Standards for Endoscopic Facilities and Services
# Table of contents

<table>
<thead>
<tr>
<th>Section</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Aims &amp; Objectives</td>
<td>5</td>
</tr>
<tr>
<td>2. Introduction</td>
<td>5</td>
</tr>
<tr>
<td>3. Patient Referral</td>
<td>5</td>
</tr>
<tr>
<td>4. Location of Services</td>
<td>5</td>
</tr>
<tr>
<td>4.1 Hospital Based Endoscopy Units</td>
<td>5</td>
</tr>
<tr>
<td>4.2 Free Standing Endoscopy &amp; Day Surgery Centres</td>
<td>5</td>
</tr>
<tr>
<td>4.3 Rural and Remote Endoscopy Services</td>
<td>6</td>
</tr>
<tr>
<td>5. Facilities</td>
<td>6</td>
</tr>
<tr>
<td>5.1 Reception Area, Office and Administration</td>
<td>6</td>
</tr>
<tr>
<td>5.2 Patient Waiting Area</td>
<td>6</td>
</tr>
<tr>
<td>5.3 Consulting Room</td>
<td>6</td>
</tr>
<tr>
<td>5.4 Storage Areas, Utility Services</td>
<td>7</td>
</tr>
<tr>
<td>5.5 Toilet and Change Room Facilities</td>
<td>7</td>
</tr>
<tr>
<td>5.6 Recovery Room</td>
<td>7</td>
</tr>
<tr>
<td>5.6.1 Primary Recovery</td>
<td>7</td>
</tr>
<tr>
<td>5.6.2 Secondary Recovery</td>
<td>7</td>
</tr>
<tr>
<td>5.7 Staff Station</td>
<td>7</td>
</tr>
<tr>
<td>5.8 Procedure Room</td>
<td>8</td>
</tr>
<tr>
<td>5.9 Staff Facilities</td>
<td>9</td>
</tr>
<tr>
<td>5.10 Interview Room</td>
<td>9</td>
</tr>
<tr>
<td>5.11 Endoscope &amp; Accessory Reprocessing</td>
<td>9</td>
</tr>
<tr>
<td>6. Equipment</td>
<td>9</td>
</tr>
<tr>
<td>6.1 Endoscopic Equipment</td>
<td>9</td>
</tr>
<tr>
<td>6.2 Resuscitation Equipment</td>
<td>10</td>
</tr>
<tr>
<td>6.3 Oxygen</td>
<td>10</td>
</tr>
<tr>
<td>6.4 Suction</td>
<td>10</td>
</tr>
<tr>
<td>6.5 Recovery Trolleys &amp; Chairs</td>
<td>10</td>
</tr>
<tr>
<td>6.6 X-ray Equipment</td>
<td>11</td>
</tr>
<tr>
<td>6.7 Electrosurgical Equipment</td>
<td>11</td>
</tr>
<tr>
<td>6.8 Lasers</td>
<td>11</td>
</tr>
<tr>
<td>6.9 Light Sources/Video Processors</td>
<td>11</td>
</tr>
<tr>
<td>6.10 Pulse Oximeters</td>
<td>11</td>
</tr>
<tr>
<td>6.11 Accessory Endoscopic Equipment</td>
<td>12</td>
</tr>
<tr>
<td>6.12 Endoscopes</td>
<td>12</td>
</tr>
<tr>
<td>6.13 Cleaning and Disinfection of Equipment</td>
<td>12</td>
</tr>
<tr>
<td>6.14 Emergency Power Backup</td>
<td>13</td>
</tr>
<tr>
<td>7. Patient Services</td>
<td>13</td>
</tr>
<tr>
<td>8. Patient Information, Education &amp; Consent</td>
<td>14</td>
</tr>
<tr>
<td>9. Organisation &amp; Administration</td>
<td>14</td>
</tr>
<tr>
<td>10. Medical Services</td>
<td>15</td>
</tr>
<tr>
<td>11. Nursing Services</td>
<td>15</td>
</tr>
<tr>
<td>12. Patient Sedation</td>
<td>16</td>
</tr>
<tr>
<td>13. Paediatric Services</td>
<td>16</td>
</tr>
<tr>
<td>13.1 Equipment</td>
<td>16</td>
</tr>
<tr>
<td>13.2 Staff</td>
<td>16</td>
</tr>
<tr>
<td>13.3 Sedation</td>
<td>16</td>
</tr>
<tr>
<td>13.4 Consent</td>
<td>17</td>
</tr>
<tr>
<td>6.5 Parental/Guardian facilities</td>
<td>17</td>
</tr>
<tr>
<td>14. Administrative Services</td>
<td>17</td>
</tr>
<tr>
<td>15. Medical Records</td>
<td>17</td>
</tr>
<tr>
<td>16. Environmental Services</td>
<td>18</td>
</tr>
<tr>
<td>16.1 Occupational Health Issues</td>
<td>18</td>
</tr>
<tr>
<td>16.2 Air conditioning</td>
<td>18</td>
</tr>
<tr>
<td>16.3 Water Quality</td>
<td>18</td>
</tr>
<tr>
<td>17. Quality Assurance Programme</td>
<td>19</td>
</tr>
<tr>
<td>18. Education</td>
<td>19</td>
</tr>
<tr>
<td>19. References &amp; Standards</td>
<td>20</td>
</tr>
</tbody>
</table>
Standards for Endoscopic Facilities and Services

Endoscopy

THIRD EDITION 2006

Acknowledgements

These guidelines were developed by a combined committee of the Gastroenterological Nurses College of Australia Inc. and the Gastroenterological Society of Australia and are in effect the third edition of “Gastrointestinal Endoscopy: Good Practice Guidelines for the Delivery of Endoscopic Services”. This document complements other professional practice guidelines and publications of the organisations.

Endoscopic services are faced with the same pressures for cost containment as other areas of the health budget. The essential difficulty is to strike a balance between the delivery of safe and effective services and the containment of those costs to a level where significant exclusion from participation in such health services is minimised. The standards outlined here represent the professional organisations’ views on what constitutes the minimum necessary facilities, equipment and staffing to deliver safe and effective endoscopy. The training and qualification of endoscopists and nursing staff, the endoscopic equipment and accessories, the reprocessing of endoscopes, monitoring and resuscitation equipment must all be of the standard specified in this document wherever endoscopy is performed.

The Digestive Health Foundation of the Gastroenterological Society of Australia has prepared this document and every care has been taken in its compilation. The document is intended to be used as a guide only and not as an authoritative statement on every conceivable step or circumstance that may or could relate to the management of gastroesophageal reflux disease in adults.

Clinicians should use this document as an aid in relation to gastroesophageal reflux disease and not as a complete authoritative statement. Medical understanding of gastroesophageal reflux is evolving. This document reflects this understanding as at February 2011 and may be subject to updating and review at a later date.

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1 AIMS & OBJECTIVES

Aims
- The aim of an Endoscopy facility is to provide a range of safe, high quality endoscopic services.

Objectives
- To provide safe and effective procedural services
- To provide a setting which promotes patient comfort
- To provide highly skilled staff who maintain and improve their skills on a continuing basis
- To provide a safe environment for patients, relatives and staff

2 INTRODUCTION

Safe and effective Gastrointestinal Endoscopy demands the availability of:
- Adequately trained and certified endoscopists
- Adequately trained nursing staff
- Adequate physical facilities
- Endoscopes able to undergo complete high level disinfection
- Appropriate equipment as specified in “Guidelines for Sedation in Endoscopy” including the ability to deliver oxygen, patient suction and provide patient monitoring equipment
- Specialised facilities and staff for paediatric services
- In most patients, reflux disease is a chronic disorder. Mild symptoms may vary in intensity and occur only on some days. With increasing severity, symptoms tend to occur daily.

The facilities, appointments, equipment and standards of procedural delivery outlined in this document are those which the professional organisations believe are appropriate for endoscopy units/centres whether they are free-standing or contained within hospitals. When simple endoscopic procedures such as flexible sigmoidoscopy are performed in doctors’ rooms it is important that there be adequate facilities which comply with the standards for reprocessing endoscopic equipment and accessories. Some of the physical facilities recommended in this document, such as clerical areas, are not necessary to perform safe endoscopy. However, regardless of where the procedure is performed, the clinical standards including qualifications and training of medical and nursing staff, the quality of endoscopy equipment, the reprocessing of endoscopes and their accessories and the monitoring and resuscitation equipment must be of the standard specified in this document.

Where endoscopy is performed in children; paediatric endoscopists, anaesthetists and nursing staff are required for endoscopy in patients under 14 years of age, or those aged 14-18 years in whom there is concern over maturity to tolerate standard adult procedural sedation. The cost of providing endoscopy services that meet the standards specified in this document is substantial. Although there is no restriction of endoscopy services to licensed facilities, the current system of registration of endoscopy work places allows independent random audit as part of quality control and compliance with standards.

3 PATIENT REFERRAL

Referral criteria appropriate to the type of facility are required and should be documented in the policy and procedure manuals of the endoscopy service. Emergency procedures or those that may be associated with major complications requiring in patient care are more appropriately undertaken in a facility with inpatient beds.

4 LOCATION OF SERVICES

4.1 Hospital Based Endoscopy Units

Endoscopy units shall be located in close proximity to acute emergency services. The location within the complex shall permit free access for out patients and for the transport of inpatients by bed, trolley or wheelchair. Where the endoscopy unit is not located within the main hospital complex, provision for enclosed transfer of patients is advisable.

4.2 Free Standing Endoscopy Centres/Day Surgery Centres

Where the endoscopy service is in a freestanding facility, it should be located within a 15 minute ambulance journey of an acute hospital that provides an intensive
care or emergency service. There should be an agreed arrangement with this hospital to admit patients in a medical emergency.

Access to the endoscopy facility should contain an area for ambulance parking which is free from other encumbrances in case of emergency and which is situated to permit rapid entrance and exit from the facility grounds. If the facility is not on the ground floor, access must be available by a lift that is of sufficient dimensions to accommodate a patient on an ambulance trolley.

4.3 Rural and Remote Endoscopy Services

In rural and remote locations it may not be possible to provide endoscopic services in a facility that is located within a 15 minute ambulance journey of an acute healthcare facility. These endoscopic services are nonetheless an important part of medical service provision to remote communities. For these units, staff must possess critical care and advanced resuscitation skills. Appropriate resuscitation equipment must be available. It is also mandatory that the unit have a patient evacuation policy and appropriate arrangement with a major teaching hospital medical evacuation or retrieval service.

5 FACILITIES

Physical facilities are designed to meet referral needs and will take into consideration specific State and Federal regulations where they exist. Physical facilities must conform to normal hospital building regulations and such special regulations as may apply in particular circumstances; such as, regulations relating to appropriate shielding of rooms containing X-ray equipment and special safety measures required for laser equipment. Consideration should be given to the provision of an emergency power supply to procedure rooms and recovery areas.

The following areas within the facility are the minimum requirements:

- Reception & administration
- Waiting area
- Procedure room/s
- Consulting / interview room
- Nurses station
- Storage areas
- Separate reprocessing area
- Staff room
- Toilets & change rooms
- Waste disposal area
- Recovery room/5.1

5.1 Reception Area, Office and Administration

This area should be of sufficient size for the expected throughput of the unit and include a desk area and seating for an appropriate number of administrative staff. The provision of sufficient area for the preparation of patient charts, reports, accounts and general office services is essential. Computerised systems that provide for electronic scheduling, endoscopy reporting and have the capacity to analyse data enable facilities to meet the quality assurance requirements of the relevant licensing authority.

Provision shall also be made for the security of patient records (see 5.4).

If the facility is sufficiently large to warrant a unit /facility manager, appropriate office space to conduct this role is required.

Due to the toxicity of the chemicals used and the fumes created from photocopy machines and laserprinters, these should not be located in poorly ventilated areas or in a position where fumes can be detected by staff engaged in normal work activities.

5.2 Waiting Area

The waiting area should provide sufficient seating for the anticipated number of patients and relatives. This will vary with the size of the facility.

5.3 Consulting Room

An area for patient consultation should be available within or nearby the facility. This area will be appointed with a desk, chairs, examination couch, clinical consumables and appropriate equipment. Hand washing facilities must also be located within this room. This room will be constructed to ensure all discussions between the patient and health care provider are private and confidential and that the patient’s privacy will be maintained at all times.
5.4 Storage Areas & Utility Services

Each facility shall have suitable storage areas for items such as patient records, other administrative records/supplies, medical supplies, clinical consumables, drug supplies, housekeeping and linen supplies.

All medical records must be kept in a locked cabinet to protect patient confidentiality and guard against unauthorised viewing. When patient records are outside this cabinet, measures will be in place to ensure that they are not left unattended or accessible to public viewing.

Storage areas must be allocated to maintain sufficient stock of consumables such as medical supplies, clean linen and housekeeping items. The unit/facility will need to identify suitable location/s for the storing of these supplies. It may be necessary to store items in close proximity to their point of use. Dirty linen and waste need to be stored in appropriate areas where infection control practices can be maintained prior to their removal from the area.

The storage requirements for endoscopes and medical equipment are described elsewhere in terms of their functional location.

5.5 Toilet and Change Room Facility

Sufficient numbers of toilets must be available complete with nurse call and emergency call systems. In some larger facilities it may be more appropriate to provide separate male and female toilets/change rooms which accommodate more than one toilet in each area. In smaller facilities, a minimum of two unisex toilets may be a more suitable option, provided that patient privacy and modesty factors are addressed. At least one toilet must be suitable for disabled access. Hand washing facilities will be provided in all toilet areas. Storage for patients’ clothing/valuables should be provided.

5.6 Recovery Room

5.6.1 Primary Recovery

A recovery area should be situated adjacent to the procedure room/s and must be freely accessible by a normal recovery room trolley. This trolley must be adjustable for Trendelenberg positioning if required. The recovery area should contain not less than six (6) bays for recovery trolleys or beds.

Where recliner chairs are used for second stage recovery, there shall be not less than two (2) bays for trolleys and not less than a total of six (6) recovery spaces including trolleys and chairs. The recovery room should have an oxygen supply dedicated to this area. Oxygen outlets will need to be provided so that each recovery bay is supplied. Wall mounted suction is desirable, however where unavailable, at least one dedicated mobile suction unit shall be provided. A pulse oximeter per patient should be available for dedicated use in the recovery area along with non-invasive blood pressure monitoring.

Access to ECG monitoring must also be available. The recovery room should be of a configuration to allow visual observation of all occupants by the nursing staff. Privacy screens that do not impede the nurse’s vision of the patient are desirable. Each trolley bay should allow full curtain screening for total privacy as is required from time to time. Emergency call systems also need to be installed in each bay.

5.6.2 Secondary Recovery

In many cases a second stage recovery area is now used due to the increased use of drugs which allow patients to progress through their primary recovery stage more quickly. A second stage recovery area will allow for a more efficient throughput of patients and better utilisation of trolleys. Upright or semi-recliner chairs should be available when the patient no longer requires primary recovery yet is not ready for discharge. Where this form of recovery is provided, it should be adjacent to the primary recovery and be under the supervision of a nurse. Emergency call systems need to be installed in this area.

Located in close proximity to the recovery room, an area should be available for making light refreshments for patients before discharge.

5.7 Staff Station

A staff station should be located within the primary recovery area for the close observation of patients. The station should be equipped with telephone and an emergency call facility. A desk area sufficient for the recording of relevant documentation and the preparation of discharge information should be available.
5.8 Procedure Rooms

In a facility where services in addition to Gastrointestinal Endoscopy are provided, it is preferable that one room be dedicated for endoscopic procedures. The room size and function is dependent on the nature of the services provided. An endoscopy procedure room should measure not less than four (4) metres x five (5) metres. The advent of video endoscopy has led to larger procedure room space requirements. The size requirements of the procedure room will depend on the equipment to be used and the expected number of personnel. Rooms of irregular shape may need to be larger to ensure efficient functioning. In teaching facilities and where interventional endoscopy procedures are performed, significantly larger space requirements will exist. It may be possible to incorporate special design features including ceiling mounted video monitors and travelling beam C arm X-ray screening which will still allow adequate function in a twenty (20) square metre room. In general for new units it is recommended that the area should be significantly larger. If X-ray screening is used the room will require radiation protection for safe operation. Reference should be made to the appropriate standards for procedure room X-ray shielding.

Where E.R.C.P. procedures are performed, a larger room will be required. It should be of sufficient size thirty five (35) square meters to allow equipment trolleys to be situated near the examination table and to allow for sterile set-up of accessory equipment when indicated. Consideration should also be given to the additional space requirements if general anaesthesia is to be performed. All surfaces within the room should be able to be cleaned with soapy solution or other cleaning agent. This is important for not only infection control purposes but also in cases where patients with latex allergy are undergoing a procedure. Where possible, cupboards should be used to store consumables so that they remain clean and are protected from surface contamination. It is advisable that infrequently used equipment is not stored in the procedure room so that the work area remains uncluttered. The floor area should be kept clear and where possible cabling should be secured and not allowed to lie on the floor where it may be damaged by trolleys or staff walking on the cable. This will also help to minimise the risk of staff tripping over unsecured cables. Where possible all cables, oxygen lines and suction hoses should be fixed to the wall or be suspended from the ceiling.

Room lighting is important and should be carefully considered when procedure rooms are being constructed or renovated. In general high quality lighting is required for the entire floor area of the room and there should be enough capacity to ensure that the room can function normally if one or two light globes should fail. It is also necessary to be able to dim the lights for certain procedures such as PEG insertion and sometimes for ERCP or colonoscopy. Emergency lighting should be connected to an emergency backup power supply to ensure that sufficient light is available in the event of a power failure.

Endoscopic procedure rooms utilise a lot of electrical equipment. Each procedure room should have sufficient power outlets to accommodate all the usual equipment and sufficient additional outlets to allow for future expansion. In general the power outlets should be supplied by at least two separate circuits in case one circuit fails. Power boards and extension cords should not be used except in emergency situations. The power outlets should be positioned so that they cannot be inadvertently splashed with water or otherwise contaminated. All power points should be protected by earth leakage devices to reduce the risk of electrical shock. The power supply should comply with the relevant hospital standard for procedure rooms.

The procedure room must be equipped with atleast the following;

- Light source / Video processor
- Medical Grade Monitor / Video
- Suction x 2 - patient and instrument
- Oxygen and accessory equipment
- Pulse oximeter
- Non-invasive blood pressure monitoring
- Hand-washing facilities
- Electrosurgical Unit
- Emergency drugs
- Intercom or emergency call system

The patient monitoring should comply with requirements as specified in the X-ray
Guidelines on Sedation for Gastrointestinal Endoscopic Procedures X-ray. Resuscitation equipment must be in close proximity to the procedure room.

5.9 Staff Facilities
An area should be available within the facility for a staff room that will allow staff to have meal breaks away from the patient area. Facilities for the storage of staff personal effects must be provided. Staff toilets must also be provided.

5.10 Interview Room
An area within the facility should preferably be available for pre-procedural anaesthetic consultation and for nursing assessment and procedural preparation instruction. A small private area with a minimum of two (2) chairs is required. The consultation room/s may be used for this purpose. As with the consulting room, this area will be constructed to ensure all discussions between the patient and health care provider are private and confidential and that the patient’s privacy will be maintained at all times.

5.11 Endoscope & Accessory Reprocessing
The ability to clean and disinfect endoscopes and their accessories efficiently and safely is one of the most important functions of an endoscopy facility. For detailed instruction see Infection Control in Endoscopy 2nd edition. (2003).

6 EQUIPMENT
It is expected that a facility that offers endoscopic services will provide the necessary endoscopes and accessory equipment for the type of procedures to be performed in that unit. The facility (or department within the facility) is responsible for the cleaning, maintenance and repair of all the equipment. It is also expected that the facility will keep up with technological advancements and replace equipment in order to maintain a high standard of service.

6.1 Endoscopic Equipment
All equipment used must be of a high standard and conform to current safety and work practice standards/guidelines.

Minimum equipment required;

Endoscopic equipment
- Endoscope light source/video processor
- High resolution medical standard monitor (CRT or LCD)
- Fully immersible endoscopes
- Gastroscopes - not less than
- Colonoscopes - not less than 2
- Valves, buttons, biopsy caps and adaptors (if required) for equipment
- Electrosurgical equipment

Endoscopic equipment
- Forceps
- Snares
- Sclerotherapy needles
- Dilators and guidewires

Ancillary equipment
- Recovery Trolleys & Chairs
- Pulse oximeter/s
- Non-invasive B/P monitoring
- Stethoscope
- Access to ECG tracing
- Glucometer
- Transportable oxygen cylinder with portable suction

Other equipment
- Separate hand washing facilities

Additional equipment required for procedures involving radiological examination
- X-ray equipment such as Image intensifier
- Radiation protected room
- X-ray aprons / thyroid collars / belts / gloves
- X-ray monitoring devices (for staff)
6.2 Resuscitation Equipment

The facility must have available on the premises, resuscitation equipment and staff trained in Advanced Life Support to deal with drug allergy, arrhythmia or anaphylaxis or adverse events related to analgesia or sedation. For paediatric procedures the facility should have standard paediatric resuscitation schedules advising on appropriate ETT size and drug doses according to patient size and age.

The resuscitation equipment must be:

- readily available
- maintained in good working order function checked daily
- maintained and checked according to manufacturers’ directions

Permanently sited in the endoscopy facility will be the following items:

- Air Viva - masks, bag, airways
- Adequate intravenous access equipment
- Plasma expanders
- Intravenous fluids including normal saline, dextrose etc.
- Full range of emergency drugs
- Portable oxygen and suction

Rapid access (within 1-2 minutes) to following equipment is also mandatory. It is acceptable for this equipment to be provided by the Cardiac Arrest team in large institutions. In free standing facilities this equipment must be available on the premises.

- Electro-cardiograph machine (compliant with Australian standards)
- Cardiac defibrillator (compliant with Australian standards)
- Two laryngoscopes
- Appropriate range of endotracheal tubes and accessories

The above equipment must be on a trolley and sited within the facility for swift access. The nursing staff must be fully trained in Advanced Life Support and these skills assessed at least annually. The emergency equipment must be checked daily and also after each use. Items need to be replaced promptly following use. Drugs and solutions must be checked for expiry dates and replaced as required.

6.3 Oxygen

Oxygen outlets (wall mounted) or oxygen cylinders restrained on trolleys or other devices must be located in the following areas:

- Each procedure room
- Recovery area
- Emergency trolley

In facilities where bronchoscopy is performed oxygen outlets may be also required in the waiting area. Where cylinders are used, an area for storage of tanks is required and cylinders must be restrained. All oxygen outlets should have storage attached containing a supply of tubing, masks, nasal prongs and nebulisers. Each oxygen outlet must be equipped with a flow regulator and checked and maintained regularly.

6.4 Suction

Piped suction or wall mounted or mobile suction motors should be located in each procedure room, recovery areas and on the emergency trolley. This equipment requires regular maintenance and service checks. Accessory equipment such as Yankauer suckers and Y suction catheters and tubing must be on the emergency trolley, recovery areas and in procedure rooms.

6.5 Recovery Trolleys & Chairs

Full recovery trolleys (a trolley which allows the foot of the trolley to be elevated) shall be available to safely recover patients. The number of trolleys required will depend on the workload of the unit. Patients will remain on a recovery trolley until such times as they can safely be transferred to a recliner or upright chair. Doorways, exits and lifts must allow for the passage of trolleys and wheelchairs within the facility. A supply of radio-translucent top trolleys will be required where X-ray is used.
6.6 X-ray Equipment

X-ray equipment must conform to the appropriate Australian Standard. Either fixed or mobile units that are suitable for fluoroscopy should be used in a radiation protected procedure room. This equipment will require calibration and servicing according to the manufacturers guidelines. X-ray apparel (such as gowns and thyroid protectors) and radiation monitoring devices must be worn by staff during screening. Dosimeters should be tested according to the Australian Standards (generally every 3 months) and reading of the dosimeters must be performed in accordance with state radiation authority guidelines. Storage of lead apparel must be appropriate i.e. hangers for gowns to prevent cracking of lead. Regular inspection and X-ray of gowns to detect faults is required.

Where ERCP and associated pancreatico-biliary therapeutic procedures are to be undertaken, the X-ray equipment must be of a more sophisticated level. The equipment must be able to produce high definition images and there must be a facility for image storage, either as hard copy or video. Appropriate radiation protection of rooms and doors in which X-ray equipment is used is necessary. "X-ray in use" signs shall be in place to alert staff outside of rooms of radiation danger.

6.7 Electrosurgical Equipment

An electrosurgical unit that is suitable for the performance of gastrointestinal procedures shall be available. The machine and other electrical equipment are required to conform to the relevant Australian standards AS/NZS 3200.1.0:1998 and AS/NZS 3200.2.2:1999.

Clinical application of diathermy in endoscopic procedures should conform to the guidelines laid down in the Gastroenterological Society of Australia’s publication “Electrosurgical Safety, 2nd Edition (October 2003)”.

6.8 Lasers

When used, lasers and the method of use must conform to the relevant Australian standards AS/NZS2211, AS/NZS 3200.2.22:1997 and AS/NZS 4173. Relevant state acts/regulations, which describe any legal requirements for mandatory health surveillance, policies and procedures, licensing requirements must be followed.

Only authorised and appropriately trained staff shall operate the laser. Training shall incorporate principles of use, clinical applications, risks to patient and staff, safety procedures and care of the equipment. This training must also be provided to all staff regularly assisting with these procedures. The laser fibre must be carefully examined prior to use to ensure that the fibre is not broken. Broken optic fibres risk potential damage to the endoscope, patient and staff.

Protective eyewear designated for the specific wave length of laser light (or just “designated for the specific laser in use”) shall be provided for both staff and patients. These should be examined prior to each use and discarded if there is any damage that is likely to reduce their effectiveness. In cases where significant amounts of laser plume or airborne debris is likely to be generated during the procedure, appropriate measures should be taken for control of these fumes. Careful work practices are paramount.

An appropriate laser warning label that conforms to the Australian standard must be in position at the entrance to the procedure room. Due to the risk of fire, a fire extinguisher should be easily accessible. Care shall be taken to ensure that the laser fibre can be seen protruding from the distal end of the endoscope and remains visible at all times whenever the laser is activated.

6.9 Light Sources/Video Processors

A processor for video equipment must be available in each procedure room. This equipment must comply with all electrical safety requirements and be compatible with the endoscope/s in use.

6.10 Pulse Oximeters

A pulse oximeter should be available in each procedure room and one per patient in the recovery area. Pulse oximeters should be checked according to the technical specifications by a qualified medical technician. The equipment must conform to the AS/NZS 3200.2.23:2001 and AS ISO 9919:2004.
6.11 Accessory Endoscopic Equipment

There should be sufficient accessory equipment to allow adequate cleaning and sterilisation to be performed. Forceps, snares, leads, handles and other necessary accessories must be available. In the last few years there have been major improvements in accessory design and manufacture. The majority are now either autoclavable or singleuse. It is critical to note that the capacity to autoclave accessories does not remove the need for adequate cleaning before hand.

Reusable accessory equipment shall be reprocessed according to the manufacturer’s protocol.

The issue of reuse of items labelled “single use only” is now regulated by the Therapeutic Goods Administration (TGA). The TGA, the national regulator for medical devices, does not permit there use of single use devices (SUDs), unless the re-processing of those devices is done to a standard that ensures the devices are safe and perform as originally intended. The TGA’s policy is that if there is to be re-use it can only be done in premises licensed by the TGA and any re-manufacturing that takes place must be in accordance with the standards that apply to the original manufacture of the device. In other words, the sterilised SUDs must be of the same quality, performance and safety as if it was a new device. Health Ministers charged the TGA with the role of developing the regulatory framework which ensures that if a health care facility re-manufactures a SUD, that facility will be regulated as a medical device manufacturer and will need to be licensed by the TGA and comply with rigorous good manufacturing requirements. These standards endorse the TGA statement. For further information please refer to the TGA website. http://www.tga.gov.au/devices/devices.htm

6.12 Endoscopes

Only fully immersible endoscopic equipment is to be used. Non-immersible endoscopes carry a higher risk for cross infection and therefore must not be used. The facility should have sufficient endoscopic equipment relevant to the service provided and in quantities to permit full cleaning and disinfection processes to be performed after every procedure.

All endoscopic equipment must conform to Australian Standards. AS/NZS 4187

6.13 Cleaning and Disinfection of Equipment

In new facilities it is recommended that endoscope reprocessing areas are separate from procedure rooms. For larger units, a central processing area will offer substantial efficiencies in reprocessing and improvements in the management of hazardous substances. For smaller units where there is minimal throughput, it is possible to develop effective reprocessing areas within the procedure room. However, these facilities must meet all the appropriate Occupational Health and Safety standards. As part of these it is critical that adequate vapour containment systems are in use.

The ability to reprocess equipment efficiently and safely is one of the most important functions of an endoscopy facility. An area dedicated to the cleaning and disinfection of endoscopic equipment must be available. This area should contain at least two (2) large sinks plus a tank/container of disinfecting solution or an automatic flexible endoscope reprocessing machine. Reprocessing should commence immediately following use of an endoscope to prevent the drying of secretions within the channels. The instrument should undergo leakage testing and then manual pre-cleaning in an enzyme detergent solution. The instrument should as a minimum then undergo high level disinfection with a TGA approved high level disinfectant solution either in an automatic flexible endoscope reprocessor or within an enclosed fume cabinet. Critical parameters for cleaning and disinfection must be documented. Instruments must not be left for long periods before reprocessing. If there is a delay in reprocessing then the instrument should be soaked in enzyme detergent solution to ensure that any organic material can be properly removed during the subsequent cleaning process. Submersible endoscopes should only be soaked for time periods specified by the manufacturer. In general most endoscopes should not be immersed for longer than one hour. The facility’s cleaning and disinfection protocol must follow the guidelines as outlined in the publication “Infection Control in Endoscopy 2nd edition”. The cleaning and disinfection of endoscopes should only
be performed by staff that have been fully trained and certified to do so. Inexperienced staff may not be aware of the specific design of the instrument and may cause severe damage or inadequately clean and disinfect the equipment.

As effective cleaning and disinfection of the equipment is a time-consuming exercise that cannot be shortened, it is desirable that each facility has sufficient numbers of instruments to allow for the procedural list to continue without delay. The instrument inventory also needs to allow for endoscopes being unavailable for use when undergoing repair work. Full protective clothing and safety devices must be provided for cleaning staff. Long cuff gloves, protective eye wear/face shield, impervious apron/gown and a suitable ventilation system to eliminate toxic vapours will be provided. Hazardous chemicals such as glutaraldehyde, OPA, peracetic acid should be used in closed or semi closed systems with forced air extraction. If glutaraldehyde is used then it is necessary to monitor workplace fume levels of glutaraldehyde to ensure that environmental contamination remains below the accepted level of 0.1 parts per million. It is desirable that staff be rotated on the cleaning roster, to reduce exposure to toxic chemicals.

Material Safety Data Sheets (MSDS) should be available for reference for all chemicals used in the endoscope reprocessing area and recommended safe handling and Occupational Health and Safety regulations relevant to these chemicals must be observed.

An ultrasonic cleaner must be available for the cleaning of accessory equipment. This equipment will conform to AS 2773.1-1998 or AS 2773.2-1999. Staff must also be instructed in the use and dangers of ultrasonic cleaning machines.

Compressed filtered air is essential to assist in the drying of endoscopic equipment and accessories. The outlet/cylinder must have a flow and pressure regulator attached to avoid excessive pressures and subsequent damage to endoscope channels.

**Equipment required for reprocessing of endoscopes & accessory equipment**

- Adequate sinks and bench areas
- Ultrasonic cleaning machine

- Medical air/Compressed air
- An autoclave is mandatory if central sterilising services are not readily available
- Water of suitable quality for the reprocessing of medical and surgical equipment, e.g. filtered water

**6.14 Emergency Power Backup**

Endoscopy units where general anaesthesia is undertaken and where complicated therapeutic procedures such as E.R.C.P. and other therapeutic procedures are undertaken require emergency power backup with circuits classified as “delayedvital”. (For definition see AS 3009:1998 Electrical Installations - Emergency Power Supplies in Hospitals.) In dedicated endoscopy units where general anaesthesia is not used and procedures are limited to endoscopy and colonoscopy, formal electrical standby supplies are recommended but not considered mandatory. Where a formal emergency electrical standby supply is not provided by a generator, it is necessary for the unit to have sufficient battery operated equipment to provide lighting for adequate care and observation of patients and operation of emergency equipment including E.C.G. machines and defibrillators. In addition, some form of emergency power to operate endoscope light sources would be necessary, e.g. battery system with inverter.

**7 PATIENT SERVICES**

The range of procedures performed will depend not only on the equipment and expertise available but also on the location of the unit. Where there is a high risk of patients requiring overnight stay following complex procedures, serious consideration should be given to restricting these examinations to a facility adjacent to or part of an inpatient hospital complex. Endoscopic services including upper and lower gastrointestinal endoscopy including biopsy, oesophageal dilatation, polyp removal, treatment of bleeding lesions and foreign body removal will normally be performed in all facilities. Emergency sclerotherapy or banding, diagnostic and therapeutic ERCP, diagnostic and therapeutic bronchoscopy, placement of oesophageal prostheses, biliary stenting, laser ablation, endoscopic ultrasound and percutaneous endoscopic gastrostomy are all procedures where
8 PATIENT INFORMATION EDUCATION AND CONSENT

Prior to the performance of an endoscopic procedure, the proceduralist should be satisfied that the patient understands the nature of the planned procedure and the risks involved. The consent process should provide the patient with sufficient information such that the patient can play a role in healthcare related decisions. This process takes into account greater patient sophistication, more diverse clinical investigations and more diverse treatment options as well as the increasing desire on the part of the community for participation in the decision making processes. The benefits and risks of alternative procedures will need to be discussed. In identifying the risk of a particular intervention the test of reasonableness applies in both the general and the particular. A shared decision making approach allows the patient to accept some responsibility for the outcome. In general, the consent process should cover the possible diagnosis, investigation or treatment alternatives, the details of the procedure involved, the benefits of that procedure, and the material risks of that procedure. There should be opportunity to discuss rare but serious risks of the treatment if the patient wishes, and the benefits and risks of alternative procedures or treatments. The risk of doing nothing may need to be discussed and the patient should have the opportunity to ask questions before the procedure is performed. Ideally written information/diagrams/videos should be used in the consent process and the assistance of other health professionals sought. The society recommends consulting the NHMRC guidelines - “NHMRC Guidelines for Medical Practitioners on Providing Information to Patients”(Commonwealth of Australia 1993).

There will always be special circumstances in the consent process and these may include the emergency situation where the reasons for clinical decisions or investigations undertaken should be carefully recorded to validate any form of consent. There is very limited justification for withholding information and even where the patient does not want the offered information, the proceduralist should provide some basic information about the procedure and any proposed intervention. In third party consent, the same principles of consent apply but there is an understanding that guardians, parents and persons holding medical powers of attorney do not have absolute power to give or withhold consent for treatment, in that any decision that the third party takes must be seen to be in the best interest of the patient.

There are special circumstances applying to the consent process in the setting of clinical teams. The senior medical practitioner must be certain that junior staff are capable of obtaining valid consent which implies that the junior staff have a full understanding of the complexities of the procedure. The Consultant can be held vicariously liable for any deficiencies in the consent obtained by junior staff.

In summary, the consent process currently should be seen as a conversation between individuals and will involve observing and listening as well as providing information. Patient autonomy should be respected and Australian law imposes an objective test and a subjective test of reasonableness. Finally the process should be documented.

Examples of appropriate procedure specific information/consent forms are available at:


9 ORGANISATION AND ADMINISTRATION

A governing body should administer the facility with a manager appointed whose authority and duties are defined and who is responsible for the day to day management.

The facility governing body and management are responsible for the;

- development of philosophy and objectives, and the revision of objectives as necessary to reflect change
- development of facility by-laws and compliance with statutory regulations
- provision for patient safety and special needs

There will always be special circumstances in the consent process and these may include the emergency situation where the reasons for clinical decisions or investigations undertaken should be carefully recorded to validate any form of consent.
• participation in Quality Assurance programmes
• Implementation of an appropriate programme of financial control, revenue collection, budgeting expenditure, insurance e.g. building and contents, financial assets, workers compensation, public and professional liability
• appointment of an accreditation and peer review committee.

10 MEDICAL SERVICES

Endoscopists must have appropriate training and have Conjoint Committee recognition for the endoscopic procedures they perform. Those undergoing training should be supervised by an endoscopist who has recognition to perform the procedure by the Conjoint Committee.

A professional and peer review committee should exist in every facility and all applications for clinical privileges should be submitted and evaluated formally by this committee.

Quality Assurance and peer review activities should be undertaken from time to time to ensure a high standard of patient care. Quality Assurance audits should include a record of any endoscopic complication occurring within the facility. The management committee should review such complications and be responsible if remedial or other action is required.

All endoscopists are to be accredited by the governing body to practice within the facility. Endoscopic procedures shall fulfil the “Guidelines for Good Clinical Practice” developed by the Gastroenterological Society of Australia including guidelines for Upper Gastrointestinal Endoscopy in the Diagnosis of Upper Gastrointestinal Disorders”, “Guidelines for Colonoscopy in the Diagnosis of Lower Gastrointestinal Disorders”, Paediatric Endoscopic Practice and such other publications as they become available.

Patient assessment must be done by experienced registered nurses. Staffing by appropriately experienced staff should be evident as routine.

An experienced nurse must be appointed to manage the nursing service. The ratio of registered to enrolled nurses must be congruent with their different roles. The number of nursing staff required for procedural rooms is outlined in the GENCA position statement “Minimal Staffing Requirements for Endoscopy Procedures”.

The number of registered/enrolled nursing staff to patient ratio should take into account facility size, patient numbers and services offered and type of patient care required.

There should be clearly established lines of responsibility, authority and communication within the facility and other services e.g. hospital, pathology, referring practitioners.

Written policies and procedures for all nursing practice should be available including:

• Cardio-Pulmonary Resuscitation
• Infection Control Procedures
• Preparation and Maintenance of Equipment
• Handling of Dangerous Drugs
• All procedures performed at the facility
• Nursing documentation in patient records (assessments/recovery notes)
• An organised process for standard admission or expedited admission to an inpatient facility in the event of a medical emergency
• Fire Safety Procedures
• Quality Assurance programmes
• Occupational Health and Safety Programme
• Patient Handling training Provision

Provision must be made for staff attendance at conferences, seminars, in-service and training programmes. Nursing staff must be competent in Cardio-Pulmonary Resuscitation and these skills must be assessed at least annually. Quality Assurance and peer review activities should be undertaken regularly to ensure a high standard of patient care.

11 NURSING SERVICES

The preparation and assessment of patients in a same day unit requires intensive medical and nursing management, time and expertise.
12 PATIENT SEDATION

Sedation for endoscopy should be administered in accordance with the guidelines as set out in the publication by the Gastroenterological Society of Australia, the Australian and New Zealand College of Anaesthetists and the Royal Australasian College of Surgeons “Guidelines on Sedation for Gastrointestinal Endoscopic Procedures”. The service provided by anaesthetists should meet the objectives of the facility and be in accordance with accepted standards of practice of the profession. Each anaesthetist must be willing to participate in Quality Assurance programmes. The governing body must accredit all anaesthetists who practice within the facility.

13 PAEDIATRIC SERVICES

Paediatric Gastroenterology is recognised as a subspecialty acknowledging the special considerations that need to be given to the process of performing endoscopic procedures in children. All patients under 14 years of age should be regarded as paediatric, while those between 14 and 8 years will be variously ascribed to paediatric, adolescent or adult categories according to state practice and individual maturity. The decision to perform an endoscopic procedure, the consent process, the diagnostic alternatives, the appropriateness and administration of sedation or anaesthesia, the management of complications and the subsequent clinical priorities are sufficiently different from adult practice that paediatric patients must be seen by paediatric specialists.

Procedures shall be conducted in accredited paediatric facilities with paediatric trained medical, nursing and anaesthetic staff. It is recognised that some patients, especially from rural areas, may have more convenient access to a rural gastroenterologist than a paediatric gastroenterologist for endoscopy services. Endoscopy on the older child (12-18) by an adult trained endoscopist in a facility accredited for paediatric anaesthesia may be in the family’s best interests, only after consultation with the local paediatrician and preferably with the regional paediatric gastroenterological service. All other quality control requirements as outlined above will also pertain to paediatric endoscopy.

13.1 Equipment

In view of the size of the paediatric patient, appropriately sized equipment and accessories will need to be available for the performance of endoscopic procedures. Appropriately sized resuscitation equipment must also be available, including endotracheal tubes, laryngoscopes, oxygen devices etc. to manage any reasonably foreseeable emergency.

Oxygen equipment must:

- Provide up to 100% and never less than 20% oxygen concentration at a flow-rate appropriate to the child’s size
- Be capable of sustaining these oxygen concentrations at 5 litres per minute for at least 60 minutes
- Have a fail-safe system that is checked and calibrated annually

Additional equipment must be available to continually monitor heart rate, oxygen saturation, respiratory rate and blood pressure. An emergency kit must be readily accessible and must include necessary drugs and equipment to resuscitate the unconscious child, and provide continuous support while that child is being transported to a high level care medical facility.

13.2 Staff

Specialist medical and nursing staff experienced in the care of the paediatric patients shall be employed.

13.3 Sedation

A paediatric-trained anaesthetist must be in attendance to administer an appropriate level of sedation to the child. Most endoscopic procedures in children (less than 14 years of age) will be carried out under general anaesthetic or deep sedation. Occasionally older children (aged 14-18) may be adequately managed using lighter or “conscious” sedation, although they are commonly less tolerant of endoscopic procedures than their adult counterparts.

Appropriately skilled anaesthetists should be aware of the potential problems associated with maintaining the airway of the anaesthetised child during endoscopic procedures. Specific problems inherent to paediatric anaesthesia for endoscopy include;
• Temperature control which is vitally important in small infants
• Airway management and availability of paediatric size instruments including endotracheal tubes
• Large variations in the size of patients with differences in fluid and drug requirements
• Duration of fasting, usually limited pre-operatively to four hours in infants, must be considered to avoid hypoglycaemia and dehydration.

Children are more sensitive than adults to the vagal effects of pharyngeal stimulation resulting in brady-arrhythmias and consideration should be given to intravenous atropine at the commencement of the procedure.

13.4 Consent
Parent or legal guardian consent is required for all endoscopic procedures performed on children. Adequate information for the parent or legal guardian must be available prior to obtaining consent with the guidelines for consent similar to those offered to adults.

13.5 Parental/Guardian facilities
In view of the role the parent or legal guardian provides for the child’s physical and emotional welfare, the provision of facilities for consultation and encouraging their involvement in the child’s pre and post procedural care should be available.

14 PAEDIATRIC SERVICES
The provision of administrative services includes;
• Patient reception, admission, discharge, procedural reports, billing, receipting, patient appointments, patient enquiries, incoming calls and ongoing maintenance and storage of patients’ medical records
• Development of policies and procedures which are performed at the facility
• The maintenance of patient and staff confidentiality and security relating to records, accounts, equipment and company/hospital documents
• Preparation of patient records and where applicable, entry of patient data and the restriction of access
• Provision of general office supplies including equipment and stationery
• Participation in Quality Assurance programmes
• Maintenance of a computerised data base for reporting and analysis of clinical information and statistics.

15 MEDICAL RECORDS
A confidential medical record system must be maintained and shall include where applicable the following;
• Patient history form
• Medical history
• Allergic reactions
• Consent
• Data required for Australian Bureau of Statistics, State Health Statistics, Diagnosis and Interventions for ICD 10 coding
• Referral details
• Nursing notes
• Observations
• Nursing care plans
• Nursing history
• Special preparation
• Recovery notes
• Discharge planning/instructions/letter
• Procedural report
• Drugs given
• Type of procedure and Interventions performed
• Findings/provisional diagnosis
• Names of endoscopist, anaesthetist, nursing staff assisting
18 Standards for Endoscopic Facilities and Services

- Record of endoscope used
- Recommendations/treatment/follow-up
- Specimen collection
- Procedure MBS item number
- Histology reports
- Account information
- Correspondence regarding the patient to and from the facility
- Incident or adverse reaction documentation.

16 ENVIRONMENTAL SERVICES

Environmental services provide for the physical safety and well being of patients, relatives, staff, visiting health professionals and the general public. Each facility should have specific guidelines /documentation relating to:

- Infection control
- Fire and evacuation plans
- Equipment maintenance
- Management of linen services
- Disposal of waste
- Accident/incidents to staff and patients
- Occupational health issues
- Register of Hazardous Substances including management of chemical substances
- Security for patients, staff, property
- Disaster plans
- Criminal threat/s.

16.1 Occupational Health Issues

Staff working in endoscopy facilities shall be advised of potential occupational hazards involved in this area. Material Safety Data Sheets shall be available in each work area where chemical substances are used. Environmental exposure to hazardous substances such as biocides used for reprocessing must be minimised by the provision of a forced air extraction system where these chemicals are used. Protective safety clothing, eye wear and gloves must be provided when using hazardous substances.

All staff must be instructed in the appropriate operation of equipment and be able to identify the safety precautions required. Documentation of induction and training is required.

All staff working in an endoscopy facility must be offered vaccination for Hepatitis A and B. Serology should be performed to individually assess immune status. Documented policies and procedures for needle stick injury and other occupational accidents must be available.

Protective clothing / equipment should be readily available and accessible. This will include gloves, eye and facial protection, gowns or aprons, adequate foot wear and the provision of safe needle handling systems. If there is a risk of significant blood or bodily fluid contamination of the workers’ clothing impermeable or fluid resistant gowns should be worn.

It is essential that consideration be given to the provision of specialised non-slip flooring for wet areas where reprocessing of equipment is performed.

16.2 Air Conditioning

Air conditioning of the entire facility is desirable to maintain comfortable temperature levels for staff, patients and visitors. Each procedure room must be equipped with an adequate air conditioning system to maintain airflow and a comfortable temperature when procedures are performed. Air conditioning maintenance should include regular cleaning of air filters and microbiological testing where a cooling tower is in operation.

16.3 Water Quality

There shall be a clean water supply of good quality. Water suitable for drinking is usually suitable for cleaning. Information on the quality of water maybe available from the local water authority. Attention must be paid to the suitability of the available water supply in the cleaning and subsequent drying of endoscopes and accessories. Unfiltered tap water may contain organisms which can adhere to the inside of an endoscope as part of a biofilm, resisting cleaning, disinfection and sterilisation.

Instruments intended for use in sterile cavities, in immuno-compromised patients, or for invasive procedures, e.g. ERCP and
flexible bronchoscopy, must be rinsed in sterile or 0.2 micron filtered water. Water with high mineral content is unsuitable for the rinsing of flexible endoscopes and accessory items due to mineral deposits permanently damaging and seriously shortening the life of the instruments. High mineral content may also interfere with the efficacy of cleaning agents.

17 QUALITY ASSURANCE PROGRAMMES

It is the responsibility of every facility to develop an appropriate Quality Assurance program relevant to the specific nature of the services provided e.g. staff for patient incidents, medication errors, complications, morbidity and mortality, waiting lists, staff utilisation. Microbiological monitoring of endoscopes and Automated Endoscope Reprocessing Machines shall be performed (see Infection Control in Endoscopy, 2nd Edition 2003). Documentation of Proof of Process of the reprocessing of endoscopic equipment and accessories shall also be performed. A unit based record shall be kept in addition to the information contained in the patient record. For more detailed instructions see Infection Control in Endoscopy 2nd Edition 2003.

18 EDUCATION

The facility should encourage ongoing training of medical, nursing, administrative and other staff within its organisation. A programme of ongoing inservice training of all staff, including staff support should be established and documented. Criteria for the training of staff in new procedures or the use of new equipment or drugs should be in evidence. All staff involved in the critical task of reprocessing flexible endoscopes and accessories must be educated and trained to do so. As a minimum, completion of the theoretical component of the web-based training program is mandatory before cleaning and reprocessing of a patient ready endoscope is permitted. See www.health.qld.gov.au/endoscopereprocessing for the web-based program.

A formal orientation, education and training program for new nursing staff is mandatory. In smaller centres where diagnostic gastroscopy and colonoscopy are performed it is likely that staff will need to be supernumery for a minimum of 2-3 weeks.

In larger acute hospitals providing tertiary level care and performing a wide range of interventional endoscopy with substantial complex equipment requirements, it is likely that a period of 6-8 weeks supernumery will be required.

Following the orientation period, clinical support should be provided to all staff until they are competent to manage all situations and emergencies.

Appraisal of competence should be performed on staff following training prior to unsupervised practice.
RESOURCE DOCUMENTS


STANDARDS


AS/NZS 2211.1


AS 2773.2-1999 Ultrasonic cleaners for health care facilities Part 2: Benchtop

AS/NZS 3009:1998 Electrical installations- Emergency power supplies in hospitals


AS/NZS 3200.2.18:1997 Approval and test specification - Medical electrical equipment Part 2.18: Particular requirements for safety - Endoscopic equipment

AS/NZS 3200.2.2:1999 Medical electrical equipment Part 2.2: Particular requirements for safety - High frequency surgical equipment


AS/NZS 3200.2.30:2001 Medical electrical equipment Part 2.30: Particular requirements for safety-Automatic cycling non-invasive blood pressure monitoring equipment.

AS/NZS 3200.2.4:1993 Medical electrical equipment-Approval and test specification Part 2.4: Particular requirement for safety-Cardiac defibrillators and cardiac defibrillator-monitors.


All ACHS and Australian Standards are available from STANDARDS AUSTRALIA - these documents are reviewed regularly and may (at any time) be superseded, amended or removed from publication. Check with your nearest office before ordering. Offices are located in the capital city of each State/Territory-addresses and phone numbers are also subject to change and should be checked with a phone directory or directory assistance.
STANDARD APPLICATION
STATEMENT

This standard has been prepared by the Gastroenterological Nurses College of Australia and the Australian Gastrointestinal Endoscopic Association which is section of the Gastroenterological Society of Australia. Every care has been taken in their compilation. The standard is intended to be used as a guide only and not as an authoritative statement of every conceivable step or circumstance which may or could relate to the performance of the procedures outlined.

The Gastroenterological Society of Australia and the Gastroenterological Nurses College of Australia and the compilers of this standard shall not be liable to users of this standard nor to any other person, firm, company or other body for any loss, direct, indirect or consequential, on whatsoever account for any omission or negligent misstatement contained herein, or by reason of, arising from or in relation to any such user, by any other person, company or body relying or acting upon or purporting to rely or act upon any matter contained therein or arising there after.