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DRAFT TANZANIA STANDARD

Textiles - Guidelines for Processing of Multiple-Use Healthcare Textiles

Draft for Stakeholders comments Only!

TANZANIA BUREAU OF STANDARDS

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0 Foreword

This Draft Tanzania Standard was developed by the Hospital Textiles Technical Committee under supervision of the Textile and Leather Divisional Standards Committee and it is in accordance with the procedures of the Bureau.

This Draft Tanzania Standard is a First edition.

In the preparation of this Draft Tanzania Standard, assistance was derived from:

IS 18552, Guidelines for Processing of Multiple-Use Healthcare Textiles

For the purpose of deciding whether a particular requirement of this Draft Tanzania Standard is complied with, the final value observed or calculated expressing the result (s) of a test or analysis shall be rounded off in accordance with TZS 4 (see clause 2).

1 Scope

1.1 This Draft Tanzania 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 facility laundry in the following areas:

- a) Hospitals—private, public and any extended
- b) healthcare facilities;
- c) Nursing homes;
- d) Rehabilitation Centre;
- e) Registered Health care laundry services provider

1.2 This Draft Tanzania 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 facility;
- b) Patient linen — Patient clothing such as pyjamas, shirts, gowns, coats etc. worn by patients;
- c) Bed linen — Bed clothing such as bedsheets, pillow covers, blankets used by the patient; and
- d) Operation theatre (OT), labour room, procedure room linen — Items such as pyjamas, 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.

2 Normative references

For the purpose of this Draft Tanzania Standard, the following references shall apply. The latest edition of the referenced document (including any amendments) applies.

ISO 11135, Sterilization of health-care products — Ethylene oxide — Requirements for the development, validation and routine control of a sterilization process for medical devices

ISO 11137 – 1, Sterilization of health care products — Radiation Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices

ISO 11137 – 2, Sterilization of health care products — Radiation Part 2: Establishing the sterilization dose

ISO 11138 -7, Sterilization of health care products — Biological indicators Part 7: Guidance for the selection, use and interpretation of results

ISO 10993 – 7, Biological evaluation of medical devices Part 7: Ethylene oxide sterilization residuals

ISO 17665, Sterilization of health care products — Moist heat — Requirements for the development, validation and routine control of a sterilization process for medical devices

ISO 11607 – 1, Packaging for terminally sterilized medical devices Part 1: Requirements for materials, sterile barrier systems and packaging systems

ISO 11737 – 1, Sterilization of health care products — Microbiological methods Part 1: Determination of a population of microorganisms on products

ISO 11737 – 2, Sterilization of health care products — Microbiological methods — Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process

3 Terms and Definitions

For the purposes of this Draft Tanzania Standard, the following terms and definitions shall apply:

3.1 Barrier Properties

ability of a protective material to resist the penetration of liquids, blood, liquid borne, air borne, blood borne and resistance to airborne and liquid borne microorganisms, blood, and Other Potentially Infectious Micro-organism (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 (such as 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 micro-organisms such as bacteria or/ and virus carried in blood or other body fluids.

3.5 Body Fluids

any liquid produced by or from the body.

3.6 Calendaring

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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 is spin-out of fabric which facilitates faster drying.

3.8 Cleaning

the process of physical removal of contaminants such as dusts, soil particle, blood stains, secretions, excretions and micro-organisms by water and detergent as preparation of healthcare textiles for disinfection or sterilization.

3.9 Cleanliness–Microbial

state of a product or a package being free from micro-organisms

3.10 Cleanliness–Particulate Matter

Free 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 Contamination

the soiling of inanimate objects or living material with harmful, potentially infectious or unwanted matter.

3.13 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.

3.14 Detergent

a cleaning agent that increases the ability of water to penetrate organic material and break down oil and dirt. Detergents are needed to allow effective cleaning to take place.

3.15 Disinfection

is a physical or/and chemical process that reduces number of microorganisms present on an object to a level at which they don't present a risk.

3.17 Doffing

removal or take off of protective materials such as gloves, aprons, and so on.

3.18 Effluent

Waste water generated from the laundry service in healthcare facilities

3.19 EPA

environmental protection agency.

3.20 Extraction

removal of excess water from a wash load prior to drying.

3.21 Germicide

a substance or other agent which destroys harmful microorganisms.

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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 include District Hospitals, Sub Divisional Hospitals, Community Health Centres, Primary Health Centres and Sub centres.

3.23 Rehabilitation Centre

is considered as post-acute care provider. They typically treat patients who require additional care i.e., physiotherapy, mental health or any other rehabilitative treatments.

3.24 Nursing Home

Is an institute providing residential accommodation with healthcare facility especially for elderly people.

3.25 Healthcare Personnel (HCP)

refers to all persons serving in healthcare settings, who have the potential for direct or indirect exposure to patients or infectious materials

3.26 Healthcare Textiles

healthcare textiles materials are mainly used for protection/prevention against contamination 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, screens, curtains, doctors' coats, theatre cloth, table cloths and drapes etc.

3.27 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 and 48 hours upon discharge, these infections were neither present nor in incubation period at the time of admission.

3.28 Hospital Linen

refers to all healthcare textiles as defined in clause 3.26

3.28 Contaminated Textiles

textiles which contain 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 into a new product having a distinct name, character and use.

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3.34 Microbial Penetration

migration of microorganisms, from one side of the material through the other.

3.35 Microorganism

microscopic entities such as bacteria, fungi, protozoa, and viruses which can be pathogenic or non-pathogenic.

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

refer to potential of hydrogen, which measures 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 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.

3.42 Reusable/Multiple Use Product

product intended by the manufacturer to be reprocessed and reused.

3.43 Rinsing

an operation designed to remove all suspended soils, soaps, detergents and bleach from the textiles being laundered.

3.44 Scrub suits

loose-fitting, usually two-piece garment, worn by surgeons and assisting personnel in an operating room.

3.45 Single-use/Disposable Product

Product intended by the manufacturer to be used only once.

3.46 Sluicing

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

3.47 Soiled Textiles

textiles that have had potential contact with blood, body fluids, or OPIM.

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3.48 Soil-Sort Area

area of a laundry facility designated for receiving, retention, handling, and sorting of soiled textiles.

3.49 Soil Sorting

process of sorting soiled items into defined or established categories so that they can be laundered together.

3.50 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.

3.51 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.

3.52 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.

3.53 Surgical Drape

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".

3.54 Validation

documented procedure for obtaining, recording, and interpreting the results required to establish that a process will consistently disinfect and sterilize healthcare textiles.

3.55 Disposal system

System for disposing of sewage, industrial or other wastes and includes sewage systems and treatment works.

4 Requirements

4.1 General Requirements

4.1.1 Laundry General Requirements

4.1.1.1 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, storing and transporting dirty linen from hospital and washing, disinfection, extracting, drying, ironing, folding, and transporting clean linen from laundry service; back to the hospital and storage of clean linen in the

4.1.1.2 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.

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4.1.1.3 The supervisors/managers and laundry staff shall be fully trained about the laundry procedure, handling 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.

4.1.2 Laundry Lay – out and Design

4.1.2.1 The laundry facility in a healthcare 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 for facilities and equipment. Maintaining hygiene and clean environment at laundry facility is essential for ensuring products that are appropriate for consumers' use. Following is 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 Area 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;
- d) 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, epoxy, tiled or with chips to ensure ease of cleaning. Floors, walls, ceilings, doors and windows shall be easy to clean and without crevices, sharp converse 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 and 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;

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- q) To minimize the potential for re-contaminating 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 positioned 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;
- u) 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; the effluent water shall be treated as per Environmental Regulations and Guidelines.
- 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.

4.1.2.2 The laundry service layout and process flow are given in Fig. 1 for guidance only.

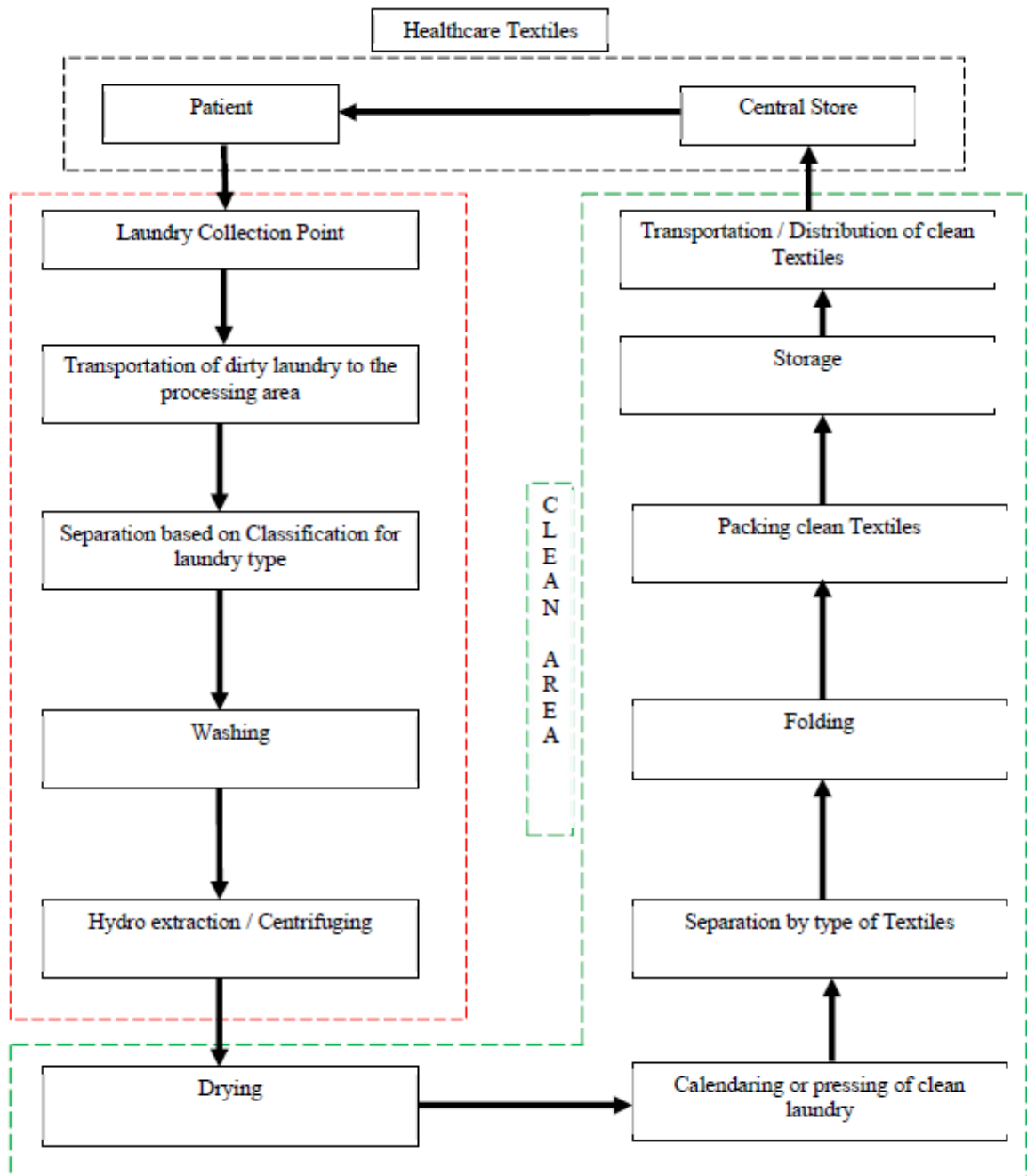


Figure 1 - Laundry Service Layout

5 Collections and Segregation of Soiled Material

5.1 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.

5.2 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.

5.3 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.

5.4 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.

5.5 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.

5.6 The following instructions and information should also be monitored at collection and segregation area in laundry service in healthcare facility:

- a) Facility should organize a daily schedule for the collection of healthcare textiles;
- b) Extra care should be taken before collection to ensure that there are no non textile 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 facility 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 to distinguish 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/contaminated healthcare textiles should be maintained for different areas for the same.

6 Transport of Contaminated Health Care Materials to the receiving area of Laundry

6.1 Soiled healthcare textiles collected from various areas of the facility 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.

6.2 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 receive 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.

6.3 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 the collection bags are leak proof and tied firmly;
- e) In case of any leakage of contaminated textile material 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 facility;
- 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 facility must keep records for laundry management of healthcare textiles to ensure quality.

7 Pre – Treatment/Disinfection before Washing

7.1 Heavily soiled textiles may sometimes 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.

7.2 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.

7.3 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 facility policy where a suitable high-level disinfectant should be used.

7.4 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 facility 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.

8 Washing

8.1 The laundry service in healthcare facility should follow the instructions 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/laundrying process depends on many factors like time and temperature, mechanical action, water quality (pH, 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 EPA or concerned regulatory authorities may also be used as an alternative for chlorine bleach.

8.2 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.

8.3 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.

8.3.1 Hand Wash

8.3.1.1 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.

8.3.1.2 The material is pre-soaked only for the soiled or contaminated textiles.

8.3.1.3 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.

8.3.1.4 Add sour (mild acid) for neutralizing 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.

8.3.2 Machine Wash

8.3.2.1 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).

8.3.2.2 Dirty healthcare textile is to be washed in the first batch, with plain water and detergent. The commercial facility laundry detergent as agreed between the buyer and seller may be used. After sluicing, the contaminated textile is treated with hot water and detergent.

8.4 Process Parameter

8.4.1 The washing process consists of a combination of mechanical action, water flow, water temperature, time, and chemicals to clean/decontaminate soiled textiles.

8.4.2 These individual processes can be adjusted in one washing machine to optimize the productivity of the operation and the performance and durability of the textiles being processed.

8.4.3 The parameters for guidance are provided as follows:

- a) The water used for washing should meet the requirement specified in TZS;

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- 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.

8.5 Hydro-Extraction and Drying

8.5.1 Washed and clean healthcare textiles should be put in the mechanized hydro-extractor for extraction of water from the processed textiles.

8.5.2 If the facility does not have hydro extracting device, then the healthcare textiles can be air dried in a direct sunlight.

8.5.3 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.

8.6 Repair

8.6.1 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.

8.6.2 The reusable healthcare textiles with crack, hole, tears and stains that cannot be removed should be incinerated.

8.6.3 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.

8.7 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.

9 Sterilization and Packing

9.1 Need of Sterilization

Critical healthcare textiles need 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.

9.2 Sterilization Methods

9.2.1 Healthcare textiles that have contact with sterile body tissues or fluids are considered critical items.

9.2.2 These items should be sterile when used because any microbial contamination could result in disease transmission.

9.2.3 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.

9.2.4 However, processing of healthcare textiles which are heat- and moisture-sensitive requires use of a low- temperature sterilization technology like ethylene oxide.

9.2.5 Other type of sterilization processes may be used if agreed between the user and laundry service provider.

9.3 Validation of Sterilization

For packaging and sterilization, shall be followed. Sterilization and validation of sterilization process shall be done as per ISO 11135, ISO 11137-1 and 2, ISO 11138-7, ISO 10993-7 and ISO 17665-1 standards.

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9.4 Packing

9.4.1 The sterile healthcare textiles shall be packed securely so as to allow normal handling and transport without tearing and exposing the contents.

9.4.2 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.

9.4.3 Packaging of the product shall be such as to maintain the integrity of the product throughout its shelf life.

9.4.4 For packaging of the products, requirements as per ISO 11607-1 and 2 should be followed.

10 Special Laundry/Other re – process consideration

10.1 For processing and disinfection, the manufacturer of the healthcare textiles is required to select and recommend a suitable method/technology for their product.

10.2 One of the following methods or their combinations as suggested by the manufacturer (complete and detailed protocol for processing, disinfection and quality control have 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) Vaporized hydrogen peroxide or gas plasma sterilization; and
- g) Steam (autoclaving).

11 Storage and Delivery

11.1 General Guidelines

11.1.1 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.

11.1.2 From the central store the clean textiles is issued to respective departments based on the indent generated from the departments.

11.1.3 The clean and hygiene healthcare textile materials is supplied from the central store to respective departments in the clean and closed trolleys.

11.1.4 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.

11.2 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 and labelled;
- 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 and labelled;
- f) The sterile storage area should be a limited access area with a controlled temperature (may be as high as 75°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

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- 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.

12 Responsibilities of Personnel in Facility Laundry Service

12.1 Personnel 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.
- f)

12.2 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.
- f)

12.3 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 and sterilized textiles to departments using closed carts.

Table 1 Responsibilities of Personnel in Facility Laundry Service (Clause 11.2)

SI No.	Steps Involved	Responsible person
i.	Change of linen	Staff nurse/ward attendant/personnel of the facility
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/personnel in-charge
vi.	Transporting dirty linen	Laundry staff
vii.	Washing, drying and ironing	Laundry staff
viii.	Sterilization of cleaned linen	Laundry staff
ix.	Receipt of washed linen in departments	Personnel in-charge
x.	Storage and issue of washed linen	Personnel in-charge

13 Quality Inspections

13.1 Process quality control

13.1.1 There are inspection methods which can be done on laundered healthcare textiles to indicate the effectiveness of laundry process performance.

13.1.2 Such process performance measures include the results of visual inspection pH tests, residual chlorine spot tests, and cleanliness/microbial load on cleaned healthcare textiles.

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13.1.3 The may randomly check the performance requirement of a specific healthcare textiles product

13.1.4 In case of sterilized healthcare textiles, the sterility tests shall be conducted in accordance with ISO 11737-2 and the applicable SOP.

13.2 Visual Inspection

13.2.1 Before each reuse, all healthcare textile products should be visually inspected against the applicable SOP

13.2.2 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.

13.2.3 After each laundering, the critical zones of healthcare textiles like surgical gowns, surgical 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.

13.1.2 The SOP 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.

13.1.3 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.

13.1.3.1 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).

13.1.3.2 Colour transfer from coloured to white fabrics, tinting the white fabrics; this tinting is permanent because polyester does not release colour.

13.1.3.3 Although dyed polyester fibers are fast to laundering, the migration of loose dye contained in new fabrics is sufficient to produce this tinting effect.

13.2 Acceptable Stains/Damages/Defects

13.2.1 The acceptability of healthcare textile products for use in surgery may be influenced by their appearance and the user's perception of cleanliness.

13.2.2 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.

13.2.3 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)

SI No.	Stain	Accept	Reject
i.	Dye transfer from product identification labels	×	

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ii.	Medicinal stains (for example, iodine, scarlet red, methyl blue) ¹	×	
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 ²	×	
vii.	Tactile stain (for example, sticky residue, foreign matter)		×
viii.	Residue; raised (for example, tape, casting material) ³		×
ix.	Elastic band marks (on wrappers)	×	
x.	Colourless oil stain ⁴		×
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 ⁵	×	
xv.	Heavy ends (thick threads or additional threads in the fill)	×	
xvi.	Slubs (knots or nubs)	×	

Note 1;

- a) 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.
- b) Continued use of healthcare textiles with bright or dark discoloration in primary areas should be discussed with and agreed to by the end user
- c) 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.
- d) 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.
- e) Legible writing should be rendered illegible to prevent potential misinterpretation in subsequent uses.

13.3 Tests to Ensure the Effectiveness and Safety of Clean Laundered Materials

13.3.1 The functional properties of all the healthcare textiles are expected to meet the quality compliance as per manufacturer's declaration.

13.3.2 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.

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13.3.3 To ensure the effectiveness and safety of clean laundered materials, the following tests may be carried out:

- a) pH test ;6 to 8 when tested as per TZS 26
- b) Chlorine spot test - absent when tested as per **13.3.3.2**; and
- c) Microbial load/cleanliness ≤ 300 CFU/ 100 cm² when tested as per ISO 11737 (Part 1).

13.3.3.1 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.

13.3.2.2 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 Ortho tolidine, which turns yellow in the presence of chlorine; the darker the yellow, the more chlorine is present.

13.3.2.3 Cleanliness/microbial load on the laundered material

- a) Healthcare textile products should be clean and possess an inherent bio burden low enough to allow for safe handling and effective sterilization.
- b) Commercially available test methods can be used to assess bio burden levels during process qualification, process validation, or ongoing process monitoring.
- c) 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.
- d) Typically, these methods involve extraction of the item and then enumeration of aerobic and spore forming organisms, reported as colony-forming units (CFU).

14 Maintenance of Records

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

- 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 facility or laundry service provider.

15 General guidelines for environmental protection

15.1 The following are the guidelines for environmental protection

- a) Laundry service in facilities have critical roles in society and their operations have major social and environmental risk.
- b) The factors including high consumption of water, high energy consumption, smoke emission by boilers, generation of biomedical waste and liquid waste, and processing and disposal of water with chemicals used in decontamination and sterilization processes will lead to environmental risks.
- c) It is imperative that the facility or laundry service provider should be concerned about the environmental risks of the laundry process.
- d) The laundry facility for healthcare textiles shall follow the applicable requirement of the concerned state/central pollution control board as per the Environmental Guidelines and Regulations of United Republic of Tanzania.

15.2 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 rules/regulation issued by the concerned regulatory authority;
- b) Effluent treatment plant (ETP) shall be necessary if discharge from laundry service in health care facility (HCF) is connected with city's/tow'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 Environmental Guidelines and Regulations of United Republic of Tanzania 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).