HLAC Accreditation Standards

2023

HLAC Accreditation Standards

Accreditation Standards for Processing Reusable Textiles for Use in Healthcare Facilities

2023 Edition, Implementation Date: January 1, 2023

THE HEALTHCARE LAUNDRY ACCREDITATION COUNCIL
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2023 HLAC ACCREDITATION STANDARDS

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PREAMBLE

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PREAMBLE

1. Introduction

The Healthcare Laundry Accreditation Council (HLAC) is the leading authority on laundry standards for the preparation of hygienically clean, reusable healthcare textiles. The HLAC Accreditation Standards incorporates federal regulations and evidence-based guidelines as well as best industry practice and are established as the minimum acceptable practice in this endeavor.

With this 2023 revision, the HLAC Accreditation Standards continue to heighten awareness of patient safety, infection prevention and control and quality improvement in the healthcare textile industry.

Major changes to the 2023 standards include:

- Highlights the standards that direct impact hygienically clean linen. Standards that do not directly affect this end outcome have been downgraded to shall or should statements or eliminated.
- NEW Addition of new standards to ensure regulatory compliance. New standards will be indicated with a "new" icon next to the item.
- Eliminating subjectivity.
- Reducing duplication.
- Emphasis on validating the effectiveness of a laundry's performance through process monitoring.
- HLAC will no longer enforce standards that are covered by other governing agencies (such as the National Fire Protection Association) unless they affect hygienically clean linen.
- Should/may statements have been removed from the body of the standards and placed in a separate section to provide additional recommendations on best practices for facilities.
- Updated terminology, citations, appendices, and references.
- New appendices include:
  - Methods to verify compliance with the standards.
  - Summary of training requirements.

2. Interpretive Guidance

2.1.1 A "must" statement is one for which compliance is required. The directive of the statement is supported by any or all of the following resources:

a. Federal mandates, regulations (e.g., OSHA, U.S. Food and Drug Administration [FDA], U.S. Environmental Protection Agency [EPA]) that are law;

b. State and/or local government regulations;

c. Evidence-based, peer-reviewed best practices/recommendations for infection prevention and laundry procedures that ***directly impact the provision of hygienically clean textiles*** from federal agencies (e.g., Centers for Disease Control and Prevention [CDC]) and professional entities (e.g., Association for the Advancement of Medical Instrumentation [AAMI],

Association of periOperative Registered Nurses [AORN], Association for Professionals in Infection Control and Epidemiology [APIC], Facilities Guidelines Institute [FGI]. Guidance documents published by these agencies and entities are typically adopted by reference by authorities having jurisdiction (AHJ) and are often cited as "gold standard" in a court of law; and

d. Healthcare Laundry Accreditation Council (HLAC) decisions specific for the laundry industry processing healthcare textiles for patients and personnel in healthcare facilities.

The "must" statements will be bold-face text in the Standards and compliance will be scored by the inspectors. The expectation is that all "must" Standards are met (i.e., 100% compliance).

2.1.2 A "shall" statement represents a best practice based on infection prevention and laundry industry consensus and compliance is strongly recommended. Such statements are intended to assist the healthcare laundry industry as it transitions to a higher standard of practice.

"Shall" statements are scored by the inspectors, but will not be presented as bold-face text. The expectation is that at a minimum 90% of these "shall" Standards are met. "Shall" Standards may, at some point in future editions, be elevated to "must" statements as industry and regulatory events warrant.

2.1.3 The combination of the "must" and "shall" statements in addition to the HLAC inspection will determine if the provider is awarded accreditation. Laundries found to be out of compliance and needing to make simple repairs or remediation are given the opportunity to correct these within a predetermined time frame and/or submit to repeat inspection.

2.1.4 "Should" and "may" statements represent suggested courses of action for which a strong industry consensus may not be available, or are part of emerging practices and/or technology, or are required for regulatory compliance.

"Should" and "may" statements are recommended for implementation, but are not scored. These statements have been removed from Parts I-III of these standards and added to a new section in Part IV titled "Best Practices". These standards may, at some point in future editions, be elevated to "shall" or "must" statements as industry and regulatory events and/or as quality published evidence warrants.

3. Safety and Regulatory Compliance

These standards do not address all of the safety or health issues associated with commercial or industrial laundry operations. It is the responsibility of the laundry facility to document and demonstrate compliance with all local, state, and federal regulations and operating permits.

It is expected that this documentation will include:

3.1 A list of all major laundry processing equipment.

3.2 Confirmation that equipment conforms to the manufacturer's recommendations and complies with applicable local, state, and federal codes/regulations.

3.3 A written routine and preventative maintenance schedule for each piece of equipment as described by the manufacturer's Instructions for Use (IFU) or appropriate regulatory requirement.

3.4 Documentation of conformation with local electrical and fire codes.

3.5 Documentation that the gas and steam supply conforms to the equipment manufacturer's recommendations and any state regulations.

3.6 Evidence of compliance with local regulations or the Authority having Jurisdiction as they pertain to air, water, and chemicals management, if applicable.

3.7 Evidence of waste water and/or air quality permit compliance, if applicable.

3.8 Compliance with hazardous chemical (e.g., hydrogen peroxide) regulations (i.e., Department of Homeland Security Chemical Security Assessment Tool [CSAT], local hazardous materials license or permit) must be documented and available for review, if applicable.

3.9 A written Regulated Medical Waste management agreement/plan, which is communicated with the customer, detailing the delegation of procedures to follow when biohazardous medical waste is found among soiled healthcare textiles.

3.10 For customers in the United States, documentation of compliance with the following OSHA requirements including:

- 29 CFR 1910.1030 - Bloodborne pathogens
- 29 CFR 1910.1030 App A - Hepatitis B Vaccine Declination (Mandatory)
- 29 CFR 1910.1200 - Hazard Communication
- 29 CFR 1910.1200 App E - Guidelines for Employer Compliance (Advisory)

4. Clarification of Universal vs. Standard Precautions

Universal precautions refers to a standard set of guidelines to prevent the transmission of bloodborne pathogens (BBP) from exposure to blood and other potentially infectious materials (OPIM).

OPIM is defined by the Occupational Safety and Health Administration (OSHA) as:

- The following human body fluids: semen, vaginal secretions, cerebrospinal fluid, synovial fluid, pleural fluid, pericardial fluid, peritoneal fluid, amniotic fluid, saliva in dental procedures, any body fluid that is visibly contaminated with blood, and all body fluids in situations where it is difficult or impossible to differentiate between body fluids;

Personnel may be exposed to BBP via contaminated laundry which may be soiled with blood or other potentially infectious materials or may contain sharps.

In 1996, the CDC created a new category referred to as ***Standard Precautions***. The term Universal Precautions is no longer used by the Infection Prevention and Control community.

Standard Precautions are the minimum infection prevention practices that apply in all settings where health care is delivered, including healthcare laundry facilities. These practices are designed to both protect personnel and prevent the transmission of infections among patients. Standard Precautions include:

- Hand hygiene.
- Use of personal protective equipment (e.g., gloves, masks, eyewear).
- Respiratory hygiene / cough etiquette.
- Sharps safety (engineering and work practice controls).
- Safe injection practices.
- Sterile instruments and devices.
- Clean and disinfected environmental surfaces.

OSHA standards for bloodborne pathogens (BBP, 29 CFR 1910.1030) and personal protective equipment (PPE, 29 CFR 1910 Subpart I) require employers to protect workers from occupational exposure to infectious agents through the use of universal precautions. Adhering to standard precautions in healthcare settings is recommended by the CDC and protects workers from a wider range of infectious disease hazards than the BBP standard.

While the terms are not interchangeable, they are safety concepts that overlap. This document will refer to both of these standards as ***Universal/Standard Precautions***.

5. Important Information About the Use of These Standards

The standards are intended to be used to obtain or maintain accreditation in the HLACA Accreditation Program. The standards represent the collective best judgment of HLAC leaders. Use of the standards is not a guarantee of health or safety of any individual. Many factors impact outcomes in individual circumstances.

BASIC ELEMENTS

★ Part I ★

PART I. BASIC ELEMENTS

Part I - 1. Textile Control Procedures

1.1. Textile Specifications

1.1.1. The provider shall have written textile specifications that meet customer needs and ensure consistent performance.

1.1.1.2. These specifications shall be reviewed, at a minimum, annually by the service provider and the customer.

1.1.2. Provider/customer contracts shall include the extent of service for the contract period, signature of both entities, and the date signed.

1.2. Textile Maintenance

1.2.1. The provider shall have a documented grading system, outlining the grading standards for the healthcare textiles being processed.

1.2.1.1. The grading documentation shall be accessible where personnel may refer to it.

1.2.2. These standards shall outline which defects may be repaired, which defects require replacement, and the point at which previously repaired textiles should be discarded.

1.2.3. If a provider has a textile repair program, the provider shall ensure that all personnel having responsibility for making repair and replacement decisions understand and comply with the grading standards.

1.3. Provider Inventory Management

1.3.1. The provider and customer shall jointly determine the par level for the facility, whereupon the provider shall use an inventory management system that ensures an adequate supply of clean textiles to meet the customer's needs.

1.3.2. Methods to ensure that an adequate supply of textiles is available to the provider and customer shall include documentation of historical fill rates for rental operations and/or documentation of clean pounds shipped as a percentage of soil pounds received for customer-owned goods (COG) operations.

1.3.3. The provider and customer shall document in writing the provision of inventory for situations where increased need (e.g., surge capacity in response to a disaster) is anticipated and what adjustments are acceptable.

Part I - 2. Laundry Facilities

2.1. Physical Design, Ventilation, Fixtures, and Signage

2.1.1. Based on the workflow pattern principle where processing of soiled textiles flows to clean textiles, the laundry facility's physical layout and maintenance procedures must ensure efficiency, minimize environmental contamination, and protect the material and hygienic integrity of the processed textiles. (CDC HICPAC GL EIC 2019; ANSI/AAMI ST65:2018 Std.3.2.3.1; FGI 2014: 2.1-5.2 Linen Services)

2.1.2. Soiled Textiles Area

2.1.2.1. The essential laundry facility design must have a functional separation of areas that receive, store, or process soiled textiles from areas that process, handle, or store clean textiles by one the following methods:

2.1.2.1.1. Physical barrier (e.g., walls or structural partitioning with a means of entry to and from the soiled textiles area), which includes negative air pressure in the soiled textiles area with venting directly to the outside (positive air flow from the clean textiles area through the soiled textiles area); or

2.1.2.1.2. Functional barrier by negative air pressure in the soiled textiles area and positive air flow from the clean textiles area through the soiled textiles area with venting directly to the outside. (CDC HICPAC GL EIC, 2019; ANSI/AAMI ST65:2018; Std.3.2.3.1, 3.3.4; ANSI/AAMI ST79:2017; Std. 3.2.2; FGI GL 2014: Table 7.1, ANSI/ASHRAE/ASHE Std. 170-2021 Table 7)

Note: Laundry facilities failing to meet this standard will be automatically re-inspected for compliance.

2.1.2.1.2.1. Air pressure differentials in these areas must be monitored and documented daily

2.1.2.2. The physical environment and layout of the soiled sorting area shall be designed to permit orderly soiled textile sorting and other manipulations and processes.

2.1.2.3. Warning signs about the presence of contaminated textiles and the need to follow Standard/Universal Precautions must be posted in work areas where potentially contaminated textiles are stored or sorted prior to processing.

NEW

2.1.2.4. PPE shall be strategically located and available in work areas where potentially contaminated textiles are stored or sorted. (OSHA 29 CFR 1910.1030)

2.1.2.5. Handwashing facilities must be located in all areas where soiled or contaminated textiles are handled in the laundry. (OSHA 29 CFR 1910.1030; CDC HICPAC GL Hand Hygiene 2002; CDC HICPAC GL EIC, 2019; ANSI/AAMI ST65:2018; Std. 3.3.7; ANSI/AAMI ST79:2017; Std. 3.2; FGI GL 2014: 2.1-5.2 Linen Services; AHE Practice GL 3rd ed. Section. 2)

2.1.2.6. Emergency eyewash equipment shall be available with unobstructed access in all areas where soiled textiles are processed. (ANSI/AAMI ST65:2018; Std. 3.3.8; ANSI/AAMI ST79:2017; Std. 3.3.7; OSHA 29 CFR 1910.1030)

2.1.3. Clean Textile Staging and Storage Areas

2.1.3.1. In the provider's facility, the textile staging and storage areas for cleaned, processed textiles must be in compliance with the following specifications: free of vermin; devoid of lint; without obvious moisture contamination. (ANSI/AAMI ST65:2018; Std. 9.6.1; ANSI/AAMI ST79:2017; Std. 11.1)

2.1.3.2.Ventilation of the storage area

2.1.3.2.1. Storage area must be free of dust and lint

2.1.3.2.2. Storage area must be under positive air pressure relative to adjacent spaces, thereby preventing intrusion of contamination from soiled textile areas. (FGI GL 2014: Table 7.1)

2.1.3.3 Policies and protocols must reflect a facility-specific strategy for ensuring the hygienically clean quality of the stored, processed textiles.

2.1.3.4. The facility shall establish a schedule of visual inspection of the stored textiles and recording the observations.

2.1.3.5. Specifications for Clean Textiles Storage Shelves

2.1.3.5.1. Shelves must be placed approximately 2 inches from the wall to safeguard package integrity. (ANSI/AAMI ST65:2018; Std. 9.6.1;ANSI/AAMI ST79:2017; Std. 11.1)

2.1.3.5.2. The bottom shelf must be of solid nonporous construction, free from visible soil and dirt, and at a minimum of 8 inches from the floor for accessible cleaning to prevent contamination. (ANSI/AAMI ST65:2018; Std. 9.6.1;ANSI/AAMI ST79:2017; Std. 11.1)

2.1.3.5.3. The top of any item on the top shelf must be a minimum of 18 inches below the ceiling to prevent impairment of ventilation, sprinklers, and lighting. (ANSI/AAMI ST65:2018; Std. 9.6.1;ANSI/AAMI ST79:2017; Std. 11.1)

2.1.3.5.4. Any porous material (e.g., cardboard, paper, etc.) must not be used as a shelf liner in the clean textiles storage area and to store clean textiles.

2.1.4. Other Fixtures and Signage

2.1.4.1. Hand hygiene resources (i.e., handwashing facilities or antiseptic hand cleaner and cleaner dispensers) must be available in or around all work areas and in personnel support areas. (OSHA 29 CFR 1910.1030; CDC HICPAC GL Hand Hygiene 2002; CDC HICPAC GL EIC, 2019; ANSI/AAMI ST65:2018; Std. 3.3.7; ANSI/AAMI ST79:2017 Std. 3.3.5.7; FGI GL 2014: 2.1-5.2 Linen Services; AHE Practice GL 3rd ed. Section. 2)

2.1.4.2. Emergency eyewash and shower equipment shall be available with unobstructed access for immediate emergency use in all areas where chemicals are used and/or stored. (ANSI/AAMI ST65:2018; Std. 3.3.8; ANSI/AAMI ST79:2017; Std. 3.3.7; OSHA 29 CFR 1910.151 (c))

2.1.4.3. Safety features (e.g., emergency lighting, signage, fire alarms, door accessibility and egress, safety perimeter for robotics, equipment guards, etc.) must be evident and operational to safeguard personnel and persons. (OSHA 29 CFR 1910.1030; OSHA Instruction PUB. 8-1.3 Guidelines for Robotics Safety)

2.2. Physical Plant and Equipment Maintenance

2.2.1. Maintenance of equipment and spaces in a laundry facility processing healthcare textiles shall follow documented provider's policies and procedures.

2.2.2. Cleaning, Decontamination, and Disinfection

2.2.2.1. The physical environment (e.g., floors, walls, ceilings, vents, working surfaces, and installed equipment) must receive scheduled cleaning appropriate for the surface, the frequency dependent upon the level of contamination, and the operation performed in the area according to facility policy. (ANSI/AAMI ST65:2018; Std. 3.3.3; AHE Practice GL 3rd ed. Section. 2)

2.2.2.1.1. The cleaning schedule must be maintained on a current basis and available for

inspection.

2.2.2.2. Environmental surfaces (e.g., walls, ceilings, vents, and equipment) must be subjected to periodic and as needed blow down processes from ceiling downward to minimize the buildup of dust and lint.

2.2.2.2.1. Blow down, vacuuming, or other suitable cleaning practice must be performed when no other processing of textiles is occurring in that area and must not be performed in pack rooms. (ANSI/AAMI ST65:2018; Std. 3.3.3)

2.2.2.3. Clean textile working surfaces (e.g., counters, benches, tables, etc.) must be kept clean of visible soil, dust, and lint. (OSHA: 29.CFR 1910.1030; CDC HICPAC GL EIC, 2019)

2.2.2.4. Working surfaces that become contaminated with blood or other potentially infectious material (OPIM) must be decontaminated, cleaned, and disinfected with hospital grade disinfectants labeled tuberculocidal or disinfectants with specific label claims for human immunodeficiency virus [HIV] or hepatitis B virus [HBV]). (OSHA: 29 CFR 1910.1030; CDC HICPAC GL EIC, 2019; AHE Practice GL 3rd ed. Section 7.1)

NEW

2.2.2.5. Process monitoring shall be used to verify cleaning effectiveness of surfaces including carts. (Guh A, Carling P for the Environmental Evaluation Workgroup. Options for evaluating environmental cleaning. December 2010; ANSI/AAMI ST65:2018; Std. 6.4 ANSI/AAMI ST79:2017; Std. 13; AHE Practice GL 3rd ed. Section 17)

2.2.2.6. Work practices when using conventional washer extractors

2.2.2.6.1. Cleaning and disinfection of surfaces

2.2.2.6.1.1. Surfaces (i.e., surfaces exterior to conventional washer extractors) that are used to both unload and load conventional washer extractors must be non-porous and easily cleaned.

2.2.2.6.1.2. Routine cleaning and disinfection of surfaces, using a cleaning/disinfection strategy appropriate for the type of contamination when loading and unloading conventional washer extractors after each load, must be consistent with the principles of functional separation.(OSHA: 29 CFR 1910.1030; CDC HICPAC GL EIC 2019: ANSI/AAMI ST79:2017 Std. 6.2, 7)

2.2.2.6.2. Work flow and functional separation

2.2.2.6.2.1. Functional and physical separation of soiled and clean textiles must be followed when conventional washer extractor equipment is used.

2.2.2.6.2.2. For conventional washer extractor equipment that utilizes sling delivery systems for loading soiled textiles, clean textiles must not be stored under the soiled slings unless there is a mechanism present to protect the clean textiles.

2.2.2.6.2.3. Personnel handwashing practices and personal protective equipment (PPE) usage while using conventional washer extractor equipment must be in accordance with Part I, Subpart 5, Sections 5.3.3 Hand Hygiene and 5.4, PPE and Attire. (CDC HICPAC GL Hand Hygiene 2002; ANSI/AAMI ST65:2018; Std. 4.4; ANSI/AAMI ST79:2017; Std.4.4, 4.5.1, 4.5.2; OSHA 29 CFR 1910.1030)

REFER TO

Part I - 5.3.3 Hand Hygiene
Part I - 5.4 PPE and Attire

2.2.3. Pest Control Program

2.2.3.1. The provider must have documentation of a current integrated pest management (IPM) program consistent with healthcare-recommended practices and with evidence of scheduled treatments. (CDC HICPAC GL EIC, 2019; EPA Integrated Pest Management in Buildings. 2011; AHE Recommended Practice Series: Integrated Pest Management 2nd ed, 2019.)

2.3. Management of Hazardous Materials

2.3.1. The provider must have knowledge of issues and regulations concerning the management and disposal of hazardous substances/wastes to facilitate any provider-customer negotiations on this topic.

2.3.2 If the customer fails to adhere to proper hazardous substances/waste management practices, the provider shall reject any laundry items contaminated with these substances/wastes and return these to the customer.

2.3.3. Hazardous substance-related wastes must be handled separately from other customer trash/ solid wastes and disposed of per facility policy developed in accordance with applicable local regulations or the AHJ for hazardous waste. (OSHA: 29 CFR 1910.1200; Integrated Pest Management in Buildings.)

2.3.4. The provider - customer Policy and Procedures shall include some indication that the issue of management of pharmaceutical contaminated textiles has been addressed (pharmaceutical definitions provided by the local regulations or the AHJ).

Part I - 3. Contingency Planning

3.1 Contingency Planning

3.1.1. Contingency planning shall provide for uninterrupted operations and services in the event of any occurrence potentially leading to serious disruption of the provider's operations. Such disruption includes, but is not limited to, loss of utilities, medical emergencies, natural and/or man-made disasters, fire, inclement weather, work stoppage, or major accidents.

3.1.2. The Contingency Plan shall include the following components:

3.1.2.1. Plant and transportation contingency protocol,

3.1.2.2. Call chain,

3.1.2.3. A list of backup laundry facilities, (ideally HLAC accredited), and

3.1.2.4. A backup source of textiles, if needed.

3.2 Plant Contingency Protocol

3.2.1. The provider shall provide a mechanism to inform a step-by-step procedure in the event of an emergency and shall be available to supervisors, each of whom may be responsible for execution of the protocol.

3.2.2. Personnel shall be familiar with the major elements of the plant contingency protocol in advance of emergencies.

3.3. Contingency Call Chain

3.3.1. The call chain shall be written, complete, current, and available to all supervisory personnel, so that timely and accurate contact can be made in case of an emergency.

3.3.2. The call chain shall be maintained by a designated person, who is responsible for updating it at least annually or when personnel changes occur, and distributing the list to personnel.

3.4. Backup Facility Contracts

3.4.1. The provider shall have written contracts in place with one or more alternate laundry providers (ideally HLAC-accredited) that can cover their volume, detailing when and how these providers will process textiles in an emergency.

3.4.1.1. These contracts shall be updated signed, and dated every three years at a minimum.

3.4.2. The provider shall have adequate transportation capabilities with contingency planning.

3.4.3. The provider shall have written contracts in place with one or more alternate textile suppliers, detailing the services and delivery times provided (does not apply to COG).

Part I - 4. Laundry Equipment

4.1. Documentation

4.1.1. Equipment safety documentation shall consist of safety instructions, describing the potential hazards associated with the equipment use; appropriate safeguards; and complies with ANSI Z8.1-2016 regarding safe operation and maintenance of equipment. (ANSI/AAMI ST65:2018; Std. 10.2.2)

4.2. Water quality

4.2.1. The operator shall confirm that incoming water used in the laundry process meets an acceptable range for hardness, alkalinity, pH, iron and other heavy metals so that wash operations of the laundry can achieve the result of hygienically clean and appropriate chemistry balance for patient use (ANSI/AAMI ST65:2018 Std. 10.3.2.2)

4.2.2. The provider should consider softening their water when the hardness is 2 grains/gallon (34.2 parts per million [ppm]) or higher. (ANSI/AAMI ST65:2018; Std. 10.4.3.3)

4.3. Equipment Operation

NEW

4.3.1. The scale for weighing load size shall be inspected and calibrated by an outside auditor on a scheduled basis, but at a minimum annually; and the results made available to the customer upon request. (ANSI/AAMI ST65:2018; Std. 6.2.2; 6.4.2)

4.3.2. The chemical delivery system must be calibrated according to the standards of the supplier at least monthly. (ANSI/AAMI ST65:2018; Std. 6.4.2)

4.3.3. The design and size of water heater equipment must be appropriate for the provider's needs at peak operating times and to maintain the specified heated water temperature per desired cycle. (ANSI/AAMI ST65:2018; Std. 10.4.3.4)

4.4. Preventive Maintenance

4.4.1. Equipment must be inspected, cleaned, and receive scheduled preventive maintenance according to the manufacturer's instructions or according to facility policy and procedures, if instructions are not available. (ANSI/AAMI ST65:2018; Std. 10.5.1-2)

4.4.2. Preventive maintenance shall include replacement of worn expendable parts, lubrication, and calibrations. (ANSI/AAMI ST65:2018; Std. 10.5.2-3)

4.4.3. Equipment preventive maintenance must be documented and kept on file. (ANSI/AAMI ST65:2018; Std. 10.5.5)

4.5. Equipment Calibrations

4.5.1. Equipment shall be calibrated periodically as specified in the manufacturer's instruction manual or as determined by facility policy and procedures, if a manufacturer's schedule is not available. (ANSI/AAMI ST65:2018; Std. 10.5.4)

4.5.2. Calibration shall be performed by personnel trained and/or certified in calibration specified by the manufacturer. (ANSI/AAMI ST65:2018; Std. 10.5.4)

4.6. Recordkeeping for New, Existing, and/or Used Equipment

4.6.1. A maintenance record shall be kept on file for each piece of equipment. (ANSI/AAMI ST65:2018; Std. 10.5.5)

4.6.2. The following information shall be recorded:

- Service details (e.g., date for request and completion, reason for service, repair);
- Equipment details (e.g., type, model, serial number, and location of the equipment);
- Parts and repair details (e.g., parts, repair descriptions);
- Personnel involved (e.g., provider authorization, service technician name).

Part I - 5. Laundry Personnel

5.1. Personnel Qualifications

5.1.1. All personnel shall be qualified for their positions through education, training, or level of prior experience, and these qualifications shall be documented in employee files. (ANSI/AAMI ST65:2018; Std. 4.1; ANSI/AAMI ST79: 2017 Std. 4.2, 4.3)

5.1.2. New personnel shall work under the close supervision of qualified personnel until they have demonstrated competency in the given task or procedure. (ANSI/AAMI ST65:2018; Std. 4.1; ANSI/AAMI ST79:2017 Std. 4.2.1)

5.2. Personnel General Responsibilities

5.2.1. Supervisors/managers/personnel shall: (ANSI/AAMI ST65:2018; Std. 4.2.1; ANSI/AAMI ST79:2017 Std. 4.2.1)

5.2.1.1. Safely and correctly operate assigned equipment;

5.2.1.2. Safely and correctly perform assigned processing activities;

5.2.1.3. Correctly interpret and safely implement the Exposure Control Plan;

5.2.1.4. Recognize and understand potential hazards from equipment defects and improper performance of the job; and

5.2.1.5. Understand the risk of injury that defective or improperly operating equipment may inflict. (ANSI/AAMI ST65:2018; Std. 4.2; ANSI/AAMI ST79:2017 Std. 4.2)

5.3. Health and Hygiene

5.3.1. The provider must have policies and procedures to prevent healthcare textiles from being handled by or exposure to personnel with potential health issues (i.e., illness, open wounds or sores, and skin injuries.) (CDC HICPAC GL IC HCW, 1998; ANSI/AAMI ST65:2018; Std. 4.4; ANSI/AAMI ST79:2017 Std. 4.4)

5.3.2 Personnel must adhere to good work practices to minimize or eliminate exposures to blood, OPIM, chemical, and mechanical hazards. This includes, but is not limited to:

5.3.2.1. Use of personal protective equipment (PPE) when handling contaminated and soiled textiles; (CDC HICPAC GL EIC, 2019; OSHA: 29 CFR 1910.1030)

5.3.2.2. Eating, drinking, smoking, applying cosmetics or lip balm, and handling contact lenses must be prohibited in work areas where there is a reasonable likelihood of occupational exposure to bloodborne pathogens (BBP). (OSHA: 29 CFR 1910.1030)

5.3.3. Hand washing and hand hygiene indications:

5.3.3.1. Personnel must wash their hands after restroom use, before eating, and when hands become inadvertently contaminated with blood, OPIM, or other body substances. (CDC HICPAC GL Hand Hygiene 2002; ANSI/AAMI ST65:2018; Std. 4.4.; ANSI/AAMI ST79:2017 Std. 4.4; OSHA: 29 CFR 1910.1030)

5.3.3.2. Personnel must practice hand hygiene (handwashing or using alcohol-based hand sanitizers) before donning gloves and after removal of gloves. (CDC HICPAC GL Hand Hygiene 2002)

5.3.3.3. Personnel responsible for packing, wrapping, storing, or transporting clean textiles must maintain proper hand hygiene at all times. (ANSI/AAMI ST65:2018; Std. 4.4)

5.4. Personal Protective Equipment (PPE) and Attire

5.4.1. Personal protective equipment:

5.4.1.1. The provider must supply the PPE to personnel in the workplace. (OSHA: 29 CFR 1910.1030)

5.4.1.2. Reusable PPE (e.g., aprons or overalls) penetrated by blood or OPIM must be removed immediately or as soon as feasible and be laundered by the provider. (OSHA: 29 CFR 1910.1030)

5.4.1.3. PPE must be changed if moving from an area where soiled operations were performed into an area where clean operations are performed. (ANSI/AAMI ST79:2017 Std. 4.5.2)

5.4.1.4. All PPE must be removed and placed in an appropriate receptacle prior to leaving the work area. (OSHA: 29 CFR 1910.1030; ANSI/AAMI ST79:2017 Std. 4.5.1)

5.4.2. Personnel attire and adornments:

5.4.2.1. All personnel must wear clean garments without visible soil or dirt in accordance with the provider's policies and procedures. (ANSI/AAMI ST65:2018;Std. 4.5; ANSI/AAMI ST79:2017 Std. 4.5)

5.4.2.2. Hair and beard covers must be worn in areas where clean textiles are processed. Beard covers do NOT need to be worn if facial hair is less than 0.5 inches long. If religious head coverings such as hijabs, veils, turbans or bonnets are worn, they should be clean, unadorned, constructed of tightly woven and low-linting material, and should fit securely, with loose ends tucked in the scrub top. Coverings such as kippahs and yarmulkes that cover only a portion of the hair and scalp may be worn under another head covering. (ANSI/AAMI ST65:2018; Std. 4.5; ANSI/AAMI ST79:2017 Std. 4.5; AORN 2019)

5.4.2.3. Artificial nails should not be worn in the laundry while processing clean textiles. Artificial nails are defined as any substance or device applied or added to the natural nails to augment or enhance the nail, including bonding, extensions, tips, wraps, gel and acrylic overlays, and tapes. (ANSI/AAMI ST65:2018; Std. 4.5; ANSI/AAMI ST79:2017 Std. 4.5; CDC HICPAC GL Hand Hygiene 2002; AORN 2020)

5.4.2.4. Personnel who handle clean healthcare textiles must change work garments whenever their garment becomes soiled or contaminated. (ANSI/AAMI ST65:2018; Std. 4.5.1; ANSI/AAMI ST79:2017 Std. 4.5.1)

5.5. Occupational Safety and Health Elements

5.5.1 The provider shall have a documented biohazard communication system, identifying soiled healthcare textiles using color-coding and/or labeling and adhere to Standard/Universal Precautions. (OSHA 29 CFR 1910.1030)

5.5.1.1. This documentation shall be accessible where personnel may refer to it.

5.5.2. The provider must implement an occupational safety and health program based on the OSHA Bloodborne Pathogen Standard and Standard/Universal Precautions to prevent personnel exposure to or contact with blood or OPIM. (OSHA: 29 CFR 1910.1030)

5.5.3. Exposure Control Plan (ECP):

5.5.3.1. The provider must develop an Exposure Control Plan (ECP) that contains, but is not limited to the following: (OSHA: 29 CFR 1910.1030)

5.5.3.1.1. Schedule for compliance (i.e., when each part of the Plan is accomplished in the facility).

5.5.3.1.2. Procedure for evaluating the circumstances surrounding exposure incidents.

5.5.3.1.3. An Exposure Determination Plan (EDP), containing: (OSHA: 29 CFR 1910.1030)

5.5.3.1.3.1. A list of all job classifications in which all personnel in those job classifications have occupational exposure,

5.5.3.1.3.2. A list of job classifications in which some personnel have occupational exposure, and

5.5.3.1.3.3. A list of all tasks and procedures that are performed by personnel in a job classification where exposure may exist.

5.5.3.1.4. The Exposure Control Plan must be accessible to all personnel.

5.5.3.1.5. The Exposure Control Plan must be reviewed and updated at least annually.

5.5.4. Develop a hepatitis B vaccination program:(OSHA: 29 CFR 1910.1030)

5.5.4.1. Records must reflect the offering of hepatitis B vaccine by the provider and the acceptance OR documented refusal of the personnel.

5.5.4.2. Hepatitis B vaccine must be offered to personnel upon hire if they are candidates for vaccination

5.5.5. Develop a standing process for post exposure management for blood and/or OPIM.

5.5.5.1. Records must reflect a standing process for post-exposure management for blood and/or OPIM

5.5.6. Develop a hazardous materials (e.g., non-biological, chemical, radiological, etc.) safety plan and policy:

5.5.6.1. Where laundry personnel may be exposed to textiles contaminated with potentially hazardous substances from the customer, a written hazardous substance safety plan must be developed. (OSHA: 29 CFR 1910.1200; The OSHA Technical Manual: Haz Drugs, Sec 6, Chap 2)

5.5.6.1.1. The hazardous substance safety plan must be readily available and accessible to all personnel (i.e., full-time personnel, temporary personnel, contractors, and trainees).

5.5.6.1.2. The hazardous substance safety plan must be reviewed and updated as appropriate at least annually.

5.5.6.2. Where laundry personnel may be exposed to textiles contaminated with potentially hazardous substances from the customer, the provider must develop a policy for management of hazardous substance-contaminated textiles that includes, but is not limited to:

5.5.6.2.1. Wash process;

5.5.6.2.2. PPE requirements for affected personnel;

5.5.6.2.3. Training records for these personnel; and

5.5.6.2.4. Written record of provider/customer discussion regarding proper containment for hazardous substance contaminated textiles.

5.5.7. All vehicle drivers shall meet all requirements of the federal and state Department of Transportation (DOT). (www.dot.gov)

5.5.7.1. The provider shall maintain documentation of this compliance and make it available for inspection.

5.6. Training and Educational Programs

5.6.1. General elements:

5.6.1.1. Personnel must receive standard safety training of laundry operations applicable to their respective position(s), including, but not limited to safe operations of equipment per manufacturer's instructions and notification procedures when malfunctions occur.

5.6.1.2. Training options shall include, but are not limited to the following:

5.6.1.2.1. In-plant (in-service) training sessions facilitated by a person experienced in the topic;

5.6.1.2.2. Formal external training programs, including classes, workshops, and seminars.

5.6.1.3. Personnel shall receive the provider's standard training for the correct handling of healthcare textiles. Topics shall include:

5.6.1.3.1. Specific types of fabrics being processed;

5.6.1.3.2. Appropriate surgical textiles pack processes according to each pack's use requirements;

5.6.1.3.3. Proper use, placement, and heat-sealing process for patching surgical textiles; (ANSI/AAMI ST65:2018; Std. 4.2.2., 4.3, 7.2.1)

5.6.1.3.4. A copy of the grading standards.

5.6.2. Bloodborne Pathogens Exposure Control Training:

5.6.2.1. Key topics for this training must include, but are not limited to:

5.6.2.1.1. Personal hygiene and proper handwashing and hand hygiene techniques; (CDC HICPAC GL Hand Hygiene 2002; CDC HICPAC GL IC HCW, 1998)

5.6.2.1.2. Use of PPE according to the facilities exposure control plan, including one or more of the following, but not limited to, gloves, gowns, aprons, safety goggles, and masks; [ANSI/AAMI ST65:2018; Std 4.5.2; CDC HICPAC GL IC HCW, 1998; OSHA: 1910.1030)

NEW

5.6.2.1.3. How to correctly don and doff PPE

5.6.2.1.4. Engineering controls and work practices to minimize the risk of exposure to blood or OPIM; (OSHA: 1910.1030)

5.6.2.1.5. Orientation on the provider's Exposure Control Program;

5.6.2.1.6. Orientation to hazard communications, including labeling and color-coding; and (OSHA: 29 CFR 1910.1030)

5.6.2.1.7. Post-exposure procedures, including immediate action, treatment, follow-up, and record keeping. (OSHA: 29 CFR 1910.1030; CDC HICPAC GL IC HCW, 1998)

5.6.3. Hazardous Substance Contaminated Textiles training:

5.6.3.1. Key topics for this training must include, but are not limited to:

5.6.3.1.1. Exposure risk to textiles contaminated with hazardous substances or excreta from patients who have received hazardous substances (e.g., radioisotopes, chemotherapeutics, etc.) in the past 48 hours; (CDC HICPAC GL IC HCW, 1998)

5.6.3.1.2. Communications among supervisors and personnel for hazardous substance management procedures;

5.6.3.1.3. Identification and segregation of soiled textiles from patients exposed to hazardous substance contaminated, reusable textiles in bags designated solely for the containment of reusable hazardous substance exposed textiles;

5.6.3.1.4. Use of PPE including one or more of the following, but not limited to, gloves, gowns, and eye protection, if splashing is possible; 5.6.3.1.5. Hand hygiene; and

5.6.3.1.6. Disposal of contaminated one time use PPE in thick, leak-proof colored or labeled plastic bags for hazardous substances-related wastes.

5.6.3.1.7. Proper handling of other reusable PPE. (OSHA: 29 CFR 1910.1200; The OSHA Technical Manual: Haz Drugs, Sec 6, Chap 2)

5.6.4. Department of Transportation (DOT) regulations (www.DOT.gov) training:

5.6.4.1. Key topics in this training shall include, but are not limited to:

5.6.4.1.1. Random drug testing;

5.6.4.1.2. Operator training;

5.6.4.1.3. Certified driver license requirements

5.6.4.1.4. Bloodborne pathogens exposure

5.6.5. Training Documentation

5.6.5.1. All training must be documented in writing and kept on file for 3 years from the date of training. [ANSI/AAMI ST65:2018; Std. 4.3; CDC HICPAC GL IC HCW, 1998; OSHA: 29 CFR 1910.1030)

5.6.5.2. The documentation must include, but is not limited to: (OSHA: 29 CFR 1910.1030)

5.6.5.2.1. Dates of training;

5.6.5.2.3. Topic;

5.6.5.2.4. Trainer's name, title, signature, and qualifications;

5.6.5.2.5. Copies of printed training materials;

5.6.5.2.6. Validation that the training objectives and a minimum level of competency were achieved; and

5.6.5.2.7. Certificates or signature proof of personnel's attendance.

NEW **5.6.5.3 The facility must demonstrate the presence of a validation process for all educational activities that includes tracking to ensure 100% completion of the training by all relevant staff.**

Part I - 6. Laundry Customers

6.1. Contact

6.1.1. The provider shall maintain a written list of all customer contacts for access of information exchange and service.

6.1.2. The provider shall have a 24/7 customer service capability to receive customer messages (e.g., voicemail, email, etc.).

6.2. Visitation

6.2.1. The provider must make their plants available to customers and prospective customers for inspection.

6.2.2. The provider should annually visit the customer's healthcare facility for the purpose of conducting a walk-through of all areas where healthcare textiles are used, collected, transported or stored.

6.3. Customer Complaints

6.3.1. The provider must maintain records of any written communication regarding administrative or policy issues or problems with customers, including names of personnel involved and the resolution.

Part I - 7. Quality Assessment

7.1. Textile products used in healthcare facilities shall be of a quality to ensure patient and healthcare personnel comfort and textile durability.

7.2. Quality Control

7.2.1. Textile quality shall be defined and documented between the provider and the customer.

7.2.2. The provider processing COG textiles shall comply with pre-established textile maintenance standards as specified by each customer.

7.2.3. Defined quality standards shall keep mending and patching to a minimum.

7.2.4. The entire processing cycle shall have documented quality control procedures to ensure the cleanliness and serviceability of the textiles to include:

7.2.4.1. Requirements to rewash, repair, or replace textiles as necessary to maintain quality standards.

7.2.4.2. Planned and posted traffic patterns where required (e.g., pony washers) to minimize the potential for contaminating clean textiles.

7.2.4.3. Limited traffic in all areas of the facility to authorized personnel as outlined in the provider's policies and procedures. (ANSI/AAMI ST65:2018; 3.2.4; ANSI/AAMI ST79:2017; Std. 3.2.3)

7.3. Quality Assurance

7.3.1. The provider shall maintain records of any laundry processing and/or quality assurance problems experienced and mutually agreed upon solutions. A customer call log may be used for this purpose.

7.3.2. The provider and personnel shall periodically review the entire service program (i.e., safe and efficient work environment, competency of the workforce, and quality assurance of the textile process and product) and make adjustments as necessary and appropriate.

7.4. Process Monitoring

7.4.1. Providers shall engage in process monitoring to verify that ongoing operations are producing clean textiles that will meet customer expectations and needs.

7.4.2. Providers shall prepare detailed process monitoring checklists and use them to document key elements of laundry processing.

7.4.2.1. Process monitoring checklists shall include, but are not limited to, the following items:

7.4.2.1.1. Chemical supplies: Refer to HLAC Standard Part I Subpart 4 Section 4.3. Elements 4.3.3. and 4.3.4.

7.4.2.1.1.1. The provider shall verify with the manufacturer and chemical supplier that laundry chemicals are appropriate for the equipment in accordance with the equipment manufacturer, textile classifications, and water temperatures being used.

7.4.2.1.2. Titration: (ANSI/AAMI ST65:2018; Std. 6.4.4)

7.4.2.1.2.1. Monthly titrations of the correct wash chemistry shall be performed according to the formula for each major classification of soil. (ANSI/AAMI ST65:2018; Std. 6.4.3.e)

7.4.2.1.3. Equipment:

7.4.2.1.3.1. All provider equipment that directly impacts hygienically clean linen (such as ironers, dryers, presses, washers, etc.) shall be included in the provider's Preventive Maintenance (PM) Program and checked according to the manufacturer's instructions.

7.4.2.1.3.2. Ironer temperatures shall be based on the equipment manufacturer's manual and recommendations appropriate for the type of fabric being processed.

7.4.2.1.4. Finished products:

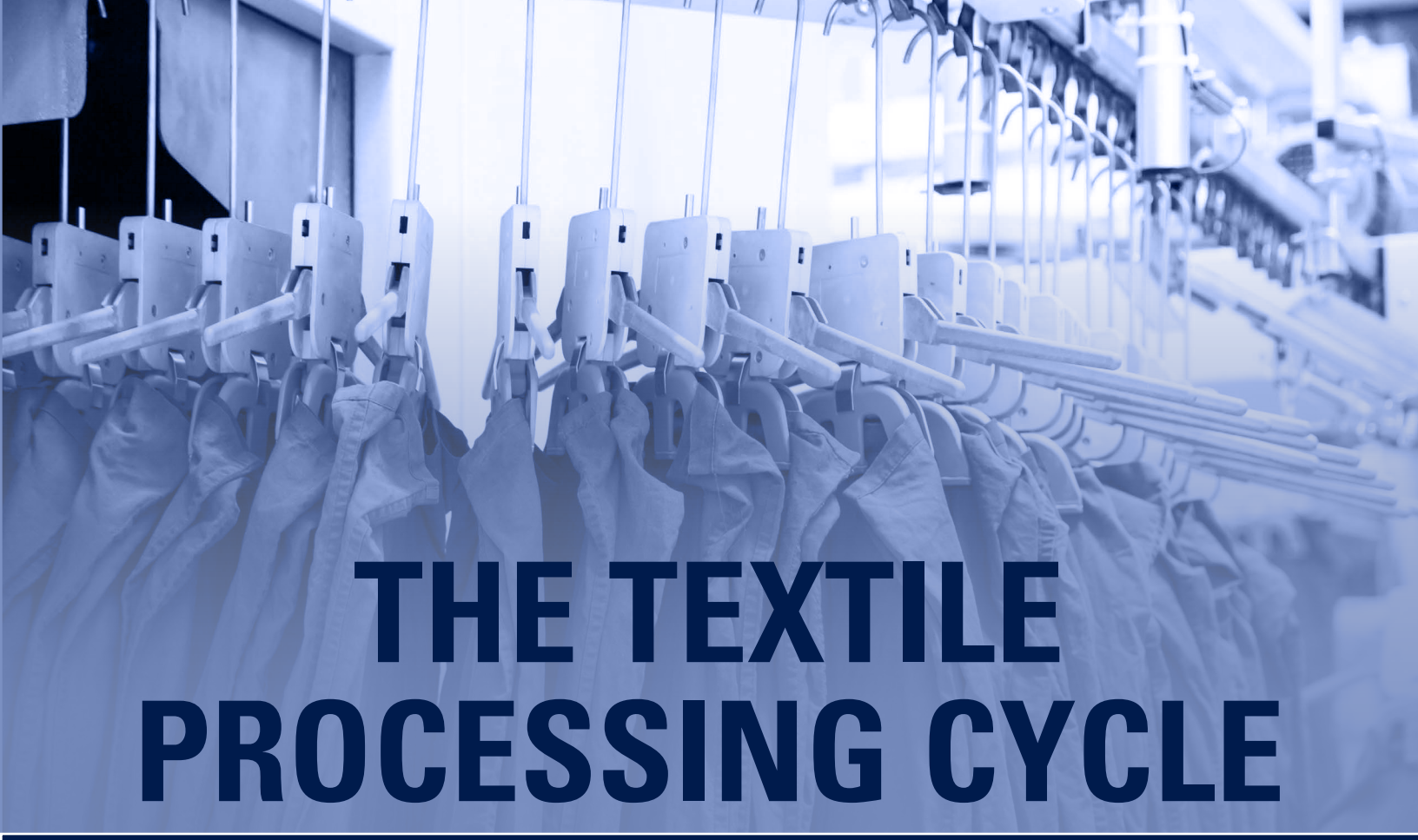
7.4.2.1.4.1. The quality of finished products shall be maintained as pre-defined by the customer and shall be sufficient to meet the needs of the customer.

7.4.2.1.4.2. A variety of process monitors should be used to indicate how the provider process has performed including:

7.4.2.1.4.2.1. Rewash rates;

7.4.2.1.4.2.2. pH spot tests; and

7.4.2.1.4.2.3. Residual chlorine spot tests.



THE TEXTILE PROCESSING CYCLE

★ Part II ★

1. Handling, Collection and Transportation of Soiled Healthcare Textiles
2. Sorting
3. Washing and Extraction
4. Drying
5. Finishing
6. Storage
7. Delivery of Cleaned Healthcare Textiles

PART II. THE TEXTILE PROCESSING CYCLE

Part II - 1. Handling, Collection and Transportation of Soiled Healthcare Textiles

1.1. Standard/Universal Precautions

1.1.1. All soiled textiles must be assumed to be contaminated. (CDC HICPAC GL EIC 2019; OSHA: 29 CFR 1910.1030; AHE Practice GL 3rd ed. Section 4)

1.1.2. Standard/Universal Precautions must apply to all personnel who handle soiled textiles during moving, containing, loading, unloading, and sorting said textiles. (CDC HICPAC GL EIC 2019; OSHA: 29 CFR 1910.1030; AHE Practice GL 3rd ed. Section 4)

1.2. Handling and Collection

1.2.1. All healthcare textiles must be handled and collected in accordance with federal regulations or the Authority having Jurisdiction (AHJ), thereby minimizing potential exposure of laundry personnel to bloodborne pathogens or other infectious agents. (CDC HICPAC GL EIC 2019; OSHA: 29 CFR 1910.1030; AHE Practice GL 3rd ed. Section 4; ANSI/AAMI ST79:2017 Std. 6.3)

1.2.2. Soiled, contaminated textiles and fabrics must be handled and collected with minimal agitation at all times to prevent contamination of air, surfaces, clean textiles, and persons. (CDC HICPAC GL EIC, 2019; OSHA: 29 CFR 1910.1030)

1.3. Transportation

1.3.1. The provider must maintain functional separation of clean textiles from soiled textiles in carts and/or vehicles at all times during handling, collection, and transportation of soiled textiles. (ANSI/AAMI ST79:2017 Std. 6.5.7; FGI GL 2014: 2.1-5.2 Linen Services 2.1-5.2.2.1, 2.2-5.2.3.1-3)

1.3.2. Functional separation of clean from soiled textiles must be maintained during transportation by:

1.3.2.1. Transport soiled textiles in fluid-resistant containers/bags.; (ANSI/AAMI ST65:2018; Std. 9.5.3)

1.3.2.2. Anchoring soiled textile containers in the vehicle to prevent spillage from their containers;

1.3.2.3. Training personnel regarding proper bagging and placement of textiles in the transporting truck; and

1.3.2.4. Ensuring that all personnel with this responsibility follow Standard/Universal Precautions when necessary (e.g., when handling loose soiled textiles not contained in bags).

1.4. Carts Used for Soiled Textiles

1.4.1. Carts, containers, covers, and liners used to collect or transport soiled textiles must be properly cleaned and disinfected after the cart is emptied and before any next use, whether to transport clean textiles or soiled textiles. (ANSI/AAMI ST65:2018; Std. 9.5.4.1, ANSI/AAMI ST79:2017; Std. 6.5.3; FGI GL 2014: 2.1-5.2.2.1. Linen Services)

1.4.2. If state regulation or AHJ indicates that carts used for soiled textiles cannot be used subsequently to transport clean textiles, the provider must comply with this restriction.

1.4.3. Proper cleaning shall include any of the following:

- Steam Cleaning
- Cleaning with a detergent and water or
- Using a hospital grade detergent disinfection
- Alternative method of disinfection such as ultraviolet-C (UV-C) systems

1.4.3.1 The laundry shall have documentation that supports the efficacy of its process in disinfection of the carts.

1.4.3.2 All methods shall follow instructions of the manufacturer and documentation is to be available to support the validation of the process used.

1.4.3.3.1. Hospital-grade cleaning products shall be used according to label instructions, ensuring that the product remains on surfaces for the full contact time. (ANSI/AAMI ST65:2018; Std. 9.5.4.1; ANSI/AAMI ST79:2017; Std. 7, 7.4; CDC HICPAC GL EIC, 2019)

Part II - 2. Sorting

2.1. Soiled Sorting Area

2.1.1. The surfaces in the soil sort room must be cleaned and disinfected in accordance with Part I Subpart 2 Section 2.2 of this HLAC Standard. (CDC HICPAC GL EIC, 2019; ANSI/AAMI ST79:2017; Std. 4.5.2, 7; OSHA 29 CFR 1910.1030)

REFER TO

Part I - 2.2.2 Cleaning, Decontamination, & Disinfection

2.2. Standard/Universal Precautions

2.2.1. All personnel who handle soiled healthcare textiles must follow Standard/Universal Precautions and use appropriate PPE for this task. (OSHA: 29 CFR 1910.1030; CDC HICPAC GL EIC, 2019; CDC HICPAC GL IC HCW, 1998)

2.3. Sorting Soiled Textiles

2.3.1. Soiled textiles shall be sorted and loaded appropriately in order to provide hygienically clean linen. (ANSI/AAMI ST65:2018; Std. 5.4.2)

2.3.2. Laundry bags and textiles contaminated with hazardous substances must be prewashed, and then the textiles added to other laundry for a second wash. (OSHA: 29 CFR 1910.1200; The OSHA Technical Manual: Haz Drugs, Sec 6, Chap 2)

2.4. Foreign Object Policies

2.4.1. Foreign objects shall be removed during the sorting process to be disposed of or returned to the customer in accordance with provider/customer contract.

2.4.1.1. Reusable surgical instruments shall be retrieved from the textiles prior to laundering, placed into designated containers, and returned to the customer. (ANSI/AAMI ST65:2018; Std. 5.3.1)

2.4.1.2. Disposable devices shall be retrieved from the textiles prior to laundering, discarded into designated containers, and/or returned to the customer. (ANSI/AAMI ST65:2018; Std. 5.3.1)

2.4.2. Sharps Policy:

2.4.2.1. The provider must maintain a written sharps policy that includes, at a minimum:

2.4.2.1.1. Appropriate sharps containers must be closable, puncture resistant, leakproof on sides and bottom, and labeled (e.g., using the biohazard symbol) or color-coded;

2.4.2.1.2. Sharps containers must be located near soiled textile handling or sorting stations for collection and proper disposal of sharps; and (OSHA: 29 CFR 1910.1030; ANSI/AAMI ST65:2018; Std. 5.3.1; CDC HICPAC GL EIC, 2019)

2.4.2.1.3. Personnel injured by a sharp shall follow OSHA's (or other relevant regulatory agency) regulations on sharps injury documentation, post-exposure evaluation, and follow-up. (OSHA: 29 CFR 1910.1030; CDC HICPAC GL IC HCW, 1998)

Part II - 3. Washing and Extraction

3.1. Washing

3.1.1. The provider shall follow fabric-care instructions and special laundering requirements for items used by the customer, thereby ensuring that washed healthcare textiles become hygienically clean. (CDC HICPAC GL EIC, 2019)

3.1.2. The provider must sort and process environmental cleaning and disinfection textiles (e.g., cleaning cloths, microfiber cloths, mop heads, etc.) in separate wash loads from healthcare textiles intended for patient use.

3.1.3. The provider shall establish the load size (weight) for each textile classification and for each type of equipment used. (ANSI/AAMI ST65:2018; Std. 6.2.2)

3.1.4. Each classification shall have established parameters to optimize the wash processes:

3.1.4.1. Cycle time: Pre-wash, wash, rinse, and final rinse times;

3.1.4.2. Water levels/usage: Total water usage and/or water levels;

3.1.4.3. Temperature: Wash cycle, bleach cycle, and rinse cycle temperatures; and

3.1.4.4. Chemical usage: Chemical types and usage levels for each step in the wash process.

3.1.5. The provider shall demonstrate that wash processes are in compliance with state and local requirements by including a copy of these requirements in appropriate documentation and referrals to these requirements in policies.

3.1.6. If soiled textiles are received from the customer as labeled with hazardous drug contamination (i.e., chemotherapy drugs), the provider shall follow an appropriate textile process that includes:

3.1.6.1. Pre-wash of contaminated textiles in a washable laundry bag (e.g., net bag) separate from all other textiles and

3.1.6.2. Second wash process with other soiled textiles prior to drying cycle.

3.2. Extraction

3.2.1. The provider shall extract and/or dry the clean healthcare textiles in a manner that preserves the integrity of the textiles, minimizes microbial growth after washing, and prepares the textiles for efficient ironing or folding. (ANSI/AAMI ST65:2018; Std. 6.2.3.8)

3.2.2. Provider shall have a process to ensure damp textiles are not stored for an inappropriate length of time. (CDC HICPAC GL EIC, 2019)

Part II - 4. Drying

4.1. Equipment

4.1.1. Dryers shall be in good operating condition.

4.2. Drying

4.2.1. Drying procedures shall be described, controlled, and monitored for each textile classification to ensure appropriate drying. (ANSI/AAMI ST65:2018; Std. 6.3.1)

Part II - 5. Finishing

5.1. Ironing Equipment

5.1.1. Ironers shall be maintained in good operating condition, so that they adequately iron, dry, and fold the textiles without excessive heat, pressure, or mechanical damage.

5.1.2. The equipment shall maintain a temperature appropriate for the type of fabric being processed and based on the equipment manufacturer's manual and recommendations, if available.

5.1.3. Documentation of monthly temperatures and preventive maintenance shall be maintained.

5.2. Folding and Stacking

5.2.1. Dry folding equipment shall be in good operating condition to properly fold the textiles without damage.

5.2.2. The folding and stacking process shall ensure that the textile merchandise is maintained in the same hygienically clean state as was achieved when it emerged from washing.

5.2.3. If any textiles become soiled in this process, they shall be rewashed in accordance with HLAC Standard Part II Subpart 3 Section 3.1. (ANSI/AAMI ST65:2018; Std. 9.4)

5.3. Packaging

5.3.1. Healthcare textile packaging must preserve textiles in a hygienically clean state for delivery to the customer. (CDC HICPAC GL EIC, 2019; ANSI/AAMI ST65:2018; Std. 9.4)

5.3.2. Textiles must be wrapped into fluid-resistant bundles or placed as unwrapped bundles into fluid-resistant covered carts or hampers.

5.3.3. Wrapping material shall be plastic or other material that will protect the textiles from inadvertent environmental contamination.

5.3.4. During packaging, textiles shall be handled as little as possible to prevent soiling or contamination. (ANSI/AAMI ST65:2018; Std. 9.4)

5.3.5. The wrapping material or the cart must be securely closed during transport to the customer.

5.4. Reprocessing Requirements

5.4.1. If any textiles become soiled during any stage of the finishing processing (including packaging), they must be rewashed and reprocessed in accordance with HLAC Standard Part II Subpart 3 Section 3.1. (ANSI/AAMI ST65:2018; Std. 9.4)

REFER TO

Part II - 3.1 Washing

Part II - 6. Storage

6.1. Rationale

6.1.1. The provider's storage strategies and handling methods of healthcare textiles must preserve the textiles in a hygienically clean state for delivery to the customer. (ANSI/AAMI ST65:2018; Std. 9.1; 9.6.1-2; ANSI/AAMI ST79:2017; Std. 9.1, 11.2.1)

6.1.2. Stock inventory of clean finished textiles shall be rotated and used in a first-in/first-out manner. (ANSI/AAMI ST65:2018; Std. 9.6.3; ANSI/AAMI ST79:2017 Std. 11.1.3, 11.3.1)

6.2. Storage Areas

6.2.1. Storage parameters must be consistent with Part I, Subpart 2, Section 2.1, Subsection 2.1.3 of this HLAC Standard.

REFER TO

Part I - 2.1.3 Clean Textile Staging and Storage Areas

6.2.2. Unwrapped clean textiles shall be stored in designated storage rooms, areas, or carts. (ANSI/AAMI ST65:2018; Std. 9.6.1-2; ANSI/AAMI ST79:2010 Std. 11.1; FGI GL 2014: 2.1-5.2 Linen Services)

6.2.3. Only clean textiles shall be stored in this area and signage posted as "Textile storage room." (ANSI/AAMI ST65:2018; Std. 9.6.2)

6.2.4. Storage area cleanliness:

6.2.4.1. A schedule of surface cleaning with a detergent and water, including floor and shelves, shall be in writing.

6.2.4.2. Should this storage area require disinfection after cleaning, the provider shall use a hospital grade disinfectant according to label instructions per provider's policy. (CDC HICPAC GL EIC, 2019; ANSI/AAMI ST79:2017 Std. 7.1)

6.2.5. Storage area entry and exit:

6.2.5.1. The doors to the clean textile storage area shall remain closed at all times, except for entrance or exit. (ANSI/AAMI ST65:2018; Std. 9.6.2)

6.2.5.2. Storage rooms shall only be accessible by authorized personnel. (ANSI/AAMI ST65:2018; Std. 9.6.2; ANSI/AAMI ST79:2017 Std. 11.1.1)

6.3. Storage Options

6.3.1. Bundled and wrapped textiles shall be stored in open racks in the laundry, on the trucks, or at the customer's facility provided the integrity of bundled and wrapped textiles is not compromised. (ANSI/AAMI ST65:2018; Std. 9.6.2; ANSI/AAMI ST79:2017 Std. 11.1.1)

6.3.2. If unwrapped textiles are placed into carts or hampers and covered, the container shall remain covered at all times until delivered to the customer's textiles storage room or other designated location in the healthcare facility.

6.3.3. If the cart does not have a solid bottom (i.e., drain holes), the bottom must be lined with a hygienically clean barrier that prevents environmental contamination before placing clean textiles inside. (ANSI/AAMI ST65:2018; Std. 9.6.1-2; ANSI/AAMI ST79:2017 Std. 11.2.2)

6.4. Reprocessing Requirements

6.4.1. If any textiles become soiled during storage, they must be rewashed and reprocessed in accordance with Part II Subpart 3 Section 3.1. of this HLAC Standard. (ANSI/AAMI ST65:2018; Std. 9.4)

REFER TO

Part II - 3.1 Washing

Part II - 7. Delivery of Cleaned Healthcare Textiles

7.1. Clean healthcare textiles must be transported, delivered to the customer's storage area, and stored by methods designed to minimize microbial contamination from surface contact or airborne deposition. (FGI GL 2014: 2.1 5.2 Linen Services 2.15.2.2.; 2.1 5.2.3.; CDC HICPAC GL EIC, 2019; ANSI/AAMI ST65:2018; Std. 9.5.1)

7.2. Delivery methods:

7.2.2. Clean textiles shall be wrapped for delivery. (ANSI/AAMI ST65:2018; Std. 9.6.1-2; ANSI/AAMI ST79: 2017 Std. 9.7)

7.3. Cart Function and Cleanliness

7.3.1. Carts shall be maintained in good working order with wheels free from strings or other debris that impairs functioning or collects dirt.

7.3.2. Cart cleanliness:

7.3.2.1. Carts must be cleaned and disinfected in accordance with Part II Subpart 1 Section 1.4 of this HLAC Standard. (CDC HICPAC GL EIC, 2019; ANSI/AAMI ST79:2017 Std. 6.5.3)

REFER TO

Part II - 1.4 Carts Used for Soiled Textiles

7.3.2.2. Carts, containers, reusable cart covers, and liners used for clean textiles shall be properly cleaned and disinfected after the cart is emptied and upon return to the facility. (ANSI/AAMI ST65:2018; Std. 9.5.4.1; ANSI/AAMI ST79:2017 Std. 6.5.7)

7.3.2.3. Reusable textile cover materials (e.g., liners) must be washed before the next use. (ANSI/ AAMI ST65:2018; Std. 9.5.4.1; ANSI/AAMI ST79:2017; Std. 11.2.2)

7.3.2.4. If a cart used to transport clean textiles appears soiled, it must be cleaned and disinfected before it is subsequently used. (ANSI/AAMI ST65:2018; Std. 9.5.4.1; ANSI/AAMI ST79:2017 Std. 11.2.2)

7.4. Vehicle Considerations

7.4.1. Functional separation:

7.4.1.1. The best practice is to transport clean and soiled linen separately, however if clean and soiled textiles are transported in the same vehicle, proper and effective functional separation must be maintained at all times.

7.4.1.2. Separation must be accomplished by the use of physical barriers and/or space separation sufficient to protect clean textiles from contact with soiled textiles. (ANSI/AAMI ST65:2018; Std. 9.5.5; ANSI/AAMI ST79:2017 Std. 11.3.5)

7.4.2. Vehicle cleanliness:

7.4.2.1. The interior of the vehicle's cargo area used to transport healthcare textiles shall be cleaned on a regular basis per provider's policies and procedures and whenever visibly soiled. (ANSI/AAMI ST65:2018; Std. 9.5.5; ANSI/AAMI ST79:2017 Std. 8.11.5)

7.4.2.2. Should the interior surfaces of the cargo area become contaminated with blood or OPIM, these surfaces must be decontaminated, cleaned with a detergent and water, and disinfected with a hospital grade disinfectant labeled as tuberculocidal and used according to label instructions. (CDC HICPAC GL EIC, 2019; ANSI/AAMI ST79:2017; Std. 11.3.5)

7.4.3. Occupational safety for drivers:

7.4.3.1. Hand care:

7.4.3.1.1. Vehicles used to transport healthcare textiles must have alcohol-based hand sanitizer (ABHS) that contains at least 60 percent alcohol available on board for the purpose of hand hygiene.

7.4.3.1.2. Drivers must use gloves to minimize contact with soiled textiles and use appropriate hand hygiene after glove removal. Gloves used to handle soiled linen must never come in contact with clean linen.

7.4.3.2. Vehicles used to transport healthcare textiles shall have PPE and Spill Kits on board for the purpose of self-protection while cleaning and disinfecting the spill according to the provider's policies and procedures.

SURGICAL PACK ASSEMBLY ROOM STANDARDS

★ Part III ★

PART III. SURGICAL PACK ASSEMBLY ROOM STANDARDS

Notes: Part III addresses facility and process elements that are unique to the presence of surgical pack assembly operations. Please refer to Parts I and II for Standards covering the laundry processes up to the point that textiles designated for surgical packs are moved to the surgical pack assembly room for subsequent management.

These Accreditation Standards do not include textile sterilization. Providers who perform sterilization of textiles should refer to American National Standard Institute (ANSI)/Association for the Advancement of Medical Instrumentation (AAMI) ST65:2018 Processing of Reusable Surgical Textiles for Use in Health Care Facilities and ANSI/AAMI ST79:2017, & 2020 Amendments A1, A2, A3, A4 (Consolidated Text) Comprehensive guide to steam sterilization and sterility assurance in health care facilities.

Part III - 1. Physical Facilities of Surgical Pack Assembly Area/Room

1.1. Floors, Walls, Ceilings and Vents

1.1.1. Floors and walls must be constructed of materials that will withstand scheduled wet cleaning as well as the heat and humidity of the laundry environment (for example, mold- and moisture-resistant gypsum board, concrete, stainless steel, copper, etc.) (ANSI/AAMI ST65:2018; Std. 3.4.3; ANSI/AAMI ST79:2017; Std. 3.3.2)

1.1.2. Particulate or fiber-shedding materials must not be used in the construction of the surgical pack assembly room. (ANSI/AAMI ST65:2018; Std. 3.4.3 ANSI/AAMI ST79:2017; Std. 3.3.5.2

1.1.3. Ceilings in clean work areas must be flush with recessed, enclosed fixtures. (ANSI/AAMI ST65:2018; Std. 3.4.3; ANSI/AAMI ST79:2017; Std. 3.3.5.3)

1.2 Separation of Work Areas

1.2.1. The surgical pack assembly room must be designed, so that areas in which clean textiles are received, stored, and assembled into packs are separated by a physical barrier from areas in which soiled textiles are received or processed. (ANSI/AAMI ST65:2018; Std. 3.2.3.2; ANSI/AAMI ST79:2017; Std. 3.2.2)

1.3. Ventilation Requirements for Proper Air Flow and Climate Control

1.3.1. Heating, ventilation, and air conditioning (HVAC) system must be designed to conform to AIA/FGI standards in effect at the time when the facility was built or renovated. (FGI GL 2014: 2.1-8; ANSI/ASHRAE/ASHE Std. 170-2021: Sec. 4,5,6,8)

1.3.2. The HVAC system in the surgical pack assembly room must maintain the appropriate positive air pressure relative to the rest of the facility, preventing intrusion of contamination from the soiled textiles area. The HVAC system must be a down-draft system for air circulation within the space, and the number of air changes/hour (ACH) (typically 10) must be sufficient to minimize lint particles in the air. (ANSI/AAMI ST65:2018; Std. 3.3.4, 3.4.4; FGI GL 2014: Table 7.1; ANSI/ASHRAE/ASHE Std. 170-2021: Table 7.1)

1.3.3. Return air registers (i.e., exhaust ducts) shall be at or near floor level, thereby facilitating the installation and effective maintenance of any filtering systems. (ANSI/AAMI ST65:2018; Std. 3.4.4)

1.3.4. Portable fans must not be permitted in the surgical pack assembly room. (ANSI/AAMI ST65:2013; Std. 3.4.4)

1.3.5. Supply air for the surgical pack assembly room must be filtered as indicated in the edition AIA/FGI guidelines in effect at the time of construction or renovation of the laundry facility, with the filters undergoing scheduled regular maintenance as determined by the HVAC system engineer. (ANSI/AAMI ST65:2018;Std. 3.4.4)

1.3.5.1. For new construction or major renovated laundry facilities' surgical pack assembly room since 2011, filtration must consist of one filter bed with an 8 MERV (minimum efficiency rating value) or 30% filtration efficiency or the FGI Guidelines at the time of the construction, as a minimum. (ANSI/ASHRAE/ASHE Std. 170-2021 Table 7.1; FGI GL 2014: 2.1-5.1.2.2 Linen Services)

1.3.6. Temperatures in the surgical pack assembly room must be maintained between 68°F - 73°F to ensure a comfortable work environment for personnel in appropriate work attire. (ANSI/AAMI ST65:2018; Std. 3.4.5; FGI GL 2014: Table 7.1; ANSI/ASHRAE/ASHE Std. 170-2021: Table 7.1)

1.3.7. Relative humidity (RH) must be maintained between 30% and 60% max in all work areas, except the sterile storage area, where the humidity must not exceed 70%, for personnel comfort and to discourage microbial (e.g., fungal) growth. (ANSI/AAMI ST65:2018; Std. 3.4.5; FGI GL 2014: Table 7.1; ANSI/ASHRAE/ASHE Std. 170-2021: Table 7.1)

1.4. Lighting

1.4.1. High intensity lighting shall be available in that part of the room or area where textiles are examined (i.e., folding, assembly, and repair areas). (ANSI/AAMI ST65:2018; Std. 3.4.6)

1.4.2. Lower intensity overhead lighting shall be employed for areas where light illumination (e.g., table, bar, tube, etc.) inspection is performed, so the light illumination equipment can be used optimally. (ANSI/AAMI ST65:2018; Std. 3.4.6)

1.5. Storage Area for Clean Textile Packs

1.5.1. The storage area for clean textile packs must be designed and managed in accordance with recommended practices for clean and sterile products as outlined in these standards. (Code of Federal Regulations 21 CFR 820.150; ANSI/AAMI ST65:2018; Std. 3.4.8, 3.4.9, 3.4.10, 9.6.1-3; ANSI/AAMI ST79:2017; Std. 11.1; FGI GL 2014: 2.1-5.2 Linen Services).

1.5.2. Bulk shipping warehouse cardboard boxes must not be in these surgical pack assembly storage rooms. (ANSI/AAMI ST79:2017 Std. 5.2.1)

1.5.3. Storage rooms must be accessible only by authorized personnel. (ANSI/AAMI ST65:2018; Std. 9.6.2; ANSI/AAMI ST79:2017; Std. 8.9.2)

1.5.4. Clean textile pack storage room doors must remain closed, except for access or exit. (ANSI/AAMI ST65:2018; Std. 9.6.2)

1.5.5. Environmental conditions in the clean surgical textile pack storage area must include:

1.5.5.1. Temperatures must not exceed 73°F to prevent microbial contamination;

1.5.5.2. Relative humidity must be less than 70% to inhibit microbial growth;

1.5.5.3. The room must be properly ventilated to prevent accumulation of dust and lint (i.e., Minimum total air exchange rate of 2 ACH); and

1.5.5.4. The room must have positive air pressure relative to adjacent spaces, preventing intrusion of contamination from the soiled textiles areas. (ANSI/AAMI ST65:2018; Std. 9.6.1; ANSI/AAMI ST79:2017; Std. 3.3.6.4-6; FGI GL 2014: Table 7.1; ANSI/ASHRAE/ASHE Std. 170-2013 Table 7.1)

1.5.6. Storage areas must be located within the surgical pack assembly room to facilitate bundling, loading onto trucks, and transportation.

Part III - 2. Surgical Pack Assembly Room Entry and Admission

2.1. Policies:

2.1.1. Criteria for authorized entry and movement within the surgical pack assembly room must be specified in written policies and procedures. (ANSI/AAMI ST65:2018; Std. 3.2.4)

2.1.2. Eating, drinking, smoking, applying cosmetics or lip balm, and handling contact lenses must be prohibited in the surgical pack assembly room. (OSHA: 29 CFR 1910.1030)

2.1.3. Traffic in the surgical pack assembly room must be limited to authorized personnel only. (ANSI/AAMI ST65:2018; Std. 3.2.4)

2.1.4. Policies and procedures must be developed to address visitor access and the circumstances for access and must establish a dress code to reduce the potential for contamination of surgical textiles. (ANSI/AAMI ST65:2018; Std. 3.2.4)

2.2. Hand Hygiene Practices

2.2.1. Personnel must wash their hands before entering and working in the surgical pack assembly room.

2.2.2. Handwashing sinks with soap and paper towels must be readily accessible in or near the surgical pack assembly room. (ANSI/AAMI ST65:2018; Std. 3.4.7)

2.2.3. Alcohol-based hand sanitizer (with minimum alcohol concentration of 60%) also must be made readily available at the entrance and exit of the surgical pack assembly room door. (ANSI/AAMI ST65:2018; Std. 3.4.7, CDC Handwashing in Communities, 2022.)

Part III - 3. Surgical Textile Assembly Process

3.1. Carts Used to Move Clean Surgical Textiles to the Surgical Pack Assembly Room

3.1.1. Carts that are utilized for clean surgical textiles must be cleaned and disinfected in accordance with Part II, Subpart 7, Section 7.3. of this HLAC Standard. (ANSI/AAMI ST65:2018;Std. 9.5.4.1)

REFER TO

Part II - 7.3 Cart Function and Cleanliness

3.2. Inspection of Clean Surgical Textiles Prior to Pack Assembly

3.2.1 Written quality standards must be developed between the linen provider and the customer. Provider must provide documentation of these standards. Standards should be reviewed annually. (ANSI/AAMI ST65:2018; Std. 7.2.1)

3.2.2. If surgical textile integrity and quality are monitored by the provider, the critical zones of surgical textiles must be visually inspected with the use of light illumination (e.g., table, bar, tube, etc.) for the presence of stains, residue, physical defects, chemical or thermal damage, and foreign debris, and to ensure that appropriate labels are in place and a tracking system is intact. (ANSI/AAMI ST65:2018; Std. 7.2.1)

3.2.2.1. The provider and customer shall agree to a written procedure for reporting, investigating, and returning surgical textile barrier efficacy issues and strike-through occurrences to the textile manufacturer and reporting to the non-COG customer. (ANSI/AAMI ST65:2018; Std. 11.4)

3.2.2.2. A tracking mechanism suitable for each surgical textile barrier product must be used to track the number of product's uses based on the textile manufacturer's recommendations. (ANSI/AAMI ST65:2018; Std. 11.5)

3.2.3. Stains:

3.2.3.1. If, during the inspection process, surgical textiles are determined to be stained, these textiles must be rewashed or retired as appropriate. (ANSI/AAMI ST65:2018; Std. 7.2.2, 7.4.3)

3.2.3.2. Surgical textiles with aesthetic stains that do not adversely affect the functionality of the textile may remain in service unless the end user determines otherwise. (ANSI/AAMI ST65:2018; Std. 7.2.2)

3.2.3.3. Stained surgical textiles must be retired if rewashing cannot successfully remove unacceptable stains or residues (e.g., medicines, lubricants, adhesives, blood and/or body fluids, hard surfaced or foreign matter of unknown composition, and raised or tactile residues). (ANSI/AAMI ST65:2018; Std. 7.2.2)

3.2.4. Physical defects:

3.2.4.1. Physical defects (i.e., loose threads, loose or missing ties/attachments, damaged/missing snaps, cuts, tears, and holes) must be repaired as appropriate with patching and mending before the textile is reused in accordance with Part III Subpart 3 Section 3.3 of this HLAC Standard. (ANSI/AAMI ST65:2018; Std. 7.2.3)

REFER TO

Part III - 3.3 Maintenance of Surgical Textiles

3.2.5. Chemical or thermal damage:

3.2.5.1. Surgical textiles must be inspected for evidence of chemical and/or thermal damages (usually apparent as discoloration, stiffening, or compromised structural integrity holes). (ANSI/AAMI ST65:2018; Std. 7.2.4)

3.2.5.2. Surgical textiles with chemical and/or thermal damage that adversely impacts the important functional attributes of the textile must be retired or removed from service. (ANSI/AAMI ST65:2018; Std. 7.2.4)

3.2.6. Foreign debris

3.2.6.1. Surgical textiles must be free of foreign debris (e.g., lint, hair, loose fibers, fibrous pills, other particulates) prior to assembly into packs. (ANSI/AAMI ST65:2018; Std. 7.2.5)

3.2.6.2. Foreign debris must be removed with an appropriate method (e.g., a delinting roller or sticky tape) as approved by the textile manufacturer. (ANSI/AAMI ST65:2018; Std. 7.2.5)

3.2.6.3. Work practices must be implemented to keep surgical textiles free from foreign debris. Such practices include, at a minimum, the following:

3.2.6.3.1. Dress code suitable for the inspection area of the surgical pack assembly room, consisting of dedicated uniforms or other suitable outerwear, hair covering, and beard covers as appropriate;

3.2.6.3.2. Handwashing procedures;

3.2.6.3.3. Housekeeping procedures to minimize dust and lint; and

3.2.6.3.4. Facility maintenance (e.g., keeping dryer lint screens clean). (ANSI/AAMI ST65:2018; Std. 7.2.5)

3.2.7. Labeling:

3.2.7.1. New surgical textiles shall be inspected for appropriate labels and accompanying manufacturer's instructions. (ANSI/AAMI ST65:2018; Std. 7.2.6)

3.2.7.2. Labels shall contain information such as manufacturer, product type, and lot code numbers. (ANSI/AAMI ST65:2018; Std. 7.2.6)

3.2.7.3. Labels with lot code information must remain intact throughout the effective life of the textile. (ANSI/AAMI ST65:2018; Std. 7.2.6)

3.2.7.4. Surgical textiles that are labeled as in compliance with ANSI/AAMI PB70 must be labeled with their barrier classification. (ANSI/AAMI PB70; ANSI/AAMI ST65:2018; Std. 7.2.6, 7.3.4.2)

3.2.8. Tracking System

3.2.8.1. If a tracking mechanism (e.g., radio frequency identification [RFID], grid, bar code) is present on a surgical textile, this must be visually inspected, marked, scanned, or read each time the product is processed. (ANSI/AAMI ST65:2018; Std. 7.2.7)

3.2.8.2. If the integrity of the tracking mechanism is in question, the textile must be pulled from service or an alternate method of tracking must be used until the tracking problem is resolved. (ANSI/AAMI ST65:2018; Std. 7.2.7)

3.2.9. Effective Life of Surgical Textiles

3.2.9.1. Methods must be designed and in place to the number of uses/washes for surgical textile barrier products. (ANSI/AAMI ST65:2018; Std. 7.3.3)

3.2.9.2. Textile manufacturers must be consulted for directions on evaluating the critical performance attributes of their textile products, to include barrier properties (e.g., repellent finish, deterioration of coatings or film), absorbency, strength, drapeability, physical defects, and signs of textile aging. (ANSI/AAMI ST65:2018; Std. 7.3.3)

3.3. Maintenance of Surgical Textiles

3.3.1. Patching and Mending

3.3.1.1. Sewing and use of patches shall be acceptable for repairs in non-critical zones of surgical textiles. (ANSI/AAMI ST65:2018; Std. 7.4.1-2)

3.3.1.2. Physical defects within the critical zones of the various surgical textiles must be repaired, following manufacturer's guidelines. (ANSI/AAMI ST65:2018; Std. 7.2.3)

3.3.1.2.1. Heat-sealed patches must be used to repair physical defects present in the critical zones of surgical textiles. Attributes of these patches must include: (ANSI/AAMI ST65:2018; Std. 7.4.1)

3.3.1.2.1.1. Meeting the same general medical device safety and effectiveness requirements as the textile being repaired, 3.3.1.2.1.2. Being applied per manufacturer's instructions,

3.3.1.2.1.3. Providing at least the same performance characteristics, including level of barrier performance as the textile being repaired,

3.3.1.2.1.4. Providing at least the same life expectancy as the textile being repaired, and

3.3.1.2.1.5. Allowing for effective sterilization. (ANSI/AAMI ST65:2018; Std. 7.4.1)

3.3.1.2.2. Patches must not be sewn to the textile. (ANSI/AAMI ST65:2018; Std. 7.4.1)

3.3.1.2.3. Patches may need to be applied on one or both sides of a textile, depending on the textile's design and according to the textile manufacturer's instructions. (ANSI/AAMI ST65:2018; Std. 7.4.1)

3.3.1.2.4. Use of sewing is discouraged for repairs in textiles' critical zones; but if sewing is indicated for a successful repair, heat-sealed patches must be used to seal the needle holes. (ANSI/AAMI ST65:2018; Std. 7.4.2)

3.3.1.3. Loose patches must be removed and new patches applied. (ANSI/AAMI ST65:2018; Std. 7.4.1)

3.3.1.4. Acceptable number, location, shape, and size of patches must be clearly delineated in written quality standards and repair procedures. (ANSI/AAMI ST65:2018; Std. 7.4.1)

3.3.1.5. If patching and/or mending is performed, the textiles must be rewashed. (ANSI/AAMI ST65:2018; Std. 7.4.3)

3.3.2. Rewashing surgical textiles

3.3.2.1. If a reusable surgical textile requires rewashing, the procedure used must be compatible with the product. (ANSI/AAMI ST65:2018; Std. 7.4.3)

3.3.2.2. Each rewash cycle must be counted as an additional life cycle for the item. (ANSI/AAMI ST65:2018; Std. 7.4.3)

3.3.3. Rejuvenation of surgical textiles

3.3.3.1. If reusable surgical textile products require rejuvenation or a laundry additive is used to maintain repellency, the process must be compatible with the textile product. (ANSI/AAMI ST65:2018; Std. 7.4.4)

3.3.3.2. Additives that maintain surgical textile performance characteristics (e.g., repellency) must be used according to product instructions. (ANSI/AAMI ST65:2018; Std. 7.4.4)

3.3.3.3. Rejuvenation cycles must be counted as additional life cycles. (ANSI/AAMI ST65:2018; Std. 7.4.4)

3.3.4. Surgical textile retirement or alternate use:

3.3.4.1. When reusable surgical textile products fail to meet their minimum functional performance criteria, they must be retired from use, downgraded to a less stringent alternate use category (e.g., cover gowns), or remade into a different product (e.g., a smaller wrapper). (ANSI/AAMI ST65:2018; Std. 7.4.5)

3.3.4.2. Products placed into alternate use or remade into different products shall continue to be safe and effective for their intended use. (ANSI/AAMI ST65:2018; Std. 7.4.5)

3.3.4.3. Items placed into alternate use must be permanently marked in some obvious fashion to prevent mix-ups or inappropriate use. (ANSI/AAMI ST65:2018; Std. 7.4.5)

Part III - 4. Preparation and Wrapping of Surgical Textiles

4.1. Preparation

4.1.1. Policies and procedures must be in place to ensure that reusable surgical textiles are laundered, dried, folded, and packed in a manner that will permit sterilization and delivered to the customer via a means such that the textiles maintain their hygienic integrity, avoiding contamination. (ANSI/AAMI ST65:2018; Std. 11.3)

4.1.2. Preparation, folding, and packing procedures for reusable surgical textiles shall be developed with consultation from the customer and documented. (ANSI/AAMI ST65:2018; Std. 8.2)

4.2. Folding

4.2.1. Reusable surgical textiles shall be folded and packaged properly and consistently each time they are processed in accordance with customer's requirements. (ANSI/AAMI ST65:2018; Std. 8.2)

4.2.2. Standards must be in place to identify the specific folds, components, and other details for each surgical pack built by the laundry. (ANSI/AAMI ST65:2018; Std. 8.2, 8.3.1)

4.2.3. The following elements must be taken into account regarding the folding of clean, reusable surgical textiles: (ANSI/AAMI ST65:2018; Std. 8.3.1)

4.2.3.1. Following inspection, all items must be folded in a manner that will allow them to be aseptically donned and/or presented to the sterile field with as little manipulation and chance of contamination as possible. (ANSI/AAMI ST65:2018; Std. 8.3.1)

4.2.3.2. The method of folding must allow for effective penetration of the steam from the autoclave into the pack. (ANSI/AAMI ST65:2018; Std. 8.3.1)

4.2.3.3. The method of folding must allow for easy identification and orientation of the items. (ANSI/AAMI ST65:2018; Std. 8.3.1)

4.2.4. Clean reusable surgical textiles must be handled with clean hands in a manner to maintain their hygienic quality in accordance with Part I Subpart 5 Section 5.3 Element 5.3.3.3 of this HLAC Standard. (ANSI/AAMI ST65:2018; Std. 4.4, 9.2)

REFER TO

Part I - 5.3.3.3

4.2.5. Procedures for folding surgical textiles shall be reviewed as needed to ensure that they are still applicable with the customer. (ANSI/AAMI ST65:2018; Std. 8.3.1, 9.2)

4.2.5.1. Folding specifications shall be provided by and/or approved by the customer for whom the surgical packs are being built. (ANSI/AAMI ST65:2018; Std. 8.3.1)

4.2.5.2. These specifications shall be documented, using photographs or drawings or other visual media with accompanying instruction notations, and a photograph or drawing of the finished products shall be included. (ANSI/AAMI ST65:2018; Annex A: Examples of Folding Procedures)

4.2.5.3. These photographs and/or drawings specifications shall be maintained in the surgical pack assembly room.

4.3. Surgical Textile Pack Assembly

4.3.1. Pack order, from top to bottom, must be developed in consultation with the customer to ensure that items can be removed from the pack, in the order of their use, without compromising the sterile field. (ANSI/AAMI ST65:2018; Std. 8.4)

4.3.2. After the order of the pack is agreed upon, the pack configuration must be documented (i.e., pack master list and/or a device master record [DMR]). (ANSI/AAMI ST65:2018; Std. 8.4)

4.3.3. The contents and order of each pack configuration shall be reviewed by the manager, who is responsible for pack assembly to ensure that the pack meets all appropriate requirements; documentation for each pack configuration shall be reviewed on a regular basis by the surgical pack assembly room manager with the customer. (ANSI/AAMI ST65:2018; Std. 8.4)

4.4. Wrapping and Packaging

4.4.1. The barrier product used to complete the pack and provide adequate coverage of the contents must be appropriate for the method of sterilization (i.e., permits maximum penetration of the sterilant during sterilization) and must maintain the content's sterility until aseptic presentation. (ANSI/AAMI ST65:2018; Std. 8.5)

4.4.2. The customer shall be consulted in the choice of appropriate barrier product.

4.4.3. The type of barrier used must be documented in the procedure (i.e., pack master list and/or a DMR). (ANSI/AAMI ST65:2018; Std. 8.5)

4.4.4. The finished pack and bulk loose textiles must be packaged in a suitable material (e.g., placed in covered carts or wrapped in plastic) to avoid contamination during transport to the customer.

4.5. Labeling and Identification of Packs

4.5.1. Prior to delivery, assembled packs must have a label that includes the following items of information:

4.5.1.1. Identification (e.g., name, Julian date, and unique pack identifier)

4.5.1.2. Pack contents, including identifying any items containing natural rubber latex

4.5.1.3. Identification or identifying barcode of who and date assembled the pack. (ANSI/AAMI ST65:2018; Std. 8.6)

Part III - 5. Storage and Transportation of Surgical Textile Packs

5.1. Storage of Surgical Textile Packs

5.1.1. Storage of Surgical Textile Packs must comply with Part I Subpart 2 Section 2.1. Element 2.1.3. and Part III Subpart 1 Section 1.5. of this HLAC Standard for statements addressing storage of clean surgical textile packs.

REFER TO

Part I - 2.1.3 Clean Textile Staging & Storage Areas
Part III - 1.5 Storage Areas for Clean Textile Packs

5.2. Transportation of Surgical Textile Packs

5.2.1. Transportation of surgical textile packs must be in accordance with Part II Subpart 7 of this HLAC Standard.

REFER TO

Part II - 7 Delivery of Cleaned Healthcare Textiles

5.2.2. Transport of the surgical textile packs within the provider's facility or to the customer must be accomplished in a manner to maintain the hygienic quality of the packs and to minimize microbial contamination from surfaces or the air. (ANSI/AAMI ST65:2018; Std. 9.5.1)

5.2.3. Clean carts or containers must be used for transport of clean surgical textile packs. Refer to HLAC Standard Part II Subpart 7 Section 7.3. (ANSI/AAMI ST65:2018; Std. 9.5.2)

REFER TO

Part II - 7.3 Cart Function and Cleanliness

5.2.4. Carts or containers used for soiled surgical textiles must not be permitted in the surgical pack assembly room.

5.2.5. Characteristics of carts or containers suitable for transporting clean surgical textile packs must be in accordance to Part II Subpart 7 Sections 7.1. and 7.3. of this HLAC Standard.

REFER TO

Part II - 7.1
Part II - 7.3 Cart Function and Cleanliness

5.2.6. Soiled fabrics must be physically separated from clean during loading procedures to prevent environmental contamination. (ANSI/AAMI ST65:2018; Std. 9.5.4.2)

Part III - 6. Surgical Textile Pack Assembly Room Personnel

6.1. Qualifications

6.1.1. General elements related to personnel qualifications shall be in accordance with Part I Subpart 5 Section 5.1. of this HLAC Standard.

REFER TO

Part I - 5.1 Personnel Qualifications

6.1.2. Surgical pack assembly room procedures must be performed correctly and supervised by knowledgeable personnel. (ANSI/AAMI ST65:2018; Std. 4.1) Refer to HLAC Standard Part I Subpart 5 Section 5.2.

REFER TO

Part I - 5.2 Personnel General Responsibilities

6.2. Training and Competency

6.2.1. General elements of personnel training must be in accordance with Part I Subpart 5 Sections 5.2. and 5.6. of this HLAC Standard.

REFER TO

Part I - 5.2 Personnel General Responsibilities
Part 1 - 5.6 Training and Educational Programs

6.2.2. Personnel must be trained on the appropriate pack processes according to each pack's use requirements. (ANSI/AAMI ST65:2018; Std. 4.3)

6.2.3. Personnel must be trained to operate surgical pack assembly room equipment safely and to recognize and report equipment malfunctions. (ANSI/AAMI ST65:2018; Std. 4.3)

6.2.4. Personnel must be trained to work with reusable surgical textiles and to be familiar with the following items:

6.2.4.1. Characteristics inherent to reusable surgical textiles;

6.2.4.2. Uses of those textiles;

6.2.4.3. Processes required to maintain those qualities, such as folding and preparations of the surgical packs; and

6.2.4.4. Infection prevention relevant to the preparation of surgical textiles. (ANSI/AAMI ST65:2018; Std. 4.3.a-e)

6.3. Health and Personal Hygiene

6.3.1. Additional health and hygiene specifics must be in accordance with HLAC Standard Part I Subpart 5 Section 5.3.

REFER TO

Part I - 5.3 Health and Hygiene

6.3.2. Fingernails must be kept short, clean, natural, and healthy. (ANSI/AAMI ST65:2018; Std. 4.4; CDC HICPAC GL Hand Hygiene 2002; AORN 2020)

6.3.2.1. Surgical pack assembly room personnel must not wear nail polish, artificial nails, or artificial eyelashes. (ANSI/AAMI ST65:2018; Std. 4.4; CDC HICPAC GL Hand Hygiene 2002; AORN 2020)

6.3.3. Jewelry of any kind must not be worn in the surgical pack assembly room. (ANSI/AAMI ST65:2018; Std. 4.4; AORN 2020)

6.3.4. Healthy skin integrity absent of abrasions, dermatitis or other skin breakdowns must be maintained. (ANSI/AAMI ST65:2018; Std. 4.4; CDC HICPAC GL Hand Hygiene 2002; AORN 2020)

6.4. Attire and Personal Protective Equipment (PPE)

6.4.1. The basic elements pertaining to personnel attire must be in accordance with Part I Subpart 5 Section 5.4. of this HLAC Standard as appropriate. (ANSI/AAMI ST 65:2018; Std. 4.5)

REFER TO

Part I - 5.4 Personal Protective Equipment (PPE) and Attire

6.4.2. Personnel attire in the surgical pack assembly room must protect personnel and the integrity of the textile product. (ANSI/AAMI ST65:2018, Std. 4.5.1)

6.4.2.1. All head and facial hair (excluding eyebrows and eyelashes) must be completely covered. Hair and beard covers must be worn in areas where clean textiles are processed. If religious head coverings such as hijabs, veils, turbans or bonnets are worn, they should be clean, unadorned, constructed of tightly woven and low-linting material, and should fit securely, with loose ends tucked in the scrub top. Coverings such as kippahs and yarmulkes that cover only a portion of the hair and scalp may be worn under another head covering. (ANSI/AAMI ST65:2018; Std. 4.5.1; AORN 2019)

6.4.2.2. Dedicated surgical pack assembly room attire laundered by the facility must be covered or changed upon leaving or entering the surgical pack assembly room in accordance with provider's policy.

6.4.2.2.1. When leaving the surgical pack assembly room, dedicated pack room personnel first must don the appropriate protective cover (e.g., cover gowns, shoe covers, hair covering, etc.) over their surgical pack assembly room attire and then must remove the appropriate protective cover (e.g., cover gowns, shoe covers, hair covering, etc.) that was over their surgical pack assembly room attire before re-entering the surgical pack assembly room in accordance with written facility policy. (AORN 2020)

6.4.2.3. Dedicated shoes and/or disposable shoe covers must be worn in the surgical pack assembly room.

CERTIFIED HYGIENIC TESTING

★ Part IV ★

PART IV. CERTIFIED HYGIENIC TESTING

Part IV - 1. Overview

1.1 Healthcare linens (HCLs) are found throughout the patient environment and represent a surface with which patients have the highest degree of contact. As such, they are subject to contamination by microorganisms, including pathogens that are present in the patient environment[1]. While the number of healthcare-associated infections (HAIs) linked to contaminated HCLs reported are few and the risk of transmission is negligible, the risks of transmitting infections via contaminated laundry and bedding are real, since various pathogens may persist on fabrics for weeks and used items may contain bacterial loads of 106 – 108 CFU/100 cm2 of fabric[2,3]. Reusable HCLs thus need verified protocols in place to ensure that they are hygienic HCLs before re-entering healthcare facilities.

1.2 Compliance with infection control measures are necessary to mitigate the risk of disease transmission through HCLs. These measures are evidence-based and grounded in scientific research. Reusable HCLs are considered non-sterile. However, total microbial loads and levels of pathogenic microbes need to be below limits specified in Part IV Section 2.3 for them to be appropriate for patient use[4].

1.3 Routine and random microbiological sampling provide objective data to validate that infection control measures and processes are consistently followed to provide hygienic HCL to healthcare facilities. These procedures provide the necessary quality control and process monitoring programs for sustained product integrity.

1.4 The Healthcare Laundry Accreditation Council (HLAC) provides customers with a certification program that includes microbiological testing best practices and protocols. These protocols are aligned with infection control measures within healthcare facilities and provide the confirmation and reassurance that hygienic HCLs are produced. A laundry must be accredited and in good standing to apply for certification. HLAC reserves the right to revoke certification if adequate compliance is not maintained.

1.5 The HLAC certification program classifies protocols as "Must", i.e., necessary to obtain HLAC certification or "Shall", i.e. Further improve the standards at your own facilities.

Part IV - 2. Testing Specifications

2.1 Guidelines

Microbiological testing of reusable HCLs is not mandated by the United States. However, third-party certification programs provide standards that are widely adopted by the industry[5]. The management of hygienic HCTs falls to the certified laundry contractor and the Healthcare facilities (HCFs). The Code of Federal Regulations, 42 CFR 483.65 Infection Control[6] , Joint Commission Standard PCI.7.1. 2[7,8] and the CDC and the Healthcare Infection

Control Practices Advisory Committee (HICPAC)[9,10] states that clean linen should be handled, transported, and stored by methods that will ensure its cleanliness and leaves the handling of hygienic HCTs to "principles of hygiene, common sense, and consensus."

HLAC offers third-party certification of the laundry facilities' testing programs and requires HCL processing facilities to implement routine microbiological and yeast/mold testing on its products. The testing must be performed by an HLAC-recommended laboratory with appropriate credentials and accreditations (Part IV Section 4).

2.2 Testing Overview

HCTs and the environments they are exposed to during production should be monitored routinely for microbiological contaminants. This includes qualitative and quantitative measurements as part of ongoing process improvement efforts and when new procedures and implemented.[11,12].

Routine testing involves random sampling of clean, laundered HCLs per protocols outlined below. This random sampling process allows facilities to determine:

a) Efficiency of laundering protocols
b) Quality control of HCLs as part of supply chain processes to healthcare facilities and
c) Rapid assessment of issues (e.g. unusual environmental contamination trends) that require root cause investigations and corrections.

The testing workflow is described below and Table 2 Quick Certification Guide:

2.2.1 Identify an HLAC-recommended laboratory (Part IV Section 4) that will perform the microbiological analyses. It is the responsibility of the laundry service provider to properly identify and document the credentials of the selected service laboratory.

2.2.2 For initial HLAC certification:

1) submit a minimum of two (2) and a maximum of five (5) random textile samples to the identified laboratory every month for three consecutive (3) months).

2) Six (6) passing test results.

2.2.3 If passing results are obtained, submit the reports along with internal documentation Part IV Sections 2.4 and 2.5 to HLAC. A total of six (6) passing results must be submitted with the application spaced out with two results per month over a three-month period.

2.2.4 Once certification is received, ongoing microbiologic sampling for quality control must be performed on a quarterly basis. HLAC requires a minimum of two (2) textile samples to be sent to the approved testing laboratory on a quarterly basis for microbiological and yeast/mold analyses.

2.2.5 When failing results are received, the plant must resubmit the same type of textile samples to the same lab for re-testing. Failed tests will be recorded in the same manner as passing tests and made available for inspection for HLAC during the accreditation and/or recertification process. Samples for re-testing must be supplied within two weeks of the initial failed test results.

2.2.6 For a third consecutive failed test, the laundry facility will consult with the laboratory to determine if a sampling error occurred and/or determine if validation of laundry processes and follow appropriate root cause investigation and/or corrective action. Laundry facilities may choose to hire expert consultants if/as required for the remediation process.

2.2.7 Quarterly testing documentation must be kept on file for five (5) years and made available to HLAC inspectors upon request.

2.2.8 Recertification will be performed once every three (3) years or if any significant changes within the laundry facility have the potential to impact the cleaning process and compliance, e.g. introduction of a new product or tunnel washer. HLAC reserves the right to revoke certification if adequate compliance is

not maintained.

2.3 What to Test For

Aerobic microbial counts and yeast/mold testing provides an assessment of overall hygiene levels of HCLs[13] and must be evaluated on a quarterly basis (4 times a year).

The United States Pharmacopeia (USP) 62 panel assesses levels of pathogenic microbes on HCLs and must be evaluated two (2) times a year[14]. This panel tests for Staphylococcus aureus, Pseudomonas aeruginosa, Escherichia coli, Salmonella enterica, Candida albicans and Clostridia.

Table 1. Pass/Fail criteria for microbiological analyses[13,14]

TEST	PASSING CRITERIA	FREQUENCY OF TEST
Total aerobic microbial count (RODAC plates)	< 20 cfu per square decimeter	Quarterly
Total Yeast and Mold Count (RODAC plates)	< 20 cfu per square decimeter	Quarterly
USP 62 panel	Absent	Two times a year

2.4 Sampling for Microbiological Testing

Textile samples submitted for microbiological testing must represent all product types (including specialty items), wash formulas and washers to provide a comprehensive assessment of hygiene of HCLs at any given facility.

2.4.1 Examples of textile samples: sheets, blankets, mattress pads, under pads, bedspreads, towels, washcloths, patient gowns, lab coats, pediatric gowns (tees), and scrubs (top, bottom, and jackets).

2.4.2 Product types must be rotated each quarter and at least eight (8) product types must be represented in the annual report. The chosen textile sample type must be rotated each quarter. For example, if a sheet and washcloth was chosen in Q1; choose a patient gown and towel for Q2.

2.4.3 If there are significant differences between wash formulas for different product types, these must also be represented in the annual report. For example, at least one product for each tunnel washer and/or pony washers as applicable.

2.4.4 HLAC requires that the initial 3 month testing to obtain certification represent the broad spectrum of products serviced in the laundry facility.

2.4.5 HLAC Recommends Ref. Standard 2.2.2.5. Process monitoring shall be used to verify cleaning effectiveness of surfaces including carts. (Guh A, Carling P for the Environmental Evaluation Workgroup. Options for evaluating environmental cleaning. December 2010; ANSI/AAMI ST65:2018; Std. 6.4 ANSI/AAMI ST79:2017; Std. 13; AHE Practice GL 3rd ed. Section 17)

2.5 Sample Shipment Protocol

Once an appropriate microbiological testing laboratory has been identified (Part IV Section 4), coordinate with the laboratory for their specific instructions on sample collection, shipment and reporting. The guideline provides a framework for this process

2.5.1 Utilizing Table 2: identify two appropriate textile samples and follow laboratory instructions on collection and packaging

2.5.2 Log, at a minimum the date and time of sample collection, type of textile(s), location of collection, laboratory name, and enter results once received

2.5.3 Fill out the Chain of Custody form

2.5.4 Results must be on file at the laundry facility and made available to inspectors during the certification inspection

2.5.5 If the sample fails, submit the same two textile samples to the same laboratory within two (2) weeks of receiving results

2.5.6 For repeated sample fails, consult with the laboratory to determine if a sampling error or as an assessment of laundry processes needs to occur

2.5.7 After a third failed test, consult with HLAC experts for root cause investigations and corrective action.

Part IV - 3. HLAC Certification

3.1 Initial Certification

HLAC provides the initial certification following submission of

3.1.1 Identified appropriate laboratory partner

3.1.2 Facility risk analyses forms

3.1.3 In-house protocols for routine microbiological sample collection and log books

3.1.4 In-house protocols for root cause analyses and corrective actions in the event of failed results

3.1.5 Passing microbiological testing results for a consecutive period of three months, including laboratory results and records.

3.1.6 Onsite inspection

3.2 Recertification

HLAC provides recertification every three years following review of reports and onsite audit process. At this time, HLAC will request all procedures and documentation listed in Part IV Section 3.1 for the three years since the initial certification as part of the review process.

3.3 Audit Process

At the discretion of HLAC and during certification and recertification process, or at any time in between, an onsite audit can be conducted. HLAC personnel may collect random textile samples for microbiological analysis following the protocols in place at the laundry facility. In the event of failed tests, the laundry facility will be expected to ensure that appropriate corrective actions are taken and passing results are obtained. NOTE: If the 3-year audit fails at the time of recertification, laundry facilities will be required to re-apply to HLAC for new certification and follow the protocols for initial certification (Part IV Section 3.1).

Part IV - 4. HLAC Recommended Laboratories

4.1 Acceptable third parties include those laboratories recognized by federal or state agencies such as CDC, CPSC, EPA, FDA, Department of Agriculture, and OSHA. Other examples include the American Association of Laboratory Accreditation and the International Accreditation Service[15,16].

4.2 Acceptable third party laboratories will have ISO 17025 accreditation and will be EPA GLP compliant.

4.3 It is the responsibility of the laundry facility to identify the appropriate microbiological service laboratory and provide the appropriate documentation to HLAC personnel during inspections. Microbiological service laboratories will provide documentation for ISO 17025 certification, GLP compliance and others upon request.

4.4 The designated laboratory must provide appropriate instructions to maintain a chain of custody for materials received and results provided.

4.5 The designated laboratory must provide copies of all testing reports to the laundry facility as part of the certification process.

Part IV - 5: Recommended Ongoing Quality Improvements

5.1 HLAC recommends laundry partners to routinely evaluate new technologies and solutions to improve the standard of their HCLs and facilities.

Examples:

- High-tech industrial washers and polymer bead technology
- Radio Frequency Identification (RFID)
- Residual antimicrobial additives
- Implementation of data-driven insights

Part IV - 6. References

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12. American National Standard Institute (ANSI)/Association for the Advancement of Medical Instrumentation (AAMI) ST79: Comprehensive guide to steam sterilization and sterility assurance in health care facilities. 2017. (Available at: www.aami.org).
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Part IV - 7. Quick Reference

7.1 Table 2. Quick Certification Guide

STEPS	CRITERIA	RECOMMENDED APPROACH
Identify a HLAC recommended laboratory	• ISO 17025 accredited • EPA GLP compliant	Obtain laboratory protocols for sampling, sample shipment and forms. Incorporate the above as part of laundry facility SOP for microbiological QC
Initial certification	Microbiological test: repeat once per month for the first 3 months Report results to HLAC 1. All textiles samples tested must pass the test 2. If the test fails, repeat process per column C 3. If the test fails a third time,conduct a root cause analyses and adjust protocols as required 4. Repeat test within two weeks of initial failed tests.	Identify two (2)- five (5) representative textiles to sample 1. Submit per shipping protocol 2. Include chain of custody forms
Ongoing maintenance	Conduct microbiological test once a quarter 1. All textiles samples tested must pass the test 2. If the test fails, repeat process per column C 3. If the test fails a third time, consult with HLAC and conduct a root cause analyses 4. Repeat test 5. If a specific item fails a test, HLAC may require that item to be included in subsequent quarterly tests until it is reasonably assured that there are no compliant issues.	Identify two (2)- five (5) representative textiles to sample 1. Submit per shipping protocol 2. Include chain of custody forms 3. Ensure that textile types and washers used for laundering are rotated every quarter. 4. Recommended: All textile types and washers are represented at least once annually for microbiological analyses.
Recertification	HLAC will renew certification for partner laundry facilities once every three years.	Review three year records Review audit reports Request additional tests on specific textile samples if applicable as deemed by HLAC official

STEPS	CRITERIA	RECOMMENDED APPROACH
Audit	Onsite inspection	Sampling of randomly selected textiles by HLAC personnel during an onsite visit. Testing per laundry onsite protocols
Process Changes	1. For minor process changes, continue with routine maintenance quarterly tests 2. For significant process changes, are notify HLAC and validate that hygiene processes are maintained per HLAC accreditation standards*	Identify two (2)- five (5) representative textiles to sample 1. Submit per shipping protocol 2. Include chain of custody forms 3. Ensure that textile types and washers used for laundering are rotated every quarter. 4. Recommended: All textile types and washers are represented at least once annually for microbiological analyses.

7.2 Documents Checklist

Microbiological sampling protocol

Laboratory credentials

Laboratory log books: products shipped, dates, lab. Results and corrective actions if applicable

Root cause analysis and corrective action procedures

BEST PRACTICES & REGULATORY REQUIREMENTS

★ Part V ★

1. Textile Control Procedures
2. Laundry Facilities
3. Regulated Medical Waste Management
4. Hazardous Materials & Pharmaceutical Waste Management
5. Piped Air, Water, Wastewater, & Chemicals Management
6. Laundry Equipment
7. Equipment Maintenance
8. Installation & Utilities Connections
9. Water Quality
10. Equipment Operation
11. Laundry Personnel Qualifications
12. Occupational Safety & Health Elements
13. Exposure Control Plan
14. Laundry Customers
15. Transportation
16. Process Monitoring

PART V. BEST PRACTICES & REGULATORY REQUIREMENTS

Coming soon!
Contents subject to change.

APPENDICES

APPENDIX A

GLOSSARY AND TERMINOLOGY

Air Sampling – Air sampling is a process used to determine what airborne contaminants are present in an environment.

Artificial nails – Artificial nails are defined as any substance or device applied or added to the natural nails to augment or enhance the nail, including bonding, extensions, tips, wraps, gel and acrylic overlays, and tapes.

Barrier properties – The ability of a material to resist the penetration of liquids (e.g., irrigating fluids, blood, and OPIM).

Bioburden – Bioburden is a term used to describe the microbial numbers, or bacteria, present on a surface that has not been sterilized.

Bioburden Analysis – Bioburden testing measures the levels of microbial contamination in water, on surfaces, raw materials, and finished products. It is an effective tool for qualifying processes, identifying best practices, and establishing continuous process improvements.

Biohazard – An infectious agent or hazardous biological material that presents a risk to the health of humans or the environment. Biohazards include tissue, blood or body fluids, and materials such as needles or other equipment contaminated with these infectious agents or hazardous biological materials.

Bloodborne pathogens – Infectious microorganisms in human blood that can cause disease in humans. These pathogens include, but are not limited to, hepatitis B (HBV), hepatitis C (HCV) and human immunodeficiency virus (HIV).

Cleaning – A process that uses a cleaning agent and physical action, such as scrubbing or wiping, to remove visible soil, organic matter, and bioburden from a surface or object and in doing so renders the surface or object safe to handle. The cleaning agent may be a wet or dry chemical. The specifics of a cleaning process are dictated by factors associated with the item to be cleaned, namely chemical compatibility, location, wetness tolerance, surface topography and complexity.

Clean textile storage area – An area where clean textiles are stored prior to delivery.

Conditioning/drying area – An area where, after extraction, textiles are either conditioned (partly dried) or fully dried in a dryer or tumbler.

Contract – Any oral or written agreement, contract, memorandum of understanding, or other documentation, addressing a mutual consensus between the provider and customer.

Critical zone – An area of protective apparel or surgical drape where direct contact with blood, body fluids, and OPIM is most likely to occur.

Contaminated laundry – According to Occupational Safety and Health Administration (OSHA), laundry that has been soiled with blood or other potentially infectious materials or that may contain sharps.

Customer – The term for the client healthcare facility (e.g., hospital, clinic, nursing home, etc.) and for its "end-user" (i.e., healthcare personnel and patient).

Customer-owned goods – Textiles that the customer have purchased and are sent out to a laundry facility for processing.

Decontamination – The use of physical or chemical means to remove, inactivate, or destroy pathogens, including bloodborne pathogens, on a surface or item to the point where any remaining pathogens are no longer capable of transmitting infection and the surface or item is rendered safe for handling, use, or disposal.

Device master record (DMR) – According to the Food and Drug Administration (FDA), a compilation of records that contain the procedures and specifications for a finishing device. [21 CFR 820.3(j)]

Extraction area – An area where excess water is removed from textiles after laundering, but before conditioning or drying.

Folding area – An area where textiles are folded.

Foreign object – Objects or items considered as non-textile items (e.g., instruments, disposable devices, sharps, personal patient information, etc.) that may potentially harm people and laundry equipment if left among the textiles.

Functional separation/barrier – An activity or structure that separates one movement, action, or space from another. Examples include structures (e.g., walls, partitions, carts) and ventilation parameters (e.g., airflow directions and pressure). Functional separation achieved through ventilation usually employs negative air pressure to prevent potential pathogens from spreading to other areas in the facility.

General work clothes – Uniforms, pants, shirts, and/or blouses not intended to function as protection against a hazard are not considered to be personal protective equipment (PPE).

Hazardous drugs/substances – A pharmaceutical, chemical, or radiological agent that presents a risk of exposure, associated injury or illness, or other mishap to humans or the environment; if not prevented, minimized, controlled, confined, and/or handled according to safety precautions. Any drug identified by at least one of the following six criteria: carcinogenicity, teratogenicity or developmental toxicity, reproductive toxicity in humans, organ toxicity at low doses in humans or animals, genotoxicity, or new drugs that mimic existing hazardous drugs in structure or toxicity.

Hygienically clean – A clean state, free of pathogens in sufficient numbers to minimize risk of infection.

Inspection – Reflect the compliance process applicable to healthcare reusable textiles processing in these HLAC Standards by HLAC Inspectors.

Ironing area – An area where textiles that require ironing are processed through a flatwork ironer.

Material safety data sheet (MSDS) – see Safety Data Sheets (SDS).

Needle holes – Structural breaches that allow strike-through of fluids to occur during the textile's use in surgery.

Negative air pressure – Directed air flow such that air flows into a room or space from a corridor or adjacent area. In a laundry facility, soiled textile sorting areas are under negative air pressure to ensure that pathogens do not spread to other areas of the facility. When a room is under negative air pressure, air flows from a clean space into the room and typically is exhausted to a diluted stable location (e.g., outside ambient air atmosphere beyond the building walls).

Non-critical zone – An area of a surgical gown or drape where direct contact with blood, body fluids, and OPIM is not likely to occur.

Other Potentially Infectious Material (OPIM) – The following human body fluids: semen, vaginal secretions, cerebrospinal fluid, synovial fluid, pleural fluid, pericardial fluid, peritoneal fluid, amniotic fluid, saliva in dental procedures, any body fluid that is visibly contaminated with blood, and all body fluids in situations where it is difficult or impossible to differentiate between body fluids; any unfixed tissue or organ (other than intact skin) from a human (living and dead); and HIV-containing cell or tissue cultures, organ cultures, and HIV- or HBV- containing culture medium or other solutions; and blood, organs, or other tissues from experimental animals infected with HIV and HBV.

Particulate or fiber-shedding materials – Porous, disintegrating construction materials that release minute separate particles, which may become airborne and/or fall on lower surfaces or substances; threadlike substance or structure, natural or artificial filament, or element that gives texture capable of becoming separated and dispersed in the air or upon surfaces.

Patching/mending area – An area where textile repairing, patching, and mending operations are performed. NOTE: If patching/mending is performed in the laundry area, the textiles should be rewashed before being moved to the surgical pack assembly area.

Personnel – Designated term for employees, workers, staff, etc.

Pharmaceutical Waste – A therapeutic drug or drug residue identified by the state health department or state environmental agency as requiring special handling, treatment, and disposal when said drug or drug residue is discarded as waste.

Physical barrier – A visible construction (e.g., floor to ceiling wall, plastic curtain, or other material) separating one area from another area.

Physical environment – Surfaces in the construction of the room and/or building, such as floors, walls, ceilings, working surfaces, installed equipment, and vents.

Positive air pressure – Directed air flow such that air flows out of a room or space from a corridor or adjacent area. In a laundry facility, clean textile processing areas are under positive air pressure to ensure that pathogens do not spread to those areas of the facility. When a room is under positive air pressure, air flows from a clean space out into an adjacent space.

Process Monitoring – Process measures are the evidence-based best practices that represent an organization's efforts to systematize its improvement efforts.

Processed – Items that have been laundered, cleaned, disinfected, or sterilized as appropriate for safe use in an intended activity.

Provider – Designated term to encompass the laundry plant as the processor of healthcare textiles, whether the laundry is an on-premise laundry (OPL) or an off-campus laundry known as a commercial or retail facility with customer-owned goods (COG) or laundry facility-provided textiles.

Receiving area – An area where soiled textiles are received in hampers or bags typically contained within carts, waiting soil sorting.

Reusable surgical textile – A drape, gown, towel, or sterilization wrapper that is intended to be used in surgery or assist in preparing the surgical team for surgery, that is made from a fabric (usually woven or knitted) or a fabric/film laminate, and that is intended to be used more than once, with appropriate cleaning, decontamination, and sterilization between uses.

Safety Data Sheets (SDS) – Formerly **Material Safety Data Sheets (MSDS)**, these standardized format sheets contain summaries provided by the manufacturer to describe the chemical properties and hazards of specific chemicals and ways in which employees can protect themselves from exposure to these chemicals in the workplace.

Soil sort area – An area where soiled textiles are sorted usually by textile category and sometimes by degree of soiling or color.

Staging – A process for preparing the textiles for delivery and having them wrapped and ready for transport.

Standard Precautions – The CDC added additional infection prevention elements to Universal Precautions in 1996 in order to protect healthcare workers not only from pathogens in human blood and certain other body fluids, but also pathogens present in body fluids to which Universal Precautions does not apply. Standard Precautions includes hand hygiene; the use of certain types of PPE based on anticipated exposure; safe injection practices; and safe management of contaminated equipment and other items in the patient environment.

Sterile field – An area created with sterile draping materials where sterile technique is required (e.g., around a surgical site, on a back table, or on a gowning table).

Sterile pack bagging area – An area where sterile packs are placed in dust covers, if used.

NOTE: HLAC Standards do not address this area nor inspect this area; provided for definition and clarification purposes only.

Sterile storage area – An area where sterile surgical packs are stored prior to delivery to the user.

Sterilization area – An area where steam sterilizers are located, including the space for loading, queuing carts, cool-down, and unloading carts.

Sterilization quarantine area – An area where sterilized surgical packs are stationed, awaiting product release.

Sterilization wrap – According to FDA, a device intended to be used to enclose another medical device that is to be sterilized by a health care provider. It is intended to allow sterilization of the enclosed medical device and also to maintain sterility of the enclosed device until used.

Storage – An area where items are stored for distribution to another area for specific activity (i.e., decontamination, cleaning, disinfection, sterilization, item for use).

Strike-through – Passage of a liquid that could contain microorganisms through a barrier product, including its seams and/or points of attachment.

Surgical pack assembly area or pack room – An area where clean surgical textiles are received, stored, inspected, mended and folded into finished components in preparation for assembly into surgical packs.

Textile barrier testing area – An area where clean surgical textiles are evaluated for barrier properties and quality.

NOTE: This area might be part of the surgical pack assembly area.

Textile inventory storage area – An area where newly purchased textiles are received and held prior to processing and placement into the circulating inventory.

Universal Precautions –Universal Precautions is an approach to infection control where all human blood and certain human body fluids are treated as if known to be infectious for HIV, HBV, and other blood borne pathogens.

Unwrapped – An item has been decontaminated, cleaned, inspected, assembled for use, placed in an appropriate container for sterilization in an autoclave, or ready for distribution.

Washing (processing) area – An area where soiled textiles are washed and in which such equipment as washers, extractors, washer-extractors, continuous-batch washers, and/or continuous processing systems are located; also known as wash floor.

APPENDIX B

ABBREVIATIONS

AAMI – Association for the Advancement of Medical Instrumentation

ABHS – Alcohol-based hand sanitizer

ACH – Air Changes per Hour

AHA – American Hospital Association

AHE – Association for the Healthcare Environment

AHJ – Authorities Having Jurisdiction

AIA – American Institute of Architects.

ANSI – American National Standards Institute

AORN – Association of periOperative Registered Nurses

APIC – Association for Professionals in Infection Control and Epidemiology

ARTA – American Reusable Textiles Association

ASHE – American Society for Healthcare Engineering

ASHRAE – American Society for Heating, Refrigeration, and Air Conditioning Engineers

BBP – Bloodborne Pathogens

CDC – U.S. Centers for Disease Control and Prevention

CFR – Code of Federal Regulations

CMS – Centers for Medicare and Medicaid Services

COG – Customer Owned Goods

DHHS – U.S. Department of Health and Human Services

DHS – U.S. Department of Homeland Security

DOT – U.S. Department of Transportation

ECP – Exposure Control Plan

EDP – Exposure Determination Plan

EPA – U.S. Environmental Protection Agency

F – Fahrenheit

FDA – U.S. Food and Drug Administration

FGI – Facilities Guidelines Institute

GL – Guidelines

GL EIC – CDC/HICPAC Guidelines for Environmental Infection Control in Health-Care Facilities

HBV – Hepatitis B virus

HCV – Hepatitis C virus

HCW – Healthcare worker

HICPAC – Healthcare Infection Control Practices Advisory Committee

HIV – Human Immunodeficiency virus

HLAC – Healthcare Laundry Accreditation Council

HVAC – Heating, ventilation, air conditioning

IAHTM - International Association for Healthcare Textile Management

IC – Infection Control

IPC – Infection Prevention and Control

IP – Infection Preventionist

IPM – Integrated Pest Management

MERV – Minimum efficiency reporting value

MOU – Memorandum of understanding

MSDS – Material safety data sheet

NFPA – National Fire Protection Association

NHTSA – U.S. Department of Transportation, National Highway Traffic Safety Administration

NIOSH – National Institute for Occupational Safety and Health

NR – No Requirement

OPIM – Other Potentially Infectious Material

OPL – On-Premise Laundry

OSHA – U.S. Department of Labor, Occupational Safety and Health

PM – Preventative Maintenance

PPE – Personal Protective Equipment

PUB – Publication

RFID – Radio frequency identification

RH – Relative humidity

SDS – Safety Data Sheet(s)

Std. – Standard

USC – United States Code

UV-C – ultraviolet-C

APPENDIX C

STANDARDS VERIFICATION METHODS

Part I. Basic Elements

Textile Control Procedures

1.1. Textile Specifications

1.1.1. The provider shall have written textile specifications that meet customer needs and ensure consistent performance. 1.1.1.2. These specifications shall be reviewed, at a minimum, annually by the service provider and the customer. 1.1.2. Provider/customer contracts shall include the extent of service for the contract period, signature of both entities, and date signed.	• Provide written specifications with evidence of annual review • Provide copy of contract

1.2. Textile Maintenance

1.2.1. The provider shall have a documented grading system, outlining the grading standards for the healthcare textiles being processed. 1.2.1.1. The grading documentation shall be accessible where personnel may refer to it. 1.2.2. These standards shall outline which defects may be repaired, which defects require replacement, and the point at which previously repaired textiles should be discarded. 1.2.3. If a provider has a textile repair program, the provider shall ensure that all personnel having responsibility for making repair and replacement decisions understand and comply with the grading standards.	• Provide written grading system • Staff can describe and locate the grading standards • Evidence of personnel training records, if applicable

1.3. Provider Inventory Management

1.3.1. The provider and customer shall jointly determine the par level for the facility, whereupon the provider shall use an inventory management system that ensures an adequate supply of clean textiles to meet the customer's needs. 1.3.2. Methods to ensure that an adequate supply of textiles is available to the provider and customer shall include documentation of historical fill rates for rental operations and/or documentation of clean pounds shipped as a percentage of soil pounds received for COG operations. 1.3.3. The provider and customer shall document in writing the provision of inventory for situations where increased need (e.g., surge capacity in response to a disaster) is anticipated and what adjustments are acceptable.	• Documentation of historical fill rates for rental operations and/or documentation of clean pounds shipped as a percentage of soil pounds received for COG operations. • Documentation of the provision of inventory for situations where increased need is anticipated and what adjustments are acceptable.

Part I - 2. Laundry Facilities

2.1. Physical Design, Ventilation, Fixtures, and Signage

2.1.1. Based on the workflow pattern principle where processing of soiled textiles flows to clean textiles, the laundry facility's physical layout and maintenance procedures must ensure efficiency, minimize environmental contamination, and protect the material and hygienic integrity of the processed textiles.

- Inspection of facility

2.1.2. Soiled Textiles Area

2.1.2.1. The essential laundry facility design must have a functional separation of areas that receive, store, or process soiled textiles from areas that process, handle, or store clean textiles by one the following methods:

2.1.2.1.1. Physical barrier (e.g., walls or structural partitioning with a means of entry to and from the soiled textiles area), which includes negative air pressure in the soiled textiles area with venting directly to the outside (positive air flow from the clean textiles area through the soiled textiles area); or

2.1.2.1.2. Functional barrier by negative air pressure in the soiled textiles area and positive air flow from the clean textiles area through the soiled textiles area with venting directly to the outside.

2.1.2.1.2.1. Air pressure differentials in these areas shall be monitored and documented daily

2.1.2.2. The physical environment and layout of the soiled sorting area shall be designed to permit orderly soiled textile sorting and other manipulations and processes.

2.1.2.3. Warning signs about the presence of contaminated textiles and the need to follow Standard/Universal Precautions must be posted in work areas where potentially contaminated textiles are stored or sorted prior to processing.

2.1.2.4. PPE shall be strategically located and available in work areas where potentially contaminated textiles are stored or sorted.

2.1.2.4. Handwashing facilities must be located in all areas where soiled or contaminated textiles are handled in the laundry.

2.1.2.5. Emergency eyewash equipment shall be available with unobstructed access in all areas where soiled textiles are processed.

- Inspection of facility
- Documentation of daily air pressure differentials
- Presence of warning signs, PPE, handwashing facilities, functional emergency eye wash equipment

2.1.3. Clean Textile Staging and Storage Areas

2.1.3.1. In the provider's facility, the textile staging and storage areas for cleaned, processed textiles must be in compliance with the following specifications: free of vermin; devoid of lint; without obvious moisture contamination.

- Observation of practices
- Documentation of a current integrated pest management (IPM) program
- Documentation of lint blow-down schedule

2.1.3.2. Ventilation of the storage area

2.1.3.2.1. Storage area must be free of dust and lint

2.1.3.2.2. Storage area must be under positive air pressure relative to adjacent spaces, thereby preventing intrusion of contamination from soiled textile areas.

2.1.3.3. Policies and protocols must reflect a facility-specific strategy for ensuring the hygienically clean quality of the stored, processed textiles.

2.1.3.4.The facility shall establish a schedule of visual inspection of the stored textiles and recording the observations.

- Inspection of facility
- Documentation of air pressure differentials
- Policies and procedures
- Documentation of storage area inspections

2.1.3.5. Specifications for Clean Textiles Storage Shelves

2.1.3.5.1. Shelves must be placed approximately 2 inches from the wall to safeguard package integrity.

2.1.3.5.2. The bottom shelf must be of solid nonporous construction, free from visible soil and dirt, and at a minimum of 8 inches from the floor for accessible cleaning to prevent contamination.

2.1.3.5.3. The top of any item on the top shelf must be a minimum of 18 inches below the ceiling to prevent impairment of ventilation, sprinklers, and lighting.

2.1.3.5.4. Any porous material (e.g., cardboard, paper, etc.) must not be used as a shelf liner in the clean textiles storage area and to store clean textiles.

- Inspection of facility

2.1.4. Other Fixtures and Signage

2.1.4.1. Hand hygiene resources (i.e., handwashing facilities or antiseptic hand cleaner and cleaner dispensers) must be available in or around all work areas and in personnel support areas.

2.1.4.2. Emergency eyewash and shower equipment shall be available with unobstructed access for immediate emergency use in all areas where chemicals are used and/or stored.

2.1.4.3. Safety features (e.g., emergency lighting, signage, fire alarms, door accessibility and egress, safety perimeter for robotics, equipment guards, etc.) must be evident and operational to safeguard personnel and persons.

- Observation of handwashing facilities, including availability of alcohol-based hand sanitizer (minimum 60% alcohol)
- Presence of unobstructed and functional eyewash and shower equipment
- Presence of required safety features

2.2. Physical Plant and Equipment Maintenance

2.2.1. Maintenance of equipment and spaces in a laundry facility processing healthcare textiles shall follow documented provider's policies and procedures.

- Policies and procedures
- Maintenance records

2.2.2. Cleaning, Decontamination, and Disinfection

2.2.2.1. The physical environment (e.g., floors, walls, ceilings, vents, working surfaces, and installed equipment) must receive scheduled cleaning appropriate for the surface, the frequency dependent upon the level of contamination, and the operation performed in the area according to facility policy.

2.2.2.1.1. The cleaning schedule must be maintained on a current basis and available for inspection.

2.2.2.2. Environmental surfaces (e.g., walls, ceilings, vents, and equipment) must be subjected to periodic and as needed blow down processes from ceiling downward to minimize the buildup of dust and lint.

2.2.2.2.1. Blow down, vacuuming, or other suitable cleaning practice must be performed when no other processing of textiles is occurring in that area and must not be performed in pack rooms.

2.2.2.3. Clean textile working surfaces (e.g., counters, benches, tables, etc.) must be kept clean of visible soil, dust, and lint

2.2.2.4. Working surfaces that become contaminated with blood or other potentially infectious material (OPIM) must be decontaminated, cleaned, and disinfected with hospital grade disinfectants labeled tuberculocidal or disinfectants with specific label claims for human immunodeficiency virus [HIV] or hepatitis B virus [HBV]).

2.2.2.5. Process monitoring shall be used to verify cleaning effectiveness

- Inspection of facility
- Verbalization of processes with staff
- Cleaning, Decontamination, and Disinfection policies
- Copy of cleaning schedule
- Documentation of lint blow-down schedule List of cleaners, disinfectants used by the facility
- Results of any verification of cleaning and disinfection processes

2.2.2.6. Work practices when using conventional washer extractors

2.2.2.6.1. Cleaning and disinfection of surfaces

2.2.2.6.1.1. Surfaces (i.e., surfaces exterior to conventional washer extractors) that are used to both unload and load conventional washer extractors must be non-porous and easily cleaned.

2.2.2.6.1.2. Routine cleaning and disinfection of surfaces, using a cleaning/disinfection strategy appropriate for the type of contamination when loading and unloading conventional washer extractors after each load, must be consistent with the principles of functional separation.

- Inspection of facility
- Cleaning, Decontamination, and Disinfection policies

2.2.2.6.2. Work flow and functional separation

2.2.2.6.2.1. Functional and physical separation of soiled and clean textiles must be followed when conventional washer extractor equipment is used in accordance with Part I, Subpart 2, Section 2.1, Element 2.1.2.1 of this HLAC Standard.

2.2.2.6.2.2. For conventional washer extractor equipment that utilizes sling delivery systems for loading soiled textiles, clean textiles must not be stored under the soiled slings unless there is a mechanism present to protect the clean textiles.

2.2.2.6.2.3. Personnel handwashing practices and personal protective equipment (PPE) usage while using conventional washer extractor equipment must be in accordance with Part I, Subpart 5, Sections 5.3 and 5.4, Elements 5.3.3. and 5.4.1. of this HLAC Standard

- Inspection of facility
- Observation of practices

2.2.3. Pest Control Program

2.2.3.1. The provider must have documentation of a current integrated pest management (IPM) program consistent with healthcare-recommended practices and with evidence of scheduled treatments.

- Documentation of a current integrated pest management (IPM) program including evidence of scheduled treatments

2.3. Management of Hazardous Materials

2.3.1. The provider must become familiar with issues and regulations concerning the management and disposal of hazardous substances/ wastes to facilitate any provider-customer negotiations on this topic.

- Policies and procedures

2.3.2. If the customer fails to adhere to proper hazardous substances/ waste management practices, the provider shall reject any laundry items contaminated with these substances/wastes and return these to the customer.

2.3.3. Hazardous substance-related wastes must be handled separately from other customer trash/solid wastes and disposed of per facility policy developed in accordance with applicable local regulations or the AHJ for hazardous waste.

2.3.4. The provider - customer Policy and Procedures shall include some indication that the issue of management of pharmaceutical contaminated textiles has been addressed (pharmaceutical definitions provided by the local regulations or the AHJ).

Part I - 3. Contingency Planning

3.1 Contingency Planning

3.1.1. Contingency planning shall provide for uninterrupted operations and services in the event of any occurrence potentially leading to serious disruption of the provider's operations. Such disruption includes, but is not limited to, loss of utilities, medical emergencies, natural and/or man-made disasters, fire, inclement weather, work stoppage, or major accidents.

- Documentation of Contingency Plan
- List of backup laundry facilities

3.1.2. The Contingency Plan shall include the following components:

3.1.2.1. Plant and transportation contingency protocol,

3.1.2.2. Call chain,

3.1.2.3. A list of backup laundry facilities, (HLAC accredited if possible), and

3.1.2.4. A backup source of textiles, if needed.

3.2 Plant Contingency Protocol

3.2.1. The provider shall provide a mechanism to inform a step-by-step procedure in the event of an emergency and shall be available to supervisors, each of whom may be responsible for execution of the protocol.

- Documentation of Plant Contingency Protocol
- Discussion with staff

3.2.2. Personnel shall be familiar with the major elements of the plant contingency protocol in advance of emergencies.

3.3. Contingency Call Chain

3.3.1. The call chain shall be written, complete, current, and available to all supervisory personnel, so that timely and accurate contact can be made in case of an emergency. 3.3.2. The call chain shall be maintained by a designated person, who is responsible for updating it at least annually or when personnel changes occur, and distributing the list to personnel.	• Documentation of Contingency Call Chain with evidence of annual reviews/ updates

3.4. Backup Facility Contracts

3.4.1. The provider shall have written contracts in place with one or more alternate laundry providers (HLAC-accredited if possible) that can cover their volume, detailing when and how these providers will process textiles in an emergency. 3.4.1.1. These contracts shall be updated signed, and dated **every three years at a minimum.** 3.4.2. The provider shall have adequate transportation capabilities with contingency planning. 3.4.3. The provider shall have written contracts in place with one or more alternate textile suppliers, detailing the services and delivery times provided (does not apply to COG).	• Documentation of written contracts

Part I - 4. Laundry Equipment

4.1. Documentation

4.1.2. Equipment safety documentation shall consist of safety instructions, describing the potential hazards associated with the equipment use; appropriate safeguards; and complies with ANSI Z8.1., regarding safe operation and maintenance of equipment.	• Observation • Review of safety documentation

4.2.4. Water quality

4.2.4.1. The operator shall confirm that incoming water used in the laundry process meets an acceptable range for hardness, alkalinity, pH, iron and other heavy metals so that wash operations of the laundry can achieve the result of hygienically clean and appropriate chemistry balance for patient use 4.2.4.2. The provider should consider softening their water when the hardness is 2 grains/gallon (34.2 parts per million [ppm]) or higher.	• Water chemistry reports • Policies and procedures

4.3. Equipment Operation

4.3.1 The scale for weighing load size shall be inspected and calibrated by an outside auditor on a scheduled basis, but at a minimum annually; and the results made available to the customer upon request.	• Auditor reports • Chemical delivery system calibration reports • Documentation of heated water temperature verification

4.3. Equipment Operation (cont.)

4.3.2. The chemical delivery system needs to be calibrated according to the standards of the supplier at least monthly.

4.3.3. The design and size of water heater equipment must be appropriate for the provider's needs at peak operating times and to maintain the specified heated water temperature per desired cycle.

- Auditor reports
- Chemical delivery system calibration reports
- Documentation of heated water temperature verification

4.4. Preventive Maintenance

4.4.1. Equipment must be inspected, cleaned, and receive scheduled preventive maintenance according to the manufacturer's instructions or according to facility policy and procedures, if instructions are not available.

4.4.2. Preventive maintenance shall include replacement of worn expendable parts, lubrication, and calibrations.

- Preventative maintenance records

4.5. Equipment Calibrations

4.5.1. Equipment shall be calibrated periodically as specified in the manufacturer's instruction manual or as determined by facility policy and procedures, if a manufacturer's schedule is not available.

4.5.2. Calibration shall be performed by personnel trained and/or certified in calibration specified by the manufacturer.

- Calibration reports

4.6. Recordkeeping for New, Existing, and/or Used Equipment

4.6.1. A maintenance record shall be kept on file for each piece of equipment.

4.6.2. The following information shall be recorded:

- Service details (e.g., date for request and completion, reason for service, repair);
- Equipment details (e.g., type, model, serial number, and location of the equipment);
- Parts and repair details (e.g., parts, repair descriptions);
- Personnel involved (e.g., provider authorization, service technician name).

- Maintenance records

Part I - 5. Laundry Personnel

5.1. Personnel Qualifications

5.1.1. All personnel shall be qualified for their positions through education, training, or level of prior experience, and these qualifications shall be documented in employee files.

5.1.2. New personnel shall work under the close supervision of qualified personnel until they have demonstrated competency in the given task or procedure.

- Employee records
- Orientation protocols

5.2. Personnel General Responsibilities

5.2.1. Supervisors/managers/personnel shall: 5.2.1.1. Safely and correctly operate assigned equipment; 5.2.1.2. Safely and correctly perform assigned processing activities; 5.2.1.3. Correctly interpret and safely implement the Exposure Control Plan; 5.2.1.4. Recognize and understand potential hazards from equipment defects and improper performance of the job; and 5.2.1.5. Understand the risk of injury that defective or improperly operating equipment may inflict.	• Discussion with employees

5.3. Health and Hygiene

5.3.1. The provider must have policies and procedures to prevent healthcare textiles from being handled by or exposure to personnel with potential health issues (i.e., illness, open wounds or sores, and skin injuries.) **5.3.2 Personnel must adhere to good work practices to minimize or eliminate exposures to blood, OPIM, chemical, and mechanical hazards. This includes, but is not limited to:** **5.3.2.1. Use of personal protective equipment (PPE) when handling contaminated and soiled textiles;** **5.3.2.2. Eating, drinking, smoking, applying cosmetics or lip balm, and handling contact lenses must be prohibited in work areas where there is a reasonable likelihood of occupational exposure to bloodborne pathogens (BBP).**	• Observation of practices • Policies and procedures

5.3.3. Hand washing and hand hygiene indications:

5.3.3.1. Personnel must wash their hands after restroom use, before eating, and when hands become inadvertently contaminated with blood, OPIM, or other body substances. **5.3.3.2. Personnel must practice hand hygiene (handwashing or using alcohol-based hand sanitizers) before donning gloves and after removal of gloves.** **5.3.3.3. Personnel responsible for packing, wrapping, storing, or transporting clean textiles must maintain proper hand hygiene at all times.**	• Observation of practices

5.4. Personal Protective Equipment (PPE) and Attire

5.4.1. Personal protective equipment: **5.4.1.1. The provider must supply the PPE to personnel in the workplace.** **5.4.1.2. Reusable PPE (e.g., aprons or overalls) penetrated by blood or OPIM must be removed immediately or as soon as feasible and be laundered by the provider.**	• Observation of practices

5.4. Personal Protective Equipment (PPE) and Attire (cont.)

5.4.1.3. PPE must be changed if moving from an area where soiled operations were performed into an area where clean operations are performed.

5.4.1.4. All PPE must be removed and placed in an appropriate receptacle prior to leaving the work area.

- Observation of practices

5.4.2. Personnel attire and adornments:

5.4.2.1. All personnel must wear clean garments without visible soil or dirt in accordance with the provider's policies and procedures.

5.4.2.2. Hair caps and beard covers must be worn in areas where clean textiles are processed. Beard covers do NOT need to be worn if facial hair is less than 0.5 inches long.

5.4.2.3. Artificial nails should not be worn in the laundry while processing clean textiles. Artificial nails are defined as any substance or device applied or added to the natural nails to augment or enhance the nail, including bonding, extensions, tips, wraps, gel and acrylic overlays, and tapes.

5.4.2.4. Personnel who handle clean healthcare textiles must change work garments whenever their garment becomes soiled or contaminated.

- Policies and procedures
- Observation of practices

5.5. Occupational Safety and Health Elements

5.5.1 The provider shall have a documented biohazard communication system, identifying soiled healthcare textiles using color-coding and/or labeling and adhere to Standard/Universal Precautions. (OSHA 29 CFR 1910.1030)

5.5.1.1. This documentation shall be accessible where personnel may refer to it.

5.5.2. The provider must implement an occupational safety and health program based on the OSHA Bloodborne Pathogen Standard and Standard/Universal Precautions to prevent personnel exposure to or contact with blood or OPIM.

- Policies and procedures

5.5.3. Exposure Control Plan (ECP):

5.5.3.1. The provider must develop an Exposure Control Plan (ECP) that contains, but is not limited to the following:

5.5.3.1.1. Schedule for compliance (i.e., when each part of the Plan is accomplished in the facility).

5.5.3.1.2. Procedure for evaluating the circumstances surrounding exposure incidents.

5.5.3.1.3. An Exposure Determination Plan (EDP), containing:

5.5.3.1.3.1. A list of all job classifications in which all personnel in those job classifications have occupational exposure,

- Exposure Control Plan indicating annual review and update
- Sample of employee records indicating offering of hepatitis B vaccine by the provider and the acceptance or documented refusal of the personnel.

5.5.3. Exposure Control Plan (ECP): (cont.)

5.5.3.1.3.2. A list of job classifications in which some personnel have occupational exposure, and

5.5.3.1.3.3. A list of all tasks and procedures that are performed by personnel in a job classification where exposure may exist.

5.5.3.1.4. The Exposure Control Plan must be accessible to all personnel.

5.5.3.1.5. The Exposure Control Plan must be reviewed and updated at least annually.

5.5.4. Develop a hepatitis B vaccination program:

5.5.4.1. Records must reflect the offering of hepatitis B vaccine by the provider and the acceptance OR documented refusal of the personnel.

5.5.4.2. Hepatitis B vaccine must be offered to personnel upon hire if they are candidates for vaccination.

5.5.5. Develop a standing process for post exposure management for blood and/or OPIM.

5.5.5.1. Records must reflect a standing process for post-exposure management for blood and/or OPIM.

- Exposure Control Plan indicating annual review and update
- Sample of employee records indicating offering of hepatitis B vaccine by the provider and the acceptance or documented refusal of the personnel.

5.5.6. Develop a hazardous materials (e.g., non-biological, chemical, radiological, etc.) safety plan and policy:

5.5.6.1. Where laundry personnel may be exposed to textiles contaminated with potentially hazardous substances from the customer, a written hazardous substance safety plan must be developed

5.5.6.1.1. The hazardous substance safety plan must be readily available and accessible to all personnel (i.e., full-time personnel, temporary personnel, contractors, and trainees).

5.5.6.1.2. The hazardous substance safety plan must be reviewed and updated as appropriate at least annually.

5.5.6.2. Where laundry personnel may be exposed to textiles contaminated with potentially hazardous substances from the customer, the provider must develop a policy for management of hazardous substance-contaminated textiles that includes, but is not limited to:

5.5.6.2.1. Wash process;

5.5.6.2.2. PPE requirements for affected personnel;

5.5.6.2.3. Training records for these personnel; and

5.5.6.2.4. Written record of provider/customer discussion regarding proper containment for hazardous substance contaminated textiles.

5.5.7. All vehicle drivers shall meet all requirements of the federal and state Department of Transportation (DOT). (www.dot.gov)

5.5.7.1. The provider shall maintain documentation of this compliance and make it available for inspection.

- Hazardous materials plan and policy
- Employee training records
- Written record of provider/customer discussion regarding proper containment for hazardous substance contaminated textiles
- Documentation of compliance with DOT requirements

5.6. Training and Educational Programs

5.6.1. General elements:

5.6.1.1. Personnel must receive standard safety training of laundry operations applicable to their respective position(s), including, but not limited to safe operations of equipment per manufacturer's instructions and notification procedures when malfunctions occur.

5.6.1.2. Training options shall include, but are not limited to the following:

5.6.1.2.1. In-plant (in-service) training sessions facilitated by a person experienced in the topic;

5.6.1.2.2. Formal external training programs, including classes, workshops, and seminars.

5.6.1.3. Personnel shall receive the provider's standard training for the correct handling of healthcare textiles. Topics shall include:

5.6.1.3.1. Specific types of fabrics being processed;

5.6.1.3.2. Appropriate surgical textiles pack processes according to each pack's use requirements;

5.6.1.3.3. Proper use, placement, and heat-sealing process for patching surgical textiles;

5.6.1.3.4. A copy of the grading standards.

- Documentation of training that includes:
  - Date of training;
  - Topic;
  - Trainer's name, title, signature, and qualifications;
  - Copies of printed training materials;
  - Validation that the training objectives and a minimum level of competency were achieved; and
  - Certificates or signature proof of personnel's attendance.
- Evidence of a validation process for all educational activities that includes tracking to ensure 100% completion of the training by all relevant staff

5.6.2. Bloodborne Pathogens Exposure Control Training:

5.6.2.1. Key topics for this training must include, but are not limited to:

5.6.2.1.1. Personal hygiene and proper handwashing and hand hygiene techniques;

5.6.2.1.2. Use of PPE according to the facilities exposure control plan, including one or more of the following, but not limited to, gloves, gowns, aprons, safety goggles, and masks;

5.6.2.1.3. How to correctly don and off PPE

5.6.2.1.4. Engineering controls and work practices to minimize the risk of exposure to blood or OPIM;

5.6.2.1.5. Orientation on the provider's Exposure Control Program;

5.6.2.1.6. Orientation to hazard communications, including labeling and color-coding; and

5.6.2.1.7. Post-exposure procedures, including immediate action, treatment, follow-up, and record keeping.

- Documentation of training that includes:
  - Date of training;
  - Topic;
  - Trainer's name, title, signature, and qualifications;
  - Copies of printed training materials;
  - Validation that the training objectives and a minimum level of competency were achieved; and
  - Certificates or signature proof of personnel's attendance.
- Evidence of a validation process for all educational activities that includes tracking to ensure 100% completion of the training by all relevant staff

5.6.3. Hazardous Substance Contaminated Textiles training:

5.6.3.1. Key topics for this training must include, but are not limited to:

5.6.3.1.1. Exposure risk to textiles contaminated with hazardous substances or excreta from patients who have received hazardous substances (e.g., radioisotopes, chemotherapeutics, etc.) in the past 48 hours;

5.6.3.1.2. Communications among supervisors and personnel for hazardous substance management procedures;

5.6.3.1.3. Identification and segregation of soiled textiles from patients exposed to hazardous substance contaminated, reusable textiles in bags designated solely for the containment of reusable hazardous substance exposed textiles;

5.6.3.1.4. Use of PPE including one or more of the following, but not limited to, gloves, gowns, and eye protection, if splashing is possible;

5.6.3.1.5. Hand hygiene; and

5.6.3.1.6. Disposal of contaminated one time use PPE in thick, leak-proof colored or labeled plastic bags for hazardous substances-related wastes.

5.6.3.1.7. Proper handling of other reusable PPE.

5.6.4. Department of Transportation (DOT) regulations (www.DOT.gov) training:

5.6.4.1. Key topics in this training must include (but are not limited to):

5.6.4.1.1. Bloodborne Pathogens Exposure

5.6.4.1.2. Random drug testing;

5.6.4.1.3. Operator training;

5.6.4.1.4. Certified driver license requirements

- Documentation of training that includes:
  - Date of training;
  - Topic;
  - Trainer's name, title, signature, and qualifications;
  - Copies of printed training materials;
  - Validation that the training objectives and a minimum level of competency were achieved; and
  - Certificates or signature proof of personnel's attendance.
- Evidence of a validation process for all educational activities that includes tracking to ensure 100% completion of the training by all relevant staff

5.6.5. Training Documentation

5.6.5.1. All training must be documented in writing and kept on file for 3 years from the date of training.

5.6.5.2. The documentation must include, but is not limited to:

5.6.5.2.1. Dates of training;

5.6.5.2.3. Topic;

5.6.5.2.4. Trainer's name, title, signature, and qualifications;

5.6.5.2.5. Copies of printed training materials;

5.6.5.2.6. Validation that the training objectives and a minimum level of competency were achieved; and

5.6.5.2.7. Certificates or signature proof of personnel's attendance.

5.6.5.3 The facility must demonstrate the presence of a validation process for all educational activities that includes tracking to ensure 100% completion of the training by all relevant staff.

Part I - 6. Laundry Customers

6.1. Contact

6.1.1. The provider shall maintain a written list of all customer contacts for access of information exchange and service.	• Written list of customer contacts
6.1.2. The provider shall have a 24/7 customer service capability to receive customer messages (e.g., voicemail, email, etc.).	• Demonstration of 24/7 customer service capability

6.2. Visitation

6.2.1. The provider must make their plants available to customers and prospective customers for inspection.	• Visitor log
6.2.2. The provider should annually visit the customer's healthcare facility for the purpose of conducting a walk-through of all areas where healthcare textiles are used, collected, transported or stored.	

6.3. Customer Complaints

6.3.1. The provider must maintain records of any written communication regarding administrative or policy issues or problems with customers, including names of personnel involved and the resolution.	• Records of written communication that includes names of personnel involved and the resolution of any problems

Part I - 7. Quality Assessment

7.1. Textile products used in healthcare facilities shall be of a quality to ensure patient and healthcare personnel comfort and textile durability.	• Discussion

7.2. Quality Control

7.2.1. Textile quality shall be defined and documented between the provider and the customer.	• Documentation of textile quality
7.2.2. The provider processing COG textiles shall comply with pre-established textile maintenance standards as specified by each customer.	• Textile maintenance standards
7.2.3. Defined quality standards shall keep mending and patching to a minimum.	
7.2.4. The entire processing cycle shall have documented quality control procedures to ensure the cleanliness and serviceability of the textiles to include:	
7.2.4.1. Requirements to rewash, repair, or replace textiles as necessary to maintain quality standards.	
7.2.4.2. Planned and posted traffic patterns where required (e.g., pony washers) to minimize the potential for contaminating clean textiles.	
7.2.4.3. Limited traffic in all areas of the facility to authorized personnel as outlined in the provider's policies and procedures.	

7.3. Quality Assurance

7.3.1. The provider shall maintain records of any laundry processing and/or quality assurance problems experienced and mutually agreed upon solutions. A customer call log may be used for this purpose.

- Customer call log or records of laundry processing and/or quality assurance problems experienced and mutually agreed upon solutions

7.3.2. The provider and personnel shall periodically review the entire service program (i.e., safe and efficient work environment, competency of the workforce, and quality assurance of the textile process and product) and make adjustments as necessary and appropriate.

- Demonstration that the service program has been reviewed on a periodic basis

7.4. Process Monitoring

7.4.1. Providers shall engage in process monitoring to verify that ongoing operations are producing clean textiles that will meet customer expectations and needs.

- Process monitoring checklists and results

7.4.2. Providers shall prepare detailed process monitoring checklists and use them to document key elements of laundry processing.

7.4.2.1. Process monitoring checklists shall include, but are not limited to, the following items:

7.4.2.1.1. Chemical supplies: Refer to HLAC Standard Part I Subpart 4 Section 4.3. Elements 4.3.3. and 4.3.4.

7.4.2.1.1.1. The provider shall verify with the manufacturer and chemical supplier that laundry chemicals are appropriate for the equipment in accordance with the equipment manufacturer, textile classifications, and water temperatures being used.

7.4.2.1.2. Titration:

7.4.2.1.2.1. Monthly titrations of the correct wash chemistry shall be performed according to the formula for each major classification of soil.

7.4.2.1.3. Equipment:

7.4.2.1.3.1. All provider equipment that directly impacts hygienically clean linen (such as ironers, dryers, presses, washers, boilers etc.)shall be included in the provider's Preventive Maintenance (PM) Program and checked according to the manufacturer's instructions.

- PM records
- Manufacturer's Instructions for Use

7.4.2.1.3.2. Ironer temperatures shall be based on the equipment manufacturer's manual and recommendations appropriate for the type of fabric being processed.

7.4.2.1.4. Finished products:

7.4.2.1.4.1. The quality of finished products shall be maintained as pre-defined by the customer and shall be sufficient to meet the needs of the customer.

- Process monitoring results

7.4.2.1.4.2. A variety of process monitors should be used to indicate how the provider process has performed including:

7.4.2.1.4. Finished products: (cont.)

7.4.2.1.4.2.1. Rewash rates; 7.4.2.1.4.2.2. pH spot tests; and 7.4.2.1.4.2.3. Residual chlorine spot tests.	• Process monitoring results

7.4.2.1.5 Biological Monitoring

7.4.2.1.5 Biological Monitoring – The hygienic nature of textiles and the environments they are exposed to during production should be quantitatively monitored for biological contaminates when new processes are qualified and as part of ongoing process improvement efforts including: **7.4.2.1.5.1 Bioburden of textiles for total aerobic and spore formers at key points in the process.** **7.4.2.1.5.2 Environmental Monitoring of surfaces, air, water and hands at key points where clean textiles are at risk of contamination.**	• Biological monitoring records/results

Part II. The Textile Processing Cycle

Part II - 1. Handling, Collection and Transportation of Soiled Healthcare Textiles

1.1. Standard/Universal Precautions

1.1.1. All soiled textiles must be assumed to be contaminated. **1.1.2. Standard/Universal Precautions must apply to all personnel who handle soiled textiles during moving, containing, loading, unloading, and sorting said textiles.**	• Observation of practices

1.2. Handling and Collection

1.2.1. All healthcare textiles must be handled and collected in accordance with federal regulations or the Authority having Jurisdiction (AHJ), thereby minimizing potential exposure of laundry personnel to bloodborne pathogens or other infectious agents. **1.2.2. Soiled, contaminated textiles and fabrics must be handled and collected with minimal agitation at all times to prevent contamination of air, surfaces, clean textiles, and persons.**	• Observation of practices

1.3. Transportation

1.3.1. The provider must maintain functional separation of clean textiles from soiled textiles in carts and/or vehicles at all times during handling, collection, and transportation of soiled textiles.	• Observation of practices • Inspection of facility • Discussion with employees

1.3 Transportation (cont.)

1.3.2. Functional separation of clean from soiled textiles must be maintained during transportation by:

1.3.2.1. Transport soiled textiles in fluid-resistant containers/bags.;

1.3.2.2. Anchoring soiled textile containers in the vehicle to prevent spillage from their containers;

1.3.2.3. Training personnel regarding proper bagging and placement of textiles in the transporting truck; and

1.3.2.4. Ensuring that all personnel with this responsibility follow Standard/Universal Precautions when necessary (e.g., when handling loose soiled textiles not contained in bags).

- Observation of practices
- Inspection of facility
- Discussion with employees

1.4. Carts Used for Soiled Textiles

1.4.1. Carts, containers, covers, and liners used to collect or transport soiled textiles must be properly cleaned and disinfected after the cart is emptied and before any next use, whether to transport clean textiles or soiled textiles.

1.4.2. If state regulation or AHJ indicates that carts used for soiled textiles cannot be used subsequently to transport clean textiles, the provider must comply with this restriction.

1.4.3. Proper cleaning shall include any of the following:

– Steam Cleaning

– Cleaning with a detergent and water or

– Using a hospital grade detergent disinfection

– Alternative method of disinfection such as UV systems

1.4.3.1 The laundry shall have documentation that supports the efficacy of its process in disinfection of the carts.

1.4.3.2 All methods shall follow instructions of the manufacturer and documentation is to be available to support the validation of the process used.

1.4.3.3.1. Hospital-grade cleaning products shall be used according to label instructions, ensuring that the product remains on surfaces for the full contact time.

- Policies and procedures
- Observation of practices
- Inspection of facility
- Discussion with employees
- Manufacturer Instructions for Use

Part II - 2. Sorting

2.1. Soiled Sorting Area

2.1.1. The surfaces in the soil sort room must be cleaned and disinfected in accordance with Part I Subpart 2 Section 2.1. Element 2.1.3.1. and Part I Subpart 2 Section 2.2. Elements 2.2.2.1. - 2.2.2.5.1.2. of this HLAC Standard.

- Policies and procedures
- Observation of practices
- Discussion with employees

2.2. Standard/Universal Precautions

2.2.1. All personnel who handle soiled healthcare textiles must follow Standard/Universal Precautions and use appropriate PPE for this task.	• Policies and procedures • Observation of practices • Discussion with employees

2.3. Sorting Soiled Textiles

2.3.1. Soiled textiles shall be sorted and loaded appropriately in order to provide hygienically clean linen. **2.3.2. Laundry bags and textiles contaminated with hazardous substances must be prewashed, and then the textiles added to other laundry for a second wash.**	• Policies and procedures • Observation of practices • Discussion with employees

2.4. Foreign Object Policies

2.4.1. Foreign objects shall be removed during the sorting process to be disposed of or returned to the customer in accordance with provider/customer contract. **2.4.1.1. Reusable surgical instruments shall be retrieved from the textiles prior to laundering, placed into designated containers, and returned to the customer.** **2.4.1.2. Disposable devices shall be retrieved from the textiles prior to laundering, discarded into designated containers, and/or returned to the customer.**	• Policies and procedures

2.4.2. Sharps Policy:

2.4.2.1. The provider must maintain a written sharps policy that includes, at a minimum: 2.4.2.1.1. Appropriate sharps containers must be closable, puncture resistant, leakproof on sides and bottom, and labeled (e.g., using the biohazard symbol) or color-coded; 2.4.2.1.2. Sharps containers must be located near soiled textile handling or sorting stations for collection and proper disposal of sharps; and 2.4.2.1.3. Personnel injured by a sharp shall follow OSHA's (or other relevant regulatory agency) regulations on sharps injury documentation, post-exposure evaluation, and follow-up	• Policies and procedures • Inspection of facility

Part II - 3. Washing and Extraction

3.1. Washing

3.1.1. The provider shall follow fabric-care instructions and special laundering requirements for items used by the customer, thereby ensuring that washed healthcare textiles become hygienically clean.

3.1.2. The provider must sort and process environmental cleaning and disinfection textiles (e.g., cleaning cloths, microfiber cloths, mop heads, etc.) in separate wash loads from healthcare textiles intended for patient use.

3.1.3. The provider shall establish the load size (weight) for each textile classification and for each type of equipment used.

3.1.4. Each classification shall have established parameters to optimize the wash processes:

3.1.4.1. Cycle time: Pre-wash, wash, rinse, and final rinse times;

3.1.4.2. Water levels/usage: Total water usage and/or water levels;

3.1.4.3. Temperature: Wash cycle, bleach cycle, and rinse cycle temperatures; and

3.1.4.4. Chemical usage: Chemical types and usage levels for each step in the wash process.

3.1.5. The provider shall demonstrate that wash processes are in compliance with state and local requirements by including a copy of these requirements in appropriate documentation and referrals to these requirements in policies.

3.1.6. If soiled textiles are received from the customer as labeled with hazardous drug contamination (i.e., chemotherapy drugs), the provider shall follow an appropriate textile process that includes:

3.1.6.1. Pre-wash of contaminated textiles in a washable laundry bag (e.g., net bag) separate from all other textiles and

3.1.6.2. Second wash process with other soiled textiles prior to drying cycle.

- Policies and procedures
- Copy of state and local requirements
- Observation of practices
- Inspection of facility
- Discussion with employees
- Manufacturer Instructions for Use
- Preventative maintenance records

3.2. Extraction

3.2.1. The provider shall extract and/or dry the clean healthcare textiles in a manner that preserves the integrity of the textiles, minimizes microbial growth after washing, and prepares the textiles for efficient ironing or folding.

3.2.2. Provider shall have a process to ensure damp textiles are not stored for an inappropriate length of time.

- Policies and procedures
- Observation of practices
- Inspection of facility
- Discussion with employees

Part II - 4. Drying

4.1. Equipment

4.1.1. Dryers shall be in good operating condition.	• Policies and procedures • Observation of practices • Preventative maintenance records

4.2. Drying

4.2.1. Drying procedures shall be described, controlled, and monitored for each textile classification to ensure appropriate drying.	• Policies and procedures • Observation of practices • Preventative maintenance records

Part II - 5. Finishing

5.1. Ironing Equipment

5.1.1. Ironers shall be maintained in good operating condition, so that they adequately iron, dry, and fold the textiles without excessive heat, pressure, or mechanical damage. 5.1.2. The equipment shall maintain a temperature appropriate for the type of fabric being processed and based on the equipment manufacturer's manual and recommendations, if available. 5.1.3. Documentation of monthly temperatures and preventive maintenance shall be maintained.	• Policies and procedures • Manufacturer Instructions for Use • Preventative maintenance records • Documentation of monthly temperatures

5.2. Folding and Stacking

5.2.1. Dry folding equipment shall be in good operating condition to properly fold the textiles without damage. 5.2.2. The folding and stacking process shall ensure that the textile merchandise is maintained in the same hygienically clean state as was achieved when it emerged from washing. 5.2.3. If any textiles become soiled in this process, they shall be rewashed in accordance with HLAC Standard Part II Subpart 3 Section 3.1.	• Policies and procedures • Inspection of facility

5.3. Packaging

5.3.1. Healthcare textile packaging must preserve textiles in a hygienically clean state for delivery to the customer. **5.3.2. Textiles must be wrapped into fluid-resistant bundles or placed as unwrapped bundles into fluid-resistant covered carts or hampers.**	• Policies and procedures • Observation of practices

5.3. Packaging (cont.)

5.3.3. Wrapping material shall be plastic or other material that will protect the textiles from inadvertent environmental contamination. 5.3.4. During packaging, textiles shall be handled as little as possible to prevent soiling or contamination. **5.3.5. The wrapping material or the cart must be securely closed during transport to the customer.**	• Policies and procedures • Observation of practices

5.4. Reprocessing Requirements

5.4.1. If any textiles become soiled during any stage of the finishing processing (including packaging), they must be rewashed and reprocessed in accordance with HLAC Standard Part II Subpart 3 Section 3.1	• Policies and procedures

Part II - 6. Storage

6.1 Rationale

6.1.1. The provider's storage strategies and handling methods of healthcare textiles must preserve the textiles in a hygienically clean state for delivery to the customer. 6.1.2. Stock inventory of clean finished textiles shall be rotated and used in a first-in/first-out manner.	• Policies and procedures • Observation of practices

6.2. Storage Areas

6.2.1. Storage parameters must be consistent with Part I, Subpart 2, Section 2.1, Subsection 2.1.3, Elements 2.1.3.1 – 2.1.3.4.4. of this HLAC Standard. 6.2.2. Unwrapped clean textiles shall be stored in designated storage rooms, areas, or carts. 6.2.3. Only clean textiles shall be stored in this area and signage posted as "Textile storage room." 6.2.4. Storage area cleanliness: 6.2.4.1. A schedule of surface cleaning with a detergent and water, including floor and shelves, shall be in writing. 6.2.4.2. Should this storage area require disinfection after cleaning, the provider shall use a hospital grade disinfectant according to label instructions per provider's policy. 6.2.5. Storage area entry and exit: 6.2.5.1. The doors to the clean textile storage area shall remain closed at all times, except for entrance or exit. 6.2.5.2. Storage rooms shall only be accessible by authorized personnel.	• Policies and procedures and procedures • Inspection of facility • Cleaning schedule

6.3. Storage Options

6.3.1. Bundled and wrapped textiles shall be stored in open racks in the laundry, on the trucks, or at the customer's facility provided the integrity of bundled and wrapped textiles is not compromised. 6.3.2. If unwrapped textiles are placed into carts or hampers and covered, the container shall remain covered at all times until delivered to the customer's textiles storage room or other designated location in the healthcare facility. **6.3.3. If the cart does not have a solid bottom (i.e., drain holes), the bottom must be lined with a hygienically clean barrier that prevents environmental contamination before placing clean textiles inside.**	• Policies and procedures and procedures • Inspection of facility

6.4. Reprocessing Requirements

6.4.1. If any textiles become soiled during storage, they must be rewashed and reprocessed in accordance with Part II Subpart 3 Section 3.1. of this HLAC Standard.	• Policies and procedures and procedures

Part II - 7. Delivery of Cleaned Healthcare Textiles

7.1. Clean healthcare textiles must be transported, delivered to the customer's storage area, and stored by methods designed to minimize microbial contamination from surface contact or airborne deposition.	• Policies and procedures and procedures • Inspection of facility

7.2. Delivery methods:

7.2.2. Clean textiles shall be wrapped for delivery.	• Policies and procedures and procedures • Inspection of facility

7.3. Cart Function and Cleanliness

7.3.1. Carts shall be maintained in good working order with wheels free from strings or other debris that impairs functioning or collects dirt. 7.3.2. Cart cleanliness: 7.3.2.1. Carts must be cleaned and disinfected in accordance with Part II Subpart 1 Section 1.4 Element 1.4.3. of this HLAC Standard. 7.3.2.2. Carts, containers, reusable cart covers, and liners used for clean textiles shall be properly cleaned and disinfected after the cart is emptied and upon return to the facility. **7.3.2.3. Reusable textile cover materials (e.g., liners) must be washed before the next use.** **7.3.2.4. If a cart used to transport clean textiles appears soiled, it must be cleaned and disinfected before it is subsequently used.**	• Policies and procedures and procedures • Inspection of facility • Process monitoring results if applicable

7.4. Vehicle Considerations

7.4.1. Functional separation:

7.4.1.1. While the best practice is to transport clean and soiled linen separately however if clean and soiled textiles are transported in the same vehicle, proper and effective functional separation must be maintained at all times.

7.4.1.2. Separation must be accomplished by the use of physical barriers and/or space separation sufficient to protect clean textiles from contact with soiled textiles.

7.4.2. Vehicle cleanliness:

7.4.2.1. The interior of the vehicle's cargo area used to transport healthcare textiles shall be cleaned on a regular basis per provider's policies and procedures and whenever visibly soiled.

7.4.2.2. Should the interior surfaces of the cargo area become contaminated with blood or OPIM, these surfaces must be decontaminated, cleaned with a detergent and water, and disinfected with a hospital grade disinfectant labeled as tuberculocidal and used according to label instructions.

7.4.3. Occupational safety for drivers:

7.4.3.1. Hand care:

7.4.3.1.1. Vehicles used to transport healthcare textiles must have alcohol-based hand sanitizer (ABHS) that contains at least 60 percent alcohol available on board for the purpose of hand hygiene.

7.4.3.1.2. Drivers must use gloves to minimize contact with soiled textiles and use appropriate hand hygiene after glove removal. Gloves used to handle soiled linen must never come in contact with clean linen.

7.4.3.2. Vehicles used to transport healthcare textiles shall have PPE and Spill Kits on board for the purpose of self-protection while cleaning and disinfecting the spill according to the provider's policies and procedures.

- Provider shall provide a copy of the cleaning protocol/ schedule
- Inspection
- Discussion with employees

PART III Surgical Pack Assembly Room Standards

Part III - 1. Physical Facilities of Surgical Pack Assembly Area/Room

1.1. Floors, Walls, Ceilings and Vents

1.1.1. Floors and walls must be constructed of materials that will withstand scheduled wet cleaning as well as the heat and humidity of the laundry environment (for example, mold- and moisture-resistant gypsum board, concrete, stainless steel, copper, etc.)

1.1.2. Particulate or fiber-shedding materials must not be used in the construction of the surgical pack assembly room.

1.1.3. Ceilings in clean work areas must be flush with recessed, enclosed fixtures.

1.2 Separation of Work Areas

1.2.1. The surgical pack assembly room must be designed, so that areas in which clean textiles are received, stored, and assembled into packs are separated by a physical barrier from areas in which soiled textiles are received or processed.

- Inspection of facility

1.3. Ventilation Requirements for Proper Air Flow and Climate Control

1.3.1. Heating, ventilation, and air conditioning (HVAC) system must be designed to conform to AIA/FGI standards in effect at the time when the facility was built or renovated.

1.3.2. The HVAC system in the surgical pack assembly room must maintain the appropriate positive air pressure relative to the rest of the facility, preventing intrusion of contamination from the soiled textiles area. The HVAC system must be a down-draft system for air circulation within the space, and the number of air changes/hour (ACH) (typically 10) must be sufficient to minimize lint particles in the air.

1.3.3. Return air registers (i.e., exhaust ducts) shall be at or near floor level, thereby facilitating the installation and effective maintenance of any filtering systems.

1.3.4. Portable fans must not be permitted in the surgical pack assembly room

1.3.5. Supply air for the surgical pack assembly room must be filtered as indicated in the edition AIA/FGI guidelines in effect at the time of construction or renovation of the laundry facility, with the filters undergoing scheduled regular maintenance as determined by the HVAC system engineer.

1.3.5.1. For new construction or major renovated laundry facilities' surgical pack assembly room since 2011, filtration must consist of one filter bed with a 7 MERV (minimum efficiency rating value) or 30% filtration efficiency or the FGI Guidelines at the time of the construction, as a minimum.

- Inspection of facility
- Certificate of annual air handling test
- Demonstration of pressure differentials
- Temperature/humidity logs

1.3. Ventilation Requirements for Proper Air Flow and Climate Control (cont.)

1.3.6. Temperatures in the surgical pack assembly room must be maintained between 68°F - 73°F to ensure a comfortable work environment for personnel in appropriate work attire. **1.3.7. Relative humidity (RH) must be maintained between 30% and 60% max in all work areas, except the sterile storage area, where the humidity must not exceed 70%, for personnel comfort and to discourage microbial (e.g., fungal) growth.**	• Inspection of facility • Certificate of annual air handling test • Demonstration of pressure differentials • Temperature/humidity logs

1.4. Lighting

1.4.1. High intensity lighting shall be available in that part of the room or area where textiles are examined (i.e., folding, assembly, and repair areas). 1.4.2. Lower intensity overhead lighting shall be employed for areas where light illumination (e.g., table, bar, tube, etc.) inspection is performed, so the light illumination equipment can be used optimally.	• Inspection of facility

1.5. Storage Area for Clean Textile Packs

1.5.1. The storage area for clean textile packs must be designed and managed in accordance with recommended practices for clean and sterile products. **1.5.2. Bulk shipping warehouse cardboard boxes must not be in these surgical pack assembly storage rooms.** **1.5.3. Storage rooms must be accessible only by authorized personnel** **1.5.4. Clean textile pack storage room doors must remain closed, except for access or exit.** **1.5.5. Environmental conditions in the clean surgical textile pack storage area must include:** **1.5.5.1. Temperatures must not exceed 73°F to prevent microbial contamination;** **1.5.5.2. Relative humidity must be less than 70% to inhibit microbial growth;** **1.5.5.3. The room must be properly ventilated to prevent accumulation of dust and lint (i.e., Minimum total air exchange rate of 2 ACH); and** **1.5.5.4. The room must have positive air pressure relative to adjacent spaces, preventing intrusion of contamination from the soiled textiles areas.** **1.5.6. Storage areas must be located within the surgical pack assembly room to facilitate bundling, loading onto trucks, and transportation.**	• Inspection of facility • Temperature/humidity logs • Demonstration of pressure differentials

Part III - 2. Surgical Pack Assembly Room Entry and Admission

2.1. Policies:

2.1.1. Criteria for authorized entry and movement within the surgical pack assembly room must be specified in written policies and procedures. **2.1.2. Eating, drinking, smoking, applying cosmetics or lip balm, and handling contact lenses must be prohibited in the surgical pack assembly room.** **2.1.3. Traffic in the surgical pack assembly room must be limited to authorized** **2.1.4. Policies and procedures must be developed to address visitor access and the circumstances for access and must establish a dress code to reduce the potential for contamination of surgical textiles.**	• Policies and procedures

2.2. Hand Hygiene Practices

2.2.1. Personnel must wash their hands before entering and working in the surgical pack assembly room. **2.2.2. Handwashing sinks with soap and paper towels must be readily accessible in or near the surgical pack assembly room.** **2.2.3. Alcohol-based hand sanitizer (with minimum alcohol concentration of 60%) also must be made readily available at the entrance and exit of the surgical pack assembly room door.**	• Inspection of facility • Observation of practices

Part III - 3. Surgical Textile Assembly Process

3.1. Carts Used to Move Clean Surgical Textiles to the Surgical Pack Assembly Room

3.1.1. Carts that are utilized for clean surgical textiles must be cleaned and disinfected in accordance with Part II, Subpart 7, Section 7.3. Element 7.3.2. of this HLAC Standard.	• Policies and procedures • Observation of practices

3.2. Inspection of Clean Surgical Textiles Prior to Pack Assembly

3.2.1 Written quality standards must be developed between the linen provider and the customer. Provider must provide documentation of these standards. Standards should be reviewed annually. **3.2.2. If surgical textile integrity and quality are monitored by the provider, the critical zones of surgical textiles must be visually inspected with the use of light illumination (e.g., table, bar, tube, etc.) for the presence of stains, residue, physical defects, chemical or thermal damage, and foreign debris, and to ensure that appropriate labels are in place and a tracking system is intact.**	• Policies and procedures • Documentation of quality standards • Demonstration of tracking mechanism • that indicate annual review • Inspection of facility • Discussion of practices with staff

3.2. Inspection of Clean Surgical Textiles Prior to Pack Assembly (cont.)

3.2.2.1. The provider and customer shall agree to a written procedure for reporting, investigating, and returning surgical textile barrier efficacy issues and strike-through occurrences to the textile manufacturer and reporting to the non-COG customer.

3.2.2.2. A tracking mechanism suitable for each surgical textile barrier product must be used to track the number of product's uses based on the textile manufacturer's recommendations.

3.2.3. Stains:

3.2.3.1. If, during the inspection process, surgical textiles are determined to be stained, these textiles must be rewashed or retired as appropriate.

3.2.3.2. Surgical textiles with aesthetic stains that do not adversely affect the functionality of the textile may remain in service unless the end user determines otherwise.

3.2.3.3. Stained surgical textiles must be retired if rewashing cannot successfully remove unacceptable stains or residues (e.g., medicines, lubricants, adhesives, blood and/or body fluids, hard surfaced or foreign matter of unknown composition, and raised or tactile residues).

3.2.4. Physical defects:

3.2.4.1. Physical defects (i.e., loose threads, loose or missing ties/ attachments, damaged/missing snaps, cuts, tears, and holes) must be repaired as appropriate with patching and mending before the textile is reused in accordance with Part III Subpart 3 Section 3.3 of this HLAC Standard.

3.2.5. Chemical or thermal damage:

3.2.5.1. Surgical textiles must be inspected for evidence of chemical and/or thermal damages (usually apparent as discoloration, stiffening, or compromised structural integrity holes).

3.2.5.2. Surgical textiles with chemical and/or thermal damage that adversely impacts the important functional attributes of the textile must be retired or removed from service.

3.2.6. Foreign debris

3.2.6.1. Surgical textiles must be free of foreign debris (e.g., lint, hair, loose fibers, fibrous pills, other particulates) prior to assembly into packs.

3.2.6.2. Foreign debris must be removed with an appropriate method (e.g., a delinting roller or sticky tape) as approved by the textile manufacturer.

3.2.6.3. Work practices must be implemented to keep surgical textiles free from foreign debris. Such practices include, at a minimum, the following:

3.2.6.3.1. Dress code suitable for the inspection area of the surgical pack assembly room, consisting of dedicated uniforms or other suitable outerwear, hair covering, and beard covers as appropriate;

- Policies and procedures
- Documentation of quality standards
- Demonstration of tracking mechanism
- that indicate annual review
- Inspection of facility
- Discussion of practices with staff

3.2. Inspection of Clean Surgical Textiles Prior to Pack Assembly (cont.)

3.2.6.3.2. Handwashing procedures;

3.2.6.3.3. Housekeeping procedures to minimize dust and lint; and

3.2.6.3.4. Facility maintenance (e.g., keeping dryer lint screens clean).

3.2.7. Labeling:

3.2.7.1. New surgical textiles shall be inspected for appropriate labels and accompanying manufacturer's instructions.

3.2.7.2. Labels shall contain information such as manufacturer, product type, and lot code numbers.

3.2.7.3. Labels with lot code information must remain intact throughout the effective life of the textile.

3.2.7.4. Surgical textiles that are labeled as in compliance with ANSI/AAMI PB70 must be labeled with their barrier classification.

3.2.8. Tracking System

3.2.8.1. If a tracking mechanism (e.g., radio frequency identification [RFID], grid, bar code) is present on a surgical textile, this must be visually inspected, marked, scanned, or read each time the product is processed.

3.2.8.2. If the integrity of the tracking mechanism is in question, the textile must be pulled from service or an alternate method of tracking must be used until the tracking problem is resolved

3.2.9. Effective Life of Surgical Textiles

3.2.9.1. Methods must be designed and in place to the number of uses/washes for surgical textile barrier products.

3.2.9.2. Textile manufacturers must be consulted for directions on evaluating the critical performance attributes of their textile products, to include barrier properties (e.g., repellent finish, deterioration of coatings or film), absorbency, strength, drapeability, physical defects, and signs of textile aging.

- Policies and procedures
- Documentation of quality standards
- Demonstration of tracking mechanism
- that indicate annual review
- Inspection of facility
- Discussion of practices with staff

3.3. Maintenance of Surgical Textiles

3.3.1. Patching and Mending

3.3.1.1. Sewing and use of patches shall be acceptable for repairs in non-critical zones of surgical textiles.

3.3.1.2. Physical defects within the critical zones of the various surgical textiles must be repaired, following manufacturer's guidelines.

3.3.1.2.1. Heat-sealed patches must be used to repair physical defects present in the critical zones of surgical textiles. Attributes of these patches must include:

3.3.1.2.1.1. Meeting the same general medical device safety and effectiveness requirements as the textile being repaired,

- Policies and procedures
- Documentation of criteria for patching
- Demonstration of adherence to the criteria

3.3. Maintenance of Surgical Textiles (cont.)

3.3.1.2.1.2. Being applied per manufacturer's instructions,

3.3.1.2.1.3. Providing at least the same performance characteristics, including level of barrier performance as the textile being repaired,

3.3.1.2.1.4. Providing at least the same life expectancy as the textile being repaired, and

3.3.1.2.1.5. Allowing for effective sterilization.

3.3.1.2.2. Patches must not be sewn to the textile.

3.3.1.2.3. Patches may need to be applied on one or both sides of a textile, depending on the textile's design and according to the textile manufacturer's instructions.

3.3.1.2.4. Use of sewing is discouraged for repairs in textiles' critical zones; but if sewing is indicated for a successful repair, heat-sealed patches must be used to seal the needle holes.

3.3.1.3. Loose patches must be removed and new patches applied

3.3.1.4. Acceptable number, location, shape, and size of patches must be clearly delineated in written quality standards and repair procedures.

3.3.1.5. If patching and/or mending is performed, the textiles must be rewashed.

3.3.2. Rewashing surgical textiles

3.3.2.1. If a reusable surgical textile requires rewashing, the procedure used must be compatible with the product.

3.3.2.2. Each rewash cycle must be counted as an additional life cycle for the item.

3.3.3. Rejuvenation of surgical textiles

3.3.3.1. If reusable surgical textile products require rejuvenation or a laundry additive is used to maintain repellency, the process must be compatible with the textile product.

3.3.3.2. Additives that maintain surgical textile performance characteristics (e.g., repellency) must be used according to product instructions.

3.3.3.3. Rejuvenation cycles must be counted as additional life cycles

3.3.4. Surgical textile retirement or alternate use:

3.3.4.1. When reusable surgical textile products fail to meet their minimum functional performance criteria, they must be retired from use, downgraded to a less stringent alternate use category (e.g., cover gowns), or remade into a different product (e.g., a smaller wrapper).

3.3.4.2. Products placed into alternate use or remade into different products shall continue to be safe and effective for their intended use.

3.3.4.3. Items placed into alternate use must be permanently marked in some obvious fashion to prevent mix-ups or inappropriate use.

- Policies and procedures
- Documentation of criteria for patching
- Demonstration of adherence to the criteria

Part III - 4. Preparation and Wrapping of Surgical Textiles

4.1. Preparation

4.1.1. Policies and procedures must be in place to ensure that reusable surgical textiles are laundered, dried, folded, and packed in a manner that will permit sterilization and delivered to the customer via a means such that the textiles maintain their hygienic integrity, avoiding contamination.

4.1.2. Preparation, folding, and packing procedures for reusable surgical textiles shall be developed with consultation from the customer and documented.

- Policies and procedures

4.2. Folding

4.2.1. Reusable surgical textiles shall be folded and packaged properly and consistently each time they are processed in accordance with customer's requirements.

4.2.2. Standards must be in place to identify the specific folds, components, and other details for each surgical pack built by the laundry.

4.2.3. The following elements must be taken into account regarding the folding of clean, reusable surgical textiles:

4.2.3.1. Following inspection, all items must be folded in a manner that will allow them to be aseptically donned and/or presented to the sterile field with as little manipulation and chance of contamination as possible.

4.2.3.2. The method of folding must allow for effective penetration of the steam from the autoclave into the pack.

4.2.3.3. The method of folding must allow for easy identification and orientation of the items.

4.2.4. Clean reusable surgical textiles must be handled with clean hands in a manner to maintain their hygienic quality in accordance with Part I Subpart 5 Section 5.3 Element 5.3.3.3 of this HLAC Standard.

4.2.5. Procedures for folding surgical textiles shall be reviewed as needed to ensure that they are still applicable with the customer.

4.2.5.1. Folding specifications shall be provided by and/or approved by the customer for whom the surgical packs are being built.

4.2.5.2. These specifications shall be documented, using photographs or drawings or other visual media with accompanying instruction notations, and a photograph or drawing of the finished products shall be included.

4.2.5.3. These photographs and/or drawings specifications shall be maintained in the surgical pack assembly room.

- Documentation of folding standards
- Discussion with employees

4.3. Surgical Textile Pack Assembly

4.3.1. Pack order, from top to bottom, must be developed in consultation with the customer to ensure that items can be removed from the pack, in the order of their use, without compromising the sterile field.

4.3.2. After the order of the pack is agreed upon, the pack configuration must be documented (i.e., pack master list and/or a device master record [DMR]).

4.3.3. The contents and order of each pack configuration shall be reviewed by the manager, who is responsible for pack assembly to ensure that the pack meets all appropriate requirements; documentation for each pack configuration shall be reviewed on a regular basis by the surgical pack assembly room manager with the customer.

- Documentation of pack configuration

4.4. Wrapping and Packaging

4.4.1. The barrier product used to complete the pack and provide adequate coverage of the contents must be appropriate for the method of sterilization (i.e., permits maximum penetration of the sterilant during sterilization) and must maintain the content's sterility until aseptic presentation.

4.4.2. The customer shall be consulted in the choice of appropriate barrier product.

4.4.3. The type of barrier used must be documented in the procedure (i.e., pack master list and/or a DMR)

4.4.4. The finished pack and bulk loose textiles must be packaged in a suitable material (e.g., placed in covered carts or wrapped in plastic) to avoid contamination during transport to the customer.

- Pack master list and/or DMR

4.5. Labeling and Identification of Packs

4.5.1. Prior to delivery, assembled packs must have a label that includes the following items of information:

4.5.1.1. Identification (e.g., name, Julian date, and unique pack identifier)

4.5.1.2. Pack contents, including identifying any items containing natural rubber latex

4.5.1.3. Identification or identifying barcode of who and date assembled the pack.

- Inspection of assembled packs

Part III - 5. Storage and Transportation of Surgical Textile Packs

5.1. Storage of Surgical Textile Packs

5.1.1. Storage of Surgical Textile Packs must comply with Part I Subpart 2 Section 2.1. Element 2.1.3. and Part III Subpart 1 Section 1.5. of this HLAC Standard for statements addressing storage of clean surgical textile packs.

- Inspection of facility

5.2. Transportation of Surgical Textile Packs

5.2.1. Transportation of surgical textile packs must be in accordance with Part II Subpart 7 of this HLAC Standard.

5.2.2. Transport of the surgical textile packs within the provider's facility or to the customer must be accomplished in a manner to maintain the hygienic quality of the packs and to minimize microbial contamination from surfaces or the air.

5.2.3. Clean carts or containers must be used for transport of clean surgical textile packs.

5.2.4. Carts or containers used for soiled surgical textiles must not be permitted in the surgical pack assembly room.

5.2.5. Characteristics of carts or containers suitable for transporting clean surgical textile packs must be in accordance to Part II Subpart 7 Sections 7.1. and 7.3. of this HLAC Standard.

5.2.6. Soiled fabrics must be physically separated from clean during loading procedures to prevent environmental contamination.

- Policies and procedures
- Inspection of practices

Part III - 6. Surgical Textile Pack Assembly Room Personnel

6.1. Qualifications

6.1.1. General elements related to personnel qualifications shall be in accordance with Part I Subpart 5 Section 5.1. of this HLAC Standard.

6.1.2. Surgical pack assembly room procedures must be performed correctly and supervised by knowledgeable personnel.

- Employee records
- Documentation of training records and evaluation of competency

6.2. Training and Competency

6.2.1. General elements of personnel training must be in accordance with Part I Subpart 5 Sections 5.2. and 5.6. of this HLAC Standard.

6.2.2. Personnel must be trained on the appropriate pack processes according to each pack's use requirements.

6.2.3. Personnel must be trained to operate surgical pack assembly room equipment safely and to recognize and report equipment malfunctions.

6.2.4. Personnel must be trained to work with reusable surgical textiles and to be familiar with the following items:

6.2.4.1. Characteristics inherent to reusable surgical textiles;

6.2.4.2. Uses of those textiles;

6.2.4.3. Processes required to maintain those qualities, such as folding and preparations of the surgical packs; and

6.2.4.4. Infection prevention relevant to the preparation of surgical textiles.

- Employee records
- Documentation of training records and evaluation of competency
- Discussion with employees

6.3. Health and Personal Hygiene

6.3.1. Additional health and hygiene specifics must be in accordance with HLAC Standard Part I Subpart 5 Section 5.3.

6.3.2. Fingernails must be kept short, clean, natural, and healthy.

6.3.2.1. Surgical pack assembly room personnel must not wear nail polish, artificial nails, or artificial eyelashes.

6.3.3. Jewelry of any kind must not be worn in the surgical pack assembly room.

6.3.4. Healthy skin integrity absent of abrasions, dermatitis or other skin breakdowns must be maintained.

- Policies and procedures
- Observation of practices

6.4. Attire and Personal Protective Equipment (PPE)

6.4.1. The basic elements pertaining to personnel attire must be in accordance with Part I Subpart 5 Section 5.4. of this HLAC Standard as appropriate

6.4.2. Personnel attire in the surgical pack assembly room must protect personnel and the integrity of the textile product.

6.4.2.1. All head and facial hair (excluding eyebrows and eyelashes) must be completely covered with a surgical-type hair covering.

6.4.2.2. Dedicated surgical pack assembly room attire laundered by the facility must be covered or changed upon leaving or entering the surgical pack assembly room in accordance with provider's policy.

6.4.2.2.1. When leaving the surgical pack assembly room, dedicated pack room personnel first must don the appropriate protective cover (e.g., cover gowns, shoe covers, hair covering, etc.) over their surgical pack assembly room attire and then must remove the appropriate protective cover (e.g., cover gowns, shoe covers, hair covering, etc.) that was over their surgical pack assembly room attire before re-entering the surgical pack assembly room in accordance with written facility policy.

6.4.2.3. Dedicated shoes and/or disposable shoe covers must be worn in the surgical pack assembly room.

- Policies and procedures
- Observation of practices

APPENDIX D

TRAINING REQUIREMENTS SUMMARY

STANDARD	TOPIC	KEY ELEMENTS
Part I		
5.6.1.1	**General Elements**	• Personnel must receive standard safety training of laundry operations applicable to their respective position(s), including, but not limited to safe operations of equipment per manufacturer's instructions and notification procedures when malfunctions occur.
5.6.1.2	**Laundry Operations**	• Personnel shall receive the provider's standard training for the correct handling of healthcare textiles. Topics shall include: – Specific types of fabrics being processed – Appropriate surgical textiles pack processes according to each pack's use requirements; – Proper use, placement, and heat-sealing process for patching surgical textiles; – A copy of the grading standards
5.6.2	**Bloodborne Pathogens Exposure Control Training**	**Key topics for this training must include, but are not limited to:** • Personal hygiene and proper handwashing and hand hygiene techniques; • Use of PPE according to the facilities exposure control plan, including one or more of the following, but not limited to, gloves, gowns, aprons, safety goggles, and masks; • How to correctly don and doff PPE • Engineering controls and work practices to minimize the risk of exposure to blood or OPIM; • Orientation on the provider's Exposure Control Program; • Orientation to hazard communications, including labeling and color-coding; and • Post-exposure procedures, including immediate action, treatment, follow-up, and record keeping.

STANDARD	TOPIC	KEY ELEMENTS
5.6.3	**Hazardous Substance Contaminated Textiles Training**	**Key topics for this training must include, but are not limited to:** • Exposure risk to textiles contaminated with hazardous substances or excreta from patients who have received hazardous substances (e.g., radioisotopes, chemotherapeutics, etc.) in the past 48 hours; • Communications among supervisors and personnel for hazardous substance management procedures; • Identification and segregation of soiled textiles from patients exposed to hazardous substance contaminated, reusable textiles in bags designated solely for the containment of reusable hazardous substance exposed textiles; • Use of PPE including one or more of the following, but not limited to, gloves, gowns, and eye protection, if splashing is possible; • Hand hygiene; • Disposal of contaminated one time use PPE in thick, leak-proof colored or labeled plastic bags for hazardous substances-related wastes. • Proper handling of other reusable PPE.
5.6.4	**Department of Transportation (DOT) Regulations**	**Key topics in this training shall include, but are not limited to:** • Random drug testing; • Operator training; • Certified driver license requirements • Bloodborne pathogens exposure
PART III		
6.2	**Surgical Pack Assembly Rooms Standards**	• Personnel must be trained on the appropriate pack processes according to each pack's use requirements. • Personnel must be trained to operate surgical pack assembly room equipment safely and to recognize and report equipment malfunctions. • Personnel must be trained to work with reusable surgical textiles and to be familiar with the following items: – Characteristics inherent to reusable surgical textiles; – Uses of those textiles; – Processes required to maintain those qualities, such as folding and preparations of the surgical packs; and – Infection prevention relevant to the preparation of surgical textiles

APPENDIX E

DESIGN VENTILATION PARAMETERS FOR HEALTHCARE LAUNDRY AREAS

LAUNDRY AREA	AIR FLOW DIRECTION	EXHAUST TO OUTSIDE?	MINIMUM TOTAL ACH*	MINIMUM # ACH OF OUTDOOR AIR	USE OF RECIRCULATED AIR	TEMP°	RELATIVE HUMIDITY
Linen and Trash Room Chute	Negative	Yes	10	NR^	No	NR	NR
Soiled Linen Sorting and Storage	Negative	Yes	10	NR	No	NR	NR
Laundry	Negative	Yes	10	2	No	NR	NR
Clean Linen Storage	Positive	NR	2	NR	NR	72° - 78° F	NR

Source: Ventilation of Health Care Facilities. ANSI/ASHRAE/ASHE Standard 170-2013 Table 7.1, p. 11 in FGI 2014.
* ACH = Air Changes per Hour
^ NR = No Requirement

APPENDIX F
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