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सत्यमेव जयते

Azadi Ka Amrit Mahotsav

GUIDELINES FOR CENTRAL STERILE SUPPLY DEPARTMENT (CSSD) & MECHANIZED LAUNDRY

MINISTRY OF HEALTH & FAMILY WELFARE
GOVERNMENT OF INDIA

Guidelines for
Central Sterile Supply Department (CSSD)
&
Mechanized Laundry

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Ministry of Health and Family Welfare

Preface

It is important that District Hospitals (DHs), being the epicenter between primary and tertiary care, provide quality healthcare including assured management of all referral cases from the primary care level. While IPHS ensures provision of range of services with defined standards, it becomes equally important that support services are also being provided without any interruption. Establishing assured critical care, High Dependency Units, Intensive Care Units and Assured Emergency Services, and their operationalization also lead to reduction in OOPE by the patients.

2. Establishment of technically efficient support services within DH can help in implementing protocols for infection prevention. Hospitals and health care facilities generate large volume of medical wastes to be managed as per the Bio-medical Waste Management Rules, 2018. In the absence of standardized practices of disinfection and sterilization in the hospital set-ups, these improperly handled wastes may lead to increased rate of Hospital Acquired Infections (HAI). To ensure prevention of transmission of infections, establishment of Centralized Sterile Services Department (CSSD) supported by a Mechanized laundry is crucial.

3. CSSD is an integrated place in hospitals, responsible for receiving, storing, processing, distributing and controlling the professional supplies and equipment (both sterile and non-sterile) for all user units of hospital for the care and safety of patient under strict quality control. It is an important facility of hospital that supplies sterile instruments and materials for dressing and procedures carried out in ward and other departments of hospital.

4. Guidelines on CSSD and Mechanized Laundry at DHs have therefore been developed by the Ministry of Health and Family Welfare to provide a process flow, layout design and define/re-affirm protocols pertaining to CSSD & Mechanized laundry. These guidelines will assist the Programme managers/Hospital Administrators in understanding the principles of setting-up of CSSD supported with Mechanized laundry & adopting strict quality control processes with latest technology to mitigate HAIs.

5. I acknowledge and compliment the contribution of the various experts for their valuable contribution in developing these guidelines. I hope that the States will adopt these guidelines for establishing/strengthening the CSSD and Mechanized laundry in secondary care facilities in the States.

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FOREWORD

Strengthening health system for improved program outcomes is one of the main objectives of the National Health Mission. Strengthening of various support services which are vital to run and efficiently manage various services in a hospital. It is also crucial to prevent transmission of infectious pathogens in hospitals and to ensure reduction in hospital acquired infections, for achieving the desired outcomes of Biomedical Waste Management Programme (BMWMP). Systemic cleaning & sterilization of linen and equipment are some of the essential activities which every hospital needs to follow and adhere.

In order to achieve these objectives it was felt necessary that guidelines for standardized practices and protocols for cleaning and sterilization be developed.

A task force was constituted by the Ministry which, after several rounds of deliberations with experts finalized these guidelines.

These guidelines are aimed at building capacities in the state and district healthcare professionals towards standardized infection prevention practices, by strengthening the support services in the critical care areas of the District Hospitals and other health facilities. One of the unique features of the guidelines is the linkage between CSSD and mechanized laundry. Adherence to guideline will help in providing quality health care services.

I extend special thanks to the experts from apex Medical colleges like AIIMS New Delhi, MGIMS Wardha, NEIGRIHMS, Shillong, PGIMER Chandigarh, program divisions, and state representatives from Maharashtra, Madhya Pradesh, Tamil Nadu, New Delhi, and Chandigarh for taking time out & providing their valuable inputs to the Guidelines. I compliment NHSRC for active support in framing these guidelines. I also thank the experts from the states and districts for their contribution in framing these guidelines.

Hopefully, the sincere efforts of all the experts and program divisions, in the implementation of these guidelines will help in improving infection prevention practices. It is expected that the state program managers and healthcare professionals find the guideline useful in ensuring decontamination, washing and sterilization of equipment and linen used in the public health facilities.

(Vikas Sheel)

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Foreword

Reducing hospital-acquired infections is one of the key commitments for ensuring quality in healthcare services. Surgeries, invasive procedures, and many other medical interventions generate body fluids, tissues, blood and these contaminate instruments, linens, and consumables. If such materials are not properly decontaminated, then it becomes one of the potential sources of infection for others.

The Central Sterile Services Department (CSSD), also called Sterile Processing Department (SPD), or Central Supply Department (CSD), is an integrated place in hospitals and other health care facilities that performs decontamination and sterilisation of medical devices, equipment, and consumables. The mechanized laundry ensures the provision of an adequate, clean, and constant supply of linen to all users in the hospital. The processes in the laundry include decontamination, washing, drying, ironing for OPD, indoors, and sending to autoclaving (CSSD) for critical care areas like OT, HDU, ICU, emergency, etc.

To address infection prevention and serious safety issues related to Hospital Acquired Infections, guidelines on planning CSSD & Mechanised Laundry in a District Hospital have been prepared. These guidelines aim to support State and District Program Officers/ Hospital Administration in planning and developing well-organized CSSD & Mechanised Laundry for District Hospitals to provide quality of care and for reducing the rate of infections in patients.

I take this opportunity to express my sincere gratitude to Sh. Rajesh Bhushan, Secretary Health & Family Welfare and Ms. Vandana Gurnani, AS&MD for their constant support and guidance to develop these guidelines. I would like to thank NHSRC team for taking the lead and also the expert group members for their time, expertise, and commitment to formulate these Guidelines.

I hope these guidelines will help the states to plan its CSSD & Mechanised Laundry with a vision to attain National Quality Assurance Standards and Indian Public Health Standards for every District Hospital.

(Vishal Chauhan)

ABBREVIATIONS

AHA	Academy of Hospital Administration
AIIMS	All India Institute of Medical Sciences
AMC	Annual Maintenance Contract
APD	The Associatation of People with Disability
CCTV	Closed Circuit Television
CMC	Comprehensive Maintenance Contract
CMHO	Chief Medical Health Officer
CSD	Central Supply Department
CSSD	Central Sterile Services Department
DH	District Hospital
DNS	Deputy Nursing Supritendent
D.PH.	Doctor of Public Health
ETO	Ethylene Oxide
FIFO	First In First Out
HAI	Hospital Acquired Infections
HDU	High Dependency Unit
HLL	Hindustan Life Care Limited
HOSMAC	Hospital Planning & Management Consultancy
HRH	Human Resources for Health
HSCC	Hospital Services Consultancy Corporation Limited
ICU	Intensive Care Unit
IIIT	Indraprastha Institute of Information Technology
IPD	In Patient Department
IPHS	Indian Public Health Standards
KW	Kilo Watt
MD	Doctor of Medicine
MGIMS	Mahatma Gandhi Institute of Medical Sciences
MS	Medical Superintendent
M.SC.	Master of Sciences
NEIGRIHMS	North Eastern Indira Gandhi Regional Institute of Health and Medical Sciences
NHM	National Health Mission
OPD	Outpatient Department

OT	Operation Theatre
PGI	Post Graduate Institute
PMSSY	Pradhan Mantri Swasthya Suraksha Yojana
PPE	Personal Protective Equipment
QA	Quality Assurance
RBSK	Rashtriya Bal Swasthya Karyakram
RCH	Reproductive & Child Health
SAL	Sterility Assurance Level
SDH	Sub-District Hospital
SNCU	Special Newborn Care Unit
SOP	Standard Operating Protocol
SPD	Sterile Processing Department
TAT	Turn-Around Time
TSSU	Theatre Sterile Supplies Unit
UPHSSP	Uttar Pradesh Health Systems Strengthening Project
WHO	World Health Organization

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INTRODUCTION

With the launch of NHM, recent years have seen renewed efforts towards strengthening public health in India. District Hospital is the epicenter between primary and tertiary care. It is so expected that provision of assured comprehensive and quality health care at district hospital will meet the expectations and referrals of the patients from primary health care facilities. This will also ensure reducing the burden of tertiary care institutions. There is growing evidence to suggest that a well-resourced district hospital is critical to reduce morbidity and mortality within the catchment of a district's population. It provides secondary health care facilities which include the range of curative, preventive, promotive, rehabilitative and palliative care to the community within the district. So, it is essential that both critical and support areas of the DH are strengthened as per IPHS. Support services for Operating Theatres, Labor Room, SNCU, High Dependency Units, and Intensive Care Unit etc. also need to be prioritized while strengthening district hospitals.

The number of procedures undertaken in an operating theatre per 100,000 population per year in India is 954[1]. For a district with an average population of 20,00,000, this amounts to 247 procedures and accounting for at least 50% of the total surgeries 124 surgeries to be at done at Secondary level per day. Each of these procedures involves contact by a medical device or surgical instrument with a patient's sterile tissue or mucous membranes. A major risk of all such procedures is the introduction of pathogenic microbes, which can lead to infection. In the developing world the health care associated infection rate is 25% or more i.e. 25 infections per 100 patient admissions[2]. So, in a district, approx. 13 patients are at the risk of acquiring hospital acquired infection per day.

An alarming rate of Hospital Acquired Infections (HAI) in Indian hospitals has highlighted the importance of disinfection and sterilization. Achieving disinfection and sterilization through the use of disinfectants and sterilization practices is essential for ensuring that medical and surgical instruments do not transmit infectious pathogens to patients. One of the most accepted systems to achieve prevention of transmitting infectious pathogens is having a Centralized Sterile Supply Department (CSSD) supported by a mechanized laundry.

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[1] The Lancet Commission on Global Surgery

[2] A guide to infection control in the hospital, International Society for infectious diseases

Sterilization refers to any process that eliminates, removes, kills, or deactivates all forms of life and other biological agents (such as fungi, bacteria, viruses, spore forms, prions, unicellular eukaryotic organisms such as Plasmodium, etc.) present in a specified region, such as a surface, a volume of fluid, medication, or in a compound such as biological culture media. The various methods of sterilization include Physical Method (Thermal (Heat), Radiation, Filtration) and Chemical Method (Gaseous).

The Central Sterile Services Department (CSSD), also called Sterile Processing Department (SPD), or Central Supply Department (CSD), is an integrated place in hospitals and other health care facilities that performs sterilization and other actions on medical devices, equipment and consumables. This helps health workers in using these equipment and tubes for subsequent use in the operating theatre of the hospital and also for other aseptic procedures, e.g., catheterization, wound stitching and bandaging in a medical, surgical, dental, maternity or pediatric ward. Similarly, the mechanized laundry ensures provision of an adequate, clean and constant supply of linen to all users in the hospital. The processes in the laundry includes decontamination, washing, drying, ironing for OPD, indoors and sending to autoclaving (CSSD) for critical care areas like OT, HDU, ICU, emergency etc.

Despite all measures and advancements in technology, hospital acquired infections remain a challenge in healthcare scenario today. The basis of aseptic surgery is to kill all micro-organisms on all instruments and dressings, preferably by exposure to steam under pressure. However, in general practice, this is not being adhered to. Sterilization by putting equipment in boiling water will kill all viruses and all vegetative bacteria, but not spores, particularly those of tetanus and gas gangrene.

Visits to various district hospitals in the states indicate that very few hospitals have CSSD and Mechanized Laundry. Even if it is there, they are not following adequately defined processes. Most of the state and district program officials and hospital staff are not aware of these processes and how to establish these.

As per IPHS, hospitals are required to establish adequate Laundry and CSSD set-up and adopt strict quality control processes with the latest technology to mitigate hospital acquired infections. Hence the concept of infection control by Florence Nightingale who said “No Stronger Condemnation of any hospital or ward could be pronounced than the simple fact that zymotic disease has originated in it or that such disease attack other patients than those brought-in with ‘’ stands true for generations of healthcare to come.

OBJECTIVES OF THE GUIDELINE

- To provide a process flow and layout design for mechanized laundry and CSSD.
- To define/ reaffirm technical protocols and procedures pertaining to mechanized laundry and CSSD.
- To prescribe a list of essential human resource, equipment and consumables as per the IPHS.
- To prescribe records and registers to monitor and enforce effectiveness of cleaning, disinfection and sterilization process.
- To orient the state and district program officials, hospital administrators and planners about principles to establish mechanized laundry and CSSD.

CSSD AND MECHANIZED LAUNDRY UNITS

The Central Sterile Supply Department (CSSD) delivers sterile supplies of surgical equipment, linen, dressing material and other such items which can be reused in various departments of a hospital or health facility (Operation Theatres, Labour Rooms, Minor OTs, HDUs, ICUs, Emergency Units, Wards (IPDs), Day Care Units and Out Patient Departments (OPDs)). This is important so that all procedures are conducted in a sterile environment in order to minimize the chance of spread of infection.

Laundry services form a critical component of service provision. Soiled and unsterile hospital linen is known to be a source of microbial contamination. The Laundry service is responsible for providing clean linen in an adequate and constant supply to all users. This also gives comfort and safety to the patients. The term 'hospital linen' includes all textiles used in the hospital including mattress, pillow covers, blankets, bed sheets, towels, screens, curtains, patient gowns, doctors' coats, theatre cloth and tablecloths etc.

The purpose of cleaning is to remove contaminants such as micro-organisms or hazardous materials, including chemicals, radioactive substances and infectious diseases. Similarly, the purpose of decontamination is to prevent the spread of micro-organisms and other noxious contaminants that may threaten the health of human beings or animals or damage the environment.

The Hospital practices in India have mostly been keeping these two functions independent of each other, despite the inter-linkages and inter-dependency that exists between them. All the critical linen

used in the hospital, to be used at service delivery points (say OT), circulate between these two units. If observed closely, it is noticeable that the pathway (at the beginning of the cycle) is common, which later merges at certain places for ensuring specific output. It is hence but natural that, while planning for these services, the hospital planner/administrator understands this concept and ideally places these two in close proximity. The sample lay out design given in this guideline aims to achieve this. In case the hospital does not have space to accommodate the lay out design in the same floor, attempts may be done to have it connected in different floors that facilitate movement of materials and HR. Operation Theatre Complexes also have a Sub-Sterilizing unit – Theatre Sterile Supplies Unit (TSSU) attached to the operation theatre limiting its role to cleaning of surgical instruments on an emergency basis only. Such TSSUs are to be located inside OT complex.

PLANNING FOR CSSD & MECHANIZED LAUNDRY

The Mechanized Laundry and CSSD should ideally be located at ground floor and mostly adjacent or well connected to each other. They should have established linkages with other critical areas utilizing clean and sterilized articles such as labor room, wards, OPD, store, etc. In case of unavailability of land or in case of outsourced/existing separate laundry & CSSD, both can be located separately from the main building of District Hospital, provided the process flow is maintained and critical linkages with the hospital are established as per the protocols. In case they are located on any floor other than ground floor, the quality of plumbing/drainage/flooring should be such ensured that leakage or damage to other floors is prevented.

The type and capacity of equipment required in a CSSD and Mechanized Laundry will also depend on expected load being generated by the hospital. Generally, it is observed that about 2.5-3 kg of the load is being generated per bed by a fully functional hospital which is following all processes and protocols. Equipment should be properly fixed to the ground so that there is minimum movement/vibration/ noise while operationalizing the equipment. This load includes both linen and equipment. The size and capacity of washing machines, sterilizers and other equipment may vary accordingly from one hospital to another.

Since Mechanized Laundry is linked with CSSD, this document gives a comprehensive plan for establishing both areas together and establishing linkages which are critical for ensuring smooth bi-directional transit of materials that require autoclaving and are used in critical care areas .

This, however, is not a limiting factor for such hospitals where both CSSD and Mechanised Laundry have been established separately. If the workflow is maintained with competency and ensuring quality, the facilities can operationalize these services in their existing CSSD and Mechanized Laundry.

In this document, a suggestive layout plan for mechanized laundry and CSSD has been provided. The essentials of the department are correct design, modern plant, skillful operators and a proper work-flow.

LAYOUT PLAN

While planning for CSSD & Laundry, the design and total area should be based on the following parameters-

- The size of the institution

- Number of beds relying on the supply from CSSD
- Average number and type of surgical procedures per day
- Equipment type, size and number to be used

An ideal layout for a CSSD and Mechanized Laundry at a 300-bedded District Hospital is placed at **Annexure 1**. The suggested layout takes into consideration the fact that adherence to unidirectional flow is essential, which can be achieved through infrastructural design.

ORGANIZATION AND FUNCTIONING OF MECHANIZED LAUNDRY

Along with the infrastructural design of the CSSD and mechanized laundry, the process flow of the two areas are equally important. The subsequent section covers the process flow and activities in terms of receiving, decontamination, sterilization and issuing of linen and equipment in respective sub-areas of CSSD and Laundry.

A. Activities before the linen and equipment are brought to CSSD and Mechanized Laundry

1. Activities at Generation Points

a. Non-critical care areas:

i. **Change of Linen:** Patient bed linen is changed once daily in the morning, whenever a new patient comes on the bed or whenever it gets soiled with vomiting, feces, blood spill, urine etc.

ii. **Sorting of used Linen:** All used linen must first be segregated into soiled & non-soiled. While changing/ removing any type of linen, principle of "segregation at source" is to be followed by every hospital staff. Linen should be discarded in the marked bags only. At no point of time, the linen should be mixed or thrown on the floor.

iii. **Disinfection of soiled/ contaminated linen:** Ideally, decontamination should be the first step in mechanized laundry and contaminated linen should be segregated before it is sent to Mechanized Laundry. In case segregation is not possible, then all wards shall also maintain a linen disinfection bin. In such cases, all soiled linen are first put into 0.5% chlorine solution for 30 min and then sent to mechanized laundry. The non-soiled can be sent directly after packing in a zip bag before sending it to laundry. There should be provision of water supply in this room.

b. Critical care areas:

i. All used linen must first be segregated into soiled & non-soiled. Soiled ones are first put into 0.5% chlorine solution for 20 min and then sent to mechanized laundry. The non-soiled can be sent directly after packing in a zip bag. All personnel working in OT and other critical areas should follow source segregation and put the discarded or reusable linen in correct bins or bags.

ii. All linen used in procedures in the OT and other critical areas (e.g. surgical drapes, gowns, wrappers) are considered to be infectious even if there is no visible stain.

iii. Disposal Zone of OT and other critical areas is where all the used linen is collected.

c. Decontamination of instruments:

Instruments used for major/minor surgeries in OT and other critical areas, various procedures in critical care areas or in wards need to be necessarily decontaminated and autoclaved before the next use. After each such surgery or procedure, there can be two processes for packaging the instruments for decontamination:

1. Decontaminate, dry and pack in OT or other services areas.
2. Double wrap and send to CSSD for decontamination, wash, dry, pack and autoclave.

2. Collection and transportation of Dirty Linen and instruments from Wards/ OTs/ other areas to Laundry and CSSD.

a. Ideally, the pathways for delivery of clean and sterile equipment and linen and collection of dirty equipment and linen should not cross each other. As far as practicable, this protocol needs to be adhered to.

b. The transportation of materials should be done through a defined corridor/dumb waiter/ service lift in a clean and covered trolley. The trolleys should be cleaned/washed with damp mop with detergent/alcohol and water. Clean the wheels by running them 10-15 times over a towel (cotton, soft and absorbent) soaked with soap and water. Persons transporting these trolleys should wear personal protective attire.

c. The linen bag must be tied once 2/3rd full and taken to the appropriate area to store neatly. Any bag which is overfilled shall be split into two bags.

d. The staff of laundry shall collect linen from each ward/OT as per the scheduled timing.

e. The laundry staff shall use gloves while handling the linen and check for any damage or tear, if any.

f. The ward staff nurse shall be present during the collection to check the count of linen and damage if any. She shall then mention details in the linen book, sign, take signature of the laundry staff too, and handover a copy to the laundry staff.

g. All the linen is transported in closed leak proof bags, containers with lids or covered carts via dumb waiters/ dedicated elevators or corridors to washing area. Contaminated and non-contaminated linen is transported separately.

B. Activities at CSSD & Mechanized Laundry

1. Entry of Staff:

i. Entry of staff into Laundry and CSSD is maintained separately. This area consists of Manager's room, male and female changing room, staff room and first aid area along with pantry, caretaker's room and washrooms for staff.

ii. The staff is supposed to change into clean and sterile uniforms in changing room before entering service area. Donning and doffing areas for Personal Protective equipment also to be clearly demarcated.

iii. CSSD in-charge will ensure adherence to Personal Protective Equipment (PPE) protocols through CCTV cameras. Please note that CCTV should not be installed in changing rooms/ washrooms to maintain dignity of staff.

2. Activities in Mechanized Laundry

a. Receiving Area

i. There should be a separate window for receiving and dispatching of items.

ii. The laundry has a passage for non soiled linen and two disinfection rooms which have tanks for soiled linen and for contaminated linen respectively.

iii. Linen is received at receiving counters in these different rooms as per the marked bags.

b. Disinfection Area

i. Soiled linen is passed through jet washer installed in the soiled linen room to remove any stain/ particle present on the linen, before decontamination.

ii. Once the linen reaches laundry, the linen shall be soaked in the tanks containing water mixed with 0.5 % sodium hypochlorite solution for 15- 20 minutes. Do not dip the linen for more than 20 minutes.

c. Washing Area

i. The disinfected linen should be washed with detergent solution in washing machines.

ii. Provision for warm water shall be made for cleaning, as that acts as disinfectant as well.

iii. The washed linen shall be put in the water extractor for 3-5 minutes.

Normal White Linen (30 kg capacity)

Steps	Temperature	Agents	Water Level	Quantity	Time
Pre-wash	Room Temperature	Detergent	High Level	150 ml	10 minutes
Drain					
Main Wash	60-70^0 C	Detergent	Low Level	250 ml	20 minutes
		Liquid Bleach		15 ml	
Drain					
Rinse-1	Room Temperature		High Level		3 minutes
Drain					
Rinse-2	Room Temperature		High Level		3 minutes
Rinse-3	Room Temperature	Liquid Blue & Optical Brightener	High Level	25 gms	10 minutes
Drain					

Coloured Linen (30 kg capacity)

Steps	Temperature	Agents	Water Level	Quantity	Time
Pre-wash	Room Temperature	Detergent	High Level	50 ml	10 minutes
Drain					
Main Wash	50-60^0 C	Detergent	Low Level	250 ml	20 minutes
		Liquid Bleach		15 ml	
Drain					
Rinse-1	Room Temperature		High Level		3 minutes
Drain					
Rinse-2	Room Temperature		High Level		3 minutes
Rinse-3	Room Temperature	Optical Brightener	High Level	25 gms	10 minutes
Drain					

Heavy, Soiled and Infected White Bed Linen (30 kg)

Steps	Temperature	Agents	Water Level	Quantity	Time
Pre-wash	Room Temperature	Detergent	High Level		10 minutes
Drain					
Main Wash	80^0 C	Detergent	High Level	250 ml	20 minutes
		Liquid Bleach		15 ml	
Drain					
Rinse-1	Room Temperature		Low Level		3 minutes
Drain					
Rinse-2	Room Temperature		Low Level		3 minutes
Drain					
Rinse-3	Room Temperature	Liquid Blue & Optical Brightener	High Level	25 gms	10 minutes

Drain					

Heavy, Soiled and Infected Coloured Linen (30 kg)

Steps	Temperature	Agents	Water Level	Quantity	Time
Pre-wash	Room Temperature	Detergent	High Level		10 minutes
Drain					
Main Wash	60-70^0 C	Detergent	High Level	250 ml	20 minutes
Drain					
Main Wash	80^0 C	Detergent	High Level	250 ml	20 minutes
		Liquid Bleach		50 ml	
Drain					
Rinse-1	Room Temperature		Low Level		3 minutes
Drain					
Rinse-2	Room Temperature		Low Level		3 minutes
Drain					
Rinse-3	Room Temperature	Optical Brightener	High Level	25 gms	10 minutes
Drain					
Rinse-4	Room Temperature	Optical Brightener	High Level	25 gms	10 minutes
Drain					

d. Dry Area

This area demarcates the zone where spill/flow of water should be minimized.

i. Water extracted linen is then dried.

e. Folding and Ironing Area

i. After drying, the linen shall be checked for wear and tear, the torn clothes shall be sent for tailoring or will be disposed of as per the institute's policy.

ii. All the linen shall be steam pressed to ensure availability of clean, wrinkle free linen.

iii. An ironing machine that can generate its own steam is recommended, this can help in saving electricity and wastage of steam.

f. Issue Area

i. Linen is then sorted into linen for critical and non-critical area as per need, and then sent to CSSD or issued to wards respectively.

ii. Transportation of linen needs to be undertaken as defined under Point 3a above.

Note: Laundry In-charge to monitor adherence to process flow of linen and take measures to prevent spillage of water in dry area.

3. Activities at CSSD

3.1. Receiving Area:

a. There should be a separate window for receiving and dispatching of items.

b. The instruments that are to be sterilized coming from various departments arrive in the reception area on stainless steel trolleys via dumb waiter/dedicated elevator or corridor.

c. The articles are sorted into different packs for different methods of cleaning.

d. The CSSD technicians or trained nurses shall receive the unsterile packs, inspect them to check the status of the item (torn, punctured, cracked etc.) and place them at the unsterile packs storing platform.

e. Entry must be made in CSSD receipts register including date, time, type of instruments in the pack, ward, 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.

3.2. Sub Store, Cotton and Gauze preparation area:

a. Staff should ensure adherence to PPE protocols to avoid inhalation of cotton dust.

b. This area is used for gauze cutting and preparation.

c. It should have provision for storage of prepared gauze as per the load calculated.

d. Proper ventilation of this room shall be maintained to avoid suffocation.

e. Prepared gauze and cotton are then sent to receipt area for further action

3.3. Cleaning Area:

a. The most common types of mechanical or automatic cleaners are ultrasonic cleaners, washer-decontaminators and washer-disinfectors.

b. Cleaning is done manually in areas without mechanical units or for fragile or difficult-to-clean instruments. With manual cleaning, the two essential components are friction and fluidics. Friction (e.g., rubbing/scrubbing the soiled area with a brush) is an old and dependable method. Fluidics (i.e., fluids under pressure) is used to remove soil and debris from internal channels after brushing and when the design does not allow passage of a brush through a channel.

c. Ultrasonic cleaning removes soil by cavitation and implosion in which waves of acoustic energy are propagated in aqueous solutions to disrupt the bonds that hold particulate matter to surfaces. Users of ultrasonic cleaners should be aware that the cleaning fluid could result in endotoxin contamination of surgical instruments, which could cause severe inflammatory reactions.

d. Washer-decontaminators/disinfectors act like a dishwasher that uses a combination of water circulation and detergents to remove soil. These units sometimes have a cycle that subjects the instruments to a heat process (e.g., 93°C for 10 minutes). Washer-disinfectors are generally computer-controlled units for cleaning, disinfecting, and drying solid and hollow surgical and medical equipment.

3.4. Assembly and Packing Area:

a. It includes checking of glass items for breakages, needles and instruments for sharpness and breakages, assembling of the equipment after washing and drying, making appropriate sets for use by various departments and packaging along with sealing either manually or using a machine before sterilization.

3.5. Labelling and Packing Area:

a. Adequate documentation and labeling of each pack should be done and records should be maintained making sure of instrument sets and source/destination. Digital records should be preferred.

b. The autoclave indicator is pasted in the packs by the CSSD technician and the packs are taken to the cleaning area where the cleaning units are placed.

c. Bowie Dick test: It uses a thermo chromatic paper which is placed inside the pack/empty chamber and indicates if a successful vacuum and full steam penetration has taken place. A Bowie-Dick test pack that shows a uniform dark black color pattern indicates a successful vacuum and full steam penetration, whereas no or partial color change indicates an unsuccessful test cycle.

3.6. Sterilization Area:

a. Sterilization is achieved by steam sterilizers working at specified cycles of temperature and duration to attain adequate sterility assurance level (SAL). Advantage of steam sterilizers are rapid heating & penetration of loads, destruction of all forms of microbial life and no residual toxicity.

b. It is better to have 2 sterilizers in case of breakdowns.

c. Sterilization Cycle: In-case of steam sterilization the type of cycle is Pre vacuum/ post vacuum. The load is either wrapped or placed in packs/porous material. The CSSD technician then places the unsterile packs under appropriate temperature and pressure specifications in the sterilizing units from one end. The temperature, pressure specifications and accordingly the temperature period are 121°C at 15 lb for 20 minutes for normal sterilization, while 140°C

at 20 lb for 15 minutes for Rapid Sterilization. Followed by dry time of approximately 30 minutes. So, one complete sterilization cycle from Pre- heating to dry time is between 50-60 minutes.

d. A material is pronounced sterile if it achieves 99.99% kill of bacterial spores.

e. In the layout design, care has been taken to ensure that the staff handling sterile articles has a separate entry and does not have access to non-sterile area.

f. At the end of the sterilization, the packs are removed from the sterilizing units from the other end of well fitted double-door autoclave., the autoclave indicators are checked to confirm adequate sterilization of the packs, and incase the sterilization is not adequate the process is to be repeated.

3.7. ETO Process Room:

a. Additionally, an ethylene oxide sterilizer can be included in a separate compartment of this area in order to sterilize heat sensitive instruments like various types of tubes. E.g. Catheters etc.

3.8. Storage Area:

a. The function includes storage of sterilized materials where space is also provided for storing distribution trolleys. Ideally, storage system should be automated and digitalized. Inventory of all types of sterile packs along with distribution (through FIFO or other methods) should be followed. Such components should have link with various service areas so that the departments are informed about the readiness of the equipment, linen etc., and accordingly arrange for receiving in the sterilized store.)

b. Packs which are adequately sterilized are stored in the sterile storage area. If the sterile packs are torn, if it has been opened, they are wet, etc., and then the whole process is to be repeated again.

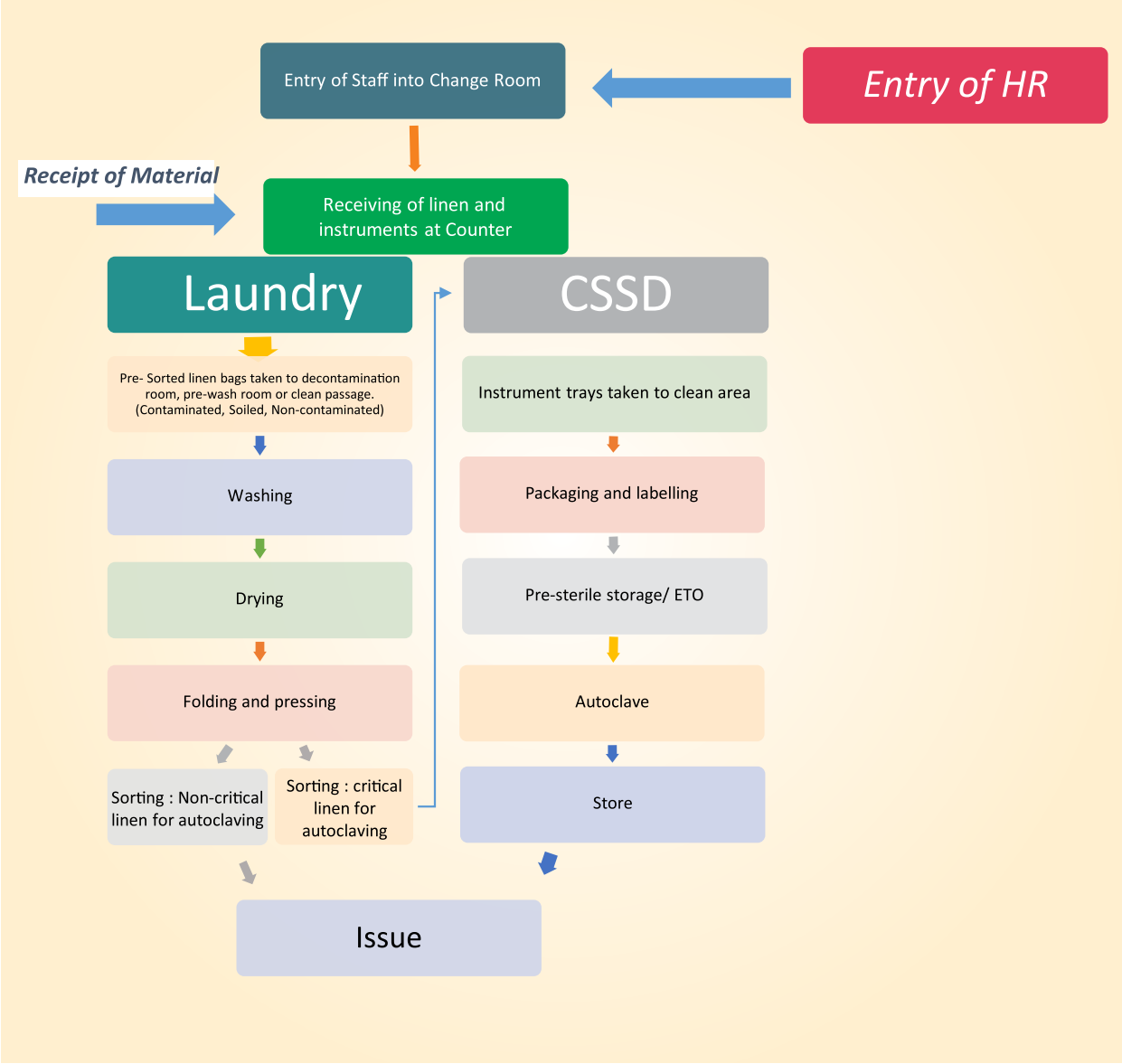
3.9. Issue and Distribution Area:

a. Issue of the sterilized packages, dressings, linen, instruments and disposables to various departments of the hospitals is done in this area.

b. Transportation of instruments needs to be undertaken as per protocols. The sterilized instruments once packed should be sent to various departments on stainless steel trolleys via dumb waiter/dedicated elevator or corridor.

c. In case the packs which are sterilized in the CSSD and issued to the departments remains un-utilized in the respective user departments for a period of 72 hours, the same are returned to the CSSD department for re-sterilization.

The flow of services explained above is summarized below for easy understanding :



Operationalizing the existing CSSD/ Laundry

Many of our district hospitals might have CSSD or Laundry (either both or stand-alone) functional through in-house staff or through outsourcing.

The purpose of this guideline is to further strengthen these units to maintain the layout, flow, processes, protocols and monitor the quality parameters as defined in these guidelines, for achieving the desired outcome.

There can be a situation where the space is less, and under such circumstances, options need to be explored for either vertical extension or reducing the number of machines so as to fit the indicated processes for ensuring quality. Supervisory and monitoring rounds are equally important both for in-house and outsourced units and as such it is important that the capacity building of both in-house and outsourced agencies (if present) needs to be undertaken and prioritized.

The hospital in-charge and supervisors should also define the pathways for delivery and collection of linen and equipment from critical care service areas to the serving units i.e. CSSD/ Mechanized Laundry. This will ensure smooth functioning of hospital OTs, HDUs, ICUs, Labour Room, Emergency and other such critical care areas.

Equipment

For effective functioning of CSSD and Mechanized Laundry, a set of equipment will be required. The list of such equipment is placed at **Annexure-2**. All the equipment purchased should be covered under comprehensive equipment maintenance programme or 3-5 years Annual Maintenance Contract (AMC).

Clean electric power supply: The public health facilities should have access to adequate, affordable and reliable electricity supply.

Distribution of electric load along with load balancing to various equipment and installations in a facility is very important since overloading at any point can result in mishappening like electric fire hazard or can damage the equipment. Similarly, fluctuation in voltage also adversely effects the equipment and hence, automatic voltage regulators, which regulate fluctuating input power voltage and maintain constant output voltage should be provided. So, putting electrical installation is a specialized job and must be given due importance to ensure proper care with reduced risks to the patients.

So, it is essential to calculate the expected electrical load required when all the equipment are fully operational during peak hours of the functioning of the unit. If a facility is planning either new construction or renovation for operationalizing CSSD and Mechanized Laundry, a proper electrical design based on the proposed civil infrastructure, capacity and type of equipment needs to be worked out in advance.

Adequate number of electric points on the various walls (at < 1.5 m height from the floor) needs to be ensured for easy connection. It has to be ensured that multiple machines are not connected through one electrical point and should be evenly distributed in the room. Use of explosion proof plugs, plug connector and socket is essential to ensure safety against explosion.

New electrical appliances should have a minimum 3-star rating from Bureau of Energy Efficiency or equivalent recognized organization to minimize the energy input.

Monitoring: Constant digital display for neutral and earthing should be there. (The voltage between neutral and earthing should not more than 5 volts otherwise it can harm the semiconductor devices. Hence, digital display should be installed to monitor the voltage between neutral and earthing).

HR REQUIREMENT

CSSD and Mechanized Laundry require dedicated and experienced staff for all shifts. Staffing should be as per the IPHS 2022 laid down for each category of staff for District Hospitals as given under:

S. No.	Designation	50-bedded DH	100-bedded DH	200-bedded DH	300-bedded DH	400-bedded DH	500-bedded DH
1.	CSSD Technician (2 shifts for hospitals more than 200 beds)	1	1	1	1	1	1
2.	CSSD Assistant (2 shifts for hospitals more than 200 beds)	2	2	4	4	4	4
3.	Laundry Technician (2 shifts for hospitals more than 300 beds)	1	1	1	2	2	2
4.	Laundry Assistant (2 shifts for hospitals more than 300 beds & SDH)	3	3	3	6	6	6
5.	Tailor for Laundry	1	1	1	1	1	1
6.	Sanitation Staff	1	1	1	2	2	2

Note: Operationalization of CSSD/Mechanized Laundry can be either in-house or outsourced but it is important to maintain the flow of services, quality of equipment and availability of adequate number of trained HR.

CAPACITY BUILDING: FOR LAUNDRY AND CSSD STAFF

Laundry

1. **Objective:** Participants should be able to acquire knowledge and skills for organizing the flow in mechanized laundry and perform laundry services. They should be able to supervise and maintain laundry equipment, take safety precautions and monitor quality indicators.

2. **Duration:** One day

3. **Participants:** All available team members of Laundry.

S. No.	Theme	Component	Duration	Methodology
1	Knowledge	Theory of Hospital Acquired Infections and importance of CSSD in reducing morbidity and mortality	1 Hr	Lecture
		Use of equipment in CSSD	30 Min	Lecture
		Documentation for services and equipment	30 Min	Lecture
2	Skills	Collection, segregation, washing of different category of equipment and packaging	1 Hr	Demonstration
		Maintenance of machine and safety measure (All decontamination equipment is used in accordance with manufacturer's guidelines and SSU policies)	1 Hr	Demonstration
		Quality indicator (infection control principles and standard precautions)	30 Min	Demonstration
3	Attitude	Communication principles within team and with patients	1 Hr	Group work and Game
4	Pre and post test	Demonstrate competency in decontamination of soiled instruments, endoscopes, surgical and medical equipment.		

RECORDS AND REGISTERS

Each CSSD complex needs to be managed systematically and professionally, for which maintaining proper records is vital. This helps in analyzing and reviewing the performance, cleanliness, adherence to technical protocols, functionality and availability of equipment etc. and also helps in identifying the gaps to plan corrective actions.

all the record should be digitalized to reduce paper work.

MONITORING AND SUPERVISION

Various functions and infrastructure as suggested in the guideline needs to be sustained for ensuring quality in service delivery. This can only be ensured through regular monitoring and supervision. The CSSD complex needs to be run with a zero tolerance for non-adherence. During rounds, all the supervisory staff need to follow protocols before entering the complex. Exclusive responsibility of ensuring this lies with the CSSD/Laundry In-charge.

- State and District Program Officers to see the layout plan, general functioning and quality parameters.
- Periodic rounds by Hospital In-charge/ MS for general overview on functioning and adherence to quality parameter.
- Daily rounds by Hospital Manager and Matron to oversee general functioning, adherence to quality parameters and identify issues being faced by the department (if any) and undertake corrective actions.

- Rounds by Supervisor for Laundry and CSSD for monitoring of quality parameters as defined under Quality and mentoring of staff to ensure adherence to various protocols.

The following activities need to be supervised by the CSSD/Laundry In-charge:

- Adherence to technical protocols and flow process as indicated in the guidelines.
- Restriction of unnecessary entry into the complex with adherence to shoe change, PPE and hand hygiene protocols by all staff and attendants.
- Collection, sorting and issuing of linen and equipment in different zipped bags (soiled/ contaminated/non-contaminated) or trays from various sources (wards/OT/departments). Number of linen items, bags, trays should be clearly mentioned in the records duly signed by department in-charge/ nurses/ ward boy.
- Functionality and regular cleaning of all equipment being used in Laundry/CSSD for autoclaving/ washing as per indicators along with records of inventory, manufacture details, AMC/CMC, etc.
- A sample monitoring checklist is placed at **Annexure 3**. A sample format for displaying key information is placed at **Annexure 4**.

QUALITY POLICY

Every hospital having CSSD and Mechanized Laundry should have a clearly defined policy for maintaining the quality in every process from structure to outcome. The aim of the policy should be to provide patients with clean, disinfected and autoclaved instruments/linen depending upon the requirement of various service areas (both critical and non-critical), thereby supporting the hospitals in ensuring infection control. Monitoring the performance indicators and quality parameters shall be the responsibility of Unit In-charge, Hospital Managers, Infection Control Committee, under the overall supervision and guidance of Hospital In-charge.

Statutory Requirements

The design and planning of CSSD & Mechanized Laundry will need compliance with mandatory regulations related to local administration such as Municipal Corporation, State By-Laws, Pollution Control Board, Fire Safety Department, Water Supply and Drainage Department, etc. While planning, provision for future expansion should be borne in mind.

QUALITY MONITORING

To check the validity of the sterilization process following points should be considered-

a. Physical monitoring through the autoclave displayed screen or printout

b. Chemical monitoring with chemical indicators

c. Efficacy testing with biological indicators

d. Operations testing of the autoclave

The following quality parameters shall be monitored

S. No.	Quality Parameter
1	Attendance, Uniform and Use of PPE during duty time of the Laundry Staff
2	Adequate supply of materials as mentioned in the service standards
3	Collection, Segregation and Transport of dirty / soiled linen in agreed timelines
4	Washing and calendaring / ironing in agreed timelines as per the service standards
5	Delivery of washed laundry in agreed timelines as per the service standards
6	Delivery of equipment in agreed timelines as per the service standards (Equipment up-time >= 95%)
7	Number of complaints from stake holders
8	Turn-Around Time (TAT)
9	% Autoclave/Sterilization achieved by CSSD

- Physical verification of linen for cleanliness and defects by Laundry In-charge before clean linen is distributed to ward and inspection by staff nurse during receipt of clean linen.
- Checking of linen inventory on quarterly basis by Matron.

CCTV Camera: All service areas, entry points inside CSSD complex should have CCTV camera which should be linked with the Laundry In-charge for continuous monitoring, so that all the technical protocols are monitored/supervised and adhered.

Fire and electrical safety audit: Periodically, a fire and electric safety audit should be done to ensure both fire and electric safety. This ideally should be done for the whole hospital and certainly include critical care and support areas. Documentation of all such audits needs to be properly maintained.

QUALITY ASSESSMENT

- All the quality parameters will be as per the guidelines of the National Quality Assurance Standards issued by GoI.
- Assessment shall be conducted as per prescribed QA checklist by the designated assessors.
- Before such assessment, the supervisor should use the checklist given in this guideline at Annexure-3 as part of routine monitoring. This will help the CSSD and Laundry services to be in readiness for quality certification.
- A Quality Management System procedure for Internal Assessment shall include the following:
    - Selection of Internal Assessors.
    - Criteria for Internal Assessors.

- Assessment Planning and methodologies.
- Assessment recording, non-conformance, and summary report preparation.

- Where assessment findings indicate deficiencies or the opportunity for improvement corrective or preventive action should be promptly taken. This should be documented and carried out within an agreed timeline.

Operational Management of CSSD & Laundry

Policies and Procedures:

1. **Administration:** There should be a laid down Standard Operating Procedure (SOP) on functioning, duties and responsibilities of staff members, infection control measures, cleaning and sterilization. Management is teamwork. All the staff work together for a long duration in a closed & stressful environment. A high level of motivation is needed for maintaining high output, high degree of asepsis and quality assurance. Normally, a hospital manager/ senior nurse is designated as Officer In-Charge of the CSSD complex for day-to-day administration, coordination and regular maintenance.
2. **Scheduling:** It is very important aspect of management of the CSSD complex. There is a need for planning of all activities. Punctuality needs to be adhered to for ensuring it.
3. **Infection Control Measures**

   Since CSSD and laundry are the most sensitive support areas for providing quality care services, so, it is of utmost importance that a high level of infection prevention and control practices are adhered by all staff. Some of the important activities for the same are explained below:

Maintaining Hand hygiene

- Any staff handling linen must wear gloves and wash hands immediately following the handling of any used linen.
- The In-charge should monitor for the adherence of hand hygiene practice.

Handling Dirty Linen

- All dirty linen shall be handled with care, to minimize transmission of micro-organisms via dust and skin scales.
- Proper PPE shall be worn when there is potential for contamination of the clothing, i.e. when changing linen.
- All dirty linen shall be placed carefully in linen bins on removal from the bed.
- Care must be taken to remove any extraneous items from dirty linen before it is placed in laundry bags. Such items are potentially dangerous to staff handling the laundry, and may also damage laundry equipment.

- The infectious linen should be tied in a yellow bag and tagged to indicate the content being infectious linen.
- To avoid spillage of dirty linen, linen bins must never be more than two thirds full, and must be securely transported to the laundry in trolley.
- Two trolleys should be maintained-one for transportation of dirty linen and other for transportation of clean linen.
- Vehicles or trolleys used for the transportation of dirty linen must be easy to clean, and must never be used to transport clean linen. “Soiled” & “Fresh” linen trolleys to be marked separately.
- The bag must be yellow in colour and tagged to indicate the ward/department in case of infectious trolley.
- Laundry personnel shall always wear apron, mask and gloves while handling linen.
- All linen trolleys to be washed on daily or weekly basis.

Handling Dirty equipment

- All dirty equipment shall be handled with care, to minimize transmission of micro-organisms.
- Proper PPE shall be worn when there is potential for contamination through the instruments
- All dirty instruments shall be packed and labelled carefully after use.
- The instruments/equipment must be securely transported to the laundry in trays/trolley.
- Trays/Trolleys used for the transportation of dirty equipment must be easy to clean, and must never be used to transport sterilized instruments.

4. Periodic Health check-up & Immunization of staff

- Periodic Medical Check-up and relevant Immunization of all staff shall be carried out and records of the same shall be maintained with the Immunization Room In-charge.
- The Infection Control Nurse shall monitor the effective conduct of the process.
- A copy of the immunization status of the laboratory staff shall be maintained with the Laundry/ CSSD In-charge.

Layout

CENTRAL STERILE SERVICES DEPARTMENT [CSSD]
PROPOSED COVERED AREA - 10500 SQFT

Flow Process of CSSD

Laundry

S. No.	Name of Sub-Areas
1.	Dirty linen receipt area (Dumb Waiter or Corridor)
2.	Decontamination area (Clean passage, decontamination room, pre-wash & decontamination for linen)
3.	Washing area (linen, blanket)
4.	Drying area (dry area)
5.	Folding & Pressing area (tailor, ironing area)
6.	Storage area (sorting area, critical linen)
7.	Linen distribution area (issue area)

CSSD

S. No.	Name of Sub-Areas
1.	Sorting area
2.	Cotton & gauze preparation area
3.	Cleaning area
4.	Ultrasonic Cleaning
5.	Automated Washer/ Disinfector
6.	Preparation and packaging area
7.	Labelling and packaging area
8.	Autoclave
9.	ETO Process
10.	Sterile Storage
11.	Change room/scrub
12.	Issue area

Common Area

S. No.	Name of Sub-Areas
1.	Supervisor room
2.	Change room (male, female)
3.	Staff Room
4.	First-aid area
5.	Pantry
6.	Janitor closet
7.	Wash room(male, female)

ANNEXURE 2

List of Equipment

CSSD

Steam Steriliser	The steriliser should meet the relevant standards. The chamber and doors should be made of solid, high quality stainless steel. The chamber should be jacketed to ensure temperature uniformity in chamber. The chamber floor is slightly sloped towards an internal drain to facilitate drainage. A stainless steel mesh strainer should be provided to protect the drain port from blockage by debris. The chamber is mounted on a stainless steel framework with height adjustable feet. The internal surface should be electro-chemically treated for high quality smooth finish to facilitate cleaning. The resultant surface should be polished to protect against corrosion. The internal corners should be rounded off to facilitate efficient cleaning. The steriliser jacket and door should be completely insulated with mineral rock wool to keep the autoclave cool on the outside. The insulation should be completely encased in a rigid removable sheet housing. The jacket should be made of quality stainless steel. The chamber should have a warranty for 10 years. The steriliser should have inbuilt steam generator of adequate capacity. It should be mounted under the steriliser chamber & should be made of quality stainless steel. The steam generator should have insulation of thick chloride free mineral rock wool with rigid aluminium sheet housing. It should have a built in thermostat, pressure safety valve & water level glass gauge inspection device visible from service area. The heating element should also be made of stainless steel. It should also have the automatic blow down valve & degassing system for feed water to steam generator. To make the sterilisation process faster, the capacity of the heating element should not be less than 36 KW.
ETO Steriliser	Ethylene oxide steriliser is defined as equipment which uses ethylene oxide as a biocide to destroy bacteria, viruses, fungi and other unwanted organisms. Ethylene oxide is used in sterilisation of items that are heat and moisture sensitive. The ETO gas steriliser should be fully automatic type for sterilisation of heat sensitive goods such as anaesthetic tubing and endoscopes.

Ultrasonic Cleaner	The unit should be a compact free-standing bench model, with a built-in tank manufactured from high-quality stainless steel and a solid-state generator that sends ultrasonic (approx. 42,000 cycles per second) impulses through wash water containing detergent and electrical heating; microprocessor controlled display with memory time and temperature functions. The electrical energy should be transformed into sound waves by transducers, fixed to the bottom of the tank. The tank should be made of solid stainless steel. The ultrasonic cleaner should have a display and control which could be easily seen and placed above any liquid for safety and reliability. It should have digital read out timer and temperature setting monitoring.
Washer Disinfector	The washer should perform pre-rinsing, cleaning, post-rinsing, thermal disinfection, final rinsing and drying phases. Validated programmes are secured by access code. Detergents and rinse agents should be automatically dispensed during the cycle.
Magnifying Lamp	Inspection tables, lamps, cleaning equipment, interior water treatment facilities
Sealing Machine	Rotary heat sealers should provide validated sealing of sterilization bags and clear-view pouches (paper/plastic laminate). These through feed-type sealers should be microprocessor-controlled for highest capacity and ease of operation. The rotary heat sealer should give documentation of process parameters via an integrated printer and could be integrated with documentation system. The ergonomically design should be tilted forward for increased user convenience and space saving installation.
Endoscope Washer	The endoscope washer/disinfector, acts as a system to clean and disinfect endoscopes safely and effectively.

Note:- For equipment wise specifications refer to the Technical Specifications of Medical Devices through the link attached here- https://nhsrcindia.org/sites/default/files/2021-05/Technical%20Specifications%20of%20Medical%20Devices%20for%20Operational%20Theatres.pdf

Laundry

Calculating Capacity of Laundry Equipment

Capacity of laundry equipment like washing machines/ dryers/ironing etc. will depend upon the requirement of individual hospital. Various international and national studies have indicated 3-7 kgs of linen/bed to be washed every day. Some of the states who have initiated mechanized laundry have proposed weight of 3 kgs per hospital bed. So, for a 300 bedded hospital, we may expect cleaning of about 900 kgs of linen i.e., @ 3 kgs/ bed/day.

Such assumptions are based on daily changing of linen and periodic cleaning of blankets.

Name of Equipment for Mechanized Laundry	300 bedded hospitals
Washing Machine (Capacity of 60 Kg)	1
Washing Machine (Capacity of 30 Kg)	4
Hydro Extractor (Capacity of 25 Kg)	2
Drying Tumbler (Capacity of 30 Kg)	2
Electric Calendar	2
Electric Press with table – 48"	3
Electric Press with table – 18"	3
Dry Linen Trolley (300 Ltr)	4
Wet Linen Trolley (300 Ltr)	6
Folding Table	1
Stainless Steel Racks	2

Equipment management

- All equipment must have manufacture's specification.
- A servicing schedule for all equipment is to be maintained to ensure that servicing is being done as per schedule and documentation of each servicing session is to be maintained in equipment register.
- Daily check of Equipment should be done every morning & before commencement of procedure.
- A monthly maintenance round by personnel from maintenance department to be done to check for any problems and repair related issues, which shall be documented in the equipment register.
- Any problem coming up should be immediately informed to maintenance department and seen that the problem is attended to as soon as possible. An equipment downtime register shall be maintained to monitor time taken for repair.

Biological monitoring of sterilization process (CSSD)

Sterilisation process is monitored by physical (time, temperature, pressure), chemical (internal and external indicators) and biological methods. Physical and chemical indicators must be used with every sterilisation cycle while biological indicators must be run weekly.

Biological indicators are the ideal monitors of sterilisation process because they measure the efficacy of sterilization process directly by using the most resistant microorganisms (i.e., Bacillus spores). Apart from routine testing, biological indicators are also required to be used in the following situations:

- o installation of a new sterilizer,
- o after relocation of an existing sterilizer,
- o after a sterilizer malfunction,

- after major repairs to a sterilizer that are outside the scope of routine or preventive maintenance; and
- after repairs to the steam generator/delivery system.

The details of the biological indicators for sterilization are given below:

Spore strain	**Bacillus atrophaeus**	**Geobacillus stearothermophilus**
Technique monitored	Ethylene oxide, dry heat	Steam, hydrogen peroxide gas plasma
Number of spores	10^6 spores	10^6 spores
Method of use*	Place strip in centre of one or more packs of chamber; transfer strips into a recommended broth	Place strip in centre of one or more packs of chamber; transfer strips into a recommended broth
Incubation	35-37^0 C x 14 days. Examine for turbidity. Incubate an unexposed spore strip simultaneously	55-56^{0}C for upto 14 days anaerobically. Incubate an unexposed strip simultaneously

* There are newer “enzyme” based methods of monitoring, where the results can be achieved much faster, in hours.

Interpretation

As per the CDC recommendations

- Objects, other than implantable objects, do not need to be recalled because of a single positive spore test unless the steam sterilizer or the sterilization procedure is defective.
- If the mechanical and chemical indicators suggest that the sterilizer was functioning properly, a single positive spore test probably does not indicate sterilizer malfunction but the spore test should be repeated immediately.
- If the spore tests remain positive, use of the sterilizer should be discontinued until it is serviced.
- For ETO and H2O2 gas plasma, a single positive spore test may be considered significant. All loads should be retrieved for re-processing.

ANNEXURE - 3

CHECKLIST FOR CSSD & LAUNDRY

SECTION A: STRUCTURE

CHECKPOINT	YES/NO (COMMENTS)
There is dedicated department of CSSD and Laundry.	
Dedicated and Full-time officer in Charge of CSSD and Laundry (Surgeon/ Anaesthetist/OT Technician).	
Unidirectional flow without any criss-crossing or back tracking.	
'Zoning Concept' with defined and demarcated Dirty, Clean and Sterile Zone.	
Entry to CSSD & Laundry is restricted.	
Adequate space to carry out various process of sterilisation(cleaning, washing, sterilization, package, storing and dispatch) and meet the daily and emergency requirements of the facility. (4-5 Square feet/bed, but may vary from hospital to hospital)	
Signage (internal demarcated area signages)	
Separate receiving and dispatching window/ area	
The facility has separate area for soiled linen and instruments	
Well demarcated areas for decontamination, preparation, sterilization and storage	
Availability of equipment: • Autoclave • Trolleys & drums • Autoclaving indicator tape • Storage racks and working benches.	
Uninterrupted water and electricity supply 24*7with power backup.	
Floors and wall surfaces are easily cleanable	
Lighting adequate for all work areas (300- 500 lux)	
Decontamination sink of adequate size (internal: 380mm x 340mm) is present for soaking, cleaning and rinsing	
Notice board for mentioning duty roster, sterilization chart, quality checklists etc.	

SECTION B: PROCESS

CHECKPOINTS	YES/NO (COMMENTS)
SOPs for CSSD & Laundry are available and the SOPs adequately describe the processes of CSSD and laundry.	
SOPs adequately describes the process of **Transfer of unsterile items from user department to CSSD & laundry.**	
Staff follows and adheres to the same, in day-to-day practices.	
SOP adequately describes the process of **Transfer of sterile items from CSSD & Laundry to user departments.**	
Staff follows and adheres to the same, in day-to-day practices.	
SOP adequately describes the process of Standardized list of the contents of sets/trays for various procedures.	
Staff maintains and adheres to the same, in day-to-day practices.	
SOP adequately describes the process of Sterilization process for different categories of items. (Linen, gauze, equipment, rubber materials, catheter).	
Staff follows and adheres to the same, in day-to-day practices.	
SOP adequately describes the Complete process cycle from start to finish (washing, cleaning, sterilization, storage and issue).	
Staff follows and adheres to the same, in day-to-day practices including • Drying, packaging and labelling of items • Application of Autoclave indicator • Setting up autoclaving parameters (Preheating & loading, ensuring time, temperature and pressure) / different for linen and equipment/different for packed and open items) • Unloading and storing in a sterile area/rack	
SOP describes the process of Internal validation of sterilization process	
Staff follows and adheres to the same, in day-to-day practices (heat sensitive indicators strips, Bovie Dick Test)	
Soiled items are contained during transportation (closed drums/packed/ enclosed in tray)	
Appropriate personal protective equipment (PPE) are used in the entire procedure of sterilization	
Cleaning agents are used according to manufacturer's instructions	
Appropriate manual/ mechanical cleaning methods are used for decontamination	
Inspection for functionality, defects/breakage is been done	
Fixing of shelf life of different sterile items. System of recall of items from user department, if their sterile status is in doubt. Sterile items are stored in a way to facilitate First-In First-Out (FIFO). S0P for maintenance and calibration of equipment.	

There is a separate register/records for various activities on daily basis of the following: Each cycle of autoclave Maintenance and breakdown of equipment Stock maintenance for the consumables Recording fumigation details Periodic cleaning of the autoclave and other equipment like drums, shelves Default sterilization/ sterilization defects	
Regular training of the staff on carrying out various process of sterilisation, infection control practices, Biomedical Waste Management, trouble shooting of equipment, handling instruments, record keeping and reporting mechanism etc.	

SECTION C: OUTCOME

CHECKPOINTS	COMMENTS
1. Number of sterilisation cycle per day/autoclave	
2. Percentage of cycles wherein in standards norms of temperature, pressure and time were adhered and recorded.	
3. Number of sterilisation failure/default sterilization cases noted/day	
4. Percentage re-sterilisation required due to improper storage	

ANNEXURE-4

SAMPLE FORMAT OF KEY INFORMATION IN CSSD & LAUNDRY

Room No._____

Employees _____

Designation (as applicable)	**Name**
CSSD/Mechanized Laundry In-Charge	
CSSD Technician/ Mechanized Laundry Technician	
CSSD/Mechanized Laundry Technician	
Sanitation Staff	
Others	

Registers/Records Maintained

S. No.	**Name f The Register**	**Key Information Recorded In The Register**	**Frequency Of Updating**	**Person Responsible**	**Supervisor**
1	CSSD autoclave Register				
2	Receipt Register				
3	Handing over & taking over				
4	Issue Register				
5	Indent Book				
6	Inventory/ Stock book				
7	Attendance Register/ Biometrics				

Cleaning Protocol

S. No.	**Sub-area**	**Number**	**Frequency Of Cleaning**	**Material Used To Clean**	**Person Responsible**
1					
2					
3					

Performance Chart

Sr. No.	Indicators (CSSD & ML)	Previous Month	Current Month
1.	No. of sterilizations cycles per day/autoclave		
2.	Number of sterilization failures/ default sterilization cases noted/day		
3.	Percentage re-sterilization required due to improper storage		

References:

1. Hospital central sterile supply departments by V. D. Allison, M.D., M.Sc., D.Ph.
2. Hospi-health- SOPs for CSSD & Laundry
3. NEIGRIHMS- SOPs for CSSD & Laundry
4. MGIMS, Wardha- SOPs for CSSD
5. Indian Public Health Standards, Government of India

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