STANDARD OPERATING PROCEDURES (SOPs)

FOR
SURGERY, ANESTHESIA AND CENTRAL STERILE SERVICES DEPARTMENT (04)

EQUITY WITH QUALITY

Book 1

Department of Health & Family Welfare, GNCTD

SOP for Surgery Department, Ist Edition: August; 2016
Quality Assurance Cell
Delhi State Health Mission
Department of Health and Family Welfare
Government of NCT of Delhi

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The SOPs have been prepared by a Committee of Experts and are being circulated for customization and adoption by all hospitals. These are by no means exhaustive or prescriptive. An effort has been made to document all dimensions / working aspects of common processes / procedures being implemented in provision of healthcare in different departments. This document pertains to Department of Surgery. The individual hospital departments may customize / adapt / adopt the SOPs relevant to their settings and resources. The customized final SOPs prepared by the respective Departments must be approved by the Medical Director / Medical Superintendent and issued by the Head of the concerned department. HOD shall ensure that all stakeholders are trained and familiarized with the SOPs and the existing relevant technical guidelines / STGs / Manuals mentioned in the SOPs are made available to the stakeholders.

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AMENDMENT SHEET

S.No.	Page no.	Date of amendment	Details of the amendment	Reasons	Signature of the reviewing authority	Signature of the approval authority

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1- SURGERY OUTDOOR PATIENT DEPARTMENT

1.1 Purpose

To facilitate smooth and efficient transit of patients from the registration counter of OPD to their respective destinations:

1. Entry to the hospital
2. Referral to emergency
3. Admitted to ward
4. Exit from the hospital

1.2 Scope

The SOP applies to OPD

1.3 Responsibility

Described in procedure at different levels

1.4 Procedure

Sr No.	Activity	Responsibility	Reference
1.4.1	**Identification of OPD & registration** a).Patient reaches the registration counter guided by various signages mounted at different places of the hospital for easy identification of route to the OPD b).A 'help desk' manned by hospital staff to guide them to the registration counters would be available c).All OPDs should display the services which are provided and significant services which are not provided.	Estate manager Staff nurse	
1.4.2	**Registration** a).At the registration counter there are easy to read displays in all common languages. • New registrations • Old registrations • Senior citizens counters	Designated OPD supervisor / Estate manager	

	• Ladies counters • Staff counters b).At each counter there will be computer literate staff who has been also trained on screening patients based on their complaints and other referral slips. The staff should be periodically trained / oriented to the methods of screening. c).Timings of the functioning of the registration counter should be clearly displayed. It should be preferably till noon. d).There should be security personnel deployed at each counter to manage the crowd and facilitate the smooth movement of the line.	Computer assistants/ Staff nurse	
1.4.3	**Registration** a).Patient will be given a Unique hospital Id. Used for various laboratory investigations and radiological tests. Computerized registration is preferable.	Computer assistants/ Staff nurse	
1.4.4	**Documentation of vitals** a).From registration counters patients can proceed to respective OPD for recording of their weight, height, BP, Pulse. Use of digital monitors would be preferred.	Staff nurse	
1.4.5	**Doctor consultation** a).The patient reaches the respective rooms clearly mentioned on the OPD slips and also displayed on boards in the registration counters b).The slip is received by the hospital staff, who would enter the details on the OPD computer/register (for census record) and also provides a token number to the patient. The staff will segregate the patients to different OPD rooms c).The patient is then asked to wait at the waiting hall which has good ventilation / is well illuminated / is hygienic and clean . The waiting hall should preferably have television / posters containing health	Designated OPD supervisor / Estate manager Staff nurse / nursing orderly (Female staff is must) PWD / Group D worker Designated OPD	

	advices for keeping the patient entertained while waiting. d).Each OPD room should have a display screen for token numbers and alarm	supervisor / Estate manager	
1.4.6	a).After the patient receives the call on the display board, he/she enters the OPD room where he will be evaluated by the doctor. All female patients should be examined in presence of a female hospital employee. b).There should be a curtain to ensure privacy of the patient. c).OPD should have basic diagnostic instruments. d).All OPDs should be under supervision of the doctor with atleast a minimum degree in the specialty. e).All rooms of the OPD must be functional during OPD hours.	Head of Dept / Doctor	
1.4.7	a).All prescriptions should be written in the generic form and the medicines should be available in the hospital pharmacy b).All laboratory / imaging tests should be written in the OPD slip for which additional forms need not be given. c).Interdepartmental referrals if needed should be mentioned in the OPD slip. No fresh slip for the referral department to be made for that day. d).All OPD slips should be signed followed by the name of the doctor/ Stamp of the doctor. e).Patients should be sent back to the staff nurse present in the room for explaining the future course of action.	Head of Department / Doctor Staff nurse	

1.4.8	a).Patients who are treated on outdoor basis need to go to the pharmacy and maintain a queue. b).Security personnel also required to facilitate the queue c).Pharmacist will dispense the medicines as per the prescription and also maintain a record of the same. He would need assistance of a nursing orderly. d).The pharmacist should clearly explain the dose and frequency in which the drug needs to be taken.	Security staff Pharmacist	
1.4.9	a).Patients who have been advised admission should go to the designated counter for completing the formalities of admission as laid down in the SOP of Indoor patients.		
1.4.10	**Investigations** a).Patients who have been advised investigations go to the respective rooms / counters where SOP for the respective department will be applicable. b).Reports should be ideally dispatched on internet which can be retrieved online or should be provided to the patient at the time of re-registration at the counter during their visit on their respective days.	Nursing staff / nursing orderly	
1.4.11	**Minor OT** a).Patients who have been referred to minor OT should go to the respective room. Proper signage are in place to help identify. b).Nursing staff should receive the patient and make necessary entries. Patients who are to be given dates , should be provided a date for the procedure and explained the procedure to be followed on that day. c).All scheduled patients will come directly to the minor OT as per the instructions given earlier . Token number to be given to the patients . She/ he should be explained the procedure.	Designated OPD supervisor/ Estate manager Nursing staff / dresser Nurse / NO on duty	

	d).When the turn of the patient comes, the doctor should take the informed consent. After receiving consent patient undergoes the procedure. e).Minor OT should have proper illumination and adequately equipped. f).There should be a separate minor OT for carrying out the procedure which comes under the National Programs like -- NSV. g).All minor OTs should have a recovery area.	Doctor on Duty PWD Head of Department	
1.4.12	**Patient Feed back** a).Before exiting the patient must be provided a feedback form and a box where the filled form can be dropped. b).Patient must be advised regarding their next visit and the days which are assigned to him.	Designated OPD Supervisor / Estate Manager. Nurse	

2- SURGERY INPATIENT DEPARTMENT (IPD)

2.1. Purpose: a). Transit of patients from the admission counter to the respective wards

b). Consent of the Patients to undergo treatment for recovery

c). Indoor Management of the patient as per the the guidelines pertaining to the ward.

2.2. Scope: The scope applies to IPD

2.3. Responsibility: Described in the procedures at different levels.

2.4. Procedure: As follows

Sr. No.	Activity/ Description	Responsibility	Ref.Doc./ Record
2.4.1	ADMISSION		
	a) After having being directed to be admitted, the patient shall visit the hospital admission counter which is situated near the reception area, emergency area, OPD service counter area which is clearly displayed.	Counter Assistant	
	b) Patient gets the requisite admission documents for the respective ward area where he or she has been admitted. The directions are clearly explained or the coloured floor marking strips painted – that will serve as a guide to the desired admission zone.	Registration Staff	
	c) The respective area is clearly highlighted and the patient gets directed to Help Desk or the Nurse Station in the ward. Here "NEW ADMISSIONS" could be displayed. Other areas of the ward are also clearly indicated viz. toilets, pantry with fridge & heater or microwave, duty rooms, store rooms, dressing rooms, drug stores, soiled linen segregation area, Nurses bay with the refrigerator for drugs and other essentials, etc.	Registration Staff Sister Incharge of the Ward.	
	d) The duty nurse makes the entry of the admission in the admission register. The nurse explains about the preliminary requisites of the ward – sort of orientation, eg. Restriction of visitors and their unnecessary movement, disposal of waste in the proper bags, Visitor timings, follow simple civilized	Staff Nurse Doctor on duty /	

	traits, no consumption of alcohol, tobacco, socializing activities in the hospital premises, look after all the amenities provided by the ward/hospital as their own, etc. These instructions can be displayed in the ward. e) Explain paper work formalities, consent, signatures, preparation of the case record, bed allocation, etc	staff nurse	
2.4.2.	ADMISSION, SHIFTING, REFERRALS a) Inform the doctor of the arrival of the patient and place it in record - the date and time of information that was sent. b) The doctor shall call on the patient and document the history, examination and make a provisional diagnosis and outline the scheme of management. The nurse shall then take custody of the care record file and carry out the treatment instructions. c) The nurse will also prepare to send the investigations that are ordered by the doctor. The doctor and the nurse shall work on this in close association so as to execute the work up of the patient at the fastest pace. d) The appointments referrals from other departments are filled in the proper forms by the doctor and the date and time fixed. The nurse will depute the ward Nursing orderlies or multipurpose workers (MPW) to run errands to the departments for collecting dates and appointments. e) Explain to the patient where he is to go and for what purpose. Briefly explain what he expects there so that his or her apprehensions are minimized. f) The NO or the MPW shall shift patients on a wheel chair or trolleys at the preset time and the nurse shall hand over the case record with proper documentation for further patient movement monitoring. g) Inform the doctor from whom the referral is to be sought and hand over the referral request and the case record for evaluation and documentation. In case there is need, the doctor incharge of the case may accompany or reach the	Concerned Doctor not below the rank of Sr. Resident Staff nurse Doctor on duty Staff nurse Staff nurse Staff nurse/Doctor on duty Staff nurse/Doctor on duty	

	referred department for discussion. The patient may be left if the procedure is going to take some time and the NO or MPW can return later to pick up the patient. h) After the procedure the patient is brought back to the primary ward or taken wherever the doctor has suggested – with proper records and documentation of sequence of events. The parent ward nurse must be kept informed of the movement of the patient or requested to send the NO or MPW to get the patient back.		
2 .4.3	INVESTIGATIONS AND REPORT COLLECTION a) The investigation forms must be properly filled with proper identification. The samples once collected must be properly labeled and matched with the form details. The data entered in the proper register and sent through the NO or MPW to the laboratory or department , where it is authentically accepted and movement register is signed clearly with the receiver's name. b) The reports will be sent back in the same fashion to the parent ward where these shall be received by the duty nurse and cross checked with the sending request register so that the samples sent and sample reports received are cross matched. Non receipt of report can then be checked for the delay. c) Nurse shall attach the reports with the case records and inform the doctor on duty.	Staff Nurse Staff Nurse Staff Nurse	
2.4.4	PATIENT PROCEDURE a) Inform the patient about the interventional /surgical procedure that is planned b) Informed consent to be taken by the nurse or the doctor on duty c) Pre operative orders to be prescribed and written by the doctor, which shall include the orders detailed by other departments especially anaesthesia (in their PAC papers or	Staff Nurse Treating physician	

	case record) d) All orders to be carried out by the nurse with the help of the NO or MPW (preferably females to work for female patients or any female to be in attendance when the male workers are on the job). Drugs, test dosing, must be properly authenticated by the person who is executing, with the name legibly readable. Identify by placing the ID band on the patient's wrist. e) Personal belonging are to be handed over to the relatives with proper record and documentation of the items removed from the patient and handed over to which relative. f) Shift the ID patient on the trolley to the respective operation theatre or department with case record, material for the procedure, with strict documentation of the movement. The receiving nurse shall document the receipt of patient and all the belongings sent by the nurse of the primary ward.	Staff Nurse Staff Nurse / NO	
2.4.5	BLOOD TRANSFUSION PROCEDURE This is to be followed as per the prescribed practice of the Blood Bank Services of the Hospital. a) Blood transfusion consent form to be filled and signed by the patient after explaining the need for transfusing blood. b) Donor or replacement donor to be arranged and sent to the blood bank for donation. Self donation can also be promoted in case of routine procedures. c) Blood grouping and cross matching form to be filled by the doctor and sent under documentation from the ward through the NO or MPW to the blood bank along with the blood sample of the patient to whom the blood is proposed to be transfused. d) Ask the blood bank, if the blood has been arranged – in an hour to 2 hr. time. e) Send in the requisition slip for the release of the blood; which	Doctor on duty	

	must be transported responsibly in a container at precise temperature through the hospital worker (NO or MPW). The time of exit from the blood bank must be documented and the time received in the ward along with the papers is documented. f) The doctor is informed and who cross checks the sent blood and authenticates in the case record that the particular batch number belongs to the same patient. g) Since blood is usually not accepted back by the Blood bank after its release (if delay is > 1/2 hours), the transfusion must start immediately (if kept then blood may get spoilt) h) Blood warmer, transfusion set, consent form reverification to be done by the doctor. Blood transfusion notes to be entered by the doctor. Any reactions and complications documented.		
2.4.6	MAINTENANCE OF RIGHTS AND DIGNITY a) Isolate patients of open tuberculosis for a period of 3 weeks after initiation of treatment b) Case records to be kept in strict custody of the sister incharge or staff nurse of the ward c) Do not display or allow scrutiny of the sensitive documents pertaining to the patient. The person must take proper consent from the doctor I/C and provide his / her identity for this purpose d) Constant reinforcement and repeatedly telling the co workers about human dignity and values in respect to fellow humans. The patients are dependant and need assistance and we must learn to respect their privacy and help them in humane manner. e) Provide privacy through curtains and screens f) Learn proper hand washing techniques and use rapid hand cleansers g) Practice barrier nursing to patient with HIV, Hepatitis B,	Doctor/Staff nurse Staff nurse Staff nurse Staff nurse Staff nurse/NO Doctor/Staff nurse/NO Staff nurse	

	immune-compromised		
2.4.7	CONSENT As per the Informed consent methods. a) General consent to be signed on the admit card for agreeability of admission, to follow norms of any civilized society, not indulge in alcoholism, smoking, drug abuse, socially unacceptable activities, etc b) Explain to the patient and relatives of the procedure.	Doctor	
2.4.8	COUNSELLING AT THE TIME OF DISCHARGE a) Preferably the decision of discharge is to be made in the morning round and the discharge slips are to be made in the morning itself. There must be prior information to patient and relatives. Check out time can be 3 p.m. (where payments are involved). b) Discharge slip copy must be attached to the care record. Give photocopies of all documents when asked for. c) Nurse must enter the data in the discharge register and get signatures of the patient or relative on it. d) Check all the ward belongings are received back and document this in the discharge register. e) All instructions as noted in the discharge slip are reiterated by the nurse and the time and date of next follow up is clearly announced. f) In case of transfer to other hospital, a proper transfer summary must be prepared and sent along with essential investigations. A proper record of this is made in the case record.	Doctor Staff Nurse Staff Nurse Staff Nurse Staff Nurse Doctor/ Staff Nurse	
2.4.9	ENVIRONMENTAL CLEANING AND PROCESSING OF EQUIPMENT a) All equipment necessary for the purpose of house keeping and cleaning is to be indented from the hospital stores on weekly / fortnightly basis.	Sister in charge Staff Nurse/NO	

	b) Free placement of hand sanitizers and their use.	Staff Incharge	
	c) The staff (safai Karamcharis and NO's) are clearly told of their areas for cleaning. Area of domain must be clearly defined and the person appointed must be accountable. A cleaning schedule is to be made and this is to be practiced mandatorily. This is to be supervised by the Sister Incharge of the ward.	Housekeeping staff Housekeeping staff	
	d) Toilets to be kept clean and dry all the time. There is a need to clean them very frequently.	Housekeeping staff	
	e) Patients bedside and surrounding to be cleaned 8 hourly, at least.	Housekeeping staff Housekeeping staff	
	f) The corridors and floors to be cleaned at least twice a day and whenever soiled.	Staff Nurse	
	g) Ceiling and walls, windows to be cleaned monthly	Staff	
	h) Sterilization of equipment as per the norms for chemical sterilization.		
	i) Packing the sets for procedures and sending to CSSD under documentation.	Nurse/MPW	
	j) Prepare Dressing sets, Aspiration set, Cut Down set, Suturing tray set, Intercostal tube drainage set, tracheostomy set, etc.	MPW	
	k) Laundry servicing through Dhobhi services. Preferable to do a prewash in the hospital or ward based fully automatic + 100% dryer machine.	Staff Incharge Housekeeping staff	
	l) If outsourced the liberal use of disinfectant and cleaning material with dedicated staff who is responsible and realizes the need for high standards of hygiene.	Staff Incharge/Staff Nurse	
	m) Use of self protection by the staff doing the job of cleaning. Wearing thick rubber gloves and boots and impervious apron.		
	n) Learn and practice proper disposal of waste. Point the wrong doers and rectify by telling them the proper methods.		
	In case of spill or needle stick injuries or exposure to		

	contaminated fluid, follow the instructions of hospital infection control committee guidelines.		
2.4.10	**BIOMEDICAL WASTE** a) As per the documented guidelines. Display of the posters and placement of bins of appropriate colour codes with representative bags in many areas. b) Constant vigil and tutoring the staff and the patients and relatives / attendants of the proper waste disposal. Sorting at the site of origin is the best way to segregate. c) Disposable use wherever appropriate, especially when managing the patients who are known to suffer from communicable / contagious /transmittable diseases.	Staff Incharge /Staff Nurse Staff Incharge /Staff Nurse/ Housekeeping staff /Staff Incharge/Staff Nurse/Doctor	

3-PRE-ANAESTHESIA CHECK UP (PAC)

3.1 Purpose

To facilitate smooth and efficient functioning of the PAC clinic and for managing Pre-Anaesthetic Check up (PAC) clinic

3.2 Scope

The SOP applies to PAC clinic

3.3 Responsibility

Described in procedure at different levels

3.4 Procedure

Sr. No	Procedure	Responsibility	Reference
3.4.1	PAC must be done in a designated room as OPD services.		
3.4.2	It should start at nine in the morning and registration should continue till forenoon. The PAC team should consist of a consultant, Senior Residents (SRs), and will supervise the working of Junior Residents (JRs), staff nurse, and a non-technical staff.	Anaesthesiologists and Nurse	
3.4.3	Following the registration, weight, height and baseline vitals including BP, HR and spO2 must be recorded in the PAC form by a trained nurse staff. A register recording the details of the patients coming to the PAC and patients for bedside pre-anaesthetic evaluation must be maintained.	Nurse Non-technical staff	
3.4.4	Patients should be allotted a token number and attended serially.	Non-technical Staff	
3.4.5	Patients who are sick, senior citizen, differently abled etc and on wheel chair or trolley should be given preference.	Anaesthesiologists and Nurse	
3.4.6	The calls for the bedside PACs for the bed-ridden or sick patients should be noted at the registration counter	Anaesthesiologists and Nurse	

	itself. The ASA class under which the patient is accepted should also be mentioned on the PAC sheet.		
3.4.7	All cases must be attended by a senior resident (SR)or higher grade. Cases attended by the under-graduates and post-graduates must be in supervision finally opined by the seniors.	Anaesthesiologists	
3.4.8	A clear instruction to the patient and the surgical team, whether the patient is being taken for routine surgery or for emergency surgery.	Anaesthesiologists	
3.4.9	The investigation slips for the investigations demanded in the PAC must be filled in the PAC clinic by the doctor or nurse and laboratory services to honour these and send reports directly to the PAC. Patients must be sent back to the parent department to be listed in the OT list only when the general condition of the patient is optimized	Anaesthesiologists and Nurse Anaesthesiologist	
3.4.10	All female patients must be examined in the presence of a female hospital employee.	Anaesthesiologists and Nurse	
3.4.11	High risk patients with co-morbidities must be sent for a consultant referral 2-3 days prior to the surgery to the consultant in-charge of the respective OT where the case will be posted. It is advisable to have those team posted in PAC who shall give anaesthesia services to the respective patient in OT.	Anaesthesiologist	
3.4.12	All PAC forms must bear clear pre-anaesthetic instructions including investigations, referrals, fasting orders, premedication and must be carried out in order to avoid cancellation on the morning of surgery. It must be duly filled and signed along with the name and designation either written or stamped.	Anaesthesiologists	

3.4.13	It is advisable to avoid follow up or review PAC on the morning of the surgery, unless it is absolutely essential.	Anaesthesiologists	
3.4.14	The final decision or pre-anaesthetic orders must be in concurrence with the senior or PAC consultant in charge.	Anaesthesiologists	
3.4.15	Patients scheduled for elective procedures should be reviewed on such dates so that the same doctor may attend the patient.	Anaesthesiologists and Nurse	
3.4.16	Once the PAC clinic is over, the PAC consultant or the senior resident along with the PG or non-PG junior resident must attend the patients for bedside pre-anaesthetic evaluation and consult with the consultant in-charge. In case of very high risk patients, the PAC consultant must assess the patient on bedside.	Anaesthesiologist (PAC consultant and senior resident, junior resident)	

CONSENT FOR ANESTHESIA SERVICES

I, _____, acknowledge that my doctor has explained to me that I will have a diagnostic or treatment procedure for which I would be given anaesthesia. Ihave also been explained the risks of the procedure and anaesthesia. Also, I have been advised of the alternative treatments, and the expected outcomes.

It has been explained to me that almost **all** forms of anesthesia involve some **risks** and no guarantees or promises can be made concerning the results of my procedure or treatment. Although rare, unexpected severe complications with anesthesia can occur and include the remote possibility of infection, bleeding, drug reactions, blood clots, loss of sensation, loss of limb function, paralysis, stroke, brain damage, heart attack or death.

I understand that above stated risks are common to all forms of anesthesia and that additional risks for different specific anesthesia techniques have been identified in the table given below and must be appropriately ticked for the respective patient in consideration for surgery.

It has been explained to me that sometimes a particular anesthesia technique which involves the use of local anesthetics, with or without sedation, may not succeed completely and therefore another technique may have to be supplemented including general anaesthesia.

I understand that the type(s) of anesthesia service checked below will be used for my procedure and that the anesthetic technique to be used is determined by many factors including my physical condition (ASA grading), the type of procedure my doctor is to do, my doctor's preference, and my own preference.

General Anesthesia	Expected Result	Total unconscious state, possible placement of a tube into the windpipe
	Technique	Drug injected into the bloodstream, breathed into the lungs, or administered by other routes
	Risks	Mouth or throat pain, hoarseness, injury to mouth or teeth, awareness under anesthesia, injury to blood vessels, aspiration, pneumonia
Spinal or Epidural Analgesia/ Anesthesia □ With sedation □ Without sedation	Expected Result	Temporary decrease or loss of feeling and/or movement to lower part of body
	Technique	Drug injected through a needle/catheter placed either directly into the spinal canal immediately outside the spinal canal

	Risks	Headache, backache, , convulsions, infection, persistent weakness, numbness, residual pain, injury to blood vessels, High spinal ,"total spinal" (Complete paralysis)
Major / Minor Nerve Block □ With sedation □ Without sedation	Expected Result	Temporary loss of feeling and/or movement of a specific limb or area of the body
	Technique	Drug injected near nerves providing loss of sensation to the area of the operation
	Risks	Infection, convulsions, weakness, persistent numbness, residual pain, injury to blood vessels
Intravenous Regional Anesthesia □ With sedation □ Without sedation	Expected Result	Temporary loss of feeling and/or movement of a limb
	Technique	Drug injected into veins of arm or leg while using a tourniquet
	Risks	Infection, convulsions, persistent numbness, residual pain, injury to blood vessels
Monitored Anesthesia Care (with sedation)	Expected Result	Reduced anxiety and pain, partial or total amnesia
	Technique	Drug injected into the bloodstream, breathed into the lungs, or administered by other routes producing a semi-conscious state
	Risks	An unconscious state, depressed breathing, injury to blood vessels
Monitored Anesthesia Care (without sedation)	Expected Result	Measurement of vital signs, availability of anesthesia provider for further intervention
	Technique	None
	Risks	Increased awareness, anxiety and/or discomfort

I hereby consent to the anesthesia service checked above and authorize that it may be administered.

I also consent to an alternative type of anesthesia, if necessary, as deemed appropriate by the Anaesthesiologist.

BLOOD TRANSFUSIONS
The likelihood of needing a blood transfusion for this procedure is: □ Highly unlikely □ Possible □ Probable I understand that there are potential risks from blood transfusions, though rare, and that some of these include transfusion reaction, hepatitis, and AIDS (Acquired Immune Deficiency Syndrome). Initial in appropriate box: □ I give consent to receive blood or blood products as deemed essential by the Anaesthesiologist and doctor to be necessary for my well-being. □ I give consent to receive blood or blood products only as an emergency life-saving measure. □ I do not want to receive blood or blood products under any circumstance.

I certify and acknowledge that I have read this form or had it read to me; that I understand the risks, alternatives and expected results of the anaesthesia service.

PATIENT IDENTIFICATION _____ _____

Patient's Signature Date and Time _____ _____

Substitute's Signature Relationship to Patient _____ _____

(Witness)

(Doctor/Anaesthesiologist)

4 - Policy on Consent

For consent to be valid, it must be voluntary and informed and the person consenting must have, the capacity to make the decision.

A. Elements of Informed Consent: Informed consent is a process in which the physician provides adequate information to the patient or patient's legal representative for making an informed decision on the proposed treatment, including medications or procedure.

B. Specifically the physician must disclose, in a reasonable manner, all significant medical information in a language that the patient and relatives understand and disclose the material that the physician believes is relevant to making an informed decision by the patient in deciding whether or not to undergo the procedure or treatment. This information should include:

1. The nature of patient's condition and reasons why it warrants surgery.
2. Brief description of the proposed treatment, possible treatment alternatives, or decision about to not to undergo the surgical procedure.
3. The benefits and risks of the proposed procedure.
4. The consequences of no treatment as advocated by physician/surgeon.
5. Expectations during recovery period.
6. If applicable, the possible use in education and/or research of blood or tissue removed from the patient and is not further needed for medical care.
7. The patient or patient's authorized representative should be given the opportunity to ask questions and receive additional information as desired by him/her. The patient should also be advised that it is not possible to predict or guarantee results in accordance to patients expectations.
8. Name of the surgeon who will perform the requisite procedure

Techniques:

- An informed consent is obtained by the surgeon prior to the procedure. In case of adult patient, his/her signature or with thumb impression is recorded in the consent form is duly attested by signature and name of the witness.
- In case of patients aged below 18 years consent is obtained from his/her legal Parents/Guardian.
- In case of mentally ill or unconscious patients Informed consent of nearest relatives or guardian (if available) is obtained.

- All the unknown patients are treated as medico-legal cases and all the life saving measures are undertaken in the best interest of patient. The left thumb impression (LTI) is recorded in presence of two witnesses; not below the rank of Senior Resident. However, in the mean time, every effort is made to trace the relatives or guardians of the concerned patient.
- There can not be a single universal Informed consent form for all the surgical procedure, as the relevant information for different procedure will vary. Hence procedure specific consent forms are to be generated.

Patient's rights:

While taking informal consent, it must be understood that the patient's rights are honoured.

1. Patients are to be given information, in a way that they can understand, to enable them to exercise their right to make informed decisions about their care.
2. A patient has the right to give or withhold consent prior to examination or treatment.
3. Patients must be allowed to decide whether they agree to the treatment and they have the right to refuse treatment or withdraw consent at any time.
4. In the case of Minors and incompetent adults, rights regarding informed consent are to be exercised through their parents or legal representative.
5. Patients are informed of their right to withdraw from the treatment at any stage and one made to understand also of the consequences (if any) of such withdrawal, whenever applicable.

Documentation

1. The physician must document in the medical record, on an approved hospital form when available, a consent for all therapeutic and diagnostic procedures. All disclosures of significant medical information, including risks involved, would assist a patient in making an informed decision whether to undergo the proposed treatment or procedure. Such procedureres should include consent for transfusion of blood and/or blood products.

C. **Role of Registered Nursing Staff in the Informed Consent Process**

1. The registered nurse should verify with the patient and/or by specific documentation of informed consent in the medical record that consent has been obtained by the physician prior to the procedure or treatment.
2. In the event the nurse determines that informed consent has not been obtained or documented, the nurse will contact the physician who will complete the consent process, speak with the patient, and/or provide specific documentation of the informed process which has previously taken place.

Treatments and Procedures where *informed* consent is necessary:

The patient's consent must be obtained for treatments and procedures that:

1. Surgical or invasive procedures
2. Involve the use of sedation.
3. Involve the use of anesthesia or narcotic analgesia.
4. Can be reasonably expected to produce significant discomfort to the patient.
5. Can be reasonably considered to have a significant risk of complication/ morbidity.
6. Require injections of any substance into a joint space or body cavity, including any nonvascular space.
7. Involve testing for human immunodeficiency virus (HIV)
8. Blood product transfusion
9. Dialysis (haemo or peritoneal dialysis)
10. Genetic testing
11. Induction of essential, though toxic drugs (e.g., cancer chemotherapy, disulfiram, methadone for narcotic dependence, naltrexone)
12. Admission
13. Research

Brief outline of Consent form:

1. The name(s) of all the practitioner(s) immediately responsible for the performance.
2. A brief description of the recommended treatment or procedure.
3. A statement that relevant aspects of the treatment, or procedure, including indications, benefits, risks, and alternatives including no treatment have been discussed with the patient in language that the patient could understand; and he/she authenticates this in writing.
4. A statement that the patient had an opportunity to ask questions.
5. The written signature of the practitioner writing the note, including the Practitioner's legibly written name.
6. Signature/Thumb impression of Patient/Next of Kin/Guardian as applicable and their names written legibly and duly attested by witness.
7. Date of Consent

Withdrawal of consent by Patient

Patients can change their minds about a decision at any time, as long as they have the capacity to do so.

Refusal of Treatment by Patient

Patients are entitled to refuse consent to treatment even when doing so may result in permanent physical injury or death. When the consequences of refusal are grave, it is important that patients and immediate relatives understand this, and also that, for clinical reasons, refusal may limit future treatment.

For further information on Statutory Requirements of Consent: Medical Council of India's Code of Medical Ethics: may be referred, which is placed at Annexure.

Annexure

Statutory Requirements of Consent: Medical Council of India's Code of Medical Ethics:

1. Before performing an operation the surgeon/ physician should obtain in writing the consent from the husband or wife, parent or guardian in the case of minor, or the patient himself as the case may be.
2. In an operation, which may result in sterility, the consent of both husband and wife is needed.
3. A registered medical practitioner shall not publish photographs or case reports of his / her patients without their permission, in any medical or other journal in a manner by which their identity could be made out. If the identity is not to be disclosed, the consent is not needed.
4. No act of in-vitro fertilization or artificial insemination shall be undertaken without the informed consent of the female patient and her spouse as well as the donor. Such consent shall be obtained in writing only after the patient is provided, at her own level of comprehension, with sufficient information about the purpose, methods, risks, inconveniences, disappointments of the procedure and possible risks and hazards.
5. **Research**: Clinical drug trials or other research involving patients or volunteers as per the guidelines of ICMR can be undertaken, provided ethical considerations are borne in mind. Violation of existing ICMR guidelines in this regard shall constitute misconduct. Consent taken from the patient for trial of drug or therapy which is not as per the guidelines shall also be construed as misconduct.
6. A Physician must attend to her/his pregnant patient in her confinement on terms agreed upon. If exceptional circumstances prevent the Physician from providing services, another physician may be sent for. When the delivery is accomplished, the visiting physician is entitled to his/her professional fees, but he/she must obtain consent from the patient to leave, when the primary Physician arrives.
7. **Obtaining Consent**
   a. Successful relationship between doctors and patient depends on trust. The Physician must respect the patients autonomy, their right to decide whether or not to undergo any medical intervention.
   b. Patients must be given sufficient information in a way they can understand to enable them to exercise their right to make informed decision about their treatment.

c. The Physician must give patients details before he/she decides to consent to an investigation or a treatment.

d. The Physician must give details of the diagnosis and prognosis of the disease, if left untreated.

e. The Physician must inform the common and serious side effect for each option available to the patient. And also of any lifestyle changes which may be caused by or necessitated by the treatment.

f. The Physician must respond honestly to any question the patient raises. She/He must answer such question as fully, accurately and objectively as possible.

g. The Physician must not exceed the scope of authority given to you by your patients, except in an emergency.

h. The Physician must obtain consent from patients before testing for a serious communicable disease. The information provided, when seeking consent, should be appropriate to the circumstances and the nature of the conditions being tested for. Some conditions such as HIV have serious social and financial as well as medical implications.

i. When investigating / treating a child who cannot give or withhold consent, seek consent from a person with parental responsibility for the child.

8. With reference to specific practice

a. The Physician may undertake in vitro fertilization and / artificial insemination with the informed consent of the patient and her spouse in writing. They should be explained, at their level of comprehension, about the purpose, method inconveniences, rate of success as well as probable and possible risks.

b. The Physician must follow Guidelines laid down by the Indian Council of Medical Research for research and therapeutics trials.

c. Special Consent provisions under PNDT Act (Form G)

d. Consent Requirements under MTP Act (Form C)

e. Consent Requirements for HIV investigations

5 - OPERATION THEATRE

5.1 Purpose: To ensure the optimal preparation of the patient for surgery and safe conduct of anaesthesia/surgery and optimal recovery in the postoperative period.

5.2 Scope: Preoperative optimization of patient's condition, transfer from ward to OT, informed consent, pre-operative preparation and safe administration of anaesthesia, safe conduct of surgical procedure and evaluation of patients' general condition following reversal of anaesthesia.

5.3 Responsibility: Described along with the procedure at each step

5.4 Procedure

5.5 PREOPERATIVE PREPARATION

Sr. No	Activity Description	Responsibility	Ref. Doc./Record
5.5.1	A tentative OT list should be sent to the department of Anaesthesia, OT and the post-operative ward.	Nursing In-charge of surgical Ward	
5.5.2	For patients with co-morbidities, a consultant Anaesthesiologist referral must be sent at least 3 days prior to the surgery. However, keeping in mind that the elective cases can be deferred till the patients' general condition is optimized.	Consultant Anaesthesiologist	
5.5.3	A bedside pre-Anaesthesiologist check-up must be done by an Anaesthesiologist a day prior to surgery. Any investigation or inter-departmental referrals or opinions may be sought, if deemed necessary.	Anaesthesiologist (Senior Resident). Not below the rank of senior resident.	
5.5.4	The informed consent shall be taken by the operating surgeon and anaesthesiologist in separate from explaining the consequences of anaesthesia and surgery, respectively. The informed consent for surgery may be signed a day prior; whereas, the consent for anaesthesia should preferably be signed on the day of surgery considering the deterioration in case of any pre-existing ailment, which may be best evaluated in terms of perioperative risk on the day of surgery itself. The written, informed consent must explain both surgical and anaesthesia risk and should be duly signed by the patient or his/her immediate relative. Common complications should also be mentioned in the informed consent.	Anaesthesiologist / Surgeon.	

	The consent should be in form of "Informed consent" with patient and the relative in counselling. In case the patient refuses surgery this should also be put in writing and should again be signed by the patient or his/her relatives and doctor.		
5.5.5	The site to be operated should be marked and prepared i.e. shaved, nail paints & mehendi to be removed, jewellery & dentures removed and handed over to the relatives. The list of the valuables should be clearly mentioned. ASA guideline on "Nil per oral" (NPO) must be followed and documented. * Patients' identity and type of surgery must be marked on the patient.	Ward Nurse	
5.5.6	The patients should be shifted to OT according to his/her turn in the OT list.	Ward Nurse	
5.5.7	All pre medications & investigations shall be positively done and affirmation must be sent along with the patients.	Ward Nurse	
5.5.8	The patient shall be dropped from the list if the pre-anaesthetic order could not be followed e.g. patient had not received medicines or the advised investigation has not been done. Compliance with above will prevent unnecessary delays, wastage of time and resentment on part of the patient for having the surgery deferred.	Surgeon/Anaesthesiologists	
5.5.9	Containers for specimens shall be available with patients and shall be properly marked beforehand showing the name, bed number, ward and specimen name.	Ward Nurse	

* ASA Protocol for pre-operative NPO status

Types of Food	**Minimum fasting period**
Clear Fluids/Water	2 hours
Pulpy fruit juice/breast milk	4 hours
Infant formula milk	6 hours
Non human milk	6 hours
Light meal	6 hours
Fatty meal	8 hours

5.6 - PATIENT CARE IN THE OPERATION THEATRE (Do not apply to cases under local anaesthesia)

Sr. NO	Activity/ Description	Responsibility	Ref. Doc/ Record
5.6.1	In the pre-operative room, all patients must be evaluated again for their readiness for surgery. A documented policy and procedure shall exist for administration of anaesthesia. The pre-anaesthesia assessment results in formulation of an anaesthesia plan which is documented.	Anaesthesiologist	
5.6.2	The identification of the patient and the site of surgery should be confirmed. Informed consent explaining the risks associated with the surgical procedure as well as anaesthesia must be rechecked and reinforced in high risk patients.	Surgeon/Anaesthesiologist Surgeon/Anaesthesiologist	
5.6.3	The anaesthesia machine along with the availability of emergency resuscitation devices, suction machine, breathing circuits, oxygen supply, defibrillator and all emergency medicines should be checked. A qualified anaesthesia personnel must check the aforementioned items. Only qualified surgeons are permitted to perform the procedures they are entitled to. Estimated time for the surgical procedure is to be documented. Surgeons along with the Anaesthesiologist will also reaffirm the patients' identity, operation site and procedure. Time of entry and time of exit from the operation theatre (OT) must be documented. Nurse shall prepare operation trolley beforehand All team members should have introduced themselves to the patient by their names and their roles. During anaesthesia, American Society of Anaesthesiologists (ASA) recommended minimal mandatory monitoring must be instituted. It includes continuous ECG, oxygen saturation, end -tidal CO_2 and intermittent NIBP. Temperature monitoring where needed. Invasive monitoring like intra-arterial blood pressure and central venous pressure (CVP) monitoring where deemed necessary.	Anaesthesiologist Surgeon Surgeon/ Anaesthesiologist OT staff nurse Anaesthesiologist	

5.6.4	Details of Anaesthesia and any adverse event must be recorded. Patient's condition following reversal of anaesthesia and before shifting to PACU must be documented. In case, the procedure is changed intra-op (and was not planned or an explicit consent taken for the same) a fresh consent needs to be taken.	Anaesthesiologist Surgeon	
5.6.5	Patients with HIV, Hepatitis B & C, Tetanus, gas, gangrene, shall be operated according to set protocol as per the local policies and infection control committee of the hospital.	Anaesthesiologist Sister in charge OT	
5.6.6	OT Staff assisting for the surgery must keep a count of instruments, sponges and gauzes and must match with the preoperative count before closure. She should also give sponges and gauzes and in fixed aliquots. The abdominal sponges must have a radio opaque line. In case of missed gauze or sponge, all possible efforts must be maintained to match the preoperative count and C-arm/X-ray evaluation must be done before shifting the patient.	Sister in-charge of OT Sister in-charge of OT/ Surgeon	
5.6.7	Prior to transfer of the patient to PACU/Post operative recovery ward, a brief operative note should be documented on the case file. The note should provide information about the name of the surgeons /anaesthesiologists, procedure performed, salient steps of the procedure or any key intraoperative observations, post-operative diagnosis and the status of the patient immediately before shifting to the recovery area. It must be signed by the operating surgeon and concerned anaestheologist.	Surgeon/Anaesthesiologist	
5.6.8	In addition to the surgical notes, the operating surgeon must document the post-operative plan of care e.g. IV fluid therapy, medications including antibiotics, wound and nursing care etc. In patients with preoperative co-morbidities, requiring special postoperative care, this plan could be written in collaboration with the anaesthesiologist.	Surgeon/Anaesthesiologists	

5.6.9	Maintenance of records: Details of Anaesthesia should be recorded 1. In the PAC chart in the patients' case sheet. 2. In the Anaesthesia OT register Details of surgical procedure should be recorded 1. In the patients' case sheet (details aforementioned) 2. In the Surgery OT register Details of specimen should also be recorded in a separate register Patient's condition following reversal of anaesthesia and before shifting to PACU must be documented	Anaesthesiologist Surgeon Staff Nurse Anaesthesiologist	
5.6.10	Surgeons and Anaesthesiologist shall be jointly satisfied about the recovery of the patient before shifting to PACU/ICU/ or postoperative ward.	Surgeon/Anaesthesiologists	
5.6.11	The infection control in OT must comply as per the local policies or Infection control committee of the hospital.	Sister in charge OT	

5.7 - Patient care under short procedures requiring administration of moderate sedation or monitored anaesthesia care (MAC)

Sr. No	Procedure	Responsibility	Reference
5.7.1	Informed consent for the surgery as well as anaesthesia in the form of moderate sedation must be obtained by the surgeon/anaesthesiologist, respectively.	Anaesthesiologists/ surgeon	
5.7.2	If, parenteral route is used to administer sedation for a surgical procedure, this shall be carried out by a trained and competent doctor. Nurse or technician should not administer sedation here.	Anaesthesiologists/ surgeon	
5.7.3	The administration / monitoring of sedation and performance of surgery must be carried out by different persons. By no mean, patients' monitoring under anaesthesia should be compromised.	Anaesthesiologists/ surgeon	
5.7.4	Intra-procedure monitoring includes at a minimum the heart rate, ECG, respiratory rate, blood pressure, oxygen saturation, and level of sedation. Other parameters may be monitored as deemed essential depending upon the case.	Anaesthesiologists/ surgeon	
5.7.5	Patients must be shifted from the OT to recovery area once the patient is conscious and responding to verbal commands and have stable vitals. Patient's vitals after sedation shall be monitored at regular intervals (as decided by the organisation) till he/she recovers completely from the sedation.	Anaesthesiologist/ surgeon Doctor/Nurse	
5.7.6	Equipment and manpower to handle any complication intraoperatively under sedation must be available. It includes emergency resuscitation drugs, equipment and also an anaesthesiologist.	Nurse/Surgeon/ Anaesthesiologist	

6 - POST ANAESTHESIA CARE UNIT (PACU)

6.1 PURPOSE

To ensure patient safety in the immediate postoperative period in the **Post- Anaesthesia Surgical Recovery Unit / Post Anaesthesia Care Unit (PACU)**

6.5 SCOPE

Transfer of patient from OT to PACU, efficient monitoring and pain management in the PACU, followed by safe transfer to the postoperative/recovery ward or general ward. In case of ambulatory surgery, patient may be shifted to the lower level of recovery i.e. postoperative ward/recovery ward without being shifted to the PACU.

6.3 RESPONSIBILITY

Described along with the procedure at each step

6.4 PROCEDURES

Sr. No	Activity	Responsibility	References
6.4.1	**The transfer of patients from the operating theatre to the PACU** The patient should have patent airway and be physiologically stable on departure from the OT table and must be accompanied by the Anaesthesiologist to the PACU along with the oxygen by face mask.	Anaesthesiologist	
6.4.2	The extent of mobile monitoring during transfer will depend upon the proximity of PACU from OT and patients' clinical status. If PACU is at a distance, a minimum of pulse oximetry, ECG and non-invasive blood pressure monitoring is must.	Anaesthesiologist	
6.4.3	Supplemental oxygen should be administered to all patients during transfer from OT table to PACU.	Anaesthesiologist	
6.4.4	It is essential that the Anaesthesiologist formally hands over the care of the patient to an appropriately trained and registered PACU practitioner/nurse/on duty anaesthesiologist.	Anaesthesiologist	
6.4.5	The Anaesthesiologist must be satisfied with the competency of the PACU staff. If this cannot be assured, the Anaesthesiologist should stay with the patient in the PACU, until the patients' condition is optimized.	Anaesthesiologist	
6.4.6	A formal handover checklist can improve the safety of handovers and should be developed for local use. Any	Anaesthesiologist	

	significant intra-operative event must be documented and should be included in the handover.		
6.4.7	Each patient must be observed by a registered PACU staff or Anaesthesiologist. Intense monitoring needed till they are awake and able to communicate, and have stable cardiovascular and respiratory systems.	Anaesthesiologist /surgeon/PACU staff	
6.4.8	**Monitoring, Equipment and Drugs** An appropriate standard of monitoring and clinical observation should be maintained until the patient is fully recovered from anaesthesia.	PACU Practitioner/ Anaesthesiologist	
6.4.9	Clinical observation is supplemented with minimal standards of monitoring i.e. pulse oximetry, non-invasive blood pressure monitoring, ECG and, if patients' tracheas remain intubated or they have an oropharyngeal /nasal airway or supraglottic or some other similar airway device in situ, continuous end-tidal capnography should also be done. However, a nerve stimulator for assessing neuromuscular blockade, a thermometer and patient warming devices should be immediately available. Difficult airway cart should also be ready all the time.	PACU Practitioner/ Anaesthesiologist	
6.4.10	All lines should be flushed and adequately secured and protected.	PACU staff	
6.4.11	Minimum information to be recorded for patients in the post-anaesthesia care unit include • Level of consciousness • Patency of the airway • Respiratory rate and adequacy • Oxygen saturation • Oxygen administration • Non-invasive blood pressure • Heart rate and rhythm • Pain intensity on a validated scale e.g. VAS • Nausea and vomiting • Intravenous drugs/ fluids • Core temperature • Other parameters depending on circumstances, e.g.	PACU staff / Anaesthesiologist / Surgeon	

	urinary output, central venous pressure, end-tidal capnography , surgical drainage volume etc. Patients must be kept under clinical observation at all times, and all parameters should be recorded. The PACU staff must call the doctor in case of any deterioration in the aforementioned parameters.	PACU staff	
6.4.12	The frequency of the aforementioned observations will depend upon the clinical condition of the patient and the nature of the surgery and clearly documented in post anesthesia recovery orders.	PACU staff/ surgeon/ Anaesthesiologist	
6.4.13	PACU staff nurse can administer intravenous analgesics, e.g. paracetamol, non-steroidal anti-inflammatory drugs (NSAIDs) and opioids prescribed by the Anaesthesiologists as part of a specific protocol.	PACU staff/ Anaesthesiologist	*Table 1 Pain assessment and scoring
6.4.14	**Transfer from the PACU** Standards for transferring the patients from the PACU are ultimately established by the department of Anaesthesiology. Criteria can vary according to whether the patient is going to be discharged to an intensive care unit (ICU), a regular ward, the recovery ward (phase 2 recovery), or directly home. PACU will function only in 2 shifts for routine surgeries for enabling the last operated patient to satisfactorily recover from anaesthesia. PACU must be free for the next day, so as to receive fresh set of patient that are to be operated on that day. For all major surgeries, the patients should preferably be shifted to the postoperative/recovery ward for at least 24 hours and then to the general ward. The patients are shifted from the PACU, if they satisfactorily meet the criteria shown in Table 1 [Post anesthestic Aldrete recovery score]. Following regional anaesthesia: recovery of proprioception, sympathetic tone, bladder function and motor strength should also be assessed. **OUTPATIENTS** In cases of ambulatory or day care procedures, these	Anaesthesiologist /surgeon/ PACU Practitioner	** Table 2 Post Anasthetic Aldrete Recovery Score

	patients may be fast-tracked i.e. allowed to safely bypass phase 1 recovery i.e. PACU and may be directly shifted to lower level of recovery area (phase 2 recovery). If indicated these patient are kept in PACU and all PACU principles shall then be undertaken.		
6.4.15	If the Aldrete criteria are not met, the patient should remain in PACU and anaesthesiologist should be informed and patient is to be transferred to an appropriate high dependency unit (HDU) or intensive care unit (ICU).	PACU staff/ Anaesthesiologist	**Table 2
6.4.16	An Anaesthesiologist must be available in PACU at all times when a patient is there who has not attained the stated criteria of recovery.	Anaesthesiologist	
6.4.17	Patients who have potential airway problems or complications should be reassessed by the Anaesthesiologist before being transferred from the PACU.	Anaesthesiologist	
6.4.18	If there is any doubt as to whether a patient fulfils the criteria, or if there has been a problem during the recovery period, the Anaesthesiologist who administered anaesthesia or a senior Anaesthesiologist must assess the patient in the PACU and uniformly agree and document the transfer from PACU.	Anaesthesiologist	
6.4.19	The anaesthetic record, together with the prescription and recovery charts, must accompany the patient and the details of relevant drugs administered in theatre and PACU, e.g. analgesics and antibiotics must be conveyed to the ward staff both verbally and in written.	PACU staff/ Anaesthesiologist	
6.4.20	Staff from ICU or trained PACU staff to accompany when patient is being transferred to ICU. The handover of equipment accompanying the patient like infusion devices, syringe pumps, mobile monitors etc. must be done.	PACU staff/ technical staff/ MPW	
6.4.21	The PACU nurse must ensure that full clinical details are relayed to the ward nurse, with particular emphasis on ongoing problems and the management of infusions	PACU staff/ ward nurse/Anaesthesiologist	
6.4.22	Formal handover checklists can improve the safety of handovers and should be developed for local use.	PACU staff/ ward nurse	

6.4.23	Patients' dignity and privacy should be respected at all times but patients' safety must always be the primary concern	PACU staff/surgeon/ Anaesthesiologist	
6.4.24	**Education of PACU staff** Staff must be educated by holding frequent classes and seminars on the management of postoperative patient with special emphasis upon the monitoring, transfer and pain management and it must be followed by frequent evaluation of their knowledge and attitude. **Learning Charts:** Various educational learning material including Post anaesthetic Aldrete scoring system, BLS/ACLS algorithms and various other educational information relevant in context to management of patient in postoperative period must be displayed on the boards inside the PACU and must be revised time to time.	Anaesthesiologists and surgeons PACU staff	

***Table 1. *Pain assessment and scoring**

Paediatrics – 0 to 1 year behavioural/facial.

2 to 5 years – facial scale.

6 to 12 years - NRS/VAS

Adult - NRS/VAS – Static and Dynamic scores

****Table 2. Post-anesthetic Aldrete recovery score**

Parameter	Criteria	Point value
Oxygenation	SpO2> 92% on room air	2
	SpO2> 90% on room air	1
	SpO2< 90% on room air	0
Respiration	Breathes deeply and coughs freely	2
	Dyspnoeic, shallow or limited breathing	1
	Apnea	0
Circulation	Blood pressure ± 20mmHg of normal	2
	Blood pressure ± 20-50 mmHg of normal	1

	Blood pressure more than ± 50mmHg of normal	0
Consciousness	Fully awake Arousable on calling Not responsive	2 1 0
Activity	Moves all extremities Moves two extremities No movement	2 1 0

Discharge Criteria - Patient is discharged from the PACU when the total score is 10, but a minimum of 9 is required.

Reference: Post-anesthesia Care. In: Morgan M, Mikhail M editors. Clinical Anesthesiology. 5th ed. New York: Mc Graw Hill Education ;2013. pp. 1257-75

7 - POSTOPERATIVE RECOVERY WARD

7.1 Purpose

To ensure patient safety in the postoperative period for around 24 hours

7.2 Scope

Receiving of the patient in the postoperative ward from PACU, where the patients stay for around 24 hours, kept under monitoring, followed by safe transfer to the general ward.

7.3 Responsibility

Described along with the procedure at each step

7.4 Procedures

Sr. No	Activity	Responsibility	References
7.4.1	**The receiving of the patients from PACU to the postoperative ward** Patients who had received anaesthesia are shifted from the PACU to the postoperative ward accompanied with a nurse/technical staff.	Nurse/technical staff/MPW	
7.4.2	It is essential that the staff formally hands over the care of the patient to an appropriately trained nurse in the postoperative ward.	Anaesthesiologist / Nurse	
7.4.3	The postoperative ward must have a surgery resident round the clock along with an Anaesthesiologist at hand. This area should preferably be located near the ICU. **Clinical monitoring:** All devices including defibrillator must be available in postoperative ward including pulse oximetry, non-invasive blood pressure monitoring, ECG. A thermometer and patient warming devices should be immediately available. Intubation kit and difficult airway cart should also be ready all the time. All vital parameters should be recorded with special emphasis to postoperative pain. Adequate measures must be taken to alleviate the same.	Surgery Resident/ Anaesthesiologist Staff Nurse/ Surgery Resident	
7.4.4	All lines should be flushed and adequately secured and protected.	Nurse	
	Nurse can administer intravenous analgesics,	Nurse	

7.4.5	e.g. paracetamol, non-steroidal anti-inflammatory drugs (NSAIDs) and opioids prescribed by the Anaesthesiologist/surgeon as part of a specific protocol as per the assessment of the pain.		
7.4.6	**Transfer from Postoperative/Recovery ward** **After major surgery-** Patients are discharged from the postoperative ward to the general ward after around 24 hours depending on the patients' general condition. **After ambulatory procedures/ Day care surgery** In cases of ambulatory or day care procedures, the patients may be fast tracked i.e. allowed to safely bypass phase 1 recovery i.e. PACU and may be directly shifted to lower level of clinical recovery area (phase 2 recovery) or postoperative ward. Recovery from anaesthesia following outpatient procedures include two additional stages: home readiness and complete psychomotor recovery. Postanesthesia Discharge Scoring System (PADS)*. PADS score can be helpful for decision making for discharge.	Anaesthesiologist/surgeon	
7.4.7	An Anaesthesiologist must take the round for all the patients in the postoperative ward and can assist in decision for discharge. The surgeon must be satisfied about the status of patient to document transfer to General ward or to home.	Anaesthesiologist / Surgeon	
7.4.8	During transfer to the ward, each patient must be accompanied by a staff/MPW (excluding the ones who had received local anaesthesia or outpatients).	Staff/MPW	
7.4.9	The recovery record, together with the prescription and recovery charts, must accompany the patient and the details of relevant drugs administered e.g. analgesics and antibiotics must be conveyed to the ward staff both verbally and in written. The use of a formal handover checklists can improve the safety of handovers and should be developed for local use.	Staff Nurse	

* Marshal S. Chung F Assessment of home readiness": discharge criteria and post criteria and post discharge complication. Curr. Opin. Anaethesiol. 1997:10:45

Discharge Criteria - Patient is discharged after ambulatory surgery when the total PADS score is ≥ 9

Reference: Post-anesthesia Care. In: Morgan M, Mikhail M editors. Clinical Anesthesiology. 5th ed. New York: Mc Graw Hill Education ;2013. pp. 1257-7

8 - PAEDIATRIC ANAESTHESIA

The guidelines for Paediatric Anaesthesia are intended to supplement rather than to replace the standards of ASA for the perioperative care of paediatric patients receiving Anaesthesia

8.1 **Purpose**: To ensure the optimal preparation, safe conduct of anaesthesia/surgery and optimal recovery in the postoperative period of the paediatric patient.

8.2 **Scope**: Preoperative optimization of patient's condition, transfer from ward to OT, informed consent, pre-operative preparation and safe administration of anaesthesia, safe conduct of surgical procedure and evaluation of patients' general condition following reversal of anaesthesia.

8.3 **Responsibility:** Described along with the procedure at each step.

8.4 **Procedure**

8.5 **Procedure for PAC Clinic**

Sr. No	Activity Description	Responsibility	Reference /Document
8.5.1	In children with co-morbid illness, Paediatrician's opinion need to be sought.	Senior resident Anaesthesia	Reference form
8.5.2	In children with congenital anomalies / syndromes , other congenital anomalies should be ruled out by Neonatologist before giving fitness for surgery.	Senior resident Anaesthesia	PAC review
8.5.3	In case of major surgery /neonate /patient with co morbid illness / syndromic child , Consultant's opinion should be sought.	Senior resident Anaesthesia	PAC review
8.5.4	Fasting orders to be followed as per recent guidelines **.Annexure attached 1**	Senior resident Anaesthesia	PAC review

8.6 PROCEDURE FOR PRE-OPERATIVE AREA

S.no	Activity	Responsibility	Reference /Document
8.6.1	Shifting from ward to OT to be done preferably by a trolley with side rails /safety belts up to prevent falls.	Nurse to accompany Nursing orderly	
8.6.2	A pre-operative checklist has to be filled	Pre-operative staff nurse	Checklist **Annexure 2**
8.6.3	A pre-operative re-evaluation should be done on the morning of surgery in the pre –op room especially in paediatric patients	Senior resident (Anaesthesia)	PAC Review form
8.6.4	Children having URI should undergo proper evaluation before taking a decision to proceed or cancel the case and blanket cancellations should be avoided .Decision for cancellation should be documented in chart .	Anaesthesiologist	PAC chart
8.6.5	Attempts should be made to reduce anxiety of parents and family and ensure their child's utmost safety as their anxiety is transferred to the child .	Anaesthesiologist	
8.6.6	Premedication – Generally Not necessary till 6 months of age. Institutional Premedication policy to be followed and vital parameters should be monitored and recorded.	Senior resident (Anaesthesia)	Pre-operative pre-medication notes.

8.7 PROCEDURE FOR OPERATION THEATRE

S.no	Activity	Responsibility	Document
8.7.1	WHO Surgical safety check list is filled which has 3 components Sign in – Before induction Time out – Before incision Sign out – Before shifting patient to post op Completed check-list has to be signed by Anaesthesiologist , Surgeon and Floor nurse	Anaesthesiologist surgeon and scrub nurse floor nurse	WHO Surgical safety check list **Annexure 3**
8.7.2	**Regular clinical privileges** can be given to the one who is Post graduate in Anaesthesia . **Special clinical privileges** can be given to one who has had special experience of Paediatric Anaesthesia practice for at least one year.	Consultant Anaesthesia	
8.7.3	Special clinical privileges are needed for patients who are at increased Anaesthesia risk like patients age , neonates ,Procedures where PICU /HDU care requirement is anticipated, patients having co-existing illnesses and where there is an indication for invasive monitoring / invasive procedures are done , regional nerve blocks in neonates and infants .	Consultant Anaesthesia	
8.7.4	**Man power planning in Paediatric OT** - At least two qualified Anaesthesiologists trained in paediatric Anaesthesia should be present in each paediatric OT. Consultant Anaesthesiologist should preferably have Neonatal and Paediatric Advanced Life Support Certification (PALS and NALS)		
8.7.5	Nursing and technical personnel involved should also be trained and	Consultant Anaesthesiologist	

	experienced in paediatric peri-operative care by external / in house training.		
8.7.6	Clinical laboratory and radiology services should be available round the clock 24/7	Medical superintendent-hospital	
8.7.7	**Paediatric Anaesthesia Equipments and drugs** All Anaesthesia equipments applicable for paediatric patients should be available, easily accessible and well maintained. (**Annexure 4)**	Medical superintendent-hospital and HOD anesthesia	
8.7.8	**Intra operative monitoring** – In addition to standard monitoring Precordial stethoscope should preferably be used in all Paediatric patients. Continuous HR,SPO2,Etco2, ECG & temperature should be the basic monitoring in all paediatric patients.	Consultant Anaesthesiologist and senior Resident (Anaesthesia)	

8.8 POST OPERATIVE ANAESTHESIA / SURGERY RECOVERY UNIT

S.no	Activity	Responsibility	Document
8.8.1	Suction equipment and oxygen outlet along with appropriate O2 delivery device should be available at each bed side. Multi para monitor and crash cart is mandatory in PACU.	Anaesthesiologist Senior resident (Anaesthesia) Consultant	
8.8.2	Policy on post operative recovery room stay should be well defined. Patients should be monitored for Heart rate, spO2 , respiration, Blood pressure(in selected cases)and pain. Any deviation in vitals(increase or decrease) ,duration of stay should be well justified accordingly.	Consultant Anaesthesiologist & Senior resident (Anaesthesia)	
8.8.3	All paediatric patients having undergone surgery should have an ideal properly secured IV canula of appropriate size.	PACU staff	
8.8.4	Post operative monitoring - Pain should be assessed as "fifth vital sign" (as per WHO guidelines). Multimodal approach for analgesia should be used a) No individual measure can be broadly recommended for pain assessment across all children or all contexts b) Children self-report of their pain is the most preferred c) Children's pain should be assessed, documented and appropriate action taken as this contributes to prevention and relief of pain d) Health care professionals and parents/care givers should receive information, education and training in pain assessment e)Pain Management of postoperative pain should include both pharmacological and non-pharmacological strategies where ever possible	Anaesthesiologist and PACU staff	Pain Assessment Tools (**Annexure 5)** Pain score sheet

8.8.5	Post operative fluid management should be on 2, 1, 0.5 rule with isotonic fluid . If after 12 hrs, patient can not be shifted to oral ,then hypotonic solution can be given at 4-2-1rule	Staff nurse & Senior resident (Anaesthesia)	Reference Miller 's Text Book of Anaesthesia latest Ed
8.8.6	Each paediatric patient should be accompanied with at least one attendant once patient is stabilised in PACU .	PACU staff.	
8.8.7	Modified Aldrete score should be used for readiness for discharge from PACU	PACU staff and Anesthesiologist	

8.9 PROCEDURE FOR POST OPERATIVE WARD –

S. no	Activity	Responsibility	Document
8.9.1	Pain monitoring should be continued even in post op period for another 72 hrs	Ward nursing staff	Pain score sheet
8.9.2	All paediatric patients with epidural or any other catheter needs to be followed up in the ward .Epidural top ups to be given with advise of consultant .A brief note to be put regarding the same and vitals monitoring to be done at appropriate time by Anaesthesiologist	Senior resident Anaesthesiology	Continuation sheet
8.9.3	Epidural Catheter removal should be done as per the institutional policy and each epidural tip should be checked for integrity and same should be documented	Senior resident Anaesthesiology	Continuation sheet

ANNEXURES of Chapter 5 & 8 are given below :

Annexure – 1

Fasting Guidelines –

Type	**Fasting Time(Hrs)**
Clear liquid	**2**
Breast milk	**4**
Infant formula	**6**
Solid	**8**

Clear liquids include – Fluids without pulp

Clear tea or coffee without milk

Clear liquid and plain toast can be allowed upto 6 hours before surgery.

Annexure – 2

PRE OPERATIVE CHECKLIST

1. CHILD IN OT DRESS, PROPER IDENTIFICATION BAND.
2. NAIL POLISH & JEWELLERY REMOVED, LONG HAIR TIED.
3. REMOVE THE PROSTHESIS AND LOOSE TEETH.
4. CONSENT - FOR ANESTHESIA
   FOR SURGERY
5. PREPARATION OF PART
6. DRUG SENSITIVITY
7. NIL PER ORALLY
8. ALL THE RELEVANT INVESTIGATION AND SPECIAL REPORT SHOULD ACCOMPANY THE PATIENT.
9. LABELLING OF INTRAVENOUS CANNULA.
10. BLOOD TO BE ARRANGED.

(SIGN. OF PRE-OPERATIVE ROOM NURSE)

Annexure – 3

SIGN IN FORM

(BEFORE INDUCTION OF ANAESTHESIA)

PT. NAME…….. AGE/SEX…… C.R. NO……..

1) **PATIENT CONFIRMED**
   a) IDENTITY CONFIRMED : YES/NO
   b) SURGICAL SITE: RIGHT/LEFT
   c) PROCEDURE (FULL NAME) : ……..
   d) LAST MEAL TIME
2) **SITE MARKED**
   a) YES/NO
   b) NOT APPLICABLE
3) **ANESTHESIA SAFETY CHECK COMPLETED**
   a) YES
   b) NO
4) **ANESTHESIA EQUIPMENTS/PULSE OXIMETER FUNCTIONING**
   a) YES
   b) NO
5) **KNOWN ALLERGY**
   a) YES
   b) NO
6) **DIFFICULT AIRWAY/ASPIRATION RISK**
   a) NO
   b) YES, EQUIPMENT & ASSISTANCE AVAILABLE / NOT AVAILABLE
7) **RISK OF BLOOD LOSS>10% OF BLOOD VOLUME (APPROXIMATE 8 ml/KG)**
   a) NO
   b) YES, ADEQUATE INTRAVERNOUS ACCESS & FLUID PLANNED/NOT
8) **SURGICAL INSTRUMENTS/IMPLANTS READY**
   a) YES
   b) NO

SIGNATURE OF ANESTHETIST……

NAME OF ANESTHETIST……..

DATE & TIME……..

ANESTHETIZING TIME / TIME READY FOR INCISION

(BEFORE SKIN INCISION)

PT.NAME:…….AGE/SEX:……**/**…..C.R.NO…….DATE:…….

9) CONFIRM ALL TEAM MEMBERS BY NAME AND ROLE

a) YES
b) NO

10) SURGEON ,ANESTHETIST, NURSE & TECHNICIAN CONFIRM

a) RIGHT PATIENT
b) RIGHT SITE
c) RIGHT PROCEDURE

11) ANTIBIOTIC PROPHYLLAXIS HAS BEEN GIVEN WITHIN LAST 60 MINUTES

a) YES
b) NOT APPLICABLE

12) ANTICIPATED CRITICAL EEVNT

a) SURGEON REVIEW
b) ANESTHESIA TEAM REVIEW
c) NURSING TEAM REVIEWS : STRICTLY CONFIRM / NOT

13) ESSENTIAL IMAGING DISPLAYED

a) YES
b) NOT APPLICABLE

(SIGN. OF ANESTHETIST) (SIGN. OF SURGEON) (SIGN. OF FLOOR NURSE)

(TIME OUT……)

1) **PATIENT NAME & PROCEDURE RECORDED**
   a) YES
   b) NO

2) **INSTRUMENTS, SPONGES & GAUZE PIECES & NEEDLE COUNT**
   a. CORRECT & COMPLETE
   b. NO, SPECIFY…….

3) **SPECIMEN LABEELED**
   a. YES
   b. NO

4) **WHETHER THERE ARE ANY EQUIPMENT PROBLEM TO BE ADDRESSED**
   a) NO
   b) YES, SPECIFY……..

(SIGN. OF SURGEON) **(SIGN. OF SCRUB NURSE)**

SURGEON NAME……. S/N NAME…….

DATE & TIME…….. DATE & TIME……..

ANNEXURE- 4

Paediatric Anaesthesia Equipments and drugs

a) Anaesthesia work station with Paediatric ventilator and other related allied equipments.

b) Resuscitation cart and defibrillator with paediatric paddles.

c) Resuscitation cardiac drugs should be available in paediatric formulations.

d) A written paediatric dose schedule should be immediately available.

e) Airway equipment and difficult airway cart

f) Devices for maintenance of normothermia

g) Intravenous fluid administration equipment No individual measure can be broadly recommended for pain

ANNEXURE -5

Post operative pain assessment tools-

- Wong and Baker FACES Pain Scale (Wong and Baker 1988): valid for 3-18 year olds.
- Faces Pain Scale-Revised (Hicks et al. 2001); see also (Goodenough et al. 1997; Hunter et al. 2000): valid for 4-12 year olds.
- Visual analogue¦ and numerical rating scales (VAS Score): valid for 8 years plus
- CRIES (Krechel and Bildner 1995) see also (McNair et al. 2004-for neonates
- Revised FLACC Scale ;Specially appropriate for cognitively impaired

FACES Score – It comprises of a series of diagrams of faces with expressions of increasing distress with smiling or neutral faces representing “no pain “on one end of the scale.

VISUAL ANALOGUE SCALE (VAS)-It is a numerical rating scale from 0-10

0- No pain , 10- worst pain

CRIES Neonatal Pain Assessment Scale			
	SCORE		
Indicators	0	1	2
Crying	No	High pitch but consolable	Inconsolable
Required oxygen for sat >95%	No	Fio2 <30%	Fio2 >30%
Increased Vital Signs	No	HR or BP increased <20%	HR or BP increased <20%
Expression	No	Grimace	Grimace & grunt
Sleepless	No	Wakes often	Constantly awake
Score <4: Initiate nonpharmacologiical measures. Score >4: Initiate pharmacologic and nonpharmacologic measures.			

Minimum score -0 , Maximum score -10, Satisfactory -less than or equal to 5

Revised FLACC for Pain Assessment in the Cognitively Impaired			
Indicators	0	1	2
Face	No particular expression or smile	Occasional grimace /Frown; withdrawn or disinterested(appears sad or worried)	Consistent grimace or frown :frequent /constant quivering chin, clenched jaw (distressed-looking face: expression of fright or panic)
Legs	Normal position or relaxed	Uneasy ,restless, tense(occasional tremors)	Kicking ,or legs drawn up (marked increase in spasticity, constant tremors or jerking)
Activity	Lying quietly normal position ,moves easily	Squirming shifting back and forth, tense (mildly agitated (e.g. head back and forth ,aggression);shallow, splinting respirations, intermittent sighs)	Arched, rigid or jerking(severe agitation, head banging; shivering(not rigors);breath-holding, gasping or sharp intake of breath; severe splinting)
Cry	No cry (awake or asleep)	Moan or whimpers, occasional complaint(occasional verbal outburst or grunt)	Crying steady ,screams or sobs, frequent complaints(repeated outbursts, constant grunting)
Consolability	Content ,relaxed	Reassured by occasional touching, hugging or talking: distractible	Difficult to console or comfort (pushing away caregiver, resting care or comfort measures)
0=Relaxed /comfortable;1-3=mild discomfort;4-6moderate pain;7-10=severe pain			

9 - CENTRAL STERILE SERVICES DEPARTMENT (CSSD)

Service Name :	**CSSD** **SOP**
Date Created :	
Approved By :	**Medical Superintendent/Medical Director** Name : Signature :
Reviewed By :	**Incharge CSSD** Name : Signature :
Issued By :	**Medical Superintendent/ Medical Director** Name : Signature :
Responsibility of Updating :	**MO I/C Incharge CSSD** Name : Signature :

9.1 - Structure and Organization of CSSD

9.1.1 Purpose: The purpose of the Central Sterile Services Department is to prepare reliable and certified sterilized items available at the required time and place for any agreed purpose in the Hospital as economically as possible, having regard to the need to conserve the time of users.

9.1.2 Objectives: To provide sterilized material from a central department where sterilizing practice is conducted under conditions, which are controlled, thereby contributing to a reduction in the incidence of hospital infection.

To avoid duplication of costly equipment's, which may be infrequently used.
To maintain record of effectiveness of cleaning, disinfection and sterilization process.
To monitor and enforce controls necessary to prevent cross infection according to infection control policy.
To maintain an inventory of supplies and equipment.
To stay updated regarding developments in the field in the interest of efficiency, economy, accuracy and provision of better patient care.
To provide a safe environment for the patients and staff.

9.1.3 Scope: It is a centralized department catering to the sterilization need of the entire hospital.
9.1.4 Procedure: as follows:

Sr No.	Activity	Responsibility	Reference
9.1.4.1	**Policy:** **A. <u>CSSD Area classification (zoning of CSSD)</u>** ***a. General Considerations*** • CSSD shall maintain uni-directional flow of the items processed. Criss-crossing of item must be avoided to reduce accidental mixing of sterile and non-sterile items. • CSSD preferably be located in the operation theatre complex or in immediate vicinity of operation theatre. • CSSD has been divided into 3 zones. There should not be cris-crossing of processes within CSSD. The three zones are: • Protective zone • Clean zone • Sterile zone **b. Protective Zone includes:-**	CSSD Incharge, Chief CSSD Technician	

	• Receiving Window (double door window to contain contamination). • Cleaning Area • Decontamination Area • Drying Area • Assembling and Packaging Area **c. Clean Zone includes:-** • Autoclaving Area/ ETO /Gas plasma Area **d. Sterile Zone includes:-** • Sterile storage room • Issuing window. • In addition to the zoning areas listed above, CSSD must have provision of Office area (for record keeping, file upkeep etc), changing rooms (if not centralized), lockers room, and store room (to maintain inventory of instruments, disinfectants and consumables).		
	B. Reception • The reception deals with the receiving of unsterile supplies and issuance of sterile supplies. It contains rooms for the CSSD workers to change and proceed to working area. No unauthorized person is allowed beyond the reception area.	CSSD Technician/assistant	
	C. Decontamination area • In the decontamination area, all reusable contaminated supplies are sorted and decontaminated. • The CSSD workers in the decontamination area should wear household-cleaning- type rubber or plastic gloves when handling contaminated instruments and items. • Face mask, eye protection such as eye shields/goggles, appropriate gowns should be worn when exposure to blood or body fluid may occur. • Sharps should never be retrieved from trays with gloved hands. Forceps may be used for this purpose. • At least six air changes per hour and a	CSSD Technician/assistant	

	negative pressure is recommended in the decontamination area. • The ceilings and walls should be constructed of a non-shedding material and the floors should be able to withstand the chemicals and disinfectants used in cleaning. • Daily cleaning and maintenance of the facility is needed. • The instruments may be manually cleaned (scrubbed using detergents and appropriate brushes) or cleaned using automated washers or disinfectors. • All instruments with dried secretions should be first soaked in detergent water to loosen up the debris. Ensure the instrument is free of any debris or proteinaceous deposits as this affects the efficiency of the sterilization process. • After washing, each device should be inspected for cleanliness, functionality, breakage or defects and then appropriately assembled. • All items should be properly dried after washing should be properly dried and moisture-free as moisture impairs many sterilization processes. Drying may be done manually or using automated dryers.		
	D. Clean packaging area • Packaging area is used for inspecting, assembling and packaging of clean, non-sterile articles. • Wrapping of the articles before sterilization should be done in such a manner that tenting and gapping should be avoided. • Workers should wear gloves, gowns and masks while packing. • The packaging procedure and material should be validated for the type of sterilization. • Double wrapping may be done sequentially or non-sequentially. • Each pack should be marked with the name and contents of the pack, the initials of the person who packed it and the date and initials of the person who	CSSD Technician/assistant	

	carried out the sterilization.		
	E. Sterilization area • The sterilizer should be loaded in accordance to the manufacturers" recommendations. • Ensure that all the physical and chemical parameters are checked before and during the sterilization cycle. • Maintain complete records of each sterilization cycle.	CSSD Technician/assistant and CSSD Technican Incharge	
	F. Sterile storage area • Following sterilization, all sterile items should be moved aseptically to the sterile area for the storage of items. • The sterile area should be a limited access area with controlled temperatures 75 F and relative humidity (30-60%). • A record of the date of sterilization, physical parameters of sterilization cycle and microbiological tests reports should be maintained for each batch. • All sterile items should be kept in the sterile area till they are supplied to the clinical areas. • Positive pressure and minimum of ten air changes per hour is recommended in the sterilizer equipment room.	CSSD Technician/assistant and CSSD Technican Incharge	
	G. <u>Personnel requirements with their Job description and Job Responsibilities</u> ***a. CSSD Incharge:*** • Responsible for administrative aspects of the department. • Ensure that CSSD delivers superior performance as per standards and hospital policies. • Monitor and control overall quality of service provided by the department. • Regularly updated in new advancements and implementation of same with regard to economy, efficiency, reliability. • Safety of procedures and safe working of personnel • Provides a comprehensive departmental orientation to all new	Medical Superintendent/ Medical Director	

	personnel and required training to all staff on an ongoing or periodic basis. ***b. OT Technician(Senior / Junior):*** • Receive and issue of sterilized items requested by the various departments • Establishes and maintains internal inventory and monitors them for proper utilization. • Sterilize instruments, equipment, linen and supplies using sterilizers/ autoclaves in prescribed manner and set controls to specified time and temperature according to the type of items being sterilized. • Ensure sterility of all materials received in CSSD. • Store all supplies and equipment, in appropriate locations with proper labels. • Responsible to run microbiological and chemical tests (sterility checks) periodically. • Perform as in-charge for various shifts and ensure quality service • Appropriate documentation of sterilization process and Maintain all registers and records. • Maintenance and efficient working of all machines & devices of CSSD (autoclaves, sterlizers, working computer) • Manage complete work flow during each assigned shifts and ensure coordination with other departments. • Perform all duties assigned by the CSSD incharge ***c. Staff Nurses:*** • Responsible for timely receiving sterilized items & handing over instruments, equipment, linen and supplies with proper labels and packing. • Disassemble, decontamination, and clean equipment using resources provided as per policy • Assemble all instruments, procedure		

	trays, packs following prescribed manner using content slip as guide. • Responsible for proper segregation of different categories of wastes generated after every procedure and handing it over to the Biomedical Waste collection personnel • Proper instructions to NO/MPW for delivery to CSSD and receive back. ***d. Nursing Orderly/Multi purpose worker:*** • Time bound delivery and transfer of items • Maintain a log of said items • Helping the staff nurse in packing, labeling and other works as assigned ***e. Housekeeping staff:*** • Responsible for Cleaning CSSD and associated area as per procedure specifications provided by the infection control program. • Responsible for proper segregation of different categories of wastes generated after every procedure and handing it over to the Biomedical Waste collection personnel. • Perform other works assigned by the CSSD incharge, other staff.		
	H. <u>Dress Code</u> • All staff of the Central Sterile Supply Department is required to follow a strict dress code, no staff is allowed to enter the department with the external clothes. Prior to the entry of the staff to the department, each and every staff of the Central sterile Supply department is required to change into appropriate departmental dress code with the required personal protective equipment (Similar to operation theatre). • Staff moving into the wash area, who will be engaged in the handling and processing of incoming equipment, will put on an extra protection gown, gloves and protective goggles (when splashing is anticipated) in addition to	CSSD Technician/assistant and CSSD Technican Incharge	

	the departmental uniform • When leaving the wash area staff will remove and discard the gown and gloves and wash their hands. • Prior to entering the preparation area all staff and visitors will wash and dry their hands and put on the relevant PPE • Staff visiting from other areas will wear the departmental uniform and must comply with the dress code when moving to other areas of the department.		
	I. <u>Receipt and Issue of Packs:</u> • Receipt of items from various point of generation: From 9.00 am to 12.30 pm. (Timings shall vary based on needs of the healthcare units/hospitals where CSSD is functioning). • Issue of sterile packs from the CSSD: • From 2.30 pm to 3.30 pm. (Timings shall vary based on needs of the healthcare units/hospitals where CSSD is functioning). • However in high-risk patient care units like OT, ICU, Dialysis and Emergency Department etc are exempted from the above mentioned time dimensions since it is difficult to restrict their activity within specific time limit due to the emergency nature of care provided by them. • Emergency staff shall make sure of all resources for the emergency situations and holidays in advance. • Emergency/OT staff should be trained periodically for the steam sterilization, autoclave or available sterilizing machine as a back-up for emergency situations demanding high turnover of resources.	CSSD Technician/assistant and CSSD Technican Incharge	
9.1.4.2	**Safety Considerations at CSSD** **A. <u>Purpose</u>** • To establish an overview of guidelines and safety awareness procedures in the Sterile service department.	All personnel that are assigned or engaged in Sterile service operation	
	B. General Procedure General Guidelines • All personnel must follow established work and traffic flow patterns. • Material Safety Data Sheets (MSDS) for	All personnel that are assigned or engaged in Sterile service operation	

	all chemicals used in the sterile service department must be available in a binder index. Risk matrix and first aid procedures of all chemicals used should be prepared based on information in MSDS and prominently displayed for the CSSD staff. • Employee must be trained in a safe work procedure and be aware of any relevant procedures, policies. • All employees must be trained in appropriate personnel protective equipment designated for each area. • Employees must adhere to dress code and policies before entering and when leaving the area. • Employees must follow and practice hand-washing guidelines (before and after each tasks) in accordance with WHO guidelines. • Eating and drinking is prohibited in all workspaces including supply storage, processing and decontamination sections. • Workspaces must be free from clutter and have un-obstructed entrances and exits. • Visitors are prohibited from entering CPD spaces without permission. • If visitors must enter restricted areas, appropriate attire is required and CSSD staff should escort them.		
	C. Patient Safety • Ensure that all items are processed according to established guidelines (manufacturer's instructions). • All CSSD personnel should be trained in Decontamination and Sterilization Practices. • Safe keeping of all items by ensuring that storage areas are kept clean, storage cupboards are locked, and equipment is covered and preventive maintenance is performed on all equipment. • Assure there is no contamination of patient care areas during collection and transportation ofcontaminated items.	All personnel that are assigned or engaged in Sterile service operation	

	D. Employee Safety • Prevent burn injuries when loading or unloading steam sterilizers and washer disinfectors by following procedure and wearing appropriate PPE. • Employees must use proper body mechanics when carrying or handling heavy items. • Use care and caution when handling sharps. • Maintain "line of light "when handling medical devices. • In the decontamination area, employees must wear proper personal protective equipment(PPE) to prevent direct exposure from contaminants and injury that could result whenhandling contaminated and sharp instruments. • Appropriate PPE must be worn when handling chemicals used for cleaning anddecontamination. • When receiving or handling contaminated items, always wear the correct PPE for the task. • Use of electrical extension cords is prohibited in sterile service areas. • All employees must be aware of fire and safety regulations. • Refer to MSDS before handling chemicals. Matrix of all chemicals used should be prepared and prominently displayed. • If spills occur, refer to policy management of body fluids spillages or consult safety representative. • Regular training of all CSSD staff should be done with regards to safety and recall procedures.		
	E. Expected Outcomes • Safety audits must be carried out on periodically (at least monthly) per prescribed format). For model safety audit sheet see Annexure 1. • Feedback of the audit must be given to all relevant CSSD staff and Hospital infection control committee.	Medical Officer incharge CSSD and CSSD Technican Incharge	
9.1.4.3	**Cleaning and hygiene at CSSD**	CSSD Technican Incharge	

	A. Purpose • To ensure an acceptable level of hygiene and cleanliness throughout the CSSD area for the upkeep a clean environment for preparing items for high level disinfection and sterilization, to maintain the cleanliness in CSSD & to reduce and minimize source of infection.		
	B. **<u>General Cleaning of the Department</u>:** **a. General Area** • The CSSD should be cleaned in accordance with the cleaning schedule • Cleaning will take place before work commences or after work is completed, in the case of a 24hour facility cleaning will be rotated through areas when work is not in progress • The cleaning schedule will specify frequency of cleaning • A departmental cleaning inspection report will be prepared each month (at random times) by the Sterile Services Manager or Senior Staff • Designated cleaning equipment will be stored in a designated area for that area's use only. • Cleaning work will only be undertaken by Staff trained to work in that area • CSSD staff are responsible for making sure that all surfaces are clean • All cleaning procedures and cleaning chemicals used in the department will be in line with • Recommendations by hospital infection control department. • The use of brooms is not recommended and is strongly discouraged. Only wet mops should be used for housekeeping work. C. **Packing area**	CSSD Technican Incharge	

	• Wipe working table, shelves and trolleys with the recommended disinfectant. • Wipe the machines with damp cloth. D. **Sterile packs Storing** • Wipe the shelves and walls with recommended disinfectant weekly. • Mop the floor twice daily and ensure that the mop that is used is only meant for the sterile store. E. **Decontamination area** • Wipe the trolleys with recommended disinfectant daily. • Wipe the machines with a damp cloth daily. • Mop twice and as and when required with the recommended disinfectant. • The floors are cleaned thoroughly and polished whenever required. **F. Expected Outcomes** • Housekeeping audits must be carried out on periodically (at least daily as per prescribed format). For model house-keeping audit sheet see Annexure 2. • Feedback of the audit must be given to all relevant CSSD staff and Hospital infection control committee at least on monthly basis.		
9.1.4.4	**Collection of contaminated/soiled items from patient care units** **A. Scope** • To define the process of receiving of contaminated/ soiled items from different patient care units of the hospital to CSSD **B. Purpose** • To ensure appropriate handling, transport and receiving of soiled/contaminated items is safe manner and appropriate	Staff nurse sending the items from different patient care unit, CSSD technician manning the CSSD receiving area, Helper/orderly/MPW transporting the items to CSSD.	

	documentation of the same.		
	C. Materials • Puncture proof and leak resistant trolleys with removable bins, dedicated instrument trolleys. • Trolleys should have covers and should be marked with "Non- sterile items" and Biohazard symbol affixed. • Personnel (Helper/Orderlies) shall wear personal protective equipment including clothing, mask, and safety footwear. **D. Procedure** • Items are sent in appropriate trays after primary rinsing (to remove gross contaminants such as blood, urine, feces etc) in the patient care unit using all safety precautions mentioned in the hospital infection control manual. • Wash hands in accordance with departmental procedures. • Non-sterile gloves must be worn for the collection of instruments and be discarded into the medical waste container at each collection point. • Contaminated linen, gowns or sheets can be packed in red bag whereas non-contaminated linen can be kept in black bag for easy identification. • Collect used items in puncture resistant containers; do not overload. • Items are listed as in tray content list with tray name, items and their nos. under the name of the tray/pack in CSSD dispatch register. • Use allocated trolleys for transport of items to CSSD • Place heavy instrument containers at the bottom of trolleys. • Secure contaminated items and cover prior to transportation. • Transport / Deliver used items and equipment to the cleaning area • Follow designated collection route, and timetable in accordance with	CSSD Technican Incharge, Nursing I/C Patient care unit	

	department guidelines. • Do not leave contaminated goods unattended during transportation. • Unload and sort items in the receiving area. • Clean and disinfect collection trolleys and bins and store appropriately. • Remove gloves and wash hands according to Policy. • The CSSD technician receives the unsterile packs, inspects them to check the status of the item (torn, punctured, cracked etc) and places them at the unsterile packs storing platform. Entry is made in CSSD receipts register including date, time, type of instruments in the pack, its source, procedure used for, and case infected or not, name and signature of person handing over, and name and signature of person receiving it. • Receiving entries are also made into the patient care unit register with name, time and date of receiving at CSSD. • All effort must be made to facilitate transport of contaminated equipment to decontamination area as soon as possible to facilitate cleaning. • Prompt processing of items will likely decrease potential hazards associated with contamination.		
	E. Expected Outcomes • Appropriate type and number of items are received from the patient care units in safe and secure manner. • Safe handling, collection and transportation of contaminated equipment, ready for further processing • Turn around time can be monitored with this initial point of receiving of items. • Items discard rates for the patient care unit can be calculated as – Total no. of trays/sets with deficient instruments/items / Total no. of sets/trays received X 100 during the	Medical Officer Incharge CSSD and CSSD Technican Incharge	

	defined period of time.		
9.1.4.5	**Processing of the contaminated/soiled instruments Decontamination** **A. Purpose** • To ensure that all soiled instruments & linen returned to the CSSD decontaminated to acceptable level **B. Scope** • All instruments and equipment returned to CSSD • All new equipment prior to introduction for use	OT technician, staff trained in decontamination process Decontamination done at source (OT/wards/procedure rooms) by staff nurse	
	C. Materials • Personal Protective Equipment • gloves • aprons, gowns, overalls (single-use, fluid- repellent, disposable) • masks • face and eye protection • footwear • Washers, Washing Machines, Ultrasonic cleaner • Double sinks with plugs, Hot and Cold running water, Elbow taps, High pressure cleaner • Detergent, Stain Remover,Brushes, Enzymatic solutions • Disinfectants • Ironing devices **D. Procedure** • Maintain segregation of decontamination area within the department. • Staff working in this area will wear protective clothing at all times in compliance with the • Standard precautions dress. PPE is additional to the uniform code for your specific workingenvironment. • Apply standard precautions for infection control and other relevant health and safetymeasures. • Linen and waste must be separated	Staff trained in decontamination process	

	from reusable medical devices at the point of use. • Gross contaminants such as large amount of blood, feces, urine, etc. must be removed at thepoint of use, in accordance with safety procedures. • Use and store all equipment chemicals and materials in accordance with manufacturer's • Instructions and institutional policies and procedures. • Ensure that stock of chemicals and materials that are rotated so that oldest is used first. • Comply with manufacturers' and organization specifications when using all appliances andprocessing of medical devices. **E. Primary Processing –Decontamination (Step 1)** • Decontaminate instruments and other items by placing them in a plastic container of 0.5% Hypochlorite solution/Bleaching Solution. Let them soak for 10 minutes. A container of this solution should be kept in every operating theatre and procedure room, so that used items can be place directly into the bucket. • Users should put instruments and other items into the solution as soon as they are finished using each item. Open or unlock jointed instruments, such as hemostats and scissors. Disassemble those instruments with sliding or multiple parts. • After 10 minutes, remove the items from the Hypochlorite solution/Bleaching Solution and either rinse with water or clean immediately. Do not leave items in the solution for more than 10 minutes, since excessive soaking in the solution can damage instruments and other items. Always wear gloves when removing instruments and other items from a chlorine solution. Dried out		

	instruments then can be taken for further processing. • STEP 1 has to be performed at User area or at source. All other steps to be performed at CSSD. **F. Primary Cleaning (Step 2)** • Cleaning is the removal of foreign material (e.g., soil, and organic material) from objects and is normally accomplished using water with detergents or enzymatic products. • Thorough cleaning is required before high- level disinfection and sterilization because inorganic and organic materials that remain on the surfaces of instruments interfere with the effectiveness of these processes. • If soiled materials dry or bake onto the instruments, the removal process becomes more difficult and the disinfection or sterilization process less effective or ineffective. • Surgical instruments should be pre-soaked or rinsed to prevent drying of blood and to soften or remove blood from the instruments. • Handle contaminated devices as little as possible. • Avoid contaminating hands with soilage. • Steps of Cleaning • Always wear utility gloves, a mask, and protective eyewear when cleaning instruments and other items. Avoid using steel wool or abrasive cleansers. These products can scratch or pit metal or stainless steel, resulting in grooves that can become a nesting place for microorganisms. This also increases the potential for corrosion of the instruments and other items. Step 1 Soak or wipe with damp cloth at a point of use to prevent drying of bio-soil on instrument.		

	Step 2 Using a soft brush or old toothbrush, detergent, and water, scrub instruments and other items vigorously to completely remove all blood, other body fluids, tissue, and other foreign matter. Hold items under the surface of the water while scrubbing and cleaning to avoid splashing. Disassemble instruments and other items with multiple parts, and be sure to brush in the grooves, teeth, and joints of items, where organic material can collect and stick. Step 3 Rinse items thoroughly with clean running water to remove all detergent. Any detergent left on the items can reduce the effectiveness of further chemical processing. **Step 4** Allow items to air-dry (or dry them with a clean towel). **Note:** Instruments that will be further processed with chemical solutions must dry completely to avoid diluting the chemicals; items that will be high-level disinfected by boiling do not need to be dried first. **G. Secondary Processing – Cleaning, washing and drying** • LINEN(Laundry function essentially) • Bags of soiled textiles should be taken to a dedicated soiled linen area i.e. a dirty area • Standardized validated washing and disinfecting processes should be used. • Moisten soiled textiles to prevent staining. Treat stains to prevent them setting. • Stains must be removed if possible, holes must be repaired • Soiled textiles should be sorted before being loaded into washer, to prevent		

	damage to machines from sharps and instruments. • A cold prewash rinse cycle will remove gross soilage preventing it from baking onto the fabric. • A hot detergent cycle of at least 91 degrees C will destroy microorganisms. • A minimum wash time of 25 minutes is commonly recommended. Soaps or detergents loosen soil and also have some microbicidal properties, so it is crucial to use only recommended detergents that will also not cause irritation to skin. • The drying cycle is an important part of the cleaning process as it assists in killing any remaining microorganisms that may be left after the laundry machine has done its work. • Drying in a dryer is recommended, as the heat can be very efficient in killing microorganisms, air drying in direct sun-light is also an option. • Linen to be sterilized must be appropriately wrapped before being sent to the sterile processing department. Linen must not be placed or stored on the floor. • Linen must be stored in a dedicated clean storage area **H. Expected Outcomes** • Cleandecontaminated items when inspected visually • Clean linen when inspected visually		
9.1.4.6	**Inspection, repair and replacement of instruments** **A. Purpose** • To ensure that all instrument are inspected and to effect repair/replacement of broken or damaged instruments. **B. Scope** • All instruments before reaching CSSD inspected at source	Incharge CSSD Technician	

	(OT/wards/procedure rooms)		
	C. Materials • Quality Manual • Relevant Repair/Condemning documents • Instruments • Lubricant • Good lighting **D. Procedure** • All instruments that needs repairs /replacement shall be done at CSSD level. Different patient care units including OTs shall send demand to the CSSD for various instruments and tray sets. • Feedback from theatres regarding repairable or damaged instruments is vital. This information must be marked on the checklist. • Broken or damaged instruments will be decontaminated prior to sending for repair and a decontamination certificate sent with the consignment. • All instruments should be visually inspected following the cleaning and drying process. • All parts of the instrument should be inspected for visible soilage: • blood • protein and other residue • body fluids • feces, vomitus • All instruments must be checked for visible damage: • breaks and cracks • deformed • signs of wear • discoloration, rust, corrosion. • All instruments with lumens must be checked for blockages. • cannulas and recessed areas • hinges, joints • serrations, shafts • Functional Checks should be performed on all instruments if possible: • Always apply lubricants to the instruments before checking function, repeated	Designated Trained CSSD personnel	

	• opening and closing of the instrument will spread lubricant. • Lubricate joints, threads and gliding surfaces prior to any function tests • Instruments must operate smoothly • Check for bent or broken tips or guide pins or broken springs • Check for bent jaws, ratchets and shanks • Grasping surfaces must be in firm contact with each other. • Serrations/grooves slot into each other when the instrument is closed. • All defective instruments should be reported and sent for repair. • Instruments identified as needing repair are placed in a dedicated tray in the preparation • room after following the wash/decontamination procedure • The records will be maintained by the technician in the area and any repair received back • will be issued to the technician who will complete the documentation. • Maintenance and care should be routinely performed. This includes targeted application • of lubricants and stain removers. • Replacement of instruments should be done after their life and as per the hospital policy. **E. Expected Outcomes** • Instruments must be free of visible soil • Instruments are suitable for their intended use • Regular servicing ensures optimal instrument life and is economical	Incharge CSSD Technician	

Sr No.	Activity	Responsibility	Reference
9.1.4.7	**Checking, assembling instruments & Packing materials** **A. Purpose** • To ensure that all instrument sets are complete and safely packed before sterilization. **B. Scope** • All instruments intended to be sterilized (at source & CSSD) **C. Materials** • All instrument sets for use in theatres and ward procedure packs. • Checklist. • Stainless steel trays, protective device covers. • Packing materials. • In pack indicators. • Labels/Labeling Gun. • Packaging Accessories e.g. Tape, sealers. **Ideal Packaging systems should :** • provide an adequate barrier to microorganisms, particulates, and fluids, • maintain sterility of package contents until opened, • allowsterilant penetration and direct contact with the item and surfaces, and removal of the sterilant, • be free of toxic ingredients and nonfast dyes, • permit aseptic delivery of contents to the sterile field (eg, minimal wrap memory, removal of lids from containers); • permit complete and secure enclosure of item(s), • protect package contents from physical damage (eg, compression, stacking), • provide adequate seal integrity, • resist tears, punctures, abrasions, and prevent the transfer of microorganisms,	Designated Trained CSSD personnel,	

	• be tamper-proof and able to seal only once, • permit adequate air removal, • be low-linting, • permit identification of contents, • allow ease of use by personnel preparing and/or opening the package or container, • have a favorable cost/benefit ratio or economical, • include manufacturer's instructions for use.		
	D. Procedure • Staff working in this area will wear protective clothing at all times in compliance with the • standard precautions dress code. • Make sure that all work surfaces are clean according to department • procedure. • It is critical that staff understand what the instruments are used for, that they are functioningcorrectly and that each set is assembled in the proper manner for any given procedure. • Trays should be perforated to allow penetration of the sterilizing agent and efficient drying. • The person checking should indicate and sign that the quantities are correct and that nothingis missing. • Instruments must be laid out according to the order on the check list. • Trays are usually packed in the order that instruments are used. • The weight of packs must be taken into consideration when assembling trays. • Instrument trays must be assembled to maximize instrument exposure to the sterilant • Choose the relevant tray checklist for the instrument set • Place a small strip of autoclave tape in the margin on the front of the tray list, making surethat no information is covered. • Check that all instruments are present		

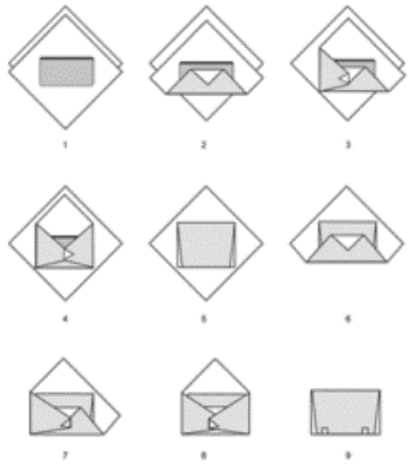
	against the checklist, check instruments one by one. • Check instruments visually for cleanliness and missing parts (tips, screws, free movement,sharpness and overall condition). • Do functionality tests on all instruments to check that they are working effectively. • Instruments with ratchets or hinges should be held in an open and unlocked position; • extended/complex multiple-part instruments should be disassembled or sufficiently • loosened to permit the sterilizing agent to come into contact with all parts of the instrument. • Instrument should be left slightly open to allow for sterilant penetration, rings should be slightly separated. • Tips of instruments should all be facing the same direction the use of tip protectors is oftenadvised by the manufacturer. • Always make sure that all parts of the instruments are present • Heavy instruments should be placed at the bottom of the tray as the weight of heavy • instruments or retractors lying on top or over other instruments can cause the instruments atthe bottom to bend and become misaligned. • Placing the instruments in a single layer will provide more protection to the instruments. • Place an in-pack chemical indicator into the densest most challenging part of the tray. This indicator will only change color if the in pack sterilization parameters have been reached, i.e. depending on class of indicator used, steam, time and temperature. • Ensure that the tray checklist is dated and signed by the packer and checked • Sterile packaging must provide protection against contamination		

	during handling as well asproviding an effective barrier against microbial penetration. • An ideal packaging should have the ability to allow sterilization agents to penetrate and thenprovide a barrier, which will maintain the sterility of the wrapped devices. • The packaging should allow air that is in the pack to be driven out and the sterilizing agent toreach all surfaces of its content. • The packaging should protect the contents against damage during handling and transport. • The packaging should be able to withstand the conditions during the sterilization process suchas pressure changes, high temperature and humidity • The packaging should bear a clearly visible marking indicating whether or not the product hasbeen through a sterilization process. • There are many different types of packaging that can be used for different items • Packaging material used in steam sterilization must be able to withstand high temperatures,allow for adequate air removal, be flexible considering changes in pressure during theprocess, permit steam penetration to the pack's contents and allow for adequate drying. • Packaging materials used with low temperature sterilization processes (e.g., ethylene oxideand gaseous hydrogen peroxide processes) must have similar properties, particularly beingcompatible with the sterilization chemicals, moisture, pressure changes and temperatureranges. • The packaging system chosen should be appropriate for the items being sterilized andcompatible with the specific methods of sterilization being used. • Choose packaging to suit the dimensions of the instruments/tray and		

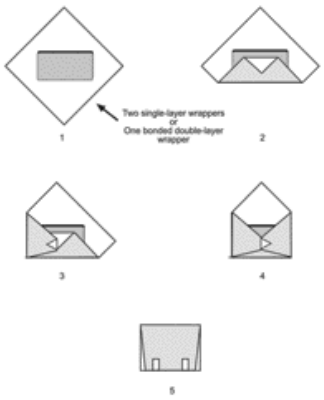
type of sterilizationtechnique to be used.

E. Medical Grade single Use Disposable Sterilization Wrap

- Double wrapping creates a package within a package.
- Two sheets of wraps are used providing multiple layers of protection of surgical instrumentsfrom contamination. Double wrap = wrap and wrap
- It can be either Sequential Wrapping Technique or Simultaneous double-wrapping: envelope fold technique
- The use of two layers of wraps reinforces the strength of the packaging.Folding the two wraps separately, one after the other makes the pack more secure, as thegreater the number of folds the more tortuous the path becomes for micro-organisms topenetrate into the packaging.
- The double wrap with two sequential folds also affords a two-step unwrapping process whichassists in aseptic presentation and creation of a sterile field for users in the operating theatre;the outer wrap is removed before entering the operating room or by an assistant.
- Use a hospital grade masking tape and autoclave tape when using wrap.



Double wrap technique (Sequential)

	 ***Double Wrap Technique (Simultaneous)***		
	F. Disposable Peel-open Pouches and Reels • Paper/Plastic peel-open packaging materials are suitable for steam, steam formaldehyde andlow temperature sterilization processes such as ethylene oxide. It is not suitable for use inhydrogen peroxide gas and ozone sterilizers, again due to the paper (cellulose) content. • Disposable peel-open pouches and reels are designed to contain lightweight or small itemsand are available in various sizes, for single use only. • Pouches are available in many sizes or can be cut to any size needed. • The open end of the pouch is closed with a sealing device. It is essential that the heat sealer isfunctioning effectively in order to get an adequate seal. • When double pouching, the inner pouch should be at least a size smaller than the outer pouchto prevent folding which may entrap air and inhibit the sterilization process. They must bepackaged paper against paper, plastic against plastic in order to enable sterilant penetration.		
	G. Reusable rigid container systems • Sterilization containers are a durable sterilization packaging system constructed of a rigidmaterial such as metal, or plastic. • A variety of sizes can accommodate a wide range of instrument sets. • Containers must be cleaned in the same way as any other reusable		

	device. • Ergonomics of container design for ease of carrying • Ease of locking and closing the container. • Ability to stack containers for storage and transportation. 		
	H. Woven fabrics • usually 100 percent cotton, cotton polyester blends and synthetic blends, either treated oruntreated **I. Nonwoven materials** • Made of plastic polymers, cellulose fibers or washed paper pulp bonded under pressure into sheets not woven on a loom. • These are usually designed for single use.		
	J. Expected Outcomes • Instrument sets are correctly assembled ready for packaging and sterilization • Pack integrity is maintained through correct use of packaging		
Sr No.	**Activity**	**Responsibility**	**Reference**
9.1.4.8	**Preparation of items for High level disinfection (HLD) and the disinfection process** **A. Purpose** • To ensure high level disinfection of equipments/instruments for their intended use **B. Scope** • Delicate& heat sensitive instruments which cannot be autoclaved **C. Materials** **a. High Level Disinfectants:** Ex.: 2%	CSSD personnel, OT staff	

	Glutaraldehyde, Ethylene Oxide, 1%Sodium Hypochlorite (10,000ppm of chlorine) **b. Intermediate Level Disinfectants:** Ex.: Isopropylalcohol (70%), ethylalcohol, sodium hypochlorite (0.1%), Chlorhexidine, hydrogenperoxide, phenolic solutions **c. Low Level Disinfectants:**Ex: Quaternary ammonium compounds like benzylkonium chloride, some soaps		
	D. Procedure **a. List of items to be subjected for HLD** Endoscopes, telescopes, laryngoscopes Heat sensitive instruments Light cables, gas tubings vaginal specula, nasal specula, etc		
	E. **Classification of Disinfectants** **Definition:** Disinfection is a process where most microbes are removed from defined object or surface, expect bacterial spores.High level disinfection is that which kills all microganism and high number of bacterial spores. **a. High Level Disinfectants:** • They destroy all microorganisms including vegetative bacteria, most bacterial spores, fungi, viruses including enteroviruses and mycobacterium tuberculosis except some bacterial spores. • Ex.:-2% Glutaraldehyde, Ethylene Oxide, 1%Sodium Hypochlorite (10,000ppm of chlorine) • Used for semi critical instruments and equipments (those that are in contact with intact mucous membrane without penetration) • For gastrointestinal endoscopes, endotracheal tubes, anesthesia breathing circuits, respiratory therapy equipments. **b. Intermediate Level Disinfectants:** • They destroy vegetative bacteria, Mycobacterium tuberculosis, most viruses e.g. entero viruses and fungi but not bacterial spores.		

	• Ex.: Isopropyl alcohol (70%), ethyl alcohol, sodium hypochlorite (0.1%), Chlorhexidine, hydrogen peroxide, phenolic solutions. **c. Low Level Disinfectants:** • They destroy most vegetative bacteria, fungi and enveloped virus e.g. HIV but will not kill bacterial spores, Mycobacteria and non enveloped viruses like enterovirus. • Ex: Quaternary ammonium compounds like benzylkonium chloride, some soaps.		
	F. Guidelines for Selection of Disinfectants: There is no ideal disinfectant. Each application requires careful view of following: • Type and number of organisms. • Type and amount of organic matter • Contact time • Type of surface (Rough / Corrugated) • Type of water (hard / soft) • Manufacturers data on efficacy • Safety and environmental aspects (chlorine is not free from toxicity) • Cost, shelf life and convenience of use • Residual activity		
	Two Approaches for Selection of Disinfectants: i. Accept the manufacturers data ii. Validate yourself		

Guidelines for Use of Disinfectants

Name of Disinfectant	Method of Dilution	Contact Time	In Use Span/ Use
Aldehyde Solutions: a. Glutaraldehyde (2%)	Add activator powder / liquid to the liquid in 5 liter jar and use undiluted	Disinfection: 20-30 mins Sterilization : 10 hours	14 days used for heat sensitive instruments e.g. Endoscopes
b. OPA (orthophthalyl aldehyde)	Same as above	Same as above	Long acting (28 days)
c. Glutaraldehyde + Formaldehyde + Benzyl chloride	water 1 part : 49 parts (20 ml + 980 ml)	Disinfection : 15 min Sterilization : 5 hours , 30 min	24 hours Used as surface disinfectant or 2% solution in operation theaters and 0.5% in wards, dressing room. Can be used in a low pressure sprayer.
1% Sodium Hypochlorite Ex. : Polar Bleach 5% Polar Bleach10%	**5%:** 80 ml water + 20 ml bleach to make it 1% solution. **10%:** 90 ml water + 10 ml bleach	20-30 minutes	8 hours Used for blood spills and laboratory decontamination
(2 propanol - 1 propanol, macetroniumethylsulfate)	Ready to use	30 seconds	Hand rub
(Stabilized H_2O_2 11% w/v with 0.01% w/v diluted silver nitrate solution)	10 % w/v solution 20% w/v solution	60 minutes 60 minutes	Surface disinfection For fogging*

*(Fogging is not routinely recommended)

General Guidelines For Disinfection

- Critical instruments /equipments - (that are those penetrating skin or mucous membrane or enter sterile tissue or vascular system) should undergo sterilisation before and after use. e.g. surgical instruments and implants
- Semi-critical instruments /equipments - (that are those in contact with intact mucous membrane without penetration or skin that is not intact) should undergo high level . e.g laryngoscopes, Aneasthesia equipment.
- Non-critical instruments /equipments - (that are those in contact with intact skin and no contact with mucous membrane) requires only intermediate or low level disinfection before and after use.e.g. ECG electrodes

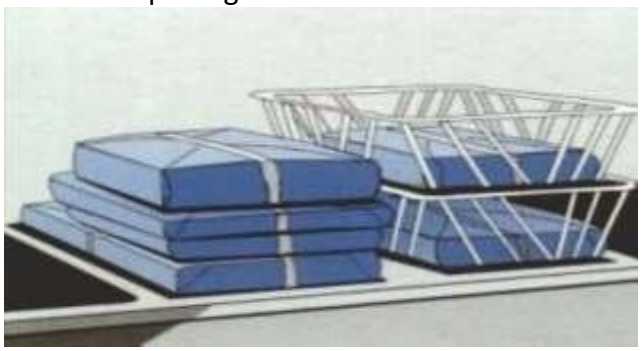
Classification	Item Use	Goal	Appropriate Process
Critical item	Items entering sterile tissue, the body cavity, the vascular system and non-intact mucous membranes Eg surgical instruments	Objects will be sterile (free of all microorganisms including bacterial spores)	Sterilization (or use of single use sterile products) (steam sterilization)
Semi-Critical items	Items that make contact, directly or indirectly, with intact mucous membranes or non-intact skin. E.g. endoscopes, anaesthetic equipments, Respiratory therapy Equipment Endocavitory probes Tonometer Diaphragm	Objects will be free of all microorganisms, with the exception of high numbers of bacterial spores	High level disinfection · Thermal disinfection · Chemical disinfection (glutaraldehyde, OPA) It is always preferable to sterilize semi-critical items whenever they are compatible with available sterilization processes.
Non-Critical items	Objects that come into contact with intact skin but not mucous membranes Eg crutches, BP cuffs, Tabletops Bed pans,bed rail, bedside table, ECG leads etc	Objects will be clean	Low level disinfection Cleaning (manual or mechanical)

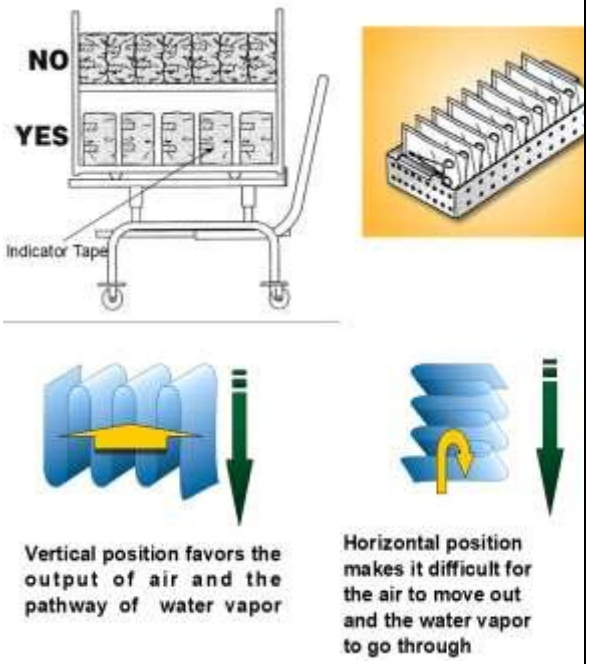
Packaging of items after High Level Disinfection (HLD)

- Processed endoscopes should be stored by hanging them in the vertical position in a clean area, preferably in a cabinet.
- Other items should be placed in clean packages or wrapped in clean cloth wraps and stored on a clean shelf or in a clean drawer.
- Date of HLD and shelf life be clearly labelled on the packet or chamber.

Expected Outcomes

- All equipment is sterilized to an acceptable level before intended use.

Sr No.	Activity	Responsibility	Reference
9.1.4.9	**Packaging of items for steam sterilization** **A. Purpose** • To ensure that the correct materials are used and that items are correctly packaged in order to maintain sterility **B. Scope** • Items meant for steam sterilization **C. Materials** • All instrument sets for use in theatres and ward procedure packs. • Checklist • Stainless steel trays, protective device covers • Packing materials • In pack indicators • Labels/Labeling Gun • Packaging Accessories e.g. Tape, sealers	Trained CSSD staff/Infection Control Department	
	D. Procedure **a. Packing & Loading** • For effective sterilization, selection of packaging material plays important role apart from sterilization parameters. The following are keys in selecting a suitable packaging material. • The packaging material must be permeable to sterilizing agent. • The packaging material must be impermeable to bacteria and other contaminants. • The packaging material must resist tears and punctures. • It should facilitate aseptic presentation of packaged content.  **Textile pack should not exceed 5kg or exceed 30cm wide by 30cm high by 50cm long.**		*Handbook of Infection Control. **Acknowledgement as on page 178**

	 **Package the object loosely** **Reference: - Acknowledgement page 179**		
	• Proper loading of material inside sterilizer is very critical for efficient sterilization. Relative humidity in the processing area should be at least 35%. • When loading sterilizer there should be space between item to facilitate circulation and penetration of sterilant. • There should be no contact between items and chamber wall. • In mixed load linen should be kept on top racks and metal on bottom • Peel pouches should be kept on the edge facing same direction • Textile should be kept on the edge • Instrument sets should be placed flat.  **Reference: ***		*Handbook of Infection Control. **Acknowledgement as on page 178**
	b. Monitoring: • Mechanical, chemical and biological monitors can be used to evaluate the effectiveness of the sterilization process. • Each load is monitored with mechanical (time, temperature, pressure) and chemical (internal and external) indicators.		

	• Biological indicators (spores) should be used weekly to monitor the effectiveness of sterilization. Vials are removed from sterilizers and put in designated incubator in CSSD. Monthly report are sent to ICN. • Chemical indicators as strips should be used with every batch. • An expiry date is given for sterile articles based on the packing material used.		
	E. <u>Quality Indicators (Before use & after use).</u> **a. Monitoring protocol of Autoclave :** • *Temperature, Pressure and time* of each cycle is recorded is followed according to manufacturer's recommendations. Records should be maintained for each cyle. • Various *quality indicators* are used to check the efficacy of sterilization: b. **Exposure control:** • Autoclave indicators tapeis pasted on all packs to be kept in autoclave. c. **Load Control:** • Biological indicators (spores of *Bacillus stearothermophilus*) are used once a week (Monday) in all autoclave machines in first load and with every load which contain any implant. This indicator gives us rapid results, i.e. positive result in one hour and negative result in 3 hours. If result is positive means sterilization is not adequate that whole load is recalled & re-autoclaved. d. **Pack control:** • Class 5 chemical integrator - It is used in every pack. e. **Equipment control:** • Bowie-dick test pack – It is used once daily in each machine. f. **Environmental monitoring in sterile zone:** c. *Air cultures* are taken once in a month from sterile zone.		
	F. ***Important considerations:*** • *Wet pack* is not accepted as sterile. These are repacked and resterilized (even if the indicators show the appropriate changes. • There are *different trolleys* for carrying sterile and unsterile instruments White (or Black)&		

	Red respectively. • No person is allowed to enter in sterile room without *Personal ProtectiveEquipments (PPE)* (i.e. Cap, mask, gown, & slippers etc.) • All sterile items must be used within 72 hours after 72 hours items should send to CSSD for re autoclaving		
	G. List of common trays and sets • Needs to be defined at hospital level as determined by types of procedures being done in the organization. • Examples of trays/sets include: • Central line insertion set • Urinary catheterization set • Lumber puncture set • Chest tube insertion set • Venous Cut down set • Clean – lacerated wound management Set • Cholecystectomy set • Exploratory laparotomy set • Herniotomy set • TURP set • Cystoscopy set • Tracheostomy set • ORIF set		
	H. Lists for Name of the tray/set, Quantity, Packaging check column, User Check Column Please refer to Section 9.17.1		
	I. Expected Outcomes • Ensure safe and sterile supplies to the HCO • Ensure monitoring of steam sterilization process in an objective manner.		

Sr No.	Activity	Responsibility	Reference
9.1.4.10	**Sterilization process for steam sterilization** **A. Purpose** • To ensure that all reprocessed medical devices are sterilized to an acceptable standard and ready for use. **B. Scope** • Metal instruments, items meant for steam sterilization • Sterilization of all critical and semi-critical items that are heat and moisture resistant (surgical instruments, surgical drapes, some respiratory and anesthetic equipments, sharps). **C. Materials** • Steam Sterilizer (Autoclave), Loading Trolleys, Log books • Testing products: Bowie & Dick test pack, Microbiology test vials	Trained CSSD personnel allocated to area	
	D. Procedure **a. General considerations and precautions** • Follow the manufacturer's instructions. • Arrange items in a way to facilitate air removal, and steam penetration of all surfaces. • Do not stack items one on top of the other. • Do not overload. • Keep the loads at the sterilizing temperature for the recommended holding time. • Close and secure lock the autoclave door. • Follow manufacturer's directions for door opening and load transfer In the event of a cycle failure / cycle aborted, the entire load will need to go through the full reprocessing cycle • Before opening the door, thoroughly wash hands according to Hospital Policy • Open the door while standing towards the side to avoid burns. • Exercise care during opening (Sterilizer is hot, potential for steam injuries and burns). • Put on heat resistant gloves and remove carrier from Autoclave. • Allow to cool for 10 – 20 minutes before storage or dispensing. • Inspect packages to ensure integrity and external chemical indicators have changed.		

	• Maintain a log of the load, parameters met and autoclave cycle.		
	b. Essential parameters • Steam (dry, saturated), time, temperature and pressure. • Time to sterilize: usual cycles: 121^{o} C for 30 minutes, 132^{o} C for 4 minutes at recommended pressures.		
	E. Monitoring of steam sterilization process: **a. <u>Physical/ Mechanical monitoring: Each cycle</u>** • Monitoring includes all sterilizer components that track and record time, temperature and pressure during each cycle, rounds, etc. • Documentation of critical cycle parameters permits the earliest detection of equipment malfunctions since they can be evaluated when the cycle is in progress.		
	b. <u>Chemical monitoring</u> • Internal indicators (placed inside the tray/pack)- Provide an indication that the load has been exposed to the conditions necessary to achieve sterilization. • External indicators-Placed on the outside of each pack to be sterilized. • Readily visible and color change provides a quick indication that the load has or has not been exposed to the sterilization process. • Residual air detection for vacuum sterilizers **(Bowie- Dick test):** Test daily. • A commercially available Bowie- Dick type test sheet should be placed in the centre of the pack. • The test pack should be placed horizontally in the front, bottom section of sterilizer rack, near the door and over the drain in an otherwise empty chamber and run at 134^{o} C x 3.5 minutes. • Residual air in the chamber will interfere with steam contact (the entrapped air will cause a spot to appear on the test sheet due to inability of steam to reach the chemical indicator). • During processing, steam must displace the air through the barrier material within the pack. A uniform change from yellow to blue/purple on the indicator sheet indicates that all the air was removed and replaced by steam. • If the sterilizer fails the test, do not use until		

	corrected. **c.** Biological monitoring: • *Geobacillus sterothermopilus* spores 10^5. • Use at least weekly (preferably daily) and with each load of implantable devices. • Loads containing implantable devices should ideally be quarantined until the results of biological indicators are available.		
	F. Expected Outcomes • Consistent sterilization of items through quality control checks of the autoclave • All packs are sterile and safe to use		

Sr No.	Activity	Responsibility	Reference
9.1.4.11	**Sterilization process for ETO** **A. Purpose** • To ensure that all reprocessed medical devices are sterilized to an acceptable standard and ready for use. • To ensure that the work environment is safe for employees **B. Scope** • Medical and surgical items that cannot support conventional high temperature steam sterilization. • For sterilization of heat and moisture labile critical and semi-critical items. • Assembled complex devices • Catheters, stents • Equipment with integrated-electronics • Multi-lumen tubing products • Wound care dressings • Disposable items **C. Materials** • ETO Sterilizer • ETO Cartridges • Aeration Cabinet • Monitoring equipment • Emergency equipment • Personal Protective equipment • Manufacturer's Manual • Logbooks • Emergency equipments and procedure manual • S*uitable*packaging materials for ethylene oxide are • woven polyester wraps • paper bags and wraps • cellulose based non woven wraps • non cellulose based non woven wraps • specific reusable rigid sterilization containers • polyethylene film • cellulose based flexible packaging material. • *Unsuitable* packaging materials for ethylene oxide include • textile linen wraps • sealed containers such as metal or glass • aluminium foil • porous non-cellulose flexible packaging • non porous non cellulose based flexible packaging.	Trained CSSD personnel allocated to area	
	D. Requirements for ETO Sterilization		

	• Ethylene oxide must have an unobstructed path to be able to sterilize the interior of devices. Complex instruments must be disassembled for sterilization, so that the gas may penetrate the most remote recesses. Caps, plugs or stylets must be removed prior to sterilization. • Thoroughly wash and dry instruments prepared for gas sterilization to remove biological matter residues and meet the standard of surgical cleanliness. • Use appropriate wrapping materials for ETO gas sterilization. • A sufficient dose of ethylene oxide must be used for an adequate length of time to kill the most resistant microorganisms. • Adequate humidity must be present to facilitate the process. Desiccated organisms may become resistant to ethylene oxide sterilization. • The dose of ethylene oxide required depends on the temperature of the process. The higher the temperature, the lower the dose of EO that will be necessary to sterilize.		
	E. Procedure • Packaging systems for ethylene oxide (ETO) should be permeable to EO, moisture, and air; permit aeration; be constructed of a material recommended by the sterilizer and sterilant manufacturer; and maintain material compatibility (ie, non-degradable) with the sterilization process. • Ensure the work environment is safe for employees before operating ETO sterilizer. • Operators must know how to operate the ETO sterilizer safely as well as the importance of adequate aeration • Operators need to understand the environment requirements and safe work practices. • Operators must know what the emergency procedures are in case of a leak or accident. • The ETO sterilizer must be operated accordance with the manufacturer's instructions • The ETO sterilizer must be used in a well ventilated controlled room with dedicated exhausts, emission control, enclosed ETO		

	sterilizer/aerator room, ventilation, air exchanges andenvironmental monitoring provided. • Complete test and record biological indicator (BI) Test according to manufacturers • Instructions. • Check with gas manufacturer/supplier for storage recommendations and MSDS sheet. • ETO gas must be stored at the prescribed temperature in a well ventilated area in a cupboardmarked with Hazardous materials label • The cycle must be long enough to allow thorough ETO penetration to kill microorganisms. • The sterilizer operating temperature is usually preset by the sterilizer manufacturer; there areusually two options: 100F (cold cycle) 130F (warm cycle) • The manufacturer of a device is responsible for providing validated information regarding proper sterilization and aeration of their products, usually between 1 to 6 hours, depending on the concentration, humidity, temperature parameters, and the type of sterilizer. • The ETO cartridge must be discarded in a safe manner according gas manufacturer/supplier and hospital policy • Average personnel exposure concentration should be measured over a specific period of time, usually 8 hours • Employer must ensure that no employee is exposed to airborne concentrations of ETO in excess of the concentration recommended by suppliers (<1 ppm) • Material compatibility with ETO must be validated by the device manufacturer • Load items in a loose fashion to facilitate air removal, humidification, ETO circulation and penetration of all surfaces, and ETO removal during aeration • Packages must not contact walls or ceiling of chamber, package damage from heat or moisture may occur • Process full loads to limit the number of cycles you need to run • Load the sterilizer according to manufacturers instructions, make sure the door to the		

	chamber is locked, and the appropriate cycle is selected based on the types of items beingprocessed • Aeration Cabinets are required to remove residual ETO before patient contact with the device. • Follow manufacturer's directions for door opening and load transfer. • When unloading some sterilizer manufacturers recommend immediate removal if transferringitems to a freestanding aerator • Opening the door 2 inches for 15 minutes is recommended…**obviously no one should remainin the area** • Aerate until potentially toxic ETO residues are removed before storage and use of medicaldevices. • ETO residues if any should be exiting through a vent, the specifications of which are provided by manufacturer. • Length of aeration depends on Composition/materials, thickness, design and weight of thedevice and it's wrapping, sterilization and aeration system used, temperature, ETO,concentration, duration of gas exposure, rate of air exchange, and air flow pattern • Device manufacturer's recommendations must be VALIDATED aeration parameters • (time/temperature) • The aeration time must be uninterrupted ➢ 8 hours at 140° F (60°C) ➢ 10 hours at 130° F (54°C) ➢ 12 hours at 120°F (49°C) ➢ 20 hours at 100° F (38°C) • DO NOT remove prematurely, with premature removal, personnel and patients may beadversely affected. • The sterilized items are properly labelled and stored. • A log is maintained of the cycle, load, temperature, time, etc		
	F. Quality control- Monitoring ETO sterilization **a. Physical monitors** • Measures that ETO machine is functioning effectively		

	• Monitoring includes all sterilizer components that track and record time, temperature and pressure during each cycle, rounds, cartridges, etc. • Documentation of critical cycle parameters permits the earliest detection of equipment malfunctions since they can be evaluated when the cycle is in progress.		
	b. Chemical indicators • Provide an indication that the load has been exposed to the conditions necessary to achievesterilization • External indicators • Placed on the outside of each pack to be sterilized. • Readily visible and color change provides a quick indication that the load has or has not beenexposed to the sterilization process • If the process indicators have not changed, the packages should NOT be released.		
	c. Biological indicators • Indicates if sterilizing conditions are adequate to achieve sterilization • *Bacillus atrophaeus*: Microorganism of choice for monitoring ETO sterilization as it offers the best test challenge since it is most resistant to kill; Non-pathogenic • BI is placed into the center of a full load. Consider placing the test pack into a small metal basket or instrument tray for easy retrieval if it must be removed before a load is transferredto a separate aerator. • Follow BI manufacturer's instructions for activation and incubation. • For example, ETO (*Bacillus atrophaeus*) is incubated at 37° C for 48 hours. Steam (*Geobacillus stearothermophilus*) is incubated at 55° C for 24 hours • The BI manufacturer must be consulted for recommendations regarding how to handle theirBI • Worker safety must be given primary consideration**.** • Proper and safe disposal practices for chemical and biological indicators.		
	d. Safety Warnings		

	• ETO is a colorless odourless gas with high reactivity. • Skin Contact with liquid EO - immediately wash affected area • Eye contact with liquid EO - flush eyes with copious amounts of water for at least 15 minutes • Ensure staff have been educated regarding safety precautions when working with ETO. • Shift the person to open well ventilated area. • Primary management should be highlighted and displaying clearly in the working area.		
	G. Expected Outcomes • All equipment is sterilized to an acceptable standard • ETO sterilizers are operated according to manufacturer's instructions • The work environment is safe for employees		
9.1.4.12	**Sterilization process for Gas Plasma Sterilization** **A. Purpose** • To ensure that all returned items are sterilized according to an acceptable standard andready to use. • To ensure the work environment is safe for all employees. **B. Scope** • Items that cannot tolerate high temperatures and humidity, such as some plastics, electrical devices, and corrosion-susceptible metal alloys **C. Materials** • Sterilizer • Cassettes / cartridges • Wrap recommended by manufacturer • Cassette collection boxes • Instrument sterilization containers recommended by manufacturer • PPE • Manufacture's manual • S*uitable* packaging materials for gas plasma sterilization are • Woven polyester • Non-cellulose based non woven wraps • Specific reusable rigid sterilization containers	Trained CSSD personnel allocated to area	

	• Porous non-cellulose based flexible packaging material. • *Unsuitable* packaging materials for gas plasma include (gas plasma sterilization is affected by absorbable packaging materials) • Textile linen wraps • Paper bags and wraps • Cellulose based non woven wraps • Sealed containers such as metal or glass • Aluminium foil • Polyethylene film • Cellulose based flexible packaging • Non porous non-cellulose based flexible packaging.		
	D. Procedure • This process inactivates microorganisms primarily by the combined use of hydrogen peroxide gas and the generation of free radicals (hydroxyl and hydroproxyl free radicals) during the plasma phase of the cycle. • Packaging systems for low-temperature gas plasma sterilization should • allow sterilizing plasmas to penetrate packaging materials; • be compatible (ie, nondegradable, nonabsorbable) with the sterilization process; • be constructed of a material recommended by the sterilizer manufacturer; and • be used according to the packaging manufacturer's written instructions. • All items must be thoroughly cleaned and dried before packaging • Use packaging and containers recommended by the manufacture • Users should obtain documentation from the manufacturer for appropriate use and restrictions. • Place chemical indicator in each packaged item. • Arrange items in such a way as to ensure sterilant will come into contact with all surfaces. • Do not allow any items to touch the walls or the door • Do not stack containers • Manufacture’s manual for details of process. • Hydrogen Peroxide Plasma / Vaporized Hydrogen Peroxide involves the combined use of hydrogen peroxide and low-temperature gas plasma to safely and rapidly sterilize medical		

	devices and materials without leaving any toxic residues. • Plasma is a state of matter distinguishable from a solid, liquid, or gas. Gas plasmas are highly ionized gases, composed of ions, electrons, and neutral particles that produce a visible glow. • A solution of hydrogen peroxide and water (59% nominal peroxide by weight) is delivered to the sterilizer, concentrated to approximately 90%, vaporized and allowed to surround and interact with the devices to be sterilized. Hydrogen peroxide is a bactericidal, virucidal, sporicidal, and fungicidal agent, even at low concentration and temperature. • Applying a strong electrical field then creates plasma. The plasma breaks down the peroxide into a cloud of highly energized species that recombine, turning the hydrogen peroxide into water and oxygen leaving no toxic residues.		
	E. Monitoring of Gas plasma sterilization. • Physical/Process parameters • The physical parameters are defined by the manufacture (cycle time, etc). • If any process parameter falls short of its acceptable limits, which were established by statistical analysis of microbiological efficacy testing, the sterilization cycle will be canceled and the printed record for the cycle will state the reason for the malfunction. • Biological monitoring • 106 G. stearothermophilus spores; to be used in accordance with manufacturer instruction.		
	F. Warning • Items that cannot be processed in a Hydrogen Peroxide Plasma / Vaporized Hydrogen Peroxide • Any item that is not completely dry • Items or materials that absorb liquids • Items made from materials containing cellulose e.g., cotton, paper, cardboard, linens, gauze or items that contain wood pulp • Manufacturer's list of what can and what cannot be processed • Concentrated hydrogen peroxide liquid will irritate skin and, like other oxidants, can cause severe damage to eyes if direct contact occurs. • Wash with copious amounts of water. • Shift to open environment or well ventilated area.		

	• Seek medical help as per institution policy.		
	G. Expected Outcome • All equipment is sterilized to an acceptable level and ready to use.		
9.1.4.13	**Storage of sterile items in sterile zone** **A. Purpose** • To ensure the safe and organised storage of all sterile packs up to release to other departments **B. Scope** • All packed sterilized items and equipments **C. Materials** • Stainless Steel slatted Shelving • Almirah racks	CSSD Incharge technician and CSSD personnel	
	D. Procedure • This is a clean area and should be kept clean and tidy at all times with limited access • Ensure that stock is rotated and monitor stock levels • Only CSSD staff should be allowed access to the storage area • Doors and windows must be kept closed • Temperature should be controlled. • Room temperature should be approximately 24ºC (75ºF). • The room(s) should have at least 4 air exchanges per hour. • Humidity should be controlled so that it does not exceed 70%. • Products should be stored away from direct sunlight and water • The Sterile Storage area should be arranged to make it easy to identify packs and be well lit and easy to clean. • There should be enough shelves and cupboards available to store all sterile goods withouthaving to stack them tightly or on top of one another. • Products should be stored away from outside walls. • There should be space between shelving and floor and ceiling to allow air to circulate and to allow cleaning of the floor area. • Surgical and medical supplies should be stored at least 25cms from the floor, 45cms from the ceiling and 5cms from outside walls to allow for air circulation in the room and to prevent		

	contamination during cleaning. • Items should not be stored next to or under sinks, on the floor or windowsills where they are likely to get wet or damaged. • Follow a system of use the First in First out (FIFO) system. Rotate stock so that oldest items are used first. • Surfaces in contact with sterile goods should be as clean as possible to prevent microorganism penetrating the packaging of these items. • Trolleys should be cleaned anddried after each use, because even though they are used with sterile items, contaminationcan be picked up during transport outside the CSSD.		
	E. Shelf life • The shelf life of a pack is dependent on packaging, handling and storage conditions. • This also applies to all commercially prepared items which are labelled as "Sterile unlessopened or damaged". • The date on a sterile package indicates the date the item was sterilized or manufactured. • Sterility is maintained as long as the integrity of all barrier properties and seals aremaintained • Expiration date is a reminder "Use Before" /"Use First"		
	F. Expected Outcomes • Sterility of all packs is maintained whilst in the CSSD		
9.1.4.14	**Issue of items from CSSD** **A. Purpose** • To ensure hospital staff receive sterile items in a safe condition and ready to use **B. Scope** • All sterile items from storage and dispatch areas **C. Materials** • Dispatch Log • Clean Trolleys	CSSD personnel managing the dispatch counter; Staff receiving the items	
	D. Procedure • All items will be checked for sterility before they are released • The following should be checked when deciding if the pack is still sterile: - • Holes or tears • Wetness or stains		

	• Broken seals • Dust • Sterility seal All items issued will be recorded so that a tracking system is effected • Various methods can be used in the transport of sterile packaged items to their point of use.This can range from hand carriage (in particular where a decontamination area is located closeor adjacent to a point of use), to the use of trolley's and other such transport systems fortaking items to a remote location (within a facility or at a different facility). • Sterile supplies should be transported in covered or enclosed trolleys with a solid bottom shelf. The solid bottom shelf prevents microorganism on the floor being picked up by the wheels of the trolley and then spun upwards onto the sterile packs. • Items must be placed onto a clean trolley that can be covered • Trolleys must not be overloaded • Soiled items must NOT be loaded onto the same trolley. • Loaded trolleys should immediately move to their respective areas. • Sterility seals should also be checked by receiver before accepting the items.		
9.1.4.15	**Recall Procedure** **A. Purpose** • To ensure that any item suspected of being substandard is identified, quarantined, collected, investigated and the findings recorded **B. Scope** • All suspected items after issuance from CSSD • Inadequacy noticed by the end user **C. Materials** • Item in question • Checklist	All personnel using CSSD items (Staff nurses, OT nurses, Surgeons, Physicians) and CSSD Incharge	
	D. Procedure • In the event of sterilization failure, such as positive biological indicators/Failed Load • Controls or sterilizer malfunction, items from that test and previous loads after the lastknown good test must immediately be		

	recalled. • All affected trays must be recalled in the event of failed quality management tests i.e. • Biological, Load Control • A written Recall Procedure must be followed in the event of a sterilization failure • The sterilizer must be shut down and all staff must be made aware that it is out ofoperation. • The sterilization record sheets should be checked for a list of "sterilized" items that needto be recalled. • The recall procedure should be documented on the sterilization record sheets listingwhat items have been retrieved and reprocessed and which items had already be usedand on whom. Note items that may have already been used on the list. • As it becomes apparent that items need to be recalled reprocessing personnel willimmediately notify users and retrieve the supplies from storage and from user as soon aspossible. • A recall is usually authorized by the most senior staff member on the shift. • Affected departments should be advised verbally as soon as possible, with a follow upwritten confirmation advisory stipulating which items, trays from a particular batch aresuspect and should be returned. • Departments should be requested to check their sterile stock as well as used stock for thesuspect batch. • CSSD staff will confirm that the check has been carried out for any breach in the cycle. • Recalled items should be labelled 'Under Quarantine' whilst in transit to the cleaning areaof the reprocessing area where it will be reprocessed or be put into quarantine. • All items retrieved from a Recall must be completely reprocessed. • All items must be disassembled, processed with fresh linen, assembled, rewrapped andsterilized. • Once the sterilizer has been repaired all monitoring results must be checked before thesterilizer is used. • The cause of the recall should be investigated and a report written.		

	E. Expected Outcome • A quality management system is in place confirming that all products leaving the CSSD are sterile and safe to use.		
S. No.	**Activity**	**Responsibility**	**Reference**
9.1.4.16	**Maintenance of CSSD equipment** **A. Purpose** • To ensure that all CSSD equipment are in good working condition with minimum downtime. **B. Scope** • Maintenance of: • Ultrasonicator • Water Jet machine • Dryer • Sealer • Labeller • Steam Sterilizer • ETO sterilizer **C. Materials** • Equipment logs to be maintained on daily basis by CSSD Technician Incharge/Supervisor • Equipment logs to be verified on monthly basis by Medical officer Incharge	CSSD technician Incharge CSSD Medical Officer Incharge	
	D. Procedure • All equipment records should have separate file. The content of the file at least include: • Equipment History (Name of Equipment, Make, Model No., Date of installation, Order No., Date, Cost of machine, Warranty period, Date of expiry of warranty period, Whether under AMC/CMC, period of AMC, Contact No. of Engineer). • Installation Report • IQ/OQ/PQ documents at the time of installation • Periodic calibration report (At least annually) • Service reports • AMC/CMC Contract sheet • Equipment downtime log • Call log in case of repairs or troubleshoot. This log should include at the minimum following		

	information: Date and time problem was noticed, description of nature of problem, Name and contact no. of person contacted to resolve the problem, Date and time of call to person for resolution of problem, Name of the person who contacted the engineer, response of the person contacted, date and time of resolution of the problem. • Any other document pertaining to the equipment.		
	E. Expected Outcomes • Improved and efficient utilization of CSSD equipment. • Timely service and calibration of equipment for improved lives of the equipment.		
9.1.4.17	**Key performance indicators for CSSD – Data collection and analysis** **A. Purpose** • To measure the structure, process and outcome of the CSSD in objective and transparent manner. **B. Scope** • To define, measure and monitor various performance indicators to monitor CSSD.	CSSD technician Incharge CSSD Medical Officer Incharge	

Indicators definition
Please use the following Matrix:

Indicator name	Numerator (N)	Denominator (D)	Formula	Remarks
Bowie-dick failure rates	No. of Bowie-dick tests failed per month	No. of Bowie-dick tests done per month	N/D x 100	See Appendix for monitoring reasons of Bowie dick failure
Recall rates	No. of loads whose packs have been recalled per month	No. of loads per steriliser carried out per month	N/D X 100	Recall may be due to failure of indicators of particluar load or packing defects. (Rates for indicator failure should be calculated separatetly for indicator failures and damged packs).
Class V integrator	No. of packs	No. of packs with	N/D X 100	

failure rates	where class V integrator failed per month	class V integrators issued per month		
Biological Indicator (BI) failure rates	No. of loads where BI have failed per month	No. of loads subjected to BI per month	N/D X 100	
Return of expired items for re-sterilization in OT	Total No. of expired items retured per unit per month	Total No. of items issued per unit per month	N/D X 100	
Critical Equipment utilization rates	Total no. of hours equipment was used	Total no. of hours the equipment was expected to be used	N/D X 100	
Critical Equipment downtime rates	Total no. of hours equipment was not used because it was out of order per month		**N/A**	
Disinfectant failure rates	Total No. of times indicator strip failed the test per month	Total no. of times indicator strip test was done per month	N/D X 100	It will be useful to monitor no. of days when the indicator strip failed.
Lost item rates	Total no. of instance where items did were missing in the tray when sent for processing in CSSD per patient care unit	Total no. of items trays sent for processing in CSSD per patient care unit per month	N/D X 100	
Turn-around-time for Sterile items	Time of receiving of items to time it reaches sterile storage area of CSSD		**N/A**	Should be monitored for each method of disinfection and sterilisation separately.
CSSD Safety score				See appedix for safety audit
Sharps injury rates	Total no. of sharp injuries among CSSD workers per month	Total no. of mandays in CSSD per month	N/D X 1000	
Blood and body fluid exposure rates	Total no. of blood and body fluid exposures among CSSD workers per month	Total no. of mandays in CSSD per month	N/D X 1000	

C. Data capturing procedure and templates

- Log registers should be prepared for each process to ensure capturing of relevant data on real time basis.

D. Monitoring frequency

- The CSSD supervisor should sign all log registers on daily basis and countersigned by Medical officer incharge on at least monthly basis.
- The data compiled through such indicators should be shared with concerned patient care unit incharges, nursing incharges and medical superintendent/director of the hospital
- Trend analysis shared should result in root cause analysis.
- Regular training of nurses, paramedical workers, doctors to sensitize them about the sterilization and its importance should be done and various deficiencies and challenges encountered through monitoring of these indicators should be included as a part of training of relevant technical, nursing staff and doctors.

E. Expected Outcomes

- Indicators monitoring shall ensure implementation and monitoring of CSSD processes and quality improvement of CSSD.

Annexure

****Annexure 1. CSSD Safety audit sheet**

HEALTH FACILITY:	
Date:	**Auditors:**
Designated area:	

Annexure 1. CSSD Safety audit sheet

Scoring System: **0 = ACCEPTABLE** **1 = UNACCEPTABLE** **N/A = NOT APPLICABLE**	**AS Standard Interpretation:** **• SHALL = Mandatory Score 0 or 1 as appropriate** **☺ SHOULD = Recommended** **Mark or ** **Note: These points are not included in the scoring system.**	**Scoring Process** **A B** **Column A = Achieved score** **Column B = Total Possible score**

Section	Standard	Compliance			Action Timeframe
		0	1	N/A	
2	**HANDLING OF USED ITEMS**				
	WATER QUALITY FOR CLEANING				
2.1	• Clean water supply of good quality (0 or 1)				
	• Care taken with selection of detergents				
	☺ Weekly testing on water hardness				
2.2	TREATMENT OF USED ITEMS				
	• Gross soil is removed as close to the point of use as possible b/f being returned to CSSD				
	• Standard precautions are used at all stages of handling used items				
	• PPE is available and is used where appropriate.				
	☺ A written description of the procedures is available in all areas				
	☺ Reusable drainage bottles are emptied at the user level, avoiding spillage.				

	☺Soiled drapes and linen are placed in soiled linen containers and sent for laundering.		
2.3	DETERGENT & RINSE ADDITIVE RESIDUES • Check washing machines daily to ensure there is no chemical residue ☺Instruments and equipment are free from residue after the cleaning process		
	Sub Total		

Annexure 2. Audit sheet for Housekeeping in CSSD area.

Area	Yes
1. Wet mops floors (vacuum first if necessary, do not sweep)	
2. Damp wipe all low-level ledges, shelves, and skirting and window ledges.	
3. Remove splash stains and finger marks from walls and paintwork using damp cloth.	
4. Empty waste bins, replace waste bags, and wash bins if necessary.	
5. Clean all internal glass surfaces.	
6. Wet wipe walls, wall fittings and ceilings. Clean light fittings.	
7. Clean all ceiling air vents.	
8. Check and clean as necessary around sinks, doors, etc.	
9. Empty waste bins and wash inside.	
10. Clean and polish all frontages of Autoclaves with Stainless Steel cleaner.	
11. Cream clean sinks taps and surrounds. Remove debris from waste outlet.	
12. Clean inside washer disinfectors according to manufacturers' instructions	
13. Clean inside washer sterilizers according to manufacturers' instructions	
14. Damp wipe pipe works, doors, door-frames and door handles.	
15. Polish washer's exterior with stainless steel cleaner.	

Annexure 3. Chemical indicator for monitoring steam sterilization process

Table 1. Chemical indicators: The devices used to monitor exposure to one or more sterilization parameters.

Class I: Process indicator that demonstrates that the package has been exposed to the sterilization process to distinguish between processed and unprocessed packages.

Class II: Process indicators that are used for a specific purpose such as the dynamic air removal test (formerly called the Bowie-Dick test).

Class III: A single-parameter indicator that reacts to one of the critical parameters of sterilization.

Class IV: A multi-parameter indicator that reacts to two or more of the critical parameters of sterilization.

Class V (integrating indicator): An indicator that reacts to all critical parameters of sterilization.

Table 2: International Classes of Steam Chemical Indicators

Class	Definition	Use	Examples
CLASS I: Process Indicators	Process indicators differentiate processed from non-processed items	In individual units (e.g., packs, containers) to indicate that the item has been directly exposed to the sterilant Usually applied to the outside of packages Responds to one process variable	Sterilization tape Indicator labels Load cards Some internal chemical indicator strips
CLASS II: Indicator for Use in Specific Tests	Indicator for use in specific test procedures as defined in sterilization standards	To verify adequate air removal and steam penetration in vacuum assisted steam sterilizers	Bowie-Dick test
CLASS III: Single Variable Indicator	Indicator that reacts to a single critical parameter in the sterilization process to indicate when a stated value has been reached (e.g., temperature)	For package monitoring Use with caution because most sterilization processes depend on more than one critical variable	Temperature tubes Some internal indicator strips
CLASS IV: Multi-variable Indicator	Indicator that reacts to two or more critical parameters in the sterilization cycle under the conditions specified by the manufacturer	For internal package monitoring	Some internal indicator strips
CLASS V: Integrating Indicator	Indicator that reacts to all critical parameters in the sterilization process (e.g. time, temperature, presence of steam) and has stated values	For internal package monitoring. Can be used in a PCD as an additional monitoring tool to	Some Internal indicator strips

	that correlate to a BI	release loads that do not contain implants before results of a BI test are known	
CLASS VI:	Indicator that reacts to all	For internal package monitoring	Internal

Annexure 4:Common Causes for Failure of a Bowie-Dick Test

Cause of Failure	Description	Possible Solution
Air Leak	If air is able to leak into the autoclave chamber, the steam will be unable to penetrate the load to the point of total sterilization.	Run a Vacuum Leak Testf to further determine if an air leak exists or not.
Unwanted Condensation	Occasionally condensation will get trapped in the jacket of the autoclave, which can lead to cold spots at the base of the autoclave. This could also indicate a wet-steam issue.	Check the steam traps on the autoclave. Check steam quality and wetness.
Faulty Test Pack	From time to time, a Bowie-Dick Test pack can be faulty.	Check the expiration date and make sure the packs are being stored in the proper environment.
No Warm-Up Cycle	A warm-up cycle allows the sterilizer chamber and jacket to reach temperature.	Run a 5 minute sterilization cycle prior to running the Bowie-Dick Cycle.
Incorrect Procedures	Test packs work under very specific conditions.	Test packs should be placed in an empty chamber directly over the drain on the bottom rack or shelf. They are designed for use at 270°-273°F (132°-134°C).

Annexure 5. Characteristics and Clinical Goals of Sterilization Wrap

Characteristics	*Clinical Goal(s)*
Barrier effectiveness	Ability to prevent microbial penetration and maintain sterility of surgical pack and prevent penetration of liquids (ie, repellent)
Penetrability (steam)	Allows steam to penetrate
Penetrability (eg, ethylene oxide; low temperature gas plasma)	Allows sterilizing gases or plasmas to penetrate
Aeration	Permits aeration post-sterilization (ie, allows ethylene

	oxide to dissipate)
Non-toxic	Promotes patient and personnel safety
Minimal wrap memory	Permits aseptic delivery of the contents to the sterile field
Drapeability	Conforms to equipment pack; contours smoothly and closely
Flexibility	Adequate sizes to accommodate any sized or shaped item
Puncture resistance	Resists puncture
Tear strength	Resists tears
Toxicity	Non-Toxic
Odor	Odorless
Low linting	Minimal linting during use
Cost	Low cost during use
Waste disposal	Adheres to local and state solid waste disposal guidelines

LIST OF ABBREVIATIONS

CSSD	Central Sterile Services Department; Central Sterile Supply Department
PPE	Post Exposure Prophylaxis
HLD	High Level Disinfection
ETO	Ethylene Oxide
MSDS	Material Safety Data Sheet
OT	Operation Theatre
OPA	Ortho-phthalaldehyde
TURP	Trans-urethral resection of prostate.
ORIF	Open reduction, internal fixation
H_2O_2	Hydrogen Peroxide

SCORING SYSTEM

Scoring System: **0 = ACCEPTABLE**	***AS Standard Interpretation:*** **•SHALL = Mandatory** **Score 0 or 1 as appropriate** **SHOULD = Recommended** **Mark ☑ or x**	***Scoring Process*** A B
1 = UNACCEPTABLE **N/A = NOT APPLICABLE**		**Column A = Achieved score** **Column B = Total Possible score**
	Note: These points are not included in the scoring system.	

Section	Standard	Compliance 0	1	N/A	Action Timeframe
2	**HANDLING OF USED ITEMS**				
2.1	*WA TER QUALITY FOR CLEANING*				
	Clean water supply of good quality **(Sample)** **0/1** →	**0**			
	Care taken with selection of detergents **1/1** →		**1**		
	☺ *Weekly testing on water hardness* ☑ **or** x		x 7		
2.2	*TREA TMENT OF USED ITEMS*				
	Gross soil is removed as close to the point of use as possible b/f being returned to CSSD →	**0**			
	Standard precautions are used at all stages of handling used items →		**1**		
	PPE is available and is used where appropriate. →	**0**			
	☺ *A written description of the procedures is available in al areas*	x			
	☺ *Reusable drainage botles are emptied at the user level, avoiding spilage.*	☑			
	☺ *Soiled drapes and linen are placed in soiled linen containers and sent for laundering.*	☑			
2. 3	*DETERGENT & RINSE ADDITIVE RESIDUES* Check washing machines daily to ensure there is no chemical residue →			**N/A**	
	- Instruments and equipment are free from residue after the cleaning process				
	Sub Total	**2**		**6**	

Scoring System:	*AS Standard Interpretation:*	Score Process	
0 = ACCEPTABLE	• **SHALL = Mandatory**	**A**	**B**
1 = UNACCEPTABLE	**Score 0, 1 or N/A as appropriate**	**Column A = Achieved score**	
N/A = NOT APPLICABLE	☺ **SHOULD = Recommended**	**Column B = Total Possible score**	
	Mark x or ✓		
	Note: These points are not included		

Section	Standard	Compliance			Action Timeframe
		0	1	N/A	
1	**SCOPE AND GENERAL**				
1.1	*SCOPE*				
	• There is a copy of AS4187 – 2003 in the CSSD /sterilising area				
	• The standard is not applied to items intended for single use only, nor to items that may be contaminated with unconventional infective agents e.g. CJD, nor for goods such as dressings and bandages which should be				
				2	
1.2	*REFERENCED DOCUMENTS*				
1.3	*DEFINITIONS*				
1.4	*PROCESSING ENVIRONMENT*				
	• The planning and construction of any new facility or major refurbishment of existing facility includes the principles of environmental control to minimise				
	☺ In a new o renovated facility consideration is given to workflow, with separated designated areas for cleaning, pack preparation, sterilisation and				
	-☺ *Existing sterilisng facilities make every endeavour to conform to the requirements of clause 1.4*				
				1	
1.5	*REPROCESSING OF INSTRUMENTS AND EQUIPMENT*				
	• Prior to use or reuse, every item is cleaned, or cleaned and disinfected or				
	• Any item used to enter a normally sterile site/tissue is sterile for use				
	• Explanted medical/dental devices are not reprocessed				
	☺*Implantable items are purchased in a sterile condition*				
				3	
	Section 1 TOTAL			**6**	

SECTION ONE TOTAL SCORE

SECTION 1 TOTAL	**6**

Section	Standard	Compliance			Action Timeframe
2	**CLEANING AND HANDLING OF USED ITEMS**	**0**	**1**	**N/A**	
2.1	WATER QUALITY FOR CLEANING • Clean water supply of good quality				
	• Care taken with selection of detergents and drying agents				
	☺*Weekly testing on water hardness and records are kept*				
				2	
2.2	*INITIAL TREA TMENT OF USED ITEMS* • Gross soil is removed as close to the point of use as possible, as soon as possible before being returned to CSSD - dry wiping, damp wiping and rinsing				
	• Standard precautions are used at all stages of handling used items				
	• PPE is available and is used where appropriate.				
	☺ *A writen description of the procedures is available in al areas*				
	☺ *Al single use items are discarded appropriately after use*				
	☺ *Soiled drapes and linen are placed in soiled linen containers and sent for laundering.*				
				3	
2.3	*COLLECTION PROCEDURES* • Procedures for the collection of used items from wards, OR and other departments have been formulated.				
	• There is separate procedures/arrangements for the collection of used itmes and the delivery of sterile items				
				2	
2.4	*COLLECTION EQUIPMENT* • Collection containers are puncture resistant, leak-resistant & have a lid that can be closed				
	• Container or trolley is cleaned at the end of each round				
	☺ *Containers and troleys are metal or plastic, capable of being cleaned*				
				2	
	Section 2 Sub Total			**9**	

Section	Standard			Action Timeframe
2.5	*CLEANING AREA* • There is a physically separate cleaning area to prevent possible contamination of processed items			
	• Written policy on the methods, and frequency of cleaning the area and equipment			
	Equipment in cleaning includes (recommended): ☺ *Separate hand washing facilities*			
	☺ *Adequate bench space*			
	☺ *Smooth surfaces without crevices*			
	☺ *Good lighting*			
	☺ *Efficient ventilation – min. 10 air changes ph with –ve pressure to sterilising area - (AS 1668.2)*			
	☺ *Temperature range maintained in the range 18°C to 22°C*			
	☺ *Adequate storage space for materials and equipment*			
	☺ *Adequate waste disposal bins*			
	☺*Non -slip flooring*			
	☺ *Sink suitable for disposal of liquid waste*			
	☺ *Cleaning sinks*			
	☺ *Ultrasonic cleaners (AS 2773*			
	☺ *Washer/disinfectors (AS 2945)*			
	☺ *Drying equipment*			
	☺ *Non-porous work surfaces for efficient cleaning*			
	☺ *Adequate plumbing with ease o f maintenance*			
	☺ *Appropriate workflow and traffic flow from reception to distribution of items*			
			2	
2.6	*SORTING OF ITEMS PRIOR TO CLEANING* • All items that have been unwrapped for use are considered to be contaminated whether they have been used or not and are subjected to the full cleaning process			
	• A check of completeness and defects is made during sorting.			
	• There is written procedures for handling specialised items, including loan instruments and sets.			
	☺ On receipt, items are sorted according to type and cleaning method			
			3	
	Section 2 Sub Total		**5**	

Section	Standard			Action Timeframe
2.7	*CLEANING PRECAUTIONS* • Care is taken to avoid direct contact with skin when using detergents, disinfectants and other chemicals			
	☺*Techniques of cleaning avoid generating aerosols*			
	☺ *Single use suction tubing is used (recommended)*			
	☺ *If accidental exposure does occur, the affected area is washed with copious amounts of clean water and treated in accordance with MSD sheets*			
	☺ *There are documented procedures to minimise risk of damage to instruments through inappropriate cleaning methods and materials*			
	☺ *Abrasive cleaners(steel wool or abrasive powders and pastes are NOT used*			
			1	
2.8	*CLEANING AGENTS* • The Material Safety Data Sheet (MSDS) is read before using agent			
	• Cleaning agents are used to remove soil - Appendix D			
	• Product Data Bulletins and MSDS are obtained for all cleaning agents and chemical and requirements are implemented			
	• Cleaning agents are dispensed in a safe manner which does not promote contamination of contents.			
	• Common household detergents are not used –high foaming, high residue			
	• Cleaning agents do not leave a residue			
	☺ *Chemical suppliers have provided evidence regarding agents compliance with Appendix D*			
	☺ *Chemical suppliers have provided chemical testing kits to test pH, chlorine content, chlorine residue, and presence of iron and water hardness.*			
	☺ *Chemical suppliers have provided training fo r staff*			
	☺ *Detergent used is a mild alkaline detergent – pH range 8.0 – 10.8 (Some items may require the use of neutral detergents)*			
	☺ *Acid-based agents are only used for stainless steel surfaces only*			
			6	
	Section 2 Sub Total		**7**	

Section	Standard			Action Timeframe
2.8 Contd	*ENZYMATIC CLEANERS* • Rubber or nitrile gloves are worn and standard precautions observed if handling enzyme cleaning agents			
	☺ *Enzymatic cleaners are no used routinely, but used to soak items where debris is congealed on them (exception - flexible endoscopes)*			
	☺ *MSDS pertaining to enzymatic cleaners are clearly displayed in work area*			
	☺ *The enzymatic cleaners used have multiple enzyme activity and are used at the correct temperature and time and within their shelf life.*			
	☺ *Different commercial products are not mixed.*			
	Agents for Manual Cleaning • Biodegradable, non-corrosive, non-toxic, non-abrasive, low foaming, free rinsing, preferably liquid and mildly alkaline			
	Agents for Mechanical Cleaning • Biodegradable, non-abrasive, low foaming, free rinsing and preferably liquid			
	Product is appropriately labeled • Product name, manufacturer's name & address, description & purpose, dilution instructions, batch number, manufacture or expiry date, advice not to mix with other chemicals, safety & first aid instructions, storage requirements.			
			4	
2.9 2.9.1	*CLEANING METHODS* *GENERAL* • Care is taken to ensure the cleaning process does not add to bioburden			
	• Cleaning methods are appropriate to the design of the items cleaned			
	• Cleaning methods are documented			
	• After cleaning the items are clean to the naked eye (macroscopic) and free from any protein residues			
			4	
2.9.2 2.9.2.1	*MECHANICAL CLEANING* *GENERAL* • Washer/disinfectors and ultrasonic cleaners are routinely cleaned and maintained to prevent colonisation and formation of biofilms			
			1	
2.9.2.2	*BA TCH-TYPE WASHER/DISINFECTORS* • Mechanical washer complies with AS 2945			
	• Final rinse water temperature is between 80°C and 90°C to ensure effective function of drying agent			
	☺ *Where multi-programmable washer/disinfectors are used, strict protocols are in place for their operation and ongoing maintenance*			
			2	
	Section 2 Sub Total		**11**	

Section	Standard			Action Timeframe
2.9.2.3	*WASHER CYCLES* The washer cycle includes: • Pre-rinse, with water			
	• Warm water wash with cleaning agent added			
	• One or more hot water (80°C & 90°C) rinses with drying agent added			
	• Drain, leaving contents at a temperature for quick drying			
	• Drying, either radiant heat from an element or a hot air blast			
			5	
2.9.2.4	*SPECIFIC CONSIDERA TIONS FOR BA TCH-TYPE WASHERS – AS 2945-1 998* • There is minimal handling of soiled items			
	• Automatic dispensers are used to add correct amount of cleaning agents			
	• Items are positioned to ensure surfaces are exposed to the cleaning process			
	• Machine is maintained by skilled personnel			
	• Internal cleanliness of machine is maintained			
	• Performance is continually monitored and documented			
	• Care is taken when unloading items capable of holding residual water			
			7	
2.9.2.5	*ANAESTHETIC AND RESPIRA TORY WASHER/DISINFECTORS (AS 2945)* • Machine/cycle is used to rinse, wash and disinfect anaesthetic and respiratory			
	The machine operates within the temperature ranges:			
	• Rinsing – 40°C to 50°C	Thermal Disinfection		
	• Washing – 50°C to 60°C	90°C for 1 minute		
	• Disinfecting – 70°C to 95°C	75°C for 30 minutes		
	Final rinsing – 80°C to 90°C			
	Machine is routinely cleaned and maintained to prevent colonisation and formation of biofilms			
			6	
2.9.2.6	*MECHANICAL CLEANING OF ANA ES THE TIC INS TR UMEN TS & EQUIPMENT* • All equipment place in the washer is processed for a complete cycle			
	• All surfaces, including internal lumens are exposed to cleaning process			
	• Clean techniques are use when handling processed anaesthetic items			
	• Items are not dried in ambient air –mechanical drying is used (2.10)			
	• Hands are thoroughly clean when handling processed items			
	• Appropriate connectors are used for drying tubing & other lumened items			
	• Items not for immediate use are reassembled in a clean area			
	• Items are packed and clearly labelled for supply to user area			
			8	
	Section 2 Sub Total		**26**	

Section	Standard			Action Timeframe
Table 7.2	*BA TCH WASHERS* *CALIBRA TION OF MEASUREMENT DE VICES/S YS TEMS* • On commissioning			
	• 6-12 monthly			
	• After repair			
	• Quarterly thermocouple temperature check			
			4	
	MONITORING • Documented time at temperature			
	• Check every cycle for thermal disinfection			
	• Continuous performance checks for temperature and cleanliness of items			
	• Documented daily test for detergent or rinse residue - processed items are selected at random, placed in a clean bowl of water, agitated and pH of water measured			
			4	
	MAINTENANCE • Quarterly preventative maintenance			
	• Descaling is performed as required			
			2	
	ROUTINE CHECKING AND CLEANING • The functions of the washer/disinfector are checked daily			
	• Check and clean jets, filters, door, door gaskets and external surfaces			
	• Check detergent and rinse dispensers are clear and functioning correctly			
	• Check filters and door seals			
			4	
	Section 2 Sub Total		**14**	

Section	Standard			Action Timeframe
2.9.2.7	*UL TRA SONIC CLEANER AS2773.2 (BENCH TOP)* • Approved detergent is added after tank is filled with water			
	• Degassing is performed before instruments are processed			
	• Instruments are rinsed free of gross soil prior to immersion			
	• Instruments are placed in basket supplied by manufacturer			
	• Instrument are rinsed in warm-to-hot running water after removal from			
	• Where fitted, pump and associated tubing are purged of cleaning solution			
	• The unit is operated with lid closed to prevent emission of aerosols and to			
	• No part of the operator's body is submerged into water during operation			
	☺*The manufacturers' instructions are considered re. suitability of equipment for ultrasonic cleaning*			
			8	
Table 7.2	*CALIBRATION OF MEASUREMENT DE VICES/S YS TEMS* • Not applicable			
	MONITORING • Daily performance testing (Section 6, AS 2773.2) o Aluminium foil test o Pencil load test			
			1	
	MAINTENANCE • Annaul electrical safety check			
	ROUN TINE CHECKING & CLEANING • Checking filters and base plate		1	
	• Wiping external surfaces			
	• Emptying of tank at least daily or more frequently, as necessary			
	• Continuous checks for correct functioning of switches, gauges and lights			
			4	
2.9.3 2.9.3.1	*MANUAL CLEANING* *GENERAL* • Delicate or complex instruments are carefully hand-washed and			
	• Cleaning equipment is non-abrasive and maintained in good			
	• Cleaning equipment is thermally disinfected or sterilised at the end of each cleaning session			
	• When not in use, it is stored clean and dry			
	• Reusable cleaning brushes are cleaned and thermally disinfected after each use			
			5	
	Section 2 Sub Total		**19**	

Section	Standard			Action Timeframe
2.9.3.2	*The folowing are available (recommended):* ☺ *Clean water supply of good quality (Section 2.1)*			
	☺ *At least two sinks large and deep sinks*			
	☺ *Smal brush with firm plastic bristles, able to withstand cleaning agents*			
	☺ *Light grade nylon o r similar non abrasive scouring pad*			
	☺ *Cleaning agent*			
	☺ *Wire dental burr brush*			
	☺ *Non-linting clotr hes (adequate supply for f equent changing)*			
			0	
2.9.3.3	*METHOD OF CLEANING (For iems that do not have electrical components, or t are not power tools operated by compressed air) – (recommended)* ☺ *Item flushed with running water, 15°C – 30°C, to remove gross soiling*			
	☺ *Sink filed with warm water (approx 45°C) and detergent*			
	☺ *Al items dismantled or opened prior to placement in cleaning solution*			
	☺ *Items held low in sink to limit generation o f aerosols*			
	☺ *Al surfaces, including lumens and valves, are washed*			
	☺ *Stubborn stains are removed using a non-abrasive pad or soaking in stain removing solution*			
	☺ *Items received a final rinse in warm-to-hot running water*			
	☺ *Items are dried in a drying cabinet (holowware is inverted)*			
			0	
2.9.3.4	*MANUAL CLEANING OF ANAESTHETIC & RESPIRA TORY EQUIPMENT* • Anaesthetic and respiratory equipment is washed in a mechanical washer, not washed manually			
	• Semi-critical anaesthetic and respiratory equipment is thermally			
	• Disinfected or sterilised (or both) between uses			
	• Where thermal disinfection is not available, semi-critical items are sterilised or are single-use devices			
			4	
2.10 2.10.2	*DR YING OF ITEMS* *DR YING METHODS* • A drying cabinet is used for tubing and anaesthetic equipment			
	• The cabinet operates between 65°C – 75°C			
	• Drying cabinets complies with AS 2514 or AS 2774			
	☺ *A drying cabinet is used for instruments and holowware*			
	☺ *When manual drying a lint free cloth is used*			
	☺ *Items are not dried in ambient air*			
	☺ *Alcohol o r other flammable liquids are not used as a drying agent (exception – endoscopes)*			
			3	
	Section 2 Sub Total		**7**	

Section	Standard			Action Timeframe
Table 7.2	*DRYING CABINET* *CALIBRATION OF MEA SUREMENT DE VICES/S YS TEMS* • On commissioning			
	• 6 –12 monthly			
	• After repair			
	• Annual thermocouple check			
			4	
	MONITORING • Documented daily visual temperature check			
			1	
	MAINTENANCE • Quarterly preventative maintenance			
			1	
	ROUTINE CHECKING AND CLEANING • Daily surface clean			
	• Filters and door seals checked and cleaned			
			2	
2.11	*MONITORING OF CLEANING PROCESSES* • Detergent and rinse additive containers are replenished when necessary			
	• There is a continuous visual inspection of cleaned items			
	☺ *Instruments and equipment are free from residue after the cleaning process*			
	☺ *Commercialy available soil tests are used to verify cleaning efficiency*			
			2	
	Section 2 Sub Total		**10**	

Section	Standard			Action Timeframe
App B B2	*CARE AND HANDLING OF POWERED TOOLS – INCL UDE DENTAL HANDPIECES CLEANING OF POWERED INS TRUMEN TS AND HOSES* • Instruments kept free of gross soiling during procedure by wiping with dry sponge or a sponge moistened with sterile water			
	• In CSSD instrument is cleaned with a non-linting cloth moistened with detergent and water			
	• Powered surgical instruments and hoses are NOT immersed in water or placed in automated or ultrasonic cleaners			
	• Unless otherwise recommended by manufacturer, hoses remain attached to hand pieces during cleaning			
	• Hoses and cords are inspected for damage and wear			
	• All traces of detergent are rinsed from instruments			
	• Instruments and air hoses are wiped with a clean non-linting cloth to remove excess water			
	• A drying cabinet or second non-linting cloth is used to dry powered instruments and hoses			
			8	
B3	*LUBRICATION* • Items are lubricated only when necessary and according to manufacturer's written instructions			
	• Lubricants are not allowed into the hose when lubricating external movable fittings on air hose			
	☺ *If required, instruments are operated after lubrication to ensure dispersal of lubricant*			
	☺*Care is taken not to generate aerosols during lubrication process*			
			2	
B4	INSPECTION AND TESTING • Instrument is tested before packaging and sterilisation			
	• Triggers and handles are in the safety position when changing attachments			
	• Medical grade compressed air or compressed dry nitrogen is used			
	• Instruments are operated at the correct pressure			
	• The rate is set while the instrument is running			
	• Damaged instruments and hoses are sent to an appropriately qualified • technician or returned to the manufacturer for repair			
	• Powered tools requiring repair are cleaned and disinfected or sterilised			
	• If it is not possible to clean and decontaminate the item it is packaged in a • container, sealed and labelled with the relevant hazard warning			
	• The health care facility complies with requirements for transporting • biohazardous goods			
			9	
B5	STERILISATION • Powered surgical instruments are disassembled before sterilisation			
	• These items are packaged prior to sterilisation			
	• Delicate and sharp parts are protected			
	• Hoses are coiled loosely when packaged for sterilisation			
			4	
	Section 2 Sub Total		**23**	
SECTION 2 TOTAL			**131**	

Section	Standard	Compliance			Action Timeframe
		0	1	N/A	
3	**PACKAGING AND WRAPPING OF USED ITEMS PRIOR TO STERILISATION**				
3.1	*GENERAL* • Each material used is tested to establish penetration times and drying characteristics				
	• Materials used are compatible with the items being packed and the sterilising method selected				
	• Textile wraps are laundered prior to use				
	• Single wraps are used once and discarded				
	• Combinations of hollowware, instruments, dressings, drapes or tubing are not				
				5	
3.2	*PACK SIZE* • Maximum size of packs has been established during the performance qualification process (Section 8 and Appendix H)				
	• If contents of pack are wet, the pack is deemed unsterile and is not used				
				2	
3.3	*LABELLING PRIOR TO STERIL ISA TION* • Prepared labelling or non-toxic solvent-based felt-tipped pens and rubber stamps				
	• Labelling includes contents of pack, batch control data				
	• Sharp-tipped, water- based or ball-type pens are not used.				
				3	
3.4 3.4.1	*SPECIFIC REQUIREMENTS*				
	INSTRUMENTS • Ratchet instruments are remain open and unlocked				
	• Multi-part instruments are disassembled or sufficiently loosed prior to packaging to allow contact with sterilisation agent				
	☺ *Sets are packed to prevent damage to delicate items*				
	☺ *Instrument trays are perforated*				
				2	
3.4.2	*HOLLOWWARE* • All openings face the same direction				
	• Items cannot move inside pack				
	• Stackable hollowware packaged together are separated by non-porous spacers when nested				
	☺ *Holowware is placed with opening against the paper and not the plastic (Section 3.4.3.3)*				
				3	
3.4.3 3.4.3.1	*TYPES OF PA CKING & WRAPPING MA TERIALS* *-Appropriate packaging materials are selected for the different sterilisation processes (See Table Page 25)*				
	Section 3 Sub Total			**15**	

Section	Standard			Action Timeframe
3.4.3.2	*WRAPS* • Textile linen wraps comply with AS 3789.2			
	• Linen with defects such as holes and threadbare patches are not used			
	• Heavy woven fabrics such as canvas, are not used			
	• Recyclable barrier fabrics comply with AS 3789.8			
	• Paper wraps conform with AS 1079.2			
			5	
3.4.3.3	*FLEXIBLE PACKAGING MATERIALS* ☺ *Tips of sharp instruments are protected to prevent damage to laminated*			
	☺ *Laminated packaging is placed on its side in the steriliser*			
	☺ *Holowware is placed with opening against the paper and not the plastic*			
3.4.3.4	*NON-POROUS, NON-CELLULOSE BASED MATERIALS* • Except for dry heat sterilisers, nylon packaging is not used			
			1	
3.4.3.5	*Celulose-based and non-celulose based non-woven wraps* • Where used they conform to AS 1079.5			
			1	
3.4.3.6	*RIGID REUSABLE STERILISA TION CONTAINER SYSTEMS* • Containers allow penetration and removal of sterilising agent, and maintain sterility following the process			
			1	
App E E3 E3. 1	*SELECTION AND USE OF RIGID REUSABLE STERILISA TION CONTAINERS* *SPECIFIC CONSIDERA TONS* *ACQUISITION* • Filters adequate to ensure sterility maintenance			
	• All components are easily disassembled for cleaning, drying and storage			
	• For DD and benchtop steam sterilisers, the base and lids are perforated			
	• Containers are compatible with cleaning and sterilisation methods and equipment			
	• Cleaning, drying, storage and transport systems are compatible with additional bulk of containers			
	• Adequate trials have been undertaken to assess use of container systems			
	• On-site testing using physical and biological testing, and efficiency of drying cycle have established compatibility of container system with sterilising process			
			7	
E3.2	*INSPECTION AND MAINTENANCE* • After cleaning and drying a visual inspection is made to establish that the trays and lids are not dented and seals/gaskets are intact			
	• A check is made that correct filters are properly fastened in place			
			2	
	Section 3 Sub Total		**17**	

Section	Standard			Action Timeframe
E3.3	*LOCKING MECHANISMS*			
	• Containers have a locking device which is tamperproof, non-resealable and has a built-in chemical indicator			
	• The manufacturer has provided education re. use of locking device			
			2	
E3.4	*VALIDATION*			
	• On-site testing using physical, chemical and biological testing, has established that container system will achieve sterilisation of contents			
	• Seals, gaskets and filter-retention plates are visually inspected after cleaning and before each use.			
	• Any change in the use of container system is validated by biological and physical testing			
			3	
E3.5	*PACKING TECHNIQUES AND PROTECTION OF INSTRUMENTS*			
	• Containers packed to allow for penetration of sterilising agent			
	• Containers are not overloaded			
	• Hollowware and textiles are not mixed in the same tray			
	• Lids are able to be removed without contaminating the contents			
	• Where used, internal wraps can be opened without risk of contamination of the contents			
	• Filters and retaining mechanisms are easily visible and secure			
	• Instrument retaining mechanisms are used to protect instruments			
			7	
E3.6	*MASS* • The mass of the container and content allows for sterilising parameters to be met			
	• The mass of container and contents complies with manual handling standards			
			2	
E3.7	*STORAGE* • Containers are compatible with storage shelving systems and space before and after sterilising process			
			1	
E3.8	*ERGONOMICS* • Design allows for ease of use			
	• Handles allow containers to be lifted easily			
	• Design allows for easy removal of basket and trays without contamination, damage to contents and strain to operator			
			3	
E3.9	*FIL TERS – where required* • Single use filters are discarded after use			
	• For reusable filters - Written data from manufacturer has been obtained regarding validation for re-use			
	• Method for affixing filters provides reliable integrity of system			
			3	
Section 3 Sub Total			**21**	

Section	Standard			Action Timeframe
E3.10	*TRANSPORT* • Transport systems prevent damage to containers, their lids and contents			
	• Transport system has adequate weight bearing capacity for number and type of container system used			
			2	
TABLE 3.1	*NOTE 1* • Packed and wrapped items are not sterilised in a "flash" steriliser			
			1	
3.6 3.6.1	*SEALING OF PACKS* *GENERAL* • Staples, pins, inappropriate tape or taping methods are NOT used			
	• String, non-adhesive tape and elastic bands are NOT used			
			2	
3.6.2	*HEA T SEALING - APPENDIX F (Page 115)* • Seals are checked to ensure complete seal			
	• Laminated pouch sealing complies with AS1079.4			
	☺ *Suitable heat sealing equipment is used*			
			2	
Table 7.2	*HEAT SEALER* *CALIBRATION OF MEASUREMENT DE VICES/S YS TEMS* • On commissioning			
	• 6-12 monthly			
	• After repair			
			3	
	Monitoring • Daily check of seal integrity pre and post sterilisation			
			1	
	MAINTENANCE • Adjustment of gap between heating elements at least quarterly (according to manufacturers specifications			
			1	
	ROUTINE CHECKING AND CLEANING • Daily wipe of external surfaces			
	• Continuous checks for correct functioning of switches, gauges and lights			
			2	
	Section 3 Sub Total		**14**	

Section	Standard			Action Timeframe
3.6.3	*STERILISING INDICA TOR TAPE* • Tape is appropriate for the mode of sterilisation			
	• Tape is compatible with wrapping material used			
	• Tape colour change after exposure is clear, distinct and uniform and markedly different to unprocessed tape			
	• Tape has name of manufacturer, batch number and date of manufacture on the core			
	• Tape is heat stable, moisture stable and permeable to sterilising process			
	• Indicator tape is removed from textile wraps before returning to linen service			
	☺ Tape adhesive is pressure-sensitive, non-toxic and adheres to clean surfaces and leaves no adhesive residue on removal			
	☺ *The use o tape to seal bags and pouches is only used in the absence o a heat-sealing machine or when the machine is broken down.*			
	☺ *Where tape is used to seal a bag, the bag is sequentialy folded over 2 – 3 times prior to taping across the entire folded edge with one continuous piece of tape extending at leat 25 mm around the back of bag on both sides*			
			6	
	Section 3 Sub Total		**6**	
	SECTION 3 TOTAL		**73**	

Section	Standard	Compliance			Action Timeframe
		0	1	N/A	
4	**STERILISING EQUIPMENT**				
4.1	*GENERAL* • Heat bead devices, microwave ovens, pressure cookers, incubators, UV cabinets, boiling water units, ultrasonic cleaners and similar appliances are not used as sterilisers – they will not sterilise				
				1	
4.2	*STEAM STERILISERS*				
	• An operators manual is in the vicinity of the steriliser at all times				
	• Operator has verified that the items is suitable for steam sterilisation				
	• The cycle time and temperature reflects the type of load and packaging material being processed				
	• Steam – dryness fraction of 97% or above				
	• Steam is not heated beyond 2$_o$C above sterilising temperature (superheated)				
	• Penetration times have been established and added to the holding time (121^{o}C-15 mins, 132^{o}C-4 mins, 134^{o}C-3 mins)				
	☺ *Manufacturers instructions for operating steriliser are folowed*				
				6	
4.2.2	*DOWNWARD DISPLACEMENTSTERILISER (HORIZONTAL)* • Complies with AS 2192				
	• Ability of steriliser to achieve sterilisation of cannulated instruments has been established at the time of validation.				
	• Drying time is determined by size and density of packs				
				3	
4.2.3	• *'FLASH' STERILISER* • Complies with AS 2192				
	• Used for dropped, single instruments where there is no sterile duplicate available only				
	• Cannulated, complex instruments, suction and other tubing are not 'flash' sterilised				
	• Used for unwrapped non- porous items only				
	• The 'flash' sterilising process is monitored to ensure efficiency				
	☺*'Flash' steril ising is not used as a convenience o as a cost saving mechanism – adequate instruments are available*				
				5	
4.2.4	*BENCH TOP STERILISER* • Complies with AS 2182				
	• Without a drying cycle – sterilise unwrapped items only				
	• Drying process via mild heating of chamber while door remains closed – used for small numbers of simple packs (scissors, forceps) packed in paper				
	• Portable pre vacuum sterilisers – appropriate requirements of AS 1410 are applied				
				4	
	Section 4 Sub Total			**19**	

Section	Standard			Action Timeframe
4.2.5	*PREVACUUM STERILISER* • Complies with AS 1410			
			1	
4.3	*DRY HEA T STERILISER (HOT AIR TYPE)* • Complies with AS 2487			
	• The door of the steriliser is not opened during the cycle			
			2	
4.4	*LOW TEMPERA TURE STERILISERS AND LIQUID STERILANTS*			
4.4.2	*ETHYLENE OXIDE STERILISERS ISO 11135* • Gas concentration not less than 400 mg/l			
	• Temperature not less than 36°C on cool cycle			
	• Not greater than 60°C on warm cycle			
	• Relative humidity greater than 40% but less than 100%			
	• Time is appropriate for temperature and gas concentration			
	☺ Reference has been made to instrument manufacturer's instruments when using EO – gases can adversely affect some materials			
			5	
4.4.3	*HYDROGEN PEROXIDE PLASMA STERILISERS*			
4.4.4	*PERACETIC ACID STERLISING EQUIPMENT*			
4.4.5	*LIQUID STERILANTS*			
	• Any liquid sterilant used is registered with the TGA			
			1	
	Section 4 Sub Total		**9**	
	Section 4 Total		**28**	

Section	Standard	Compliance			Action Timeframe
		0	1	N/A	
5	**LOADING OF STERILISERS**				
5.1 5.1.1	*STEAM STERIL ISA TION* *GENERAL* The sterilising load is commences immediately after loading				
	Loads are not pre-heated				
				2	
5.1.2	*LOADING PORTABLE, DOWNWARD DISPLACEMENT AND PRE- VACUUM STERILISERS* • Hollowware is tilted on edge in a draining position				
	• Packs of drapes are loaded with layers vertical				
	• Items do not touch chamber walls				
	• Laminated pouches are loaded on edge with paper to laminate or flat with paper surface down				
	• Hollowware items are packed with the opening against the paper				
	• Loading carts are loosely loaded to capacity				
	• Only a single layer of packs is placed on each tray				
	☺ *Racks are used to alow for adequate separation of packaged instruments*				
	☺ *Packs of holowware and trays of instruments are NOT place above textile packs*				
				7	
5.1.2.2	*'FLASH' STERILISERWITHOUT A DRYING STAGE* • Items are not bagged or wrapped				
	• Items placed on a perforated or mesh tray				
	• Tray placed flat on steriliser shelf				
	• A new chemical indicator is place in each tray being processed				
	☺ *Performance of specificaly designed containers for sterilising and transporting 'flash' sterilised instruments has been established*				
				4	
5.2.2	*DRY HEAT STERILISATION* • Space is left between items to allow adequate circulation of air				
	• Items are not in contact with chamber walls				
				2	
5.3 5.3.2	*ETHYLENE OXIDE GAS STERIL ISA TION* *BASKETS AND LOADING CARS* • Items are placed in a metal basket or on a metal rack or loading cart				
				1	
	Section 5 Sub Total			**16**	

Section	Standard			Action Timeframe
5.3.3	*LOADING OF BASKETS AND LOADING CARS* • Items are placed loosely within the confines of the basket or loading car			
	• Packages do not touch chamber walls			
	• Items in flexible packaging materials are loaded on edge with paper to laminate, or flat with paper down			
			3	
5.4 5.4.2	*HYDROGEN PEROXIDE PLASMA STERILISA TION* • Space is left between items to allow adequate circulation of the sterilising agent			
	• Items are well away from chamber walls			
			2	
5.5 5.5.2.1	*PERACETIC ACID LIQUID CHEMICAL STERILISA TION* *DIRECTED FLOW PROCESSING CON TAINER/TRAY* ☺ *Care is taken to load machine in a manner that wil alow penetration of liquid sterilant to al surfaces*			
5.5.2.2	*FLEXIBLE PROCESSING TRAY* • Each instrument channel is directly connected to the machines fluid npathways via a purpose-designed tubing adaptor kit			
	☺ *Instrument manufacturer's insructions regarding leak and pressure testing are considered before loading flexible endoscopes into the machine*			
			1	
5.6	• Care is taken to ensure load content and manner of loading facilitates air removal and steam penetrations			
	- For al other methods of sterilisation consideration is given to manufacturer's instructions regarding load content and loading techniques			
			1	
	Section 5 Subtotal		**7**	
	Section 5 Total		**23**	

Section	Standard	Comliance			Action Timeframe
		0	1	N/A	
6	**UNLOADING OF STERILISERS**				
6.1 6.1.1	*STEAM STERILISERS* *WITH DR YING STA GE*				
	• On completion of drying stage the load is immediately removed from steriliser				
	• A visual inspection is made to ascertain that the load is dry, and the sterilising indicators have made the required colour change				
	• On removal of load the recording charts or printouts are checked and designated record sheets are signed that required parameters have been met				
	• Supervisor is notified if deviation of any parameter is detected				
	• Loading carts with cooling items are kept away from high activity areas				
	• Forced cooling with fans or boosted air conditioning is NOT used.				
	• Cooling items are NOT placed on solid surfaces				
	• Damaged, wet or dropped items are considered unsterile and are reprocessed				
	• Where unwrapped items are sterilised, appropriate handling procedures for unloading have been developed and documented				
				9	
6.1.2	*FLASH STERIL ISA TION (without a drying stage)* • Wrapped items are not sterilised without a drying stage				
	• Procedures for unloading 'flash' have been developed and documented				
	• Sterile 'set up' personnel wear a surgical mask and full sterile attire when transferring items from steriliser to point of use				
				3	
6.5	*PERACETIC ACID LIQUID CHEMICAL STERILISA TION* • When complete the air seal is released to access instruments				
	• Chemical indicator strip is visually inspected for colour change				
	• Load print out is checked to confirm parameters have been met				
	• Where instruments are transferred directly to sterile field, procedure in 6.1.2 is followed				
	• Attachments for purging of chemical steriliant are checked to ensure they have remained attached to instrument throughout cycle				
				5	
6.6	*MONITORING OF UNLOADING PROCEDURE* • Procedures for unloading each type of steriliser have been developed and documented				
	• Compliance with procedures are monitored (section 8)				
				2	
	TOTAL SECTION 6			**19**	

SECTION SIX TOTAL SCORE	**Section 6 Total**		**19**	

Section	Standard	Compliance			Action Timeframe
		0	1	N/A	
7	**PURCHASING, COMMISSIONING, CALIBRATION, PERFORMANCE TEST, MAINTENANCE AND VALIDATION**				
7.1	*GENERAL* *Al stages of the sterilisation process have been developed and documented to ensure that the items can be sterilised* • Cleaning				
	• Inspection				
	• Assembly				
	• Packaging				
	• Loading				
	• Sterilisation Cycle				
	• Calibration, routine monitoring and recording				
	• Unloading				
	• Storage				
	• Distribution				
	• Validation of the process				
	• The process can be reliably reprocessed				
	• The process is routinely monitored to the desired probability of a non-sterile item			13	
7.2	*PURCHASING* • All new sterilisers and associated equipment purchased complies with appropriate Australian Standards ➢ AS 1410 – Pre vacuum Steriliser □ ➢ AS 2182 – Sterilisers-Steam-Benchtop □ ➢ AS 2192 – Sterilisers-Steam-Downward displacement □ ➢ AS 2437 – Flushers/sanitisers for bedpans & urine bottles □ ➢ AS 2487 – Dry heat sterilizers □ ➢ AS 2514 – Drying cabinet for medical equipment □ ➢ AS 2773.1 – Ultrasonic cleaner-non portable □ ➢ AS 2773.2 – Ultrasonic cleaner-benchtop □ ➢ AS 2774 – Drying cabinet for respiratory equipment □ ➢ AS 2945 – Batch-type washer/disinfector □ ➢ AS 3836 – Rack conveyor washers □				
	☺ *Instalation qualification and operational qualification are included as part of the purchasing agreement with the supplier of al associated equipment*				
				1	
7.3 7.3.2 7.3.2.1	*VALIDATION* *COMMISSIONING OF STERILISERS* *GENERAL* • The tests and check to be performed during commissioning are specified, documented and recorded				
				1	
	Section 7 Sub Total			**15**	

Section	Standard	Carried Forward		Action Timeframe
7.3.2.1 Contd	• These include: ➢ calibration of all gauges, recording equipment and indicators, ➢ parameter monitoring, ➢ specific steriliser performance tests, and ➢ any process indicator tests			
			1	
7.3.2.2	*INS TALLA TION QUALIFICATION* • IQ demonstrates the steriliser and the area in which it is installed comply with the manufacturer's specifications			
			1	
7.3.2.3	*OPERA TIONAL QUALIFICATION* • OQ demonstrates that installed equipment operates within predetermined limits when used in accordance with its operational procedures			
			1	
7.3.3	*PERFORMANCE QUALIFICATION* • PQ demonstrates the attainment of the required sterilising conditions throughout the specified load(s)			
	• PQ has been achieved through: o Verification of physical parameters o Demonstration of microbiological lethality			
	• If used – process challenge devices are in accordance with EN 867-5			
	• Each sterilisation process and each type of steriliser load and loading pattern for the PQ process is specified and documented			
	• PQ is performed after completion of commissioning and ➢ On the introduction of new or modified items, ➢ New or modified packaging/loading patterns, ➢ New or modified or processing parameters (unless equivalence, either to validated reference loads or cycles or to a previously validated product, packaging or loading pattern, is demonstrated)			
			5	
7.3.4	*CERTIFICATION OF PERFORMANCE QUALIFICATION OF STERILISER* • Reports on commissioning, PQ, recommissioning and performance requalification have been prepared and signed and a copy filed in the sterilising processing facility			
			1	
7.4 7.4.1	*RECOMMISSIONING AND PERFORMANCE REQUALIFICA TION* • The recommissioning and performance requalification process is documented and a copy filed in sterilising facility			
			1	
	Section 7 Sub Total		**10**	

Section	Standard			Action Timeframe
7.4.2	*RECOMMISSIONING*			
	• Recommissioning is performed if: ➢ Changes or engineering work is carried out on equipment which could effect the performance of the steriliser ➢ A review of records indicated unacceptable deviation(s) from data determined during validation			
	• The responsibility for determining the necessity and extent of repeating elements of commissioning is assigned to a designated person trained in this speciality			
	• Recorded data for each type of test or check during recommissioning is within specified limits of the data recorded during commissioning			
			3	
7.4.3	*PERFORMANCE REQUALIFICA TION (PReQ)*			
	• PReQ is performed at least annually and whenever a change is made to a steriliser load which is not within the limits specified in the performance qualification report			
	• The responsibility for determining the necessity and extent of repeating parts of PReQ is assigned to a designated person trained in this speciality			
			2	
7.5	*CALIBRA TION OF STERILISER* • A calibration schedule, based on the steriliser history, has been established and maintained			
	• Documentation is requested from the service provider that includes: o Actual and adjusted values			
	• When faults arise corrective action is taken			
	☺ *Routine calibration checks and maintenance o al measuring devices, timers, gauges and displays on steriliser are checked by a trained competent person*			
	☺ *Measuring equipment is certified by a recognised certification body e.g. (NATA)*			
	☺ *The report is made available and includes the certification number of the calibration device used*			
			3	
7.6	*MONITORING OF STERILISER* • Routine sterilisation cycle performance is monitored accordance with the test frequencies specified in Table 7.1 (attached)			
			1	
	Section 7 Sub Total		**9**	

Section	Standard			Action Timeframe
7.7	*MAINTENANCE OF STERILISERS* *A preventative maintenance schedule, based on the history of the equipment is established and maintained.*			
	• Where faults arise, corrective action is undertaken			
	• A preventative maintenance contract is entered into with a trained competent maintenance contractor or the equipment manufacturer			
	• Where this is not possible a skilled person has been trained for the task			
	• Filters on equipment are checked every 6 months and results recorded			
	• A program of routine replacement or revalidation of filters has been established			
	• A cleaning and maintenance program is in place			
	• After repairs testing is done to establish compliance with original installation or operation qualification specifications			
	• Repairs are assessed to establish if they have altered the performance of the equipment since most recent validation			
			8	
7.8 7.8.1	*ASSOCIA TED EQUIPMENT* *GENERAL* • This may include: ➢ Drying cabinets ➢ Aeration cabinets ➢ Batch washers ➢ Rack conveyor washers ➢ Ultrasonic cleaners ➢ Heat sealer			
			1	
7.8.2	*VALIDATION OF PROCESSES* • Processes for associated equipment have been established, documented and validated			
			1	
7.8.3	*COMMISSIONING* • All associated equipment has under gone a commissioning process ☺ *Reference is made to the applicable Standard and the manufacturer's operational instructions for guidance on the commissioning procedue for each type of associated equipment*			
			1	
	Section 7 Sub Total		**11**	

Section	Standard			Action Timeframe
7.8.4	*PERFORMANCE QUALIFICATION*			
	• The PQ consists of the following three steps: ➢ Choice and performance and practical test(s) to evaluate proper functioning			
	➢ Determination that operating conditions are being reliably achieved ➢ That gauges, where fitted, are indicating accurately ➢ Test results are documented			
	(Not all associated equipment can undergo PQ – refer to applicable Standard for guidance)			
			1	
7.8.5	*RECOMMISSIONING AND PERFORMANCE QUALIFICATION* • Where performance or qualification procedures are not applicable recommissioning (usually only OQ) is undertaken at least annually • Where applicable, performance requalification is undertaken annually			
			2	
7.8.6	*CALIBRA TION, MONITORING AND MAINTENANCE* • A preventative maintenance contract is entered into with a trained competent maintenance contractor or the equipment manufacturer • Or a skilled person has been trained for the task • Calibration, monitoring and maintenance of associated equipment is performed in accordance with Table 7.2 (attached)			
			3	
	Section 7 Sub Total		**6**	

TOTAL SECTION 7		**51**	

CALIBRATION, MONITORING AND MAINTENANCE OF ASSOCIATED EQUIPMENT Pre-vacuum Steriliser –

Table 7.1	ACTION REQUIRED
CALIBRATION OF MEASURMENT DEVICES/SYSTEMS	IQ, OQ, PQ, recommissioning and PReQ 3, 6, 12 monthly – depending on calibration history
MONITORING	Daily: External chemical indicator Leak rate test where no air detector Bowie Dick test Weekly: Leak rate test if air detector fitted Every Pack: External chemical indicator Every Cycle: Electronic printout Optional: Biological/enzymatic indicator Internal chemical indicator Process challenge devices Electronic data loggers
AFTER REPAIR OR MODIFICATION	Recommissioning or PReQ as required depending on the extent of the repairs or modification (7.4)
MAINTENANCE	Monthly, quarterly or annually – as established by HCF in conjunction with manufacturer or maintenance contractor
ROUTINE CHECKING AND CLEANING	Daily Check: Floor is free of debris Chamber drain and filter are clear Correct functioning of recording devices, gauges and timers Door gasket – undamaged Cleaning: Loading tray and external surfaces cleaned daily Steri liser chamber cleaned weekly
CRITERIA FOR RELEASE OF PROCESSED ITEMS	Achievement of set cycle parameters Correct colour change of chemical indicators Packaged items dry and intact Correct result of BI/EI, process devices or data loggers

DOWNWARD DISPLACEMENT (JACKETED) (AS 2192) AND PORTABLE BENCHTOP (AS 2182) WITH DRYING CYCLE

Table 7.1	ACTION REQUIRED
CALIBRATION OF MEASURMENT DEVICES/SYSTEMS	IQ, OQ, PQ, recommissioning and PReQ 3, 6, 12 monthly – depending on calibration history
MONITORING	Every Pack: External chemical indicator Every Cycle: Electronic printout Optional: Biological/enzymatic indicator Internal chemical indicator Process challenge devices Electronic data loggers
AFTER REPAIR OR MODIFICATION	Recommissioning or PReQ as required depending on the extent of the repairs or modification (7.4)
MAINTENANCE	Monthly, quarterly or annually – as established by HCF in conjunction with manufacturer or maintenance contractor
ROUTINE CHECKING AND CLEANING	Daily Check: Floor is free of debris Chamber drain and filter are clear Correct functioning of recording devices, gauges and timers Door gasket – undamaged Cleaning: Loading tray and external surfaces cleaned daily Steri liser chamber cleaned weekly Water reservoir emptied and cleaned – portable type
CRITERIA FOR RELEASE OF PROCESSED ITEMS	Achievement of set cycle parameters Correct colour change of chemical indicators Packaged items dry and intact Correct result of BI/EI, process devices or data loggers

DOWNWARD DISPLACEMENT (NON JACKETED) (FLASH) WITHOUT DRYING CYCLE
(AS 2192)

Table 7.1	ACTION REQUIRED
CALIBRATION OF MEASURMENT DEVICES/SYSTEMS	IQ, OQ, PQ, recommissioning and PReQ 3, 6, 12 monthly – depending on calibration history
MONITORING	Every Cycle: Electronic printout Chemical indicator (Class 4,5,or 6) Optional: Biological/enzymatic indicator Process challenge devices Electronic data loggers
AFTER REPAIR OR MODIFICATION	Recommissioning or PReQ as required depending on the extent of the repairs or modification (7.4)
MAINTENANCE	Monthly, quarterly or annually – as established by HCF in conjunction with manufacturer or maintenance contractor
ROUTINE CHECKING AND CLEANING	Daily Check: Floor is free of debris Chamber drain and filter are clear Correct functioning of recording devices, gauges and timers Door gasket – undamaged Water reservoir (portable types) Cleaning: Loading shelves and external surfaces cleaned daily Steri liser chamber cleaned weekly Water reservoir emptied and cleaned – portable type
CRITERIA FOR RELEASE OF PROCESSED ITEMS	Achievement of set cycle parameters Correct colour change of chemical indicators Correct result of BI/EI, process devices or data loggers

Table 7.1	ACTION REQUIRED
CALIBRATION OF MEASURMENT DEVICES/SYSTEMS	According to manufacturer's recommendations
MONITORING	Every Cycle: Electronic printout Chemical indicator Daily: Diagnostic cycle Weekly: Biological indicator
AFTER REPAIR OR MODIFICATION	Recommissioning or PReQ as required depending on the extent of the repairs or modification (7.4)
MAINTENANCE	Monthly, quarterly or annually – as established by HCF in conjunction with manufacturer or maintenance contractor (or both)
ROUTINE CHECKING AND CLEANING	Daily Check: (According to manufacturer's recommendations) May include: Drip pan, Chamber drain, Water filter, Air filter, Recording device, Lid seal and carrier Cleaning: Carriers, containers and external surfaces cleaned daily
CRITERIA FOR RELEASE OF PROCESSED ITEMS	Achievement of set cycle parameters Correct colour change of chemical indicators

COMMENTS:

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HYDROGEN PEROXIDE PLASMA

Table 7.1	ACTION REQUIRED
CALIBRATION OF MEASURMENT DEVICES/SYSTEMS	According to manufacturer's recommendations
MONITORING	Every pack: External chemical indicator Every Cycle: Electronic printout Weekly: Biological/enzymatic indicator Optional: Internal chemical indicator Process challenge device
AFTER REPAIR OR MODIFICATION	Recommissioning or PReQ as required depending on the extent of the repairs or modification (7.4)
MAINTENANCE	Monthly, quarterly or annually – as established by HCF in conjunction with manufacturer or maintenance contractor (or both)
ROUTINE CHECKING AND CLEANING	Daily Check: Floor is free of debris (According to manufacturer's recommendations) May include: Chamber drain, Air filter, Recording device, Lid seal and carrier, Vaporizer system Cleaning: Carriers, containers and external surfaces cleaned daily
CRITERIA FOR RELEASE OF PROCESSED ITEMS	Achievement of set cycle parameters Correct colour change of chemical indicators Packaging intact Correct result of process challenge devices

COMMENTS:

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BATCH WASHER – AS2945 -1998

Table 7.2	ACTION REQUIRED
CALIBRATION OF MEASURMENT DEVICES/SYSTEMS	On commissioning 6 - 12 monthly After repair Quarterly thermocouple temperature check
MONITORING	Documented time at temperature Check every cycle - thermal disinfection required Continuous performance checks for: - temperature - cleanliness of items Documented daily test for chemical residue
MAINTENANCE	Quarterly preventative maintenance Descaling preformed at required
ROUTINE CHECKING AND CLEANING	Daily: Check and clean jets, filters, doors, door gaskets and external surfaces Check detergent and rinse dispensers are clear and functioning correctly Check door seals

COMMENTS:

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ULTRASONIC CLEANER – AS 2773

Table 7.2	ACTION REQUIRED
CALIBRATION OF MEASURMENT DEVICES/SYSTEMS	Not applicable
MONITORING	Daily performance testing • Aluminium foil test or • Pencil load
MAINTENANCE	Annual electrical safety check
ROUTINE CHECKING AND CLEANING	Daily: Check filters Check base plates Wipe external surfaces Empty tank at least daily or more frequently, as necessary Continuous: Correct functioning of switches, gauges and lights

COMMENTS:

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CALIBRATION, MONITORING AND MAINTENANCE OF ASSOCIATED EQUIPMENT

DRYING CABINET – AS 2514 or AS 2774

Table 7.2	ACTION REQUIRED
CALIBRATION OF MEASURMENT DEVICES/SYSTEMS	On commissioning 6 - 12 monthly After repair Annual thermocouple temperature check
MONITORING	Daily visual temperature check
MAINTENANCE	Quarterly preventative maintenance
ROUTINE CHECKING AND CLEANING	Daily: Surface cleaning Check and clean filters Check and clean door seals

COMMENTS:

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INCUBATORS FOR SELF CONTAINED BIOLOGICAL INDICATORS

Table 7.2	ACTION REQUIRED
CALIBRATION OF MEASURMENT DEVICES/SYSTEMS	Annual temperature check
MONITORING	
MAINTENANCE	Following of manufacturer's guidelines
ROUTINE CHECKING AND CLEANING	Following of manufacturer's guidelines

COMMENTS:

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HEAT SEALER

Table 7.2	ACTION REQUIRED
CALIBRATION OF MEASURMENT DEVICES/SYSTEMS	On commissioning 6 - 12 monthly After repair
MONITORING	Daily check of seal integrity pre-and post-sterilisation
MAINTENANCE	Adjustment of gap between heating elements in accordance with manufacturer's specifications, at least
ROUTINE CHECKING AND CLEANING	Daily: wiping of external surfaces Continuous checks for correct functioning of switches, gauges and lights

COMMENTS:

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AUTOMATED ENDOSCOPE REPROCESSOR (WASHER/DISINFECTOR)

Table 7.2	ACTION REQUIRED
CALIBRATION OF MEASURMENT DEVICES/SYSTEMS	On commissioning After repair Annually
MONITORING	Daily check of chemical levels Every cycle: Check process recorder for critical process parameters – time, temperature, chemical concentration, and, where possible, flow rate and pressure Monthly: Microbial monitoring of rinse water quality of the automatic endoscope reprocessor (refer to GENSA guidelines)
MAINTENANCE	Check and change internal water, chemical and air filters according to manufacturer's instructions Treatment of external water filters by heat or chemical means is essential – frequency depends on local conditions and water quality Descaling of machine lines and tanks according to manufacturer's instructions
ROUTINE CHECKING AND CLEANING	Daily: Cleaning of soak basins Lids and All surface areas of machine

COMMENTS:

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Section	Standard	Compliance			Action Timeframe
		0	1	N/A	
8	**QUALITY MANAGEMENT**				
8.1	*FACILITY MANAGEMENT* • The person in charge of sterilising facility has specific qualifications and experience in sterilising technology				
	• Person in charge has the authority to implement the requirements of AS4187				
	• Is actively involved in supervising the day-to-day activities of the CSSD				
	☺ The sterilising services line of responsibility is directly to the executive director (or director) of clinical services to ensure neutrality of service				
				3	
8.2	*DOCUMENTA TION* • Policies and procedures for all activities in the processing of sterile items are documented				
	• Records are maintained and reviewed at frequent intervals and dated				
	• Records are kept for a period of time not less than that defined by regulatory authorities or Health Care Facility				
	• Records include: o Daily production statistics				
	o All tests performed on equipment				
	o Steriliser cycling records				
	o Employee training records				
	o Staff work rosters				
	o Incident reports				
	o Quality and procedure/operational manual				
	o Maintenance records				
	o Certification of validation – IQ, OQ and PQ data				
	o ☺Tray/instrument tracking records				
				4	
8.3	*PERFORMA NCE MA NA GEMENT* • Staff qualifications and staffing levels are sufficient to ensure ontinuous, safe and efficient operation				
	• There are written job descriptions for each category of staff				
	• The manager is qualified to appropriate level by education, training and experience in sterilising processes				
	☺ There is a system for assessing staff performance after orientation and at regular intervals				
				3	
8.4	*EDUCATION AND TRAINING* • There is a formal orientation program in place for new staff				
	• Formal orientation is followed by on-the-job practical training				
	☺ *Staff members are encouraged to participate in appropriate external education courses*				
				2	
	Section 8 Sub Total			**12**	

Section	Standard			Action Timeframe
8.5	*MATERIAL MANAGEMENT* • There are protocols for inventory control			
			1	
8.5.2 8.5.2.1	*PRODUCT IDENTIFICA TION AND TRACEABILITY* *BATCH CONTROL NUMBERS* Procedures are in place to link steriliser cycle batch information to items that have been sterilised, to the patient			
	• Each packaged item is labelled with a batch control identification:- o Steriliser number or code			
	o Date of sterilisation			
	o Cycle or load number			
	o Manufacturers batch/lot no. of any unsterile commercially prepared implantables placed in pack			
			1	
8.5.2.2	*STERIL ISA TION CYCLE RECORDS* • Date of cycle			
	• Steriliser number or code (if > one steriliser)			
	• Cycle or load number (if > one load)			
	• Exposure time and temperature			
	• Name of loading operator			
	• Name of person releasing load			
	• Specific contents of load			
	• Results of physical, chemical and biological monitoring			
			8	
8.5.3	*DEVIATION AND FAULT ANALYSIS* • A procedure is in place to review any quality or procedural problems			
			1	
8.5.4	*PRODUCT COMPLAIN TS* • A complaints procedure is in place and corrective action taken is documented			
			1	
8.5.5	*RECALL PROTOCOL* Recall policies and procedure are in place and include:- • Criteria for issuing recall notice			
	• Person responsible for issuing notice			
	• Person responsible for reporting on recall activities			
	• Persons to be notified when recall event occurs			
			4	
	Section 8 Sub Total		**16**	

Section	Standard			Action Timeframe
8.5.6	*RECALL NOTICE* includes: • Name of person or department for which notice is intended			
	• Sterilisation batch information			
	• Product name and quantity of products returned			
	• Specifies action to be taken by persons receiving the notice, e.g. return or destruct or hold			
			4	
8.5.7	*RECALL REPORT* includes: • Circumstances that initiated need for recall			
	• List of total number of products for recall and actual number located and recalled			
	• Identifies the number of patients potentially exposed and action taken			
	• Provision to document the actions taken to prevent a similar situation from occurring in the future (if necessary)			
			4	
8.6 8.6.1	*MONITORING STERILISER CYCLES* (see table 7.1 attached) *PHYSICAL INDICATORS* • Parameters are measured with continuous automatic permanent monitoring			
	• No permanent record – readings from gauges and devices are documented for every cycle at intervals of 10 seconds (steam)			
	• Record chart is examined and labelled with operators identification at the end of each cycle			
	• Any variations from normal is noted and action taken			
	• Where no record of physical parameters is obtained a BI/EI or a Class 4, 5 or 6 chemical indicator is used with each load			
			5	
8.6.2	*CHEMICAL INDICATORS* • *Used as recommended in table 7.1*			
			1	
8.6.3	*BIOLOGICAL/ENZYMATIC INDICA TORS* • *Used as recommended in table 7.1*			
			1	
8.6.4 8.6.4.1	*SPECIAL PERFORMANCE TESTS FOR PRE- VACUUM STEAM STERILISERS* *- Used as recommended in table 7.1* • Leak rate test			
8.6.4.2	• Bowie Dick type test			
8.6.4.3	• Air detector function test			
8.6.4.4	• Air detector performance test			
			4	
Section 8 Sub Total			**19**	

Section	Standard			Action Timeframe
8.7	*VALIDATION PROCESS – detail of process in Appendix H* • The sterilisation process has been validated			
	• The results have been documented			
			2	
8.8	*CRITERIA FOR RELEASE FOR PROCESSED ITEMS*			
8.8.1	• Prior to release there is evidence to indicate that the process has met all specified requirements			
	• The person responsible for authoring release has full knowledge of all aspects of the validation process			
	• The person responsible for authoring release is satisfied that monitoring and control of the entire process has met specifications			
			3	
8.8.3	*PA RA ME TRIC REL EA SE (if used)*			
	• The process record shows compliance with all processing specifications achieved during performance qualification			
	• The process record shows compliance with processed used in:- o Cleaning o Packaging o Loading o Unloading o All cycle parameters			
	• There is evidence that the equipment control and any associated monitoring devices have continuously recorded all stages of the sterilisation cycle – record comply with specifications			
	• Equipment and component parts are current in terms of calibration and maintenance			
			4	
8.8.4	*NON-PARA ME TRIC REL EA SE*			
	• Biological/enzymatic and chemical indicators are used to determine that the sterilisation process has met processing specifications			
	• The load is not released until the results of tests are interpreted as successful			
			2	
8.8.5	*RELEASE DOCUMENTA TION*			
	• The are records of items released			
	• The record includes identification of items, identification of cycle, time of release and name of person authorising release			
			2	
	Section 8 Sub Total		**13**	

Section	Standard			Action Timeframe
8.9	*MONITORING OF PACKAGING PROCESS* Continuous checks are made of: • Integrity of outer wrap & seals			
	• Correct labelling			
	• Correct colour change of external indicator			
	In addition, the end user knows to check sterilised packs for: • Integrity of outer wrap & seals and correct labelling			
	• Ease of opening			
	• Correct packaging techniques			
	• Correct contents			
	• Correct layout of contents			
	• Condition of contents – cleanliness, alignment and function			
	• Correct performance of internal indicator (if used)			
			10	
8.10 8.10.1	*OCCUPA TIONAL HEALTH & SAFETY* • Staff are immunised in accordance with immunisation guidelines			
	• Immunisation records are kept in staff files			
	If immunisations are declined this recorded			
	Staff health is monitored to ensure: • Superficial skin lesions are covered by an occlusive dressing and staff are made aware of cross infection hazards			
	• Accidents are recorded and treatment is provided as required			
	Staff with dermatitis, skin infections or infected lesions are examined by a MO			
			4	
8.10.2	*STAFF ATTIRE* • A clean uniform is worn for each shift			
	• Hair is safely secured and covered while preparing items for sterilisation			
	• PPE is worn when handling used/soiled items			
	Hand and wrist jewelery including plain wedding bands are NOT worn			
	Nail polish or acrylic nails are not worn, nails are kept short			
	Uniforms worn in sterilising department are not worn outside the health care facility			
			3	
	Section 8 Sub Total		**17**	

Section	Standard			Action Timeframe
8.10.3	*HA ND WASHING* • Handwashing techniques and the importance of handwashing are taught to all staff during orientation and reiterated regularly			
	• Single use towels are used			
	• Hand creams are NOT used by staff on arrival at work & whilst on duty			
	- Mechanical hot air drying is NOT used			
			3	
8.11	*ENVIRONMENTAL CONTORL* • Work practices and stock control ensure that sterile and clean items are separated from soiled items			
	• Environment is in a hygienic state at all times			
	• Adequate facilities for personal hygiene are readily accessible			
	• Efficient ventilation is in place			
	• Lint production is minimised			
			5	
8.12	*EVALUA TION, FEEDBACK & OUTCOMES* • Processes and procedures are evaluated			
	• Regular audits provide a mechanism for analysis, feedback and quality improvement			
			2	
	SECTION 8 Sub Total		**10**	
	TOTAL C3ECTION 8		**87**	

Section	Standard	Compliance			Action Timeframe
		0	1	N / A	
9	**STORAGE & HANDLING OF STERILE ITEMS**				
9.1 9.1.1	*GENERAL* *STERILE ITEMS* • Sterile items are stored and handled in a manner that maintains the integrity of pack and prevents contamination				
	• This applies to items sterilised by facility and commercially procured items				
	• Policies and procedures for storage, handling and issuing of sterile stock have been developed and documented				
	• Items to remain sterile for use are NOT stored in ultraviolet cabinets or in disinfectants				
				4	
9.1.2	*STORA GE OF UN WRAPPED CRITICAL MEDICAL ITEMS*				
	• Items stored unwrapped are cleaned and sterilised before storage				
	• Items are cleaned and resterilised immediately prior to use				
				2	
9.1.3	STORAGE OF UNWRAPPED SEMI-CRITICAL AND NON-CRITICAL MEDICAL ITEMS • After processing, items are stored in clean, dry, dust free, dedicated containers/drawers to protect them from environmental contamination				
	• If necessary they are reprocessed prior to use				
				2	
9.2	*STORAGE AREA* • Sterile storage areas are dedicated to that purpose only				
	• Clearly sign-posted & traffic flow controlled/restricted				
	• Dust free, insect free & vermin free				
	• Open shelves - 250mm above floor level & 440mm below ceiling level				
	• Items protected from sunlight				
	• Storage containers are kept clean, dry and in good condition				
	• Cardboard boxes are NOT used as storage containers *(porous, cannot be adequately cleaned and may harbour organisms)*				
	• Commercial dispenser boxes are not topped up or reused				
	• Walls, floors, ceiling lights and work surfaces are constructed so that difficult-to-clean corners are minimised				
	• Surfaces non-porous & smooth & easily cleaned				
	Overhead lighting is fitted flush with ceiling to minimise dust entrapment				
	Air-conditioning – 18^{O}C – 22^{O}C (Complies with AS 1668.2)				
	Ventilation – RH 35% – 68% (Complies with AS 1668.2)				
				10	
	Section 9 Sub Total			**18**	

Section	Standard			Action Timeframe
9.2.2	*ACCESS TO STORED ITEMS* • Access to sterile store area is restricted to those who have had adequate education and training in handling of sterilised items			
	• Who do not have discharging or open wounds, abrasions or scaling skin disorders and;			
	• Who have washed and dried their hands			
	• Access is restricted			
	Trafic within area is controled – minimise movement of airborne contaminants			
			4	
9.3	*PLASTIC DUST CO VERS* • Plastic (polyethylene) used is new, clean and intact and of sufficient strength			
	• Covers are applied immediately they are cool, in a clean environment using clean techniques			
	• Dust covers are sealed (sealing by hermetic means is recommended)			
	• All batch information is marked on the packaged and not on dust cover			
	Items are placed in dust covers within 2 hours of sterilisation			
			4	
9.4	*TRANSPORT/DISTRIBUTION OF STERILE ITEMS* • Sterile items transported outside the HC facility are packaged securely and protected against damage and contamination during transport			
	• All transport equipment is maintained in a clean, dry state and in good working order			
	A system has been instituted that pro vides a record as to stock levels and to the disbursement of items to users			
	Transport vehicle has adequate segregation and meets the requirements of Clause 9.2.1			
	Equipment used to move and transport items is dedicated to that purpose and is kept clean			
	It is not used to colect used items, transport food or garbage			
	Where unsterile but clean linen, such as instrument wraps, are transported with sterile items, the sterile items are separately protected e.g. in a plastic bin with lid			
	Care is taken to ensure stock is not tightly packed into storage containers or shelving, o r wrapped with elastic bands			
			2	
	Section 9 Sub Total		**10**	

Section	Standard			Action Timeframe
9.5	*COMMERCIALL Y PREPA RED ITEMS* • Dust is wiped from the store pack before it is opened			
	• Sterile items are removed from the store pack before entering clean area			
	• Sterile items from external suppliers are inspected for cleanliness and/or damage to unit packs or their contents			
	Grossly soiled or damaged store packs are not accepted – return to supplier for replacement or refund			
			3	
9.6 9.6.1	*SHELF-LIFE/STOCK ROTA TION* *GENERAL* • Shelf life is event related			
	• A stock rotation system is based on the date of sterilisation			
	• Stock is maintained at adequate levels (do not overstock)			
			3	
9.6.2	*STOCK WHICH IS NONCONFORMING* • A package is considered nonconforming (non sterile and not fit for use) when: - ➢ It is incorrectly wrapped ➢ Damaged or open ➢ Water after the sterilisation cycle or comes in contact with wet ➢ surface ➢ Is placed or dropped on a dirty surface (e.g. floor or sink area) ➢ It has no indication of having been through a sterilising process			
	• Nonconforming stock is totally re processed as soon as identified			
			2	
9.6.3	*FACTORS WHICH COMPROMISE STERILE STOCK* • Processes and procedures are in place to protect sterile stock from the following factors that will compromise sterile stock ➢ Incorrect cleaning procedures in storage areas ➢ Moisture or condensation ➢ Incorrect temperature ➢ Excessive exposure to sunlight and other sources of ultraviolet light ➢ Vermin and insects ➢ Inappropriate packaging materials ➢ Incomplete sealing ➢ Sharp objects or rough handling or use of elastic bands which may ➢ cause damage to packaging materials ➢ Incorrect handling during transportation			
			1	
	SECTION 9 Sub Total		**9**	

TOTAL SECTION 9		**37**	

Section	Standard	Compliance			Action Timeframe
		0	1	N/A	
10	**DISINFECTION**				
10.1	GENERAL • Sterilisation is used for all reusable instruments and equipment that can withstand the process				
	• Disinfection is not carried out as a substitute for sterilisation – disinfection is not a sterilising process				
	• Items for disinfection are clean and able to withstand the process				
	• Items are not stored in disinfectant before or after any form of processing				
				4	
10.2 10.2.1	MEANS OF DISINFECTION THERMAL DISINFECTION • Item is thoroughly cleaned before disinfection				
	• All parts of the item is subjected to moist heat at or above the recommended temperature for the recommended duration (see below)				
	Surface temperature / Minimum disinfection time (minutes) 90°C / 1 80 oC / 10 75 oC / 30 70 oC / 100				
				2	
10.2.2 10.2.2.1	CHEMICAL DISINFECTION GENERAL • Chemical disinfection is only used when thermal disinfection is unsuitable				
	• Any chemical disinfectants used are registered with the TGA in Australia				
				2	
10.2.2.2	INSTRUMENT GRADE DISINFECTANTS • Only disinfectants labelled as **'instrument grade disinfectant'** are used for reprocessing reusable instruments				
	• A high-level instrument grade disinfectant is the minimum level used for semi-critical instruments which contact unbroken mucous membranes that are not normally sterile				
	• A intermediate-level or low-level instrument grade disinfectant is used for disinfection of non-critical instruments which contact unbroken skin				
	• Care is taken to follow manufacturers specific instructions				
	• Directions for use are not interchanged between formulations				
	• Relevant OH&S regulations are follow MSDS are available				
	• Extreme care is taken when using instrument grade disinfectants				
	Where practicable, the concentration of the solution is monitored at least daily in line with manufacturer's instructions				
				7	
	Section 10 Sub Total			**15**	
	TOTAL SECTION 10			**15**	

Section	Standard	Compliance			Action Timeframe
		0	1	N/A	
11	**CLEANING OF THE STERILISING PROCESSING FACILITY AND ASSOCIATED EQUIPMENT**				
11.1	*GENERAL* • Routine and special-purpose cleaning is performed to prevent cross-contamination				
	• There is a policy documenting areas and equipment to be cleaned, the methods used and the frequency of cleaning				
	• Completion of cleaning activities is documents				
	• Surfaces are impervious and intact to allow effective cleaning				
	• Blood and body spills are wiped up and the area washed with detergent and water				
	• Standard precautions are taken				
				6	
11.2	EQUIPMENT There is written procedures for all sterilising and ancillary equipment indicating:-				
	• Method,				
	• Frequency,				
	• Manufacturer's instructions and				
	• Cleaning agents and materials				
				4	
11.3	WASTE DISPOSAL • Waste disposal is in accordance with local regulations				
	• Waste is placed in appropriate containers				
	• Waste is not transferred from bag to bag during collection				
	• Sharps containers are available (comply with As4031 or AS/NZS4261				
	Waste is removed via designated disposal exits				
				4	
	Total Section 11			**14**	

TOTAL SECTION 11		**14**	

Section	Standard	Compliance			Action Timeframe
		0	1	N/A	
12	**SELECTION AND CARE OF INSTRUMENTS**				
12.1	GENERAL				
	• Those responsible for reprocessing instruments are involved in the selection process				
	• It is established that the cleaning methods used are compatible with the instrument to be purchased				
	• It is established that the cleaning agents or available water will not cause removal of surface finishing, corrosion or pitting				
	• Where manufacturers make claims or recommendations for reprocessing of their items, details of validation of the reprocessing procedure is obtained in writing				
				4	
12.2	GENERAL CONSIDERATIONS				
12.2.1	GENERAL				
	• Staff responsible for instrument reprocessing have had appropriate education and training				
	• Instrument repairs are performed by qualified instrument technician				
				2	
12.2.2	IDENTIFICATION *A system for identifying instrument is established* *Engraving is not used* *High quality etching is used to mark instruments* Care is taken when using colour coded devices – may detach during surgery and may habour m/organism beneath adhesive layer				
12.2.3	REMOVAL OF SOIL				
	• Removal of soil is performed at point of use				
	• Cannulated instruments are not allowed to become dry				
	Saline is not used to rinse o r wipe instruments				
				2	
12.2.4	SORTING INSTRUMENTS AND INSPECTION				
	• Light or delicate instruments are kept separately from heavy instruments				
	• Instruments that can be taken apart are disassembled prior to terminal cleaning and inspected				
	• Any defective instruments are cleaned, dried and sterilised prior to being sent for repairs				
	• A validated and documented process is used for multi-part instruments and equipment designed not to be disassembled - according with manufacturer's instructions				
				4	
12.2.5	INSTRUMENT (FLASH) STERILISATION *Cleaned items are not 'flash' sterilised prior to further cleaning*				
	Section 12 Sub Total			**12**	

Section	Standard			Action Timeframe
12.2.6	LUBRICATION • When required lubricants are water miscible, compatible with the sterilising process and used according to manufacturer's instructions			
	• Lubrication is not used to overcome inadequate cleaning practices			
	Note: Stiffness may be due to - ❖ 'flash' sterilisation ❖ exposure to saline solutions ❖ inadequate cleaning ❖ malalignment and will not be corrected by lubrication			
			2	
12.3	SPECIAL CONSIDERATIONS The following are considered in the continued care and maintenance of all instruments: -			
	• Instruments are free from soil, rust or line			
	• Lumens, grooves and articulations are free of debris. A stillette is able to be passed through the lumen wherever applicable			
	• Joints are free of debris and move freely			
	• All surfaces and edges are smooth, well finished, un-pitted and free of burrs			
	• Tips of instruments are not hooked, snagged and approximate accurately			
	• Jaw serrations are visible along length – instruments with worn areas are sent for repair (qualified repairer)			
	• Stiff or loose instruments are sent for repair (qualified repairer)			
	• Cutting edges are sharp – sharpness is tested according to manufacture's instructions			
	• Valves move freely and are left in the 'on' position			
	• All multi-part components of instruments are present			
	• Components are reassembled correctly			
	• Instruments are tested to ensure they are functioning correctly			
	• Fine instruments and their tips are protected in a manner that does not inhibit the sterilisation process			
	• Templates are used to check shape and tips of fine instruments			
			14	
12.4	SPECIALISED INSTRUMENTS			
12.4.1	MICROSURGICAL INSTRUMENTS – care according to manufacturer			
12.4.2	INSULATED INSTRUMENTS - care according to manufacturer			
	Section 12 Sub Total		**16**	

Section	Standard			Action Timeframe
12.4.3	INSTRUMENTS ON LOAN • Loan instruments undergo a complete routine cleaning and processing prior to sterilisation by the wrapped method			
	• Perceived lack of time does not permit the cleaning process to be bypassed			
	• Any soil or debris found on the instruments is reported to the supplier			
	• All instruments are subjected to the full cleaning process and sterilised before being returned to their source			
	• Loan instruments are not interchanged between human, necroscopy and animal use			
	There is a contracted arrangement in place to define the responsibilities of the supplier and the health care facility			
			5	
12.4.4	HANDPIECES - care according to manufacturer			
12.4.5	ASPIRATION SYSTEMS FOR DENTAL PROCEDURES - care according to manufacturer			
12.4.6	TRIPLEX SYRINGE FOR DENTAL PROCEDURES - care according to manufacturer			
12.4.7	ULTRASONIC SCALERS FOR DENTAL PROCEDURES - care according to manufacturer			
12.5	USE OF INSTRUMENT SHEATHES/SLEEVES • Sheaths/sleeves for instruments and equipment are not used as a substitute for cleaning, disinfection or sterilising procedures			
			1	
	Section 12 Sub Total		**6**	

TOTAL SECTION 12		**34**	

Section	Standard	Compliance			Action Timeframe
		0	1	N/A	
13	**USE OF OPERATING ROOM TEXTILES**				
13.1	GENERAL • Where the laundry is attached to the HCF the processing of operating room textiles is under the direction of the sterilising manager				
	• Laundry processing is in accordance with AS/NZS 4146				
	• Textiles used for draping and surgical gowns comply with As 3789.2 and AS 3789.6				
				3	
13.2	SPECIFIC CONSIDERATIONS • Inspection, folding and assembly of linen is performed in a dedicated area which is separated from others				
	• Air conditioning and air extractors are installed to assist in removal of airborne lint				
	• Linen is discarded if patches exceed more than 1% of total drape or garment				
	• Linen is discarded if there are signs of deterioration (threadbare)				
	• Linen is re-laundered if there are visible signs of dirt, stains, grease or oil				
	• Gauze swabs and abdominal sponges are not incorporated into linen packs				
				6	
13.3	INSPECTION • Linen required to be sterile, including wrapsper, is inspected over an illuminated table to determine presence of holes or other damage				
				1	
13.4	MENDING • Mending is done using textile patches with thermally-setting adhesive				
	• Patches are round in shape, 10mm – 20mm in diameter and attached to • one side only – they do not represent more than 1% of total area				
	• Patches are not applied to seams but re-seamed if in need of repair				
	• Fenestrated openings are not repaired – when in need of repair a new • fenestration is fitted or item is condemned				
	• Patches that are lifting are not accepted				
	• Linen is laundered after repair				
				6	
13.5	EQUIPMENT				
	• Light table complies with AS 3789.2				
	• Patching machine complies with AS 3789.2				
	• Machines have preventative maintenance in accordance with manufacturer's recommendations				
	• There are handwashing facilities within the OR textile area				
				4	
	Section 13 Sub Total			**20**	

TOTAL SECTION 13		**20**	

OVERALL SCORE SHEET

TOTAL SCORES	A	B	%
COLUMN A = TOTAL ACHIEVED SCORE **COLUMN B = TOTAL POSSIBLE SCORE**			
Section One		6	
Section Two		131	
Section Three		73	
Section Four		28	
Section Five		23	
Section Six		19	
Section Seven		50	
Section Eight		87	
Section Nine		37	
Section Ten		15	
Section Eleven		14	
Section Twelve		34	
Section Thirteen		20	
TOTAL SCORE		**537**	
% = A ÷ B x 100	**A**	**B**	

The audit can be scored to provide a basis for comparison over time and to answer the question 'do we comply with AS/NZS 4187-2003?'

The scoring system is based on the Cleaning Standards for Victorian Public Hospitals audit system where compliance with a criteria is deemed to be acceptable then no demerit points are deducted. If a criteria is deemed to be non compliant then it will score 1 or one demerit point.

AUDITORS COMMENTS:

SECTION	COMMENTS
ONE	
TWO	
THREE	
FOUR	
FIVE	
SIX	
SEVEN	
EIGHT	
NINE	
TEN	
ELEVEN	
TWELVE	
THIRTEEN	

ACKNOWLEDGEMENT:

*Handbook of Infection Control. Safe-I; National Board for Accreditation of Hospitals and Healthcare Providers (NABH)

**Mary Smith, Regional Infection Control Practioner, March 2001, Revised May 2001 October 2003.

(In pages 123 to 180)

दिल्ली सरकार

आप की सरकार

Department of Health & Family Welfare, GNCTD