



Quality Manual

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(Approved: Dale Luttrell Chief Executive Officer)

ISSUE No. 5

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1. INTRODUCTION

Purpose

This manual describes the organisation of Eskleigh, and defines the procedures for the maintenance of the organisation's quality system.

This manual also details how we meet the requirements of ISO 9001:2008.

This manual is supported by detailed policies, procedures and work instructions that are held in electronic format and in hard copy and can be accessed by staff members at all times

Scope of activities and services of Eskleigh:

The principal activities of Eskleigh are:

The provision of disability services through a state-wide network of group homes, community care programs and in a nursing home setting at Perth, Tasmania.

The Head Office for Eskleigh is located at:

16087 Midlands Highway, Perth, Tasmania, 7300

Postal Address: PO Box 42, Perth Tasmania 7300

Telephone: (03) 6398 7100

Facsimile: (03) 6398 2928

Email: office@eskleigh.com.au

Group Homes are located at:

- 10 Phillip Avenue, Montrose, Tas
- 33 High Street, Longford, Tas
- Esk Banks, Scone Drive, Perth, Tas
- 36 Ryton Street, Kings Meadows, Tas
- 37 Carbeen Street, Mornington, Tas

Board Members & Staff

Eskleigh operates in team structures comprising:

Board: 10 Directors

Management Team: Chief Executive Officer and three nominated managers

Nursing Home & Group Homes: Nominally 85 team members

2. AMENDMENT RECORD SHEET

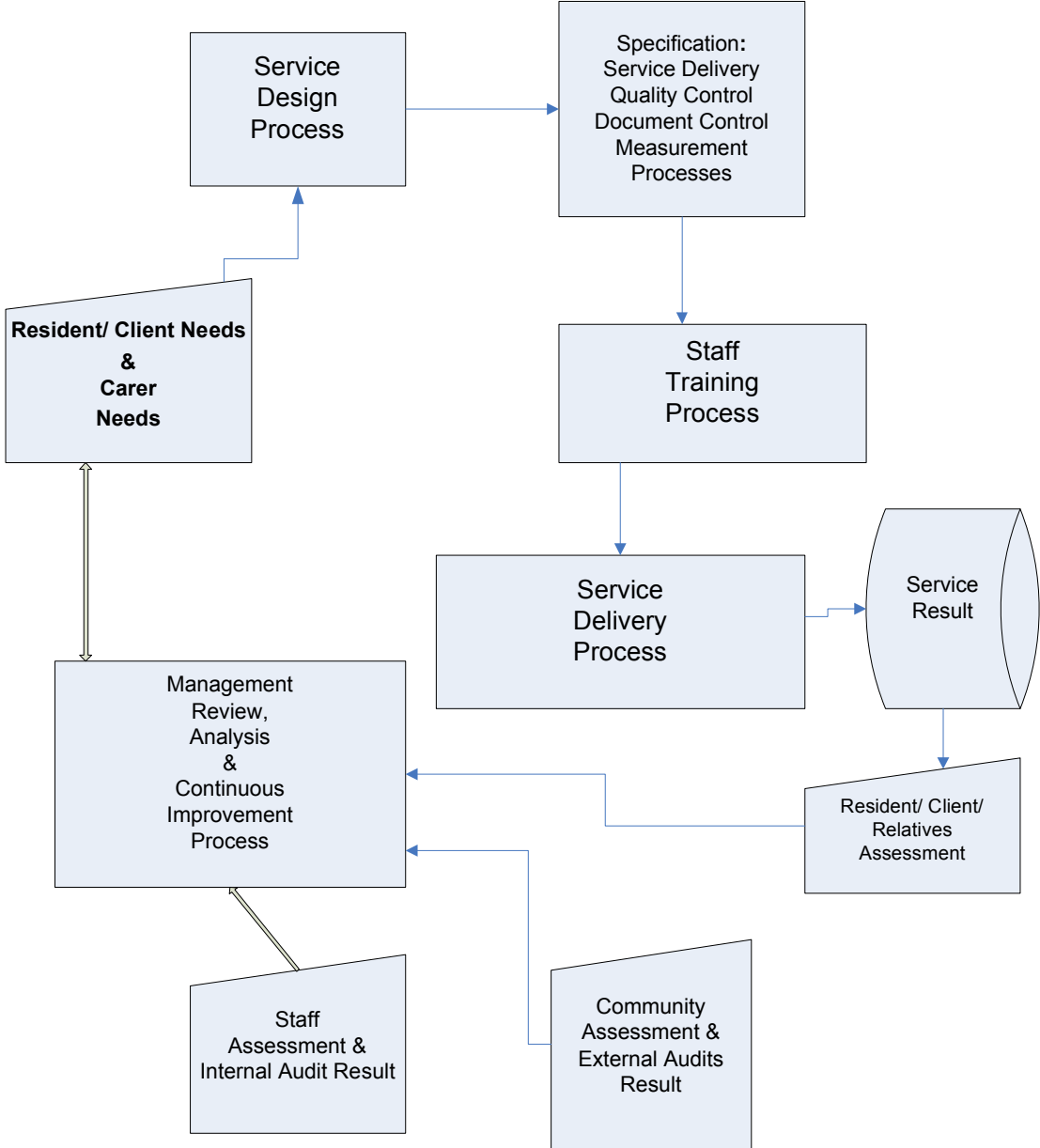
All amendments to this manual must be authorised by the Chief Executive Officer, who is also responsible for maintaining the amendment record sheet.

Changes shall not be implemented by Teams until amendments have been formally issued. Each amendment shall be introduced by the issue of a new page or pages for each copy of this manual in existence.

The issue number of each amended page shall be incremented and dated.

Copy No	Issued To	Issue 1	Issue 2	Issue 3	Issue 4	Issue 5
1	Board of Directors, Eskleigh Home	20/10/2004	9/1/2007	9/12/2007	6/1/2009	23/2/2010
2	CEO, Eskleigh Home	20/10/2004	9/1/2007	9/12/2007	6/1/2009	23/2/2010
3	Eskleigh R/N	20/10/2004	9/1/2007	9/12/2007	6/1/2009	23/2/2010
4	Eskleigh Home Office	20/10/2004	9/1/2007	9/12/2007	6/1/2009	23/2/2010
5	Southern Services Manager	20/10/2004	9/1/2007	9/12/2007	6/1/2009	23/2/2010
6	Longford Group Home	20/10/2004	9/1/2007	9/12/2007	6/1/2009	23/2/2010
7	Kings Meadows Group Home	20/10/2004	9/1/2007	9/12/2007	6/1/2009	23/2/2010
8	Esk Banks Group Home	20/10/2004	9/1/2007	9/12/2007	6/1/2009	23/2/2010
9	Philip Avenue Group Home	20/10/2004	9/1/2007	9/12/2007	6/1/2009	23/2/2010
10	20 Flamenco Circle Glenorchy	20/10/2004	9/1/2007	9/12/2007	6/1/2009	23/2/2010
11	37 Carbeen Street, Mornington	20/10/2004	9/1/2007	9/12/2007	6/1/2009	23/2/2010

Eskleigh
The Quality
Management
System



4. QUALITY MANAGEMENT SYSTEM

The quality management system, as defined in this manual, is inherent in the Eskleigh controlled documentation system. It is defined by policies and procedures as well as work instructions, care plans and other resident/client related documents.

Review of the quality management system is accomplished during the management review process at monthly meetings of the Management Team.

Our service plans, process plans and improvement plans and care plans are developed at the system, subsystem and component level and as required for individual residents and clients.

Eskleigh has a comprehensive continuous improvement philosophy throughout the organisation, including business processes and support services. Monthly meetings of the Management Team document on-going improvement activities.

4.1 General Requirements

Quality System Processes

Processes needed for the quality management system are identified within this quality manual and in associated policies, operational procedures and work instructions. The documentation defines these quality system processes and their sequence and interaction, and instructs on how to implement and apply them throughout the organisation.

The quality system documentation also defines criteria and methods needed to ensure that the operation and control of quality system processes are effective. This includes the assignment of responsibilities and allocation of resources for the process, instructions on how to carry out the process, and definitions for monitoring and/or measuring the effectiveness of the process. Actions to ensure the continuous improvement of processes are documented, implemented, monitored and reviewed for effectiveness.

Resources and Information

The CEO is responsible for determining and maintaining resources and information requirements necessary to support the operation and the monitoring of quality system processes and for communicating these processes to employees.

Monitoring and Measurement

The performance of the quality system processes is systematically monitored and measured. This is to ensure the effectiveness of the quality system and to identify opportunities for improvement.

The performance of service realisation processes is usually monitored by measuring process parameters and/or service characteristics resulting from the process and through the program of reviews applied to the service.

The performance of processes required for quality management is usually monitored through internal quality audits. The overall performance of the quality system is monitored by measuring customer satisfaction.

Monitoring and measuring activities are defined in Sections 8.1 & 8.2 of this quality manual, and in the relevant procedures.

Conformance and continuous improvement

Quality management system processes are regularly reviewed by the CEO and the Management Team to identify any possible failures as well as opportunities for improvement.

Actions necessary to address actual or potential problems and to improve the quality system are implemented through corrective and preventative actions and management improvement projects.

Sections 5.6 and 8.5 of this quality manual and the corresponding policies and procedures define how management reviews and how corrective/preventative actions are used to ensure conformance and improvement.

Outsourced processes

When processes that affect service conformity are outsourced, special controls are implemented to ensure that these processes meet specified requirements. Such controls may include evaluation and pre-evaluation of suppliers, assessment of supplier realisation processes and (their) quality system, monitoring of supplier quality performance and requirements for inspection, testing or other records demonstrating service conformity. Section 7.4 of this quality manual and the corresponding procedures define the purchasing control system.

Note: Outsourced processes affecting service conformity usually relate to services provided by allied health professionals.

4.2 Documentation Requirements

4.2.1 General

The scope of the quality system documentation is defined. Establishment and revision of documents and their distribution is controlled. New documents are reviewed and approved prior to issue and are identified in respect to their revision level. Appropriate documents are available at the locations where they are used. Obsolete documents are removed from points of use. Documents of external origin are identified and their distribution is controlled.

Quality records are identified and indexed to facilitate their retrieval and are stored in a suitable environment to minimise deterioration. Quality records are retained for a period of seven years.

The quality system includes the following documents:

- Quality Manual
- Policies and procedures
- Work instructions
- Agreements
- Service realisation (care) plans
- Forms
- Staff training records
- External disability services standards and regulations
- Quality records including Minutes of the Management Review of the Quality Management System Meetings, Internal Audit Reports, Survey Reports and Analysis of Data, Corrective Action Requests and Speak Up forms received.

4.2.2 Quality Manual

The overarching document defining the overall quality management system is this Quality Manual. It includes:

- The scope of the quality system
- A description of quality processes, their sequence and interrelation
- References to documented procedures

The Quality Manual version number and amendments listing reflects the changes and updates to the Quality Manual.

4.2.3 Document Control

New documents and document changes may be initiated by anyone in the organisation, but only the CEO may authorise the issue of new documents and authorise any changes to existing documents. These requirements are defined in the Document Control policy and procedures.

Documents are distributed to staff members and locations where they are used. When appropriate and relevant, documents display a distribution list.

Obsolete documents are removed from points of use. Retained masters or copies of obsolete documents are properly marked and are kept separate from active documents. Obsolete electronic documents are removed from the system, and if retained are stored in directories that are only accessible to authorised personnel.

Document changes are reviewed by the CEO and as appropriate are authorised for distribution. Revised documents are distributed with a brief summarising the changes. A document register is maintained specifying the latest issues and revisions of all controlled documents.

The Document Register reflects revision level, date of revisions, and documents that have been withdrawn because of obsolescence.

4.2.4 Control of Records

The CEO is ultimately responsible for the maintenance of the records system. Records are retained for a minimum period of seven years.

Records are established and maintained to provide evidence that:

- Service designs satisfy input requirements
- Services conform to specifications
- The quality system is operated in accordance with documented procedures and that it is effective
- Where required, records also include traceability information.

Records are established and maintained by staff members performing the task or activity for which the results need to be recorded. Records are dated and they identify the service, process, person or event to which they pertain.

Records are indexed and grouped to facilitate their retrieval. Cabinets, binders, computer discs and other storage media are clearly labelled with the identification of their content.

These requirements are contained within the Records Integrity Policy and Procedures.

5. MANAGEMENT RESPONSIBILITIES

5.1 Management commitment

Eskleigh recognises that an effective quality management system requires the involvement and commitment of the Management Team and all staff members.

All staff members are responsible for their own work and actions.

The Management Team is responsible for the following:

- Overseeing the creation and implementation of the Quality Management System
- Communicating the objectives and outcomes of the Quality Management System with all Board members, staff, volunteers, residents/clients, relatives, suppliers and any other interested parties
- Making sure there are adequate resources committed to the operation of the Quality Management System
- Reviewing on a regular basis to make sure the Quality Management System is operating as planned

The CEO is the management representative who is ultimately responsible for the Quality Management System.

5.2 Customer focus

The Eskleigh Quality Management System identifies customer requirements in each important area of service delivery.

Eskleigh customers are: Clients, Residents, Relatives, Government Agencies and Departments, Eskleigh Staff Members, Volunteers.

The Quality Management System works to make sure that these requirements are fulfilled.

The goal of the Quality Management System is to continuously improve customer satisfaction with all services provided.

5.3 Quality Policy

Eskleigh in serving residents and clients will:

- Operate cost efficient and caring quality accredited disability services facilities and community based care
- Deliver a diverse range of care services;

- Ensure an unsurpassed caring service;
- Reflect residents and clients values in policy and practice.

Eskleigh operates to a quality management system. This system complies with the requirements of ISO 9001:2008 and legislative and regulatory requirements relevant to the service.

All Directors and employees shall be made aware of the requirements of this quality policy. Adherence to the systems and procedures defined in this manual is mandatory for all Directors and employees.

All Directors and employees are directly responsible for the quality of their own work and actions.

The quality system shall be systematically reviewed for continuous improvement.

Signed



Dale Luttrell
Chief Executive Officer

The CEO is responsible for the establishment of the Quality Policy. Any changes to the Quality Policy must be authorised and issued by the CEO.

The main role of the Quality Policy is

- To communicate the Eskleigh commitment to quality and to define the objectives of the quality management system.
- To establish a culture of sustainable quality management focusing on continuous improvement and customer satisfaction.
- To maintain a quality management system that ensures compliance with applicable resident/clients requirements as well as the requirements of ISO 9001:2008

The Quality Policy is explained to all employees and is discussed during induction training. The Quality Policy is also communicated to residents/clients, relatives, suppliers and any other interested parties.

The Quality Policy is periodically reviewed during the framework of management review of the quality management system. This is to ensure its continual relevance and suitability.

5.4 Planning

5.4.1 Quality Objectives

The Eskleigh objectives for quality are to:

- ◆ Deliver quality accredited service
- ◆ Value and respect the individuality of each resident/client
- ◆ Provide care options to existing residents/clients and potential residents/clients
- ◆ Maintain and extend the skills and knowledge of every employee
- ◆ Provide a financially viable service

These quality objectives have been established to support and implement the Quality Policy and continuous improvement imperatives.

5.4.2 Quality Management System Planning

Quality management system elements and processes are planned to ensure that the system is appropriate for its intended purpose, and that it is effective and efficient. The purpose of the quality management system is:

- To achieve the Quality Policy
- To ensure, and to demonstrate our ability to consistently provide services that meet resident/client, regulatory and legislative requirements
- To ensure a high level of resident/client satisfaction
- To facilitate continuous improvement
- To comply with the requirements of ISO9001:2008
-

Quality management system planning also ensures that the integrity of the quality management system is maintained when changes to the quality management system are planned and implemented

The output of the quality management system planning process is documented within this Quality Manual, in associated policies, procedures and in other documentation (as referenced).

Changes within the quality management system are planned within the framework of management reviews. These changes may be in response to changing circumstances, such as resident/client service requirements, processes, capacity or other organisational change; or to improve the effectiveness and efficiency of the quality management system. Whenever changes occur, appropriate policies, procedures and processes are put into place to ensure that the integrity of the quality management system is maintained.

Improvements to the quality management system are planned within the framework of management team reviews. The output is expressed in terms of the Quality Objectives (above) and in operational policies and procedures.

5.5 Responsibility, Authority and Communication

Organisation

The management and employees of Eskleigh have the necessary authority and resources required to meet the mandates assigned to their areas.

5.5.1 Responsibility and authority

Chief Executive Officer

- Overall responsibility for the operation of Eskleigh within relevant legislation, Articles of Association, Policy and Quality Management System requirements.
- Ultimate responsibility for the correct implementation and maintenance of the Quality Management System (QMS).
- Responsible for the day to day management of QMS for all Eskleigh operations
- Internal Audits of the QMS - audit procedures, on-site inspections and for the maintenance of corrective action request records, ensuring that all corrective action requests are reviewed, considered, actioned and closed out.
- The organisation of quality improvement projects and the facilitation of quality improvement teams
- Promulgation of QMS throughout the organisation
- Facilitating quality awareness training
- Ultimate responsibility for resident/client care
- Financial management of all Eskleigh operations
- Ultimate responsibility for human resources management
- Responsible for reporting to the Board of Directors
- Supervision of the Management Team.
- Organisational planning and development.
- Communications, major negotiations

- Responsible for all marketing strategies and activities
- Responsible for all corporate communications and media releases
- Responsible for liaison and public relations with government departments, agencies and funding bodies

Eskleigh Home Manager

Member of the Management Team -

- ◆ Responsible for the day to day management of Eskleigh Home
- ◆ Responsible for the overall care of Eskleigh Home residents
- ◆ Developing and maintaining care plans for each resident
- ◆ Regular review of client care
- ◆ Programming
- ◆ Assessment of requirements for care and service for new residents
- ◆ Liaison and communications with new residents
- ◆ Staff recruitment (Eskleigh Home)
- ◆ Staff training
- ◆ Rostering staff members
- ◆ Budget control and administration (Eskleigh Home)
- ◆ Liaison and public relations with external services and associations
- ◆ Assessment of equipment requirements
- ◆ Equipment maintenance

Service Managers and Co-ordinators

Managers and Co-ordinators are employed to administer the following specialist areas:

- ◆ Service Manager– North & South (Members of the Management Team)
- ◆ Training and Human Resources Manager
- ◆ Leisure & Lifestyle Co-ordinator
- ◆ Catering & Cleaning Co-ordinator
- ◆ R/N level 2 Eskleigh Home

5.5.2 Management Representative

The CEO is the management representative who has the responsibility and authorisation to ensure that the quality management system is established, implemented and maintained in accordance with ISO 9001:2008

The quality system is structured to ensure, through monitoring, that residents and clients receive only quality care and services. This is accomplished by providing staff members the freedom and authority to identify and record quality problems, initiate action to prevent the occurrence of care and service nonconformity and verify the implementation of solutions.

5.5.3 Internal Communication

The CEO ensures that appropriate communication processes are established within Eskleigh and communication takes place regarding the effectiveness of the quality management system, quality performance, and customer satisfaction levels. This communication includes on-going employee meetings and documented employee communications including the publication "From the CEO's Desk". Resident and client meetings are held on a regular basis to receive and provide feedback regarding satisfaction levels with service delivery.

5.6 Management Review

5.6.1 General

The Management Team reviews the Eskleigh quality management system on a monthly basis. This review considers the suitability of the system, the adequacy of the system and its effectiveness. Survey reports, Audit reports, Corrective Actions, Speak Up forms received and any other opportunities for continuous improvement are considered and any required changes are planned.

Records of management reviews are maintained.

5.6.2 Review Input

The management review includes information on results of audits, resident/client, relatives and staff member's feedback and satisfaction that is obtained through the results of surveys, Speak Up forms received, letters, compliments, comments and complaints received, process performance and service conformity, the status of preventive and corrective actions, follow-up actions from previous management reviews, changes that could affect the quality management system and consideration of improvements.

The Management Review consists of analysis data from audit results and corrective / preventative action to ensure continuing suitability and effectiveness of our systems to meet these principles.

The review is an effective tool used to support decision making and long-term planning. This review is under the administration of the CEO.

5.6.3 Review Output

All management review meetings are documented.

This documentation includes any decisions and actions related to the improvement and effectiveness of the quality system, improvements to care and services and any associated resource needs.

6. RESOURCE MANAGEMENT

6.1 Provision of Resources

As part of its annual budget allocation process, management determines and allocates sufficient resources to implement and maintain the quality management system and to enhance client/relative satisfaction by providing sufficient resources to continuously improve the standard of care and services that are provided.

These resources may include people, supplies, information, infrastructure, work environment and financial resources.

The CEO is ultimately responsible for determining the resource requirements for the implementation and improvement of the quality management system.

6.2 Human Resources

6.2.1 General

All staff members are appropriately trained and competent for the role that they perform. Performance is assessed on an annual basis, or sooner if warranted by circumstances.

As required by legislation and regulatory controls, staff members who are required to be credentialed shall have their credentials verified through workplace assessment and training.

6.2.2 Competence, Awareness & Training

Eskleigh is committed to the continuous improvement of the skills and knowledge and the professional development of its staff members. Eskleigh continually evaluates the knowledge and skills of its staff by comparing their abilities to the job requirements and then identifies the areas requiring knowledge and skill improvements.

Accordingly, Eskleigh provides training programs by utilising the expertise of in house qualified staff members and (where required) outside professionals. Training in all areas is evaluated for effectiveness on a periodic basis.

By providing staff with on-the-job training, Eskleigh ensures that employees have hands-on experience with a qualified person until they can demonstrate the ability to perform each task satisfactorily.

All employees receive induction training which ensures that they are aware of the relevance and the importance of their activities and how they contribute to the achievement of the quality objectives.

Personnel must be competent on basis not only of education and training, but also skills and experience as defined in the position descriptions and Eskleigh enterprise specific competency standards.

Records are maintained for all training undertaken. A record is maintained of the education, skills and experience of each employee, and where required, the employee's registration status with the relevant registration board.

6.3 Infrastructure

Suitable buildings, facilities, grounds, equipment, supporting services and other infrastructure needed are determined, provided and maintained as required to support care and service conformity to requirements.

Eskleigh buildings are maintained to provide a safe and home-like environment for residents/clients and a safe working environment for staff members. Grounds are maintained to provide a pleasant retreat for residents/clients and their families.

Equipment is maintained in accordance with equipment manufacturers' specifications and instructions.

Supporting services include transportation (such as buses and motor vehicles) and communication equipment and devices and information systems.

6.4 Work environment

Eskleigh provides for employees a suitable and safe work environment to achieve conformity to service requirements. All work environments have been considered.

Each member of the Management Team is responsible for ensuring suitable conditions in the workplace. This includes interactions and communication between employees, conflict resolution and negotiation.

Relevant workplace policies and procedures are implemented through training and awareness, and when necessary, disciplinary action.

All staff members are required to adhere to occupational health and safety policies, procedures and where applicable, work instructions.

7. SERVICE REALISATION

7.1 Planning of service realisation

In planning the provision of service, the management of Eskleigh takes into consideration all legislative requirements, regulatory controls and professional standards that are applicable to the operations of the organisation. Residents/Clients and relatives requirements, third party provider requirements, and required resources and resources implications are all inputs into the service planning process.

Planning of service realisation processes includes the determination of requirements and quality objectives for services; development of required processes and process documentation; and the establishment of service verification and validation programs.

The plan also defines requirements for records necessary to demonstrate process and service conformity.

Service requirements and quality objectives

Service requirements and quality objectives for the service are defined and communicated in agreements, contract documents, internal and external standards, and applicable legal and regulatory requirements.

The CEO reviews these specifications before the acceptance of the agreement or contract of service.

Service realisation planning

Service realisation planning includes, as applicable:

- The definition and evaluation of operations and processes to deliver the required care and services to clients and residents,
- The development of adequate and capable processes,
- The identification of special processes and consideration of associated risks and consequences,
- The establishment and implementation of appropriate process control measures,
- The development of work instructions and training for staff members, and
- The requirements for records necessary to demonstrate service conformity.

Service realisation plans are established in collaboration between the CEO and relevant personnel.

Operational procedures related to Section 7.5, Service Provision, explain how outputs of service realisation planning are used.

Service verification and validation planning

Service verification and validation plans determine the inspection and testing program for a service.

This includes:

- Identification of audit and review points
- Audit and review scope, frequency, and method,
- Acceptance criteria, and
- Requirements for records necessary to demonstrate service conformity.

The Management Team is responsible for development of service verification plans.

7.2 Customer Related Processes

7.2.1 Determination of requirements related to the service

Service requirements are determined to include resident/client requirements and legal, regulatory, and other necessary requirements.

Each resident/client (or their representative) is consulted and has input into the design of the service to be provided. This is then documented and contained within a formal agreement and individual care plan and associated documentation and records for the resident/client.

In situations where Eskleigh provides the care and service to a resident/client on behalf of a third party (such as a Government Agency), a formal contract of service is also entered into with the third party prior to the provision of service to the resident/client.

7.2.2 Review of requirements related to the service

Agreements and contracts are reviewed to ensure that service requirements are defined and can be met, and to resolve any incomplete or conflicting requirements.

Agreements and contract amendments and changes are likewise reviewed and are communicated to all relevant functions.

Agreement and contract reviews are recorded.

The resident/client's care plan and associated documentation is reviewed every six months (or sooner if required) to ensure the validity and currency of the care and service being provided. Where changes are made, they are communicated to all relevant staff members.

Care plans and associated documentation are subject to internal quality audits on a scheduled basis.

7.2.3 Customer Communication

Arrangements for communication with residents/clients relating to service information, and customer feedback and complaints are defined and implemented.

Where appropriate, operational procedures and instructions for these activities are established and implemented.

Each resident/client (or their representative) is provided with a Client Information Handbook prior to entering into agreement for care and service provision. This handbook provides general details on the operations of the service, as well as residents/client's rights and responsibilities and the complaints and comments mechanisms available at all times to the resident/client (or their representative).

The Management of Eskleigh operates an open door policy in relation to all suggestions, comments and complaints from residents/clients, their representatives, relatives, staff members, volunteers and any other interested parties. Clients and Residents Meetings are also held on a regular basis to provide a forum to receive and provide feedback.

Formal avenues for suggestions, comments and complaints also include:

- ◆ Speak Up forms
- ◆ Corrective Action Requests
- ◆ Advocacy Services
- ◆ Surveys

7.3 Design & Development

7.3.1 Design & Development Planning

The Management Team as a whole is responsible for the overall design and development planning of services to be provided, and the CEO has ultimate responsibility for the overall planning function.

Before a new service can be introduced, the Management Team must first determine:

- ◆ The objectives of the service
- ◆ The resource requirements of the service
- ◆ How the resource requirements can be met
- ◆ Timeframes involved

Before introduction, a new service is subject to the design review process to identify and anticipate problem areas and inadequacies, and initiate corrective actions.

As well as design review, a new service is subject to design verification in which the new service is tested as a trial before full implementation.

Following design verification, a new service is also subject to design validation processes to ensure that the objectives of the service are met within the required timeframes and resources requirements and that any identified risks are addressed.

It is the responsibility of each individual manager to tailor existing services to comply with the individual needs and requirements of residents and clients.

7.3.2 Design and Development Inputs

When designing a service, the Management Team takes into consideration the functional requirements of the proposed service, residents/client/relatives needs and requirements, third party requirements (where applicable), staff needs and requirements, resources needs, legislative and regulatory requirements and the marketability of the service.

All of these inputs are reviewed for adequacy and to ensure that requirements do not conflict.

7.3.3 Design and Development Outputs

Information included in the output of design and development of services will include sufficient information to show that the requirements specified in the inputs document are being met by the service as designed, and how potential risks have been mitigated.

It will also include information on how the service will be delivered, including such things as service specifications, (any) equipment and resources purchasing, testing and audit requirements, the records and documentation required to be established and maintained

during service delivery, training requirements, user and client/resident information, and any other information needed by Eskleigh to deliver the service so that it meets the requirements.

This process will be documented and approved.

7.3.4 Design & Development Review

After determination of the design and development requirements, a review to make sure that requirements are being met is undertaken.

Staff who have been involved in the process are used to perform this review and determine that the design and development processes are in fact meeting the requirements, problems are identified and solutions are proposed.

7.3.5 Design and Development Verification

Once the design and development process has been planned and reviewed, a test, or verification is undertaken to ensure that the final output meets the requirements

The verification results are maintained together with the records of any follow up actions taken. The method of verification may vary according to the type of service being provided.

7.3.6 Design & Development Validation

After the design outputs have been verified, validation is performed under actual operating conditions. If the service has multiple uses, each use may be validated separately. The methods for validation defined in the design output are followed.

Whenever possible, the validation of a new service is performed prior to delivery to the resident/client.

7.3.7 Control of Design and Development Changes

Initial service designs are often changed to accommodate individual resident/client requirements, to try to improve performance, to accommodate a changing input component, or for some other valid reason.

We identify and document these change requests within the resident/client's care plan. We also analyse the changes prior to implementation and consider what the total impact of the changes may be. We maintain records of these analyses, and any follow up actions taken.

7.4 Purchasing

7.4.1 Purchasing Process

The CEO is responsible for all capital expenditure. The members of the Management Team are responsible for all other purchasing functions and processes within each of their individual areas of responsibility, control and delegated authority.

The methods employed to ensure that the purchased items/services conform to the requirements of the quality system are:

- Approval of suppliers and sub contractors – all possible suppliers and sub contractors are assessed to ensure that they are capable of supplying goods and services to the quality standards required by Eskleigh.
- A full description of the items/services is provided on the purchase order or as a cross reference to the purchase order if applicable

Goods inwards inspection procedures are undertaken as detailed in the purchasing procedures.

Full details of purchasing procedures are contained in the Policies and Procedures Manual.

Supplier evaluation

All new suppliers are evaluated with regard to their quality and process capability.

The CEO establishes the criteria for selection of suppliers, and conducts supplier evaluation. Suppliers are rated “approved”, “provisional”, or “not approved”.

The Approved and Provisional suppliers are entered on the approved supplier list.

Existing suppliers with a satisfactory quality performance history may be exempted from the initial evaluation and be initially rated as “approved” or “provisional”.

Records of the initial supplier evaluation are maintained.

Supplier quality performance monitoring

The quality performance of suppliers is monitored. Suppliers showing inadequate performance may be asked to implement corrective actions, and be downgraded to the “provisional” rating. If the requested corrective actions are not implemented and there is no

improvement, the supplier is further downgraded to the “not approved” rating and is discontinued.

Records of supplier monitoring and re-evaluations are maintained.

Approved supplier list

An approved supplier list is maintained. Except in an emergency, orders may only be placed with vendors that are on the list

7.4.2. Purchasing information

Purchasing documents are prepared. The documents clearly and completely describe ordered products, including precise product identification, price and quality requirements.

Where applicable any attachments to purchase orders will be clearly cross referenced.

The preparation, review, and approval of purchasing documents is explained in the Purchasing Policy and Procedures.

7.4.3 Verification of purchased product

Purchased products are inspected by the staff member receiving the goods. This includes verification of product identity and quantity, visual inspection and, where applicable, verification that all requested certificates and quality records are available.

Quality control inspection or testing may not be necessary when products are supplied with records or certificates demonstrating conformity; or when the supplier is qualified based on their quality system certification or supplier audits, and a satisfactory quality performance history.

When verification of purchased product is to be performed at supplier’s premises, purchasing documents specify the intended verification arrangements.

7.5 Service Provision

Service and process information and appropriate work instructions are established and are communicated to relevant personnel.

Service provision processes are monitored and controlled, and are validated where appropriate.

Machines and equipment used in service provision and for monitoring and measurement activities are maintained and records are maintained of inspection and calibration activities.

Materials, consumables and pharmaceuticals used in service provision are identified. When required, the traceability of materials and pharmaceuticals are recorded and maintained.

Resident/client supplied products are normally controlled in the same manner as are purchased products.

7.5.1 Control of Service Provision

Information regarding the provision of services generally is available through brochures, the Eskleigh web site, Resident/Client Information Books and Staff Handbooks.

Information regarding the care and service characteristics designed to meet individual resident/client needs and requirements is contained with the resident/client care plans and associated documentation.

Individual care plans are monitored for effectiveness and signed off by the staff member providing the service.

Policies, procedures, work instructions and competency standards and where required, checklists are available to all employees

The need for work instructions is evaluated on the basis of criticality, importance and complexity of the process; the ability to verify results of the process; staff member qualifications; and history of quality problems associated with the process.

The maintenance of equipment, machines, hardware, and software is addressed in Section 6.3 of this manual

The requirements for measuring and monitoring equipment are determined in accordance with residents/client's needs.

Service provision is monitored and controlled through a variety of approaches, activities and techniques.

The quality system is designed to control:

- Information, material and human input into the process;
- Technology, and equipment used;
- The service provision environment and performance; and
- Service provision output.

Service provision monitoring activities are further defined in Section 8.2 of this manual.

7.5.2 Validation of processes for service provision

When it is not possible to verify the service provided through monitoring or measurement, the quality management system calls for validation. Validation is particularly important where deficiencies are not identified until the service is delivered to the resident/client.

When validation is appropriate, the criteria for the following areas involved in the process are defined as:

- Approval of validation procedures by the manager or supervisor responsible for the area where the service is being delivered
- Qualification of personnel
- A backup plan if validation fails must have been developed

The process is then re-validated.

A record of all process validations is maintained.

7.5.3 Identification and traceability

When a service is tested or measured, at any point in the delivery cycle, it must be identified. Tests and measurements are usually undertaken by the process of internal audits. All audit documentation provides sufficient detail to identify what was measured, where it was measured and when it was measured.

This identification provides for traceability or the ability to follow the service throughout the process.

7.5.4 Customer property

This element of the standard is applicable to Eskleigh through:

- Third party customer property (such as property owned by a government agency on whose behalf Eskleigh provides service to residents/clients) and used by Eskleigh during service provision

- Property that is owned by residents/clients (such as personally owned wheelchairs) and is used by Eskleigh during service provision to that resident/client

Records are maintained for all property that is used during the provision of resident/client service but is not owned by Eskleigh.

If any customer owned property is lost, damaged or found to be unsuitable for the purpose, it is immediately reported to the property owner or their representative and records are maintained.

Customer property may also include personal data that is collected and recorded about a resident/client.

7.5.5 Preservation of Service

This element of the standard is not applicable to Eskleigh

7.6 Control of Monitoring and Measuring Equipment

Appropriate measuring and monitoring instruments are maintained and selected to ensure that measurement capability is consistent with the measurement requirements.

Equipment used is calibrated using calibration standards traceable to the national standard. The calibration status of measuring equipment is identified with calibration stickers. Measuring equipment is properly maintained and its placement and use are controlled.

8. MEASUREMENT, ANALYSIS AND IMPROVEMENT

8.1 General

Measurement and monitoring activities required to assure service provision conformity, and to achieve improvement, are planned and defined.

When applicable, statistical techniques are used for analysing measurement data.

Measurement and monitoring activities to assure and verify service conformity are defined in care plans, policies, procedures, and work instructions. These activities are further defined in this manual in Section 8.2, Measurement and Monitoring.

The effectiveness of the quality system is monitored by internal audits and by measuring quality performance and customer satisfaction and by Management Team reviews. The results of these activities are reported to the CEO and are used to identify opportunities for improvement.

Activities related to internal audits and to measuring customer satisfaction and quality performance are further defined in this manual in Sections 8.2.

8.2 Measurement, analysis and improvement

8.2.1 Customer satisfaction

Residents/clients/relatives satisfaction is the principal objective of the quality system, and the level of satisfaction is the most important measure of the effectiveness of the system.

Customer satisfaction is measured by collecting and analysing direct customer feedback, and by measuring secondary indicators of customer satisfaction. Customer satisfaction data is used by the Management Team to identify opportunities and priorities for improvement.

All activities and areas relevant to the quality system are audited at least once a year. Audits are scheduled on the basis of the status and importance of the activity. Internal auditors are independent of those having direct responsibility for the audited activity. Identified nonconforming conditions are brought to the attention of the responsible persons and corrective actions are implemented in response to audit findings. Corrective actions are reviewed at Management Team meetings for effectiveness.

Quality system processes are monitored to ensure that they achieve planned results. Relevant service characteristics are measured through inspections, tests, and other service verification activities, as specified in control plans. Evidence of service conformity is recorded.

The Management Team is responsible for developing suitable indicators of customer satisfaction, and for defining methods for collecting and analysing the relevant information.

Information and data pertaining to customer satisfaction are collected from several sources.

Specifically, these are:

- Resident/client/relatives feedback and complaints
- Resident/client/relatives surveys

Resident/client/relatives complaints, spontaneous expressions of satisfaction, and other unsolicited customer feedback are collected and processed. The resulting data is periodically analysed.

Survey results are compiled and analysed, and are combined with customer satisfaction data for compatible aspects of services. Conclusions are used to initiate improvements.

8.2.2 Internal Audit

Planning and scheduling

The CEO establishes an internal audit plan and schedule in accordance with the Internal Quality Audits Policy and Procedures. Every activity and area is audited at least once a year. Selected activities are audited more frequently, depending on their importance and quality performance history.

Audit team and preparation for audit

Only personnel independent of the audited activities are assigned to conduct internal audits.

Auditors prepare for audits by reviewing applicable standards, policies and procedures, analysing quality records, and establishing questionnaires and checklists.

Conducting the audit

When conducting the audit, auditors seek objective evidence indicating whether the audited activities comply with the requirements of the documented quality system and ISO

9001, and whether the quality system is effective. The evidence is collected by observing activities, interviewing personnel, and examining records.

Audits are conducted in a way that minimises disruption of the audited activities.

Corrective action and follow up

When nonconforming conditions are identified, a Corrective Action Report or (CAR) is written up and entered in the database. The person responsible for the affected area or activity is requested to propose and implement a corrective action.

Implementation and effectiveness of the action are verified by a follow-up audit.

Reporting

When the auditing cycle is completed, all nonconformity reports established during the cycle are compiled and analysed to determine the effectiveness of the system.

8.2.3. Monitoring of Quality System processes

Quality system processes are monitored by variety of approaches and techniques, as appropriate for a particular process and its importance.

These include:

- Conducting internal audits of the quality system
- Monitoring trends in corrective action reports
- Analysing service conformity and other quality performance data and trends
- Measuring and monitoring customer satisfaction

8.2.4 Monitoring and Measurement of Service

Eskleigh monitors and measures the characteristics of the provision of service to verify that service requirements (including legislative requirements) have been met.

The following is documented:

- The service meets acceptance criteria
- The service is reviewed
- The person who authorised the service to be delivered to the client

8.3 Control of non conforming service

Nonconforming service is identified, documented, evaluated, and prevented from being provided.

Responsibility for the evaluation and correction of nonconforming service is established and defined. Appropriate actions are taken when service nonconformity is identified after provision.

When appropriate, corrective and preventive actions are implemented to prevent recurrence of identified nonconformities.

8.4 Analysis of Data

Eskleigh collects, compiles and analyses information and data required for evaluating the suitability and effectiveness of the quality system and for identifying opportunities for continuous improvement.

General

Data and information recorded in quality records are compiled and analysed periodically to determine trends in the performance and effectiveness of the quality system and to identify opportunities for improvement.

Scope

The following categories of information and data are recorded, compiled and analysed:

- Conformity to service and resident/client requirements:

Suppliers:

- Supplier quality performance — recorded in supplier quality performance files

Customer satisfaction and dissatisfaction:

- Customer satisfaction levels — recorded in customer satisfaction surveys and reports
- Customer complaints — recorded in customer complaints log and evaluated for trends

Quality System:

- Effectiveness of training — recorded in training evaluation reports
- Effectiveness of quality system — recorded in internal audit reports and evaluated for trends

8.5 Improvement

Eskleigh promotes a continual improvement philosophy throughout the entire organisation.

The improvement effort is driven by goals defined in the quality policy and quality objectives.

Improvement opportunities are identified by analysing quality performance data and information.

Improvement projects are defined and implemented through the system of corrective and preventive actions and management review actions.

Causes of identified nonconformities are investigated and, where appropriate, corrective actions are implemented to ensure that nonconformities do not recur. Preventive actions are implemented to eliminate the causes of potential nonconformities. Corrective and preventive actions taken are recorded and are followed up to ensure that they have been properly implemented and that they are effective.

8.5.1 Continual Improvement

Opportunities for improvement

Opportunities and priorities for improvement are identified by comparing present quality performance to objectives defined in the quality policy and quality objectives.

Quality performance is determined by analysing information about customer satisfaction, records of service and process nonconformity, results of internal audits, and other data and information relevant to quality performance.

Section 8.4, Analysis of Data, defines the scope and system for collecting and analysing such information.

Quality performance is evaluated by management reviews of the quality system. Where quality performance falls short of a defined objective, the management review identifies specific improvement actions to reach the objective. When a quality objective is reached, the management review may set a new, higher objective in this area and specify new improvement actions for reaching it.

In addition to management reviews, managers and supervisors identify improvement opportunities, based on daily feedback from their operations and other activities.

Employees are also encouraged to come forward with ideas for improving services, processes, systems, productivity, and the working environment.

These improvement opportunities are evaluated and prioritised by the Management Team and, where appropriate, are implemented through the system of corrective and preventive actions

Implementation of improvement projects

Improvement projects are usually implemented through management review actions and through corrective and preventive actions. Where appropriate, improvement projects may be also initiated by management directives, such as policy statements, announcements and memoranda

8.5.2 Corrective Action

Preventive versus corrective action

Preventive actions are requested and implemented when there are trends of decreasing quality capability and/or effectiveness of the quality system that create a risk for a potential nonconformity. (Such as a "near miss" reported on an Adverse Incident form). Corrective actions are used when an actual nonconformity is identified.

Recognising this difference, Eskleigh has separate systems for identifying the need for corrective and preventive actions. However, once the need is identified, a common system is used to process both types of actions. Forms, logs and other documents and records for processing of corrective and preventive actions are the same.

Corrective actions

The need for corrective action is determined on the basis of identified actual nonconformities.

Corrective action requests are typically triggered by such events as a failed inspection, staff member comment or complaint, resident/client/relative's complaint or comment, nonconforming delivery from a supplier, or a quality system audit finding.

Implemented corrective actions are recorded and the results of actions taken are recorded. The effectiveness of the correction action taken is then reviewed, and should the result be unsatisfactory, then the corrective action cycle would be re-implemented.

8.5.3 Preventive actions

The need for preventive action is determined on the basis of information and data regarding the capability and performance of processes, service nonconformity rates, post-service experience feedback (such as feedback from respite residents and their families), service records, customer complaints, and quality system audit findings.

Such information and data are collected and analysed to detect unfavourable trends that, if not checked, will increase the risk of nonconformities. The system for collecting and analysing quality performance information and data is defined in Section 8.4 of this manual.

Processing of corrective and preventive actions

Preventive and corrective actions are initiated, processed and followed up using a CAR (Corrective Action Request). This record documents the unsatisfactory condition and the corrective or preventive action to be taken, and is used to record the verification and closure of the action.

Open CARs are reviewed regularly to ensure that the actions are implemented and followed up in a timely manner.

Continual improvement

Continual improvement actions are often defined as corrective and preventive actions. This is especially true for preventive actions.

Correspondence between ISO 9001:2008 and Eskleigh Quality Manual, Policies Procedures and other documentation		
Element No	Description	Eskleigh Policy, Procedures & Processes
4.	Quality Management System	Described in this Quality Manual
4.1	Quality System Processes	Quality Management System Policy & Procedures, operational procedures, work instructions, records and documentation
4.2	Documentation requirements	Described at Page 8 of this Quality Manual
4.2.1 4.2.2		
4.2.3	Documentation Control	Document Control Policy & Procedures & Document Control Process
4.2.4	Control of Records	Records Integrity Policy & Procedures
5.	Management Responsibilities	Described in this Quality Manual
5.1	Management commitment	Described in this Quality Manual & in the Quality Management System Policy & Procedures
5.2	Customer focus	See Quality Management System
5.3	Quality Policy	Described at Page 11 of this Quality Manual and prominently displayed in Eskleigh facilities
5.4	Planning	
5.4.1	Quality Objectives	Described at Page 12 of this Quality Manual
5.4.2	Quality Management System Planning	Quality Management System Policy & Procedures
5.5	Responsibility, Authority & Communication	
5.5.1	Responsibility & Authority	Described at Pages 14 – 16 of this Quality Manual and on relevant Position Descriptions
5.5.2	Management Representative	Described at Page 16 of this Quality Manual and within the Corrective Actions Requests Policy & Procedures
5.5.3	Internal Communication	Internal Communications Policy & Procedures
5.6	Management Review	
5.6.1	General	Quality Management System Policy & Procedures & Quality workshops documentation
5.6.2	Review Input	Quality Management System Policy & Procedures & Quality workshops documentation
5.6.3	Review Output	Quality workshops documentation
6	Resource Management	

6.1	Provision of Resources	Documented at Page 18 within this Quality Manual and within budget/financial documentation
6.2	Human Resources	
6.2.1	General	Performance Assessment Policy & Procedures, Performance Assessment processes
6.2.2	Competence, Awareness & Training	Staff Training and Development Policy & Procedures, Induction Policy & Procedures, Eskleigh Competency Standards, Position Descriptions, Nursing Board of Tasmania Competency Standards
6.3	Infrastructure	Inventory & Equipment Policy & Procedures, Maintenance Policy & Procedures
6.4	Work environment	Occupational Health & Safety Policy & Procedures and processes, Manual Handling Policy & Procedures
7.	Service Realisation	
7.1	Planning of service realisation	Quality Management System Policy & Procedures, Service Entry Policy & Procedures, Contracts Policy & Procedures
7.2	Customer Related Processes	
7.2.1	Determination of requirements related to the service	Service Entry Policy & Procedures, Care Plan Policy & Procedures, Contracts Policy & Procedures, Service Exit Policy & Procedures
7.2.2	Review of requirements related to the service	Security of Tenure Policy & Procedures, Care Plan Policy & Procedures, Contracts Policy & Procedures, Service Exit Policy & Procedures, Internal Audits Policy & Procedures
7.2.3	Customer communication	Comments & Complaints Policy & Procedures
7.3	Design & Development	
7.3.1	Design & development planning	Design & Development Planning & Review Policy & Procedures
7.3.2	Design & development inputs	Design & Development Planning & Review Policy & Procedures
7.3.3	Design & development outputs	Design & Development Planning & Review Policy & Procedures
7.3.4	Design & development review	Design & Development Planning & Review Policy & Procedures
7.3.5	Design & development verification	Internal Audits Policy & Procedures
7.3.6	Design & development validation	Internal Audits Policy & Procedures
7.3.7	Control of design & development changes	Design & Development Planning & Review Policy & Procedures, Care Plan Policy & Procedures
7.4	Purchasing	

7.4.1	Purchasing process	Purchasing Policy & Procedures
7.4.2	Purchasing information	Purchasing Policy & Procedures
7.4.3	Verification of purchased product	Purchasing Policy & Procedures
7.5	Service provision	Described in relevant Client/Resident Care Policies and Procedures, Internal Audits Policies & Procedures
7.5.1	Control of Service Provision	Described in brochures, Eskleigh web site, Resident/Client Information Books, Staff Handbooks, relevant Client/Resident Care Policies and Procedures, Internal Audits Policies & Procedures, work instructions and checklists
7.5.2	Validation of processes for service provision	Internal Audits Policy & Procedures
7.5.3	Identification & traceability	Internal Audits Policy & Procedures
7.5.4	Customer property	Property Policy & Procedures
7.5.5	Preservation of Service	Not applicable to Eskleigh
7.6	Control of monitoring and measurement devices	Equipment maintenance Policy & Procedures
8.	Measurement, analysis & improvement	
8.1	General	Quality Management System Policy & Procedures, Corrective Action Request Policy & Procedures
8.2.1	Customer satisfaction	Comments & Complaints Policy & Procedures, Survey Reports
8.2.2	Internal Audit	Internal Audits Policy & Procedures, Corrective Actions Policy & Procedures
8.2.3	Monitoring and measurement of service	Internal Audits Policy & Procedures, Corrective Actions Policy & Procedures
8.3	Control of non conforming service	Corrective Actions Policy & Procedures
8.4	Analysis of data	Described at Page 31 of this Quality Manual
8.5	Improvement	
8.5.1	Continual Improvement	Quality Management System Policy & Procedures, Quality workshops documentation
8.5.2	Corrective Action	Corrective Actions Policy & Procedures
8.5.3	Preventative Action	Corrective Actions Policy & Procedures

DEFINITIONS

Acceptance Criteria:	Standards or criteria that characteristics, materials, products and services must meet.
Audit:	An evaluation to determine if present activities conform to specified requirements and whether services conform to acceptance criteria
Calibration:	Comparison and adjustment to a standard of known accuracy.
Conformance:	Compliance with specified requirements.
Control:	An activity to ensure conformance with acceptance criteria.
Corrective Action:	Action taken to correct the conditions that are adverse to quality
Defect:	A product or service that does not meet acceptance criteria.
Documentation:	Recorded information.
Failure:	Any condition that prevents the product or service from performing its specified function.
Inspection:	Activities such as measuring, examining or testing one or more characteristics of a product or service, and comparing these with specified requirements to determine conformity.
Nonconformity:	The non-fulfilment of specified requirements.
Objective Evidence:	Facts that are observed and documented.
Operating Procedure:	A document that specifies or describes how an activity is to be performed including methods, equipment to be used and a sequence of operations.
Quality:	Conformance to specified requirements
Quality Control:	The operational techniques and activities used to fulfil requirements for quality.
Quality System:	The organisational structure, responsibility, procedures, processes and resources for implementing a quality management system.
Supplier:	Vendors and subcontractors who furnish materials, products or services
Specification:	The document that prescribes the acceptance criteria with which a product or service has to conform.
Traceability:	The ability to trace the history, application or location of an item or activity by means of recorded identification