



# QUALITY SYSTEMS MANUAL

Authorised by:

A handwritten signature in black ink, appearing to be 'C. Miller', written over a horizontal line.

Date:

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## INTRODUCTION

Albury Day Surgery (ADS) is a privately-owned day surgery located in Albury, which provides day surgery facilities to local and interstate medical specialists, and their associates. It comprises a three operating theatre complex and IVF facilities.

### MISSION STATEMENT

The Albury Day Surgery is committed to:

- Provide patients with the highest level of care
- Treat patients and carers with respect
- Provide an effective and safe environment and treatment
- Provide sound, efficient management
- Provide a safe and happy workplace for workers

## THE SCOPE OF THE MANAGEMENT SYSTEM

### Surgical Services

- Endoscopy
- Maxillofacial
- Plastic Surgery
- Ophthalmic
- General Surgery
- IVF
- Gynaecological
- Dental
- Urology

### Medical Services

- Dispensary Stock – limited medications, dressings, slings
- Diagnostic services – Pathology, ECG, ultrasound
- Diagnostic imaging procedures are only undertaken at ADS where there is an identified clinical need and where the practitioner interpreting the image is permitted to self determine the service for which a Medicare benefit is payable under the Act.
- ADS does not administer drugs for diagnostic imaging services

### Patient Services

- Pre Admission phone calls
- Patient Discharge Information
- VMO and specialist appointments made
- Food and fluids for patients
- Domiciliary Care Service post-discharge

The following is designed to provide an overview of how Albury Day Surgery meets the requirements of the ISO 9001:2008 standard and the NSQHSS. In order to assist with referencing, it has been written in the same format as the standard.

## 4.0 Quality Management System

### 4.1 General Requirements

Management is committed to and accepts the responsibility of implementing the Quality Manual Policies. This is to be achieved by educating, encouraging, and supporting all personnel involved in the service and practice of the Albury Day Surgery (ADS).

The Quality Management System will be maintained by ongoing monitoring, evaluation, and review of all processes. This will allow ADS to understand their customers and continually meet their requirements, as well as all relevant statutory and regulatory requirements.

The Quality Management System has been designed and implemented to ensure:

- Customer needs and expectations are met, and where possible exceeded
- Management infrastructure has been organized to enable staff to achieve ADS quality objectives
- Individual authority and work practices have been established and communicated
- Availability of all required resources and information
- Commitment to continuing improvement and the ongoing review of efficiency and effectiveness of work practices
- Effective partnership with suppliers and service providers

### 4.2 Document Requirements

#### 4.2.1 General

The Quality Management System at Albury Day Surgery includes the following documents:

- Quality Systems Manual with included Quality Management Policies
- Procedure documents for all procedures and practices undertaken at Albury Day Surgery, and Work Instructions where appropriate
- Company forms for recording of activities at ADS
- Quality Index on computer desktop
- Copies of all relevant Australian and International Standards, Regulations and Acts.

#### 4.2.2 Quality Manual

The Quality Systems Manual is the main document covering all of the requirements of ISO 9001:2008 and the NSQHS standards.

Management encourages all staff to contribute to the continual improvement of the Quality System. The Nurse Unit Manager/Quality Manager and the Quality Co-Coordinator are responsible for updating and amending the system following Issue/Incident/Improvement Requests (IIIR), Audits, or staff feedback as discussed in “Coordinating Quality”.

### 4.2.3 Control of Documents

All documents required by the Quality Management System at ADS are controlled. The control is predominately of the flow and content of the documents, and allows staff to be aware if the document is current, and is an approved document. By controlling these documents, updates and improvements are efficiently implemented.

Controlled documents of the ADS Quality System are:

- Quality Policies
- Procedures
- Work Instructions
- Company Forms
- Patient Files – Clinical Pathway
- Job Descriptions
- Surgeons Preferences

Documents at ADS are controlled using the following processes:

- Designation and Date in Header and Footer
- Review following internal audit or improvement request (IIR form)
- Any required changes made and approved
- Document saved and distributed
- Previous document archived
- Documents are presented in a hard copy format, as well as being on the “Quality Assurance” ADS computer system. ON SHARED FILES
- All documents are approved by NUM. An index of External Documents is kept in the Company Forms Folder. This is updated when changes are made.

Refer:

IWI 4	Changing Quality Controlled Documents
ICF 4	Request for new ISO Document or update existing ISO Document
ICF 6a	Company Forms Register – External Documents
QP 1	Quality Procedure – “Co-ordinating Quality”

### 4.2.4 Control of Records

All records used in Quality activities at ADS are retained and archived as they provide evidence of conformity to requirements in our practice.

Quality records are either archived electronically or, if not internally generated, by safely storing on site, both allowing for retrieval of documents if required. Retention times of quality records shall be established and recorded as per NSW Health Department Regulations.

All data is automatically backed up nightly on server and a back-up disc taken off-site every evening by the Office Manager.

Refer:

CWIoC2 Controlling Medical Records

ICF 4 Request for new ISO Document or update existing ISO Document

Ext Doc. I T Policy by 'NET INTELLECT' in Front Office



## **5.0 Management Responsibility**

### **5.1 Management Commitment**

Senior Management at ADS are committed to ensuring the needs of all our customers are met, as well as all statutory and regulatory requirements of our operation as a Day Surgery.

This will be achieved by the establishment of a Quality Policy and Quality Management System, the support and education of all personnel involved, ensuring all necessary resources made available, and ongoing reviews of all management and quality activities.

The Executive of ADS adopt the principles of the National Disclosure Statement

- Acknowledgment of the incident.
- Openness and timeliness of communication
- Expressions of regret/ apology
- Recognition of the reasonable expectations of patients and carers
- Support for staff to enable effective open disclosure
- Confidentiality

### 5.2 Customer Focus

Effective customer focus is achieved at ADS by acquisition of and response to direct feedback and by the utilization of all available professional resources.

The Private Patients Hospital Charter is available for patients to read and “The Australian Charter of Healthcare Rights” is on display in foyer. The guidelines within this charter have been adopted by Albury Day Surgery

Direct feedback is available via Patient Questionnaires, the Patient Complaints Policy, and by Issue, Incident and Improvement Requests (IIIRs), Domiciliary Care follow-up phone calls, Carer Surveys and corrective actions generated in response to these.

Professional resources used are approved documents/guidelines i.e. ACORN Standards, Private Patients Hospital Charter, Australian Charter of Healthcare Rights, International Assoc. of Ambulatory Surgery (IAAS), Aust. Day Surgery Nurses Assoc.(ADSNA), NSW Health Dept. regulations, NSW WH&S Regulations 2011.

#### Refer:

ICF 1 Issues, Incidents, & Improvement Request form  
DCF 3 Patient Questionnaire  
OWI P1 What to do if you have a Complaint  
ICF 7 Patient Complaints Form  
ACF 2 Domiciliary Care Form  
Private Patients Hospital Charter  
Australian Charter of Healthcare Rights  
National Open Disclosure Statement  
Management Review, Medical Advisory, and Staff Meetings

### 5.3

#### Quality Policy

## QUALITY POLICY

Albury Day Surgery is committed to continual improvement. To support this, the company has developed and implemented a Quality Management System, with the intention of satisfying the requirements of:

**AS/NZS ISO 9001:2008 and NSQHS Standards**

**“Quality Management Systems – Requirements” and HB 90.8 – 2000 Health Care Services Guide and ISO 9001:2008 Overview**

The Quality Management System is reviewed annually, in accordance with ISO elements 5.6.1 and 5.6.2 to ensure continued effectiveness of the Quality Management System and the highest standard of patient care.

Management ensures, through ongoing training, that all staff remains aware of the latest developments in their field and has adequate resources to conduct business safely and effectively. It is the prime objective of ADS to provide quality health care, in a safe, skilled, caring and supportive environment, which safeguards the confidentiality and rights of our patients and Visiting Medical Officers.

The Chief Executive Officer (CEO) fully endorses this policy document and the formal Quality Management System that has been implemented.

A copy of this Quality Policy shall be displayed and it is the responsibility of all management and supervisory staff to ensure that it is understood, implemented and maintained at all levels in the company.

**AUTHORISED BY :..... CEO**

## 5.4 Planning

### 5.4.1 Quality Objectives

OBJECTIVE	STRATEGY	SUCCESS INDICATOR
To meet all relevant health authority requirements	<ul style="list-style-type: none"> <li>-External Audits</li> <li>-Internal Audits</li> <li>-Infection Control Policy</li> <li>-Management of Poisons</li> <li>-Material Safety Data Sheets</li> <li>-Radiation License</li> <li>-Dept. of Health Audits</li> </ul>	<ul style="list-style-type: none"> <li>-Successful Accreditation</li> <li>-Registration with NSW Health Dept</li> </ul>
To provide a high level of care to patients	<ul style="list-style-type: none"> <li>-Patient Satisfaction Survey analysis of results</li> <li>-Post Discharge follow up</li> <li>-Clinical Indicators</li> <li>-Post discharge infection and complication surveillance</li> </ul>	<ul style="list-style-type: none"> <li>-Positive Patient Satisfaction Survey results</li> <li>-Minimal post discharge infections and complications</li> <li>-Successful Patient flow</li> </ul>
To provide a safe environment for all patients , staff and visitors	<ul style="list-style-type: none"> <li>-WH&amp;S inspection/audit</li> <li>-Allocation of staff WH&amp;S representative</li> <li>-Support and training of above representative</li> <li>-WH&amp;S component included in annual staff mandatory training</li> <li>-Risk Assessment and Register with regular review</li> <li>-IIR forms</li> </ul>	<ul style="list-style-type: none"> <li>-Minimal Work-Cover claims</li> <li>-Minimal recording of Near Misses</li> <li>-Prompt response to any perceived risks and minimal incidents</li> </ul>

OBJECTIVE	STRATEGY	SUCCESS INDICATOR
To provide and support high standards of medical technology for patients and staff	Monitor the following -Approved Suppliers -Maintenance/service contracts -Capital expenditure -Biomedical Consultants -Staff education -IIIR forms	-Nil down time due to breakdown of equipment -Nil evidence of ongoing equipment and maintenance issues -Nil staff and VMO dissatisfaction due to equipment failures
Maintain high level of clinical standards through strategic staff recruitment, staff education, and quality assurance programs.	-Staff Personnel Files available and maintained -External education information available to staff -Education calendar -Membership of professional bodies -Internal audits -Monitoring by MAB -IIIRs and staff/patient complaints -Performance appraisals	-Continual improvement from internal auditing -Minimal complaints from patients and VMOs -Good attendance at in-services -Some staff membership of professional bodies such as: -ADHA -ACORN -GENCA -ADSNA
Develop high level of staff involvement and "Team Approach"	-Communication Book -Staff Meetings -In-service calendar -IIIRs	-Minimal staff complaints -Evidence of attendance and participation at meetings -Timely action on suggestions for improvements (IIIRs)

### 5.4.2 Quality management system planning

The Quality System has been set up to incorporate all elements of the Quality Plan. These include:

- Commitment to continuing improvement
- Provision for the plan to be reviewed and updated as part of the management review
- Quality objectives
- Ongoing reviews and updates of procedures and documents
- Process and Document Control Audits
- Control over documents reviewed
- Identification of requirements for improved quality outcomes

## **ROLE OF ORGANISATION MEMBERS**

### **5.5 Responsibility, authority and communication**

#### **5.5.1 Responsibility and authority**

##### **LICENCEE COMPANY – ALBURY DAY SURGERY PTY LTD**

- Albury Day Surgery Pty Ltd is responsible for all operations of the business

##### **BOARD OF DIRECTORS**

- The Board of Directors (BOD) is the governing body of Albury Day Surgery. As such they have ultimate responsibility and accountability for the strategic, financial and operational aspects of the facility.

##### **NEW SOUTH WALES MINISTRY OF HEALTH**

Albury Day Surgery is responsible for the reporting of certain Reportable Incidents to the NSW Ministry of Health. This Department must be notified of the following:

- Death of a patient
- Procedures involving the wrong patient / body part regardless of the outcome
- Retained instruments or other material after surgery requiring reoperation or further surgical procedure
- Medication error leading to the death of a patient reasonably believed to be due to incorrect administration of drugs
- Intravascular gas embolism resulting in death or neurological damage
- Unexplained death of a staff member
- Fire, bomb or other threatening activities in the health facility
- Critical equipment breakdown or failure
- Serious threats affecting the facility's operation
- Complete loss of service i.e. power or water failure
- Criminal activity in or related to the workplace
- Non-accreditation of service provider
- Violence or threats of assaults on patients, staff or other persons in the Health

Incidents briefs are to be prepared and authorised by the Chief Executive Officer and are to be submitted within 24 hours. Further information can be found at [http://www0.health.nsw.gov.au/policies/pd/2014/pdf/PD2014\\_004.pdf](http://www0.health.nsw.gov.au/policies/pd/2014/pdf/PD2014_004.pdf)

The NSW Poisons and Therapeutic Goods Regulation 2008 requires persons who are authorised to be in possession of a drug of addiction (Schedule 8 substance) or a 'prescribed restricted substance' (Schedule 4 Appendix D substance) to immediately notify the Director General of Health of any loss or theft of these drugs. Further information can be found at: <http://www.health.nsw.gov.au/pharmaceutical/Pages/lost-stolen-drugs.aspx>

### MEDICAL ADVISORY COMMITTEE

This Medical Advisory Committee (MAC) meets annually or more frequently if required and is responsible for:

- Overseeing the provision of clinical services including maintaining and monitoring the safety and quality of patient care
- Ensuring that clinical practice reflects current legislative requirements and requirements of ISO International Standards and National Safety and Quality in Health Services Standards
- VMO credentialing and determination of individual scope of practice
- Making recommendations on the introduction of new technology, procedures and clinical services

### VISITING MEDICAL OFFICERS

VMOs are responsible for operating at Albury Day Surgery in accordance with procedures and policies, adhering to State laws and relevant standards.



### CHIEF EXECUTIVE OFFICER

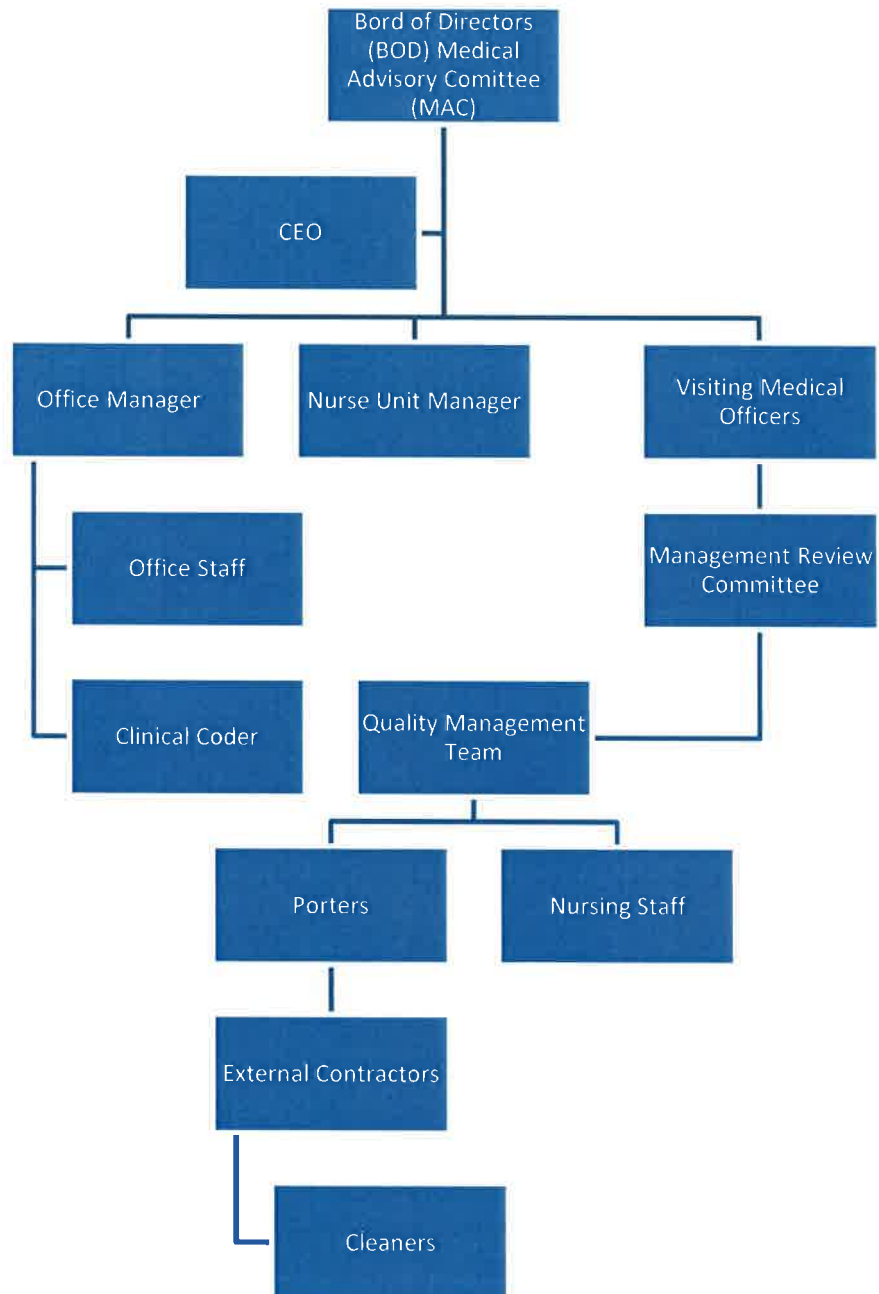
The CEO is responsible for

- Overseeing of day to day operation of the Day Surgery
- Financial Planning, management and reporting
- Demonstration of leadership
- Human Resources management
- Adherence to regulations and statutory guidelines
- Organising and conducting Board meetings
- Endorsements of the Quality Management System
- Health Fund contracting

### STAFF

Copies of Job descriptions for Nursing Unit Manager (NUM), Office Staff, Registered Nurses, Enrolled Nurses, Anaesthetic Technicians, Purchasing Officer and Theatre Orderly/Cleaner can be located in the Staffing Folder at Nurses Station and an appropriate copy given to each staff member on employment and filed in their Personnel file. Staff Meetings are held whenever deemed necessary and when time permits. All staff should attend and address any issues pertaining to specific areas of responsibility. Those unable to attend will read the meeting minutes.

## ORGANISATIONAL STRUCTURE



### 5.5.2 Management Representative

The Chief Executive Officer at Albury Day Surgery fully endorses the Quality Management System and ensures all processes required are supported. Further responsibilities of the CEO are outlined in 5.5.1.

### 5.5.3 Internal Communication

To ensure that all staff within Albury Day Surgery is kept informed of relevant matters, the following communication strategies are in place:

- An organisational chart which indicates lines of authority and reporting
- Staff Meetings
- Communication Book
- Request for New & Update Documents folder
- Formalised Committees (MAB & MRC) with agendas and minutes
- Issue, Incident and Improvement Request forms (IIIR's)
- Procedures and Work Instructions
- Job Descriptions

These communication strategies allow the staff at ADS to stay informed of any changes in practice or current issue or events.

## 5.6 **Management Review**

The Management Review Committee (MRC) meets 6 monthly or more frequently if required. The MRC also incorporates the Drug and Therapeutic Committee. (DTC)The agenda (QCF 8) is used as a plan for the meeting. The outcomes of MRC meetings are documented in the form of Minutes (QCF 9). These are filed in the Meeting Minutes folder at Nurses Station.

The MRC consists of:

- Nursing Unit Manager/Quality Manager/Chairperson
- Quality Co-ordinator
- Infection Control officer
- Deputy NUM
- WH&S Officer
- Fire Officer
- Office Manager

A review of the resources required to maintain the Quality Management System will also take place annually, to ensure the effectiveness of the System and initiate changes where necessary. The review will use the following data:

- Audit results
- Patient Satisfaction Survey results
- Review of updated documents
- Staff feedback
- Infection Control, WH&S issues, patient and staff issues
- Review of meeting minutes

## **6.0 RESOURCE MANAGEMENT**

### **6.1 Provision of Resources**

Management at ADS is committed to ensuring appropriate skill mixes for the provision of our customers' needs.

### **6.2 Human Resources**

#### **6.2.1 General**

All roles performed at ADS are assigned to staff members based on their training, skills and job description. No staff member is to be requested to work outside their scope of practice.

#### **6.2.2 Competence, training and awareness**

As part of ADS Professional Development policy, the Management will:

- Ensure that all staff are qualified on the basis of appropriate education, training and experience
- Ensure annual mandatory training is provided for all staff eg. CPR, Fire and Safety, and Manual Handling, Hand Hygiene
- Encourage staff with their ongoing professional development, by allowing opportunities for on or off site training and education
- Utilize a Professional Development Plan to track staff progress in requested areas of improvement
- Allow for records of training to be documented and maintained for use in CPD folio

The practice of staff will be monitored and reviewed by Patient Satisfaction Survey results, Patient Complaints, Internal Audits, and Performance Appraisals.

Staff registration details will be viewed online annually to ensure registrations are kept current. See SCF 1 Professional Registration record.

Records of Medical Staff registrations will be maintained as part of the VMO registration register.

Refer:

SWIoS1 Reviewing VMO Applications and SCFoS7 VMO Registration Register

ECFoE1 New Office Performance Appraisal

SCF 1 Nurses' Professional Registration Record

PCF 2 New Employee Induction

PCF 3 Fire Safety Orientation Check List

PCF 6 In-service Training Record

PCF 7 WH&S Training Checklist

PCF 8 Performance Appraisal

PCF 9 Orientation Program

PCF 14 Workforce Development Plan

### 6.3 Infrastructure

Albury Day Surgery is a purpose built, stand alone Day Surgery facility constructed in 1993. It was designed and built to provide all aspects of Day Surgery patient care. These facilities include: patient waiting, admission bays, operating rooms, a recovery area, and a day room. All areas are inclusive of up to date medical and ancillary equipment.

The adequacy of these facilities and equipment is reviewed through internal auditing and IIIR forms.

The following controls are in place to ensure that a consistent and acceptable standard of service occurs for customers at ADS:

- Relevant qualifications and experience of personnel
- Compliance with relevant standards/codes
- The use of appropriate equipment and suitable working conditions
- Suitable maintenance of equipment to ensure reliable service
- Monitoring and control of work practices
- Provision of resources, knowledge, advice and support to ensure patient and staff safety
- Spot audits, with numbers for referencing and continuity

**Refer:**

MP 1	Maintenance Procedure
ICF 1	Issue /Incident & Improvement Request Form - IIIR's
MCF 2	Maintenance Schedule
MCF 3	Equipment Repair/Service Log
MCF 4	Calibrated Equipment List
MCF 5	Maintenance Register
MCF 7	Compressor Checklist
MCF 9	Generator Check List
QWI 3	Process Audits
QWI 4	Document Control Audits
-	Plus all relevant equipment User Manuals

### 6.4 Work Environment

The work environment at ADS is enhanced by its design, and by Management's commitment to Work Health and Safety and Infection Control. This commitment is maintained in the following ways:

- Cleaning Standards and Procedures
- Adherence to AS4187:2003 guidelines
- Adherence to 2011 WH&S Regulations
- Annual WH&S training for all staff
- Adequate supply of Personal Protective Equipment for staff
- Air Conditioning Maintenance procedures
- Equipment Maintenance procedure
- Disposal of rubbish and biomedical waste

Refer:

M-CP 1 Maintenance - Cleaning Procedure

H-ICP 1 Health- Infection Control Procedure

HWI 5 Handling and Disposal of Cytotoxic agents

MaWI 5 Waste Management Protocol

EWI 6 Gluteraldehyde Handling

Material Safety Data Sheet Register (at Nurses Station)

Environmental Cleaning Policy PD 2012\_061

Australian Guidelines for the prevention and control of infection in healthcare  
(on nurses station desktop)



## **7.0 SERVICE DELIVERY MANAGEMENT**

### **7.1 Planning**

The following processes have been implemented to ensure that the service we provide complies with our customer requirements:

- Clinical supervision and leadership
- Medical Records and documentation
- Medical Advisory Board co-ordination
- Management Review Committee co-ordination
- Patient satisfaction and Complaints handling
- Poisons Licence and “Medication Handling in NSW Hospitals”
- License to supply Drugs of Addiction
- Radiation Management License
- NSW Health Department Auditing
- Board of Management Reporting
- Financial Analysis and Budget reporting
- Health fund negotiation and setting of Self-Funded rates
- Service and Materials management
- Supply Contracts

These processes are continually reviewed, monitored, and documented to ensure our customers’ requirements will continue to be met.

### 7.2 Customer-related processes

#### 7.2.1 Determination of Customer Requirements

At ADS we have the ability to provide all standard and regulatory customer requirements, as well as the flexibility to assess and provide any differing requirements.

#### 7.2.2 Review of Customer Requirements

Qualified personnel at ADS are responsible for:

- Establishing a clear understanding of customer requirements to ensure that the service supplied will comply with all relevant legislative and regulatory obligations and meet customers' needs and expectations
- Ensuring that all customers are treated with care and dignity
- Ensure that all customers are aware of the availability of an Interpreter Service
- Patient Identification and procedure matching for the safety of the client is carried out in accordance with our time out procedure and is documented in patient admission kit.
- Ensuring that all customers know the identity and professional standing of personnel involved in their care
- Ensuring that all patients have a clear understanding of the likely costs involved
- Ensuring that all customer complaints and queries are promptly and fairly dealt with
- Ensuring that patients may obtain information from their medical records in accordance with the Privacy Act 2000 & Health Records & Information Privacy Regulation 2012

### Refer:

ACP 1 Accountable Drugs Procedure  
AP 1 Admissions Procedure  
TWI 1 Admission to the Operating Theatre  
QP 1 Quality Systems Procedure  
ICF 1 Issues, Incidents, and Improvement Request form  
IWI 2 Reporting of Issue/Incidents  
DCF 3 Patient Questionnaire  
ICF 7 Patient Complaints Form  
PAWIo P3 Interpreter Service  
AcP 1 Accountable Drug Procedure  
AWIo A6 What to do if you have a complaint  
OCF C7 Accessing your Medical Records  
PD 2007\_077 Medication Handling in NSW Hospitals  
Private Hospital Charter  
Australian Charter of Healthcare Rights

### 7.2.3 Customer Communication

Procedures are in place to ensure there is effective communication with customers regarding the following:

- Availability of information relating to service provision
- Complaints procedure, and follow-up actions
- Ensuring that all patients have a clear understanding of the likely costs involved in their treatment
- Customer feedback/satisfaction

### Refer:

DCF 3 Patient Questionnaire  
ACF 2 Carer Survey in Domiciliary Care Report Sheet  
QP 1 Quality Systems Procedure  
IWI 2 Reporting of Issue/Incidents  
ICF 1 Issues, Incidents & Improvement Requests Form  
OWI P1 What to do if you have a Complaint  
OWI E Informed Financial Consent  
PAWIoP3 Interpreter Service  
Private Hospital Charter  
Australian Charter of Health care Rights

### **7.3 Design and Development**

This clause of the standard is not applicable to our product at Albury Day Surgery, which is patient care.

### **7.4 Purchasing**

#### **7.4.1 Purchasing Process**

- Purchasing procedures are in place to ensure purchased goods and services conform to requirements. A list of acceptable suppliers is maintained.
- All purchasing documents are reviewed and authorized prior to use

#### **7.4.2 Purchasing information**

Purchasing procedures relate to the following:

- Service Providers
- Tradesmen
- Equipment and Capital expenditure
- Consumables

### 7.4.3 Verification of Purchased Product

All items purchased are inspected for appropriate quality and quantity on arrival at ADS, as is the quality of all services provided by external providers.

**Refer:**

MP 01 Maintenance Procedure  
MCF 1 Acceptable Medical Suppliers  
GWI 2 Purchasing Drugs and Medical Supplies  
MCFoM3 Acceptable General Office Supplies  
DWI 1 IGA Ordering  
DWI 4 Ex-Flow Ordering  
GWI 7 Re-Ordering Plates and Screws  
AcP 1 Accountable Drug Procedure  
AcWI 1 Storage and Dispensing of Accountable Drugs

## 7.5 Product and Service Provision

### 7.5.1 Control of Product and Service Provision

Services provided at ADS are controlled through the following conditions:

- Company Procedures
- Work Instructions
- External documents in the form of guidelines (ADSNA, IAAS) NSW Health Department and International and Australian Standards
- The use and maintenance of approved equipment
- The provision of a suitable work environment
- Quality Management System
- ADS adopt the RMA (Reproductive Medicine Albury) protocol for conduction of IVF procedures by IVF surgeons.

### 7.5.2 Validation of Processes for Production and Service Provision

Validation of services provided at ADS will be undertaken to ensure they meet customer requirements following the completion of the care. This will include reviews of:

- Patient referral and admission processes
- Rostering and allocation of staff according to skills and qualifications required
- Checking adequacy of customer outcomes
  - Patient surveillance
  - Patient Questionnaire
  - Post Discharge (Domiciliary Care) Phone calls with Carer Survey

To ensure patient safety and an optimum outcome at ADS, selected patients will be contacted via telephone the day following their procedure to assess their condition and provide any ongoing information or support as required following their discharge.

A record will be kept of the outcomes from these calls, and all issues to be followed up as necessary.

#### Refer:

AP 1	Admissions Procedure
DWI 5	Issuing and Collating Patient Questionnaire surveys
ICF 5d	Patient Satisfaction Survey Results
PCF 10	Job Descriptions
External Doc. "Clinical Protocols – 2.1 Vaginal Oocyte Collection"	

### 7.5.3 Customer Identification and Traceability

Customer identification and any traceability of service provision occurring at ADS will occur using the following processes:

- Thorough positive patient identification processes, both during administrative and nursing admissions
- Allocation of unique identification number (MRN)
- Patient identification checks and documentation. Prior to transfer to the Operating Room, and a “Time Out” with Medical Staff prior to procedure commencing
- Accurate labeling and care of patient’s pathology specimens
- Completion of OR Record (TCF 10) during procedure, including sterilization labels of all instruments used which are processed at ADS
- Patient Handovers between departments
- Records kept in CSSD and Endoscopy Cleaning Room allowing reconciliation of all items processed at ADS
- Final assessment of patient at completion of service/care and prior to discharge
- All records of care at ADS to be kept
- All non-conformances recorded and followed up

#### Refer:

OAP 1	Admission Procedure - Office
OWI 0	Controlling Medical Records
AP 1	Admissions Procedure
DP 1	Dayroom and Discharge Procedure
TWI 1	Admission to Operating Theatre
TP 1	Theatre Procedure
RP 1	Recovery Procedure
CP 1	CSSD Procedure

EWI 1	Cleaning and Disinfection Protocol for Pentax endoscopes
RWI 1	Handling of Specimens for Pathology
IWI 2	Reporting of Issue/Incident
TCF 2	Sterilisation Validation Record
CWI 4	Sterilisation Tracking System

### 7.5.4 Customer Property

Due care will be applied to all aspects of the service delivery, both to the customer and/or their belongings, inclusive of care and transport 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, records will be kept and the relevant 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.

#### Refer:

ACP 1	Admissions Procedure
RWI 1	Handling of Specimens for Pathology
OWI 0	Controlling Medical Records
GWI 3	Medical Emergency
AWI 6	Securing Patient's Valuables
Emergency Flip Chart	



### 7.5.5 Preservation of Product

#### General

Documented procedures have been implemented to ensure the safe handling, storage, and preservation of incoming goods and documentation directly affecting service delivery.

#### Handling

Procedures are in place to ensure that all incoming goods and information are handled to maintain their safety and to prevent any deterioration according to the supplier's specifications.

#### Storage

Fully maintained, purpose built storage areas exist at ADS, designated for equipment, sterile storage, and general storage, dangerous goods, oxygen and medical air. This ensures that all incoming goods and equipment are stored in well defined, clean areas consistent with legislation and supplier recommendations.

#### Non-Conformance

Non-conforming goods or information delivered, or those outside their use by dates or other specifications must be protected from inadvertent use whilst decisions are made to their disposition. All non-conformances are reported and followed up.

#### Refer:

GW1 2	Purchasing Drugs and Medical Supplies
AcWI 1	Storage and Dispensing of Accountable Drugs
AcWI 3	Disposal of out-of-date Schedule 8 Drugs
RWI 6	Checking of MH Box and Drug Fridge
MaWI 1	Changing and Ordering of Gas Cylinders
IWI 2	Reporting of Issue/Incidents

## 7.6 Control of Measuring and Monitoring Devices

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

**Refer:**

MCF 1	Acceptable Medical Suppliers
MP 1	Maintenance Procedure
MCF 3	Equipment Repair/Service Log
MCF 4	Calibrated Equipment List
MCF 5	Maintenance Register
MCF 7	Suction Unit Check List
MCF 8	Temperature Testing of Thermostatic Mixing Valves

## **8.0 MEASUREMENT, ANALYSIS AND IMPROVEMENT**

### **8.1 General**

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

- The type and frequency of measurements will be defined and documented.
- The effectiveness of the measures will be periodically evaluated.
- Statistical tools will be used to supply data required.
- Outcomes from data analysis and improvement activities will be submitted for Management Review.

### **8.2 Measurement and Monitoring**

#### **8.2.1 Customer Satisfaction**

Customer satisfaction and internal auditing will be used to evaluate ongoing system compliance.

Procedures are in place to generate and review customer feedback regarding their level of satisfaction or dissatisfaction. A formal complaint system is available to all customers, as well as the information collected when staffs contact patients for their post operative phone call.

#### **8.2.2 Internal Audits**

ADS use two types of Internal Audits – Process Audits and Document Control Audits for the quality system and Environmental audits for WH&S and cleaning.

### Document Review

These audits ensure a regular review of designated areas to ensure that all documents being used are included in the appropriate document control system and that each document is still relevant and that there is no discrepancy between any copies.

### Process Audits

Procedures for planning and implementing internal quality audits have been established to provide verification that our quality activities and practices are achieving the quality goals. Internal auditing will also provide evidence that customer needs and expectations are being met.

Internal quality audits address processes identified as more important in the day surgery setting. These areas are to be audited by personnel not usually working in these areas.

Process Audit results, once compiled, will be brought to the attention of personnel working in the area, along with any new documents raised. A senior staff member from each area will be made responsible for correcting any deficiencies found during the audit process.

- Follow up audit activities will verify and record the implementation and effectiveness of any corrective action taken.
- A report of internal audit outcomes and trends will be presented to management for consideration and inclusion in ongoing quality strategies.

The Board of Management, along with the CEO and NUM, will be responsible for evaluating the impact of the Quality Management System on the financial status of the facility.

#### Refer:

Quality Index on computer desk top

QCF 2a Internal Audit Index

QCF 3 Internal Audit – Document Review

QCF 3a Internal Audit Report

QWI 3	Process Audits
QWI 4	Document Control Audits
QCF 11	Process and Competency Assessment List
RiCF 3	WHS environmental audit & Mc CF 2 Environmental cleaning audit

### 8.2.3 Monitoring and measurement of Processes

Using statistics and clinical indicators as a reference, Albury Day Surgery ensures it will conduct ongoing reviews of its management system for effectiveness and efficiency. The following outcomes will also be reviewed:

- Patient numbers
- Staff utilisation
- Patient Care outcomes
- Time management
- Service costs and budgets
- Reviews of equipment and facility

### 8.2.4 Monitoring and Measurement of Product

Satisfaction with the outcomes of the service is reviewed as part of the formal management review process.

Interested parties include staff, patients, practitioners, shareholders, and suppliers. Information regarding the expectations and requirements of these parties is gathered through a range of strategies.

- Patient Satisfaction Surveys
- Carer Surveys
- Risk Assessments
- Yearly survey of consumers and VMO's and feedback from website
- Board of Management meetings
- Issue, Incident, and Improvement Requests (IIIRs)
- Informal requests to management

This information is assessed to determine the extent to which the needs and expectations are known, understood and being met.

### 8.3 Control of Non-conformances

Non-conformances at Albury Day Surgery are reported on product, service, or practice.

Albury Day Surgery is committed to ensuring that service exceptions are identified and reviewed. Documentation exists for the recording and notification to the relevant personnel and appropriate action taken.

#### Refer:

QP 1      Quality System Procedure  
IWI 2      Reporting of Issue/Incident - IIIRs  
ICF 1      Issue, Incident and Improvement Request Form  
DCF 3      Patient Questionnaires  
Risk Register (Quality Index)  
Minutes of MRC, Medical Advisory Committee and Staff Meetings.

### 8.4 Analysis of Data for Improvement of Services

Procedures are in place to ensure data is collected 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 will be collected by monitoring and measuring activities, and any other relevant sources.

Analysis of applicable data will be undertaken to:

- Demonstrate effectiveness and adequacy of the Quality Management System
- Report on process operation trends
- Report customer satisfaction and/or dissatisfaction
- Demonstrate conformance to customer requirements
- Determine the effectiveness of external services

Refer:

IWI 2 Reporting of Issue/Incidents

ICF 3 Post-op follow ups

ICF 5b Dom. Care Patient Participation

ICF 5d Patient Satisfaction Survey Results

ACFoA14 Consumer Letter

ACFoA15 Doctor's Letter

ACFoA16 Reviewing Consumers Survey Results

Risk Register (Quality Index)

Minutes of Management Review Committee, Medical Advisory Board and Staff Meetings

### 8.5 Improvement

#### 8.5.1 Continual Improvement

Continuous Quality Improvement is a key element in being accountable for the quality service delivered at Albury Day Surgery. This will be achieved by the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventative actions, and management review.

#### 8.5.2 Corrective Action

Albury Day Surgery procedures ensure:

- The effective handling of customer complaints and non-conforming goods and services
- The results of investigations are reported at relevant committees
- The elimination of non-conforming goods and services
- Controls are applied to ensure corrective action is taken and is effective
- Reports detailing corrective actions are reported to management for review

### 8.5.3 Preventative Action

Albury Day Surgery procedures ensure that any potential non-conformances, and their causes, can be determined and any action required implemented.

This is achieved by:

- Analysis of service documents and customer complaints
- Determining steps needed to deal with problems requiring preventative action and initiating preventative action.
- Submitting relevant information on actions for management review

Refer:

IWI 2 Reporting of Issue/Incidents

QP Quality Procedure

- Minutes of Management Review Committee, Medical Advisory Board, and Staff Meetings
- Risk Register (Quality Index)



## COMPANY POLICIES

### GENERAL POLICIES

#### Alcohol and Drugs

All employees are to refrain from duty if they are under the influence of alcohol, illicit drugs or banned substances. Non-compliance with this matter could incur suspension of duty without pay or instant dismissal. Employees who place themselves in a position, which may endanger patients or their colleagues whilst on duty and deemed to be demonstrating serious misconduct, may face instant dismissal.

#### Smoking

There is a NO SMOKING policy inside and on the grounds of the Albury Day Surgery.

#### Security

During office hours - All visiting tradesmen must register with the office staff on arrival and departure from the building.

After operating hours all staff must register with office staff on entering and departing the building. If the office is unmanned the staff member must make an entry in the register and have it validated by NUM or Deputy NUM on the next working day.

#### Medical Emergencies

In the event of a medical emergency where a patient requires transfer to another hospital for ongoing management, the attending VMO will determine the receiving hospital for the transfer.

Nursing staff will have accredited CPR training and be competent in handling a medical emergency. In the event of a clinical misadventure e.g., medication error, surgical procedure error, diagnostic error, clinical misinformation that results in harm or risk to the patient; immediate steps will be taken to stabilize the patient and accurately document the event. The patient will not leave the premises until the attending doctor or anaesthetist sees them on site.

Any adverse drug reaction is reported as indicated in IWI 6 “Reporting Adverse Drug Reactions”.

National open disclosure procedure will be observed in the handling of medical emergencies.

### Unplanned Transfer of Patients to another hospital

The Albury Day Surgery has an arrangement with the Albury Wodonga Private Hospital regarding patient transfer for overnight stay. The agreement states that in the event that an Albury Day Surgery patient is unfit for discharge to home and requiring overnight observation, the senior staff at Albury Day Surgery in consultation with the Surgeon or Anaesthetist will contact the Supervisor at the AWPB to request a bed. If a bed is available all handover documentation will be provided on transfer.

### Risk Assessment

Albury Day Surgery is committed to minimizing risks and hazards by staff consultation and education, recognizing, assessing, monitoring and correcting any identified problems as soon as practicable according to the Risk Assessment Rating Chart which is part of the Risk Assessment Control Form. Risks are documented in the Risk Register in Quality Index. ADS follow NSW Health Risk Management guidelines PD 2009\_039.

### Reportable Incidents Reporting and investigation    Root Cause Analysis

The Licensee of the private health facility must advise the Secretary, NSW Ministry of Health of all reportable incidents within 2 days of the incident occurring

Incidents recorded on Issues, Incidents & Improvement Request Form ICF 1 are assessed for severity as per the NSW Ministry of Health PD 2014\_004 *Incident Management Policy* using the SAC code in appendix B. In the event of a SAC classification not being able to be applied to an incident the criteria of reportable incident are those as outlined in section 3.1 of Policy Directive 2014\_004.

The Licensee is responsible for appointing a Root Cause Analysis Team (RCAT) within 30 days of the incident occurring. The team will consist of members deemed appropriate by the Licensee and the Medical Advisory Committee. The principles and process of the Root Cause Analysis is to be conducted in accordance with Section 44-45 of the Private Health Facilities Act 2007. The RCAT is responsible for submitting its incident report to both the Licensee and the Medical Advisory Committee within 70 days of the reportable incident. The Licensee is responsible for forwarding a copy of the incident report to the Secretary of the NSW Ministry of health within 30 days receipt from the Root Cause Analysis Team.

- For reportable incidents the NUM will categorize the incident using the Severity Assessment Code (SAC) issued by NSW Health Dept. Any incident resulting in a SAC score 1 will be reported to NSW Health Dept as per PD2014\_004 "Incident Management Policy". Ref p38.
- Adverse events are required to be reported in accordance with clause 21, schedule 1 Private Health Facilities regulation 2010:.
- An adverse event means an unintended injury to a patient, or a complication caused by the health care management of a patient that result in disability death of a patient or a prolonged hospital stay by the patient."
- 

### Paediatric Policy

ADS is approved to admit paediatric patients from 2 – 14 yrs and the maximum number of paediatric patients to be accommodated at any one time is 8. The type of procedure and duration of stay is determined by the medical advisory board.

## **HEALTH AND RELATED POLICIES**

### **Infection Control**

All staff is reminded that the most effective barrier to infection is hand washing and thorough drying of skin and personal hygiene. There are specific procedures in place for cleaning and sterilizing equipment and the environment (Environmental Cleaning Policy PD 2012\_061 ). All staff is responsible for the implementation of the best practice standards, aseptic technique and compliance with the infection control policies and procedures as documented in the Quality System. Our strategic vision for Albury Day Surgery's infection control program is to keep our staff educated on contemporary practices.

This will be monitored through regular in-servicing, surveillance and auditing of current practices in accordance with Infection Control Policy 2007\_036 and Hand Hygiene Policy 2010\_058.

The NSW Department of Health Infection Control Policy and Guidelines for the prevention of infection in Healthcare 2010 are the basic benchmark standards for infection control at Albury Day Surgery. Precautions above these guidelines are encouraged and are in the best interest of patient care and safety as well as all staff employed at Albury Day Surgery.

### **Methicillin-Resistant Organisms.**

Under normal circumstances, patients with known Methicillin resistant staphylococcus aureus , Vancomycin resistant enterococi or Clostridium difficile would not be admitted to ADS for elective routine surgery.

Should a patient be admitted and then found to have MRSA, VRE or CD, conditions of the New South Wales Health Dept "infection control policy" PD 2007\_036 and PD 2007\_084 "Prevention and management of multi resistant organisms" (found in I/C folder) would be adopted i.e. transmission-based precautions

### Antimicrobial Stewardship.

Albury Day Surgery abides by the TGA recommendations for the use of antibiotics in surgery. As seen in Therapeutic Guidelines (Antibiotic) 2010 Ver 14. This is monitored by an annual audit and only stocking antibiotic drugs that appear on the recommended list. Any take home antibiotics are supplied on script only by VMO.

### Notifiable Diseases.

Should a patient be admitted to ADS and found to have a notifiable disease, conditions of the NSW Health Circular PD2006\_035 "Notification of Infectious Diseases (found in "Vaccination – NSW Health" folder) would apply ie. the patient would be isolated and notification would be made to the Local Public Health Unit.

Outbreaks or unusual clusters of communicable infections should be notified if they fit the criteria as per NSW Dept of Health regulations.

### Communicable Diseases

If it is suspected pre-surgery that a patient may have a communicable disease (eg influenza) their surgery will be deferred after consultation with their VMO. If it is recognized during admission, the VMO should be made aware and review the patient re their fitness for surgery. Staff has been informed that if they suspect they have a communicable disease they should not attend work.

### Work Health and Safety

Albury Day Surgery is committed to ensuring that all employees, patients, VMO and visitors to the facility are welcomed into a safe environment. It is the responsibility of management and staff to report issues, incidents, injuries and hazards that may affect a safe environment. It is the responsibility of management to provide Personal Protective Equipment (PPE) and the responsibility of all staff to wear the appropriate safety clothing and use safety equipment (PPE) as and when necessary, such as gowns, gloves, eyewear and aprons as outlined in ADS Infection Control Procedure.

Management is committed to reducing the risks of occupational exposure to communicable disease and occupational product sensitivity/allergy by monitoring, assessing and reviewing practices and procedures in place for prevention of exposure. Regular audits are carried out to assess the use of PPE by staff and the availability and accessibility of PPE.

### Return to Work

It is the policy of ADS to assist a staff member returning to work following ,either a work related or non work related injury/illness, by consultation and communication with them regarding their return to their normal work or in a lesser capacity as outlined by their Treating medical practitioner. (See Return to work procedure).

### Bariatric (severely obese) Patients

The weight and BMI limit is determined by the surgeon and anaesthetist prior to admission.

Patients weighing more than 100 kgs must be placed on Hausted or Select trolleys which have a larger weight capacity and can also be lowered and raised to an appropriate level to minimize bending, stretching and reaching. The lifter should be used when required (limit of 170k).

Bariatric stirrups are available to prevent pressure on calves if the patient needs to be in the lithotomy position.

All nursing staff are required to attend Manual Handling lectures annually at ADS to help prevent injury and to be aware of the best manual handling practices.

Other principles for the care of Bariatric patients can be found in the NSW Health Dept. guideline "Occupational Health & Safety Issues Associated with the Management of Bariatric Patients" (GL2005\_070) on line.

### Prevention of Venous Thromboembolism (VTE)

All patients should be screened for VTE risk by their Surgeon or Anaesthetist prior to admission to ADS.

The ADS patient admission kit contains a question relating to VTE risk and previous history. The Pre admission clinic nurse will ask the patient at phone interview:

- Age and estimated weight
- Previous medical and cardiac history
- Current medications
- Any history of stroke with immobility or cancer chemotherapy
- Recent surgical history
- Potential of prolonged travel before surgery

Any relevant information learned at interview is passed on to the Anaesthetist before the scheduled surgery time

Obese patients are placed on a designated trolley with a thicker mattress to prevent pressure areas. For obese patients needing to be in lithotomy, Bariatric stirrups are available to prevent pressure on their calves. During procedure IPC (Intermittent pneumatic compression) is available for use on high risk patients, for long procedures or at anesthetists' discretion. In Recovery, high risk patients are encouraged to move limbs and mobilize as soon as possible.

\*For survey and analysis of potential risks this information is recorded on the Pre Admission Statistics form (Pa CF4)

Refer:

Admissions Procedure

PaP 1 Pre Admission Procedure

Pa CF 1 Pre Admission Interview Form

Pa CF 4 Pre Admission Statistics Form

Ri P1 Risk Assessment Procedure

Ri CF 1 Risk Assessment Control Form

HICP 1 Health and Infection Control Procedure

PCF 11 Hand Hygiene Assessment

PCF 12 Sharps Injury Checklist

SWI 6 Return to Work Process

- Risk Register in Quality Index

HWI 8 Occupational allergies and Health care workers

GWI 10 Evaluating and Reviewing new products and procedures

HWI 7 Care and Handling of Invasive Devices

MCP 1 Maintenance Cleaning Procedure and associated work instructions  
and company forms

Health Dept policy directive 2014\_004

Health dept policy directive 2009\_039

Environmental cleaning PD



## **EQUIPMENT AND PURCHASING POLICIES**

### **ADS Equipment policy**

All equipment owned and operated by the Day Surgery or associated with the operation of ADS will be scheduled on an assets list. All equipment will be maintained according to manufacturer specifications. Services and calibration of all identified equipment will be scheduled and detailed on to a quality plan for regular attention. A record of this maintenance is kept for the life of each piece of equipment.

Equipment not covered by a service agreement is serviced regularly and repaired as necessary on a purchase order number.

New equipment will be evaluated and reviewed as deemed necessary by the NUM

### **ADS Purchasing Policy**

ADS will continually have the need for purchasing of valuable and specific medical equipment. The purchases must be made when there is a justified and qualified need to provide a service for patient care or to enhance the operations of the center. All purchases must be fully considered and remain within the scope of the budget of the company. Staff does not have the authority to order stock or equipment without raising a purchase order form and no order will be placed without authority by the CEO, NUM or the Purchasing Officer.

Selection of suppliers for goods and services is as per company policy. Two quotes are to be obtained and reviewed before selection of a supplier. In the event that a product is only supplied by one company, quotes for the products must be obtained prior to purchase order being approved.

## **Diagnostic Imaging Equipment Inventory Maintenance and Servicing**

Albury day surgery is committed to quality patient outcomes and understands that equipment performance can have a significant impact on the quality and accuracy of diagnostic reports.

### **Diagnostic Imaging Equipment Inventory**

A Diagnostic Imaging Equipment inventory is maintained that includes:

- Registering all relevant equipment on Medicare's Diagnostic Imaging Register
- Submitting annual Location Specific Practice Number Declarations to Medicare.

### **Diagnostic Imaging Equipment Servicing**

The following equipment has been identified as critical for achieving quality outcomes:

- IT systems
- Ultrasound equipment

Albury Day surgery maintains a register of faults and service reports for the life of each piece of equipment in individual files that includes:

- Equipment name
- Make/Model
- Equipment Number
- Date of service/repair
- Who provided the service – Company / Individual
- Details and results of the service (e.g., calibrated)
- Action, if any, required.
- Date of next service

All ultrasound equipment will be maintained according to manufacturer specifications to ensure optimum operation and safety.

## REFERENCES

Refer:

IWI 2 Reporting of Issue/Incidents  
QP Quality Procedure  
ICF 1 Issues, Incidents & Improvement Request Form  
GWI 10 Evaluation and Reviewing new products and procedures  
PCF 6a Infection Control Training Record  
H-ICP 1 Health- Infection Control Procedure  
PCF 9 Orientation Programme  
MCF 5 Maintenance Register  
External Doc. RMA – “Cleaning Ultrasound”  
\*Work Health and Safety Act 2011  
\*Private Health Facilities Regulation 2010  
\*Private Health Facilities Act 2007(in pink folder in bookcase NUM’s office)  
NSW Health Dept Policy Directives.  
PD 2007\_036  
PD 2007\_084  
PD 2012\_061  
PD 2010\_058  
PD 2006\_014