker & Co Ltd ensures the following:

- identification and description (e.g., a title, date, author, or reference number);
- format (e.g., language, software version, graphics,) and media (e.g., paper, electronic);
- review and approval for suitability and adequacy.

(Refer to QPD 77 Document Control and QPD 77A Control of Records)

7.5.3 Control of documented information

7.5.3.1 Documented information required by the QMS and by BS EN9100:2018 is controlled to ensure:

- It is available and suitable for use;
- It is adequately protected (e.g. from loss of confidentiality, improper use, or loss of integrity).

(Refer to QPD 77 Document Control, QPD 77A Control of Records, FMP 18 Standards Library and FMP 19 Restricted Documents)

7.5.3.2 For the control of documented information, James Walker & Co. Ltd has addressed the following activities, as applicable:

- Distribution, access, retrieval, and use;
- Storage and preservation, including preservation of legibility;
- Control of changes (e.g., version control);
- Retention and disposal;
- Prevention of unintended use of obsolete documented information by removal or by application of suitable or controls if kept for purpose.

James Walker & Co. Ltd has established a documented procedure to define the controls needed for the identification, storage, protection, retrieval, retention and disposition of records. Records, which are legible and identified, are indexed and filed relative to the Quality system activity as appropriate and suitably stored and maintained in their particular location during their retention period, which is normally a minimum of 5 years, unless specifically requested for a longer period by individual customers.

Documentation relating to Aviation, Space and Defence customer orders shall be maintained indefinitely (at least for the life of the finished product/vehicle) and should be destroyed only with the agreement of the customer.

(Refer to QPD 77 Document Control, QPD 77A Control of Records, FMP 18 Standards Library and FMP 19 Restricted Documents)

8.0 Operation

8.1 Operational Planning and Control

James Walker & Co Ltd has planned, implemented and controls 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:

determining the requirements for products and services; including consideration of:

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- personal and product safety;
- producibility and inspectability;
- reliability, availability, and maintainability;
- suitability of parts and materials used in the product;
- ~ selection and development of embedded software;
- ~ product obsolescence;
- ~ prevention, detection, and removal of foreign objects;
- ~ handling, packaging, and preservation;
- ~ recycling or final disposal of product at end of life.
- establishing criteria for the:
 - ~ processes;
 - acceptance of products and services;

(Refer to QSM01 – Process Interactions and F392 key process diagrams)

 determining the resources needed to achieve conformity to the product and service requirements and to meet on-time delivery of products and services;

(Refer to Management and Operations Org Chart)

- implementing control of processes in accordance with this criteria;
- determining, maintaining, and retaining documented information to the extent as necessary;
 - to have confidence that the processes have been carried out as planned;
 - ~ to demonstrate the conformity of products and services to their requirements.

(Refer to QPD 77 Document Control and QPD 77A Control of Records)

- determining the processes and controls needed to manage critical items, including production process controls when key characteristics have been identified;
- engaging representatives of affected organisation functions for operational planning and control;
- determining the process and resources to support the use and maintenance of the products and services;
- determining the products and services to be obtained from external providers;
- establishing the controls needed to prevent the delivery of nonconforming products and services to the customer.

The output of operational planning and control includes documented quality plans, resource requirements, processes, equipment requirements, procedures, test data, and design outputs.



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8.1.1 Operational Risk Management

The senior management team at James Walker & Co. Ltd establishes, implements and maintains a process for managing risk to achieve the applicable requirements, that includes as appropriate to James Walker & Co. Ltd products and services:

- assignment of responsibilities for risk management;
- definition of risk criteria (likelihood, consequences, risk acceptance)
- identification, assessment and communication of risks throughout product realisation
- identification, implementation and management of actions to mitigate risks that exceed the defined risk acceptance criteria
- acceptance of risks remaining after implementation of mitigating actions

(Refer to QPD87 Risk Mitigation, QPD164 Product Risk Register and QPD165 PFMEA)

8.1.2 Configuration Management

James Walker & Co. Ltd has planned, implemented and controls a process for configuration management as appropriate to the organisation and its products and services in order to ensure the identification and control of physical and functional attributes throughout the product lifecycle. The process ensures:

- Control of product identity and traceability requirements, including implementation of changes;
- That the documented information (e.g., requirements, design, verification, validation and acceptance documentation) is consistent with the actual attributes of the products and services.

(Refer to key process diagrams for Configuration, Product Engineering and Technical Support)

8.1.3 Product Safety

James Walker & Co. Ltd has planned, implemented and controls the processes needed to assure product safety during the entire product lifecycle, as appropriate to the organisation and the product.

Where the customer provides no documented statement of requirement, the customer requirements shall be confirmed by James Walker UK Ltd and/or James Walker sales company before acceptance. When the product requirements are changed, James Walker UK Ltd and/or James Walker sales company ensures the relevant documents are amended and relevant personnel are made aware of the changed requirements.

(Refer to PL&SO3 Product Liability and Safety)

8.1.4 Prevention of counterfeit parts

James Walker & Co. Ltd has implemented and controls a process appropriate to the organisation and the product, for the prevention of counterfeit or suspect counterfeit part use and their inclusion in product(s) delivered to the customer.

(Refer to QPD02 Counterfeit, Fraud and Suspect Items)

8.2 Requirements and Product Services

8.2.1 Customer Communication

James Walker and Co. Ltd determines and implements effective arrangements for communicating with customers in relation to

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

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(Refer to key process diagrams for <u>Customer Support</u>, <u>Configuration</u> and <u>OPI 44 Care of mould's</u>, <u>FMP 03</u> <u>Customer Concerns</u> and <u>Customer Satisfaction Surveys</u>)

8.2.2 Determining the Requirements of Products and Services

James Walker and Co. Ltd ensures that:

- the requirements for products and services are defined, including:
 - ~ any applicable statutory and regulatory requirements;
 - those considered necessary by the organisation;
- the organisation can meet the claims for the products and services it offers;
- special requirements of the products and services are determined;
- operational risk (e.g., new technology, ability and capacity to provide, short delivery timeframe) have been identified.

(Refer to key process diagrams for <u>Technical Support</u>, <u>Product Engineering</u>, <u>Process Engineering</u>, <u>Product Testing</u>, <u>Laboratory</u>, <u>Configuration</u> and <u>Planning</u>)

8.2.3 Review of requirements for products and services

8.2.3.1 James Walker and Co. Ltd ensures it has the ability to meet the requirements for products and services before committing to supply products and services to the customer, to include:

- requirements specified by the customer, including the requirements for delivery and post-delivery activities;
- requirements not stated by the customer, but necessary for the specified or intended use, when known;
- requirements specified by the organisation;
- statutory and regulatory requirements applicable to the products and services;
- contract or order requirements differing from those previously expressed.

This review shall be coordinated with applicable functions of the organisation. If upon review the organisation determines that some customer requirements cannot be met or can only partially be met, the organisation shall negotiate a mutually acceptable requirement with the customer.

8.2.3.2 James Walker and Co. Ltd will retain documented information, as applicable:

- on the results of the review;
- on any new requirements for the products and services.

(Refer to FMP 33 Design and Development Control and FMP 58 Internal Customer Enquiries)

8.2.4 Changes to requirements for products and services

James Walker and Co. Ltd will 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.

8.3 Design and development of products and services

8.3.1 General

James Walker & Co. Ltd has established, implemented and maintains a design and development process that is appropriate to ensure the subsequent provision of products and services.

8.3.2 Design and development planning

In determining the stages and controls for design and development, James Walker & Co. Ltd has considered:

- the nature, duration and complexity of the design and development activities;
- the required process stages, including applicable design and development reviews;
- the required design and development verification and validation activities;
- the responsibilities and authorities involved in the design and development process;
- the internal and external resource needs for the design and development of products and services;

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- the need to control interfaces between persons involved in the design and development process;
- the need for involvement of customers and users in the design and development process;
- the requirements for subsequent provision of products and services;
- the level of control expected for the design and development process by customers and other relevant interested parties;
- the documented information needed to demonstrate that design and development requirements have been met.

Where required, James Walker & Co. Ltd divides the design and development effort into activities and, for each activity, defines the tasks, necessary resources, responsibilities, design content and inputs and outputs.

Design and development planning consider the ability to provide, verify, test and maintain products and services.

(Refer to key process diagram for <u>Product Engineering</u> including <u>FMP 33 Design & Development Control</u>, <u>FMP 39</u> Technical Services and QPD 06 Approved Signatories)

8.3.3 Design and development inputs

James Walker & Co. Ltd has determined the requirements essential for the specific types of products and services to be designed and developed taking into consideration:

- functional and performance requirements;
- information derived from previous similar design and development activities;
- applicable statutory and regulatory requirements;
- standards or codes of practice that the organisation has committed to implement;
- potential consequences of failure due to the nature of the products and services;
- when applicable, the potential consequences of obsolescence

Inputs shall be adequate for design and development purposes, complete and unambiguous and; and conflicting design and development inputs shall be resolved.

James Walker & Co. Ltd retains documented information on design and development inputs.

(Refer to FMP 33 Design & Development Control)

8.3.4 Design and development controls

James Walker & Co. Ltd applies controls to the design and development process to ensure that:

- the results are defined;
- reviews are conducted to evaluate the ability of the results of design and development to meet requirements;
- verification activities are conducted to ensure that design and development outputs meet the input requirements;
- validation activities are conducted to ensure that the resulting products and services meet the requirements for that specified application or intended use;
- any necessary actions are taken on problems determined during the reviews, or verification and validation activities;
- documented information on these activities is retained;
- progression to the next stage is authorized.

(Refer to key process diagrams for Technical Support, Product Engineering, FMP 33 Design & Development Control)

8.3.4.1 When tests are necessary for the verification and validation, these tests shall be planned, controlled, reviewed and documented to ensure the following:

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- test plans or specifications identify the test item being tested and the resources being used, define test objectives and conditions, parameters to be recorded and relevant acceptance criteria;
- test procedures describe the test methods to be used, how to perform the test and how to record the results;
- the correct configuration of the test is submitted for the test;
- the requirements of the test plan and the test procedures are observed;
- the acceptance criteria are met.

Monitoring and measuring devices used for testing shall be controlled as defined in clause 7.1.5.

At the completion of design and development, James Walker & Co. Ltd shall ensure that reports, calculations, test results, etc, are able to demonstrate that the design for the product or service meets the specification requirements for all identified operational conditions.

(Refer to key process Product Testing)

8.3.5 Design and Development outputs

The outputs of design and development are in a format that is suitable for verification against the inputs, and are approved prior to release. These outputs:

- meet the input requirements;
- are adequate for the subsequent processes for the provision of products and services;
- include or reference monitoring and measuring requirements, as appropriate and acceptance criteria;
- specify the characteristics of the product that are essential for their intended purpose and their safe and proper provision;
- specify, as applicable, any critical items, including key characteristics, and specific actions to be taken for these items;
- are approved by authorised person(s) prior to release.

All data required to allow the product to be identified, manufactured, inspected, used and maintained has been defined by James Walker & Co. Ltd and documented information on design and development outputs is retained.

(Refer to key process diagrams for <u>Technical Support</u>, <u>Product Engineering</u>, <u>FMP 33 Design & Development Control</u>)

8.3.6 Design and development changes

James Walker & Co. Ltd identifies, reviews and controls the 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.

James Walker & Co. Ltd retains documented information on:

- design and development changes;
- the result of reviews;
- the authorization of the changes;
- the actions taken to prevent adverse impacts.

(Refer to FMP 33 Design & Development Control)

8.4 Control of externally provided processes, products and services

8.4.1 General

James Walker & Co. Ltd ensures that externally provided processes, products and services conform to requirements.

James Walker & Co. Ltd are responsible for the conformity of all externally provided processes, products and services, including from sources defined by the customer

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James Walker & Co. Ltd ensures that, when required, that customer-designated or approved external providers, including process sources (e.g. special processes), are used.

James Walker & Co. Ltd identifies and manages the risks associated with the external provision of processes, products and services, as well as the selection and use of external providers.

James Walker & Co. Ltd requires that external providers apply appropriate controls to their direct and sub-tier external providers, to ensure that requirements are met.

James Walker & Co. Ltd has determined the controls to be applied to externally provided processes, products and services when:

- products and services from external providers are intended for incorporation into the organisation's own products and services;
- products and services are provided directly to the customer(s) by external providers on behalf of the organisation;
- a process, or part of the process, is provided by an external provider as a result of a decision by the organisation.

James Walker & Co. Ltd has determined and applies 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 organisation will retain documented information of these activities and nay necessary actions arising from the evaluations.

8.4.1.1 James Walker & Co. Ltd:

- defines the process, responsibilities and authority for the approval status decision changes of the approval status and conditions for a controlled use of suppliers depending on the supplier's approval status;
- maintains a register of its suppliers that includes approval status (e.g., approved, conditional, disapproved) and the scope of the approval (e.g., product type, process family)
- periodically reviews external provider performance including process, product and service conformity and on time delivery performance;
- defines the necessary actions to take when dealing with external providers that do not meet requirements;
- define the requirements for controlling documented information created by and/or retained by external providers

(Refer to key process diagram for <u>Purchasing</u> and <u>QPD 49 Purchasing</u>)

8.4.2 Type and extent of control

James Walker & Co. Ltd ensures that externally provided processes, products and services do not adversely affect the organisation's ability to consistently deliver conforming products and services to customers by:

- ensuring that externally provided processes remain within the control of its quality management system;
- defines both the controls that it intends to apply to an external provider and those it intends to apply to the resulting output;
- takes into consideration:
 - the potential impact of the externally provided processes, products and services on the organisation's ability to consistently meet customer and applicable statutory and regulatory requirements;
 - the effectiveness of the controls applied by the external provider;
 - the results of the periodic review of external provider performance;
- determining the verification, or other activities, necessary to ensure that the externally provided processes, products and services meet requirements.

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Verification activities of externally provided processes, products and services are performed to the risks identified by the organisation including inspection or periodic testing as applicable, when there is high risk of non-conformities including counterfeit parts.

When externally provided product is released for production use pending completion of all required verification activities, it has been identified and recorded to allow recall and replacement if it is subsequently found that the product does not meet requirements.

When the organisation delegates verification activities to the external provider, the scope and requirements for delegation have been defined and a register of delegations maintained. This will be periodically monitored.

When external provider test reports are utilized to verify externally provided products, the organisation has implemented a process to evaluate the data in the test reports to confirm that the product meets requirements. When a customer or organisation has identified raw material as a significant operational risk, the organisation has implemented a process to validate the accuracy of test reports.

(Refer to QPD 49 Purchasing, OPI 28 Vendor Approval & Supplier Rating System, QPD 52 Goods Receiving and QPD 54 Goods Inwards testing)

8.4.3 Information for external providers

James Walker & Co. Ltd ensures the adequacy of requirements prior to their communication to the external provider.

James Walker & Co. Ltd communicates to external providers its requirements for:

- the processes, products and services to be provided including the identification of relevant technical data;
- the approval of:
 - products and services;
 - ~ methods, processes and equipment;
 - the release of products and services;
- competence, including any required qualifications of persons;
- the external providers' interactions with the organisation;
- control and monitoring of the external providers' performance to be applied by the organisation;
- verification or validation activities that the organisation, or its customer, intends to perform at the external providers premises;
- design and development control;
- special requirements, critical items, or key characteristics;
- test, inspection and verification (including production process verification);
- the use of statistical techniques for the product acceptance and related instructions for acceptance by the organisation
- the need to:
 - ~ implement a quality management system;
 - ~ use customer-designated or approved external providers, including process sources;
 - notify the organisation of nonconforming processes, products, or services and obtain approval for their disposition;
 - ~ prevent the use of counterfeit parts;
 - notify the organisation of changes to processes, products, or services, including changes, their external providers or location of manufacture and obtain the organisation approval;
 - ~ flow down to external providers applicable requirements including customer requirements;
 - ~ provide test specimens for design approval, inspection/verification, investigation, or auditing;
 - ~ retain documented information, including retention periods and disposition requirements;

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- the right of access by the organisation, their customer and regulatory authorities to the applicable areas of facilities and to applicable documented information, at any level of the supply chain;
- ensuring that persons are aware of;
 - ~ their contribution to product or service conformity;
 - their contribution to product safety;
 - ~ the importance of ethical behavior.

(Refer to key process diagram for Purchasing including QPD 49 Purchasing)

8.5 Production and service provision

8.5.1 Control of production and service provision

James Walker & Co. Ltd plans and carries out production and service provision under controlled conditions. Controlled conditions include, as applicable:

- the availability of documented information that defines:
 - ~ the characteristics of the product;
 - the results to be achieved;
- the availability and use of monitoring and measuring resources;
- 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;
 - criteria for acceptance and rejection;
 - ~ where in the sequence verification operations are to be performed;
 - measurement results to be retained (at a minimum an indication of acceptance or rejection);
 - ~ any specific monitoring and measurement equipment required and instructions associated with their use;
- ensuring that when sampling is used as a means of product acceptance, the sampling plan is justified on the basis of recognised statistical principles and appropriate for use;
- the use of suitable infrastructure and environment for the operation of processes;
- 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;
- the implementation of actions to prevent human error;
- the implementation of release, delivery and post-delivery activities;
- the establishment of criterial for workmanship;
- the accountability for all products during production;
- the control and monitoring of identified critical items, including key characteristics, in accordance with established processes;
- the determination of methods to measure variable data
- the identification of in-process inspection/verification points when adequate verification conformity cannot be performed at later stages;
- the availability of evidence that all production and inspection/verification operations have been completed as planned, or as otherwise documented and authorised;
- the provision for the prevention, detection and removal of foreign objects;
- the control and monitoring of utilities and supplies;
- the identification and recording of products released for subsequent production use pending completion of all required measuring and monitoring activities, to allow recall and replacement if it is later found that the product does not meet requirements.

(Refer to key process diagram for Manufacturing Units)

8.5.1.1 Control of equipment, tools and software programs

Production equipment, tools and software programs used to automate, control, monitor or measure product

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realisation processes are validated prior to release for production and are maintained.

Storage requirements, including periodic preservation and condition checks, are defined for production equipment or tooling in storage.

(Refer to key process diagrams for <u>Tooling Manufacture</u>, <u>Maintenance Engineering</u> and <u>QPD 50 Training</u> and <u>QPD 21</u> Calibration of onsite measuring equipment procedures)

8.5.1.2 Validation and control of special processes

James Walker & Co. Ltd validates any processes for production and service provision where the resulting output cannot be verified by subsequent monitoring or measurement and, as a consequence, deficiencies become apparent only after the product is in use or the service has been delivered.

Validation demonstrates the ability of these processes to achieve planned results. James Walker & Co. Ltd establishes arrangements for these processes including, as applicable:

- defined criteria for review and approval of these processes;
- determination of conditions to maintain the approval;
- approval of facilities and equipment;
- qualification of personnel
- use of specific methods and procedures for implementation and monitoring the processes;
- requirements for documented information to be retained.

(Refer to QPD 50 Training and OPI172 – Laser welding of springs and inserts)

8.5.1.3 Production process verification

James Walker & Co. Ltd has implemented production process verification activities to ensure the production process is able to produce products that meet requirements.

James Walker & Co. Ltd uses a representative item from the first production run of a new part or assembly to verify that the production processes, production documentation and tooling are capable of producing parts and assemblies that meet requirements. This activity is repeated when changes occur that invalidate the original results

James Walker & Co. Ltd retains documented information on the results of production process verification.

(Refer to QPD 08 General Inspection and F009 AS9102 First Article Inspection Report)

8.5.2 Identification and traceability

James Walker & Co. Ltd uses suitable means to identify outputs when it is necessary to ensure the conformity of products and services.

James Walker & Co. Ltd maintains the identification of the configuration of the products and services in order to identify any differences between the actual configuration and the required configuration.

James Walker & Co. Ltd identifies the status of outputs with respect to monitoring and measurement requirements throughout production and service provision.

When acceptance authority media are used (e.g., stamps, electronic signatures, passwords), the James Walker has established controls for the media.

James Walker & Co. Ltd controls the unique identification of the outputs when traceability is a requirement and retains documented information necessary to enable traceability.

(Refer to QPD 06 Approved Signatories and QPD 79A Control of Records)

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8.5.3 Property belonging to customers and external providers

James Walker & Co. Ltd exercises care with the customer property while in control or being used by James Walker & Co. Ltd.

James Walker & Co. Ltd identifies, verifies, protects and safeguards customer property provided for use or incorporation into product and services.

If any customer product is lost, damaged or otherwise found to be unsuitable for use, James Walker & Co. Ltd reports this to the customer or external provider and retains documented information on what has occurred.

(Refer to QPD 50 Training and OPI 44 Care of moulds)

8.5.4 Preservation

James Walker & Co. Ltd preserves the outputs during production and service provision to the extent necessary to ensure conformity to requirements.

Preservation of outputs also includes, where applicable in accordance with product specifications and applicable statutory and regulatory requirements, provisions for;

- cleaning;
- prevention, detection and removal of foreign objects;
- special handling for sensitive products;
- marking and labelling including safety warnings and cautions;
- shelf-life control and stock rotation;
- special handling of hazardous materials.

(Refer to QPD 50 Training, OPI 08 General Guide to packaging procedures and QPD 08 General Inspection)

8.5.5 Post-delivery activities

James Walker &Co. Ltd shall meet requirements for post-delivery activities associated with the products and services. In determining the extent of post-delivery activities that are required, consideration has been made through below information:

- statutory and regulatory requirements;
- the potential undesired consequences associated with its products and services;
- the nature, use and intended lifetime of its products and services;
- customer requirements;
- customer feedback
- collection, analysis of in-service data (e.g., performance, reliability, lessons learned)
- control, updating, and provision of technical documentation relating to product use, maintenance, repair and overhaul;
- controls required for work undertaken external to the organisation (e.g., offsite work);

When problems are detected after delivery, James Walker & Co. Ltd takes appropriate action including investigation and reporting.

(Refer to FMP 33 Design & Development Control, FMP 39 Technical Services, QPD164 Product Risk Register Procedure, QPD 101 Control of Product and Process Change, QPD 79A Control of Records, FMP 03 Customer Concerns and Customer Satisfaction Surveys; and key process diagram for Customer Support, Configuration, Product Testing)

8.5.6 Control of changes

James Walker & Co. Ltd shall review and control changes for production or service provision, to the extent necessary to ensure continuing conformity with requirements.

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Person(s) authorised to approve production or service provision changes shall be identified.

James Walker & Co. Ltd 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.

(Refer to QPD 101 Control of Product and Process Change and QPD 06 Approved Signatories)

8.6 Release of products and services

James Walker & Co. Ltd has implemented planned arrangements, at appropriate stages, to verify that the product and service requirements have been met.

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.

James Walker & Co. Ltd shall retain documented information on the release of products and service including:

- evidence of conformity with the acceptance criteria;
- traceability to the person(s) authorizing the release.

When required, James Walker & Co. Ltd can demonstrate product qualification, ensuring that documented information provides evidence that the products and services meet the defined requirements.

James Walker & Co. Ltd shall ensure that all documented information required to accompany the products and services are present at delivery.

(Refer to QPD 06 Approved Signatories, QPD 79A Control of Records and FMP 06 Logistics)

8.7 Control of non-conforming outputs

8.7.1 James Walker & Co. Ltd shall ensure that outputs that do not conform to their requirements are identified and controlled to prevent their unintended use or delivery.

James Walker & Co. Ltd shall take appropriate action based on the nature of the non-conformity and its effect on the conformity of products and services. This shall also apply to non-conforming products and services detected after delivery of products, during or after the provision of services.

James Walker & Co. Ltd has established a nonconformity control process that is maintained as documented information and includes the provisions for:

- defining the responsibility and authority for the review and disposition of nonconforming outputs and the process for approving persons making these decisions;
- taking actions necessary to contain the effect of the nonconformity on other processes, products, or services;
- timely reporting of nonconformities affecting delivered products and services to the customer and to relevant interested parties;
- defining corrective actions for nonconforming products and services detected after delivery, as appropriate to their impacts.

The ways of dealing with nonconforming outputs must be according to one or more of the following ways:

- correction;
- segregation, containment, return or suspension of provision of products and services;
- informing the customer;
- obtaining authorisation for acceptance under concession by a relevant authority and as applicable, by the customer.

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Dispositions of use-as-is or repair shall only be used:

- after approval by an authorised representative of James Walker & Co. Ltd responsible for design or by person(s) having delegated authority from the design organisation;
- ~ after authorisation by the customer, if the nonconformity results in a departure from contract requirements.

Product dispositioned for scrap shall be conspicuously and permanently marked, or positively controlled, until physically rendered unusable.

Counterfeit, or suspect counterfeit, parts shall be controlled to prevent re-entry into the supply chain.

When non-conforming product is corrected it is subject to re-verification to ensure conformity to the requirements.

(Refer to QPD 06 Approved Signatories, QPD 88 Control of non-conforming product, QPD 08 General Inspection, QPD 77A Control of Records and QPD 50 Training

9.0 Performance Evaluation

9.1 Monitoring, measurement, analysis and evaluation

9.1.1 General

James Walker & Co. Ltd shall determine:

- what needs to be monitored and measured;
- the methods for monitoring, measurement analysis and evaluation needed to ensure valid results;
- when the monitoring and measuring shall be performed;
- when the results from monitoring and measurement shall be analysed and evaluated.

James Walker & Co. Ltd shall evaluate the performance and the effectiveness of the quality management system.

James Walker & Co. Ltd retains appropriate documented information as evidence of the results.

9.1.2 Customer Satisfaction

James Walker & Co. Ltd 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.

Information to be monitored and used for the evaluation of customer satisfaction includes, but is not limited to, product conformity, on-time delivery performance, customer complaints and corrective action requests. The Organisation has developed and implemented plans for customer satisfaction improvement that address deficiencies identified by these evaluations, and assess the effectiveness of the results. Analysis and evaluation of this activity shall be reviewed by top management of James Walker & Co. Ltd as required by clause 9.3 Management Review of this Quality Manual.

(Refer to FMP 03 Customer Concerns and Customer Satisfaction Surveys)

9.1.3 Analysis and evaluation

James Walker & Co. Ltd shall analyse and evaluate appropriate data and information arising from monitoring and measurement.

The results of analysis shall be used in accordance with below table;

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Method of Monitoring and Evaluation	Evaluation Analysis	Frequency of Monitoring (Data Collection)	Frequency of Analysis on Results
a) conformity of products and services;	Key Performance Indicators	Monthly	Quarterly
b) the degree of customer satisfaction;	Customer Satisfaction Survey	Bi-annually	Bi-annually
c) the performance and effectiveness of the quality management system:	Key Performance Indicators	Monthly	Quarterly
d) if planning has been implemented effectively	Internal Audit	Quarterly	Annually
e) the effectiveness of actions taken to address risks and opportunities;	Internal Audit, and Clause 10.2 Nonconformity and corrective action	Quarterly	Annually
f) the performance of external providers;	Supplier evaluation	Annually	Annually
g) the need for improvements to the quality management system.	Management Review	Monthly	Annually

Result of analysis and evaluation shall be reviewed by top management of James Walker (UK) Ltd as it required by clause 9.3 Management Review of this Quality Manual.

9.2 Internal Audit

9.2.1 James Walker & Co. Ltd conduct internal audits at planned intervals to provide information on whether the quality management system:

- conforms to:
 - ~ the organisation's own requirements for its quality management system;
 - ~ the requirements of this International Standard.
- is effectively implemented and maintained.

9.2.2 The organisation shall:

- plan, establish, implement and maintain an audit program(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;
- define the audit criteria and scope for each audit;
- select auditors and conduct audits to ensure objectivity and the impartiality of the audit process;
- ensure that the results of the audits are reported to relevant management;
- take appropriate correction and corrective actions without undue delay
- retain documented information as evidence of the implementation of the audit program and the audit results.

(Refer to **QPD10** Internal Auditing)

9.3 Management Review

9.3.1 General

The senior management team at James Walker & Co. Ltd reviews the quality management system, at planned intervals, to ensure its continuing suitability, adequacy, effectiveness and alignment with the strategic direction of

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9.3.2 Management review inputs

The management review by James Walker & Co. Ltd shall be planned and carried out taking into consideration:

- the status of actions from previous management reviews;
- changes in external and internal issues that are relevant to the quality management system;
- information on the performance and effectiveness of the quality management system, including trends in:
 - customer satisfaction and feedback from relevant interested parties;
 - ~ the extent to which quality objectives have been met;
 - ~ process performance and conformity of products and services;
 - nonconformities and corrective actions;
 - monitoring and measurement results;
 - ~ audit results;
 - ~ the performance of external providers;
 - ~ on time delivery performance;
- the adequacy of resources;
- the effectiveness of actions taken to address risks and opportunities (see 6.1);
- opportunities for improvement.

9.3.3 Management review outputs

The output from management reviews includes any decisions and actions related to:

- opportunities for improvement;
- any need for changes to the quality management system;
- resource needs;
- risks identified.

Documented information of Management Review outputs shall be retained as an evidence of the results of management reviews

(Refer to QPD166 Annual Management Review)

10.0 Improvement

10.1 General

James Walker & Co. Ltd shall determine and select opportunities for improvement and implement any necessary actions to meet customer requirements and enhance customer satisfaction. These shall include:

- improving products and services to meet requirements as well as to address future needs and expectations;
- correcting, preventing, or reducing undesired effects;
- improving the performance and effectiveness of the quality management system.

10.2 Nonconformity and corrective action

10.2.1 When nonconformity occurs, including any arising from complaints, the organisation shall:

- react to the non-conformity and, as applicable:
 - ~ take action to control and correct it;
 - ~ deal with the consequences;
- evaluate the need for action to eliminate the cause(s) of the non-conformity, in order that it does not recur
 or occur elsewhere, by:
 - reviewing and analysing the nonconformity;

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- ~ determining the cause of the nonconformity
- ~ determining if similar nonconformities exist, or could potentially occur.
- implement any actions needed;
- review the effectiveness of any corrective action taken;
- update risks and opportunities determined during planning, if necessary;
- make changes to the quality management system, if necessary.
- flow down corrective actions requirements to an external provider when it is determined that the external provider is responsible for the non-conformity;
- take specific actions when timely and effective corrective actions are not achieved.

Corrective actions shall be appropriate to the effects of the non-conformities encountered.

(Refer to FMP 03 Customer Concerns and QPD10 Internal Auditing)

10.2.2 James Walker & Co. Ltd shall retain documented information as evidence of:

- the nature of the nonconformities and any subsequent actions taken;
- the results of any corrective action.

10.3 Continual improvement

James Walker & Co. Ltd shall continually improve the suitability, adequacy, and effectiveness of the quality management system.

The organisation 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.

The organisation shall monitor the implementation of improvement activities and evaluation of the effectiveness of the results.

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