भारतीय मानक Indian Standard

> बहुउपयोगी हेल्थकेयर वस्त्रों के प्रसंस्करण के लिए दिशानिर्देश

# Guidelines for Processing of Multiple-Use Healthcare Textiles

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**Price Group 9** 



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### Technical Textiles for Medtech Applications Sectional Committee, TXD 36

### FOREWORD

This Indian Standard was adopted by the Bureau of Indian Standards, after the draft finalized by the Technical Textiles for Medtech Applications Sectional Committee had been approved by the Textiles Division Council.

With the rise in the demand of reusable (multiple use) healthcare textiles, it is more imperative than ever that these products are to be processed according to the highest standards of infection prevention, quality, and safety.

Concern is rising about the risk of spreading infections from reusable healthcare textiles/linen used in healthcare setting (bed sheets, blankets, towels, personal clothing, patient apparel, uniforms, scrub suits, gowns, and drapes etc) to patient, healthcare personnel, staff and the public, if not washed under a monitored environment. Reusable textiles used in healthcare settings can be a component in the chain of infection transmission.

The risk is greater in such cases because contaminated garments have to be handled properly. Such garments can be a source of microbes, if the laundry process fails to eliminate contamination, it can spread to the other items in the laundry load. For example, if laundry is left damp, this encourages microbial survival and residual microorganisms could grow. A healthcare facility can avert this risk by having these garments professionally laundered by a hygienically clean healthcare certified linen & uniform service. Thus, laundering is a very necessary process in the life cycle of reusable textiles.

However, this process consumes large amounts of water and consequently produces the same amount of wastewater. And, even if the resulting wastewater is fully treated and recycled to reduce detrimental effects to the environment, there is still the problem of energy consumption during the laundry operation. From a material life cycle perspective, however, reusable textiles (woven or knitted) have the advantage of a longer lifetime, capable of surviving up to 50 or more hospital laundry cycles and thereby offering an additional saving to users and the environment.

This recommended practice is intended to provide guidelines that will help material managers, laundry managers, central service managers, and other health care professionals implement effective quality assurance systems for the processing of reusable healthcare textiles. The guidelines provided may also be useful to hospitals/users in evaluating the capabilities of facilities being considered for the processing of reusable healthcare textiles.

The composition of the Committee responsible for the formulation of this standard is given in Annex B.

In reporting the result of a test or analysis made in accordance with this standard, if the final value, observed or calculated, is to be rounded off, it shall be done in accordance with IS 2 : 2022 'Rules for rounding off numerical values (*second revision*).'

# Indian Standard GUIDELINES FOR PROCESSING OF MULTIPLE-USE HEALTHCARE TEXTILES

# **1 SCOPE**

**1.1** This standard provides the general guidelines for processing of multiple-use (reusable) healthcare textiles under hospital laundry whether in-house or outsourced laundry services. The processing guidelines are applicable to hospital laundry in the following areas:

- a) Hospitals-private, public and any extended healthcare facilities;
- b) Clinics;
- c) Dental services;
- d) Nursing homes;
- e) Mental health institutions;
- f) Diagnostics sector; and
- g) General healthcare centres etc.

**1.2** This standard generally covers reusable healthcare textiles for general ward linens and operating theatre textiles such as:

- a) General purpose linen Patient care like curtains, drapes, table clothes and similar items commonly used in all parts of the hospital;
- b) Patient linen Patient clothing such as pyjamas, shirts, gowns, coats etc. worn by patients;
- c) Bed linen Bed clothing such as bed sheets, pillow covers, blankets used by the patient; and
- d) Operation theatre (OT), labour room, procedure room linen — Items such as pyjamas, kurtas, gowns, coats, shirts, surgical gowns, caps, masks etc. worn by healthcare personnel and also trolley covers, towels required in operation theatre, labour room and procedure room.
- **1.3** This standard does not cover the following:
  - a) Design, specification or construction criteria for machine and equipment used to processing of reusable healthcare textiles;
  - b) Criteria for staff qualification who handles the processing of healthcare textiles;
  - c) Role of infection control committee in healthcare facility and the application of any sterilization technology or sterility assurance practices;

- d) Selection of reusable healthcare textiles;
- e) Performance standards for reusable healthcare textiles;
- f) Special laundry situations such as neonatal intensive, burn care, HIV, Hepatitis (B, C) etc; and
- g) Other laundry service purpose like commercial, hotel, industrial and institutional laundry, etc.

# **2 REFERENCES**

The standards listed in Annex A contain provisions, which through reference in this text, constitute provisions of this standard. At the time of publication, the editions indicated were valid. All standards are subject to revision and parties to agreements based on this standard are encouraged to investigate the possibility of applying the most recent editions of these standards.

### **3 TERMS AND DEFINITIONS**

For the purposes of this standard, the following terms and definitions shall apply:

**3.1 Barrier Properties** — Ability of a protective material to resist the penetration of liquids and resistance to airborne and liquid borne microorganisms, blood, and OPIM.

**3.2 Bio-hazardous Bags** — Bags used to collect, compile, pack, and dispose the harmful and infectious wastes that are generated by the clinical laboratories, healthcare facilities, and pharmacy industries.

**3.3 Bleaching** — Use of an oxidizing agent (usually sodium hypochlorite or hydrogen peroxide) within a laundry formula to decompose some types of stains and/or disinfect contaminated textiles

**3.4 Blood-borne Pathogen** — Infectious microorganisms including virus carried in blood or other body fluids.

**3.5 Body Fluids** — Any liquid produced (secreted/excreted) by body.

**3.6 Calendaring** — Calendaring is a finishing process used on cloth in which fabric is passed between rollers at high temperatures and pressures.

**3.7 Centrifuging** — Excess water from the washed clothes are spin-out of fabric which facilitates faster drying.

**3.8 Cleaning** — The process to physically remove contamination by foreign material, for example, dust, soil. It will also remove organic material, such as blood, secretions, excretions and microorganisms, to prepare a healthcare textiles for disinfection or sterilization.

**3.9 Cleanliness–Microbial** — Freedom from population of viable microorganism on a product and/or a package.

**3.10 Cleanliness–Particulate Matter** — Freedom from particles that are contaminating a material and can be released but are not generated by mechanical impact.

**3.11 Colony Forming Unit (CFU)** — Unit by which culturable number of microorganisms is expressed.

**3.12 Contaminated** — State of having been actually or potentially in contact with microorganisms.

**3.13 Contamination** — The soiling of inanimate objects or living material with harmful, potentially infectious or unwanted matter.

**3.14 Decontamination** — The use of physical or chemical means to remove, inactivate, or destroy blood-borne pathogens on a surface or item to the point where they are no longer capable of transmitting infectious particles and the surface or item is rendered safe for handling, use, or disposal.

**3.15 Detergent** — A cleaning agent that increases the ability of water to penetrate organic material and break down greases and dirt. Detergents are needed to allow effective cleaning to take place.

**3.16 Disinfection** — Process that kills pathogenic and other microorganisms by physical or chemical means.

**3.17 Doffing** — Removal or take off of protective materials such as gloves, aprons, and so on.

**3.18 Effluent** — Effluent is wastewater from sewers or industrial outfalls that flows directly into surface waters either untreated or after being treated at a facility.

**3.19 EPA** — Environmental protection agency.

**3.20 Extraction** — Use of physical forces (usually centrifugal or strike/impact) to remove excess water from a wash load prior to drying.

**3.21 Germicide** — a substance or other agent which destroys harmful microorganisms.

**3.22 Health Care Facility** — means a place where diagnosis, treatment or immunization of human beings is provided irrespective of type and size of health treatment system, and research activity pertaining thereto. Health care facilities includes District Hospitals, Sub Divisional Hospitals, Community Health Centres, Primary Health Centres and Sub centres.

3.23 Healthcare Personnel (HCP) — Refers to all paid and unpaid persons serving in healthcare settings who have the potential for direct or indirect exposure to patients or infectious materials, including body substances (for example blood, tissue, and specific body fluids); contaminated and equipment; medical supplies, devices, contaminated environmental surfaces; or contaminated air. These HCP may include, but are not limited to, emergency medical service personnel, nurses, nursing assistants, physicians, technicians, therapists, phlebotomists, pharmacists, students and trainees, contractual staff not employed by the health care facility, and persons (for example clerical, dietary, environmental services, laundry, security, maintenance, engineering and facilities management, administrative, billing, and volunteer personnel) not directly involved in patient care but potentially exposed to infectious agents that can be transmitted among from HCP and patients.

**3.24 Healthcare Textiles** — Healthcare textiles materials are mainly used for protection from infections in hospital environment. They are used either in the operation theatre or in the hospital wards for safety of healthcare personnel/staff, doctor and patients. For example, bed sheets, blankets, towels, patient apparel, uniforms, scrub suits, coverall, mask, cap, gowns, and drapes etc.

**3.25 Hospital Acquired Infections (HAI)** — The hospital-acquired infection (HAI) also referred to as healthcare-associated infections or nosocomial infections is defined as the infections that develops in patient within 48 hours to 72 hours of admission to a hospital for treatment, these infections were neither present nor in incubation period at the time of admission.

**3.26 Hospital Linen** — Refers to all textiles used in the hospital including mattress, pillow covers,

blankets, bed sheets, towels, screens, curtains, doctors' coats, theatre cloth and table cloths etc.

**3.27 Hydro-extraction** — It is a process of extracting water from the textiles usually done after laundry.

**3.28 Infected Textiles** — Textiles which holds pathogenic disease-causing bacteria or virus.

**3.29 Infective Agent** — Microorganism that has been shown to potentially cause infections.

**3.30 Invasive Surgical Procedure** — Surgical procedure penetrating skin or mucosa.

**3.31 Laundry Processes** — Activities that encompass the handling, washing, and drying of soiled textiles.

**3.32 Liquid Penetration** — Migration of liquid(s) through the material.

**3.33 Manufacturer** — Natural or legal person with responsibility for the processing of raw material or inputs in any manner that results in the emergence of a new product having a distinct name, character and use.

**3.34 Microbial Penetration** — Migration of microorganisms, from one side of the material through the other.

**3.35 Microorganism** — Entity, encompassing bacteria, fungi, protozoa, and viruses, of microscopic size.

**3.36 OT** — Operation theatre

**3.37 Other Potentially Infectious Materials** (OPIM) — Any materials, other than blood or body fluids, containing blood-borne pathogens or materials that have been linked with the potential transmission of infectious disease.

**3.38 Personal Protective Equipment** — Commonly referred to as "PPE", is specialized clothing or equipment worn to minimize exposure to hazards that cause serious workplace injuries and illnesses. These injuries and illnesses may result from contact with chemical, radiological, physical, electrical, mechanical, or other workplace hazards.

**3.39** pH — A measure of how acidic or basic a substance or solution is.

**3.40 Processing Area** — Area of the laundry containing the processing equipment used to decontaminate and clean soiled textiles.

**3.41 Protective Textiles** — Used to prevent or minimize exposure to hazards biological hazards.

**3.42 Processing** — All steps that are necessary to make a contaminated reusable healthcare textile ready for its intended use. These steps may include cleaning, functional testing, packaging, labelling, disinfection and sterilization.

**3.43 Reusable/Multiple Use Product** — Product intended by the manufacturer to be reprocessed and reused.

**3.44 Rinsing** — An operation designed to remove all suspended soils, soaps, detergents and bleach from the textiles being laundered.

**3.45 Scrub suits** — Loose-fitting, usually two-piece garment, worn by surgeons and assisting personnel in an operating room.

**3.46 Single-use/Disposable Product** — Product intended by the manufacturer to be used only once.

**3.47 Sluicing** — It is the process of freeing potentially harmful or infectious substances from laundry and flushing it away prior to the main washing cycle.

**3.48 Soiled (Contaminated) Textiles** — Textiles that have had potential contact with blood, body fluids, or OPIM.

**3.49 Soil-Sort Area** — Area of a laundry facility designated for receiving, retention, handling, and sorting of soiled textiles.

**3.50 Soil Sorting** — Process of sorting soiled items into defined or established categories so that they can be laundered together.

**3.51 Sterile Field** — An area created by placing sterile surgical drapes around the patient's surgical site and on the stand that will hold sterile instruments and other items needed during surgery.

**3.52 Sterilization** — Sterilization is defined as a process of complete elimination or destruction of all forms of microbial life (that is, both vegetative and spore forms), which is carried out by various physical and chemical methods.

**3.53 Surgical Gown** — Protective clothing that is intended to be worn by healthcare workers during surgical procedures to protect both the surgical patient and the operating room personnel from the transfer of microorganisms, body fluids and particulate matter.

**3.54 Surgical Drape** — A covering for the patient for the prevention of transfer of infective agents, such as microorganisms, body fluids and particulate material. "Surgical drapes are used during surgery to prevent contact with unprepared surfaces and to maintain the sterility of environmental surfaces, equipment and the patient's surroundings".

**3.55 Validation** — Documented procedure for obtaining, recording, and interpreting the results required to establish that a process will consistently disinfect and sterilize instruments and other medical devices.

# 4 GENERAL REQUIREMENT FOR LAUNDRY SERVICES MANAGMENT

**4.1** Laundry service in a hospital is one of the major components which directly affects the patient and hospital staff's health and hygiene. It is accountable for supplying clean and adequate linen to the hospital. It includes collecting, sorting, storage and transportation of dirty linen from hospital and washing, disinfection, extracting, drying, ironing, folding, transportation of clean linen from laundry service; back to the hospital and storage of clean linen in the hospital.

4.2 The laundry service shall establish, document, implement and maintain a quality policy for laundry infection control which includes risk management and maintain its effectiveness. The purpose of this policy is the prevention of infection or injury in service users and laundry staff involved in the use, handling or laundering of healthcare textiles. Policies and procedures shall be framed to provide a clear framework for ensuring that all individuals involved in the handling, processing, and transport of used/soiled healthcare textiles understand their roles and responsibilities for preventing contamination.

**4.3** The supervisors/managers and laundry staff shall be fully trained about the laundry procedure, handing of equipment, machine operation etc. Regular training shall be provided to supervisor and laundry staff about potential infectious hazards and techniques to prevent the spread of micro-organisms in the environment to finished healthcare textiles/linen. The role and responsibility of the supervisors/managers and laundry staff shall be defined by the laundry service provider.

# 5 LAUNDRY LAYOUT AND DESIGN — GENERAL REQUIREMENT

**5.1** The laundry facility in a health-care setting shall be designed for efficiency in providing hygienically clean textiles, fabrics, and apparel for healthcare personnel and patient. The laundry facility shall

comply with all the relevant regulatory requirements (amended from time to time) by Government of India for facilities and equipment. Maintaining hygiene and clean environment at laundry facility is essential for ensuring products that are appropriate for consumers use. Following are recommended guidelines for ensuring adequate infrastructure, hygiene and clean environment at laundry facilities:

- a) Location of laundry facility should be free from objectionable odours, smoke, dust and other contaminants;
- b) The building shall be of adequate size to hold the required equipment, services and systems, and afford comfort to and protection of staff, equipment and goods;
- c) The laundry facility shall be designed to have a physical barrier or functional separation between areas in which soiled textiles are received and processed and areas in which clean textiles are handled and stored for distribution to the pack assembly area. This is done to prevent cross- contamination and maintain hygiene standards;
- A laundry facility is usually partitioned into two separate areas - a "dirty" area for receiving and handling the soiled laundry and a "clean" area for processing the washed items;
- e) If healthcare textiles are processed outside the building (off site laundry), provisions shall be made for a service entrance, protected from inclement weather, for loading and unloading of healthcare textiles; an area for pick-up and receiving;
- f) Machine, equipment and systems shall be designed to reduce the risk of injury to operators/staff and to provide safe working conditions particularly with respect to odours, noise, lighting, heating, cooling, standing, sitting, stretching, bending and lifting;
- g) Work area design should allow adequate space for all functions and should promote efficiency by minimizing distances between related areas;
- h) Flooring shall be either concrete, tiled or with chips to ensure ease of cleaning. Floors, walls, ceilings, doors and windows shall be easy to clean and without crevices or openings that shall not allow accumulation of dirt;
- j) Appropriate lighting and proper ventilation of the facility shall be ensured;

- k) Separate areas shall be demarcated for sorting/collection, handling, segregation of soiled and cleaned products. Dedicated areas for washing, disinfection, sterilization and packing of cleaned healthcare textiles shall be provided;
- m) Separate area shall be demarcated for storing personal effects and personal protective equipment of unit workers to minimize risk of contamination;
- n) All personnel involved in the collection, transport, sorting, and washing of soiled linen shall be adequately trained and wear appropriate personnel protective equipment (PPE);
- p) The standard operating procedures (SOPs) should be developed and implemented to ensure that all the employees/staff shall follow the same procedures for handling contaminated materials and minimizing exposure to bloodborne pathogens;
- q) To minimize the potential for recontaminating cleaned laundry with aerosolized contaminated lint, areas receiving contaminated textiles should be at negative air pressure relative to the clean areas;
- r) Toilet and hand-washing station shall be provisioned away from cleaning and storage area;
- s) There should be an eyewash station located near the equipment(s) where staff/workers are handling chemicals or other hazardous materials;
- t) Provision of 70 percent isopropyl alcohol (IPA) solution or equivalent or soap for hand sanitization inside the production

facility. Hand hygiene shall be practiced before packing of cleaned products;

- A cleaning and maintenance schedule shall be drawn up for cleaning of the facility, machine, equipment, toilets, washing areas, waste receptacles and for cleaning/ disinfection of the equipment;
- w) Regular pest control measures and fly screen shall be put in place;
- y) Drain outlets carrying effluent from washing machines should be sealed (close piped) into the disposal system. If a washing machine drains into an open sump, this should, where practicable, be covered to prevent the spread of organisms by aerosol when the water is dumped from the machine and also to minimize the potential chemical hazard from splashing;
- z) The humidity should not exceed 65 percent and the temperature should be in a controlled condition from 20 °C to 27 °C. If the laundry facility is in the basement, adequate ventilation will be provided through proper installation and management of heating, ventilation, and air conditioning (HVAC), fresh air blowers and exhaust lines;
- aa) The environment should be made as comfortable as possible, which can generally be accomplished by proper ventilation in the work area; and
- bb) The exhaust in the laundry section should be provided with the necessary filters to capture the dust and lint.

**5.2** The laundry service layout and process flow are given in <u>Fig. 1</u> and <u>Fig. 2</u> for guidance only.

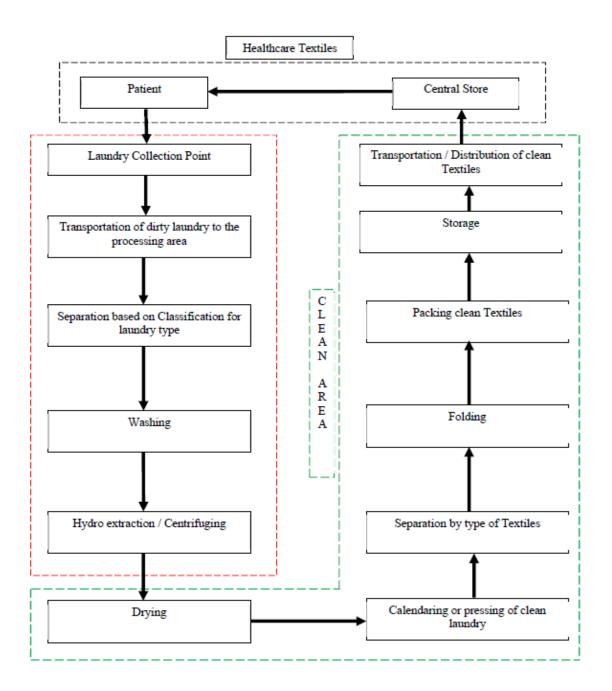


FIG 1 LAUNDRY LAYOUT

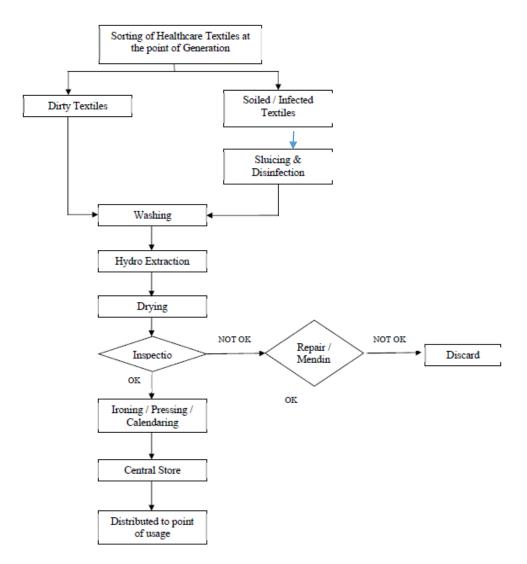


FIG 2 LAUNDRY PROCESS FLOW

# 6 COLLECTION AND SEGREGATION OF SOILED MATERIAL

**6.1** The soiled/contaminated healthcare textiles are collected from the patient wards, patient-care areas, surgical areas, operation theatres and clinical laboratories in bio-hazardous bags. The soiled healthcare textiles may be sorted out in two ways - pre-sort systems and post-sort systems. Pre-sort systems involve sorting soiled healthcare textiles at the point of use, before they are transported to the laundry soil-sort area. Post-sort systems involve sorting soiled healthcare textiles in the laundry soil-sort area, after they have been transported from the point of use.

**6.2** Sorting must be performed carefully as the textiles from operating room or other procedure areas may often contain sharps (suture needles, razor blades, scalpel blades etc) and the bedding from patient's rooms may contain soiled dressings or

bloodstains, as well as other body fluids. Such materials should be handled cautiously by wearing gloves, goggles, apron of high protection and disposed after sorting.

**6.3** Disposable gloves and personnel protective equipment shall be used during collection and the person should not touch his/her personnel before doffing. The bags and gloves should be leak proof and possess for optimum tensile strength and high thickness. The contamination levels of the collected healthcare textiles are identified by the colour codes or labelling the bags.

**6.4** The textiles with soil stain and dirt to be segregated in one cluster and the material with blood stains and infected textiles from operation theatre are to be grouped separately based on the hazardous rate, nature and depth of the stain. Segregation reduces the exposure of laundry workers to the infected material. It protects the textile and

processing machinery from hard objects such as needles, syringe and sharp objects from patients.

**6.5** The soiled textile materials are removed carefully by folding and rolling to avoid unnecessary agitation and directly placed into the appropriate bags. Separate areas should be used for the processing of soiled textiles from those used for folding clean healthcare textile, patient wards and food preparation areas. The areas for clean and soiled healthcare textiles should be adequately ventilated and separated by physical hindrance.

**6.6** The following instruction and information should also be monitored at collection and segregation area in laundry service in healthcare facility:

- a) Hospital should have organize a daily schedule for the collection of healthcare textiles;
- b) Extra care should be taken before collection to ensure that there is no nontextile items namely syringes, needles etc are presented;
- c) Reusable healthcare textiles from operation theatre, procedure areas and patient wards should be changed on daily basis and the healthcare material of hospital staffs should be replaced weekly;
- d) Whenever any reusable healthcare textile material is visibly dirty or soiled in the hospital, it should be changed;
- e) Hand hygiene should be followed strictly before and after handling of the healthcare textiles. In case of any skin lesions, it should be covered properly;
- f) Infected textiles must be collected only in bags and should not be placed in any other surfaces. It should be stored only in the designated area;
- g) Different colour codes or labels should be followed for distinguishing the textiles collected from different areas; and
- h) The supervisor/in-charge of the area should update the daily records every time when the soiled or infected textile is collected from the area. It includes the type and number of items collected from the particular area. The record of soiled/infected healthcare textiles should be maintained for different areas for the same.

### 7 TRANSPORT OF CONTAMINATED HEALTHCARE MATERIALS TO RECEIVING AREA OF LAUNDRY

**7.1** Soiled healthcare textiles collected from various areas of the hospital should be transported in different trolleys, bins, bags or other transport means. Transportation of soiled healthcare textiles is an important aspect of the overall process of handling these materials. Proper transportation procedures help to minimize the risk of infection transmission and ensure that textiles are effectively cleaned and disinfected.

**7.2** Healthcare textiles collected through chutes should have proper design, and maintained periodically as the piston-like action of a laundry bag traveling in the chute can propel airborne microbial contaminants throughout the facility. It should be maintained in negative air pressure to avoid the transmission of microbes from floor to floor. Laundry personnel who receives the reusable healthcare textiles must enter the details in the receiving and distribution register which includes the type and quantity of item received, department that receives the material, date and time of receiving.

**7.3** The following the key steps involved during transportation of contaminated healthcare textiles to receiving area of laundry service:

- a) Soiled materials should be transported in separate trolleys, bins, bags or other transport means;
- b) The containers for transportation shall be selected based on their ability to contain the materials being transported, as well as their durability and ability to prevent leaks or spills;
- c) Dedicated trolley/container should be used for transportation and the trolleys used for any other purposes should not be used;
- d) While transportation, it is to be ensured that that the collection bags are leak-proof and tied firmly;
- e) In case of any leakage of infected textile materials during transport, it needs to be placed securely in the trolley and the spilled surface should be cleaned as per the spill management protocol of the hospital;
- f) Loose and contaminated pieces of healthcare textiles should not be placed in transport media to prevent the contents from falling out; and

g) The hospital must keep records for laundry management of healthcare textiles to ensure quality.

# 8 PRE-TREATMENT/DISINFECTION BEFORE WASHING

**8.1** Heavily soiled textiles may sometime require additional pre-treatment, such as soaking in chemical/disinfectant/spot cleaning, before laundering to ensure that all soil is removed. Healthcare textiles used during radiotherapy also require special handling and washing to ensure they are properly disinfected and free of any radioactive particles.

**8.2** The laundry service in healthcare facility shall decide the suitable and effective processing and disinfection method depending upon fibre content of fabric, manufacturing process, design, level of contamination, anticipated risk, type of coating etc. The most common method used for disinfection of soiled healthcare textiles is by using sodium hypochlorite solution. Hydrogen peroxide is also used as disinfectant for soiled healthcare textiles.

**8.3** Disinfecting the contaminated textile material is the first step for processing. Soiled healthcare textiles should be stripped from the bed with care taken not to shake the textiles during this action. It should be soaked in 1 : 50 hypochlorite solution for 30 min for white textiles and the coloured materials to be processed as per hospital policy where a suitable high-level disinfectant to be used.

**8.4** It is then rinsed in water until the residual bleach is removed and handed over for washing. If the laundry services are outsourced, it is the responsibility of the hospital to disinfect and sluice the soiled textile material within the facility itself before handing over the same to the outsourced agency or personnel for further processing.

# 9 WASHING

**9.1** The laundry service in healthcare facility should follow the instruction of manufacturer of the finished healthcare textile product before deciding the washing and drying procedures to be followed. The laundry service shall have ongoing programs that record and monitor all key laundry processes. The programs shall include clear procedures for:

- a) Achieving and maintaining effective washing, disinfection, drying, finishing as well as appropriate product life;
- b) Preventative maintenance systems that ensure correct and safe operation of all plant and equipment including appropriate calibration of all key equipment such as

water level controls, agitation level, temperature controls and other process timer controls that ensures compliance and process stability;

- c) The effectiveness of the washing/laundering process depends on many factors like time and temperature, mechanical action, water quality (*p*H, hardness), volume of the load, extent of soiling, model/availability of commercial washers and dryers; and
- d) Bleach/detergent acts as a chemical germicide to kill the microbes present in the contaminated textiles. Chlorine bleach is safer and provide colour safety and better anti-microbial activity. Oxygen-based bleach or detergent registered under environmental protection agency (EPA) or concerned regulatory authority authorities may also be used as an alternative for chlorine bleach.

**9.2** Textiles contaminated with blood and body fluids collected in a leak-proof bag should be immersed in compatible disinfectant. Washing of the contaminated textile material should be performed immediately after the removal. During washing soiled healthcare textiles, the washing person should be given PPE.

**9.3** The soiled healthcare textiles may be reprocessed with hand wash or machine wash at laundry facility as per the agreement between the user and laundry service provider.

# 9.3.1 Hand Wash

Heavily soiled or contaminated healthcare textiles should be separated from the non-soiled material. The whole material is washed in water with liquid soap to remove the dirt, soil and spillages. The material is pre-soaked only for the soiled or infected textiles. The usage of warm water for washing is preferred based on availability. Add 30 ml to 60 ml of a 5 percent chlorine solution (bleach) for cleaning the soiled material and to assist the microbial removal. Add sour (mild acid) for neutralizing and to avoid textile materials from yellowing. Evaluate the final material for its cleanliness (wash again if it is dirty) Rinse the item with clean water.

#### 9.3.2 Machine Wash

Soiled textile material is separated from non-soiled and washed heavily. When the wash cycle is complete, check the material for cleanliness. Rewash if it is dirty or stained. (Heavily soiled may require two wash cycles). Dirty healthcare textile is to be washed in the first batch, with plain water and detergent. The commercial hospital laundry detergent as agreed between the buyer and seller may be used. After sluicing, the infected textile is treated with hot water and detergent.

# 9.4 Process Parameter

The washing process consists of a combination of mechanical action, water flow, water temperature, time, and chemicals to clean/decontaminate soiled textiles. These individual processes can be adjusted in one washing machines to optimize the productivity of the operation and the performance and durability of the textiles being processed. The parameter for guidance are provided as follows:

- a) The water used for washing should meet the requirement specified in IS 201;
- b) Hot water with temperature > 71 °C is recommended;
- c) Bleaching should be performed at 22 °C to 25 °C for heat sensitive fabrics;
- d) 50 mg/L to 150mg/L of chlorine bleach should be used in rinsing cycles after disinfection; and
- e) Wash cycle -30 min.

### 9.5 Hydro-Extraction and Drying

Washed and clean healthcare textiles should be put in the mechanized hydro-extractor for extraction of water from the processed textiles. If the hospital does not have hydro extracting facility then the healthcare textiles can be air dried in a direct sunlight. During the process of drying of the healthcare textiles it is to be ensured that the material is kept off the ground and away from dust exposure.

# 9.6 Repair

All the healthcare textile material is checked for any damage, wear and tear. In case of any damage like minor hole or tear observed, it should be sent for repair and mending. The reusable healthcare textiles with crack, hole, tears and stains that cannot be removed should be incinerated. If the textile material is severely damaged and cannot be repaired, the same can be discarded or condemned as per the hospital condemnation policy, by the laundry supervisor.

# 9.7 Calendaring and Iron

Hospital should have a provision for a calendaring machine for calendaring the heavy reusable textile materials. If the hospital does not have the facility of calendaring machines, the textile material needs to be ironed using flat work iron and should be folded properly.

### **10 STERILIZATION AND PACKING**

### **10.1 Need of Sterilization**

Critical area of healthcare textiles are needed to be sterilized after every wash. Most of the textiles at healthcare facilities which includes surgical drapes and reusable gowns must be sterilized before use and therefore require steam autoclaving after laundering.

# **10.2 Sterilization Methods**

Healthcare textiles that have contact with sterile body tissues or fluids are considered critical items. These items should be sterile when used because any microbial contamination could result in disease transmission. If healthcare textiles are heat resistant, the recommended sterilization process is steam sterilization, because it has the largest margin of safety due to its reliability, consistency, and lethality. However, processing of healthcare textiles which are heat- and moisture-sensitive requires use of a low- temperature sterilization technology like ethylene oxide. The other type of sterilization process may also be used if agreed between the user and laundry service provider.

# 10.3 Validation of Sterilization

For packaging and sterilization, the *Medical Device Rule*, 2017 shall be followed. Sterilization and validation of sterilization process shall be done as per IS/ISO 11135, IS/ISO 11137-1 and 2, ISO 11138-7, IS/ISO 10993-7 and ISO 17665-1 standards.

#### **10.4 Packing**

The sterile healthcare textiles shall be packed securely so as to allow normal handling and transport without tearing and exposing the contents. The details of the packing shall be legibly made to provide necessary information for usage including sterilization date, identification, lot details, list of pack contents, etc. Packaging of the product shall be such as to maintain the integrity of the product throughout its shelf life. For packaging of the products, requirements as per IS/ISO 11607-1 and 2 should be followed.

# 11 SPECIAL LAUNDRY/OTHER RE-PROCESS CONSIDERATIONS

For processing and disinfection, the manufacturer of the healthcare textiles is required to select and recommend a suitable method/technology for their product. One of the following methods or their combinations as suggested by the manufacturer (complete and detailed protocol for processing, disinfection and quality control has to be prepared by manufacturer) based on the scientific experimentations, specific to their product and agreed by the user may be used:

- a) Washing with detergent;
- b) Sodium hypochlorite and/or soap solution;
- c) Ultraviolet (UV) irradiation;
- d) Gamma and electron beam irradiation;
- e) Ethylene oxide sterilization;
- f) Vapourised hydrogen peroxide or hydrogen peroxide or gas plasma sterilization; and
- g) Steam (autoclaving).

# **12 STORAGE AND DELIVERY**

## **12.1 General Guidelines**

The processed textile is transported in clean covered trolley to the central store. It is to be ensured that the storage of clean healthcare textiles before distribution is separate from dirty material. From the central store the clean textiles is issued to respective departments based on the indent generated from the departments. The clean and hygiene healthcare textile materials is supplied from the central store to respective departments in the clean and closed trolleys. Record of issued healthcare textiles needs to be updated in the central store room while the respective departments need to update the transaction register with the details of textile material received in the department.

**12.2** The following instruction shall be followed for storage area in laundry service at healthcare facility:

- a) The trolleys used for transporting clean textiles should be washed routinely. It should be washed in a washing station after use and clean trolleys should be separated;
- b) Good ventilation systems to prevent the accumulation of soil, dirt and micro dusts;
- c) Sewage apertures or water pipers should not be present near the storage area;
- d) The shelves for storage placed should be 15 cm to 20 cm above the floor, 2.5 cm to 5 cm away from the walls and 25 cm below ceiling;
- e) The storage shelves should be used only for storing clean reusable healthcare textile materials and the door of the storage shelf should be always closed;
- f) The sterile storage area should be a limited access area with a controlled temperature

(may be as high as 75  $^{\circ}$ F) and relative humidity (30 percent to 60 percent) in all works areas except sterile storage, where the relative humidity should not exceed 70 percent; and

g) The floors and walls should be constructed of materials capable of withstanding chemical agents used for cleaning or disinfecting. Ceilings and wall surfaces should be constructed of non-shedding materials.

#### **13 RESPONSIBILITIES OF PERSONNEL IN HOSPITAL LAUNDRY SERVICE**

# 13.1 Nursing In-Charge

- a) Manage the process of collecting and transporting used textiles from the health care facilities;
- b) Ensure that the central laundry documentation reflects infection control requirements;
- c) Observe and monitoring the infection control requirements in the outsourced laundry service with a documented book;
- d) Engaging and assisting in the renovation of the laundry department; and
- e) Infection control basics should be taught annually and prior to starting any new contracts.

#### 13.2 Laundry Supervisor

- a) Ensure these guidelines are implemented, monitored and supervised;
- b) Establish an open communication channel between the laundry department and the users;
- c) Provide training on these guidelines to all employees in the laundry;
- d) Inspect linen for correct and safe handling; and
- e) Maintenance and calibration of laundry equipment.

#### **13.3 Laundry Workers**

- a) Collecting used linen from wards or operation theatre and transporting it to laundry facilities;
- b) The used linen must be sorted, handled by wearing impermeable aprons, gloves and using standard measures; and
- c) The safe transportation of clean textiles to departments using closed carts.

Sl No.	Steps Involved	Personal Responsible
(1)	(2)	(3)
i)	Change of linen	Staff nurse/ward attendant
ii)	Sorting and storing of used linen	Ward attendant/housekeeping staff
iii)	Disinfection of soiled/infected linen	Housekeeping/laundry staff
iv)	Collection of used/soiled linen	Laundry staff
v)	Counting of collected linen	Laundry staff/nursing in-charge
vi)	Transporting dirty linen	Laundry staff
vii)	Washing, drying and ironing	Laundry staff
viii)	Receipt of washed linen in departments	Nursing in-charge
ix)	Storage and issue of washed linen	Nursing in-charge

# Table 1 Responsibilities of Personnel in Hospital Laundry Service

10		1.2.
(C	lause	13)

### **14 QUALITY INSPECTION**

There are inspection methods which can be done on laundered healthcare textiles to indicate the effectiveness of laundry process performance. Such process performance measures include the results of visual inspection pH tests, residual chlorine spot tests, and cleanliness/microbial load on cleaned healthcare textiles. The user may randomly check the performance requirement of a specific healthcare textiles product as per the Indian Standard published by Bureau of Indian Standard.

## **14.1 Visual Inspection**

**14.1.1** Before each reuse, all healthcare textile products should be visually inspected against written quality standards. These standards should be developed by individuals responsible for product inspection, in consultation with end users, and should be based on the functional requirements and the identified important related attributes, which may vary depending on product classification, design, construction, and intended end use. After each laundering, the critical zones of healthcare textiles like gowns, drapes, table covers, and sterilization wraps should be visually inspected with the assistance of a light table to determine if:

- a) Stain or residue removal is necessary;
- b) Physical defects, such as holes and missing components, need to be repaired;
- c) Chemical or thermal damage needs to be repaired;
- d) Foreign debris (for example, lint, hair) needs to be removed;
- e) Appropriate labels are in place; and
- f) The tracking system is intact.

**14.1.2** The written quality standards should define the acceptance and rejection criteria for each product type and explain how rejected items should be handled. Depending on the functional requirements, there may be different limitations for different items or even for different areas within the same item.

14.1.3 The results of quality control inspections can provide valuable feedback regarding the performance of the process. Increased levels of lint, colour loss or transfer, ineffective removal of tape, and the development of holes can provide an indication that the process can be improved upon or is out of alignment. Colour transfer on healthcare textiles occurs when hospital greens, blues, and whites are laundered together (that is, textile classifications have been incorrectly combined in laundering). Colours transfer from coloured to white fabrics, tinting the white fabrics. This tinting is permanent because polyester does not release colour. Although dyed polyester fibres are fast to laundering, the migration of loose dye contained in new fabrics is sufficient to produce this tinting effect.

# 14.2 Acceptable Stains/Damages/Defects

The acceptability of healthcare textile products for use in surgery may be influenced by their appearance and the user's perception of cleanliness. Discolorations that do not interfere with the functional performance of a textile are acceptable, and every effort should be made to allow for their continued use. However, discolorations caused by certain types of residual soils might have to be removed before the item can continue in service, because they could affect the functional performance of the product, potentially introduce particulate matter into the surgical site, and potentially prevent effective sterilization.

# Table 2 An Example of Inspection Criteria for Stains

# (Clause 12.2)

Sl No.	Stain	Accept	Reject
(1)	(2)	(3)	(4)
i)	Dye transfer from product identification labels	×	
ii)	Medicinal stains (for example, iodine, scarlet red, methyl blue) <sup>1</sup>	×	
iii)	Colour lift/change from closure tape (e.g., autoclave tape on wrappers)	×	
iv)	Dark brown or rust-coloured stains resembling blood		×
v)	Light or dull discoloration	×	
vi)	Bright or dark discoloration covering a total area that is smaller than a 6-inch square (36 square inches), with the exception of medicinal stains (for example, iodine, scarlet red, methyl blue) caused by the user/customer <sup>2</sup> )	×	
vii)	Tactile stain (for example, sticky residue, foreign matter)		×
viii)	Residue; raised (for example, tape, casting material) <sup>3</sup>		×
ix)	Elastic band marks (on wrappers)	×	
x)	Colourless oil stain <sup>4</sup>		×
xi)	Dye/colour fade because of repeated laundering	×	
xii)	Yellow tie-dyed effect on wrappers, mayos, table covers	×	
xiii)	Scorched, burned, or melted fabric		×
xiv)	Ink or marker stains <sup>5</sup>	×	
xv)	Heavy ends (thick threads or additional threads in the fill)	×	
xvi)	Slubs (knots or nubs)	×	

NOTES

1 Medicinal stains typically do not affect the performance of healthcare textiles; however, they may present an aesthetic issue for some users. Continued use of products with such stains should be discussed with and agreed to by the end user.

2 Continued use of healthcare textiles with bright or dark discoloration in primary areas should be discussed with and agreed to by the end user.

**3** Items with raised residues may be acceptable for an alternative use, such as a decontamination gown. If acceptable for an alternative use, the items should be appropriately marked to ensure that they are not used inadvertently in clinical applications.

4 An item with a colourless oil stain may continue to be used if it can be demonstrated that the oil does not affect the performance of the item.

5 Legible writing should be rendered illegible to prevent potential misinterpretation in subsequent uses.

# IS 18552 : 2024

# 14.3 Tests to Ensure the Effectiveness and Safety of Clean Laundered Materials

**14.3.1** The functional properties of all the healthcare textiles are expected to meet the quality compliance as per manufacturer's declaration. However, to ensure the effectiveness of the laundering process and to have an evidence that the laundry process has not left the healthcare textiles harm to use after chemical exposures, the following two tests at the healthcare settings are recommended after every batch laundering on sampling basis. To ensure the effectiveness and safety of clean laundered materials, the following test may be carried out:

- a) pH test 6 to 8 when tested as per IS 1390;
- b) Chlorine spot test absent when tested as per <u>14.3.1.2</u>; and
- c) Microbial load/cleanliness  $\leq 300$  CFU/ 100 cm<sup>2</sup> when tested as per ISO 11737 (Part 1).

# 14.3.1.1 pH spot test

The pH of a finished product can indicate whether it has been appropriately rinsed and soured. Depending on the product type and end use of the product, the final pH of the finished product can vary. However, all textiles should be soured to a pH in the range of 6.0 to 8.0 to be compatible with human skin and to maximize their durability. The pH of a finished product can be measured by means of a "universal" or "sour" tester. In these qualitative tests, a pH indicator is dropped on the product and gives a visual indication of the product's pH by the resulting colour change of the indicator. The indicator is usually placed on a white portion of the textile after extraction but before drying.

# 14.3.1.2 Spot chlorine test

The presence or absence of residual chlorine indicates whether chlorine was appropriately used in the laundry process and rinsed from the product. Residual chlorine can reduce the life expectancy of textiles and is also a potential skin irritant. The presence of residual chlorine can be detected by means of orthotolidine, which turns yellow in the presence of chlorine; the darker the yellow, the more chlorine is present.

# **14.3.1.2** Cleanliness/microbial load on the laundered material

Healthcare textile products should be clean and possess an inherent bio burden low enough to allow for safe handling and effective sterilization. Commercially available test methods can be used to assess bio burden levels during process qualification, process validation, or ongoing process monitoring. ISO 11737-1 provides guidance on the selection and use of these methods; this standard should be referenced for all bio burden assessments for industrial or other commercial applications. Typically, these methods involve extraction of the item and then enumeration of aerobic and spore forming organisms, reported as colony-forming units (CFU).

# 15 Maintenance of Records

The following record of files and registers should be maintained for processing of healthcare textiles management in the hospital:

- a) Linen stock register at the central store;
- b) Area wise daily transaction register;
- c) Laundry and linen receiving register and distribution register at the laundry; and
- d) Any other record as per the policy and procedure of hospital or laundry service provider.

# 16 GENERAL GUIDELINES FOR ENVIRONMENT PROTECTION

**16.1** Laundry service in hospitals have critical roles in society and their operations have major social and environmental risk. The factors including high consumption of water, high energy consumption, smoke emission by boilers, generation of bio medical waste and liquid waste, and processing and disposal of water with chemicals used in decontamination and sterilization processes will lead to environmental risks. It is imperative to be that the hospitals or laundry service provider should be concerned about the environmental risks of the laundry process. The laundry facility for healthcare textiles shall follow the applicable requirement of the concerned state/central pollution control board as per the provisions of water (Prevention and Control of Pollution) Act, 1974 and Air (Preventions and Control of Pollution) Act, 1981 under the Environment (Products) Act, 1986 and the rules made thereunder.

# 16.2 Treatment, Disposal and Re-use of Waste Water

The following steps should be taken for treatment and disposal of waste water to minimize or avoid those environmental risks due to processing of healthcare textiles:

a) Chemical disinfection is to be performed by 1 percent to 2 percent hypochlorite solution or equivalent disinfectant like aldehydes, lime, ammonium salts, phenolic compounds etc. Chemical disinfection performed must meet the standard of chemical disinfection as listed in Schedule II of *Bio Medical Waste Management (BMWM) Rules*, 2016 or other rules/regulation issued by the concerned regularity authority;

b) Effluent treatment plant (ETP) shall be necessary if discharge from laundry service in health care facility (HCF) is connected with city's/town's public sewerage network not having any terminal sewage treatment plant or if the HCF is not connected to public sewerage network. Treated wastewater from healthcare facility should conform to the standards of liquid waste as listed in Schedule II of *BMW Rules*, 2016; and

c) Wastewater generated from the laundry service in healthcare facilities is treated in the ETP and shall be disposed into drain/sewer or may be reused in: flushing, horticulture, and scrubber. The effluent from the laundry facility, after treatment in an ETP shall meet the general standards for discharge of environmental pollutant and common effluent treatment plants emission as stipulated in *The Environment* (*Protection*) *Rules*, 1986 (as amended from time to time).

# ANNEX A

# (Clause 2)

# LIST OF REFERRED STANDARDS

IS No.	Title	IS No.	Title
IS 201 : 2022	Quality tolerances for water for textile industry ( <i>third revision</i> )	IS/ISO 11607- 1 : 2019	Packaging for terminally sterilized medical devices: Part 1 Requirements for
IS 1390 : 2022/ ISO 3071 : 2020	Textiles — Determination of $pH$ of aqueous extract ( <i>third</i> revision)		materials, sterile barrier systems and packaging systems
IS/ISO 10993- 7 : 2008	Biological evaluation of medical devices: Part 7 Ethylene oxide sterilization residuals	IS/ISO 11607- 2 : 2006	Packaging for terminally sterilized medical devices: Part 2 Validation requirements for forming, sealing and assembly processes ( <i>first revision</i> )
IS/ISO 11135 : 2014	Sterilization of health-care products — Ethylene oxide — Requirements for the development, validation and routine control of a sterilization process for medical devices	ISO 11138-7 : 2019	Sterilization of health care products — Biological indicators — Part 7: Guidance for the selection, use and interpretation of results
IS/ISO 11137- 1 : 2006	Sterilization of health care products — Radiation: Part 1 Requirements for development, validation and routine control of a sterilization	ISO 11737-1 : 2018	Sterilization of health care products — Microbiological methods — Part 1: Determination of a population of microorganisms on products
IS/ISO 11137- 2 : 2013	process for medical devices Sterilization of health care products — Radiation: Part 2 Establishing the sterilization dose	ISO 17665-1 : 2006	Sterilization of health care products — Moist heat — Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices

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#### ANNEX B

# (Foreword)

# **COMMITTEE COMPOSITION**

Technical Textiles for Medtech Applications, TXD 36

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The South India Textile Research Association, Coimbatore

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Alpha Foam Limited, Pune

- All Indian Institute of Medical Sciences, New Delhi
- Association of Indian Medical Devices (AiMeD), New Delhi

Business Coordination House, New Delhi

Cologenesis Healthcare Pvt Ltd, Salem

Defence Research & Development Establishment (DRDE), Gwalior

DGAFMS, Ministry of Defence, New Delhi

DGQA (Ministry of Defence), New Delhi

Dima Products, Mumbai

Director General of Health Services, New Delhi

Dispoline India Private Limited, Bengaluru

DMSRDE, Kanpur

Federation of Indian Chambers of Commerce & Industry, New Delhi

Ginni Filaments Limited, Noida

Govt Medical College & ESI Hospital, Coimbatore

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KOB Medical Textiles Pvt Ltd, Palladam

Kovai Medical Centre and Hospital (KMCH), Coimbatore

Livinguard Technologies Pvt Ltd, Mumbai

Maulana Azad Medical College, New Delhi

Medline Healthcare Industries Pvt Ltd, Pune

National Physical Laboratory, New Delhi

Nobel Hygiene, Mumbai

Office of the Drug Controller (CDSCO), Delhi

Office of the Textile Commissioner, Mumbai

PGIMER, Chandigarh

Procter and Gamble Co, Mumbai

Sabharwals Manufacturing Labs Pvt Ltd, Manchkula

Suryatextech, Chandigarh

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The Bombay Textile Research Association, Mumbai

The Pad Project (NGO) India, New Delhi

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# **Amendments Issued Since Publication**

Amend No.	Date of Issue	Text Affected

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