Andhra Pradesh MedTech Zone Ltd (AMTZ)

TECHNICAL DOCUMENT

Healthcare Textiles Processing Facility Certification (HEALTEXPROF) Scheme

INDEX

FOREWORD:

Concern is rising about the risk of spreading infections from Healthcare Worker's Garments (Scrubs, Jackets, Lab Coats etc.) to patient, staff and the public, if not washed under a monitored environment. Garments 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.

Linen and laundry is a recognized support service which not only ensures prevention and containment of hospital infection but also contributes to widen the image of the hospital in the eyes of the public. The dictionary meaning of linen is a flax or an article of cotton. However, in hospitals the term is used for clothing of the patient, medical and Para-medical staff and also the clothing material used for the patients care services in operation theaters, bedsheets, trolley covers including the mattresses, pillows, blankets, sheets and towels etc.

Hospital-owned laundry and outsourced services of healthcare facilities provide clean and disinfected healthcare textiles, non-sterile multiple-use healthcare textile packs, and/or sterile multiple-use healthcare textile packs to health care facilities. It is pertinent to mention that the ability of such service providers to furnish multiple-use products that meet the performance requirements of end users while providing quality patient care has been enhanced by technological advances in multiple-use textiles.

Note: ***Healthcare textiles labeled for single-use only shall not be reprocessed or reused, because it may not be possible to adequately reprocess them and maintain their performance and safety attributes. In addition, the health care facility's liability may be affected if the manufacturer's written instructions for use are not followed.***

For purposes of this Scheme, "healthcare facility" means hospitals, nursing homes, extended care facilities, standalone surgical centres, clinics, medical, surgical, and dental facilities. For convenience, the term "hospital" is sometimes used in this Scheme; in all instances, the term should be taken to encompass all other healthcare facilities.

As used within the context of this document:

A. “shall” indicates requirements strictly to be followed in order to conform to the Scheme;
B. “should” indicates that among several possibilities one is recommended as particularly suitable, without mentioning or excluding others, or that a certain course of action is preferred but not necessarily required, or that (in the negative form) a certain possibility or course of action should be avoided but is not prohibited;
C. “may” is used to indicate that a course of action is permissible within the limits of the Scheme;
D. “can” is used as a statement of possibility and capability.
E. “Must” is used only to describe “unavoidable” situations, including those mandated by government regulation.

1. OBJECTIVE:

The aim of the Scheme is to provide optimum performance levels in the processing of multiple-use healthcare textiles. The concepts incorporated in the Scheme shall be flexible and dynamic. This Scheme is intended to provide mandatory requirements for the processing facilities, that will help material managers, laundry managers, central service managers, and other health care professionals implement effective quality assurance systems for the processing of multiple-use healthcare textiles.

2. SCOPE:

This Scheme provides mandatory requirements for the proper handling, processing, and preparation of multiple-use healthcare textiles either on-site or off-site for use in health care facilities. This Scheme describes a quality assurance program for the processing of multiple-use healthcare textiles, which includes processes and techniques for the preparation of clean bulk items for delivery to user sites and/or the assembly of textile packs for sterilization prior to end use. The Scheme applies to multiple-use healthcare textile processing services of health care facilities, contracted processors, repacking operations, and/ or sterile pack lease/rental operations servicing health care facilities.

2.1. This Scheme addresses the following:

- Design criteria for functional work areas involved with the receiving, staging, and handling of soiled healthcare textiles, the separation of soiled and clean textiles
- The laundering of multiple-use healthcare textiles
- The inspection and preparation of clean bulk items and healthcare textile packs
- Staff qualifications, education, training, dress codes, and other personnel considerations
- Transporting, receiving, and handling of newly purchased and used healthcare textiles
- Laundry processing (loading, washing, drying)
- Inspection, testing, and maintenance of laundered healthcare textiles
- Preparation and packaging of laundered healthcare textiles
- Handling, transport, and storage of laundered healthcare textiles
- Installation, operation, care, and maintenance of laundry equipment

- Quality control measures, procedures, and practices
- Regulatory considerations
- The application of any sterilization technology or sterility assurance practices
- Performance standards for multiple-use healthcare textiles

2.2. This Scheme does not address the following:

- Design or construction criteria for equipment used to process multiple-use healthcare textiles;
- Selection of multiple-use healthcare textiles as per risk associated;
- Healthcare textiles labeled for single-use.

For the purpose of the Scheme, applied definitions are annexed as **ANNEXURE-A- DEFINITIONS** (AMTZ/HEALTEXPROF/ATD/R00)

3. WORK AREA(S):

This section provides the definition of various work area(s) of processing healthcare textiles.

3.1. Laundry Area: In order of the general workflow, as soiled textiles are received and proceed through the laundry facility to the clean textile storage area, the following are the definitions of Laundry Area:

- **Receiving Area:** The receiving area in a laundry facility is where the incoming soiled laundry items are received.

- **Soil-Sort Area:** The soil sort area in a laundry facility is where the incoming soiled or dirty laundry items are sorted and processed before being washed. This area is usually located near the laundry's entrance, and it is designed to prevent cross-contamination between the dirty and clean laundry. The soil sort area typically includes the following functions:

  - **Sorting:** Soiled laundry items are sorted based on their type, color, and degree of soiling. This helps to ensure that items are washed together with similar items and that heavily soiled items are properly treated.

  - **Pre-treatment:** Certain heavily soiled laundry items may require pre-treatment, such as the application of stain remover or soaking in a cleaning

solution. This step is usually performed in the soil sort area before the items are sent to the washing area.

- **Weighing:** The soiled laundry items are weighed to determine the appropriate amount of detergent and water needed for washing.

- **Recording:** The items are recorded and tracked using a laundry management system to ensure that they are processed correctly and returned to the proper owner.

- **Washing Area:** The washing area is a designated space for doing laundry. The washing area typically includes equipment as washers, extractors, washer–extractors, continuous-batch washers. It is also known as the wash floor.

- **Extraction Area:** An extraction area in laundry refers to the process of removing excess water from clothes after they have been washed. This is typically done using a machine called a spin dryer or a tumble dryer. After washing, clothes are placed in the spin dryer, which uses centrifugal force to remove water by spinning the clothes at high speed. This process can remove up to 80% of the water in the clothes, making it easier and faster to dry them.

  - In a tumble dryer, clothes are placed in a rotating drum with hot air blown through it. The hot air evaporates the water, which is then removed through a vent. Tumble dryers can be used for clothes that cannot be dried outside or when there is limited space for drying.

  - It's important to follow manufacturer's instructions when using a spin dryer or tumble dryer. Overloading the machine or using incorrect settings can damage clothes and the machine itself. It's also important to regularly clean the lint filter in a tumble dryer to prevent the buildup of lint, which can be a fire hazard.

  - Having an extraction area as part of a laundry setup can help make the process of doing laundry more efficient and convenient. It can also help extend the life of clothes by reducing the time they are exposed to water and by preventing damage caused by excessive wringing or hanging.

- **Conditioning Area:** A conditioning area in laundry refers to the process of softening and refreshing clothes after they have been washed and extracted. This is typically done using a fabric conditioner or a dryer sheet.

    - Fabric conditioners are added to the washing machine during the rinse cycle. They help to soften fabrics, reduce static cling, and give clothes a fresh scent. Dryer sheets are added to the tumble dryer, where they release a similar conditioning effect.

    - Using a fabric conditioner or dryer sheet can help reduce wrinkles, make clothes feel softer, and prevent static cling. They can also help extend the life of clothes by reducing wear and tear caused by friction during washing and drying.

    - When using a fabric conditioner, it's important to follow the manufacturer's instructions regarding the amount to use and when to add it to the machine. Adding too much conditioner can leave a residue on clothes and reduce their absorbency. It's also important to use the correct type of conditioner for the fabric being washed, as some fabrics may be sensitive to certain ingredients.

    Overall, having a conditioning area as part of a laundry setup can help ensure that clothes come out feeling soft, fresh, and wrinkle-free. It can also help extend the life of clothes by reducing the damage caused by washing and drying.

- **Drying Area:** A drying area in laundry refers to the space or equipment used to dry clothes after they have been washed and extracted. There are several options for drying clothes, including air-drying, tumble-drying, and using a clothesline or drying rack.

    - Air-drying involves hanging clothes on a drying rack or clothesline and letting them dry naturally. This is a cost-effective and environmentally-friendly option, as it does not require any energy usage. However, air-drying can take longer and may not be practical in humid or rainy weather.

    - Tumble-drying involves using a machine that blows hot air through a rotating drum, which evaporates moisture from the clothes. Tumble-drying is faster than air-drying but uses energy and can be more expensive. It's important to follow manufacturer's instructions when using a tumble dryer,

as overloading the machine or using incorrect settings can damage clothes and the machine itself.

- Using a clothesline or drying rack is another option for air-drying clothes. Clothes can be hung on the line or rack and left to dry naturally. This option is also cost-effective and environmentally-friendly but may not be practical for those with limited outdoor space.

- When using any drying method, it's important to ensure that clothes are completely dry before storing them, as damp clothes can develop mold and mildew. It's also important to avoid over-drying clothes, as this can damage fabrics and reduce their lifespan.

Overall, having a drying area as part of a laundry setup can help make the process of doing laundry more efficient and convenient. Choosing the right drying method for your needs and following best practices can help ensure that clothes are dried effectively and with minimal damage.

- **Ironing Area:** An ironing area in laundry refers to the space or equipment used to remove wrinkles and create a smooth finish on clothes after they have been dried. This is typically done using a clothes iron, ironing board, and other accessories.

  - When ironing, it's important to select the correct temperature setting on the iron based on the type of fabric being ironed. Ironing at too high a temperature can damage delicate fabrics, while ironing at too low a temperature may not remove wrinkles effectively. It's also important to iron clothes in the correct order, starting with the items that require the lowest temperature and working up to those that require higher temperatures.

  - An ironing board provides a flat, stable surface for ironing clothes. It's important to ensure that the ironing board cover is clean and free of any stains or debris that can transfer to clothes during ironing. It's also important to use a steam iron for best results, as the steam can help remove wrinkles more effectively.

  - In addition to an iron and ironing board, other accessories can be useful for ironing, such as a pressing cloth to protect delicate fabrics, a spray

bottle for adding moisture to clothes, and an iron cleaner to remove any buildup on the iron's soleplate.

Overall, having an ironing area as part of a laundry setup can help ensure that clothes come out looking neat and professional. Following best practices for ironing, including using the correct temperature setting and using accessories as needed, can help ensure that clothes are ironed effectively and with minimal damage.

- **Folding Area:** A folding area in laundry refers to the space or equipment used to fold and organize clothes after they have been ironed or air-dried. This can include a folding table, a countertop, or even a bed.

    - When folding clothes, it's important to ensure that they are neatly folded and organized in a way that makes them easy to store and access. Different types of clothing may require different folding techniques, such as rolling or folding in thirds.

    Overall, having a folding area as part of a laundry setup can help make the process of doing laundry more efficient and ensure that clothes are neatly folded and organized for storage. Following best practices for folding and organizing clothes can help ensure that they stay in good condition.

- **Clean Textile Storage:** Clean textile storage in laundry refers to the space or equipment used to store clean, freshly laundered textiles prior to delivery. This can include closets, dressers, and storage bins.

    - When storing clean textiles, it's important to ensure that they are completely dry and free of any stains or odors. This can help prevent mold and mildew growth and keep textiles smelling fresh. When storing textiles in drawers or on shelves, it can be helpful to fold them neatly and place them in a way that prevents wrinkles and damage. If hanging textiles, it's important to use sturdy hangers that won't stretch or damage the fabric. Hanging clothes on hangers with clips can also help prevent wrinkles and keep clothes organized.

    Overall, having a clean textile storage area as part of a laundry setup can help ensure that freshly laundered textiles are kept in good condition and are easy to access when needed. Following best practices for textile storage, such as

selecting appropriate storage methods and folding or hanging clothes carefully, can help prolong the life of textiles.

- **Inventory Storage Area:** Textile inventory storage in laundry refers to the space or equipment used to store and organize newly purchased textiles that are not currently in use. This can include closets, shelves, and storage bins.

    - When storing textile inventory, it's important to keep track of the quantity and type of textiles to prevent overstocking or running out of necessary items. A good inventory management system can help keep track of what items are in stock, when they were last used, and when they need to be replaced. It's also important to consider the storage conditions for different types of textiles. For example, textiles that are susceptible to damage from moisture or pests may need to be stored in sealed bags or containers. When storing textiles on shelves or in closets, it can be helpful to organize them by type or size, making them easier to find when needed. Labeling shelves or storage bins can also help ensure that items are easy to locate and keep track of.

  Overall, having a textile inventory storage area as part of a laundry setup can help ensure that there are always enough clean textiles available for use, while preventing overstocking or wasting resources. Following best practices for textile inventory storage, such as keeping track of inventory levels and storing textiles appropriately, can help prolong the life of textiles and ensure that they are always in good condition when needed.

3.2. Medical/ Surgical Pack Area: After receiving cleaned healthcare textiles storage, inspection, mending, folding, packing/ assembling of pack and disinfection/ sterilization process is done at Medical/ Surgical Pack Area.

- **Mending Area:** A mending area in laundry refers to the space or equipment used to repair or mend healthcare textiles that have been damaged or torn. This can include a sewing machine, a needle and thread, and other sewing supplies. When mending such healthcare textiles, it's important to select appropriate materials and techniques to ensure that the repair is durable and does not cause further damage to the textile. Different fabrics may require different types of thread or needles, and some types of damage may require more extensive repairs than others.

  Overall, having a mending area as part of a laundry setup can help prolong the

life of clothes and other textiles, reduce waste, and save money. Following best practices for mending, such as selecting appropriate materials and techniques and seeking out resources for learning and troubleshooting, can help ensure that repairs are effective and long-lasting.

Note: If mending/ patching/ alteration is performed in the laundry area, the textiles shall be rewashed before being moved to the medical pack area.

- **Barrier Testing Area:** A barrier testing area in healthcare textiles refers to a space or equipment used to test the effectiveness of fabrics used in healthcare settings to prevent the spread of infection or other contaminants. Testing the barrier properties of healthcare textiles help ensure that they are able to provide the necessary protection for patients and healthcare workers. Tests may include evaluating the fabric's ability to repel liquids, prevent the penetration of microorganisms, or resist tears and abrasions.

  Testing may be conducted in a specialized laboratory or using portable testing equipment. In addition to testing the barrier properties of textiles, it may also be necessary to test for other properties such as durability and comfort or conducting tests as per relevant available Standards for various Protection Levels.

  Overall, barrier testing is an important part of ensuring the safety and efficacy of healthcare textiles. Having a dedicated testing area and following best practices for testing and evaluation can help ensure that fabrics are able to provide the necessary protection for patients and healthcare workers.

- **Sterilization/ Disinfection Area:** A sterilization or disinfection area in healthcare textiles refers to the space or equipment used to clean and sanitize fabrics used in healthcare settings. Sterilization refers to the process of completely eliminating all microorganisms, including bacteria, viruses, and fungi, from a surface or object. Disinfection refers to the process of reducing the number of microorganisms on a surface or object to a level that is considered safe for human contact.

  The specific methods used for sterilization or disinfection of healthcare textiles may vary depending on the type of fabric and the intended use. Common methods include steam sterilization, chemical disinfection, Ethylene Oxide Sterilization, Plasma Sterilization and ultraviolet (UV) radiation.

Overall, sterilization or disinfection of healthcare textiles is an important part of ensuring the safety and efficacy of these materials. Having a dedicated area for cleaning and sanitizing fabrics, and following best practices for sterilization or disinfection, can help ensure that fabrics are properly cleaned and safe for use in healthcare settings.

- **Quarantine Area:** The area where healthcare textiles, which are sterilized have to be kept before being released for delivery & usage is known as Sterilization Quarantine Area.

- **Sterile Storage Area:** A sterile storage area is a designated location in which sterilized/ disinfected healthcare textiles are stored until they are dispatched. This area is designed to maintain the sterility of the items and prevent contamination from pathogens or other sources. Here are some key features of a sterile storage area:

  - **Controlled access:** The sterile storage area should have controlled access, which means that only authorized personnel are allowed to enter the area. Access may be controlled by key cards, passwords, or other security measures.

  - **Positive pressure environment:** The sterile storage area should be maintained at a positive pressure relative to the surrounding areas, which helps prevent the entry of airborne contaminants.

  - **Clean and dry environment:** The sterile storage area should be clean and dry to prevent the growth of bacteria or other microorganisms that could compromise the sterility of the stored items.

  - **Proper storage containers:** Sterilized items should be stored in appropriate containers that are sealed, labeled, and stored in an organized manner. The containers should be made of materials that are resistant to moisture, dust, and other contaminants.

  - **Regular monitoring:** The sterile storage area should be regularly monitored for temperature, humidity, and other environmental factors that could affect the sterility of the stored items. Monitoring should be documented in order to track any changes over time.

- **Strict inventory management:** A strict inventory management system should be in place to track the location, quantity, and expiration dates of all stored items. This helps ensure that items are dispatched well in time before they expire and that there is no risk of dispatching expired or contaminated items.

3.3. Other Important Area(s): Following are the other important areas:

- **Personnel Support Area:** A Personnel Support Area is a designated location where personnel can take breaks, rest, eat, and receive support services. This area is designed to provide a safe and comfortable environment for personnel who are working at various facilities. Here are some key features of a Personnel Support Area:

  - **Rest areas:** Personnel support areas typically include areas where employees can take breaks, rest, and recharge. This may include cots, sleeping bags, chairs, and other comfortable seating options.

  - **Food and water services:** A personnel support area should provide access to food and water services to ensure that responders have access to the nourishment they need to stay alert and focused. This may include catering services, snack bars, and water stations.

  - **Sanitation facilities:** A personnel support area should include clean toilets, hand washing stations, and shower facilities.

  - **Communication facilities:** Personnel support areas should include communication facilities such as radios, telephones, and internet access.

  - **Medical support:** In case of injuries or illness, a personnel support area should have medical support services available. This may include medical personnel, first aid supplies, and basic medical equipment.

  - **Counseling services:** A personnel support area should provide access to counseling services to help employees cope with the stress.

  - **Conference Areas:** There should be adequate space and equipment in support areas to allow teaching and staff conferences, where training for various processes can be imparted at regular intervals.

- **Administrative Area:** Administrative Area is space designated for administrative personnel, department supervisors and support personnel.

- **Housekeeping Storage Area:** A housekeeping storage area is a designated space within a facility where cleaning supplies and equipment are stored. This may include items such as cleaning solutions, brooms, mops, vacuum cleaners, and other tools necessary for cleaning and maintenance tasks.

- **Consumable Storage Area:** A consumable storage area is a designated space within a facility where items which are regularly used and need to be replaced on a regular basis. consumable items such as paper, ink, toner, packaging items, tapes, pass cards, dust covers and other consumable supplies are stored.

- **Chemical Storage Area:** A chemical storage area in the context of laundry typically refers to a designated space within a laundry facility where chemicals used in the laundering process are stored. These chemicals may include detergents, fabric softeners, bleach, and other cleaning agents. The storage area is designed to keep these chemicals secure and organized, and to ensure that they are used safely and efficiently.

  Chemical storage areas for laundry facilities are typically designed with ventilation systems to ensure that fumes and vapors are safely removed from the area. The chemicals are typically stored in containers that are properly labeled and secured to prevent spills or leaks. The storage area may also include spill containment systems or other safety features to minimize the risk of accidents.

- **Boiler Room:** A boiler room in the context of laundry typically refers to a designated space within a laundry facility where a boiler is housed. The boiler is used to provide steam or hot water for the laundry process, including washing, drying, and ironing. The boiler room may also house other equipment related to the laundry process, such as steam turbines or compressors, water softeners, heat exchangers, water heaters and air compressors etc.

3.4. DESIGN CRITERIA FOR WORK AREA(S):

This section is about the design requirements of the workplace which can help in efficient & effective processing, maintain the cleanliness of processed healthcare textiles & minimize environmental impact. While preparing the

design of the healthcare textile processing, workflow of operations and quality assurance shall be defined, the inventory of supplies and textiles shall be projected, the type of distribution system to be used shall be selected, and functional work areas shall be designed accordingly. Following factors shall be considered for design criteria of functional areas:

- Whether the healthcare textile processing unit will be an in-house facility or an off-site facility
- Whether the facility will only process healthcare textiles only or other general-use textiles as well
- Whether the facility will inspect & maintain the healthcare textiles in-house or transport them to an off-site facility
- Whether the facility will provide mending/ alteration services in-house or transport them to an off-site facility
- Whether the facility will do the pack assembly in-house or transport them to an off-site facility
- Whether the facility will carry on sterilization/ disinfection process in-house or transport them to an off-site facility
- Whether the facility owns the healthcare textiles to be processed
- Whether the facility will store new or uncirculated healthcare textiles
- Whether the facility will deploy recycling water process
- What type of laundry systems, sterilization/ disinfection equipment, mending/ alteration machinery etc. will be needed to process the anticipated volumes.

Backup systems shall be in place for the critical processes including methods for providing hot water, electrical generators, standby washing equipment & drying equipment. Backup processing facilities and alternate transport methods shall be planned for uninterrupted supplies of processed healthcare textile to healthcare facilities, in the event of a natural disaster or catastrophic event. The processing facility shall be designed to minimize environmental impact using means such as (but not limited to) energy efficient equipment, heat exchangers, water reclamation system, wastewater filtering system. If providing Sterilization/ disinfection services, factors including Sterility assurance using pre & post sterilization processing functions & controls shall be kept in mind while designing the workplace. Healthcare textiles are a critical supply to health care facilities, and every effort should be made to ensure uninterrupted supplies.

3.5. WORKFLOW PATTERNS:

This section describes the functional workflow pattern of various functional

areas.

- **Laundry Area:** 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.

    - The physical barrier can be in the form of walls, doors, or partitions, which prevent the movement of soiled textiles into clean areas. The functional separation can be achieved by maintaining separate processing equipment, workstations, and storage areas for soiled and clean textiles. This separation helps in minimizing the risk of contamination and maintaining a clean environment for the handling and distribution of clean textiles.

    - In addition to the physical and functional separation, it is also essential to have a robust cleaning and disinfection protocol for the soiled textile processing area to maintain hygiene standards and prevent the spread of infectious agents. The design of a work area shall allow adequate space for all functions and promote efficiency. Adequate space is necessary to ensure that all functions can be carried out effectively, without compromising on quality or safety. Efficiency in the work area can be achieved through various design elements, such as:

    - **Layout:** The layout of the work area should be designed to minimize the distance that materials and employees need to travel between functions. This can be achieved through a logical flow of work, with workstations arranged in a sequence that supports the process flow.

    - **Equipment placement:** The placement of equipment should be carefully considered to ensure that it is located in the most appropriate location for its function. This can include the placement of washing machines, dryers, ironing stations, and folding tables.

    - **Storage:** The work area should have adequate storage space for materials, equipment, and finished products. Storage should be easily accessible and organized, with items located in a logical sequence to support the process flow.

- **Lighting:** Adequate lighting is important to ensure that employees can see clearly and work effectively. Natural light should be maximized where possible, and artificial lighting should be provided where necessary.

- **Ergonomics:** The work area should be designed to minimize physical strain on employees. This can include the use of ergonomic equipment, such as adjustable workstations and chairs, to promote comfort and reduce the risk of injury.

Workflows in a laundry shall be designed to ensure that contaminants are contained and that employee exposure to bloodborne pathogens is minimized. Bloodborne pathogens are microorganisms that are present in blood and other body fluids, which can cause serious diseases if they enter the body. To minimize employee exposure to bloodborne pathogens, the following measures can be implemented:

- **Containment:** Contaminants, such as soiled textiles and linens, should be contained in designated areas or containers to prevent cross-contamination with clean textiles. These areas or containers should be clearly labeled and easily accessible.

- **Disinfection:** All equipment and surfaces that come into contact with contaminated materials should be cleaned and disinfected regularly to prevent the spread of pathogens.

- **Standard operating procedures (SOPs):** SOPs should be developed and implemented to ensure that all employees are following the same procedures for handling contaminated materials and minimizing exposure to bloodborne pathogens.

Workflow patterns in a laundry shall be designed so that items are moved progressively from being contaminated to being safe to handle. This is important to minimize the risk of cross-contamination and to ensure that clean textiles remain free from pathogens and other contaminants.

- **Medical/ Surgical Pack Area:** The packing area shall be designed, so that where the processed clean healthcare linen is received, stored and then folded or assembled into packs, are separated by a physical barrier from the area where soiled healthcare linen is received or processed. It's important to ensure

that there is enough space for workers to move around and perform each task without obstruction or interference.

Additionally, the workspace should be designed in such a way that workers can easily access the tools and materials they need to perform their tasks. The packing/ assembly area shall have controls for proper airflow and exhaust. This will ensure in reducing and controlling the number of foreign particles, lint & other environmental contaminants in the area.

- **Movement Management:** Effective movement management is critical to ensure that healthcare linen is processed quickly and efficiently, and that the processing operations are able to meet demand while minimizing delays and errors. Some strategies for effective movement management in laundry may include:

  - Designing the layout of the laundry facility to minimize the distance that laundry items need to travel between stages of the process.
  - Using conveyor belts or other automated systems to move laundry items between stages of the process.
  - Assigning workers specific tasks and responsibilities within the laundry operation to minimize confusion and ensure that tasks are completed efficiently.
  - Implementing tracking systems to monitor the location and progress of laundry items through the process, allowing workers to quickly identify and address any delays or issues.
  - Regularly evaluating the laundry operation and making adjustments as needed to optimize efficiency and minimize delays or errors.
  - Movement in the Laundry area and Medical/ Surgical pack area shall be limited to authorized personnel only. Criteria for movement within the areas, authorized entry, and attire as per risk associated should be specified in written policies and procedures.

  It is necessary to restrict the entry of visitors in restricted areas. It shall be made sure that visitors follow the dress code as per defined attire policies of visiting areas. Visitors & personnel can be exposed to microorganisms on soiled healthcare textiles or they can carry microorganisms into areas where clean healthcare textiles are packed/ assembled.

3.6. Infrastructure: Following are the infrastructure requirements of various areas for processing of soiled healthcare textiles various areas:

- **Laundry Area:**

  - **Space Requirement:** The space requirement for laundry shall be determined by factors such as the size of the equipment, the amount of laundry to be processed, and the workflow of the facility. Adequate space shall be allocated for each functional area of the laundry so that space is sufficient for the systems, equipment, and work load of that area. The turnaround time for receiving and processing textiles, and the number of personnel required to process healthcare textiles shall also be considered while computing space requirements.

  - **Mechanical System Requirements:** The mechanical system requirements will depend on the size and type of the laundry operation. Some of the requirements of the mechanical systems are that the HVAC system shall be designed to provide adequate heating, ventilation, and air conditioning to maintain a comfortable and safe indoor environment. The facility may require an exhaust system to remove heat, humidity, and chemical fumes generated during the laundering process. The laundry will require a sufficient and reliable supply of hot and cold water, as well as an adequate drainage system for wastewater.

    - Compressed air system for sufficient capacity shall be installed for pneumatic equipment and machinery. The electrical system shall be designed to provide sufficient power to operate the facility's equipment and lighting. The facility shall be equipped with appropriate fire protection systems, including but not limited to, smoke detectors, fire alarms, and fire suppression systems. The facility shall consider implementing energy-efficient equipment and systems, as well as waste reduction and recycling programs. The above list of requirements is not exhaustive and may vary on the capacity and area of the healthcare textiles processing facility.

  - **Construction Requirements:** The construction requirements for the facility shall depend on the size and type of the laundry operation. Here are some important instructions for Building, Floor, Walls, Ceilings and Vents. The building shall be designed and constructed to accommodate the facility's equipment and workflow, with adequate space and clearances for the machinery and workers.

- The facility shall have a durable and slip-resistant seamless flooring material including but not limited to, PU/ EPOXY/ VINYL Flooring, which is easy to clean and maintain.

- The walls and ceilings shall be constructed with materials that are resistant to moisture, chemicals, and damage from equipment and carts. The plumbing and electrical systems shall be designed and installed to meet the demands of the laundry's equipment and operations.

- There shall be provision of ventilation and exhaust systems with sufficient capacity to remove heat, humidity, and chemical fumes generated during the laundering process. The facility needs to be designed to comply with accessibility standards and provide access to people with disabilities.

- The facility shall consider implementing sustainable construction practices and materials, such as using energy-efficient equipment and incorporating green building strategies. It's important to work with a qualified architect and contractor to design and construct the healthcare textiles processing unit that meets the specific requirements of the operations and complies with local codes and regulations.

- Avoid running power cords and computer cables across the floor, as this can pose a tripping hazard and potentially damage the cables. Instead, cables and cords should be run along walls or ceiling-mounted cable trays to keep them out of the way and prevent them from becoming tangled or damaged.

- Additionally, using wireless connectivity technology can reduce the need for cables altogether. If it is absolutely necessary to run cables across the floor, it is important to ensure that they are secured and marked with warning signs to prevent tripping hazards.

- The materials of construction of floors, walls, and ceilings must be able to withstand frequent cleaning and must not be adversely affected by chemical agents typically used for cleaning or by “blow-down” to eliminate lint and other soils that are associated with the processing and cleaning of healthcare textiles.

- **Air Circulation:** A suitable air circulation system will depend on several factors such as the size of the laundry and the number and type of machines being used. It is important to maintain a pressure differential between the clean textile areas and the soiled areas to prevent the spread of contaminants such as lint, dust, and bacteria.

    - The clean textile areas shall have positive pressure, meaning that the air pressure inside these areas is higher than outside, while the soiled areas should have negative pressure, meaning that the air pressure inside these areas is lower than outside. This pressure differential helps to ensure that air flows from clean areas to soiled areas, preventing the spread of contaminants.

    - Additionally, the exhaust system shall be designed to vent the contaminated air outside the building to maintain indoor air quality and prevent moisture-related issues.

- **Thermal & Moisture control:** Temperature and humidity control are critical aspects of healthcare textiles processing operations. Laundries typically use hot water, steam, or a combination of both to clean textiles. The temperature of the water and steam must be controlled to ensure proper cleaning and disinfection of the textiles.
    - Temperature control can be achieved through the use of temperature sensors and control systems that regulate the temperature of the water and steam. A lot of moisture is generated due to the use of steam and hot water. If the humidity is too high, it can lead to mold growth, corrosion of equipment, and other moisture-related problems. Ensure proper provisioning of dehumidifiers, air conditioning systems, and ventilation systems.

- **Lighting setup:** A good lighting system shall provide adequate illumination for workers to perform their tasks safely and efficiently. The lighting system should be bright enough to provide sufficient illumination for workers to see the textiles they are handling. Brightness can be measured in lumens, and brightness shall be between 100-200 lux.

    - The color temperature of the lighting system should be chosen carefully. A color temperature of 5000-6500 Kelvin is must as it

provides a natural, bright light that helps to distinguish colors accurately.

- The lighting system shall be energy-efficient to reduce energy costs and minimize the environmental impact. The lighting system shall be placed in such a way that it does not create shadows or glare that could impair workers' vision. The lighting fixtures shall be placed in strategic locations to ensure that the entire laundry area is adequately illuminated.

- The lighting system shall be designed for easy maintenance to ensure that the fixtures are always working correctly. This includes easy access for replacing bulbs and ensuring that the lighting system is wired correctly.

- **Hand Hygiene Stations:** A handwashing facility is an essential component as it helps to maintain good hygiene and prevent the spread of germs and bacteria. The handwashing facility should be located in a convenient and accessible location to encourage regular handwashing by workers. Ideally, it should be located near the laundry equipment, the entrance/exit to the laundry and all personnel support areas.

  - The handwashing facility shall be designed to promote good hygiene practices. It shall include a sink, soap dispenser, and paper towel dispenser. The sink shall be large enough for workers to wash their hands comfortably and deep enough to prevent splashing.

  - The soap and paper towel dispensers shall be located within easy reach of the sink. The handwashing facility shall be designed for easy maintenance to ensure that it is always clean and functional. This includes easy access to water and drainage, as well as regular cleaning and disinfection of the sink and dispensers.

  - The handwashing facility shall be clearly labeled with signage to encourage workers to wash their hands regularly. This includes signage that reminds workers to wash their hands before and after handling textiles, using the restroom, and eating.

  - Handwashing stations which provide hands free operations such as Elbow operated, foot operated or sensor controlled shall be preferred.

- **Shower/ Eyewash Stations:** An emergency eyewash station is an important safety feature. The emergency eyewash station should be located in a visible and easily accessible location, ideally near the equipment(s) where workers are handling chemicals or other hazardous materials.

    - The eyewash station shall be designed to provide a steady flow of water to flush chemicals or other foreign substances out of the eyes. It shall have a minimum flow rate of 0.4 gallons per minute and a minimum water pressure of 30 psi. The eyewash station shall be activated by a quick and easy-to-use mechanism, such as a push-button or foot pedal.

    - The eyewash station shall be designed for easy maintenance to ensure that it is always in working condition. This includes regular inspection and testing to ensure that the water flow rate and pressure are within the recommended range. The eyewash station shall be clearly labeled with signage that indicates its location and provides instructions for use.

    - The signage shall be highly visible and easily readable from a distance. Emergency eyewash stations shall be located within 10 seconds' travel time of all chemical usage locations and for areas where strong acid or strong caustic chemicals are used, emergency eyewash stations shall be located immediately adjacent to the hazard.

- **Soil-sort Area:** A soil sort area is an important component, as it is the area where soiled healthcare textiles are sorted for processing. The soil sort area shall be located near the entrance of the laundry facility to facilitate the easy and safe transport of soiled healthcare textiles from outside the facility. It shall be separated from the clean textile area to prevent cross-contamination.

    - The soil sort area shall be designed to promote efficient and safe sorting of soiled healthcare textiles. It shall include sorting tables or bins for different types of soiled healthcare textiles, as well as hampers or carts for transportation.

- The area shall be well-lit and have a ventilation system to remove odors and airborne particles. The sorting tables or bins shall be at a comfortable height for workers to prevent strain and injury. The hampers or carts shall be on wheels to make transportation easier and safer.

- The area shall also have an emergency eyewash station and a spill kit in case of accidents. The soil sort area shall be designed for easy cleaning and disinfection to prevent the spread of germs and bacteria. Regular cleaning and disinfection of the sorting tables, hampers, carts, and other equipment is necessary to maintain a hygienic environment.

- The work surfaces shall be constructed of nonporous materials capable of withstanding frequent cleaning. Chances of airborne microbial and particulate contamination will be high in the soil-sort area due to the type of work performed and this shall be controlled through work practices and engineering controls.

- Air from the soil-sort area shall be exhausted to the outdoors without recirculation. If it is necessary to recirculate air, the air shall only be recirculated back into the soil-sort area and it shall be filtered.

- **Chemical Storage:** When it comes to chemical storage, it's important to take the necessary precautions to ensure the safety of employees, customers, and the environment. Choose a location that is well-ventilated, dry, and away from sources of heat, sparks, and flame.

  - The chemical storage area shall be separate from the main laundry area to minimize the risk of accidental exposure. Chemicals shall be stored in their original containers with proper labels and safety data sheets (SDS) readily available. Make sure the containers are tightly sealed to prevent leaks or spills.

  - Chemicals shall be stored in separate areas based on their compatibility. For example, oxidizers should be stored away from flammable materials and reducing agents. Acids shall be stored away from alkalis or bases. Provide appropriate handling equipment such as carts, dollies, and forklifts to move and transport chemicals safely.

- Ensure your chemical storage area complies with local, state, and government regulations. Clearly state the name of the chemical(s) contained in the container or packaging. Identify any hazards associated with the chemical(s), such as flammability, corrosiveness, or toxicity. Include any necessary precautions related to the contents, such as instructions for handling, storage, or disposal.

- All such information shall be easy to read and located prominently on the label. Liquid spill containment systems such as but not limited to Spill Pallets, Spill Berms, Portable Spill Kits and Drain Covers, that handle chemicals, such as detergents, bleach, and fabric softeners shall be installed.

- **Clean Healthcare Textiles Storage:** Clean healthcare textiles must be stored in a way that maintains their cleanliness and prevents contamination.

  - Choose a location that is clean, dry, and well-ventilated. Ideally, the storage area should be separate from high-traffic areas to minimize the risk of contamination. Maintain appropriate temperature and humidity levels to prevent moisture buildup and mold growth.

  - The ideal temperature for healthcare textile storage is around 70 degrees Fahrenheit with a relative humidity of 50%. Use shelving and storage containers that are clean and easy to sanitize.

  - Clean healthcare textiles shall be stored in clean, dry containers or wrapped in plastic to prevent dust and other contaminants from settling on them.

  - Establish a system for tracking inventory to ensure that clean healthcare textiles are rotated regularly and not left in storage for extended periods of time. Implement measures to prevent pests such as rodents and insects from entering the storage area. This may include sealing gaps and cracks, using pest repellents, and regular cleaning.

  - For Sterile Healthcare Textiles, the final pack shall meet the same criteria as of storage of Sterile Medical Devices or comply with

instructions of storage provided by the relevant national/ international product standard.

- **Housekeeping:** Housekeeping is an essential aspect. Standard Operating Procedures shall be developed that outlines the frequency and scope of cleaning tasks, such as mopping floors, wiping down equipment, and cleaning lint filters. These procedures shall include schedules for daily, weekly, and monthly cleaning tasks.

    - Ensure that staff members are trained on proper cleaning procedures and safety protocols. Stock up on cleaning supplies such as mops, buckets, and cleaning solutions, and ensure they are easily accessible to staff members.

    - Train staff members to quickly address spills and stains to prevent them from spreading and becoming more difficult to clean. Implement a quality control program to ensure that cleaning is being done effectively and efficiently. Regular inspections can help identify areas for improvement and prevent issues from arising.

- **Medical/ Surgical Packing/ Assembly Area:**

    - **Space Requirements:** While computing space requirements for a healthcare textile packing/ assembling area, few points shall be taken into consideration such as the number of textiles being processed, the type of packing equipment being used, and the layout of the facility.

        - The packing area shall have enough well lighted floor space to accommodate the patching/ mending equipment, packing equipment, tables for folding, inspection, packing and assembling and space for storage of packed items.

        - Adequate storage space shall be available for both unpacked and packed textiles. This may include shelving, carts, or other storage solutions. If the facility is conducting Sterilization/ Disinfection, then a separate area shall be there having adequate space, ventilation, air circulation & particle control system.

        - The packing area shall be easily accessible to other areas of the facility, such as the laundry or storage areas. The layout of the packing

area shall be designed to promote efficient workflow, allowing workers to move easily from one task to another. Adequate space shall be provided for workers to move around safely.

- Adequate ventilation and exhaust systems are critical for maintaining a clean and safe environment in a healthcare textile packing area. These systems are necessary to ensure appropriate air exchange and environmental controls, which are essential for preventing the spread of airborne pathogens, controlling humidity levels, and removing unpleasant odors.

- Healthcare textile packing areas must comply with regulations governing air quality and environmental control for healthcare settings to ensure the safety and health of workers and users.

- **Mechanical Requirements:** Mechanical system requirements for a healthcare textile packing area are essential to ensure that the area is designed for efficient and safe processing of healthcare textiles.

  - A conveyor system should be used to transport textiles from one area to another in the packing area, which can help to streamline the process and reduce manual handling.

  - Automated packing equipment, such as automatic bagging machines or wrapping machines, can help to speed up the packing process while maintaining consistency and quality.

  - Material handling equipment, such as carts or dollies, can help to transport textiles between different areas of the packing facility, reducing manual handling and improving efficiency.

  - An HVAC system shall be installed to maintain appropriate temperature and humidity levels in the packing area, which is important for maintaining the integrity of the textiles and preventing the growth of bacteria or mold.

  - Proper lighting is essential for ensuring that workers can see what they are doing and identify any potential quality issues with the healthcare textiles being processed.

- A fire suppression system, such as but not limited to sprinklers or fire extinguishers, shall be installed to prevent and contain fires that may occur in the packing area.

- **Construction Requirements:** Construction requirements for a healthcare textile packing area are essential to ensure that the area is designed for safe and efficient packing of healthcare textiles.
  - The flooring in the packing area shall be durable, easy to clean, and able to withstand heavy foot traffic and equipment. Floors shall be slip-resistant and should not create static electricity that can damage textiles.

  - Walls and ceilings shall be constructed of materials that are easy to clean and resistant to moisture and bacteria. The walls shall be smooth and seamless to prevent the accumulation of dirt or bacteria.

  - Doors shall be constructed of materials that are easy to clean and resistant to moisture and bacteria. They shall be wide enough to accommodate the movement of carts or other equipment and should be equipped with self-closing mechanisms to prevent the spread of airborne contaminants.

  - Adequate plumbing is essential for a healthcare textile packing area, including access to hot and cold water, drainage, and waste disposal.

- **Air Circulation:** Proper ventilation is crucial in a healthcare textile packing area to ensure a safe and healthy environment for workers.

  - The packing area shall be designed to promote good airflow, with proper ventilation systems in place to ensure adequate air exchange and environmental controls. This is important for preventing the spread of airborne contaminants and maintaining a clean and safe environment.

  - Air filtration systems, such as HEPA filters, shall be installed to remove contaminants from the air and maintain a high level of indoor air quality. These filters shall be regularly cleaned and maintained to ensure proper functioning.

- Exhaust systems are must to remove unpleasant odors and harmful fumes from the packing area, reducing the risk of worker exposure to these hazards.

- **Thermal & Moisture Control:** Temperature and humidity control are critical for ensuring the quality and integrity of healthcare textiles and for maintaining a safe and healthy environment for workers in the packing area.

  - The packing area shall be designed to maintain appropriate temperatures, typically between 20°C to 24°C (68°F 75°F), to ensure the quality and integrity of the healthcare textiles being packed.
  - The packing area shall be designed to maintain appropriate humidity levels, typically between 40% and 60%, to prevent the growth of bacteria or mold on the healthcare textiles.

  - An HVAC system can help to maintain appropriate temperature and humidity levels in the packing area, which is important for maintaining the integrity of the textiles and preventing the growth of bacteria or mold.

  - The HVAC system shall be designed to provide adequate air exchange and filtration to maintain good indoor air quality. The packing area shall be insulated to prevent temperature and humidity fluctuations caused by external factors such as weather conditions.

  - Temperature and humidity monitoring systems shall be installed to ensure that the packing area remains within the appropriate range. These systems can alert workers if the temperature or humidity levels fall outside the acceptable range.

  - Packing area shall be comfortable for properly attired personnel. Higher temperature and humidity can promote microbial growth and have the potential to increase bioburden.

  - Temperature and humidity lower than those recommended can adversely affect sterilization. Relative humidity lower than 30 % may permit absorbent materials to become excessively dry, which can adversely affect the efficacy of the sterilization process and the

performance of biological indicators and chemical indicators.

- **Lighting Setup:** When it comes to lighting setups for healthcare textile packing, the goal shall be to have adequate lighting that allows for accurate color recognition, good contrast, and minimal glare or shadows.
    - Adequate lighting should be provided for various operations like mending, folding and packing in accordance with the tasks performed in each specific area.
    - For healthcare textile packing, it's recommended to use a color temperature between 3500K and 4100K, which is a cool white or neutral white. This helps to accurately distinguish between colors and avoid any tinting or color distortion.
    - Avoid harsh, direct lighting as it can cause glare or shadows that can make it difficult to see the details of the textiles. Instead, use diffused lighting, such as soft boxes or diffusers, to create a more even and uniform light.
    - Position the lighting at an angle that illuminates the work area without casting shadows or creating glare.
    - Lighting shall come from above and the sides, and it's important to ensure that there is no lighting directly behind the worker. Multiple light sources will help to eliminate shadows and provide better visibility.
    - Consider using a combination of overhead and task lighting to achieve the best results.
- **Hand Hygiene Stations:** Hand hygiene is essential in any healthcare setting, including areas where healthcare textiles are packed.
    - Hand hygiene stations, such as sinks or alcohol-based hand sanitizers, shall be placed in easily accessible areas near the workstations where healthcare textiles are packed.
    - The number of hand hygiene stations shall be adequate for the number of workers in the area. This helps to prevent crowding and reduces the risk of cross-contamination.

- It's important to provide clear instructions on when and how to perform hand hygiene, as well as the importance of hand hygiene in preventing the spread of infections.

- **Clean Healthcare Textile Storage:** Clean healthcare textile storage is essential for preventing the spread of infections and ensuring that healthcare textiles remain in good condition.

  - The storage area shall be clean and well-maintained, free from dust, dirt, and other contaminants. It should also be regularly cleaned and disinfected to prevent the growth and spread of microorganisms.

  - Healthcare textiles shall be stored in an area with appropriate temperature and humidity control to prevent moisture buildup and the growth of mold and bacteria.

  - The ideal temperature range is typically between 20-25°C (68-77°F) and the relative humidity should be kept below 60%.

  - Healthcare textiles should be stored in a secure and organized manner to prevent damage and contamination.

  - Storage racks or shelves shall be used to keep textiles off the floor and avoid contact with other materials.

  - All healthcare textiles shall be properly labeled and tracked to ensure they are used in a timely manner and not past their expiration date.

- **Sterilization/ Disinfection Area:** Sterilization or disinfection of healthcare textiles is an important process that helps to prevent the spread of infections.

  - Dedicated areas for the sterilization & disinfection of healthcare textiles are required to prevent cross-contamination and ensure that the sterilization process is performed in a controlled environment.

  - Areas shall be separate for each type of sterilization & disinfection process. The sterilization room shall have appropriate ventilation to

ensure that any airborne contaminants are removed from the environment.

- The sterilization & disinfection areas shall be equipped with appropriate sterilization or disinfection equipment, such as but not limited to steam sterilizers, chemical sterilizers, UV Sterilizers, Washer-disinfectors and Hydrogen Peroxide Vapor machines.

- The equipment shall be properly maintained and validated to ensure that they function correctly.

- A quality control program shall be in place to ensure that the sterilization or disinfection process is effective and that healthcare textiles are properly sterilized before use. This can include routine testing of equipment and monitoring of sterilization cycles.

- **Sterile Storage Area:** A dedicated storage area for sterile healthcare textiles is required to prevent cross-contamination from non-sterile items.

  - The storage area shall be separated from other storage areas and shall not be used for other purposes. The sterile storage area shall have a positive pressure relative to the surrounding areas to prevent the entry of non-sterile air.

  - The temperature and humidity in the sterile storage area shall be controlled to prevent moisture buildup and the growth of bacteria and other microorganisms. The temperature shall be kept between 20-25°C (68-77°F) and the relative humidity shall be kept below 60%.

  - Sterile healthcare textiles shall be stored in a secure and organized manner to prevent damage and contamination.

  - Storage racks or shelves shall be used to keep textiles off the floor and avoid contact with other materials.

  - All sterile healthcare textiles shall be properly labeled and tracked to ensure they are used in a timely manner and not past their expiration date.

- **Housekeeping:** The packed/ sterilized healthcare textile storage area shall be cleaned regularly using appropriate cleaning agents and methods.

    - The cleaning schedule shall be clearly defined and followed consistently to prevent the buildup of dust, debris, or contaminants.

    - The packed/ sterilized healthcare textile storage area shall be free of pests, including insects and rodents. Pest control measures shall be implemented and regularly monitored to prevent infestations.

4. **Equipment:** To ensure that textiles are consistently cleaned, disinfected, and produced to meet their predetermined performance attributes, it is important to follow the guidelines in this section for optimizing the performance of processing equipment and support systems.

4.1. Processing equipment is necessary to clean and finish soiled textiles, which includes washing, extracting, conditioning or drying the items and ironing. These tasks can be performed in the same machine or in separate processes for washing and extraction. Drying and conditioning are typically done separately.

- A program to maintain and repair the equipment used for cleaning soiled textiles is essential to ensure the proper operation and function of the equipment. Regular maintenance and repair work can help prevent breakdowns, reduce downtime, and extend the life of the equipment.

- In addition to maintenance and repair, washing and drying equipment relies on certain support systems to function correctly or at peak efficiency. Proper support systems can help ensure that the equipment operates correctly and safely, and can also help to improve the overall efficiency of the cleaning process.

- The support systems required for washing and drying equipment may consist of chemical delivery systems, water softeners, water heaters, boilers, air compressors, heat exchangers, and/or water reuse systems, among others.

- In addition, there are other types of processing equipment that can be used to improve productivity or the appearance of the cleaned textiles. These might include steam tunnels, flatwork ironers, and small-piece folders, among others.

- These machines are designed to handle specific tasks, such as removing wrinkles, folding small pieces of fabric, or pressing large sheets. By using these machines in combination with washing and drying equipment, the cleaning process can be made more efficient and the quality of the finished product can be improved.

4.2. **Documentation:** Documentation plays a critical role in equipment for the laundry process. The documentation required for equipment for healthcare textile processing typically includes:

- **Equipment specifications:** This includes the make and model of the equipment, the capacity, serial number or other unit identification, voltage requirements and any specific features or capabilities.

- **Installation and operation instructions:** This documentation shall provide instructions for installing and operating the equipment. It shall include safety procedures, setup instructions, and step-by-step procedures for operating the equipment.

- **Maintenance and cleaning procedures:** This documentation shall outline the recommended maintenance and cleaning procedures for the equipment. It shall include information on how to inspect and clean the equipment, as well as how often to perform maintenance tasks.

- **Troubleshooting guide:** A troubleshooting guide shall be included in the documentation to help diagnose and fix any issues that may arise during operation.

- **Warranty information:** The documentation shall include information on the warranty provided by the manufacturer, including the length of the warranty, what is covered, the life-cycle of the equipment and any limitations or exclusions.

- **Safety information:** The documentation shall include safety information, such as warnings, cautions, and safety procedures, to ensure the safe operation of the equipment. It shall be verified that the manufacturer has provided safety instructions describing the potential hazards associated with equipment use, as well as certification that the equipment incorporates appropriate safeguards conforming to all local, state, and national regulations.

- Manufacturer of the equipment shall also provide documentation demonstrating that the equipment complies with regulatory requirements.

- When integrating or automating laundry equipment or using robot systems, personnel shall follow guidelines for proper safeguarding to ensure the safety of the operators and other personnel in the area.

- Before implementing any automation or robotics system, it's essential to conduct a thorough risk assessment to identify potential hazards and risks.

4.3. **Manuals:** When it comes to laundry equipment, such as washing machines, dryers, and ironing machines, installation and operating instructions are essential to ensure proper use and maintenance of the equipment.

To allow for preventive maintenance, calibration, and repair to be carried out by personnel who are not employees or representatives of the manufacturer, it is crucial to provide detailed and comprehensive information. To ensure safe and effective operation of the system, comprehensive instructions manuals shall be provided that cover the following:

- **Installation Manual:** Detailed and thorough instructions for installing the system, encompassing information such as the necessary utilities (including line size and pressure specifications), support system requirements, space needs, foundation or footing prerequisites, and drainage requirements.

- **Programming Manual:** Clear instructions shall be given on how to program the system, including setting appropriate processing parameters for various applications.

- **Recommended Processing Limits:** Information shall be provided on recommended processing limits for the system, including capacity and performance specifications.

- **Emergency Shut-offs:** The manufacturer shall provide clear instructions on how to shut down the system in the event of an emergency, such as a power outage or equipment malfunction.

- **Safety Precautions:** The manufacturer shall provide information on necessary safety precautions for operating the system, including instructions on how to avoid hazards such as electrical shocks, burns, or cuts.

- **Maintenance Instructions:** To ensure optimal performance and longevity of the system, the manufacturer shall provide detailed instructions on how to perform regular maintenance, including cleaning, lubrication, and replacement of components.

- **Troubleshooting Instructions:** In the event of a system malfunction, the manufacturer shall provide clear instructions on how to troubleshoot and resolve common issues.

- **Operating Tips:** The manufacturer shall provide useful operating tips to ensure efficient and effective use of the system, including how to optimize processing times and minimize energy usage.

- **Schematic Drawings:** Schematic drawings that depict the arrangement of equipment, pipework, and control systems should be provided.

4.4. **Installation:** Installation documentation shall be prepared to demonstrate the following before commissioning the equipment:

- Compliance with regulations and standards, proper installation, functioning of necessary utilities and support systems, suitable foundation and footing, and proper functioning of control systems.

- Ensure that the installers, including any subcontractors, possess appropriate qualifications or training to deliver installation services.

- Ensure that utilities and other support services are suitable for the proper functioning of processing units.

- Confirm that each individual piece of equipment has been installed in accordance with the manufacturer's instructions, as evidenced by the work order and the installer's signature. In case it becomes necessary to modify the equipment or support systems design, all such modifications must be clearly identified in the final design drawings or equipment specifications.

- Verify that all safety equipment is functioning correctly and in accordance with the manufacturer's specifications.

4.5. Water & Steam Quality: Water is the single most important utility used in laundering, and its quality can have a significant impact on the effectiveness and efficiency of the laundry process.

- The quality of the water used for laundering can vary greatly depending on its source and whether it has been treated or reused. It is important to assess whether the water to be utilized in the processing requires pretreatment, and if so, to identify the suitable pretreatment methods.

- A water quality determination shall be tested for a range of physical, chemical, and biological parameters to ensure that the water is safe and suitable for use in the laundry process. To ensure compatibility with the chemicals to be used, the facility shall consult the chemical supplier for both the wash floor and the boilers regarding the pretreatment requirements.

- The quality of water used for reprocessing medical devices is critical to ensure the safety and efficacy of the sterilization process. Following shall be complied for water quality and steam quality in medical device reprocessing facilities:

  - **Water Quality:** Water shall meet the criteria for "purified water" as defined by the recognized national/ international standards & regulatory requirements.
    - Total dissolved solids (TDS) should be less than 10 ppm.
    - Endotoxin levels shall be less than 0.25 EU/ml
    - Bacterial levels shall be less than 10 CFU/ml.
    - pH shall be within the range of 5.0 to 8.0.

  - **Steam Quality:** The quality of steam used for sterilization shall be monitored regularly to ensure that it meets the required standards.

    - Steam shall be free of impurities, such as dissolved solids, oils, and other contaminants.
    - The quality of the steam shall meet the criteria for "clean steam" in accordance with recognized national/ international standards & regulatory requirements.
    - Clean steam shall be generated using appropriate equipment and processes, such as reverse osmosis, deionization, and distillation.

  It is important to ensure that the steam supply used in any equipment conforms to the manufacturer's recommendations and any relevant regulations. For

choosing the relevant & appropriate test methods & standards for water and steam, refer to **Annexure- C**: **Table I- Applicable Standards & Test Methods** (AMTZ/HEALTEXPROF/ATD/R00)**.**

4.6. **Electricity:** It is essential that the electrical power supplied to processing equipment is installed in accordance with international standards to ensure safe and reliable operation. Failure to adhere to these standards could lead to electrical hazards, equipment damage, and even injury to personnel.

- **International standards for electrical installation and equipment** include the **International Electrotechnical Commission (IEC) standards**, which provide guidelines for the design, installation, and testing of electrical equipment. These standards cover a range of topics, including electrical safety, performance, and efficiency.

4.7. **Gas:** The equipment manufacturer's recommendations for the gas supply shall be followed carefully, as they will specify the required gas quality, pressure, and flow rate needed for optimal performance. In addition to the manufacturer's recommendations, regulations may also apply to the gas supply, depending on the type of equipment and application. These regulations may include requirements for gas quality, pressure, and flow rate, as well as requirements for regular testing and maintenance of the gas supply. Ensure that the gas supply used in any equipment conforms to the manufacturer's recommendations and any relevant regulations.

4.8. **Operations:** It is essential that before any piece of equipment is commissioned into service, it is verified that its performance meets the manufacturer's specifications. The proper functioning of washing, extracting, and drying equipment relies on the correct operation of a range of utilities, mechanical systems, automated controls, and support systems. These systems and components work together to ensure that the equipment operates safely, efficiently, and effectively, while also providing the necessary control and monitoring capabilities.

- Utilities such as water, steam, and electricity are essential for the operation of these machines, and it is important to ensure that the supply and quality of these utilities meet the manufacturer's specifications and industry standards. Failure to supply these utilities at the correct pressure, temperature, or flow rate can result in decreased performance, increased wear and tear on equipment, or even equipment failure.

- Mechanical systems such as valves, level sensors, temperature sensors, safety door locks, and drum rotation systems are also crucial for the proper functioning of washing, extracting, and drying equipment. These systems must be installed and maintained correctly to ensure that they operate reliably and safely.

- Automated controls are used to manage the operation of the equipment, including setting and monitoring parameters such as temperature, time, and rotation speed. It is essential to ensure that these controls are programmed correctly and that they function as intended, as any errors or malfunctions can lead to incorrect operation of the equipment.

- Microprocessor or card controls are commonly used to operate equipment in many industries, including laundry and manufacturing. Verify that the controls are sending the right signals to the equipment and that the equipment is responding as expected. Any software updates or changes to the controls should be carefully evaluated and tested to ensure that they do not adversely affect the equipment's performance or safety.

4.9. Chemical Delivery Systems: Verifying the performance of the chemical delivery system is an essential step to ensure that the correct amount of detergent or other cleaning chemical is delivered to the washer at the right time.

- One way to check the performance of the chemical delivery system is to verify the chemical delivery rates. This involves measuring the amount of chemical delivered to the washer during a specific period and comparing it to the expected delivery rate. Any deviations from the expected delivery rate shall be investigated and corrected to ensure that the system is delivering the correct amount of chemical.

- Another method for checking the performance of the chemical delivery system is by conducting chemical titrations. This involves testing the concentration of the cleaning chemical in the washer and comparing it to the expected concentration. If the actual concentration is too high or too low, adjustments to the chemical delivery system may be necessary to ensure that the correct amount of chemical is being delivered to the washer.

- Regular checks of the chemical delivery system shall be performed at least monthly to ensure that the system is operating correctly and delivering the correct amount of chemical to the washer. Any issues shall be addressed

promptly to avoid any negative impact on the quality of the wash and the performance of the equipment.

4.10. **Water Softeners:** Softening water can be beneficial for laundries, particularly when the water has a high hardness level. Hard water can cause issues such as scaling, reduced efficiency of cleaning chemicals, and damage to laundry equipment. The hardness level for laundry water shall be less than 50 parts per million (ppm).

- It is important to note that softening water can also increase sodium levels in the water, which can be an issue for individuals with sodium-sensitive health conditions. Facilities shall consider the potential impact on their customers and adjust their processes accordingly.

4.11. **Water Heaters:** Ensure that their water heaters are appropriately sized for their peak operating times. The size of the water heater shall be able to provide enough hot water to meet the needs of the facility during these periods. It is also important to consider any future expansion plans when selecting the size of the water heater.

- In addition to the size of the water heater, it is crucial to control the temperature of the heated water. The temperature of the water shall be set according to the manufacturer's recommendations and any applicable regulations. It is important to monitor the temperature of the water regularly and make adjustments as needed to ensure that it remains within the recommended range.

- The design of the water heater shall also be considered when selecting a system for a laundry facility. There are various types of water heaters available, such as electric, gas, and oil-fired heaters.

4.12. **Boilers:** Boilers play a critical role in laundry operations as they produce steam that is used to power a variety of equipment, such as washing machines, dryers, and ironers. Therefore, it is essential to ensure that boilers are appropriately designed and installed to generate the correct steam quantity and purity for the intended use.

- Boilers shall be designed to meet the steam demand of the laundry facility during peak periods while ensuring energy efficiency.

- Boilers shall also be designed to produce steam that meets the purity requirements of the laundry operation. Steam quality is critical as poor-quality steam can result in reduced equipment performance, increased energy consumption, and reduced product quality.

- The steam shall be free from impurities such as minerals, chemicals, and bacteria that could affect the laundry operation or damage equipment.

- Equipment that uses steam directly in contact with textiles, it is essential to ensure that the steam is free of any harmful or toxic substances that can be introduced from the boiler. This can be achieved by performing regular boiler chemical maintenance to ensure that the boiler is not using any toxic compounds and that there is no risk of these compounds being introduced into the system.

- It is also important to use appropriate steam filters and traps to remove any impurities that may be present in the steam, such as rust or debris, which can cause damage to the equipment and affect the quality of the processed textiles.

- Boiler treatment compounds for use in laundry or sterilization equipment that comes into direct contact with textiles, it is important to choose products that are approved for use in the food industry.

- In laundry, the steam is used mainly for heating and humidification, and its degree of saturation (i.e., the ratio of the actual moisture content to the maximum moisture content) is less critical than steam used for sterilization.

- It may be necessary to install steam filters in the lines before the sterilization equipment to remove any impurities that may be present in the steam, such as rust or debris. These filters are designed to capture any contaminants that could potentially affect the sterilization process and shall be installed according to the manufacturer's instructions.

- In steam dryers, the steam does not come into direct contact with the textiles being processed, so the purity and quality of the steam are generally less critical than in applications such as steam sterilization. In these cases, it is generally sufficient to ensure that the steam used conforms with the manufacturer's recommendations, as specified in the equipment manual.

4.13. Air Compressors: It is important to use compressed air that meets the equipment manufacturer's recommendations when operating valves. Using compressed air that does not meet the manufacturer's recommendations can lead to several problems including damage to the valve, safety hazards and reduced efficiency.

- It is also important to keep the moisture content of compressed air at a low level because high levels of moisture can cause corrosion and damage to the internal components of the compressor, as well as lead to contamination of downstream equipment and processes.

- To prevent contamination, it is important to filter the compressed air used to dry transportation or storage carts. This can be done by using filters that are specifically designed for compressed air systems and that are capable of removing oil and other contaminants.

- The filters shall be installed at the point of use, as close as possible to the drying equipment, to ensure that the compressed air is filtered before it comes into contact with the carts or the products being transported or stored.

4.14. Heat Exchangers: Heat exchanger systems are often piped in a way that allows hot wastewater (effluent) to circulate around incoming water to preheat it for use in boilers, hot water heaters, or within the laundering process.

- A typical heat exchanger system consists of two separate and isolated piping systems. One system carries the hot wastewater (effluent) while the other carries the incoming water that needs to be heated.
  - The two systems are connected through a heat exchanger, which allows the heat from the hot wastewater to be transferred to the incoming water without the two fluids mixing.

  - Preventing direct contact or mixing of the two water sources in a heat exchanger system is essential for ensuring safe and efficient operation.

  - The welds and connections shall be of high quality to ensure there is no leakage. Direct connection of lines to a drain without an atmospheric break should be avoided to prevent back-siphoning.

- It is important to properly manage the steam condensation in the heat exchanger to ensure efficient operation and avoid any potential issues such as corrosion or damage to the equipment.

- Develop procedures for the care, maintenance, and operation of heat exchangers that will prevent cleaning compounds from coming into direct contact with textiles being processed.

- It is also recommended to use dedicated cleaning systems for the heat exchangers, separate from the systems used for cleaning other equipment or areas in the facility.

4.15. **Water Reuse and Recycle:** Water reuse systems shall be carefully designed to capture suitable water for subsequent reuse in a suitable part of the cycle. This is because not all water is appropriate for reuse, and using the wrong type of water in the wrong part of the cycle can lead to reduced efficiency, increased wear and tear on equipment, and potential contamination of the product.

- To ensure that the water reuse system captures appropriate water for reuse, the system shall be designed to account for the specific water requirements of each part of the cycle. For example, some parts of the cycle may require high-quality water, while others may be able to use lower-quality water.

- The system shall also be designed to remove any contaminants or impurities from the water before it is reused, as these can cause problems with equipment or product quality.

- Document the design of water systems and provide written operating instructions that address subsequent monitoring and control. This documentation and instruction shall be kept up to date and made available to all personnel involved in the operation and maintenance of the water system.

- The operating instructions shall also include information on how to respond to potential problems or emergencies, including procedures for shutting down the system, isolating affected areas, and addressing any potential safety hazards.

4.16. **Routine Maintenance:** Manufacturers of processing and support equipment shall provide written instructions for the routine care and preventive maintenance of the equipment and its components. These instructions shall be clear, concise, and easy to understand, and should be made readily available

to all personnel responsible for the operation and maintenance of the equipment.

- The instructions shall cover all aspects of routine care and preventive maintenance, including cleaning procedures, lubrication requirements, and inspections for wear and damage.

- They shall also include recommendations for the frequency of maintenance tasks and the use of any special tools or equipment required for maintenance.

- Additionally, the instructions shall provide guidance on how to identify potential problems and how to troubleshoot and address any issues that may arise during the operation of the equipment.

- This may include instructions on how to perform diagnostic tests, how to identify and replace faulty components, and how to adjust settings and parameters to optimize performance.

4.17. Preventive Maintenance: Preventive maintenance is an essential component of ensuring optimal performance and longevity of processing and support equipment.

- Facilities can choose to either conduct the maintenance program in-house or contract it out to the equipment manufacturer or other qualified service companies.

- Regardless of the option chosen, it is essential to ensure that the preventive maintenance program is comprehensive, consistent, and carried out regularly to prevent equipment damage, breakdown, and safety hazards.

- Facilities shall also keep detailed records of all maintenance activities, including dates, tasks performed, and any repairs or replacements carried out.

- To ensure optimal performance and longevity of processing and support equipment, it is crucial that they are inspected and cleaned in accordance with the instructions provided by the manufacturer.

- The inspection process shall be carried out at predetermined intervals and should involve a detailed examination of all the equipment's components to identify any signs of wear or damage.

- Any worn-out or damaged parts shall be immediately replaced or repaired to prevent any further damage or safety hazards.

- It is also important to note that the frequency of maintenance may need to be adjusted based on the equipment's usage patterns and environmental conditions.

- Cleaning procedures shall be carried out regularly to prevent any buildup of debris, contaminants, or other residues that could negatively impact the equipment's performance or cause safety hazards.

- Proper cleaning methods shall be used as recommended by the manufacturer to avoid any damage to the equipment.

- Replacing door gaskets and other expendable parts shall be done by qualified personnel who are trained and experienced in performing these tasks.

- Replacement shall be done according to the manufacturer's instructions, which will typically provide guidelines for the recommended replacement schedule and procedures.

- Certain maintenance tasks that require specialized tools or calibration equipment shall be performed by qualified service personnel, such as the equipment manufacturer, the manufacturer's representative, or another qualified service facility.

- Engaging qualified personnel for these tasks is essential to ensure that the equipment is maintained correctly and safely.

- Facilities shall establish a maintenance schedule that includes both routine maintenance tasks that can be performed in-house and a plan for engaging qualified service personnel for complex maintenance tasks.

4.18. Unscheduled Maintenance: Prompt replacement of worn, malfunctioning, or broken parts is essential to prevent equipment failure, reduce downtime, and ensure efficient and effective operation of processing and support equipment.

- Facilities shall establish a system for identifying and replacing defective parts promptly, including regular inspections, availability of spare parts, and qualified personnel responsible for replacement.

- When worn, malfunctioning, or broken parts are identified in processing and support equipment, it is important to ensure that the equipment is not used until the necessary repairs have been made.

- Lock-out tag-out procedures and other safety precautions shall be observed during maintenance activities to prevent injury, equipment damage, and potential contamination.

- Ensure that repairs requiring specialized tools or calibration equipment are performed by qualified personnel with the necessary expertise and resources. This may involve contacting the equipment manufacturer or a qualified service facility to perform the necessary repairs.

4.19. **Calibration:** It is important to calibrate processing and support equipment periodically from any accredited lab traceable to ILAC Signatory members to ensure that they are operating within the required specifications and tolerances. The frequency of calibration may vary depending on the type of equipment, the manufacturer's recommendation, usage and age of the equipment and it shall be performed as specified in the manufacturer's instruction manual.

4.20. **Records:** Keeping a maintenance record for each piece of equipment is important to track its maintenance history and ensure that it is operating safely and efficiently.

- The maintenance record shall include information such as the equipment's make and model, serial number, and installation date.

- It shall also include the maintenance and repair history of the equipment, including dates of service, parts replaced, and any repairs or adjustments made.

- The maintenance record shall be easily accessible to authorized personnel, such as maintenance technicians, supervisors, or regulatory inspectors.

- It shall be in the form of a logbook or electronic record, but it shall be accurate, up-to-date, and legible. When keeping maintenance records for equipment, the following information shall be recorded:

- **Equipment identification:** Make, model, serial number, location and installation date of the equipment shall be recorded for easy identification.

- **Maintenance History:** The dates of all maintenance and repair work shall be recorded along with details of the date of service request, service requested, service authorized by, reason for service request and work performed. This can include replacement of parts, adjustments, calibration, and cleaning.

- **Parts and Materials Used:** Record the parts, materials, and supplies used during maintenance and repair work, including the manufacturer, model number, and serial number of the parts.

- **Technicians Involved:** Record the names and signatures of the technicians involved in maintenance and repair work, as well as their qualifications.

- **Calibration and Testing Results:** Record the results of any calibration and testing procedures performed on the equipment, including the date of the test and the technician who performed it.

- **Inspection Reports:** If the equipment is subject to regulatory inspection, record the results of the inspections and any corrective actions taken to address any identified deficiencies.

- **Equipment Downtime:** Record the amount of time the equipment is out of service for maintenance or repair work.

5. Human Resource Requirements: This section defines requirements for staff qualifications, training, and education as well as minimum criteria for personnel health and personal hygiene. All aspects of processing in a healthcare textile processing facility shall be performed correctly and be supervised by knowledgeable personnel.

5.1. Qualification Criteria of Staff: The qualification criteria for staff working in healthcare textile processing facilities shall vary depending on the specific job duties and responsibilities. Below are qualifications for Supervisors/ managers, Technical and non-technical staff:

- **Supervisors/ Managers:** Supervisors at healthcare textile processing facilities typically require a higher level of qualification compared to the general staff. Processing multiple-use healthcare textiles is a multistep process that shall be supervised by a team of professionals who have the knowledge of the properties of multiple-use healthcare textile products, equipment operations, principles of infection prevention and control, and principles of sterilization to ensure that the textiles are properly cleaned and sterilized before being used again. Following shall be the qualification criteria of Supervisors/ Managers:

    - Supervisors/ Managers shall have a degree in engineering of any stream/ bachelor's degree in any stream including bachelor's degree in healthcare administration or healthcare management/ diploma in any mechanical stream.

    - Supervisors/ Managers having Degree in Textile Technology shall have minimum experience of one years in related field and in any other stream of Engineering shall have minimum experience of two years in a related field, Supervisors having bachelor's Degree in any stream shall have minimum experience of three years in a related field, Supervisors having Diploma in mechanical stream shall have minimum experience of four years in a related field.

    - Supervisors/ Managers shall correctly interpret manufacturers' instructions for equipment operation, recognize process and equipment malfunctions, develop and correctly interpret policies and procedures for handling, transporting, sorting, laundering, inspecting, preparing, and sterilizing/ disinfecting multiple-use healthcare textiles based on recognized standards and guidelines. Supervisors/ Managers shall be familiar with the relevant Product standards & regulatory requirements.

    - Supervisors/ Managers shall have a good understanding of laundry processes, equipment, and technologies. Supervisors/ Managers shall have leadership skills to manage a team effectively. This includes the ability to delegate tasks, provide guidance, and motivate staff. Effective communication skills are important for Supervisors/ Managers to work effectively with other employees, interact with customers, and manage relationships with suppliers.

    - Supervisors/ Managers shall have a good understanding of all the processing equipment, processes, and technology including laundry

process, medical device packaging process and/or sterilization process. This includes knowledge of washing machines, dryers, and ironing equipment, as well as the proper use of detergents and chemicals. Supervisors/ Managers may be required to have good customer service skills, such as the ability to answer questions, handle complaints, and ensure customer satisfaction.

- Successful completion of a government certified skill course in the field of Commercial Laundry/ Medical Device Manufacturing shall be a preferred criteria for selection of Supervisors/ Managers.

- **Technical Staff:** The qualifications for technical staff of a healthcare textile processing unit will depend on the specific roles and responsibilities of the position.

  - A bachelor's degree (science preferred) or diploma in any stream (mechanical preferred) is required for technical positions in healthcare textile processing units. Technical staff shall also have completed training programs in textile processing, quality control, and safety procedures.

  - Technical Staff having bachelor's Degree in any stream shall have minimum experience of two years in a related field, Technical Staff having Diploma in mechanical stream shall have minimum experience of three years in a related field.

  - Technical staff shall have experience in textile processing, including experience in operating textile processing equipment such as dyeing, finishing, and sewing machines.

  - They shall also be familiar with textile production quality control procedures, such as inspections and testing. Technical staff shall have a good understanding of processes and be proficient in the use of processing equipment. They shall also be able to troubleshoot equipment malfunctions and implement repairs.

  - Technical Staff shall have the ability to run safely and correctly operate assigned processing equipment, safely and correctly perform assigned processing activities, including handling, transporting, sorting, laundering, inspecting, preparing, and/ or sterilizing multiple-use healthcare textiles, understand the potential device defects, safety hazards, and other

consequences that could result from the improper performance of their specific jobs, understand the risk of injury that a faulty/ defective healthcare garment could pose to end users and/or patients.

- Technical staff must have good communication skills to interact with other members of the production team, such as operators, supervisors, and quality control personnel.

- **Non-technical Staff:** The qualifications for non-technical staff in a healthcare textile products processing unit will depend on the specific roles and responsibilities of the position.

  - Non-technical staff in a healthcare textile products processing unit shall have matriculation as minimum qualification. Some positions may require additional education or training, such as an associate degree/ diploma in business, logistics, or a related field.

  - Non-technical staff having diplomas in any field shall have minimum experience of one year in a related field, and non-technical staff having matriculation/ high school qualification shall have minimum experience of two years in a related field such as customer service, logistics, packaging or inventory management.

  - Non-technical staff must have good communication skills to interact with customers, suppliers, and other members of the production team. They must be able to communicate clearly and effectively in person, by phone, and by email. Non-technical staff must be detail-oriented and able to follow procedures and guidelines precisely.

  - They must be able to identify and correct errors and discrepancies in orders and shipments. Non-technical staff must have basic computer skills to operate inventory management software, shipping software, and other office applications.

5.2. Training & Development: Periodic training and education of staff for healthcare textile products processing are essential to ensure the safety and quality.

- Staff shall receive training on the standard operating procedures (SOPs) for each assigned process. This shall include instructions for handling equipment, and processing soiled textiles, quality control measures, and safety procedures.
- Staff must receive training on safety procedures for handling equipment, chemicals, and hazardous materials. This includes training on the proper use of personal protective equipment (PPE) and procedures for emergency response.

- Staff must be trained on quality control procedures to ensure that the regulatory requirements and manufacturers' guidelines are met. This shall include training on inspection procedures, testing protocols, and record-keeping. Staff must receive training on the proper use and maintenance of the equipment used. This shall include training on operating procedures, troubleshooting, and maintenance procedures.

- Non-technical staff must receive training on customer service procedures, including communication skills, conflict resolution, and problem-solving. Staff shall be encouraged to participate in ongoing training and education programs to keep up with advances in technology, quality control standards, and regulatory requirements.

- To ensure that all aspects of processing are performed correctly, staff shall receive extensive training on proper sterilization techniques, including how to prepare, package, and sterilize medical instruments and equipment. Staff shall also receive ongoing education and training to stay up-to-date with the latest advancements in sterilization technology and best practices.

5.3. Health & Hygiene: Maintaining good health and personal hygiene is crucial for staff to prevent the spread of infections and maintain a safe and healthy work environment. Developing written policies on personal hygiene and communicating them to employees is essential to ensure that all staff members understand the importance of maintaining good personal hygiene practices.

- A pre-employment health check shall be mandatory to assess the health status of a potential employee before they are hired. This is to ensure that the employee is physically and mentally capable of performing the job duties and to prevent any potential health and safety risks to themselves and others in the workplace.

- It's important to note that pre-employment health checks must comply with the relevant laws and regulations, including those related to privacy and discrimination. Employers must also ensure that the health check is job-related and consistent with business necessity, and that all candidates are treated equally.

- The policy shall specify that staff must wash their hands frequently with soap and water for at least 20 seconds, particularly before and after handling textiles, before and after breaks, and after using the restroom. Alcohol-based hand sanitizers should also be made available to staff.

- The policy shall specify that staff must wear clean work clothes and avoid wearing jewelry, watches, or other items that could harbor bacteria. Hair shall be tied back, and beards and mustaches shall be kept trimmed and neat.

- The policy shall specify that staff must report any signs of illness, including fever, cough, or other symptoms of infectious diseases, to their supervisor and stay home if they are feeling sick.

- The policy shall specify that staff should avoid eating or drinking in the processing area to prevent contamination of the healthcare textiles. The policy shall specify that all staff members must receive training and education on personal hygiene practices and be informed of any updates or changes to the policy.

- The policy shall define that neither nail polish nor artificial nails should be worn, fingernails shall be kept short and clean and should not extend beyond the fingertips. Uniforms or other garments that become soiled or wet during wear shall be changed immediately.

- The policy must address the reporting, treatment, and disposition of employees who are at risk of acquiring or transmitting infections. Policy on exposures to bloodborne diseases shall be well defined including guidelines on staff who can potentially come into contact with items contaminated with blood or body fluids shall be encouraged to accept hepatitis B immunization or other immunizations that could become appropriate in future.

- Any employee who declines immunization/vaccination shall sign the immunization declination statement (**Annexure-B, AMTZ /HEALTEXPROF/**

ATD/R00). The employer shall have the discretion to reject the candidature if the employee declines immunization/vaccination.

- Hand hygiene policies and instructions in proper hand hygiene procedures shall be conveyed to all employees, especially when policies are more stringent for a particular work area including the soil-sort area and the pack assembly area. Staff shall be instructed to wash/sanitize their hands and remove PPE when they leave the soil-sort area.

- The policy must address the proper disposal of sharps and other biohazardous waste that could have been left inadvertently in soiled textiles for processing. Soiled healthcare textiles shall not be tossed or thrown. The final disposition of sharps and other biohazardous waste must be in accordance with applicable regulations.

5.4. Clothing: All staff members shall wear clean uniforms at the workplace. Professional clothing used shall be changed daily or more often as needed and must be changed if visibly soiled. If the multiple-use uniforms for staff gets contaminated by blood or body fluids then it must be laundered & cleaned at the designated facility.

- Shoes to be worn at the facility shall be clean to maintain hygiene and prevent the spread of contaminants. Additionally, the shoes should have non-skid soles to prevent slipping on wet or slippery surfaces, which can lead to accidents and injuries and the shoes should be sturdy enough to protect the feet in case an item falls on them, which is a common hazard.

- All head and facial hair, excluding eyebrows and eyelashes, should be covered with a surgical-type hair covering. This is to prevent hair from falling onto surfaces, equipment, or products and potentially contaminating them. It can also help to prevent hair from coming into contact with hazardous substances or equipment, such as chemicals or machinery.

- Individuals working in these areas shall not wear any jewelry or wristwatches. This is to prevent the risk of foreign objects, such as metal or gems from jewelry, contaminating the healthcare textiles being processed. Jewelry is not easily or routinely cleaned daily, it can harbor microorganisms, and it can cause holes in gloves or other barrier protection. Additionally, jewelry and wristwatches can pose a risk of getting caught in machinery or equipment, causing injury to the wearer or damage to the equipment.

- A policy shall be made to determine by each individual facility the use of cover apparel by employees when they leave the department to travel to other areas of a facility. This is because different facilities may have different requirements based on their specific circumstances and the type of the process carried out at the facility.

- Employees shall change into street clothes whenever they leave the facility or travel between buildings. This is to prevent the spread of contaminants from the healthcare facility into the surrounding community or other buildings on separate campuses. Changing into street clothes can help to remove any potentially contaminated clothing or equipment and prevent the spread of germs or hazardous materials. Additionally, it can help to maintain a professional appearance when employees are interacting with the public outside of the healthcare facility.

- **Personal Protective Equipment:** A policy on exposure control shall be defined for the right PPE (Personal Protective Equipment). The policy for PPE shall address the requirements such as but not limited to, use of normal gloves, heavy duty protection gloves, protective apron/ gown, face masks, face shields, eye protection and shoe covers.

    - Employees shall be instructed on when and how to use the PPE for the area in which they are working and how the PPE is to be removed and cleaned or disposed of. The specific PPE requirements may vary depending on the type of process and the chemicals used in the laundering process. It is important to follow all established safety protocols and wear the appropriate PPE to ensure the safety and health of staff.

    - Regular reviews of PPE policies shall be conducted to ensure that they are up to date and reflect the most current safety standards and best practices. Additionally, regular training and updates on PPE policies can help ensure that employees are using the appropriate equipment and attire in the correct manner to prevent workplace injuries or accidents.

    Relevant records pertaining to the above requirements shall be maintained.

6. **Handling Practices for Healthcare Textiles:** This section is about handling and receiving of soiled healthcare textiles and also about receiving and handling of newly purchased healthcare textiles.

- It is essential to handle used/soiled healthcare textiles with the utmost care to prevent the spread of infections and maintain a safe and healthy environment for staff, users and patients.

- Used/soiled healthcare textiles shall be handled with appropriate precautions, regardless of whether or not they are visibly soiled. This shall include appropriate handling, segregation, transport, and cleaning procedures to prevent the spread of bacteria, viruses, or other harmful pathogens. Failure to handle used/soiled healthcare textiles with appropriate precautions can result in the transmission of infections, which can be particularly dangerous for vulnerable populations such as patients in healthcare facilities.

- 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. This shall include establishing protocols for handling contaminated textiles, properly disposing of waste materials, and maintaining appropriate cleaning and sterilization practices.
- Regular training and updates on policies and procedures are also essential for ensuring that all individuals involved in healthcare textile processing are aware of best practices and comply with established guidelines.

- **Newly Purchased Healthcare Textiles:** It is essential to verify the identity of newly purchased healthcare textiles. Many products may have similar appearances but different functional performance characteristics, and using the wrong product can compromise the safety and effectiveness. It ensures that they are the correct product and meet the specified requirements for use in the healthcare facility. This includes verifying the type of material, size, and any other specifications outlined in the product purchase agreement. Failure to verify the identity of incoming textiles can result in the use of substandard or incorrect products, which can compromise the safety and effectiveness of healthcare/ surgical procedures.

    - All newly purchased healthcare textiles shall be removed from their external shipping cartons before they are introduced into laundry areas. Removing items from external shipping cartons helps prevent the spread of contaminants and reduces the risk of contamination in the laundry environment. External shipping cartons may have come into contact with various contaminants during transportation and introducing them into the

laundry area can increase the risk of contamination for both personnel and healthcare textiles.

- There shall be separate areas for receiving and unboxing newly purchased healthcare textiles, as well as holding these healthcare textiles before their first laundering. Having separate areas for these activities helps reduce the risk of contamination by keeping newly purchased healthcare textiles separate from used textiles and other potentially contaminated materials. By having a separate area for receiving and unboxing new healthcare textiles, it is easier to ensure that these textiles are properly identified, labeled, and stored before they are laundered.

- All newly purchased healthcare textiles after their removal from shipping cartons and packaging shall be laundered. Laundering newly purchased healthcare textiles before use will help in removing any residual contaminants that may be present on the surface of the item from the manufacturing and transportation processes. Laundering will also help to soften new items and can improve their absorbency, which is important for some types of healthcare textiles.

- It is mandatory to purchase the products from a licensed manufacturer for all regulated healthcare textile (classified as Medical Device) products if the facility is sourcing the Newly Purchased healthcare textiles on behalf of the user. And if the facility is manufacturing these products, then it is mandatory for the facility to comply with regulatory requirements for all healthcare textiles which are classified as Medical Devices.

- **Handling Used/Soiled Healthcare Textiles:** Proper handling of used or soiled healthcare textiles is critical in preventing the spread of infectious agents. Following established protocols and taking appropriate precautions can help to ensure the safety of those handling these materials.

- **Collection of Used/ Soiled Healthcare Textiles:** All used healthcare textiles including gowns, drapes, wrappers, towels, and patient-care textiles, after each use shall be considered as contaminated. Used/ Soiled healthcare textiles shall be handled as little as possible to reduce the risk of spreading infectious agents. When handling these textiles, healthcare workers shall take appropriate precautions to minimize the risk of contamination and infection.

- One way to reduce handling is to place the textiles directly into a designated, leak-proof container immediately after use. This container shall then be properly labeled and stored in a designated area to prevent accidental exposure to others, till the time it is transferred to the healthcare textile soil-sort area. At soil-sorting areas, personnel protected by appropriate attire and trained in handling potentially infectious soiled textiles shall initiate sorting procedures.

- Labeling of used/ soiled healthcare textiles is an important aspect of handling these materials. Labels help to ensure that used/ soiled healthcare textiles are properly identified, segregated, and processed in accordance with applicable regulations. Labels shall include information such as the date of collection, the name of the facility or department where the textiles were collected, and the level of contamination (i.e., whether the textiles are contaminated with blood or other potentially infectious materials).

- Labels may also include information about the type of textiles being collected (e.g., surgical gowns, linens, etc.) and any other relevant information that may be necessary for proper handling and processing. Labels shall be attached securely to the outside of the container or bag containing the used/ soiled healthcare textiles. They should be legible and clearly visible and should not be removed until the textiles have been properly processed and laundered.

- The use of color-coded labels or tags can also be helpful in ensuring that used/ soiled healthcare textiles are segregated by product type and level of contamination. For example, red labels may be used for textiles contaminated with blood or other potentially infectious materials, while yellow labels may be used for textiles that are less contaminated.

- Used/ soiled healthcare textiles shall not be sorted or rinsed in patient care areas. Doing so can increase the risk of cross-contamination and the spread of infectious agents to patients, healthcare workers, and other individuals in the area.

- It is necessary to segregate all sharps used during healthcare procedures from the used/ soiled healthcare textiles before they are packed for transferring to soil-sort areas.

- **Transport of Used/ Soiled Healthcare Textiles:** Transportation of used/ 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.

    - 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. Containers shall also be securely closed and properly sealed to prevent any leaks or spills during transport and must be capable of preventing soak-through or leakage of liquids to the outside of the containers. When transporting containers, they shall be handled with care and stored in a secure location to minimize the risk of damage or accidental exposure.

    - Reusable collection containers, used for collecting and transporting used/ soiled healthcare textiles, shall be made of materials that can withstand the decontamination process without being damaged or losing their effectiveness. These containers shall be properly labeled and maintained to prevent cross-contamination. Containers designed for single use, such as sharps containers, shall be made of materials that can be safely disposed of following use. These materials may include plastics or other materials which can be disposed of through incineration, autoclaving, or other methods that effectively destroy infectious agents and other contaminants. Sharps may also be recycled or otherwise disposed of in accordance with applicable regulations.

    - Biohazardous waste, including sharps, must be disposed of in accordance with regulations. These regulations may specify the type of container to be used, the method of transport and disposal, and other requirements to ensure the safe handling and disposal of biohazardous waste.

    - Transportation procedures shall also include regular monitoring and inspection of transport vehicles and containers to ensure that they are clean, free of damage or leaks, and appropriately labeled. Transport vehicles shall be dedicated to the transport of healthcare textiles and should not be used for other purposes.

    - In addition, transport personnel shall be trained in proper handling procedures and shall wear appropriate PPE, such as gloves and gowns,

masks etc. They shall also be instructed to avoid touching their face or other surfaces during transport and to wash their hands thoroughly after handling used/ soiled healthcare textiles.

- **Sorting System for Used/ soiled Healthcare Textiles:** There are two types of systems that can be used to sort used/ soiled healthcare textiles: pre-sort systems and post-sort systems.

  - Pre-sort systems involve sorting used/ soiled healthcare textiles at the point of use, before they are transported to the laundry soil-sort area. This can involve placing different types of textiles, such as gowns or towels, into separate bags or containers to facilitate sorting and processing in the laundry. Pre-sort systems can be useful in reducing the risk of cross-contamination during transport and handling of soiled textiles.

  - Post-sort systems involve sorting used/ soiled healthcare textiles in the laundry soil-sort area, after they have been transported from the point of use. This shall involve separating textiles based on their type, color, level of soiling, or other characteristics to facilitate processing in the laundry. Post-sort systems can be useful in handling large volumes of soiled textiles efficiently.

  - Both pre-sort and post-sort systems have their advantages and disadvantages, and the choice of system will depend on factors such as the volume of soiled textiles, available space in the laundry area, and capabilities of the laundry equipment and staff.

  - Both pre-sort and post-sort systems require the establishment of classification procedures to assist in employee training and ensure proper grouping of healthcare textiles for laundering, inspection, folding, and pack preparation. Classification procedures can involve sorting soiled textiles by type, color, level of soiling, and other characteristics to facilitate processing in the laundry. For example, gowns may be separated from towels, and heavily soiled healthcare textiles may be separated from those with lighter soil loads. Effective classification procedures can help to improve efficiency and reduce the risk of cross-contamination during processing of healthcare soiled textiles. They can also help to ensure that clean textiles are returned to the appropriate area or department.

- **Pre-sort System:** In pre-sort system, the soiled healthcare textiles are sorted before being laundered. This involves sorting the used/ soiled textiles at the point of use, such as in a designated soiled linen collection area. Pre-sorting can involve separating different types of textiles, such as gowns, drapes, and towels, or grouping textiles by their level of soiling or other characteristics. This helps to streamline the laundry process and ensure that the healthcare textiles are properly cleaned and disinfected. By sorting the textiles at the point of use, staff can ensure that the textiles are properly classified and labeled before being transported to the laundry.

    - There are several types of classification procedures that can be employed when sorting soiled textiles. The specific procedures used will depend on the needs and resources of the healthcare facility, as well as the types and volumes of textiles being processed. Some common types of classification procedures are Sorting by type, sorting by color, sorting by level of soiling, sorting by location and sorting by date.

    - Effective classification procedures are essential for ensuring that soiled textiles are properly processed and that clean textiles are returned to the appropriate area or department. It is important to establish clear protocols and procedures for classification, and to train staff on these procedures. Staff shall be provided with the necessary equipment, such as sorting bins and labeling systems, to ensure that textiles are properly sorted and processed.

- **Post-sort System:** In post-sort systems, the various categories of products and materials are sorted before they are laundered, just like in pre-sort systems. The difference between pre-sort and post-sort systems is when the sorting occurs in the overall process of handling used/ soiled healthcare textiles. The purpose of post-sort systems is to minimize the handling of used/ soiled healthcare textiles and reduce the risk of cross-contamination during the transportation process. Post-sort systems can also be useful in facilities with limited space for sorting and storage of used/ soiled healthcare textiles.

    - The degree of soiling, the fiber content of the products, and the type of soiling will affect the processing required for soiled textiles. Heavily soiled textiles may require additional pre-treatment, such as soaking or spot cleaning, before laundering to ensure that all soil is removed. Textiles with certain types of soil, such as blood or bodily fluids, may require special handling or processing to ensure that all pathogens are destroyed.

- The fiber content of the textiles is also important to consider. Some fibers, such as cotton and polyester, are more durable and can withstand high temperatures and harsh chemicals, while others, such as silk or wool, may require gentler processing to avoid damage. In addition, the type of soiling can affect processing requirements such as, textiles soiled with infectious waste may require special handling and processing to ensure that all pathogens are destroyed, while textiles soiled with chemicals may require special treatment to remove the chemicals.

- Segregation of products allows for customization of laundry formulas based on the mix of products in the system and the types of soils encountered. This is because different types of textiles and soils may require different laundering processes and formulas in order to achieve optimal cleaning and disinfection. Increasing the amount of segregation by specific product types can lead to greater work efficiency and improved quality control during textile processing operations, ultimately resulting in higher-quality, more effective textile processing and reduced risk of infection transmission.

- **Handling Textiles used during Radiotherapy:** Healthcare textiles used during radiotherapy, such as gowns, linens, and towels, require special handling and washing to ensure they are properly disinfected and free of any radioactive particles. The following steps can be taken to handle and wash healthcare textiles used during radiotherapy:

  - **Segregation:** Textiles used during radiotherapy shall be segregated from other laundry to prevent contamination.

  - **Handling:** When handling textiles, wear gloves and use proper personal protective equipment to prevent exposure to radioactive particles.

  - **Drying:** Dry the textiles at a high temperature to further disinfect and eliminate any remaining radioactive particles.

  - Processing facilities shall have policies and procedures in place for the handling and washing of healthcare textiles used during radiotherapy and provide appropriate training to staff to ensure compliance with these guidelines.

7. **Laundry recommendations:** Processing of multiple-use Healthcare textiles is a complex task that necessitates specialized equipment, ample space, well-trained personnel who receive ongoing training, and constant quality assurance monitoring. The processing of healthcare textiles can be carried out by an internal operation such as an in-house or on-site or on-premise laundry OPL (may be owned and operated by the hospital or by another outsourcing agency), external off-site hospital-owned facility, or shared laundry service, depending on the healthcare organization. Alternatively, the task may be outsourced to an off-site commercial laundry or to a facility that provides finished sterile/ non-sterile healthcare textile packs.

   This section is about the laundry processes such as washing, extracting & drying etc. It is necessary to follow the wash care instructions provided by the finished healthcare textile manufacturer. Before using alternative washing and drying procedures, it is important to consult with the manufacturer of the finished healthcare textile product and also to ensure that performance attributes of the finished healthcare textiles are met after laundering. Formalizing internal work procedures and laundry formulas is essential for each facility to achieve consistent and dependable results.

   The use of home washers for processing healthcare textiles is strictly prohibited because home washers are not designed to meet the rigorous requirements of processing healthcare textiles. Healthcare textiles require specialized cleaning and processing techniques to ensure that they are free of all contaminants, including blood, bodily fluids, and other potentially infectious materials, OPIMs. Home washers may not be able to achieve the high temperatures required to effectively remove these contaminants and may not have the appropriate disinfecting agents needed to kill all potentially harmful microorganisms. In addition, home washers may not be able to provide the mechanical action needed to remove all debris from the healthcare textiles, which can compromise their effectiveness.

7.1. **Washing Procedures:** Each step of the washing process shall be described in detail, including the type, concentration and dosage of chemicals used, the temperature and duration of each cycle / step, and any other relevant parameters as per the Validated Process defined from time to time in the Quality Control Program. The process shall also be monitored and controlled to ensure that it is effective and consistent, and any deviations or issues shall be addressed promptly. Different classifications of healthcare textiles may have different requirements for the washing process, depending on their intended

use and the type and level of contamination they are likely to encounter. It is important to follow industry standards and guidelines for each classification to ensure that the healthcare textiles are properly cleaned and disinfected, and that patient safety is not compromised.

- **Washing Process:** The washing process involves several elements working together to effectively clean and decontaminate soiled textiles. It is a combination of mechanical systems, water flow, water temperature, time and chemicals including detergents and certain other types of chemicals. Commercial washing machines typically have a range of settings and controls that can be adjusted to optimize the washing process for different types of textiles and levels and types of soiling or contamination.

- Modern commercial washing machines often use microprocessors to automatically control the different settings and processes, based on pre-programmed instructions. The microprocessor can monitor the temperature, water flow, chemical dispensing, and other factors, and adjust the settings as needed to ensure that the fabrics are properly cleaned and / or disinfected and sanitized and protected.

- In older models of commercial washing machines, punch cards were commonly used to control the washing process. These cards would be pre-programmed with instructions for the desired wash cycle, and then inserted into the machine to initiate the process. As the machine progressed through the cycle, it would read the information from the card to determine the appropriate settings for each step.

- To ensure that each load of laundry is properly cleaned and protected, it is important to have a clear and detailed laundry formula that specifies the appropriate process settings for each step of the washing process. This formula shall be translated into a machine-readable format, such as a punch card or a unique formula number for use in a microprocessor-controlled system.

- The laundry formula shall clearly define Water level, water temperature, processing temperature, duration of the step/ process, type of chemical & amount of chemical.

    - **Wash Load Process:** Loading of washing equipment in healthcare textile laundry is an important step in the textile processing cycle that can impact the effectiveness of the cleaning and disinfection process. It is important

to follow industry standards and guidelines for loading to ensure that the textiles are properly cleaned and disinfected and that the equipment operates efficiently.

- Before starting the washing cycle, inspect the load to ensure that the textiles are properly positioned for free circulation. Adjust the load if necessary to ensure that the textiles have adequate space to move freely. It is necessary to not load the washer unit beyond 90% of its rated capacity provided by the washer manufacturer.

- Under-loading the washing equipment can also compromise the effectiveness of the cleaning and disinfection process by allowing excessive movement of the textiles, reducing the exposure of the textiles to the cleaning agents, and increasing the risk of tangling or damage to the textiles. Underloading also leads to wastage of water, chemicals and electricity.

- Overloading the washing equipment can compromise the effectiveness of the cleaning and disinfection process by preventing adequate mechanical action, reducing the exposure of the textiles to the cleaning agents, and increasing the risk of tangling or damage to the textiles.

- The order in which the textiles are loaded can impact the effectiveness of the cleaning and disinfection process. Generally, heavier items such as bed linens should be loaded first, followed by lighter items such as gowns and drapes. The textiles should be placed in the washing equipment according to the manufacturer's instructions and any industry standards or guidelines. This may include placing textiles in specific compartments or sections of the equipment to ensure that they are processed properly.

- Consistency in loading can help ensure that each load is processed consistently and effectively. This includes ensuring that textiles are loaded in the same orientation, that the same number of items are loaded in each cycle, and that the same cycle is used for each load of a specific classification.

- Choose the appropriate cycle for the load to ensure that the textiles are properly cleaned and disinfected. This may include selecting a

cycle with appropriate water temperature, cycle time, and chemical concentrations.

- Textiles should be loaded in a way that avoids tangling or bunching, which can restrict the flow of water, detergent, or disinfectant through the load. This can be achieved by loading textiles in a consistent orientation or using loading aids such as mesh bags.

- **Flushing:** In the washing process, the flushing step (also called the prewash or soaking step), is designed to remove bulk soils (which adhere loosely to the surface of the textiles) from the textiles being washed. During the flushing step, large particles of dirt, debris, and other contaminants are rinsed away from the fabric, helping to prepare it for the more intensive cleaning steps that follow.

  - The flushing step typically involves a combination of water flow, temperature, and mechanical action, which work together to loosen and remove the bulk soils from the fabric. The specific settings used during the flushing step will depend on the type of textiles being washed and the level of soiling or contamination. In some cases, some chemicals might be added to the water during the flushing step.

  - The flushing step is typically performed using high water levels to ensure that bulk soils are effectively removed from the textiles being washed. The use of high-water levels creates a strong water flow that helps to loosen and rinse away dirt, debris, and other contaminants from the fabric.

  - The water temperature during the flushing step is typically set at a lower temperature range, between 32°C (90°F) and 46°C (115°F), to avoid setting blood and embedded stains. This is because higher temperatures can cause some types of stains, particularly protein-based stains like blood or dairy, to set into the fabric and become more difficult to remove.

  - By using lower water temperatures during the flushing step, the risk of setting stains is minimized, while still allowing for effective removal of bulk soils from the textiles being washed. Additionally, lower water temperatures can help to reduce energy costs associated with heating the water, making the washing process more energy-efficient overall.

- After the flushing step is complete, the washing machine will typically proceed to the main wash, which involves a more intensive cleaning process using detergent and other chemicals to remove stubborn stains and contaminants from the fabric. By removing bulk soils during the flushing step, the main wash can be more effective, and the textiles being washed can be cleaned more thoroughly and efficiently.

- **Breaking:** The breaking step is a critical stage of the washing process. It is a part of the main wash process. Breaking (also called building-up or boosting) is the name given to the activity of adding to the wash-water during the main wash step, chemicals that produce an alkaline pH, such as alkalis or alkaline salts. Alkalis or alkaline salts added to the wash-water help enhance soil-removal and cleaning performance. Alkalis or alkaline salts, which are used as additives or auxiliaries during the main wash, work by breaking down and neutralizing acidic soils, such as those from food, sweat, and other organic materials, making them more soluble and miscible with water and easier to remove from the fabric.

  - The breaking step typically involves a combination of water flow, temperature, and mechanical action, which work together to agitate and scrub the fabric, helping to dislodge and remove soils from the textile. The specific settings used during the breaking step will depend on the type of fabric being washed and the level of soiling or contamination.

- **Main Washing:** The main wash, also known as the suds stage, is the most important stage of the washing process. Alkalis or alkaline salts are added to the wash-water during this stage as additives or auxiliaries. The most important chemical used during the main wash is the detergent, which contains a surfactant or a combination of different surfactants and various other chemicals to enhance soil-removal, ensuring superior cleaning performance and efficiency.

  - The surfactants in the detergent help lift and suspend soils in the wash water, preventing them from re-depositing onto the fabric during the main washing process.

  - Some detergents also contain other chemicals, such as enzymes or bleach, which further enhance soil-removal and cleaning

performance, depending on the type of fabric being washed and the type of soiling and the degree of soiling or contamination. In some cases, these chemicals (enzymes and bleach) may also be added externally during the main wash step.

- During the suds stage, the washing machine will typically agitate the fabric using a combination of water flow and mechanical action, which work together to help dislodge and remove soils from the textile.

- The main wash step involves a combination of chemical action, mechanical action, temperature (often up to 70 Celsius) and water flow to help loosen and remove soils and stains from the fabric. Chemical action is provided by the detergent and other cleaning chemicals that are added to the wash water, including alkalis or alkaline salts, enzymes, and bleach. These chemicals work to break down and neutralize soils, making them more soluble and miscible with water and easier to remove from the fabric.

- Mechanical action is provided by the washing machine's agitator or drum, which helps agitate and scrub the fabric, dislodging and removing soils from the textile. The mechanical action also helps create friction between the fabric and the washing machine's drum or agitator, which can help further loosen and remove soils and stains.

- Water flow is also an important factor during the main wash step, as it helps rinse away soils and prevent them from re-depositing onto the fabric during the washing process. The washing machine's pump helps to circulate the wash water, creating a strong water flow that helps to lift and suspend soils in the water and carry them away from the fabric.

- Solvents are sometimes added to the laundry detergents and other cleaning products to help remove stubborn stains and soils from fabrics. These solvents are organic compounds that can dissolve or break down certain types of soils and stains, such as grease, oil, and ink. Certain other types of solvents are often used in dry cleaning processes. These solvents are used in isolation and not in combination with the typical water-based washing systems based on detergents, alkalis, alkaline salts, enzymes and bleaches. However,

such drycleaning processes and solvents are less commonly used in healthcare textile laundry process applications.

- Enzymes, on the other hand, are naturally occurring proteins that can break down specific types of soils and stains, such as proteins, starches, and fats. Enzymes are commonly used in laundry detergents to help break down and remove these types of soils and stains from fabrics. Some common types of enzymes used in laundry detergents include proteases, amylases, and lipases. Enzymes are generally considered safe and effective for use in laundry detergents, and many consumers prefer laundry detergents that contain enzymes for their superior stain-fighting power. However, some people may be allergic to certain types of enzymes, so it's important to read manufacturer's instructions on product labels carefully and follow all safety precautions when using enzyme-containing laundry detergents.

- **Bleaching:** Bleaching is a process that involves the use of oxidizing agents, such as chlorine bleach or hydrogen peroxide, to disinfect items and/or to remove or reduce stains.

  - Oxidizing agents work by breaking down and oxidizing the chemical bonds in certain types of soils and stains, making them more soluble and easier to remove from the fabric. Oxidizing agents can also help to kill bacteria and other pathogens on the fabric, making bleaching a common method for disinfecting and sanitizing laundry items.

  - Chlorine (Sodium Hypochlorite) bleach is a commonly used oxidizing agent in laundry applications, and it can be effective at removing tough stains and disinfecting items. However, chlorine bleach can also be harsh on fabrics and may cause damage or discoloration if not used properly. It's important to follow all safety instructions and product labeling when using bleach or other oxidizing agents in laundry applications.

  - Hydrogen peroxide is another commonly used oxidizing agent in laundry detergents and other cleaning products. It is generally considered safer and less harsh than chlorine bleach, although it may be less effective at removing certain types of stains. Hydrogen peroxide can also be used as a natural alternative to chlorine bleach

for disinfecting and sanitizing laundry items. Hydrogen peroxide is particularly effective in maintaining the whiteness of white textiles.

- Chlorine bleach is often recommended in concentrations of 50 to 150 parts per million (ppm) to help reduce levels of microbial contamination associated with laundering processes. It's important to note that the concentration of chlorine bleach used will depend on a variety of factors, including the type of laundry item being washed, the level of contamination, and the specific bleach product being used. It's also important to follow all safety instructions and product labeling when using bleach or other oxidizing agents in laundry applications, as misuse or overuse can result in damage to fabrics and potential health hazards.

- If alternative bleaching processes are used for disinfection, it's important to verify from the textile product manufacturer to qualify the bleaching agent and/or the entire process to ensure that it is effective and safe for use on their specific products. Qualification of an alternative bleaching process may involve testing and evaluation of the process on various types of fabrics and soil types, as well as verification of its efficacy in reducing microbial contamination.

- **Rinsing:** Rinsing is an important step in the laundering process, as it helps to ensure that all traces of detergent, bleach, and other laundry chemicals are removed from the fabric. This can help to prevent damage to the fabric and to reduce the risk of skin irritation or allergic reactions.

  - Rinsing typically involves several cycles of adding fresh water to the washing machine and agitating the load to help remove any remaining soils and laundry chemicals. The water temperature used during rinsing may be cooler than during the washing or bleaching steps, as cooler water can help to reduce the risk of setting any remaining stains or soils.

  - Residual soils and laundry chemicals left on fabrics after the laundering process can be a source of skin irritation and contamination. They can also compromise the effective barrier performance of certain types of fabrics and liquid-repellent/resistant finishes. Many laundry chemicals, such as detergents, fabric softeners, and bleach, can leave behind residues on fabric after

washing. These residues can contain irritants, allergens, and even harmful chemicals that can cause skin irritation, allergic reactions, or even toxic effects.

- To minimize the risks associated with residual soils and laundry chemicals, it's important to ensure that fabrics are thoroughly rinsed and dried after laundering.

- **Neutralization / Souring:** The souring or neutralization process in laundry refers to a technique used to chemically neutralize alkaline residues from textiles after they have been washed in an alkaline wash-bath or wash-liquor. A laundry sour is an acidic substance, which neutralizes any remaining alkalinity on the fabric and brings the pH of the textile to a level that is compatible with human skin.

  - Alkaline substances used during the main wash, if not removed fully, will leave a residue on the textile and raise its pH level to more than 7. This can cause skin irritation and other issues, especially for people with sensitive skin. Using a laundry sour ensures this doesn't happen.

  - Laundry sours can be made from various acidic substances such as vinegar (which is based on acetic acid), citric acid, oxalic acid, fluoro-silicic acid, or sulfurous acid. Some sours also perform another function: they neutralize and remove residual chlorine bleach and hydrogen peroxide bleach from the textiles.

  - The choice of sour depends on the type of textile being laundered and the desired level of acidity. It's important to follow the manufacturer's instructions when using a laundry sour and to use the appropriate safety precautions, as some acids can be hazardous if not handled properly.

- **Finishing (optional):** Finishing can be the final step in the laundering process, but it's not always necessary. Finishing refers to the process of treating the laundered textile to give it the desired properties such as softness and fluffiness (specially to towels), wrinkle resistance, water repellency, anti-bacterial protection and so on. Finishing can be done through different methods such as chemical treatments, mechanical treatments, or a combination of both.

- **Extraction:** The extraction process in laundry refers to the removal of excess water from the washed textile before drying. There are different methods used for extraction depending on the type of laundry equipment used.

    - In commercial laundry operations, specialized equipment called a washer-extractor is used for the washing and extraction process. These machines can have high-speed spin cycles that can extract up to 95% of the water from the textile, reducing drying time and energy costs.

    - Another method of extraction is the use of a press or wringer, which squeezes water out of the textile between two rollers. This method is typically used in small-scale laundry operations or in home laundry settings. In tunnel washers (also called CBW, continuous batch washers), extraction is done by pressing (squeezing) out excess water using a hydraulic press.

    - It's important to ensure that the extraction process is adequate to remove excess water from the textile to avoid damage or other issues during the drying process. Insufficient extraction can lead to longer drying times, increased energy costs, and decreased textile lifespan. Conversely, over-extraction can cause damage to the textile or the laundry equipment. The appropriate extraction method and speed shall be selected based on the type and condition of the textile being laundered.

- **Drying Process:** Drying is the final stage in the laundering process, where the washed and extracted textile is exposed to heat and air to remove any remaining moisture. Proper drying is essential to prevent mold, mildew, and unpleasant odors from forming on the textile.

    - The most common method of drying textiles is through the use of a clothes dryer. The dryer uses heat to evaporate the moisture from the textile, while the tumbling action helps to prevent the textile from becoming wrinkled or creased. In commercial laundry operations, specialized equipment such as tunnel dryers or conveyor dryers can be used for bulk drying. These machines use hot air to dry large quantities of textiles quickly and efficiently. In some cases, textiles may be air-dried by hanging them outside or indoors on a clothesline or drying rack. This method is more

environmentally friendly but can be less effective and may take longer to dry.

- It's important to ensure that the drying process is appropriate for the type of textile being laundered. Overheating or over-drying can cause shrinkage, fading, or damage to the textile, while under-drying can result in a damp and unpleasant-smelling textile. The manufacturer's instructions and care labels should be followed to ensure that the textile is dried properly and to prevent any damage or adverse effects.

- **Loading:** The loading practices for drying textiles are important in order to achieve efficient and effective drying results, and to ensure the safety of the textiles being dried. Allowing for free circulation of air around the load is important because it helps to distribute heat and moisture evenly throughout the load, which promotes faster and more uniform drying. This is particularly important for larger loads or thicker textiles, which can take longer to dry and may be more prone to uneven drying if airflow is restricted.

    - The specific loading practices required for each textile classification and type of equipment may vary depending on factors such as the material, weight, size, and shape of the textiles being dried, as well as the type of drying equipment being used.

    - It is important to follow the equipment manufacturer's recommendations when drying textiles to ensure that the equipment is used safely and effectively. The manufacturer's recommendations will typically provide guidance on the appropriate loading practices, such as the maximum weight limits and the recommended load sizes and configurations for the specific equipment.

- **Heating:** The first step in the drying process is to deliver heat to the damp load of textiles. Heat is typically delivered through the use of a dryer, which can be powered by electricity, natural gas, propane, or other fuel sources.

    - The heat energy helps to vaporize the moisture trapped in the textiles, turning it into water vapor which is then removed from the dryer through a vent or exhaust system. As the moisture evaporates, the textiles gradually become dry and ready for use. The amount of time it takes to dry the textiles will depend on a variety of factors, such as

the type and thickness of the fabric, the size of the load, and the heat output of the dryer.

- Temperature control is important because different fabrics require different drying temperatures to ensure that they are not damaged during the drying process. For example, delicate fabrics such as silk or wool require lower temperatures to prevent shrinkage, stretching, or damage to the fabric fibers. In contrast, more durable fabrics such as cotton or polyester may require higher temperatures to effectively remove moisture from the fabric.

- Time control is also important because over-drying or under-drying can lead to problems with the final product. Over-drying can cause the fabric to become brittle, stiff, or damaged, while under-drying can result in the retention of moisture that can lead to the growth of mold or mildew. Thus, it is essential to carefully monitor the drying time to ensure that the fabric is dried to the appropriate level of moisture.

- Modern dryers often have built-in sensors and programmable settings that can automatically adjust the temperature and drying time based on the type of fabric being dried. However, it is still important to periodically check the fabric during the drying process to ensure that it is not being over-dried or under-dried.

- **Cooling:** After the drying cycle is complete, it is important to allow the hot, dry load to cool down before handling it to prevent the risk of burns and also to reduce the likelihood of wrinkles.

  - When textiles are subjected to high heat, the fibers become more pliable, making them more susceptible to wrinkling. If the hot, dry load is removed from the dryer and immediately folded or stacked, the weight of the fabric can cause creases and wrinkles to form. Allowing the load to cool down for a few minutes can help to reduce the likelihood of wrinkles and make the textiles easier to handle.

- **Process Control:** Monitoring the laundry process is essential to ensure that the process is running smoothly and producing clean and properly laundered products that meet the needs of end users. The type and frequency of process monitoring for healthcare textiles processing depend on several factors, including but not limited to, volume of textiles processed, age of equipment, type and degree of automation of controls and historical level of consistency of

the process. Process monitoring can be divided into three general categories; Input monitoring, in-process monitoring and output monitoring.

- **Input Monitoring:** The correct use of supplies is an essential part of each laundry formula. When considering laundry supplies, factors to take into account include the chemicals/ detergents used, the delivery system of the pump, the quality of the water being used, and the type and amount of dirty textiles being processed. To ensure proper laundry operations, common monitoring practices involve confirming the appropriate chemical is utilized, ensuring correct timing of chemical injection, accurate delivery through the pump system, consistent water quality, and appropriate processing of soiled textiles in terms of type and load size for specific laundry equipment and formulas as per the Validated Process obtained from Quality Control Program.

- **Chemical Verification:** Chemical verification is an important step in laundry settings to ensure that the correct chemicals are being used in the right concentrations and under safe conditions. All containers of chemicals shall be properly labeled with the name of the chemical, its concentration, and any other important information.

    - Employees shall be properly trained on how to handle chemicals safely and how to use them correctly. If chemicals are being diluted, it is important to verify that the correct amount of chemical is being used and that it is being diluted to the correct concentration. This can be done by using a calibrated measuring device and following the manufacturer's instructions. It may be necessary to test the pH and other properties of the solution to ensure that it is within the correct range. This can help ensure that the solution is effective and safe to use.

    - It is important to have an MSDS (Material Safety Data Sheet) on file for each chemical product that is in use, and to make copies of the MSDS available at the point of use. In addition to having an MSDS on file, it is also important to ensure that the information on the MSDS is up-to-date and accurate. MSDSs shall be reviewed and updated regularly to reflect any changes in the properties or hazards of the chemical, as well as any new safety or regulatory information.

- Proper verification procedures shall be established and followed to ensure that bulk shipments of chemicals are being handled safely and correctly. Chemical verification shall be done before pumping chemicals into storage tanks to prevent mixing or contamination of different chemicals, which can result in hazardous conditions or ineffective treatment processes.

- It is important to keep records of the chemicals used, their concentrations, and any other important information. In addition to labeling secondary containers with the necessary information, it is also important to ensure that the labeling is clear, legible, and durable, and that it is placed in a prominent and visible location on the container.

- pH measurement is an important aspect of laundry chemical management, as many laundry chemicals have a unique pH that affects their effectiveness and safety. The pH of a laundry chemical can affect its solubility, reactivity, and stability, as well as its ability to remove stains and soil from fabrics. Manufacturers typically specify the allowed pH tolerance for their laundry chemicals, which indicates the acceptable range of pH values for the product. This tolerance is important to ensure that the chemical is effective and safe for use, and to prevent damage to fabrics or equipment.

- Specific gravity is an important property of many laundry chemicals that can affect their performance and safety. Manufacturers of laundry chemicals often specify the allowed tolerances for specific gravity, which indicates the acceptable range of specific gravity values for the product. Specific gravity can be measured using a hydrometer or a digital density meter.

- Many chemical suppliers use dyes or colorants to allow for easy identification and differentiation of their products. In addition to aiding in product identification, dyes may also serve other purposes, such as indicating the strength or concentration of a product, or providing a visual cue for safe handling or disposal of the product. When using a chemical product with a dye, it is important to follow appropriate handling and disposal procedures to prevent potential harm to human health or the environment.

- Chlorine bleach is a powerful oxidizing agent that can lose its effectiveness over time as the active chlorine molecules break down. As a result, the concentration of available chlorine in the bleach can decrease, which can reduce its ability to whiten fabrics and disinfect surfaces. The shelf life of liquid chlorine bleach can be affected by factors such as temperature, exposure to light and air, and the presence of contaminants. Routine checks of liquid chlorine bleach shall be performed according to the storage conditions and frequency of use, with more frequent checks needed for bleach that is stored in warm or humid conditions or that is used frequently.

- **Pump Delivery:** Regularly checking the pump delivery system is important for ensuring efficient and safe laundry operations. Pump delivery systems shall be checked on a routine schedule, with more frequent checks needed if the system is used heavily or if there are concerns about its performance. Checking the pump delivery system involves a series of steps, including:

  - **Inspecting the system for leaks or damage:** The first step in checking the pump delivery system is to visually inspect it for any signs of leaks or damage. This can include looking for wet spots, corrosion, or other signs of wear and tear. If any issues are identified, they should be addressed promptly to prevent further damage or potential safety hazards.

  - **Testing the pumps:** The next step is to test the pumps to ensure that they are functioning properly. This can involve running the pumps at different flow rates and pressures, and checking for any unusual noises or vibrations. If any issues are identified, the pumps may need to be repaired or replaced.

  - **Checking the flow rate:** It is important to check the flow rate of the pump delivery system to ensure that it is delivering the correct amount of chemicals to the point of use. This can be done using a flow meter or by measuring the volume of liquid delivered over a set period of time. If the flow rate is not within the desired range, adjustments may need to be made to the system.

  - **Verifying the chemical concentration:** The final step in checking the pump delivery system is to verify the concentration of the chemicals being delivered. This can be done using a chemical test kit or other

appropriate method. If the concentration is not within the desired range, adjustments may need to be made to the system or the chemicals being used.

- **Water Quality:** Laundry facilities use large quantities of water for washing clothes, linens, and other textiles. Maintaining water quality in laundry operations is essential to ensure that the laundering process is effective and that the finished products meet quality standards. Poor water quality can lead to issues such as staining, fabric damage, and reduced effectiveness of detergents and other laundry chemicals. Some common factors that can affect water quality in laundry operations include: Hardness, TDS (Total Dissolved Solids), pH Level, alkalinity-content, & contaminants like iron. To ensure water quality in laundry operations, there are several key steps that can be taken:

  - **Water testing:** Regular water testing can help identify and address any issues with water quality. The main QUANTITATIVE testing parameters are pH, hardness, TDS, alkalinity-content, and iron-content, since they have a significant impact on the suitability of the water for laundry-processes and can also adversely affect certain laundry-processes. It is mandatory to measure and record pH, TDS & hardness of water daily and rest of the parameters every 45 days.

  - **Water softening:** Hard water can cause mineral buildup on fabrics, resulting in fabric damage and reduced textile life. It also severely hampers the performance of some laundry-chemicals. And, it leads to the formation of crusty, scaly deposits in the pipelines and on the parts of the washing machines, thus leading to a wide range of major problems, such as choked pipelines, damage to machine-parts and reduced thermal efficiency. Installing a water softening plant can help remove hardness-causing minerals from the water, resulting in cleaner textiles with a longer life-span. Water with a hardness of more than 50 ppm (parts per million) or 50 mg. / litre shall be softened.

  - **Chemical treatment:** Chemicals such as chlorine, hydrogen peroxide, and ozone can be added to the water to disinfect and remove stains. However, it's important to ensure that the chemicals used are appropriate for the fabrics being washed and that they do not cause any harm to the environment.

- **Proper maintenance of equipment:** Regular maintenance of washing machines and other equipment can help prevent buildup of dirt, grime, and other contaminants that can affect water quality.

- **Use high-efficiency equipment:** Investing in high-efficiency washing machines can significantly reduce water usage and decrease the volume of wastewater generated.

- **Implement a wastewater treatment system:** Installing a wastewater treatment system can help remove contaminants from wastewater before it is discharged into the environment.

- **Use eco-friendly detergents:** Choose detergents and cleaning products that are biodegradable, phosphate-free, and free of other harmful chemicals such as formaldehyde. This can reduce the number of pollutants that are discharged into the environment.

  Note: The chemicals/ detergent used shall comply with the local regulatory requirements.

- **Monitor and control wastewater discharge:** Regular monitoring and testing of wastewater discharge can help identify potential contaminants and ensure that discharge meets applicable water quality standards.

- **Reuse of Water:** Implementing water reuse systems, such as recycling wastewater for use in laundry operations or for irrigation, can help reduce overall water usage and limit the amount of wastewater generated. It is very important to identify the source of water being reused and its quality, as well as any necessary treatments needed to ensure its appropriateness for reuse.

  - Some sources of water that may be suitable for reuse include treated wastewater, stormwater, and greywater (which is water from sources such as sinks, showers, and washing machines).

  - When reusing water, it is essential to ensure that the water is appropriate for its intended use. For example, water that has been used for washing clothes may not be suitable for irrigation or other

non-potable uses due to the presence of detergents, chemicals, and other contaminants.

- It is important to consider the potential risks associated with water reuse, such as the potential for cross-contamination or the risk of exposure to pathogens or other contaminants. Proper treatment and monitoring of the water being reused is must to help mitigate these risks and ensure that the water is safe for its intended use.

- **Loading by Type of Soiled Healthcare Textiles:** It is necessary to determine the correct classification of soiled textiles. Pre-sorting soiled textiles based on their classification, such as heavily soiled, moderately soiled, or lightly soiled, can help ensure that they are cleaned effectively and efficiently.

  Soiled textiles can be classified into different categories based on the type of soil and the source of the textile. Here are some common categories for pre-sorting soiled textiles:

  - **Color:** Sort soiled textiles based on their color, as darker colored textiles may bleed and stain lighter colored textiles during washing.

  - **Fabric type:** Sort soiled textiles based on their fabric type, as different fabrics require different cleaning processes, different water temperature, different soaking methods, different wash cycles & different types of detergents. For example, synthetic surgical gowns have different fabric properties from reinforced surgical gowns, OR towels made of blended fabrics can be soaked but patient uniforms & bed sheets made of cotton fabric can't be soaked.

  - **Soil type:** Sort soiled textiles based on the type of soil present, as different types of soil may require different cleaning methods. For example, textiles with oil-based stains may require a pre-treatment with a solvent or a special type of detergent, while textiles with protein-based stains such as blood or sweat may require enzymatic cleaners.

  - **Water temperature:** Sort soiled textiles based on the recommended water temperature for washing. Some textiles may require cold water, while others may require hot water to effectively remove soil. For example, stretchable scrub suits made of blended fabric & spandex

cannot be washed at higher temperature, otherwise they might lose their elasticity.

- **Source:** Sort soiled textiles based on their source, as textiles from healthcare facilities or industrial settings may require special handling due to the presence of hazardous materials.

- **Loading Size of Soiled Healthcare Textiles:** In addition to pre-sorting, controlling the load size for each laundry formula used is also essential for ensuring proper cleaning and minimizing wear and tear on equipment.

  - When the load size is too large, it can lead to inadequate cleaning, as the detergent and water may not be able to reach all the fabrics properly. On the other hand, if the load size is too small, it can lead to excessive wear and tear on the equipment, wastage of water & chemicals and higher energy costs.

  - To ensure proper cleaning and minimize wear and tear on equipment, it's essential to use the right amount of laundry formula for the load size. This means following the manufacturer's instructions for each laundry formula used, as they typically provide recommended load sizes for optimal cleaning performance. Additionally, it's important to avoid overloading or underloading the washing machine, which can cause mechanical stress on the machine and reduce its lifespan.

  - It's also important to note that different types of fabrics require different load sizes and laundry formulas. By adjusting the load size and laundry formula for each type of fabric, it can be ensured that they are properly cleaned without causing damage to the equipment or the fabrics themselves.

- **Equipment Operation:** The correct performance of laundry equipment is indeed a critical aspect of the laundry process. The efficient operation of laundry equipment, including washing machines, dryers, ironers, and other related equipment, is crucial to ensure that laundry is cleaned and processed effectively.

  - The laundry equipment controls play a critical role in correctly controlling the various parameters of the wash cycle. These controls are responsible for sending the right signals at the right time to ensure

that the wash cycle is carried out effectively and efficiently. Laundry equipment controls typically include a variety of settings and options, such as temperature, water level, agitation speed, and cycle time. Each of these parameters must be adjusted to suit the specific needs of the laundry load, such as the fabric type, soil level, and load size.

- To ensure that these parameters are set correctly, the laundry equipment controls must send the right signal at the right time. For example, the temperature control must send a signal to the heating element to raise or lower the water temperature to the desired level. The water level control must send a signal to the water inlet valve to adjust the water level to the correct amount for the load size. The agitation speed control must send a signal to the motor to adjust the speed to the appropriate level for the load type.

- The parameters that control the wash cycle of laundry equipment include several factors such as the duration of each step, water level, water temperature and pH, and chemical activity. Each of these parameters is essential to ensure the proper cleaning of laundry.

- **Duration of each step:** The duration of each step in the wash cycle, such as the pre-wash, main wash, rinse, and spin cycle, is essential to ensure the proper removal of dirt and stains from the laundry. Each step has a specific duration that should be followed for optimal cleaning performance.

- **Water level:** The water level is an important parameter that determines the amount of water used in the wash cycle. The correct water level is essential to ensure that all fabrics are adequately soaked, and the detergent is distributed evenly throughout the load.

- **Water temperature and pH:** The water temperature and pH are critical factors that affect the cleaning performance of the detergent. Higher temperatures can increase the activity of the detergent, while pH levels that are too high or too low can reduce the effectiveness of the detergent. Therefore, maintaining the correct water temperature and pH level is essential to ensure proper cleaning.

- **Chemical activity:** The chemical activity of the detergent is another important parameter that affects the cleaning performance. The

correct amount of detergent must be used to ensure that the correct chemical activity is achieved, and the laundry is cleaned effectively.

- Verification activities shall take place on a regular basis to ensure that laundry equipment is operating correctly and producing satisfactory results. Verification activities can include a range of tests and checks that help to identify any issues with the equipment or the washing process. Some examples of verification activities that can be carried out on laundry equipment include:

- **Performance testing:** Performance testing involves running a load of laundry through the washing process and then assessing the results to ensure that the equipment is functioning correctly and producing satisfactory results.

- **Calibration checks:** Calibration checks involve testing and adjusting the equipment to ensure that it is accurately controlling the various parameters of the wash cycle, such as temperature and water level.

- **Equipment inspection:** Equipment inspection involves visually inspecting the equipment for signs of wear and tear, damage, or other issues that could affect its performance.

- **User feedback:** User feedback involves soliciting feedback from users of the laundry equipment to identify any issues or areas for improvement.

- **Finished Products:** There are certain process monitors that can be used on processed fabrics to indicate how the laundry process has performed. These process monitors are used to evaluate the effectiveness of the washing process and ensure that the laundry is thoroughly cleaned. Some examples of process monitor that can be used on processed fabrics include:

  - **ATP testing:** ATP testing is a method of testing for the presence of adenosine triphosphate (ATP), a molecule found in all living cells. ATP testing can indicate the presence of bacteria and other microorganisms on processed fabrics, which can indicate that the washing process was not effective in removing them.

- **Swab testing:** Swab testing involves taking a sample of a processed fabric and testing it for the presence of bacteria and other microorganisms. Swab testing can help to identify areas of the laundry process that may need to be improved to ensure that the laundry is properly cleaned.

- **Spectrophotometry:** Spectrophotometry is a method of measuring the absorption and transmission of light by a material. Spectrophotometry can be used to measure the whiteness and brightness of processed fabrics, which can indicate how effectively the washing process has removed dirt and stains.

- **Fabric strength testing:** Fabric strength testing involves testing the tensile strength of processed fabrics to ensure that the washing process has not caused excessive wear and tear on the fabric.

- **Visual Inspection:** Visual inspection is an important part of the laundry process that involves visually inspecting laundry items for cleanliness, stains, damage, and other issues that may affect their appearance or performance. Visual inspection is typically carried out before and after the washing process to ensure that the laundry has been properly cleaned and to identify any issues that may need to be addressed.

- **Rewash Rate:** Rewash rate refers to the percentage of laundry loads that have to be re-washed due to inadequate cleaning or other issues in the first wash cycle. Rewash rates can be calculated by dividing the number of loads that need to be rewashed by the total number of loads processed during a specific time period, typically a day, week, or month. This will give you the percentage of loads that require rewash.

- A high rewash rate can have several negative consequences, including increased water, energy, and detergent usage, as well as longer processing times, decreased productivity, and increased wear and tear on equipment. It can also result in lower customer satisfaction and damage to the laundry's reputation.

- **pH Spot Solution:** pH spot tests are a type of process monitor that can be used to measure the pH level of laundry solutions, including water and detergents, to ensure that they are within the correct range

for effective cleaning. pH spot tests are typically carried out using a small, disposable test strip that changes color in response to the pH level of the solution being tested. The pH scale ranges from 0 to 14, with a pH of 7 being neutral. Solutions with a pH below 7 are considered acidic, while solutions with a pH above 7 are considered alkaline. For laundry solutions, the ideal pH range is typically between 7 and 10, as this range is most effective for removing dirt, stains, and other contaminants from fabrics.

- **pH Spot Product:** pH spot tests shall also be used on finished laundry products, to ensure that the pH level of the final product is within the acceptable range. By measuring the pH of a finished product, laundry facilities can determine whether the rinse and sour steps were carried out properly. If the pH is too high, it may indicate that the laundry was not rinsed thoroughly enough, while if the pH is too low, it may indicate that too much sour was added or that the laundry was not rinsed enough to remove the sour.

- Healthcare Textile products shall be soured to a slightly acidic pH range of 5.5 to 7.0, the fabric becomes compatible with the natural pH of human skin, reducing the likelihood of skin irritation. Additionally, this pH range helps to maximize the durability of the fabric, as it is less likely to break down or degrade over time.

- **Residual Chlorine:** Residual chlorine spot tests shall also be used in laundry settings to determine the amount of free chlorine remaining on laundered fabrics after a bleach treatment. Proper use of bleach in laundry settings can be challenging, as over-bleaching can cause damage to fabrics and under-bleaching can leave behind harmful bacteria and other pathogens. Residual chlorine spot tests can help ensure that the appropriate level of disinfection has been achieved, without causing damage to the fabric.

  - Residual chlorine spot tests can be performed using orthotolidine. When orthotolidine is added to a solution containing residual chlorine, it will produce a yellow or brown color, depending on the concentration of chlorine present, the darker the yellow color produced by an orthotolidine-based chlorine test.

- It is important to note that the intensity of the yellow color can be affected by other factors as well, such as the pH of the solution and the presence of other chemicals or contaminants. Therefore, it is important to use proper controls and follow manufacturer guidelines when using orthotolidine-based chlorine tests to ensure accurate and reliable results.

- **Laundry Swatches:** Laundry swatches also known as laundry test pieces or patches, are small pieces of fabric that are used to test the performance of laundry detergents, bleach, or other laundry additives. Laundry swatches are made from the same material as the fabrics being laundered, and they are treated with the same process and chemicals as the full load of laundry. They are then evaluated for a range of performance metrics, including cleaning efficacy, stain removal, color fastness, and fabric durability.

8. Quality Control System: Quality Control System involves implementing and maintaining established policies and procedures to ensure that products or services consistently meet specified quality standards. It also involves ongoing assessment and improvement of process performance to identify areas where processes can be improved and quality can be enhanced.

8.1. Quality control activities involve monitoring and verifying that processes are being performed correctly, identifying and addressing deviations from established procedures, and taking corrective actions to prevent quality problems from occurring or recurring. The goal of a quality control system is to ensure that products or services meet customer expectations and are delivered in a timely and efficient manner.

- Quality control System is important for maintaining the performance characteristics of multiple-use healthcare textiles. These measures include developing and implementing appropriate policies and procedures for processing textiles, monitoring and verifying that processes are being performed correctly, and taking corrective actions when necessary to prevent quality issues. Additionally, quality control measures shall involve ongoing assessment and improvement of process performance through regular review of quality data, process audits, and other means of evaluating process effectiveness.

- A documented quality assurance program shall be prepared. In addition, the program shall include procedures for maintaining the integrity of the products during storage and handling. These systems of control shall ensure that the multiple-use healthcare textile products are processed, packaged, sterilized/ disinfected and labeled in accordance with manufacturer's instructions, applicable regulatory requirements and applicable product standards. In absence of any relevant product standards, the written quality system for analyzing the quality of processed healthcare textile products shall be developed by individuals responsible for product inspection, in consultation with end users & manufacturers.

- During development of the Quality Control Program, the manufacturers' recommendations shall be taken into account. Manufacturer's recommendations may include specific inspection procedures, recommended inspection frequencies, and guidelines for interpreting inspection results. The facility's experience with the particular product can provide valuable insights into the specific issues and concerns that may arise during inspection. This can include factors such as the frequency and nature of defects or wear and tear that may occur, as well as any challenges or limitations in the inspection process itself.

- Careful consideration shall be given to those attributes that can affect the important functional characteristics of healthcare textile items during processing. The key elements of the quality assurance program for multiple-use healthcare textile products that help ensure important functional characteristics shall include:

8.2. Functional requirements: Functional requirements describe what a product should do and how well it should do it. Some of the key elements to determine the functional requirements of a product are:

- Ensure that multiple-use healthcare textiles consistently meet the required functional performance criteria for safety and effectiveness each time they are used. This includes meeting established standards for cleaning, drying, inspection, testing, and maintenance, as well as appropriate assembly for sterilization processing and clinical use during invasive and aseptic procedures. This helps to ensure that the textiles provide adequate barriers to microorganisms, particulates, and liquids, meeting the requirements for draping, gowning, and wrapping materials. It is important to establish and implement procedures.

- These procedures shall be aimed at maintaining the functional performance characteristics of the products. Additionally, it is necessary to define and test the effective life of these products. If the processing facility also performs sterilization, then the procedures for sterilization shall be defined.

- **Process Specifications:** Process specifications shall be documented for each process.

    - Documentation shall include identifying the process, detailed information about the process, defining process, identifying process requirements, developing process specifications and verification of process.

    - The process specifications shall be updated from time to time as needed to reflect any changes in the process or the requirements that must be met.

- **Policies:** Written policies and procedures for appropriate treatment and laundry processing of multiple-use healthcare textiles shall be developed.

    - These policies and procedures shall be developed based on industry standards, guidelines and regulatory requirements including those established by organizations such as the Occupational Safety and Health Administration (OSHA).

    - It is also important to incorporate procedures for the evaluation and maintenance of identified functional performance characteristics.

    - Annual reviews shall be carried out by designated personnel who are knowledgeable about the handling and processing of healthcare textiles. The review shall assess whether the policies and procedures are being followed effectively and whether any changes or updates are necessary.

    - Any changes shall be documented and communicated to relevant personnel to ensure that they are aware of the updated procedures. In addition, whenever new products or processes are introduced, a review of the policies and procedures shall be carried out to ensure that they are compatible with the new products or processes. This will help ensure that the textiles are being handled and processed in a manner that is safe and effective.

8.3. Important attributes: Identifying the important attributes that are likely to be affected by processing and reuse is an important step in ensuring the safety and effectiveness of multiple-use products. These attributes may include: dimensional stability, material integrity, performance characteristics, durability, comfort & fit and appearance.

- **Barrier Efficacy:** Barrier efficacy refers to the ability of healthcare textiles to prevent the transmission of microorganisms, fluids, and other contaminants between the patient and the healthcare worker or between patients. In healthcare settings, textiles such as surgical gowns, drapes, and uniforms are critical components of infection prevention and control measures. To check the barrier efficacy after every wash process, a written policy shall be prepared including:

  - **Testing methods of barrier efficacy:** If a healthcare facility reports any strike-through event for reprocessed healthcare textile, then collection of data of strike-through events.

    - Data shall include: was the usage of the product as per exposure control plan, was the strike-through an isolated incident or is it recurring, was the correct level of protection chosen, was the selected size appropriate, details of strike-through, was there any visible damage on product before/ during use and was the product used after expiry date.

    - Return procedure of faulty products to the manufacturer using safe practices.

- **Tracking/ Monitoring:** A written policy to be prepared to determine whether the functional performance of a surgical textile barrier product has been significantly affected by repeated processing and usage, a tracking mechanism such as a marking grid, barcode system, radiofrequency chip, or other suitable method shall be included in each product. Additionally, the manufacturer shall provide recommendations for the number of times the product can be safely used. This will assist in ensuring that the product retains its required functional performance attributes and is suitable for use in medical settings.

- **Mending/ Repair:** Developing appropriate policies for rewash, repair, retirement, and alternate use of healthcare textiles.

8.4. **Quality Analysis:** An ongoing program of quality assessment and improvement shall be established for ensuring that an organization's products, services, and processes are of the highest possible quality. Selection of appropriate quality control procedures including process validation, sampling plan, testing methods and acceptable quality limits.

- **Quality Process:** Procedures for all the processes shall be based on a documented quality process that measures objective performance criteria.

  - Development of the quality process shall be in conjunction with all connected departments and shall be integrated into the overall quality process to ensure that all aspects of the facility are aligned and working towards common quality goals.

  - Variables in the system shall be controlled because it is an important part of achieving assurance of product quality and process efficacy.

  - The areas within the facility where quality standards and monitoring programs shall include design considerations of all departments, installation/ operation/ care/ maintenance of equipment, personnel considerations, receiving & handling of multiple-use healthcare textiles, laundry processing, quality control, inspection, testing & maintenance of products, packaging, disinfection/ sterilization, handling/ transportation & regulatory considerations.

8.5. **Problem Analysis:** A problem analysis program shall be prepared to address any problem related to processing of multiple-use healthcare textile processing that could pose a risk to personnel or patients. A problem analysis involves identifying the problem, determining the root cause, and developing a plan to address the issue.

8.6. **Compliance:** Policy for verifying of compliance shall be prepared to ensure quality processes in multiple-use healthcare textile processing. Audits are an effective tool for verifying compliance and identifying areas for improvement. To ensure a planned, systematic, and ongoing process for verifying compliance with procedures, the policy shall include developing audit criteria, conducting audits, developing corrective actions, implementing corrective actions and monitoring/ evaluating processes.

9. Inspection of Products: It is important for processing facilities to follow the manufacturer's instructions for processing and inspection of the product for any damage or defects prior to packing for use. Under normal conditions of use and for the duration of time in which they will be used, healthcare textile products shall perform their intended function as represented by the manufacturer's label claims. Inspecting laundered textiles is an important step in ensuring that they are clean and ready for use.

By taking into account both the manufacturer's recommendations and the facility's experience with the particular product, the inspection procedures can be designed to be comprehensive, effective, and tailored to the specific needs and requirements of the facility and the product being inspected.

9.1. Visual Inspection: After each laundering, all healthcare textile products classified as FOR CRITICAL/ SURGICAL USE shall be visually inspected with the assistance of a light table to determine if any damage or wear and tear has occurred.

- The use of a light table can help enhance the visibility of any defects or damage that may be present, making it easier to identify potential issues and take appropriate action.

- During the inspection, any defects or damage shall be carefully documented, and appropriate action shall be taken to repair or replace the affected product as needed.

- This inspection shall be conducted after the products have been laundered according to the manufacturer's instructions and any applicable industry standards.

- Visual inspection of healthcare textile products shall include determining the presence of any damage, wear and tear, or other defects that may compromise the safety or effectiveness of the product. This can include factors such as:

    - **Stains or discoloration:** Any stains or discoloration that may have occurred during use, laundering, or storage should be identified and documented.

- **Damage or tears:** Any damage or tears to the product, including holes, fraying, or other signs of wear and tear, should be identified and documented.

- **Missing or broken components:** Any missing or broken components, such as snaps or fasteners, should be identified and documented.

- **Integrity of seams and stitching:** The integrity of seams and stitching should be inspected to ensure that they are intact and have not been compromised.

- **Foreign Debris:** During the visual inspection process, foreign debris should be carefully evaluated and removed if possible.

- **Chemical damage:** Chemical damage can occur due to exposure to harsh chemicals or cleaning agents during laundering. This can cause discoloration, fading, or even holes in the fabric.

- **Thermal damage:** Thermal damage can occur due to exposure to high temperatures during sterilization or drying. This can cause the fabric to shrink or warp

- **Proper labeling:** The product shall be inspected to ensure that it is properly labeled with any relevant information, including its intended use, processing instructions, and any special handling or care requirements.

- **Tracking:** Checking the integrity of the tracking system.

- **Stains:** Stains inspection shall be performed after each laundering cycle of healthcare textile products to help ensure that they are free from visible stains and meet the established quality standards.
  - Stains on healthcare textiles can be caused by a number of factors, and not all of them may represent a significant problem or affect the performance of the textiles. Some examples of non-problematic stains include water stains or discoloration from exposure to certain chemicals during the sterilization process. However, it is still important to identify and evaluate all stains during the visual inspection process, regardless of their cause or severity.

- Some stains, such as those caused by blood or other bodily fluids, can carry infectious agents and may pose a significant risk to patients and healthcare workers if not properly removed or addressed. In these cases, stains must be evaluated carefully to determine if the affected product must be removed from use and replaced. If the stain seems to be so severe that it is not safe to use the product, even if it can be removed, the product shall be discarded and replaced.

- Even if a stain is purely aesthetic and does not affect the functionality of the textile, it can still be a potential source of contamination and pose a risk to patients and healthcare workers. Allowing stained items to remain in service can also send the message that cleanliness and infection control are not a top priority, which can compromise the overall culture of safety in the healthcare facility.

- Therefore, all stains on surgical textiles shall be evaluated and addressed during the visual inspection process, regardless of their cause or severity. Any items with stains that cannot be safely removed or that may pose a risk of contamination shall be removed from service and replaced, even if this results in higher costs in the short term. Prioritizing patient safety and infection control can ensure the best possible outcomes for patients and reduce the risk of adverse events.

- **Physical Defects:** Physical defects inspection is an essential process. It involves examining products or materials to identify any defects or imperfections that may affect their quality or safety.

  - Physical defects inspection shall involve examining loose threads, loose or missing ties or other attachments, damaged or missing snaps, cuts, tears, integrity of seams & stitching and holes that are generated through normal wear and tear or improper use and handling.

  - Physical defects within the critical zones of gowns, patient drapes, table covers, and wraps shall be done under supervision of trained people.

  - If such defects are identified, specialized repair procedures must be followed and such mending, repairs of healthcare textiles shall be carried out at designated areas by trained professionals in accordance with manufacturers' instructions, regulatory procedure & relevant product standards.

- Healthcare textile products with physical defects that compromise the function or don't meet the performance requirements shall be discarded.

- **Foreign Debris:** Healthcare textile products shall be as free from foreign debris as possible to ensure their safety and effectiveness for patient care. Foreign debris can include particles, fibers, hair, lint, and other materials that are not part of the original product and may cause contamination or irritation to the patient.

  - Sticky-surfaced tape or adhesive lint rollers can be used to remove loose debris, such as fibers, hair, or lint, from the surface of healthcare textile products. The tape or roller is simply rolled over the surface of the product to pick up any debris.

  - Delinting rollers, also known as fabric shavers, can be used to remove more stubborn debris, such as pills or knots, from the surface of the fabric. The roller has a rotating head with a blade that gently shaves the surface of the fabric to remove any debris.

  - It is important to use appropriate methods for removing debris to avoid damaging the healthcare textile products. For example, using a sharp object or abrasive material to remove debris may cause damage to the fabric, compromise its integrity, and make it unsuitable for use in healthcare settings.

  - If foreign debris cannot be removed using appropriate methods, the product shall be removed from service. Any damaged or contaminated products shall be documented and reported to the appropriate personnel to prevent future use of the damaged product.

  - During inspection, care shall be taken to distinguish between nubs and debris. This can be done by carefully examining the surface of the fabric and using appropriate tools, such as a magnifying glass or microscope, to identify any foreign matter.

  - If there is any doubt about whether a particular spot on the fabric is a nub or foreign debris, the inspecting person(s) shall err on the side of caution and remove the spot using appropriate methods.

- **Chemical/ Thermal Damage:** Placing inappropriate or excessive chemical or thermal stresses on healthcare textile products during processing can cause damage. Healthcare textiles are designed to withstand a certain level of stress and wear and tear, but excessive or inappropriate stress can compromise their integrity and effectiveness.

    - Chemical stressors can include exposure to harsh detergents, disinfectants, or other chemicals that may weaken the fibers or cause them to break down over time. Thermal stresses can include exposure to high temperatures during washing or drying, high temperatures can cause the fibers in the textile to break down or melt.

    - Discoloration, stiffening of the fabric and holes in the fabric are clear signs of chemical & thermal damage. If any of these signs of damage are observed in healthcare textile products, they shall be removed from use immediately, and the damage shall be documented to prevent future use of the damaged product.

    - Damaged healthcare textile products can continue in service depending on the extent and nature of the damage. If the important functional attributes of the product have not been significantly changed, and the item can be repaired, it may be possible to continue using it safely.

- **Product Labeling:** Healthcare textile products shall be visually inspected for appropriate labels. Labels provide important information about the manufacturer, product type, and lot code number, which can be used to track the product and ensure that it meets quality standards. Lot code numbers are particularly important as they allow us to identify the date of production and the specific batch of material used to produce the product.

    - During visual inspection it shall be ensured that the labels are legible and that the information on the label matches the product type and lot code number. If there are any discrepancies or missing labels, the product shall be removed from service and reported to the appropriate personnel.

    - Make sure that healthcare textile products also have the manufacturer's care and handling instructions. Labels providing information of the lot code number for healthcare textile products shall remain intact throughout the effective life of the product. All products under regulatory compliance must

have labels as per relevant product standards and shall provide performance/ barrier protection level.

- Changes in laundering or sterilization processes, such as changes in detergents or sterilization cycles, can impact label durability and may result in label damage or detachment. It is important to evaluate the impact of any changes in the laundering or sterilization processes on label durability to ensure that the labeling remains intact throughout the effective life of the product.

- **Tracking:** Tracking mechanisms including RFID, grid, bar code, QR code or other suitable devices are used to identify and track healthcare textile products throughout their effective life and can be used to ensure that the products are properly cleaned, sterilized, and maintained.

  - Visual inspection, marking, scanning, or reading of the tracking mechanism shall be performed each time the product is processed to ensure that the product is correctly identified and tracked.

  - During visual inspection, it shall be ensured that the tracking mechanism is intact and that the information on the tracking mechanism matches the product type and lot code number. If there are any discrepancies or missing tracking mechanisms, the product shall be removed from service and reported to the appropriate personnel.

  - Marking, scanning, or reading of the tracking mechanism shall be performed according to facility protocols, guidelines and manufacturer's instructions to ensure that the product is correctly identified and tracked. This is important to ensure that the product is not used beyond its effective life and that any potential quality issues are identified and addressed.

  - Tracking mechanisms also provide valuable information that can be used for quality control and quality assurance purposes.

  - By tracking products and monitoring any quality issues, it can be ensured that the products meet the necessary quality standards and appropriate action can be taken to address any issues that arise, hence all healthcare textile products shall contain a tracking mechanism that is maintained in good working order throughout the effective life of each product.

10. **Testing of Products:** Multiple-use healthcare textiles require testing procedures, every time they are processed for reuse, to ensure their safety and efficacy. Commercially available test methods can be used for testing and assessment during process qualification, process validation, or ongoing process monitoring. These tests involve collecting samples from the healthcare textiles and using various laboratory techniques for testing.

    Process qualification involves testing the effectiveness of a new process or equipment, while process validation involves testing the effectiveness of an established process to ensure that it consistently produces high-quality products. Ongoing process monitoring involves regular testing of the process to ensure that it continues to produce high-quality products over time.

    For choosing the relevant & appropriate test methods, refer to **Annexure-C**: **Table I- Applicable Standards & Test Methods** (AMTZ/HEALTEXPROF/ATD / R00)**.**

    The following are some of the testing procedures that may be used for reusable healthcare textiles:

- **Microbial testing:** Multiple-use healthcare textiles can harbor harmful microorganisms if they are not properly cleaned and sanitized. Microbial testing can be used to assess the effectiveness of the cleaning and sanitation procedures used to prepare the textiles for reuse.

- **Physical properties testing**: Multiple-use healthcare textiles shall maintain their physical properties, such as tensile strength, abrasion resistance, pilling resistance, tear resistance, seam strength, dimensional stability, durability, drapability and thermal stability after repeated use and cleaning. Physical properties testing can be used to assess the durability and longevity of the textiles.

- **Performance testing:** Performance testing of multiple-use healthcare textiles is critical to ensure their safety & effectiveness. Tests include Barrier efficacy, Fluid repellency, Breathability tests.

- **Flame resistance testing:** Hospital gowns and other healthcare textiles shall be flame-resistant to reduce the risk of fire-related injuries. Flame resistance testing can be used to assess the ability of the textiles to resist flames.

- **Chemical testing:** Multiple-use healthcare textiles shall not contain harmful chemicals or residues that could cause adverse reactions in patients or healthcare workers. Chemical testing can be used to assess the presence of any harmful substances in the textiles.

- **Colorfastness testing:** Multiple-us healthcare textiles shall maintain their color after repeated use and cleaning. Colorfastness testing can be used to assess the ability of the textiles to maintain their color over time.

- **Environmental testing:** Multiple-use healthcare textiles must be tested for their impact on the environment, including their biodegradability and potential to release harmful substances into the environment.

- Other than above mentioned tests, monitoring of important functional performance characteristics provided by manufactures is also important. Tests shall be conducted as per relevant product standards and regulatory requirements.

- The above tests shall be conducted by a third-party laboratory or in house laboratory. Tests conducting Laboratory shall be Accredited from accreditation body **MRA (Mutual Recognition Arrangements) signatory to ILAC (International Laboratory Accreditation Cooperation).**

10.2. **Microbial Testing:** Healthcare textile products shall be hygienically clean and have a low bioburden to ensure that they are safe for use in healthcare settings.

- Hygienic cleanliness refers to the absence of visible soil and organic material, as well as the presence of low levels of microorganisms. This is important because healthcare textiles can harbor harmful microorganisms that can cause infections if they are not properly cleaned and sterilized.

- Bioburden refers to the total number of microorganisms present on a surface, and it can impact the effectiveness of sterilization processes. If healthcare textiles have a high bioburden, it may be difficult to achieve complete sterilization, which can increase the risk of infection. Therefore, it is important to use healthcare textiles that have been properly cleaned and have a low bioburden to ensure the safety of patients and healthcare workers.

- Laundering at high temperatures is an effective way to reduce microbial loads on healthcare textiles. Temperatures of 71°C (160°F) are commonly

recommended because they can effectively kill many types of microorganisms, including bacteria and viruses. However, it is important to follow manufacturer's instructions for laundering healthcare textiles to ensure that the appropriate temperature and chemicals are used for each specific product.

- In addition to using appropriate laundering temperatures and chemicals, good environmental and personnel controls can help to maintain the cleanliness of healthcare textiles during transportation and handling. This can include using clean transport containers and storage areas, minimizing handling of clean textiles, and ensuring that personnel involved in handling and transporting healthcare textiles are trained in proper hygiene practices.

10.3. Physical Properties Testing: Physical properties testing involves evaluating the mechanical, thermal, and other physical properties of healthcare textiles to ensure that they meet the necessary standards for their intended use. Some of the key physical properties that may be tested for healthcare textiles include:

- **Tensile strength:** Tensile strength testing is a physical properties test used to measure the maximum force that a healthcare textile can withstand before breaking under tension. The force required to break the textile is then measured, and this value is used to calculate the tensile strength of the material. The test may be conducted in both the warp and weft directions of the textile to assess its strength in both directions.

- **Abrasion resistance:** Abrasion resistance testing is a physical properties test used to evaluate the ability of healthcare textiles to withstand wear and tear caused by rubbing or repeated contact with other surfaces. Abrasion resistance testing involves rubbing a sample of the healthcare textile against a standardized abrasive surface under controlled conditions. The sample is rubbed back and forth against the abrasive surface for a specified number of cycles, and the amount of wear or damage to the fabric is evaluated using visual inspection or other measurement methods.

- **Pilling resistance:** Pilling resistance testing is a physical properties test used to evaluate the tendency of healthcare textiles to develop small balls or pills of fiber on the surface of the fabric through repeated use or laundering. Pilling resistance testing involves subjecting a sample of the healthcare textile to friction or rubbing, either by a machine or by hand, to simulate wear and tear. After a specified number of cycles, the sample is evaluated for the presence and severity of pilling using a standardized grading system.

- **Tear strength:** Tear strength testing is a physical properties test used to measure the resistance of healthcare textiles to tearing or ripping under stress. Tear strength testing involves cutting a sample of the healthcare textile into a specific shape, then applying a controlled force to the sample to create a tear. The force required to tear the fabric is measured, and this value is used to calculate the tear strength of the material. The test may be conducted in both the warp and weft directions of the textile to assess its strength in both directions.

- **Seam Strength:** Seam strength testing involves pulling the textile fabric along the sewn seam until the seam fails, and measuring the force required to cause the failure. The test is typically conducted using a universal testing machine, which applies a controlled force to the fabric until the seam fails. The results of seam strength testing are used to evaluate the quality of the sewing process used to manufacture the healthcare textile, as well as to assess the suitability of the textile for its intended use.

- **Dimensional Stability:** Dimensional stability testing is a physical properties test used to evaluate the ability of healthcare textiles to maintain their size and shape after being subjected to various conditions, such as washing or stretching. Dimensional stability testing involves washing or conditioning a sample of the healthcare textile according to standardized procedures, and then measuring its size and shape before and after the conditioning process. The difference between the original dimensions and the dimensions after conditioning is used to calculate the degree of shrinkage or expansion of the material. The test may be conducted in both the warp and weft directions of the textile to assess its dimensional stability in both directions.

- **Durability:** Durability testing is a physical properties test used to evaluate the ability of healthcare textiles to withstand repeated use and laundering without significant damage or deterioration. Durability testing involves subjecting a sample of the healthcare textile to a series of simulated use and laundering cycles, using standardized conditions and procedures. After each cycle, the textile is evaluated for damage or degradation, such as pilling, seam failure, or loss of tensile strength. The number of cycles that the material can withstand before significant damage or degradation occurs is used to determine its durability.

- **Drapability:** Drapability testing is a physical properties test used to evaluate the flexibility of healthcare textiles. Drapability testing involves draping a sample of the healthcare textile over a standardized object, such as a cylinder, and measuring the angle of the fabric's drape. The angle of draping is a measure of the fabric's flexibility and ability to conform to the shape of the object. The test may be conducted in both the warp and weft directions of the textile to assess its drapability in both directions.

- **Thermal stability:** Thermal stability testing is a physical properties test used to evaluate the ability of healthcare textiles to maintain their structural and functional integrity when exposed to high temperatures. Thermal stability testing involves subjecting a sample of the healthcare textile to a standardized high-temperature environment for a specified period of time, and then evaluating the material for any changes in its physical properties, such as shrinkage, discoloration, or loss of strength. The test may be conducted using dry heat or moist heat, depending on the intended use and expected exposure of the material.

10.4. **Performance testing:** Performance properties testing involves evaluating the barrier efficacy and liquid repellency of healthcare textiles to ensure that they provide intended safety to users. Some of the key performance parameters that may be tested for healthcare textiles include:

- **Barrier Efficacy:** Barrier efficacy consists of a few tests including:

  - **Blood borne pathogen test** is used to determine the ability of the healthcare textile to resist penetration of microorganisms such as hepatitis B and C viruses and HIV. The textile is placed under stress conditions, and a viral suspension is applied to the surface of the fabric. The test measures the ability of the fabric to prevent the penetration of the virus

  - **Synthetic Blood Penetration Test** is used to evaluate the resistance of healthcare textiles to synthetic blood penetration. The textile is exposed to synthetic blood under controlled conditions, and the test measures the amount of blood that passes through the fabric

  - **Viral Barrier Test** is used to evaluate the resistance of healthcare textiles to viral penetration. The textile is exposed to a viral suspension under

controlled conditions, and the test measures the ability of the fabric to prevent the penetration of the virus

- **Dry Microbial Penetration Test** is used to evaluate the ability of healthcare textiles to prevent the penetration of dry microorganisms. The test involves applying a dry microbial powder to the surface of the textile and measuring the number of microorganisms that penetrate through the fabric. The microorganisms used in the test are typically bacteria or fungi

- **Wet Microbial Penetration Test** is used to evaluate the ability of healthcare textiles to prevent the penetration of wet microorganisms. The test involves exposing the textile to a suspension of microorganisms and measuring the number of microorganisms that penetrate through the fabric. The microorganisms used in the test are typically bacteria or viruses.

- **Fluid Repellency:** Fluid repellency testing is done to evaluate the effectiveness of healthcare textiles in protecting against fluids and other liquids. The testing includes:

  - **Hydrostatic Pressure Test** evaluates the resistance of healthcare textiles to the penetration of liquids under pressure. The textile is placed under a specific amount of hydrostatic pressure, and the amount of liquid that penetrates through the fabric is measured
  - **Spray Impact Test** evaluates the ability of healthcare textiles to resist penetration of fluids under splatter conditions. The textile is exposed to a spray of liquid droplets under controlled conditions, and the amount of liquid that penetrates through the fabric is measured

  - **Impact Penetration Test** evaluates the resistance of healthcare textiles to penetration of liquids under impact conditions. The textile is exposed to a specific amount of liquid under controlled impact conditions, and the amount of liquid that penetrates through the fabric is measured.

- **Breathability:** Breathability testing measures the ability of a textile material to allow moisture vapor and air to pass through it, which is important for ensuring the comfort and safety of healthcare workers and patients. Breathability testing is conducted using a device called a Textile Moisture Management Tester or a Differential Pressure Tester which measures the rate of air flow through a sample of the textile material, and the results are expressed in units such as air

permeability, **Water Vapor Transmission Rate (WVTR)** or **Moisture Vapor Transmission Rate (MVTR)** and pressure drop.

10.5. **Flame resistance testing:** Flame resistance testing evaluates the safety of healthcare textiles in high-risk environments where exposure to flames and heat sources is a possibility. The testing includes:

- **Flame Resistance of Textiles (Vertical Test)** which evaluates the flame resistance of textiles exposed to a specified source of ignition. The test method measures the after-flame time, char length, and hole formation after the sample is subjected to a controlled flame source for a specific duration and **Effects of Flame Impingement on Materials Used in Protective Clothing Not Designated Primarily for Flame Resistance** which evaluates the extent and duration of flame spread over the surface of a material when it is exposed to a flame source. The test involves exposing a small sample of the material to a flame source for a specified amount of time. The sample is then observed to see how far the flame spread and how long it continued to burn after the flame source was removed.

10.6. **Chemical Testing:** Chemical testing is used to assess the chemical properties of healthcare textiles. The test procedures include:

- **Formaldehyde Content Test** measures the formaldehyde content of textiles using a colorimetric method. The method involves extracting the formaldehyde from the sample using water or alcohol and reacting it with a reagent to produce a colored complex that can be measured spectrophotometrically.

- **Skin Irritation/ Sensitization Test** is used to determine whether the textile material causes any skin irritation or sensitization when it comes in contact with the skin. The test involves applying a small patch of the textile material to the skin of a group of test subjects for a specified period of time, usually 24 or 48 hours. The skin is then evaluated for any signs of irritation or sensitization, such as redness, swelling, or itching.

- **Cytotoxicity Test** is a type of biological safety testing that evaluates the potential for a material to cause harm to living cells. The test involves exposing cultured cells to extracts of the textile material and observing any changes in the cells, such as cell death or changes in morphology.

10.7. Colorfastness Testing: Colorfastness is the ability of a textile material to maintain its original color when exposed to various conditions such as washing, light exposure, and rubbing. Colorfastness testing includes:

- **Washing Test** evaluates the colorfastness of healthcare textiles when they are washed using a standard laundry procedure. The test involves washing the textile material a specified number of times and then evaluating the colorfastness using a color comparison method.

- **Lightfastness Test** evaluates the colorfastness of healthcare textiles when they are exposed to light. The test involves exposing the textile material to a light source for a specified period of time and then evaluating the colorfastness using a color comparison method.

- **Rubbing Test** evaluates the colorfastness of healthcare textiles when they are subjected to rubbing or friction. The test involves rubbing the textile material against a standard rubbing fabric for a specified number of cycles and then evaluating the colorfastness using a color comparison method.

10.8. Environmental Impact Testing: Environmental testing of healthcare textiles refers to the evaluation of the impact of textile materials on the environment during their entire lifecycle, from production to disposal. This includes assessing the use of natural resources, energy consumption, waste generation, and the potential environmental impacts associated with the production and disposal of textile materials. Testing procedures include:

- **Life Cycle Assessment (LCA)** is a comprehensive method for evaluating the environmental impact of a product or material throughout its entire lifecycle. This includes assessing the impact of raw material extraction, manufacturing, transportation, use, and disposal.

- **Carbon Footprint Analysis** which evaluates the amount of greenhouse gas emissions associated with the production and use of a product or material.

- **Waste Management Analysis** which evaluates the amount of waste generated during the production and disposal of healthcare textiles.

All the above tests help in preparing criteria of processing Validation of healthcare textile products for reuse. However, the effective life of multiple-use

healthcare textile products can be influenced by a combination of many things, including product durability, use conditions, and process control.

If the product durability is consistent and processing is done in accordance with the labeling and recommendations provided by the manufacturer which constitute the specifications for products being processed and delivered for use in the health care facility, an appropriate level of functional performance testing to ensure product quality can be determined.

Validation of the process can further minimize the need for performance testing. Membranes and coatings used to improve the barrier properties of textiles may also require specialized testing and evaluation as per manufacturer's recommendations on appropriate testing methods and evaluation criteria.

11. **Acceptable Quality Level:** AQL refers to the maximum number of defective items or defects allowed in a batch of products or materials while still being considered acceptable. The AQL is expressed as a percentage or a number of defects per unit, and it is determined based on the product's criticality and the risk associated with the defect.

- The AQL for a batch of less critical healthcare shall be 2.5%, which means that no more than 2.5% of the scrub suits in the batch can have defects such as loose threads or seams. If the actual number of defects in the batch exceeds the AQL, the entire batch may be rejected or subject to additional testing or inspection. AQL sampling plan for less critical healthcare textiles shall be in accordance with IS/ ISO 3951 (part-1, part-2, part-3) or any equivalent national/ international sampling plan/ standard.

- AQL for critical healthcare textiles classified as medical devices shall be in accordance with the barrier efficacy level as per the relevant product standard/ regulatory requirements. AQL sampling plan for critical healthcare textiles classified as medical devices shall be as per the relevant product standard/ regulatory requirements.

12. **Service Life:** To ensure that healthcare textiles are safe and effective for user/ patient use, it is important to establish guidelines for their effective service life, based on factors such as the type of product, frequency of use, and washing procedures.

- These guidelines shall include a determination of the maximum number of wash cycles that can be performed before retirement or replacement of the item is required.

- Developing appropriate policies for rewash, repair, retirement, and alternate use of healthcare textiles is critical to ensure that these products are used safely and effectively throughout their service life.

- The policy shall be designed with the recommendations of manufacturers and healthcare facilities and shall be based on industry guidelines, relevant product standards and regulatory requirements, and shall be regularly reviewed and updated to reflect changes in best practices, technology, and regulatory requirements.

    - **Rewash Policy:** The rewashing policy shall outline the circumstances under which a textile product may be rewashed, and the maximum number of rewashes allowed before retirement of the product. The policy shall also include guidelines for testing the textile after each rewash to ensure that it meets the necessary standards for cleanliness and functionality.

    - **Repair Policy:** The repair policy shall identify the types of damage that can be repaired, and the maximum number of repairs that are allowed before retirement of the product. The policy shall also outline the procedures for repairing the textile, including any necessary testing or validation.

    - **Retirement Policy:** The retirement policy shall identify the circumstances under which a textile product must be retired, such as when it is no longer functional or when it has exceeded the maximum number of rewashes or repairs. The policy shall also include guidelines for disposing of retired textile products in an environmentally responsible manner.

    - **Alternate Use Policy:** The alternate use policy shall outline the circumstances under which a textile product may be used for a different purpose than originally intended, such as when it is no longer suitable for use as a healthcare textile product. The policy shall include guidelines for testing the textile to ensure that it meets the necessary standards for the new use.

Overall, the development of these policies is an important aspect of ensuring the safety and effectiveness of healthcare textiles. Healthcare Textiles Processing facilities shall work closely with textile suppliers and Healthcare providers to develop and implement policies that are appropriate for their specific needs and circumstances. Regular review and evaluation of the policies is essential to ensure that they remain effective and up-to-date with current best practices and regulatory requirements.

13. Maintenance of Products: In addition to the general maintenance and care tips for reusable healthcare textiles, mending, patching, rewash & alternate use can also be an important part of their maintenance.

13.1. Here are some steps to follow when repairing healthcare textiles:

- **Identify the damage / stain:** Inspect the healthcare textile carefully to identify any damage, such as tears, holes, or frayed edges or any stain which can be removed by rewash.

- **Assess the damage:** Assess the extent of the damage to determine whether it can be patched/ repaired or if the item needs to be replaced or the item can be altered for another product or downgraded to a lesser risk classification. For example, if the damage is extensive or affects the integrity of the textile, it may not be possible to repair it or if a bed sheet is torn then it can be converted to pillow covers etc., or a Gown of Barrier protection level 3 doesn't qualify for the performance criteria of level 3 but fulfills the requirement of Level 2, then it can be labeled to be used for Level 2.

- **Choose appropriate materials:** Select appropriate materials for the repair, such as thread or fabric that matches the original textile.

- **Prepare the textile:** Before repairing, ensure that the healthcare textile is clean and dry.

- **Repair the damage:** Use appropriate techniques to repair the damage, such as patching holes or tears, or stitching up frayed edges. Use a needle and thread or a sewing machine as necessary.

- **Reinforce the repair:** If necessary, reinforce the repair with an additional layer of fabric or a stronger stitch pattern to ensure durability.

- **Inspect the repair:** Once the repair is complete, inspect the healthcare textile to ensure that the repair is strong and secure, and that there are no additional issues.

  It is important that all such processes of patching/ repairing/ rewashing shall be done prior to the disinfection/ sterilization process.

13.2. **Patching:** The purpose of patching is to extend the useful life of textiles and to minimize the cost of replacing them. Patching involves attaching a piece of fabric over a damaged or worn area of a healthcare textile item. When patching healthcare textiles, it is important to follow certain guidelines to ensure that the textiles remain safe and effective for their intended use. Following recommendations shall be considered when patching laundered healthcare textiles:

- Use fabric that is similar to the original textile item in terms of material, weave, and color. This will help maintain the integrity of the textile and minimize the risk of damage or contamination.

- Make sure the patch is securely sewn onto the textile item. Loose or poorly attached patches can come off during use or laundering, which can create a hazard for patients and staff. While applying patches inside the critical zones of gowns, patient drapes, table covers, and wrappers heat-sealed patching shall be done. Loose patches shall be removed and new patches applied.

- When applying heat-sealed patches, it is important to follow the manufacturer's instructions and guidelines to ensure that the patch adheres properly to the textile.

- The patch shall be placed in the appropriate location, and the heat and pressure should be applied evenly to create a strong bond between the patch and the textile. Whether to apply the heat-sealed patch on one or both sides of the textile depend on the purpose and use of the item.

- Avoid patching areas that come into direct contact with patients, such as the center of a bed sheet or the front of a gown. Patching these areas can compromise the cleanliness and sterility of the textile item, which can increase the risk of infection.

- Make sure that the patched product meets the same general medical device safety and effectiveness requirements as the textile being repaired, patches are applied according to the original manufacturer's written instructions, repaired products provide the same performance characteristics, including level of barrier performance as mentioned on the label and allow for effective sterilization (if required).

- The written quality standards and repair procedures shall include detailed instructions on how to inspect and repair healthcare textiles, including guidelines for patching. These guidelines shall specify the acceptable locations for patches, such as areas that do not come into direct contact with patients or that do not compromise the functionality of the textile item. They shall also specify the number of patches that can be applied to a single item, as well as the size and shape of the patches.

- Inspect the patched textile item carefully before putting it back into use. Look for any signs of damage, wear, or contamination that may have occurred during laundering or patching. If the item is no longer safe or effective for use, it should be discarded.

13.3. **Repairing:** Physical defects in healthcare textile products shall be repaired in order to ensure their proper functionality and safety. Loose threads, missing ties or attachments, and damaged or missing snaps can all compromise the integrity of an item and potentially lead to accidents or injuries.

- It is generally acceptable to use sewing to repair non-critical zones of healthcare textile products, such as replacing missing ties or snaps and fixing fraying hems or seams. However, it is important to ensure that proper procedures are followed to maintain the safety and effectiveness of the product. Healthcare textiles are subject to stringent regulations and standards to ensure their safety and effectiveness in clinical settings.

- In particular, when using sewing to repair surgical textiles, it is important to use sterile materials and techniques to minimize the risk of introducing infection into the surgical site. This may involve using specialized equipment and techniques.

- Furthermore, any repairs made to healthcare textile products shall be thoroughly inspected and tested to ensure that they meet the same quality and safety standards as the original product. This may involve conducting additional quality control checks, such as visual inspections and performance testing.

- When sewing is performed in critical zones, the needle creates small holes in the material that could potentially allow bacteria or other microorganisms to pass through and contaminate the surgical site. To prevent this, a patch made of the same material as the product shall be placed over the needle holes to seal them. The patch shall be sterile and securely affixed to the product using a suitable method, such as heat sealing or adhesive bonding. This helps to maintain the integrity of the product and reduce the risk of infection.

- It is important to note that any repairs made to surgical textile products, whether in critical or non-critical zones, shall be performed by trained personnel using appropriate equipment and techniques.

13.4. **Rewashing:** Stains, foreign debris, and residues can compromise the cleanliness of healthcare textiles and increase the risk of transmission of infections.

- If during the inspection process healthcare textiles are found to contain stains, foreign debris, or residues and those stains, foreign debris, or residues can be removed through re-laundering, the textiles shall be sent for reprocessing. However, if they cannot be effectively removed or if the textiles are damaged, they shall be retired and replaced.

- In some cases, certain types of staining, color loss, or color transfer might be deemed acceptable and re-laundering of the item might not be required. This decision will depend on several factors such as the location and size of the stain, the type of product, and the intended use of the product. It is important to ensure that the washing method to be used shall be appropriate for the specific product and that it is performed correctly.

- There shall be clear written policies and procedures in place for evaluating and determining the acceptability of staining or discoloration on healthcare textiles. These policies shall take into account the specific requirements for maintaining a hygienic environment and minimizing the risk of infection transmission.

- Each rewash cycle shall be considered an additional life cycle for the item, as it contributes to the wear and tear of the textile. This means that after a certain number of wash cycles, the item may need to be retired or replaced, even if it appears to be in good condition.

- It is important to consult with the manufacturer before using any "special" chemicals, stain removal procedures, or wash process parameters that are not specified in the manufacturer's instructions. This allows the manufacturer to assess the compatibility of the proposed procedure with the product and provide guidance on any modifications that may be necessary to maintain the product's safety and effectiveness.

- Repeated rewashing of a product may help to remove some stains or soiling, but if a stain remains in a critical area of the product after multiple wash cycles, it is likely that the stain has become set and cannot be removed. In this case, the product shall be removed from service or downgraded to a less stringent category to ensure that it is not used in critical applications where its effectiveness may be compromised.

13.5. **Revitalization:** If revitalization procedures such as ozone treatment, plasma treatment, or other advanced textile treatments are used to restore the performance of multiple-use healthcare textile products, it is important to ensure that these procedures are compatible with the product and do not damage or degrade the material.

- It is also important to follow the manufacturer's instructions and guidelines for the use of any laundry additives or revitalization procedures to ensure that they are appropriate for the product and do not negatively impact its performance or useful life. This may involve testing the product with the revitalization (rejuvenation) procedure under controlled conditions to ensure that it meets the required performance specifications.

- For example, if a repellency treatment is used to maintain the water and/or fluid resistance of a surgical gown or other healthcare textile product, the treatment shall be applied in accordance with the manufacturer's recommendations and using appropriate laundering procedures.

13.6. **Alternate use or Discarding:** When multiple-use healthcare textile products fail to meet their minimum functional performance criteria, they must be retired from use, downgraded to a less stringent alternate-use category, or remade into a different product to ensure that they are not used in critical applications where their effectiveness may be compromised.

- Discarding/ Retiring a product means that it is taken out of service and no longer used. This is typically done when a product has reached the end of its useful

life, or when it has failed to meet its minimum functional performance criteria and cannot be used safely or effectively.

- Downgrading a product to a less stringent alternate-use category involves reclassifying the product for use in applications where its minimum functional performance criteria are less critical. For example, a surgical gown that fails its minimum barrier performance criteria may be downgraded to a less stringent category for use as a cover gown or patient apparel.

- When products are downgraded to a less stringent alternate-use category or remade into different products, it is important to evaluate their new use and ensure that they meet the necessary safety and performance requirements. This may involve testing the products under the new conditions to ensure that they continue to meet the necessary performance criteria.

- Remaking a product into a different product involves repurposing the material into a new product that meets the required functional performance criteria. This may involve cutting and sewing the material into a different shape or form, or applying additional treatments or coatings to enhance its performance.

- Products that are re-designed/ re-made or downgraded shall be permanently marked in easily recognizable predefined pattern to prevent mix-ups or inappropriate use. This requires using a marking system that is easily visible, durable, and resistant to cleaning processes, as well as providing staff training to ensure that everyone is aware of the marking system and the new use of the products.

14. **Packaging:** Proper packaging of healthcare textile is crucial to maintain their sterility and ensure they are safe to use in the healthcare settings. The packaging materials used shall be robust to withstand transportation and compatible with the sterilization method being used, and shall be able to withstand the sterilization process without degrading or compromising the sterility of the items inside.

    Items shall be assembled in a way that minimizes the need for handling and manipulation by the end-user, and packaged in a way that allows for easy and aseptic opening. For example, peel pouches or pouches with self-sealing adhesive strips can be used to allow for aseptic opening without the need for additional handling or opening tools.

14.1. Packing Procedure: Standard preparation and packaging procedures for healthcare to ensure that they are folded and packaged properly and consistently every time they are processed. These procedures shall be developed and documented.

- Standard preparation and packaging procedures shall include the steps for assembling and folding each item, selecting the appropriate packaging material, labeling the package with all necessary information, and ensuring that the package is sealed properly. These procedures shall be based on relevant product standards and guidelines and shall take into consideration the specific requirements of the healthcare textile items being processed, as well as the sterilization method being used. It is also important that packaging shall comply with the regulatory requirements.

- Documenting these procedures is important to ensure that they are followed consistently and correctly. This documentation shall include a detailed description of each step in the process, including any required measurements, folding techniques, or other specific instructions. It shall also include any required quality control checks or other verification steps to ensure that each package meets the necessary standards for sterility and safety.

- Involving end-users and manufacturers in the development of preparation and packaging procedures is essential to ensuring that these procedures are effective, efficient, and tailored to the specific needs of the healthcare community. By involving end-users, manufacturers and other stakeholders in the development of these procedures, processing facilities can tailor their processes and products accordingly. This can help to ensure that the products are packaged in a manner that is both safe and efficient for use in the healthcare settings, and that they meet the needs of the end-users.

- In addition to developing and documenting standard procedures, it is also important to periodically review and update them to ensure that they remain current and effective. This can be done through regular quality control checks and staff training sessions, as well as through ongoing evaluation of industry standards and best practices.

14.2. Folding: It is important that items are folded in a manner that allows them to be presented to the sterile field in an aseptic manner. This means that the folding technique shall minimize the potential for contamination during handling and transfer of the item to the sterile field.

- The folding method used for surgical items shall allow for effective sterilization. This means that the items shall be folded in a way that allows steam, ethylene oxide gas, or other sterilization methods to penetrate all parts of the item, including any folds or crevices. In addition, care shall be taken to ensure that the items are not folded too tightly, which could prevent effective sterilization by inhibiting the flow of steam or gas. Conversely, items shall not be folded too loosely, which could create pockets of air that may interfere with sterilization.

- The method of folding shall allow for easy identification and orientation of the item. This is important to ensure that the correct item is used for the intended procedure and that it is oriented correctly to provide optimal coverage and protection. In addition, the folding method shall be standardized and consistent across all items to ensure that healthcare workers are familiar with the proper folding techniques and can easily recognize and handle the items during use.

- It is important that the method of folding is mutually agreed upon between the using department and the processing facility. This ensures that the folding method used is suitable for the intended use of the item and that it is consistent with the sterilization and packaging procedures used by the processing facility

- The using department may have specific preferences or requirements for the folding method based on their experience and expertise in using the items in the surgical environment. For example, they may prefer a certain type of fold that makes it easier to don the item aseptically or that minimizes the risk of contamination during use. On the other hand, the processing facility may have specific requirements for the folding method based on the sterilization and packaging equipment and procedures used. For example, certain folding methods may be more effective at maintaining sterility during transport and storage, or may be better suited for the packaging materials used by the facility.

- Once the method of folding is agreed upon, the procedure shall be documented and followed consistently to ensure that all items are processed in the same way each time. The procedure shall also include instructions for inspecting the items prior to folding and packaging to ensure that they meet the necessary quality standards for use in the healthcare environment.

- Correct folding procedures for healthcare textiles also involve a variety of concepts and principles that ensure that the textiles are folded accurately and efficiently. Below are some examples:

- When folding surgical gowns, it is common to use a "closed" folding technique, in which the outer surface of the item is not exposed during the folding process. This helps to minimize the risk of contamination from contact with the outside of the item. surgical gowns may have specific markings or labels indicating the size and intended use. The folding method used should preserve these markings and allow for easy identification of the size and type of gown.

- When folding other healthcare textile items such as bed sheets, pillow covers, towels etc. care should be taken to ensure that the folded edges are not exposed to potential sources of contamination. This may involve using a specific folding technique or wrapping the item in a manner that ensures that the folded edges are protected.

- Surgical procedure drapes and plain sheets/ drapes are usually fan-folded for contactless spreading. These sheets are generally fan-folded in a way that they are first unfolded for the right/ left side and then unfolded towards the head/ feet side. Folding of fenestrated drape is done in a manner that during placement of drape the opening is above the site where the surgical incision will be made. Similarly, surgical drapes may have markings indicating the location of fenestrations or other features, and the folding method should preserve these markings and allow for easy orientation of the drape during use.

14.3. Assembling: While assembling a pack of items the textile products shall be arranged in the pack or container in a way that places the most critical or frequently used items at the top or front of the pack for easy access. For example, if preparing a pack for a surgical procedure, the surgical drapes and gowns may be placed at the top or front of the pack for easy retrieval by the surgical team.

- Additionally, it is important to consider the size and shape of the textiles when arranging them in the pack or container. Textile products shall be placed in a way that maximizes the available space and ensures that there are no air pockets or gaps that could prevent proper sterilization.

- The end user will be the one opening the pack and using the contents during a procedure. Therefore, it is important to involve the end user in the development of the pack order to ensure that the pack is arranged in a way that meets their

needs and allows them to access the contents in a convenient and aseptic manner.

- Once the order of the pack has been agreed upon, it is important to document the pack configuration in a procedure as a Device Master Record. The procedure shall outline the steps for preparing the pack, including the order in which items should be placed in the pack and any specific instructions for folding or arranging the items. It shall also include information on the type of sterilization process that will be used, such as steam sterilization or ethylene oxide sterilization, and the appropriate parameters for that process.

- Each pack may have different contents, configurations, and sterilization requirements, and therefore it is important to develop a separate procedure and/or DMR for each one. This helps to ensure that each pack is prepared and sterilized correctly, and that the contents are arranged in a logical and efficient manner for use in the sterile field.

- The assembled pack shall be wrapped in a barrier material to ensure the sterility of the contents. The barrier material shall be selected based on the method of sterilization that will be used and the characteristics of the contents. The barrier material shall be able to maintain its integrity and provide adequate protection against contamination during handling, transport, and storage. It shall be impermeable to microorganisms and have sufficient strength to withstand the rigors of sterilization and handling.

14.4. **Labeling:** Proper labeling of individual items/ assembled packs is important for ensuring traceability, identifying the contents, and providing important information to the end user. It is important to follow relevant applicable regulations and guidelines for labeling of medical devices and supplies. After packaging all the products shall be labeled with the following information:

- **Pack identification code:** The label shall indicate the unique identifier code assigned to the pack, which can be used to track its processing and sterilization history.

- **Product Name:** The label shall indicate Name of the Product

- **Contents:** The label shall indicate the contents of the pack, including the name and quantity of each item

- **Lot Number:** The label shall indicate Lot Number of Processing/ Sterilization

- **Sterilization method and date:** The label shall indicate the method of sterilization used and the date of sterilization.

- **Expiration date:** The label shall indicate the expiration date of the contents, which is typically based on the shelf life of the least stable component.

- **Storage instructions:** The label shall include any special storage instructions, such as temperature or humidity requirements.

- Labeling and procedures must clearly distinguish non-sterile items from sterile items to prevent the accidental use of non-sterile items in a sterile field. One effective way to distinguish sterile from non-sterile items is through the use of a visual/ chemical indicator. It is important to follow the manufacturer's instructions for the use of throughput indicators and to select an indicator that is appropriate for the sterilization method being used. Improper use of throughput indicators can compromise the sterility of the contents and increase the risk of infection.

- When non-sterile packs are transported in finished form, it is important to ensure that the packs are not mixed with or mistaken for sterile items. In addition to proper labeling and packaging, it is important to implement proper handling and storage procedures for non-sterile packs. They shall be stored separately from sterile items. Regular audits and inspections can also help to ensure that non-sterile and sterile items are properly segregated during transport and storage. This includes verifying that labeling and packaging are clearly distinguishable and that staff are following proper handling and storage procedures.

- When choosing marker inks for labeling, it is important to consider certain properties that ensure the ink remains legible and safe for use. The ink shall be indelible, sterilization-stable, non-bleeding and nontoxic.

- It is important to document the history of pack assembly for each pack to ensure that all appropriate inspections and processes have been successfully completed. This documentation is often referred to as a "packaging record" or "assembly record."

- Labeling of healthcare textiles classified as medical device shall be done in compliance with the regulatory requirements.

15. **Disinfection/ Sterilization:** Proper disinfection or sterilization of laundered healthcare textiles are essential to prevent the spread of infectious diseases and to ensure a safe and healthy environment for patients and healthcare workers. While disinfection and sterilization both involve killing or eliminating microorganisms, there are some differences between the two processes.

- Disinfection refers to the process of killing or reducing the number of microorganisms on a surface or object to a level that is considered safe for use. Disinfection can be achieved through various methods, including chemical disinfection, thermal disinfection, and UV light disinfection. In the context of healthcare textiles, disinfection is typically achieved through the use of chemical disinfectants, such as chlorine bleach or hydrogen peroxide, or thermal disinfection, which involves exposing the textiles to high temperatures for a specified period of time.

- Sterilization, on the other hand, refers to the complete elimination or destruction of all microorganisms on a surface or object. Sterilization can be achieved through various methods including steam sterilization, and radiation sterilization.

  It's important to follow established guidelines, protocols, applicable disinfection standards and regulatory requirements for disinfection to ensure that the textiles are properly disinfected and safe for use in healthcare settings. For choosing the relevant & appropriate disinfection/ sterilization methods, refer to **Annexure-C**: **Table I- Applicable Standards & Test Methods** (AMTZ/ HEALTEXPROF / ATD / R00)**.**

- **Disinfection:** There are several methods for disinfecting hospital textiles, including:

  - **Chemical disinfection:** This involves using chemicals, such as chlorine bleach liquid (sodium hypo-chlorite) or hydrogen peroxide, to kill microorganisms on the textiles. Chemical disinfectants can be effective and are relatively cheap, but they can also damage the textiles if not used properly.

- **Thermal disinfection:** This involves exposing the textiles to high temperatures, usually in excess of 70°C for a specified period of time. Thermal disinfection can be achieved using hot water or steam.

- **Ultraviolet (UV) light disinfection:** This involves using UV light to kill microorganisms on the textiles. UV disinfection is effective, but it can be time-consuming and may not be practical for large volumes of textiles.

- **Gas disinfection:** This involves using gas to kill microorganisms on the textiles. Gas disinfection can be effective, but it requires specialized equipment and can be expensive.

The specific method of disinfection used for hospital textiles will depend on factors such as the type of textiles being disinfected, the level of contamination, and the resources available.

- **Sterilization:** There are several methods for sterilizing healthcare textiles, including:

  - **Steam sterilization:** This involves exposing the textiles to high-pressure steam at a high temperature, typically around 121-132°C, for a specified period of time. Steam sterilization also known as Autoclaving is a widely used method of sterilization and is effective at killing a wide range of microorganisms.

  - **Gas sterilization:** This involves exposing the textiles to a sterilizing gas, such as hydrogen peroxide vapor, for a specified period of time. Gas sterilization is effective at killing a wide range of microorganisms and is often used for heat-sensitive items.

  - **Radiation sterilization:** This involves exposing the textiles to ionizing radiation, such as gamma radiation or electron beams, to kill microorganisms. Radiation sterilization is effective but is typically reserved for items that cannot be sterilized by other methods.

    The specific method of sterilization used for healthcare textiles will depend on factors such as the type of textiles being sterilized, the level of contamination, and the resources available.

16. **Handling & Transportation:** After laundered textiles have gone through the washing and drying process, they need to be inspected to ensure they meet certain standards. Once the textiles have been inspected and deemed acceptable, they are transported to an environmentally controlled area to ensure they remain clean and free from contamination.

16.1. In this controlled environment, the textiles are assembled into packs according to specific requirements. After the packs are assembled, they may be sterilized using a variety of methods, including steam or gas sterilization. Once the packs have been sterilized, they may be distributed to the end user.

- Maintaining a high level of cleanliness during handling, transport, and storage of surgical textiles is crucial to ensuring that the textiles remain free from harmful microorganisms and are safe for use in healthcare settings. To maintain a high level of cleanliness, it's important to follow established protocols and guidelines for handling, transport, and storage of surgical textiles.

- It's important to minimize the possibility of overtaxing the sterilization process, which can lead to inadequate sterilization and an increased risk of infection. To achieve these goals, guidelines on work practices and environmental controls have been developed to help healthcare facilities maintain the quality and safety of healthcare textiles. These guidelines include:

- **Work practices:** Staff shall follow established protocols and guidelines for handling and processing healthcare textiles. This includes using appropriate personal protective equipment (PPE) when handling contaminated textiles, such as gloves and gowns, and washing their hands frequently to prevent the spread of microorganisms.

- **Environmental controls:** Processing facilities shall implement appropriate environmental controls to prevent contamination of healthcare textiles. This includes maintaining a clean and dry environment for textile storage, implementing procedures to prevent the spread of microorganisms in the facility, and using appropriate cleaning and disinfection procedures for equipment and surfaces.

- **Minimizing cross-contamination:** Processing facilities shall implement procedures to minimize the potential for cross-contamination between healthcare textiles and other items in the facility. This includes using separate storage areas for clean and contaminated textiles, ensuring that contaminated

textiles are properly labeled and packaged, and using appropriate handling techniques to prevent the spread of microorganisms.

- **Monitoring and quality control:** Processing facilities shall implement procedures to monitor the quality and safety of healthcare textiles. This includes regular testing of textiles for bioburden and other quality indicators, as well as monitoring the sterilization process to ensure that it is effective and reliable.

16.2. **Transportation:** Transporting clean or sterile surgical textiles within the laundry facility, sterile processing department, or to the end user requires careful consideration to avoid physical damage and minimize the risk of microbial contamination. This is important to ensure that the textiles remain suitable for use and do not pose a risk of infection to patients or healthcare workers. To achieve this, transport methods shall be designed with the following considerations in mind:

- **Avoid physical damage:** Clean and sterile healthcare textiles are delicate and can be easily damaged during transport. To avoid physical damage, textiles shall be handled gently and transported in containers that provide adequate protection from impacts and other forms of physical stress.

- **Minimize microbial contamination:** Transport methods shall also be designed to minimize the risk of microbial contamination from surface contact or airborne deposition. This can be achieved by using clean containers or carts to transport textiles, avoiding contact with contaminated surfaces, and using appropriate PPE to prevent the spread of microorganisms.

- **Ensure suitability for use:** The textiles must remain suitable for use throughout the transport process. This requires ensuring that textiles are not exposed to environmental factors that could compromise their integrity, such as excessive heat or moisture.

16.3. **Clean/ Soiled Healthcare Textiles:** Transporting surgical textiles from the user facility to the laundry in vehicles (e.g., trucks, vans, carts) that allow for separation of clean/sterile and soiled items is an important step in maintaining the quality and safety of the textiles. To achieve this, vehicles used for transporting healthcare textiles shall be designed with the following features:

- **Separation of clean/sterile and soiled items:** The vehicle shall be designed to allow for separation of clean/sterile and soiled items. This can be achieved

by using separate compartments or containers for clean/sterile and soiled textiles.

- **Adequate ventilation:** The vehicle shall have adequate ventilation to prevent the buildup of moisture and odors, which can promote the growth of microorganisms.

- **Security:** The vehicle shall be secure to prevent theft or tampering with the textiles during transport.

- **Proper labeling and documentation:** Each container or compartment shall be properly labeled and documented to ensure that the textiles are traceable and properly sorted. Carts or bins can be appropriately marked with signage or color coding that distinguishes clean/sterile products from soiled products.

16.4. **Cart Cleaning:** Depending on where and how clean/sterile surgical textiles are transported and stored within each facility, it is important to develop procedures for laundry cart cleaning and disinfection to prevent the spread of microorganisms and maintain the integrity of the textiles. Here are some general considerations for developing procedures for laundry cart cleaning and disinfection:

- **Identify high-risk areas:** Identify areas within each facility where carts are likely to come into contact with potentially contaminated surfaces or materials, such as floors or soiled textiles.

- **Establish cleaning and disinfection protocols:** Develop cleaning and disinfection protocols for each type of cart based on the identified risks. Protocols should specify the frequency of cleaning and disinfection, the type of cleaning agent or disinfectant to be used, and the method of application.

- **Train staff:** Train staff on the importance of cart cleaning and disinfection and the proper procedures to follow.

- **Monitor compliance:** Monitor compliance with cart cleaning and disinfection procedures to ensure that they are being followed consistently and effectively.

- **Document procedures and results:** Document cart cleaning and disinfection procedures and results to provide a record of compliance and identify areas for improvement.

16.5. Cart Loading: Developing loading procedures is an important step in ensuring that surgical textiles are properly segregated and labeled for identification during transport and storage. This helps to minimize the possibility of gross environmental contamination and ensure that the textiles are suitable for use. Here are some general considerations for developing loading procedures:

- **Segregation of textiles:** Develop protocols for segregating clean/sterile and soiled textiles during loading to prevent cross-contamination. This can be achieved by using separate carts or containers for clean/sterile and soiled textiles, or by loading them on separate sections of the same cart.

- **Labeling:** All containers or sections used to transport textiles shall be clearly labeled to indicate the contents and their intended use (e.g., clean/sterile, soiled, contaminated).

- **Loading order:** Establish loading order protocols to ensure that clean/sterile textiles are loaded first, followed by soiled textiles. This helps to prevent cross-contamination and minimize the possibility of gross environmental contamination.

- **Loading process:** Develop protocols for the loading process, including requirements for protective equipment, handling, and lifting techniques. This helps to minimize the possibility of physical damage to the textiles during loading.

- **Documentation:** Document the loading process, including the identification of the textiles being loaded, the loading order, and any deviations from established protocols.

16.6. Truck Cleaning & Loading: While it is generally recommended to transport clean/sterile and soiled textiles in separate vehicles or containers to prevent cross-contamination, it is possible to transport them in the same vehicle if certain precautions are taken. One way to do this is to use physical barriers and/or space separation to contain the soiled textiles and prevent them from coming into contact with the clean/sterile textiles. For example, clean/sterile textiles can be loaded in the front of the vehicle or container, while soiled textiles are loaded in the back. A physical barrier, such as a wall or partition, can be used to separate the two areas.

- It is important to clean vehicles used to contain and transport surgical textiles on a regular basis, or whenever they become visibly soiled. The frequency of cleaning will depend on several factors, including the volume of textiles transported, the type of textiles, and the conditions under which they are transported.

- However, as a general guideline, vehicles used to transport surgical textiles shall be cleaned and disinfected at least once per day, or more frequently as needed. If the containment systems used for the transport of soiled items are not effective in preventing contamination of the vehicle, then it is necessary to clean the vehicle after each use. When cleaning and disinfecting vehicles used to transport surgical textiles, it is important to follow established protocols to ensure that the process is effective in eliminating microorganisms.

- When handling soiled textiles, the operator shall wear appropriate personal protective equipment (PPE), such as gloves and a gown, to prevent direct contact with the soiled items. After handling the soiled items, the operator shall remove the PPE and perform hand hygiene using soap and water or a waterless hand sanitizer.

- When handling clean/sterile textiles, the operator shall also practice appropriate hand hygiene to prevent contamination of these items. If the same operator is handling both soiled and clean/sterile textiles during the same transport process, then it is important to practice hand hygiene between handling these items to prevent cross-contamination. This may include using a waterless hand sanitizer or washing hands thoroughly with soap and water before handling the clean/sterile textiles.

16.7. **Storage:** It is important to develop written procedures for the storage and handling of clean/sterile surgical textiles to ensure that these items remain in a suitable condition for use and are not subject to contamination or damage. To prevent the use of incorrect items in packs, stored textiles should be easily identifiable and labeled appropriately. Storage bins or containers shall be labeled with a detailed description of their contents to prevent confusion and ensure that the correct items are used in packs.

- Storage bins or containers shall be designed to completely contain all products and prevent the overflow of items into adjacent storage bins or containers. This can help to prevent cross-contamination and ensure that each item is stored in a designated and appropriate location. Additionally, it is important to establish

clear procedures for tracking and identifying stored textiles. This may involve the use of barcodes or other tracking systems that enable staff to quickly and easily identify the location and status of each item.

- **Bulk Textile Storage:** Bulk textiles that have been laundered and are awaiting folding, and folded items that are awaiting assembly into finished packs, shall be stored in controlled areas to prevent contamination. These areas shall be designated and maintained as clean areas, separate from areas where soiled textiles are handled. The controlled storage areas shall meet specific environmental requirements, such as temperature and humidity control, to prevent microbial growth and ensure the quality of the textiles. The storage areas shall be well-ventilated and well-lit, and shall be designed to prevent environmental contamination, including the ingress of pests.

- **Folded Items:** Folded items that are awaiting assembly into finished packs shall also be stored in a controlled area to prevent contamination. The items shall be stacked neatly on clean, covered carts or shelving, and shall be protected from dust, insects, and other potential sources of contamination.

- **Packed Items:** Textile packs shall be stored on solid shelving that is at least 8 inches above the floor to prevent contamination from floor-level contaminants such as dust, dirt, and moisture. Additionally, textile packs shall be stored at least 18 inches below the ceiling to allow for proper air circulation and prevent the accumulation of dust and other airborne contaminants. Textile packs shall also be stored at least 2 inches from outside walls to prevent moisture buildup and ensure adequate air circulation. It is important to ensure that the storage area is clean and free of debris, and that shelving is sturdy and properly secured to prevent collapse or damage to the packs.

- Textile packs shall be stored in a way that protects them from physical damage, such as being crushed, compressed, or punctured.

- They shall also be kept away from any potential sources of moisture or exposure to water, such as sinks or water pipes, as moisture can compromise the integrity of the packs and lead to microbial growth.

- Textile packs shall not be stored on floors, windowsills, or other non-designated areas as this can increase the risk of contamination. Instead, they shall be stored on designated shelving counters that are kept clean and free of debris.

- When storing textile packs, it is important to ensure that they are positioned in a way that allows for proper air circulation to prevent any buildup of dust or other contaminants.

- **Shelving:** Closed or covered cabinets are recommended for the storage of clean/sterile surgical textile items to protect them from environmental contaminants. However, open shelving or carts can also be used under certain conditions, such as restricted access to authorized personnel, proper ventilation, and regular cleaning to minimize the risk of contamination. The air exchange rate and air flow shall also be monitored and controlled to prevent the accumulation of dust and other particles that can compromise the cleanliness of the textiles.
  - Shelving or carts used for storage of clean/sterile surgical textiles shall be kept in a clean and dry condition to prevent contamination. If shelving is used, the bottom shelf shall be solid or lined with plastic to prevent dust or debris from accumulating on the shelf and contaminating the textiles. Alternatively, items stored on the bottom shelf can be placed in containers to protect them from environmental contaminants and prevent cross-contamination.

  - Outside shipping containers and corrugated cartons are not suitable for use as containers in clean storage areas. They are not designed to prevent contamination of the contents from dust, moisture, or other environmental factors. Instead, closed or covered cabinets, or designated containers designed for clean storage should be used to maintain the cleanliness and sterility of healthcare textiles.

16.8. **Rotation:** The use of healthcare textile packs shall follow the FIFO principle to ensure that the oldest packs are used first and the newest ones are kept for later use. This helps prevent the expiration of shelf life and to ensure that packs are used before they become outdated. Additionally, a tracking system shall be in place to monitor the age and use of packs and to ensure that expired or damaged packs are removed from circulation.

- It is important to maintain proper control of textile inventories to ensure that surgical textiles are available when needed and to avoid waste or expiration of items. Shelves shall be labeled with clear descriptions of the items stored on them, and inventory procedures shall be established to track when items are added or removed from storage. Any processed healthcare textile, if not used for 90 days, shall be reprocessed before reuse.

17. Regulatory Considerations:

- Processing facilities are required to comply with applicable regulatory requirements for processing multiple-use healthcare textile products.