This Quality Manual is designed to provide an overview of how The Digestive Health Centre (DHC) meets the requirements of AS/NZ ISO 9001:2016. In order to assist with referencing, it has been written in the same format as the standard.

3 Terms and Definitions

ACSQHC	Australian Commission on Safety and Quality in Healthcare
Audit	An audit is a "systematic, independent and documented process for obtaining audit evidence [records, statements of fact or other information which are relevant and verifiable] and evaluating it objectively to determine the extent to which the audit criteria [set of policies, procedures or requirements] are fulfilled." Several audit methods may be employed to achieve the audit purpose. *(As defined in ISO 19011:2016—Guidelines for auditing management systems)*
Authority	The right to command others, the right to make and enforce decisions.
BOM	Board of Management
DHC	The Digestive Health Centre
CEO	Chief Executive Officer
Clinical Governance	The system by which the governing body (BOM), managers, clinicians and staff share responsibility and accountability for the quality of care, continuously improving, minimising risks and fostering an environment of excellence in care for consumers. Safer Care Victoria set out the Victorian Clinical Governance Policy Framework. It is defined by the following domains to support safe and quality care. These are Leadership

	and culture, consumer partnership, workforce, risk management and clinical practice.
Contract	Any formal or verbal agreement between the facility and a customer for the delivery of a service. Medical services enter formal, contract based agreements to utilise the facility. Patients who are referred to the facility for treatment enter verbal agreements for admission and treatment in accordance with the referrers' specifications
Corrective Action	Action taken to eliminate the causes of an existing nonconformity, defect or other undesirable situation in order to prevent recurrence.
Credentialing	Credentialing by health service organisations is a process used to verify the qualifications and experience of primarily medical practitioners to determine their ability to provide safe, high quality health care services within a specific health care setting. It has the potential for wider application to other health professions. Credentialing has the potential to improve safety for patients by ensuring clinicians practice within the bounds of their training and competency, and within the capacity of the service in which they are working. Credentialing is part of a wider organisational quality and risk-management system designed primarily to protect patients.
Consumer	Consumers and/or carers are members of the public who use, or are potential users, of healthcare services. When referring to consumers and/or carers, the Commission is referring to patients, consumers, families, carers, and other support people.

Consumer centred care	A consumer-centred approach to care involves: – treating consumers and/or carers with dignity and respect – communicating and sharing information between consumers and/or carers and healthcare providers – encouraging and supporting participation in decision making – fostering collaboration with consumers and/or carers and healthcare organisations in the planning, design, delivery and evaluation of health care.
Customer	Includes patients and carers, referring medical staff, funding bodies and government.
DER	Defined Events Register
DON	Director of Nursing
DHS	Department of Human Services
External Contractors/Suppliers	External companies that provide goods and services to assist with the provision of patient care at DHC
IIIR	Issues, Incident and Improvement Requests.
Management System	Policies, procedures and all supporting documents that direct work practices.
Nonconformance	Nonconformity; non-fulfilment of a specified requirement.
Nonconforming Service	Any action taken/or task performed which is inconsistent with a procedure laid down as part of the management system.

NSQHSS	National Safety and Quality Health Service Standards
Open Disclosure	Open disclosure is the open discussion of incidents that result in harm to a patient while receiving health care with the patient, their family, carers and other support persons.
Statutory Duty of Candour	Statutory Duty of Candor is the open discussion of adverse events SAPSE that result in harm to a patient while receiving health care with the patient, their family, and carers. When responding to a SAPSE, the immediate priority is the safety and care of the patients and staff involved, and then identifying if there is a risk to other patients, members of the public or other staff members. The SDC process must commence as soon as a health service entity becomes aware of the SAPSE, either through the clinical incident management system or when identified by a clinician, patient, NOK, family or carer. The 3 stages of Statutory Duty of Candour are: Stage 1: Apologise and provide initial information. Stage 2: Hold the SDC meeting. Stage 3: Complete a review of the SAPSE and produce report.
Position (Role/Job) Description	A written description of work inclusive of responsibilities and tasks or activities to be performed at a specific location. Each position description should be a statement which distinguishes a particular task or set of responsibilities from all others in the organisation. Position (Role/Job) descriptions should clearly define the parameters within which an individual is expected to

	perform; they should also clarify the hierarchy of authority. Responsibility for the quality of the key functions and activities must be individually defined and documented.
Preventive Action	Action taken to eliminate the causes of a potential nonconformity, defect or other undesirable situation in order to prevent occurrence.
Products & Services	Result of activities or processes, which may include service, hardware, processed materials or intangibles such as knowledge or concepts or a combination of these. In this case, it is patient care
Risk	A probability or threat of damage, injury, liability, loss, or any other negative occurrence that is caused by external or internal vulnerabilities, and that may be avoided through pre-emptive action.
Risk Management	A structured approach to managing uncertainty related to a threat, through a sequence of human activities including: risk assessment, strategies development to manage it, and mitigation of risk using managerial resources. The strategies include transferring the risk to another party, avoiding the risk , reducing the negative effect of the risk, and accepting some or all of the consequences of a particular risk.
Responsibility	The state of being held accountable for the outcomes of actions and decisions.

Senior Management	The personnel with executive responsibility for the management of the facility.
VA	Virtual Assistant Failed to book letters (FTB) FTA & Cx letters Importing patient portal Medical Wizard referrals MW monthly report update Paed bookings Path VA task Recalls SMS

4 Context of the organisation

4.1 Understanding the organisation and its context

The Digestive Health Centre is a privately owned, free standing, purpose built facility providing specialist gastroenterological endoscopy procedures as well as specialist consultancy suites incorporating integrative health services such as: specialist gastroenterology, paediatric gastroenterology, psychology, continence therapy and dietetics, as well as PillCam and telehealth consulting. The centre continues to grow and offer a full range of digestive health services. The centre is ideally located in a medical precinct, adjacent to Dandenong Public Hospital, which if necessary would provide excellent back-up in case of unexpected emergencies. Intravenous sedation is provided by specialist anaesthetists.

The organisation was the first free standing day procedure centre in Australia, founded in May 1977 by Dr John Goy. The centre is currently owned by four specialist consultant gastroenterologists; Dr Wayne Friedman, Dr Malcolm Barnes, Dr Jacqui Dobson and Dr Shara Ket.

The day procedure centre is licenced for 10 beds. There are 3 private consulting rooms, a pre-admission clinic room, pre-procedure consulting room, anaesthetic consulting room and Allied Health consulting rooms, administration areas, as well as 1 procedure room, a dedicated paediatric gastroenterology consulting area with 2 rooms and separate waiting area and pathology administration office. A pathology collection centre is located directly behind our centre in Bruce Street & is accessible to patients.

The facility performs approximately 4000 procedures and 6000 consultations per annum.

The Digestive Health Centre is registered with the Victorian State Government Department of Human Services.

4.2 Understanding the needs and expectations of interested parties

Interested parties include (but not limited to)

- Health funds
- Accrediting agency
- DHS
- Referring GPs
- VMOs
- Staff
- Consumers
- Volunteers
- Contractors/Suppliers
- Local community etc.

DHC has various methods of understanding the needs and expectation of the interested parties including (but not limited to)

- By exception via the Incident reporting system
- Health fund negotiations/health fund payments
- Accrediting agency reports
- DHS reports
- Audits (both internal and external)
- Patient throughput
- Credentialing
- Staff appraisals/retention rates
- Consumer complaints and feedback mechanism

- Information received during post procedure consultation with both the referring practitioner and surgeons
- Review of contractors/suppliers
- Minutes of meetings

4.3 Determining the scope of the quality management system

The scope of the Management system is as follows:

The provision of specialty health services including endoscopy and specialist consulting.

Note: Design and Development is excluded from the scope of this organisation as clinical pathways are based on evidence based best practice.

4.4 Quality management system and its processes

In order to achieve the scope of the quality management system, DHC is managed by a Board of Management committed to Best Possible Digestive Health Care. There are 3 independent members on the Risk management committee and a senior anaesthetist.

The Management system is maintained through the systematic monitoring, evaluation and review of outcomes, for which objective evidence is collected, maintained and utilised for improvement.

5 Leadership

5.1 Leadership and Commitment

Management is committed to the quality management system with management review occurring at the Board of Management committee where all Directors attend. Noted that this is considered to be the highest governance for both ISO 9001 and the NSQHS standards 1 (Governance) and 2 (Partnering with Consumers). A medical executive meeting is also conducted annually.

Management at DHC is committed to and accepts the obligation to implement the Quality Policy by fostering a culture of Best Practice, Patient Focus and Corporate and Personal responsibility.

5.2 Policy – OSP-CG-005

Mission Statement: To Provide the Best Possible Digestive Health Care

Our Values: A Friendly, Caring, Efficient Environment
Communication, Trust and Teamwork
Ethics and Confidentiality
Social Responsibility
Traditional and Integrative Health Care

Our Philosophy and Aims:

- To uphold the right of all patients to expert, professional, efficient and courteous service.
- To protect the patient's rights privacy by maintaining confidentiality.
- To provide inclusive quality patient care at all times
- To promote a harmonious environment, whereby all DHC personnel work together, as a team, To provide the highest standard of patient care.
- To maintain a high level of service whilst preserving budgetary constraints.

- To appreciate and acknowledge the worth and contribution of all personnel in the delivery of quality patient care.
- To attract new consultants, staff and patients to DHC by maintaining our reputation for safety, quality and excellence.
- All staff are required to abide by the DHC Code of Conduct.

This manual and the Quality policy is available

- On the intranet
- Orientation pack for new staff

A copy of the Quality Policy is

- Supplied to VMOs as part of their credentialing pack
- Available for external suppliers upon request
- Displayed throughout the facility
- Included in the relevant area of the website
- On the intranet
- On the SONIQ screen

NB: other interested parties can have access if requested (e.g. Health funds, DHS etc.)

5.21 Establishing the quality policy

Top management shall establish, implement and maintain a quality policy that:

a) Is appropriate to the purpose and context of the organisation and support the strategic direction
b) Provides a framework for setting quality objectives
c) Includes a commitment to satisfy applicable requirements
d) Includes a commitment to satisfy applicable requirements
e) Includes a commitment to continual improvement of the quality management system.

5.22 Communicating the quality policy

The quality policy shall:

a) Be available and maintained as documented information
b) Be communicated, understood and applied within the organisation;
c) Be available to relevant interested parties, as appropriate

5.3 Organisational roles, responsibilities and authorities

The CEO, with support from the Business Operations Manager & DON, and with executive authority and responsibility is appointed to:

- Ensure that a management system is established implemented and maintained in accordance with the AS NZ ISO 9001:2016 standard.
- Coordinate and report on the performance of the management system to the Directors for review and as a basis for improvement of the management system.
- Ensure that customer requirements are understood and are being met throughout the service
- To be responsible for liaising with external parties on matters relating to the quality management system

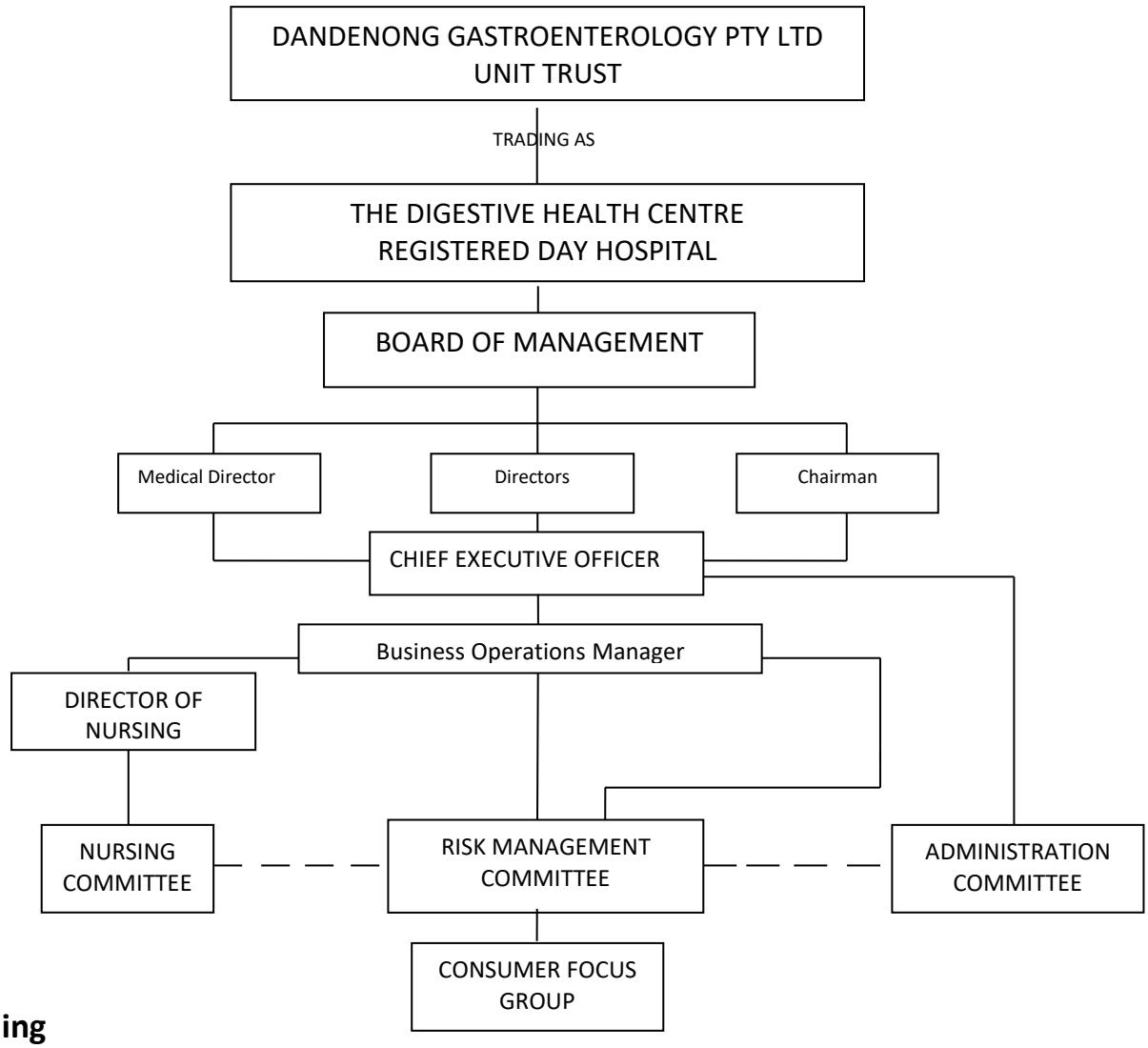
Systems are in place to facilitate and encourage staff to work in partnership with the management and peers in achieving the quality policy and quality objectives.

Position (Role/Job) descriptions define each staff member's delegated level of authority and responsibility for standard of service delivery will be in accordance with management system. Communication occurs as per 7.4 below.

Supporting documents

- *Position (Roles/Job) Descriptions*
- *Minutes of meetings*
- *Emails*
- *Reports*
- *DER forms*
- *Incident reports*

ORGANISATIONAL CHART



6 Planning

6.1 Actions to address risks and opportunities

DHC has considered risks and requirements for the scope of this quality management system which have been identified in the Board of Management meetings, Risk Management meetings and Specialty meetings and Medical Executive meetings as well as the Risk Register and Board of Management

Supporting documents

- *DHC Risk Register*
- *Minutes of meetings*

6.2 Quality objectives and planning to achieve them

In order to support the Mission, Values and Philosophy & Aims, Management are committed to meeting the following Quality Objectives:

Objective	Strategy	Success Indicator
To meet all relevant health authority requirements in both facilities and standards	– Internal and external audits – Independent Contractors for Infection Control, Quality, coding and reporting and financial reporting – Strategic Plan	– ISO:9001 2016 – Standards 1-8 for Quality & safety (NSQHSS) V2 in 2021 – DHS Registration-Vic (Specifying Paediatric patients 12yr-18yr) – No errors or rejections - DHS Victorian Admitted Episode data base – Address any safety & quality issues or recommendations raised at our next accreditation and these will be thoroughly examined.
Provide a high level of professional care ensuring cultural awareness and inclusivity of diversity.	– Patient experience surveys – Post discharge follow-up – QPS KPI's – Incident and DER Reporting – Staff competencies – Staff & Medical Practitioners Credentialling – Nursing staff registration – Medical Practitioners registration – Provide Cultural & diversity education to staff	– Positive patient satisfaction & testimonials & patient referral – Patient experience surveys – Minimal complaints – Minimal incidents – Staff competency through commitment to education – All Medical Practitioners Credentialled – Cultural & diversity education provided to staff 2024 – Demographics audit

		–
Design, develop & maintain high operational standards utilizing current & future technological advancements to achieve optimum safety & comfort for all patients and staff &other DHC personnel	– Monitor the following: – Approved suppliers – Maintenance /service contracts – Capital expenditure – Monitored by: – Board Meetings (inc. via zoom) – Risk Management Meetings – Departmental Meetings – Attendance at Industry/Scientific meetings by key personnel – Staff Education – IIIR System – Suggestions for Improvement – Internal Audits – External audits eg: DHS, certification bodies – Portal – IPad Trial – E2 endoscopes –	– Recommendations from internal auditing – Nil down time due to injury or equipment – Consistent equipment upgrades and purchases as a result of suggestions for improvement & business development – Nil evidence of ongoing equipment maintenance issues – Strategic Plan – Preventative maintenance performed on schedule – Refurbishment/ – implementation plans – Gap analysis updated – Corrective action plan IFC – Implementation of My Health Record - ongoing – Comprehensive Care Gap Analysis – ongoing – E-prescription implemented – Education of nursing staff to specific admin duties to assist in dedicated duties as a portfolio – Introduction of Riskclear. Compatible computer purchased 2023
		Posters – Falls – calls Feeling unwell AS 19/01 Gap Analysis-

		Recognising and responding to Acute deterioration. – Disposable biopsy caps introduced – Review of micro testing protocols for endoscopes stored in drying cabinets as per 2021 ICE document update.
Develop & achieve a high level of staff involvement & ensure a client focussed, team approach to all patient & doctor services	– Memo's – Staff Departmental meetings & minutes – All staff meetings – Multi disciplinary Risk Management meeting – Staff education Programme & requests for Professional development – Suggestions for Improvement – Patient feedback – Staff social events – Staff emails	– Minimal staff complaints – Evidence of attendance at meetings (inc. via zoom) – Evidence of professional development (inc. online) – staff involvement in internal audits – Staff portfolio's – Staff suggestions for improvement noted & actioned in a timely manner where appropriate – Employee satisfaction surveys – Clinician survey
Maintain the best clinical Standards through strategic staff recruitment, staff retention, staff training, peer review & update, quality assurance programmes & critical	– IIIR System – Staff education Programme & requests for Professional development – External education available to staff – In house library maintained & current via external library – Suggestions for improvement – Internal Audits – Staff/patient complaints – Performance Appraisals	– Minimal Incidents reported – Minimal staff & medical complaints – KPI's within approved industry parameters – PACU observation graph chart – updated NICMR chart to EHR – Recruitment of staff with >5 years clinical experience – Minor

evaluation of services.	– Staff Competencies – QPS KPI's – Board of Management – Medical Practitioners credentialing by Medical Director, CEO via BOM between Medical Executive Meetings	recommendations from internal & external audits – Independent IFC Audit Yearly – Contract with SIAG (Service Industry Advisory Group) – High level of Membership to Professional Bodies, such as: GENCA, – SAI Global, WMA – High staff attendance via zoom for educational sessions – SAI Global member – Reprocessing Nurse auditor – Expand consumer feedback processes and involvement – Biannually Consumer focus group meeting – Consumer, anaesthetist, and associate gastroenterologist joined Risk Committee. – Consumer, anaesthetist, and associate gastroenterologist on Risk Committee.
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6.3 Planning of Changes

Any changes in scope, services provided or technology introduced will be discussed and considered at the Risk Management meetings (where appropriate) need to be approved by the Board of Management committee where all Directors attend.

Considerations include (but not limited to)

- *Physical space required*
- *Scheduling/room availability*
- *Information Technology capability*
- *Regulatory approvals (licensing, health fund contracts and accreditation)*
- *Personnel (both availability and skill)*
- *Training requirements*
- *TGA approved*
- *Reprocessing requirements if not single use*

Supporting documents

- *Minutes of Risk Management and Board of Management*

6.4 Strategic planning

A annual meeting is held where all Directors attend. This is chaired by the CEO. The scope, services provided, clinical governance, new technology, HR & success planning and consumer participation is discussed and considered.

Considerations include (but not limited to)

- *Quality management*
- *Physical space required*
- *Scheduling/room availability*
- *Information Technology capability*
- *Regulatory approvals (licensing, health fund contracts and accreditation)*
- *Personnel (both availability and skill)*
- *Training requirements*
- *TGA products*
- *Financial position*
- *Recruitment*

Supporting documents

- *Minutes of Strategic planning meeting*
- *Strategic planning policy OSP-CG-001*

7 Support

7.1 Resources

Responsibility for service delivery is assigned to personnel on the basis of their qualifications, education, training, skills and experience.
The management will provide adequate resources, including the assignment of qualified and experienced staff for the delivery of the expected standard of health care services. Evidence of relevant qualifications and experience will be maintained in staff files.
Credentialling of medical staff is the responsibility of the Medical Director and the CEO in compliance with the National Standards.
All employees are assessed as competent to perform the tasks allocated. Records are maintained which indicate qualifications, skill level training needs and functions for which employees are trained. The effectiveness of training programs is regularly evaluated.
DHC has designed the facility to ensure the provision and maintenance of facilities that enhance the delivery of the service. The facilities include: patient waiting, operating and recovery areas inclusive of furnishings, medical equipment, office equipment, IT hardware/software and support services as required.

A commitment to the safety of clients and personnel is given through the design of the facility. The aim was to ensure that the cleanliness and maintenance of the facility could be achieved in such a way that it meets the current industry standards with minimal effort on the part of the personnel. This includes attention to such design concepts as:
Minimal lifting

- Easy care surfaces
- Waste disposal, including clinical and, confidential and recycling
- Staff knowledge in Infection Control Standards
- Workplace culture free from all forms of discrimination, or harassment
- Appropriate heating and cooling systems
- Maintenance programme
- Windows with 100mm glass to remove exterior noise
- Ergonomic workstations, chairs and aids where appropriate

Documented procedures are in place to provide assurance that measuring and monitoring devices that are utilised to evaluate the status of equipment and assessment tools in the delivery of the service, are calibrated and maintained in accordance with national standards. Records of the assessment status of these devices are maintained

Where test software or hardware are used in the testing process they are regularly checked to assess the reliability of measurement.

Where the availability of technical data pertaining to equipment performance testing is a specified requirement such data will be made available when required by the customer for verification that the equipment is functioning adequately.

DHC will ensure sufficient organisation knowledge by developing, maintaining and reviewing policies and procedures to meet the requirements of the NSQHSS and legislative requirements.

The adequacy of resources is reviewed through internal auditing, staff reports, service exception reporting and management review at the Board of Management meetings.

Supporting documents

- *Minutes of meetings including Board of Management and staff meetings*
- *Maintenance Program*
- *Equipment Register*
- *Internal Audit reports*
- *External audit reports*
- *Hazard identification*
- *Incident reports*
- *DERs*
- *Risk register*
- *Calibration Records*
- *Microbiological Testing records*
- *Validation Records*
- *Daily Checklists*
- *Infection Control Procedures*
- *Manual Handling*
- *Waste Management*
- *Security*
- *Emergency Response Manual*
- *Environmental Cleaning inclusive of schedules and records*
- *Orientation*
- *Training records*

7.2 Competence

The Director of Nursing, as well as the Chief Executive Officer and the Business Operations Manager

- Ensure that all staff are qualified on the basis of appropriate education, training and competence.
- Establish and maintain documented procedures identifying and providing for the training needs of the organisation
- Appropriate records of all training are documented and maintained.

Procedures are in place ensuring all staff:

- Are aware of and comply with the policies and procedures of DHC.
- Fulfil their level of responsibility for complying with the requirements of the Quality Management System.
- Understand the Impact of their work on the overall quality of the service
- Benefit from opportunities to improve personal performance
- Understand the consequences of departure from the specified quality management policies and procedures
- Comply with Code of Conduct Policy OSP-HR-003

Supporting documents

- *Staff Orientation, Training, Appraisals and Competence Policy OSP-HR-001*
- *Workplace Bullying and Harassment Policy OSP-HR-004*
- *Information Management Policy OSP-RM-018*
- *Social Media Policy OSP-RM-019*
- *Security Management Policy OSP-RM-020 – cyber security incorporated into this document*
- *Position Descriptions (Role/Job)*
- *Enterprise Agreement*
- *WHS Policy OSP-RM-013*
- *Credentialling Criteria & Scope of Practice OSP-HR-002*
- *Dress Code and Identification Policy OSP-HR-005*
- *Independent Agreements*
- *Risk Management Policy OSP-RM-001*
- *Staff Complaints & Dispute Resolution Policy OSP-HR-006*
- *Staff Performance Appraisals - Nursing Performance Appraisal HR-001-F002*
  - Administration Performance Appraisal HR-001-F013

7.3 Awareness

DHC ensures that all personnel both external and internal are aware of the quality policy, vision, mission and quality objectives to the effectiveness of the quality management system by having this manual:

- On the intranet

A copy of the Quality Policy is

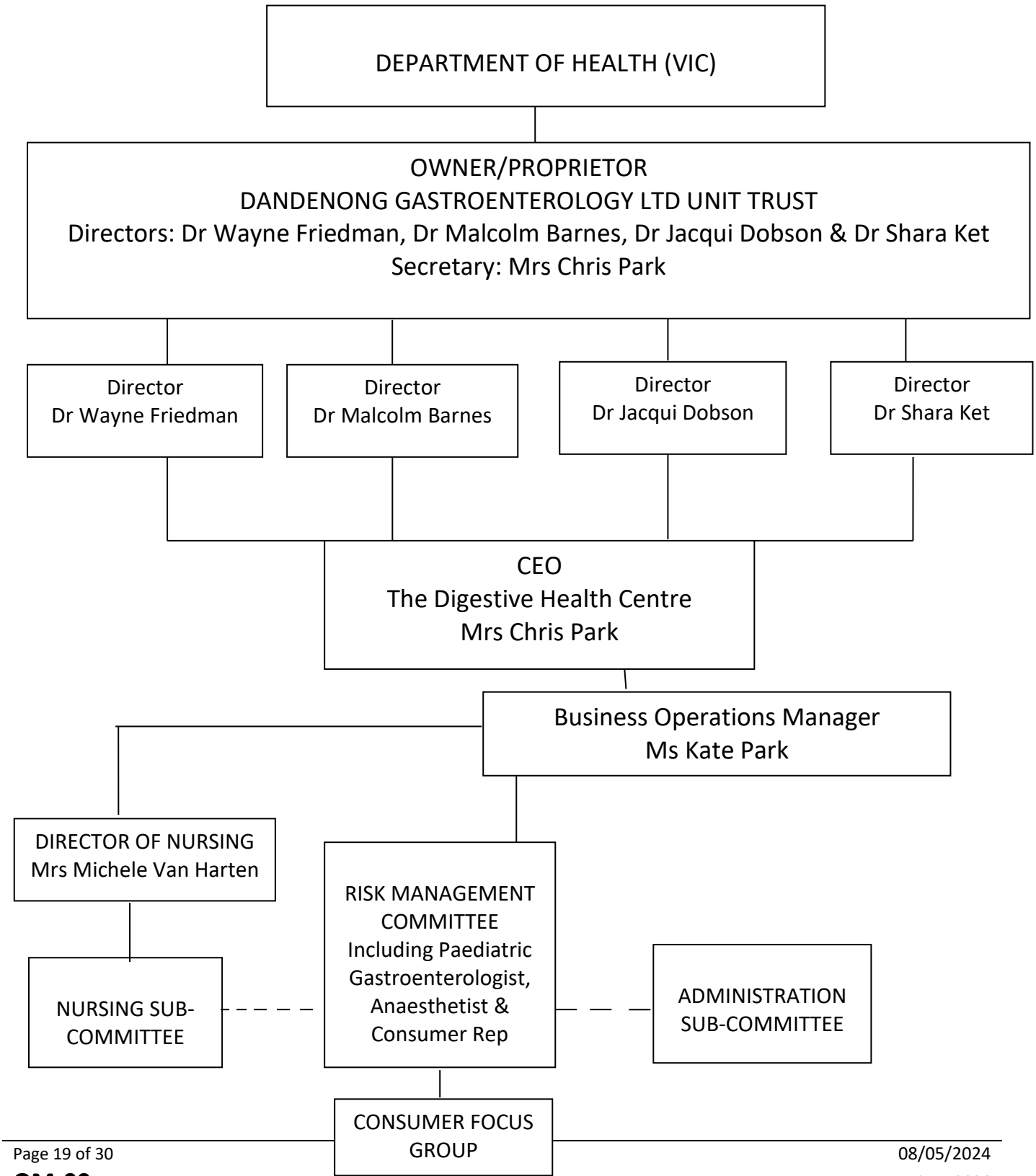
- Supplied to VMOs as part of their credentialing pack
- Available for external suppliers upon request
- Displayed throughout the facility
- Included in the relevant area of the website
- On the intranet
- Orientation pack for new staff

NB: other interested parties can have access if requested (e.g. Health funds, DHS etc.)

7.4 Communication

The internal communication system is based on clearly defined communications and reporting channels

Lines of Communication



In addition, there are:

- A documented Organisational chart defining lines of authority and reporting
- Staff meetings (Face to Face or via Zoom)
- Education/training days
- Memos
- Minutes of meetings
- Incident forms
- DER
- Hazard Identification Forms
- DHC Risk register
- Staff Notice Board
- Website and Intranet
- Emails

7.5 Documented Information

Documents are defined as electronic or hard copied text based objects that contain information on company activities and process related requirements. They include the following:

- Documents
  - Policies
  - Forms
  - Work Instructions
  - Brochures
  - Steam Consulting (Policies and Procedures)
- Uncontrolled Documents
  - Registers
- External Documents

Records include both paper- based and electronic records. Documented procedures have been established and maintained to describe what records have to be kept, where they should be kept , length of time records must be kept, the person responsible for their disposal and whether they are hard copy or electronic.

Supporting documents:

- *Document Control Policy OSP-DC-001*

DHC Policies and Procedures on Intranet including but not limited to:

- *Information Management Policy OSP-RM-018*
- *Computer Usage Policy OSP-RM-025*
- *Privacy Policy OSP-CG-004*
- *Security Management Policy OSP-RM-020 – cyber security incorporated into this document*

8 Operation

8.1 Operational planning and control

Our Clinical Pathway Policy OSP-RM-006 outlines the process that the patient will follow from booking to discharge. Processes are implemented to ensure the delivery of service in compliance with customer/patient requirements. These include:

- Booking process (patient age, Diabetic status, anticoagulant status, BMI, OSA, weight loss medication
- Online Patient Portal
- Pre Admission Clinic
- Health Fund Eligibility Checking
- Medical & financial consent
- Medical Records and documentation
- Clinical supervision and leadership
- DH documentation
- Goals of care
- Healthcare Rights

Supporting documents

- *Clinical Pathway OSP-RM-006*
- *Gastroscopy Screening Procedure PCP-003-WI001*
- *Patient Selection Policy OSP-RM-005*
- *Patient Exclusion Policy OSP-RM-005a*
- *Interpreter Services Policy OSP-CP-003*
- *Consumer Rights Policy OSP-CP-001*
- *Consumer Responsibilities Policy OSP-CP-002*
- *Translated Information, consent, rights and responsibilities & goals of care.*
- *Privacy Policy OSP-CG-004*
- *COVID-19 forms/policies*

8.2 Requirements for products and services

Processes are implemented to ensure the delivery of service in compliance with customer/consumer requirements. These include:

- Preadmission assessment
- Health fund checks
- Medical records and documentation
- Financial Analysis, Reports, Cash flow, Budget setting
- Health Fund Negotiation, Setting Uninsured Rates
- Suppliers contracts, bio-medical testing, linen, environmental cleaning & security
- AER & Drying cabinet
- Compliments and complaints handling

Procedures are in place to enable effective communication with consumers regarding the following:

- Availability of information relating to service provision

- Accessing the service and any amendments to the service delivery process
- Process of submitting complaints and notification of actions being implemented to correct problems
- Feedback from customers regarding the quality of the service

Supporting Documents

- *Endoscopy Record Paperwork including; Informed medical & financial consent*
- *Clinical Pathway OSP-RM-006*
- *Patient Selection Policy OSP-RM-005*
- *Patient exclusion policy OSP-RM-005a*
- *Consumer Rights Policy OSP-CP-001 & Consumer Responsibilities Policy OSP-CP-002*
- *Consumer Complaints Policy OSP-CP-004*
- *QPS Patient Experience Survey*
- *Consumer interview form CP-006- F001 & procedure CP-006- WI001*
- *Facebook reviews/posts & visitor book*
- *Privacy Policy OSP-CG-004*
- *Gastroscopy Screening Procedure PCP-003-WI001*
- *COVID-19 forms/policies*

8.3 Design and development of products and services

This clause of the international standard is excluded from the scope of this organisation as clinical pathways are based on evidence based best practice.

8.4 Control of externally provided processes, products and services

DHC maintains a register of contractors that supply DHC with processes, products and services. The level of control and management of these contractors is risk assessed and documented on the register. This register is monitored via the internal audit system.

To ensure the availability of the resources required to support the delivery of the service, there are purchasing procedures in place to ensure that purchased goods and services conform to requirements. All purchases will be made in accordance with Purchasing, Maintenance & Repairs Policy OSP-RM-015.

Purchased goods and services are verified as meeting the specifications as detailed in the purchasing orders or contractual agreements prior to use.

Documented procedures have been implemented to ensure the safe handling, storage and preservation of incoming goods (eg: supplies) and documentation directly affecting service delivery. Fully maintained and clearly defined storage areas are provided for the storage of goods and information. This ensures that all incoming goods are stored in well defined, clean areas consistent with legislation and supplier recommendations.

Appropriate methods for authorising receipt of, or dispatch from, such areas have been stipulated for incoming goods and client records.

To facilitate access and traceability:

- All stored goods and records are clearly identified. This applies equally to physical products as it does to data and software.
- All storage facilities are checked at appropriate intervals are checked at appropriate intervals to ensure the preservation of it's condition and for the actual stock conformity with stock records.

Non conforming goods or information on delivery, or those outside their use by dates or other specifications, or which show other evidence of deterioration must be protected from inadvertent use whilst decisions are made as to their disposition.

Supporting Documents

- *Purchasing, Maintenance and Repairs Policy OSP-RM-015*
- *Audits*
- *Product Evaluation Forms RM-015-F002 &RM-004-SC4-F001*
- *Reusable Medical Devices on Loan RM-004 SC 4.13*
- *Storage& Handling of sterile medical devices RM-004-SC-1.20*
- *Contingency Plans Policy OSP-RM-021*
- *Essential Services Management Policy OSP-RM-030*
- *Contractors Policy OSP-RM-022*
- *Current Contractors RM-022-F001*
- *Tender – WHS Management System Questionnaire RM-022-F002*
- *Contractors Site Safety Code RM-022-F003*
- *Contractor Information Package RM-022-F004*
- *Contractor WHS Procedure Questionnaire RM-022-F005*
- *External Contractors RM-022-F006*

8.5 Production and service provision

Processes are in place to ensure a complete understanding/patient needs and expectations. These processes are designed to ensure the differences in expectations between the various customers/patients are identified and resolved prior to the entry into a contract.

Regardless of the type of agreement or contract being entered into, qualified personnel are responsible for:

- Establishing a clear understanding of customer/patient requirements to ensure that the service supplied complies with relevant, legislative and regulatory obligations and meet customer/patient needs and expectations.
- Ensuring that verbal requests and subsequence acceptance are adequately documented.
- Ensuring that any difference between the service requested and those services that can be supplied are resolved with customer/s.

- Ensuring that where prior arrangements were made, any differences between the service requested and those services that can be supplied are resolved with the customer and where prior arrangements were not made and the service supplied was different to the service expected, then a mechanism exists to investigate and resolve the difference.

Processes are in place to ensure that required amendments to contractual arrangements are identified, are agreed and notified to relevant personnel to enable the delivery of a consistent service.

Records of the review of contractual arrangements will be maintained and stored to meet the requirements of the provider and the standard.

Examples of contracts entered into by the facility:

- Patients as recorded in their medical records
- Supplier contracts
- Health Funds & DVA contracts

Procedures are in place to enable effective communication with customers/patients regarding the following:

- Availability of information relating to service provision
- Accessing the service and any amendments to the service delivery process
- Process of submitting complaints and notification of actions being implemented to correct problems
- Feedback from customers regarding the quality of the service

Supporting documents

- *Clinical Pathway OSP-RM-006*
- *Open Access Gastroscopy Screening Procedure PCP-003-WI001*
- *Consumer Rights Policy OSP-CP-001*
- *Consumer Responsibilities Policy OSP-CP-002*
- *Interpreter Services Policy OSP-CP-003*
- *Privacy Policy OSP-CG-004*
- *Endoscopy Record Paperwork including; Informed Medical & Financial consent*
- *Patient Selection Policy OSP-RM-005*
- *Patient Selection Policy OSP-RM-005*
- *Patient exclusion policy OSP-RM-005a*
- *COVID-19 forms/policies*

8.6 Release of products and services

Policies and Procedures are in place to control the delivery of the service from receipt of request for service (referral and or booking) through to completion of the service (post procedure follow up).

Validation of services are undertaken to ensure they meet customer requirements following the completion of care via the DER, Incident reporting and Post Discharge Follow up Telephone calls and Patient experience Surveys.

Validation and verification of scopes and sterile RMDs occurs after every cycle prior to release for use by attaching validation tickets onto proof of process & batch cycle record.

The status of the clinical services is assessed through a review of the service outcomes through the DER/Incident Reporting System which includes the collection of clinical indicators/benchmarking.

Non-conformances are identified via the DER/ IIIR, sterilising services non-conformance register and autoclave daily audit certificate. Appropriate corrective action is taken.

To ensure individual patient and customer safety and confidentiality a system has been implemented to differentiate between them through the allocation of a unique identification number. This applies to all records relating to the patient care.

Due care is applied to all aspects of the service delivery, both to the patient and or their belongings inclusive of care and transport of care of any pathology samples. Due care also includes all aspects of confidentiality, inclusive of information provided in confidence. In the event of an exception occurring, the DER/ Incident Reporting System and the relevant patient/customer notified.

As part of this responsibility, procedures are also in place to access emergency treatment in the event of an unexpected deterioration of a patient's condition. Steps are taken to ensure that any confidential information is delivered to the appropriate person in the receiving institution.

Information, pathology specimens and any other products are packaged and labelled prior to dispatch in accordance with specified requirements and records kept.

Specimens and other products are delivered in accordance with legislation and customer specifications.

Supporting Documents

- *Patient Selection Policy OSP-RM-005*
- *Patient exclusion policy OSP-RM-005a*
- *Gastroscopy Screening Procedure PCP-003-WI001*
- *Deterioration of a patient and Transfer Policy OSP-RM-009*
- *Malignant Hyperthermia Policy RM-009-WI1005*
- *Consumer Rights Policy OSP-CP-001*
- *Consumer Responsibilities Policy OSP-CP-002*
- *Information Management Policy OSP-RM-018*
- *Computer Usage Policy OSP-RM-025*
- *Privacy Policy OSP-CG-004*
- *Infection Control Policies and Procedures OSP-RM-004 in conjunction with Steam Consulting*
- *Audits*

- *Clinical Pathway Policy OSP-RM-006*
- *Consumer Participation Policy OSP-CP-006*
- *Staff Orientation, Training, Appraisal and Competency Policy OSP-HR-001*
- *Patient Identification and Procedure Matching Policy OSP-RM-011*
- *Risk Management Policy OSP-RM-001*
- *DER and IIIR (Incident, Issue, Improvement Request) Policy OSP-RM-003*
- *Medical Records*
- *Risk RegisterRM-001-F002*
- *Staff Rosters*
- *Sterilising Services non-conformance register RM-004-SC4.24*
- *COVID-19 forms/policies*

8.7 Control of nonconforming outputs

DHC is committed to ensuring that non-conformances are identified and processes for review and documentation exist for the recording and notification to the relevant personnel and appropriate action taken.

Strategies are in place to ensure that non-conformances are reviewed and actioned according to the IIIR, DER and Hazard Identification process.

Supporting Documents

- *DER and IIIR (Incident, Issue, Improvement Request) Policy OSP-RM-003*
- *Risk Management Policy OSP-RM-001*
- *Risk RegisterRM-001-F002*
- *Hazard Identification Audits*
- *Minutes of the Risk Management Meeting*
- *Board Meeting Minutes*

9 Performance evaluation

9.1 Monitoring, measurement, analysis and evaluation

Procedures are in place to facilitate measurement, monitoring, analysis and improvement processes to ensure that the quality management system, service delivery processes and outputs conform to customer requirements.

Customer satisfaction is collected in a number of ways:

- Compliment, Complaint and suggestion forms
- Annual QPS patient experience survey
- Post-discharge follow up including 3 targeted questions about patient experience meeting goals of care
- Pre Assessment Clinic
- Consumer interviews
- Facebook reviews/post & visitor book

Internal audits are scheduled on the basis of the status and importance of the activity to be audited and will where possible be carried out by personnel independent of those having direct responsibility for the activity being audited. There are numerous indicators, including financial and clinical collected and submitted to QPS Benchmarking.
Patient, staff and visiting Accredited Practitioner surveys are conducted annually.
Procedures are in place to ensure the collection of data to support an objective analysis of the effectiveness of the quality management system and for identifying where improvements to the system can be made. Data is collected via measuring and monitoring activities and any other relevant sources. Specifically analysis of applicable data will be undertaken to:

- Demonstrate the suitability, effectiveness and adequacy of the quality management system
- Report on process operation trends
- Report customer satisfaction and/or dissatisfaction
- Demonstrate conformance to customer requirements
- The characteristics of processes and services

DHC has a firm commitment to Customer Focus. Customer feedback is collected in the following ways:

- Compliments, complaints, and suggestion forms
- QPS Patient experience Survey
- Consumer Feedback for Patient Publications CP-005-F001
- Consumer Focus Group review of documentation & annual forum
- Facebook Reviews/Posts & Visitor book
- Post-discharge follow up including 3 targeted questions about patient experience meeting goals of care
- Consumer representative on Risk Management Committees
- Consumer interviews

Supporting Documents

- *Internal audits*
- *Patient, comments, complaints and compliments*
- *Board minutes*
- *Risk Management Meeting Minutes*
- *Performance Appraisals*
- *QPS Benchmarking Indicators*
- *DER & IIIR reporting*
- *DHC Policies and Procedures*
- *Consumer Rights and Responsibilities*
- *Patient Recalls*
- *Follow up telephone calls*
- *Visitors Compliments and Suggestions Book*
- *QPS Reports*
- *Consumer participation policy OSP-CP-006*
- *Consumer interviews*

9.2 Internal Audit

Internal quality audits are scheduled on the basis of the status and importance of the activity to be audited and are carried out by personnel independent of those having direct responsibility for the activity being audited.

Supporting documents

- *Internal & External Quality Audit Procedure OSP-RM-002*
- *Internal & External Audit Log RM-002-F001*
- *Internal & External Audit report formRM-002-F002*
- *Minutes of BOM & RISK meetings*
- *Minutes of staff meetings*

9.3 Management Review

Management Review occurs on several levels throughout the organisation, including informal discussions, IIIR's, Board meetings (BOM), Medical executive and Risk management Meetings.

The formal process for review is via the Board Meetings held a minimum of 4 times per annum.

Terms of reference:

- Board of Management
- Medical Executive Committee

Standing agenda items include but are not limited to:

- Risk Management
- Infection control incorporating hand hygiene and Antimicrobial stewardship
- Human Resources
- Marketing
- IT Review
- Credentialing of medical staff
- Maintenance review
- Consumer Focus/Participation
- Management Issues
  - Business KPI's
  - Quality
  - Evaluation and updating as required of the quality policy and objectives

Supporting Documents

- *Minutes of the Board of Management meetings*
- *Minutes of the Medical Executive Committee meetings*
- *Minutes of the Risk Management Committee meetings*

10 Improvement

10.1 General

Continuous Quality Improvement is a key element in being accountable for the Quality Service delivered at DHC.

There are policies and procedures at DHC to deal with Corrective Action and Preventative Action.

Supporting Documents

- *DER and IIIR (Incident, Issue, Improvement Request) Policy OSP-RM-003*
- *Hazard Identification Process*
- *Internal Audits*
- *QPS Benchmarking Audits*
- *Minutes of Board of Management, Medical Executive Risk Management and Departmental Meetings*
- *Risk Register RM-001-F002*

10.2 Nonconformity and corrective action

DHC is committed to ensuring that non conformances are identified and processes for review and documentation exist for the recording and notification to the relevant personnel and appropriate action taken.

Strategies are in place to ensure that all non conformances are reviewed and actioned according to the DER and Incident Reporting Systems (IIIR).

Supporting Documents

- *DER and IIIR (Incident, Issue, Improvement Request) Policy OSP-RM-003*
- *Risk Register RM-001-F002*
- *Minutes of Board of Management, Medical Executive, Risk management and Departmental meetings*
- *Consumer Complaints Policy OSP-CP-004*
- *Audits and Benchmarking*

10.3 Continual Improvement

As per 10.1

Version	Date	Author	Description
5	18/11/2014	IM	Update Staff names
6	05/09/2016	IM	Review & Update staff & policy names
7	10/08/2017	CEO/IM/BDM/ADON	Review & Update in line with AS NZS ISO 9001: 2016
8	20/07/2018	BDM	Lines of communication updated
9	14/09/2018	BDM	Inserted 5.2.1 & 5.2.2 and removed IM, added business operations manager, removed development
10	18/04/2019	DON/BOM	Reviewed & updated quality objectives and success indicators
11	27/07/2019	CEO/DON	Updated 2 x success indicators
12	31/07/2019	CEO	Updated organisational chart
13	07/02/2020	DON	Updated x 1 success indicator
14	19/01/2021	DON/BOM	Updated x 17success Indicators, Updated organisational chart to include consumer focus group & BOM (also) in definitions
15	30/04/2021	BOM	Expanded on consumer participation in 9.1. Added to 6.2 inclusive of diversity and being culturally aware'. Added 6.4 Strategic planning
16	02/02/2022	CEO/BOM/DON/BOM	Updated quality objectives & terms of definition. DHHS now DH. Added JD & SK as owners. Added independent persons to 4.4. Updated supporting documents. Deleted "memos". Updated 7.4 lines of communication. Added reference to exclusion policy and covid-19 forms & polices. Added goals of care to 8.1. Updated consent to state medical & financial. Removed survey monkey. Biannual now annual for consumer forum 9.1. Infection control & AMS added to 9.3. Updated meeting to include risk management 9.3. Added Medical executive minutes to 10.1 supporting documents.
17	25/02/2022	BOM/DON	Updated success indicators
18	06/05/2023	DON/BOM	Reviewed success indicator objectives
19	08/05/2024	DON/BOM	Reviewed quality manual, reviewed success indicators objectives Pg 4 added Statutory of candour and definition, pg 9 removed director of administration. Pg17 added cyber security added in policy. Pg20 goals of care, healthcare rights, weight loss medication.pg26 added meeting goals of care.