



The Healthcare Laundry Accreditation Council

**Accreditation Standards
for
Processing
Reusable Textiles
for Use in
Healthcare Facilities
2011 Edition**

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by

The Healthcare Laundry Accreditation Council

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2011 HLAC Accreditation Standards

Preamble

1. Introduction

Healthcare textiles are fabric products that touch patients and employees directly or indirectly on a daily basis. The Healthcare Laundry Accreditation Council (HLAC) is the authority on laundry standards for the preparation of hygienically clean, reusable healthcare textiles for patient care. HLAC offers a voluntary accreditation to those laundry facilities processing reusable healthcare textiles. The HLAC Accreditation Standards are established as the minimum acceptable practice in this endeavor. However, laundry operators may choose to exceed these standards, thereby providing exceptional benefit to patients through excellence in healthcare textiles processing.

The 2011 HLAC Accreditation Standards represent a major revision and updating of the 2006 standards, the modifications of which include the addition of substantial evidence-based references, best practices, and common sense regarding the laundry processing of reusable healthcare textiles. These revisions represent fundamental principles and are based on the highest standards for patient infection prevention, safety regarding textiles, and occupational and workplace safety. The 2011 HLAC Accreditation Standards will heighten awareness of and increase laundry personnel understanding of the infection prevention and safety culture of the healthcare arena where programs, policies, procedures, and practices as stated in this revision are common concepts and language. The central focus of health care is the patient followed by the healthcare personnel. The elements of laundry processing are specific operations involving procedures, facilities, administrative activities, equipment, personnel, quality monitoring, and advanced technologies as appropriate.

A Part III has been added to the Standards, addressing the surgical pack assembly room and its activities. This section is based on the American National Standards Institute (ANSI)/Association for Advancement of Medical Instrumentation (AAMI) reference regarding reusable surgical textiles processing. References support the Standards and are available for supplemental reading.

2. Important Terminology and Interpretive Guidance

In this document, “provider or service provider” is the designated term to encompass the laundry plant as the processor of healthcare textiles, whether the laundry is 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. The “customer” is 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). Additionally, the terms “inspectors” and “inspection” reflect the compliance process applicable to healthcare reusable textiles processing in these HLAC Standards by HLAC Inspectors.

As defined by the U.S. Department of Labor, Occupational Safety and Health Administration (OSHA), Universal Precautions is the preferred approach to infection control in the laundry industry where all human blood and certain human body fluids are considered to be infectious with blood borne pathogens. Therefore, Universal Precautions will be the common term used in these Standards. Contaminated laundry, according to OSHA, means laundry which has been soiled with blood or other potentially infectious materials or may contain sharps.

The verbs indicate the requirement status for each individual Standard statement. The following definitions of the statement categories will apply:

A “must” statement is one for which compliance is required, and the directive of the statement is supported by any or all of the following resources:

- 1. Federal mandates, regulations (e.g., OSHA, U.S. Food and Drug Administration [FDA], U.S. Environmental Protection Agency [EPA]) that are law;**
- 2. State and/or local government regulations;**
- 3. Evidence-based, peer-reviewed best practices/recommendations for infection prevention and laundry procedures 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], Textile Rental Services Association of America [TRSA]).**
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

4. 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).

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 will also be 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.

“Should” and “may” statements represent suggested courses of action for which a strong industry consensus is not available for all regions of the country, or are part of emerging practices and/or technology.

“Should” and “may” statements are recommended for implementation, but are not scored.

The combination of the “must” + “shall” statements + HLAC review 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 survey.

3. Disclaimer

An HLAC inspector’s assessment of a provider’s facility and processes for the production of hygienically clean reusable healthcare textiles is based on the integrated requirements, best practices, and guidance from diverse entities adopted by reference in the 2011 HLAC Accreditation Standards. HLAC inspectors are not trained as official OSHA surveyors nor should compliance with HLAC Standards be interpreted as compliance with all OSHA requirements. Neither are HLAC inspectors

qualified to certify compliance with local regulations or the Authority Having Jurisdiction (AHJ).

Part I. Basic Elements

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.

1.1.1.1. For customer-owned goods (COG), the provider should obtain textile specifications from the customer and resolve any questions or concerns prior to agreeing to a contract.

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 be on file, signed by both entities and dated, and specify the process details and extent of service for the contract period.

1.1.3. The provider shall have a documented biohazard communication system, identifying soiled healthcare textiles using color-coding and/or labeling and adhere to Universal Precautions. (OSHA 29 CFR 1910.1030.(d)(4)(iv)(A)(2))

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

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 documentation shall be accessible where personnel may refer to it.

1.2.2. Providers processing COG textiles shall comply with pre-established textile maintenance standards as specified by each customer, including consideration of the textile manufacturer's instructions.

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

1.2.4. 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 and end-users' needs.

1.3.2. Methods to insure that an adequate supply of linen 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. Providers and customers shall document in writing provision of inventory for situations where increased need (i.e., surge capacity in response to disaster) is anticipated and what adjustments are acceptable.

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 shall ensure efficiency, minimize environmental contamination, and protect the material and hygienic integrity of the processed textiles. (JCHLGL Guidelines for Healthcare Linen Service, 1994, 8.)

2.1.2. If the laundry facility is situated within a health care facility (e.g., a hospital), the physical layout and utilities infrastructure shall be in accordance with the provisions of the edition of the Facility Guidelines Institute (FGI) "Guidelines for Design and Construction of Health Care Facilities" in effect at the time of facility construction or renovation. [FGI GL Construction HCF 2010: 2.2-5.2 Linen Services, 2.6-5.2; JCHLGL Guidelines for Healthcare Linen Service, 1994; 8.B)

2.1.3. Soiled Textiles Area

2.1.3.1. 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 of the following methods:

2.1.3.1.1. 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

2.1.3.1.2. 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. (JCHLGL Guidelines for Healthcare Linen Service, 1994; 6.B.3, 8.A.1-3; CDC HICPAC GL EIC, 2003:II.G.II.A; ANSI/AAMI ST65:2008; Stds.3.2.3.1, 3.3.4; ANSI/AAMI ST79:2010; Stds. 3.2.3, 3.3.7.1; FGI GL 2010: 2.2-5.2 Linen Services 2.2-5.2.2.1-2, 2.2-5.2.3.1, 2.6-5.2.1.1-2, ANSI/ASHRAE/ASHE Std. 170-2008: Table 7.1, p. 9)

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

2.1.3.3. Warning signs about the presence of contaminated textiles and the need to follow

Universal Precautions must be posted in work areas where potentially contaminated textiles are stored or sorted prior to processing. (JCHLGL Guidelines for Healthcare Linen Service, 1994; 8.E)

2.1.3.4. Handwashing facilities must be located in all areas where soiled or contaminated textiles are handled. (OSHA 29 CFR 1910.1030 (d)(2)(iii, iv); CDC HICPAC GL Hand Hygiene: 8 D; JCHLGL Guidelines for Healthcare Linen Service, 1994; 8.C.; CDC HICPAC GL EIC, 2003:II.G.II.B; ANSI/AAMI ST65:2008; Std. 3.3.7; ANSI/AAMI ST79:2010 Std. 3.3.6.8; FGI GL 2010: 2.2-5.2 Linen Services 2.2-5.2.2.5, 2.2-5.2.3.4, 2.6-5.2.1.4)

2.1.3.5. Emergency eyewash equipment must be available with unobstructed access (i.e., requiring no more than 10 seconds to reach) in all areas where soiled textiles are processed. (ANSI/ISEA Z358.1-2009:5.4.2; ANSI/AAMI ST65:2008; Std. 3.3.8; ANSI/AAMI ST79:2010 Stds. 3.3.7.1, 3.3.8; OSHA 29 CFR 1910.1030. (d)(2)(i))

2.1.4. Clean Textile Staging and Storage Areas

2.1.4.1. In the provider's facility, the textile staging and storage areas for cleaned, processed textiles must be in compliance with the following specifications:

2.1.4.1.1. Free of vermin;

2.1.4.1.2. Devoid of lint;

2.1.4.1.3. Without obvious moisture contamination. (ANSI/AAMI ST65:2008; Std. 9.6.1-2; ANSI/AAMI ST79:2010; Std. 8.9.2)

2.1.4.2. The ventilation of the storage area shall:

2.1.4.2.1. Be designed to prevent accumulation of dust and lint; and

2.1.4.2.2. Be under positive air pressure relative to adjacent spaces, thereby preventing intrusion of contamination from soiled textile areas.

2.1.4.3. Policies and protocols should reflect a facility-specific strategy for ensuring the hygienically clean quality of the stored, processed textiles, and should include the following:

2.1.4.3.1. Establishing a schedule of visual inspection of the stored textiles and recording the observations;

2.1.4.3.2. Developing a remediation plan in response to customer-returned, moist textiles.

2.1.4.4. Specifications for Clean Textiles Storage Shelves

2.1.4.4.1. Shelves shall be placed approximately 2 inches from the wall to safeguard package integrity. (ANSI/AAMI ST65:2008; Std. 9.6.1; ANSI/AAMI ST79:2010; Std. 8.9.2)

2.1.4.4.2. The bottom shelf shall be free from visible soil and dirt and a minimum of 8 inches from the floor for accessible cleaning and shall be of solid nonporous construction. (ANSI/AAMI ST65:2008; Std. 9.6.1; ANSI/AAMI ST79:2010; Std. 8.9.2)

2.1.4.4.3. The top shelf shall be a minimum of 18 inches below the ceiling to prevent impairment of ventilation, sprinklers, and lighting. (ANSI/AAMI ST65:2008; Std. 9.6.1; ANSI/AAMI ST79:2010; Std. 8.9.2)

2.1.4.4.4. Cardboard must not be used as shelf liner material in the clean textiles storage area.

2.1.5. Other Fixtures and Signage

2.1.5.1. Hand hygiene resources (i.e., handwashing facilities or antiseptic hand

cleaner/cleaner dispensers) must be available in or around all work areas and in personnel support

areas. (OSHA 29 CFR 1910.1030 (d)(2)(iii, iv); CDC HICPAC GL Hand Hygiene: 8 D; JCHLGL Guidelines for Healthcare Linen Service, 1994; 8.C.; CDC HICPAC GL EIC, 2003:II.G.II.B; ANSI/AAMI ST65:2008; Std. 3.3.7; ANSI/AAMI ST79:2010 Std. 3.3.6.8; FGI GL 2010: 2.2-5.2 Linen Services 2.2-5.2.2.5, 2.2-5.2.3.4, 2.6-5.2.1.4)

2.1.5.2. Emergency eyewash/shower equipment must be available with unobstructed access (i.e., requiring no more than 10 seconds to reach) for immediate emergency use in all areas where chemicals are used and/or stored. [ANSI Z358.1-2009:4.5.2; ANSI/AAMI ST65:2008; Std. 3.3.8; ANSI/AAMI ST79:2010 Stds. 3.3.7.1, 3.3.8; OSHA 29 CFR 1910.151 (c)]

2.1.5.3. Safety features (e.g., emergency lighting, signage, fire alarms, door accessibility and egress, safety perimeter for robotics, equipment guards) must be evident and operational to safeguard persons and personnel. (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) shall receive, according to facility policy, scheduled cleaning appropriate for the surface, the frequency dependent upon the level of contamination, and the operation performed in the area. (ANSI/AAMI ST65:2008; Std. 3.3.3; ANSI/AAMI ST79:2010 Stds. 3.3.6, 3.4; ASHES Practice GL Sec 1.2)

2.2.2.1.1. The cleaning schedule shall be maintained on a current basis and posted for inspection.

2.2.2.2. Environmental surfaces (e.g., walls, ceilings, vents, and equipment) shall be subjected to periodic blow down processes from ceiling downward to minimize the build-up of dust and lint.

2.2.2.2.1. Blow down shall be performed when no other processing of textiles is occurring and not in pack rooms. (ANSI/AAMI ST65:2008; Std. 3.3.3)

2.2.2.3. Working surfaces (e.g., counters, bench tops, and table tops) must be kept clean of visible soil, dust, and lint through use of a detergent/cleaner and water. [OSHA: 29.CFR 1910.1030 (d)(4)(ii); CDC HICPAC GL EIC, 2003: II.E.I.E.2; ANSI/AAMI ST79:2010 Std. 3.4]

2.2.2.4. Working surfaces that become contaminated with blood or other potentially infectious material (OPIM) must be decontaminated, cleaned, and disinfected with EPA-registered hospital disinfectants labeled tuberculocidal or registered disinfectants on the EPA Lists D and/or E (i.e., products with specific label claims for human immunodeficiency virus [HIV] or hepatitis B virus [HBV]) according to label instructions. [OSHA: 29 CFR 1910.1030 (d)(4)(ii, iiA) memorandum 2/2/97; CDC HICPAC GL EIC, 2003: E.I.A, II.A-D; EPA Lists of Registered Pesticides]

2.2.2.5. When disinfecting working surfaces that may be contaminated with patients' body substances other than blood or OPIM, the surface shall be decontaminated, cleaned, and an EPA-registered hospital disinfectant shall be used in accordance with the manufacturer's instructions. (CDC HICPAC GL EIC,

2003:II.E.I.A.; ANSI/AAMI ST79:2010 Std. 6.2)

2.2.2.6. Contaminated work surfaces shall be decontaminated, cleaned, and disinfected with an EPA-registered hospital disinfectant after completion of soiled textile handling activities; immediately or as soon as feasible when surfaces are visibly contaminated; and at the end of the work shift, if the surface may have become contaminated since the last cleaning. [CDC HICPAC GL EIC, 2003: II. E.I.A.; II. E.1.; II.H.; II. A-D; ANSI/AAMI ST79:2010 Std. 6.2.]

2.2.2.7. Work practices when using conventional washer extractors

2.2.2.7.1. Cleaning and disinfection of surfaces

2.2.2.7.1.1. 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.

2.2.2.7.1.2. Routine cleaning and disinfection of surfaces that are used to both load and unload conventional washer extractors must be consistent with the principles of functional separation.

2.2.2.7.1.3. Spot cleaning of visibly soiled surfaces that are used to both load and unload conventional washer extractors must be done as soon as possible after surface contamination occurs, using a cleaning/disinfection strategy appropriate for the type of soil (see Part I, Subpart 2, statements 2.2.2.4 and 2.2.2.5 of this HLAC Standard). [OSHA: 29 CFR 1910.1030 (d)(4)(ii, iiA), memorandum 2/2/97; CDC HICPAC GL EIC 2003: E.I.A., II.A-D; EPA Lists of Registered Pesticides; CDC HICPAC GL EIC, 2003: II. E.I.A.; ANSI/AAMI ST79:2010 Std. 6.2]

2.2.2.7.2. Work flow and functional separation

2.2.2.7.2.1. 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, statement 2.1.3.1 of this HLAC Standard.

2.2.2.7.2.2. For conventional washer extractor equipment that utilizes sling delivery systems for loading soiled textiles, clean textiles must not be stored under the soiled slings.

2.2.2.7.3. Employee 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, statements 5.3.3.1 and 5.4.1.4 of this HLAC Standard. [CDC HICPAC GL Hand Hygiene 1.G, 1.J, 1.K, 6.C; ANSI/AAMI ST65:2008 Std. 4.4; ANSI/AAMI ST79:2010 Std. 4.4, 4.5.1, 4.5.2; OSHA 29 CFR 1910.1030 (d)(2)(v), and (d)(3)(vii)]

2.2.3. Pest Control Program

2.2.3.1. The provider shall 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, 2003: II. E.V.A-C; ASHES Recommended Practice Series: Integrated Pest Management)

2.3. Management of Foreign Items and Regulated Wastes

2.3.1. Miscellaneous Foreign Items

2.3.1.1. The provider shall follow the customer's policy for returning items found among healthcare textiles, especially personal patient information as described in Part II, Subpart 2, Section 2.4 of this HLAC Standard.

2.3.2. Regulated Medical Waste Management

2.3.2.1. The provider must have 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. [OSHA: 29 CFR 1910.1030 (d)(4)(iii)(C); CDC HICPAC GL EIC, 2003: II.I.II.A]

2.3.2.1.1. The Regulated Medical Waste Management Plan must be in accordance with local regulations or the Authority Having Jurisdiction (AHJ). [OSHA: 29 CFR 1910.1030 (d)(4)(iii)(C); CDC HICPAC GL EIC, 2003: II.I.I.B]

2.3.2.1.2. Documentation identifying what waste items were sent, the date, the disposition of the items, and notification of the customer must be available for review.

2.3.2.1.3. Appropriate containers must be provided for collection and proper disposal of sharps and other non-textile waste objects. [JCHLGL Guidelines for Healthcare Linen Service, 1994; 8.D.; OSHA: 29 CFR 1910.1030 (d)(4)(iii)(A); CDC HICPAC GL EIC, 2003: II.I.III.C]

2.3.3. Hazardous Materials and Pharmaceutical Waste Management

Note: Compliance with statement 2.3.3. and its sub-statements is limited to those providers who have affirmed current experience with customers who send textiles contaminated with hazardous substances for laundering.

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

2.3.3.2. If the provider accepts bagged textiles contaminated with hazardous substances/wastes, the provider must demonstrate in policies and/or contracts how to manage such textiles in accordance with federal regulations intended to minimized laundry employees' exposure to hazardous substances. (OSHA 29 CFR 1910.1200; OSHA Technical Manual: Hazardous Drugs, Sec. 6, Chapter 2)

2.3.3.3. 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.

2.3.3.4. Hazardous substance-related wastes must be handled separately from other customer trash/solid wastes and disposed as per facility policy developed in accordance with applicable local regulations or the AHJ for hazardous waste. (OSHA: 29 CFR 1910.1200; The OSHA Technical Manual: Haz Drugs, Sec 6, Chap 2)

2.3.3.5. 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).

2.3.3.5.1. The provider and the customer should establish a mutually agreeable determination and course of action as to when a pharmaceutical-contaminated textile is to be managed as pharmaceutical waste (i.e., the item is to be discarded) or when the pharmaceutical-contaminated textile is to be returned to the customer.

2.4. Piped Air, Water, Wastewater, and Chemicals Management

2.4.1. Provider's facility documents must contain evidence of compliance with local regulations or the AHJ as they pertain to air, water, and chemicals management.

2.4.2. There must be evidence of waste water and/or air quality permit compliance, if applicable.

2.4.3. 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. (OSHA: 29 CFR 1910.1200; DHS 6 CFR 27).

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, 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. Workers 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 Agreements

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

(JCHLGL Guidelines for Healthcare Linen Service, 1994; 12)

3.4.1.1. These agreements shall be updated annually, signed, and dated.

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

3.4.3. The provider shall have written agreements in place with one or more alternate textile suppliers, detailing the services and delivery times provided (does not apply to COG). (JCHLGL Guidelines for Healthcare Linen Service, 1994; 12)

4. Laundry Equipment

4.1. Documentation

4.1.1. A list of all equipment shall be prepared, kept on file, and made available prior to inspection.

(ANSI/AAMI ST65:2008 Std. 10.2.1)

4.1.2. An occupancy permit shall be kept on file, if available.

4.1.3. Documentation concerning equipment safety:

4.1.3.1. The provider should verify that the manufacturer has provided safety instructions, describing the potential hazards associated with the equipment use. (ANSI/AAMI ST65:2008 Std. 10.2.2)

4.1.3.2. The provider should provide the documentation and/or means to ensure that the equipment incorporates appropriate safeguards. (ANSI/AAMI ST65:2008 Std. 10.2.2)

4.1.3.3. The provider should demonstrate the equipment complies with ANSI Z8.1., regarding safe operation and maintenance of equipment. (ANSI/AAMI ST65:2008 Std. 10.2.2)

4.1.4. Documentation concerning equipment maintenance:

4.1.4.1. The maintenance personnel should have access to equipment manuals to inform them on installation, operation, preventive maintenance, repairs, replacements, and illustrations of the equipment components. (ANSI/AAMI ST65:2008 Std. 10.2.3)

4.1.4.2. Providers should retain evidence of an ongoing maintenance program, including work orders and a current inspection tag if one has been issued from inspection. (ANSI/AAMI ST65:2008 Std. 10.2.2)

4.1.4.3. Equipment preventive maintenance should be documented and kept on file. (ANSI/AAMI

ST65:2008 Std. 10.5.5)

4.2. Installation and Utilities Connections

4.2.1. Equipment installation should involve trained or qualified installers, appropriate utilities and support services, compliance with the equipment manufacturer's instructions, and properly functioning safety equipment specified by the manufacturer. (ANSI/AAMI ST65:2008 Std. 10.3.1)

4.2.2. Before any piece of equipment is commissioned into service, either initially or after maintenance or repair, it should be verified that its performance meets the manufacturer's specifications. (ANSI/AAMI ST65:2008 Std. 10.4.1; CDC HICPAC GL EIC, 2003:II.G.II.C)

4.2.3. Machinery connected to utilities shall appear to be properly installed and operating correctly.

4.2.3.1. Providers shall ensure safe and correct connection of any piece of equipment to utilities (i.e., water, electrical power, gas, and/or steam) as appropriate, and that the connection includes the proper controls for the incoming utilities. (ANSI/AAMI ST65:2008 Std. 10.3.2.1)

4.2.3.2. The electrical power supplied to processing equipment shall be installed in conformance with local electrical and fire codes to prevent fires. (ANSI/NFPA No. 70; ANSI/AAMI ST65:2008 Std. 10.3.2.3)

4.2.3.3. The gas supply shall conform to the equipment manufacturer's recommendations.

4.2.3.4. The connection of equipment to the gas line must be done by a licensed person authorized by state regulations to perform this function. (ANSI/AAMI ST65:2008 Std. 10.3.2.4)

4.2.3.5. The steam supply and its quality shall conform to the equipment manufacturer's recommendations and any state regulations. (ANSI/AAMI ST65:2008 Std. 10.3.2.5; ANSI/AAMI ST79:2010 Stds. 3.3.4.1, 3.3.4.2)

4.2.4. Water quality

4.2.4.1. The provider should determine whether pretreatment of the water to be used for processing is needed, the appropriate type of pretreatment, compatibility between pretreatment and chemicals to be used in processing, and local wastewater disposal guidelines. (ANSI/AAMI ST65:2008 Std. 10.3.2.2)

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. (ANSI/AAMI ST65:2008 Std. 10.4.3.3)

4.3. Equipment Operation

4.3.1. The commercial equipment shall be appropriate for laundry operations.

4.3.2. The proper functioning of equipment shall involve correct utilities, mechanical systems (e.g., valves, level sensors, temperature sensors, safety door locks, and drum rotation), automated controls, and support systems according to manufacturer's operational specifications. (ANSI/AAMI ST65:2008 Std. 10.4.2.1)

4.3.3. The mechanical systems should function according to manufacturer's specifications, including, but not limited to, valve openings and closures, water level in inches for each level setting, tilting for loading and unloading, temperature sensor design, correct operational safety features, and speed and direction of drum rotation. (ANSI/AAMI ST65:2008 Std. 10.4.2.2)

4.3.4. Automated controls should be verified, calibrated, and checked at least annually. (ANSI/AAMI

ST65:2008 Std. 10.4.2.3)

4.3.5. The performance of the chemical delivery system should be checked at least monthly by verifying chemical delivery rates (e.g., correct chemical delivered in correct amount during the correct cycle) and/or by conducting chemical titrations (e.g., activity, concentration, and loading). (ANSI/AAMI ST65:2008 Std. 10.4.3.2)

4.3.6. The design and size of water heater equipment should be appropriate for the provider's needs at peak operating times and in order to maintain the specified heated water temperature per desired cycle. (ANSI/AAMI ST65:2008 Std. 10.4.3.4)

4.4. Preventive Maintenance

4.4.1. Equipment shall 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 ST65:2008 Std. 10.5.1-2)

4.4.2. Preventive maintenance shall include replacement of worn expendable parts, lubrication, and calibrations. (ANSI/AAMI ST65:2008 Std. 10.5.2-3)

4.5. Equipment Calibrations

4.5.1. Equipment should 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 ST65:2008 Std. 10.5.4)

4.5.2. Calibration should be performed by personnel trained and/or certified in calibration specified by the manufacturer. (ANSI/AAMI ST65:2008 Std. 10.5.4)

4.6. Repairs

4.6.1. Worn, malfunctioning, or broken parts should be replaced promptly by qualified personnel. (ANSI/AAMI ST65:2008 Std. 10.5.3)

4.6.2. Safety precautions, including lock-out tag-out procedures, must be observed. (ANSI/AAMI ST65:2008 Std. 10.5.3; OSHA 29 CFR 1910.147 App A)

4.6.3. Repair records shall be kept for all equipment. (ANSI/AAMI ST65:2008 Std. 10.5.3)

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

4.7.1. A maintenance record shall be kept on file for each piece of equipment. (ANSI/AAMI ST65:2008 Std. 10.5.5)

4.7.2. The following information shall be recorded:

4.7.2.1. Service details (e.g., date for request and completion, reason for service, repair);

4.7.2.2. Equipment details (e.g., type, model, serial number, and location of the equipment);

4.7.2.3. Parts and repair details (e.g., parts, repair descriptions);

4.7.2.4. Personnel involved (e.g., provider authorization, service technician name). (ANSI/AAMI

ST65:2008 Std. 10.5.5)

5. Laundry Personnel

5.1. Personnel Qualifications

5.1.1. The provider shall establish hiring policies and procedures based on all applicant local regulations or the AHJ employment laws.

5.1.2. 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 ST65:2008 Std. 4.1; ANSI/AAMI ST79:2010 Std. 4.1)

5.1.3. Clearly defined job descriptions for all personnel, including front-line supervisors, shall be in place and include qualifications, responsibilities, and assignments.

5.1.4. New personnel shall work under the close supervision of qualified personnel until they have demonstrated competency in the given task or procedure. (ANSI/AAMI ST65:2008 Std. 4.1; ANSI/AAMI ST79:2010 Std. 4.2.1)

5.2. Personnel General Responsibilities

5.2.1. Supervisors/managers shall: (ANSI/AAMI ST65:2008 Std. 4.2.1; ANSI/AAMI ST79:2010 Std. 4.2.1)

5.2.1.1. Ensure that tasks are performed by qualified personnel;

5.2.1.2. Document or staff can articulate or demonstrate manufacturer's instructions;

5.2.1.3. Recognize process and equipment malfunctions;

5.2.1.4. Develop and interpret policies and procedures for all aspects of healthcare textile processing;

5.2.1.5. Develop and correctly implement an Exposure Control Plan; and

5.2.1.6. Correctly interpret textile labels and recommended instructions for processing and handling.

(ANSI/AAMI ST65:2008 Std. 4.2.1; ANSI/AAMI ST79:2010 Std. 4.2.1)

5.2.2. Personnel shall:

5.2.2.1. Safely and correctly operate assigned equipment;

5.2.2.2. Safely and correctly perform assigned processing activities;

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

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

5.2.2.5. Understand the risk of injury that defective or improperly operating equipment may inflict.

(ANSI/AAMI ST65:2008 Std. 4.2.2; ANSI/AAMI ST79:2010 Std. 4.2.2)

5.3. Health and Hygiene

5.3.1. The provider shall have policies and procedures, addressing the health status of laundry workers (i.e., illness, open wounds or sores, and skin injuries) to prevent contamination of healthcare textiles. (CDC HICPAC GL IC HCW, 1998: II.B-F; ANSI/AAMI ST65:2008 Std. 4.4; ANSI/AAMI ST79:2010 Std. 4.4)

5.3.2. Employee Safety:

5.3.2.1. 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:

5.3.2.1.1. The use of personal protective equipment (PPE) when handling contaminated and soiled textiles; (OSHA: 29 CFR 1910.1030 (d)(3)(ii))

5.3.2.1.2. The safe operation of equipment;

5.3.2.1.3. Documentation of OSHA Lock-Out Tag-Out requirements; (OSHA 29 CFR 1910.147 App A)

5.3.2.1.4. Hazard communications; and (OSHA: 29 CFR 1910:1200)

5.3.2.1.5. Safe transportation and the proper handling of 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). [OSHA: 29 CFR 1910.1030 (d)(2)(ix)]

5.3.2.3. Provider personnel must handle chemicals safely in accordance with Material Safety Data Sheets (MSDS) in the laundry facility. (OSHA: 29 CFR 1910.1200; ANSI/AAMI ST65:2008; Std. 3.3.10)

5.3.2.3.1. MSDS information shall be readily accessible to employees in a location for immediate access where chemicals are handled.

5.3.2.4. Personnel who are exposed to hazards (e.g., biological, chemical, mechanical) shall report such occurrences to their supervisor according to the provider's policies and procedures. [OSHA: 29 CFR 1910.1030 (f) (3) (vii) (K); CDC HICPAC GL IC HCP, 1998: II.B.4]

5.3.3. Hand washing and hand hygiene indications:

5.3.3.1. Provider 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 1.G; 1.J; 1.K; 6.C.; ANSI/AAMI ST65:2008 Std. 4.4.; ANSI/AAMI ST79:2010 Std. 4.4; OSHA: 29 CFR 1910.1030 (d)(2)(v)]

5.3.3.2. Provider personnel shall practice hand hygiene (handwashing or using alcohol-based hand sanitizers) after removal of gloves. (CDC HICPAC GL Hand Hygiene 1.G; 1.J; 1.K; 6.C)

5.3.3.3. Personnel responsible for packing, wrapping, storing, or transporting clean textiles shall maintain proper hand hygiene at all times. (ANSI/AAMI ST65:2008 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 (d)(3)(i)]

5.4.1.2. Contaminated disposable PPE (e.g., gloves) must be discarded into appropriately labeled waste containers. [OSHA: 29 CFR 1910.1030 (d)(iii)(8)]

5.4.1.3. 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 (d)(3)(iv)]

5.4.1.4. PPE must be changed if moving from an area where soiled operations were performed into an area where clean operations are performed. (ANSI/AAMI ST79:2010 Std. 4.5.2)

5.4.1.5. All PPE must be removed prior to leaving the work area. [OSHA: 29 CFR 1910.1030 (d)(3)(vii); ANSI/AAMI ST79:2010 Std. 4.5.1]

5.4.1.5.1. A proper receptacle must be available for the disposal of PPE.

5.4.2. Personnel attire and adornments:

5.4.2.1. All personnel shall wear dry garments without visible soil or dirt in accordance with the provider's policies and procedures. (ANSI/AAMI ST65:2008; Std. 4.5; ANSI/AAMI ST79:2010 Std. 4.5)

5.4.2.2. For safety reasons, loose or dangling jewelry or rings shall not be worn. (ANSI/AAMI ST65:2008; Std. 4.5; ANSI/AAMI ST79:2010 Std. 4.5)

5.4.2.3. Hair covering shall be used where deemed appropriate and/or within provider's written policies and procedures. (ANSI/AAMI ST65:2008; Std. 4.5; ANSI/AAMI ST79:2009 Std. 4.5)

5.4.2.4. Artificial nails must not be worn in the laundry and while processing healthcare textiles. (ANSI/AAMI ST65:2008; Std. 4.5; ANSI/AAMI ST79:2010 Std. 4.5; Clin Infect Dis 2001; J Eur Acad Dermatol Ven 2008; J Pediatr Oncol Nurs 2002)

5.4.2.5. Personnel who handle clean or soiled healthcare textiles shall change work garments daily and whenever their garment becomes soiled. (ANSI/AAMI ST65:2008 Std. 4.5.1; ANSI/AAMI ST79:2010 Std. 4.5.1)

5.5. Occupational Safety and Health Elements

5.5.1. Provider must implement an occupational safety and health program based on the OSHA Bloodborne Pathogen Standard and Universal Precautions to prevent employee exposure to or contact with blood or OPIM. [OSHA: 29 CFR 1910.1030 (c)(1)(i)]

5.5.2. Exposure Control Plan (ECP):

5.5.2.1. The provider must develop an Exposure Control Plan (ECP) that contains, but is not limited to the following: [OSHA: 29 CFR 1910.1030 (c)(1)(ii)]

5.5.2.1.1. Schedule for compliance (i.e., when each part of the Plan is accomplished in the facility). [OSHA: 29 CFR 1910.1030 (c)(1)(ii)(b)]

5.5.2.1.2. Procedure for evaluating the circumstances surrounding exposure incidents. [OSHA: 29 CFR 1910.1030 (c)(1)(ii)(c)]

5.5.2.1.3. An Exposure Determination Plan (EDP), containing: [OSHA: 29 CFR 1910.1030 (c)(2)]

5.5.2.1.3.1. A list of all job classifications in which all personnel in those job classifications have occupational exposure, [OSHA: 29 CFR 1910.1030 (c)(2)(i)(A)]

5.5.2.1.3.2. A list of job classifications in which some personnel have occupational exposure, and [OSHA: 29 CFR 1910.1030 (c)(2)(i)(B)]

5.5.2.1.3.3. A list of all tasks and procedures that are performed by personnel in a job

classification where exposure may exist. [OSHA: 29 CFR 1910.1030 (c)(2)(i)(C)]

5.5.2.1.4. The Exposure Control Plan must be accessible to all personnel. [OSHA: 29 CFR 1910.1030 (c)(1)(iii)]

5.5.2.1.5. The Exposure Control Plan must be reviewed and updated at least annually. [OSHA: 29 CFR 1910.1030 (c)(1)(iv)]

5.5.3. Develop a hepatitis B vaccination program: [OSHA: 29 CFR 1910.1030 (f)]

5.5.3.1. Records must reflect the offering of hepatitis B vaccine by the employer and the acceptance OR documented refusal of the personnel. [OSHA: 29 CFR 1910.1030 (f)(1)(i)]

5.5.3.2. Hepatitis B vaccine must be offered to employees upon hire if they are candidates for vaccination. [OSHA: 29 CFR 1910.1030 (f)(2)(i)]

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

5.5.4.1. Records must reflect a standing process for post-exposure management for blood and/or OPIM. [OSHA: 29 CFR 1910.1030 (h)(3)(i)]

5.5.5. Personnel who are potentially exposed to occupational biological hazards may be monitored in a systematic program of serologic testing and HBV testing intended to prevent occupational injury and disease. [OSHA: 29 CFR 1910.1030 (c)(1)-2); CDC HICPAC GL IC HCW, 1998: II.B.4-5; II.E-F]

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

Note: Compliance with statement 5.5.6. and its sub-statements is limited to those providers who have affirmed current experience with customers who send textiles contaminated with hazardous substances for laundering.

5.5.6.1. Where laundry workers 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 employees, temporary employees, contractors, and trainees). (OSHA: 29 CFR 1910.1200; The OSHA Technical Manual: Haz Drugs, Sec 6, Chap 2)

5.5.6.1.2. The hazardous substance safety plan must be reviewed and updated as appropriate at least annually. (OSHA: 29 CFR 1910.1200)

5.5.6.2. Where laundry workers 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 employees;

5.5.6.2.3. Training records for these employees; 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 must meet all requirements of the federal and state Department of Transportation (DOT). (www.dot.gov)

5.5.7.1. The provider must 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 shall receive standard safety training in all aspects of laundry operations applicable to their respective position(s), including, but not limited to safe operations of equipment as per manufacturer instructions and notification procedures when malfunctions occur.

5.6.1.2. Training options should 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; and

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. The specific types of fabrics being processed;

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

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

(ANSI/AAMI ST65:2008 Stds. 4.2.2., 4.3, 7.2.1)

5.6.1.4. A copy of the grading standards should be included in the annual training package for each affected employee.

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/hand hygiene techniques; (CDC HICPAC GL Hand Hygiene 2.A-D; CDC HICPAC GL IC HCW, 1998: II.B.3)

5.6.2.1.2. Use of PPE appropriate to the task, including one or more of the following, but not limited to, gloves, gowns, aprons, and masks; [ANSI/AAMI ST65:2008; Std 4.5.2; CDC HICPAC GL IC HCW, 1998: II.B.3; OSHA: 1910.1030 (d)(3)(ii)]

5.6.2.1.3. Engineering controls and work practices to minimize the risk of exposure to blood or OPIM; [OSHA: 1910.1030 (d)(2)(i)]

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

5.6.2.1.5. Orientation to hazard communications, including labeling and color-coding; and (OSHA: 29 CFR 1910.1030 (g)(1); (g)(2)(vii)(M))

5.6.2.1.6. Post-exposure procedures, including immediate action, treatment, follow-up, and record keeping. [OSHA: 29 CFR 1910.1030 (f)(3); CDC HICPAC GL IC HCW, 1998: II.B.3-5; E-F]

5.6.3. Hazardous Substance Contaminated Textiles training:

Note: Compliance with statement 5.6.3. and its sub-statements is limited to those providers who have affirmed current experience with customers who send textiles contaminated with hazardous substances for laundering.

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) in the past 48 hours; (CDC HICPAC GL IC HCW, 1998: II.B.4.c; E-F)

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

5.6.3.1.3. Identification and segregation, and identification 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; NIOSH Publication No. 4; 2009)

5.6.4. Department of Transportation (DOT) regulations training:**5.6.4.1. Key topics in this training must 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; and

5.6.4.1.4. Bloodborne pathogens exposure. (www.DOT.gov)

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 ST65:2008; Std. 4.3; CDC HICPAC GL IC HCW, 1998: II.B.3-5; II.E-F; OSHA: 29 CFR 1910.1030 (h)(2)(ii)]

5.6.5.2. The documentation must include, but is not limited to: [OSHA: 29 CFR 1910.1030 (h)(2)(i)(A-D), (h)(2)(ii)]

5.6.5.2.1. Dates and times of training;

5.6.5.2.2. Method 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.

6. Laundry Customers

6.1. Provider Policy

6.1.1. The provider should have a policy on file that reflects the interaction with customers as described in the following statements of this subpart.

6.2. Contact

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

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

6.3. Visitation

6.3.1. The provider shall make their plants available to customers and prospective customers for inspection.

6.3.2. An authorized provider representative(s) shall 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.

6.3.3. An authorized provider representative(s) shall annually meet with the customer's representative(s) to determine the textile products used, expected textile usage, and their service expectations.

6.4. Customer Complaints

6.4.1. The provider shall maintain a written log of administrative or policy issues or problems with customers, including names of personnel involved and the resolution. (JCHLGL Guidelines for Healthcare Linen Service, 1994; 11.B)

7. Quality Assessment

7.1. General Rationale

7.1.1. 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.

7.2.4.1. These procedures should include requirements to rewash, repair, or replace textiles as necessary to maintain quality standards.

7.2.4.2. Traffic patterns shall be planned and posted to minimize the potential for contaminating clean textiles.

7.2.4.3. Traffic in all areas of the facility shall be limited to authorized personnel only as outlined in the provider's policies and procedures. (ANSI/AAMI ST65:2008; 3.2.4; ANSI/AAMI ST79:2010; Stds. 3.2.4, 8.9.2)

7.3. Quality Assurance

7.3.1 The provider shall have written policies and procedures, covering all areas of responsibility relating to services provided to the customer. (ANSI/AAMI ST65:2008; Stds. 6.4, 11.4)

7.3.2. The provider shall maintain records of any laundry processing and/or quality assurance problems experienced and mutually agreed upon solutions.

7.3.2.1. A customer call log may be used for this purpose.

7.3.3. 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.

7.3.3.1. This should be accomplished through monthly reports, regularly scheduled meetings with personnel, and/or annually.

7.3.3.2. Adjustments should be documented and filed for future use or reference.

7.3.4. Each classification of healthcare textiles shall be evaluated and/or tested to assure the established standards are met.

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:

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.

7.4.2.1.1.2. Every chemical used must have an MSDS on file.

7.4.2.1.1.3. Every chemical must have an appropriate label on every container into which the chemical is placed in accordance with OSHA Hazard Communications Standard. (OSHA: 29 CFR 1910.1200; ANSI/AAMI ST65:2008; Std. 6.4.2.2)

7.4.2.1.2. Water:

7.4.2.1.2.1. Incoming water shall be tested for hardness, alkalinity (active and total), iron content, and pH.

7.4.2.1.2.2. Testing shall occur on a regular basis, at a minimum monthly or more often during periods of abnormal water conditions (e.g., when water quality advisories are issued by the municipal water utility).

7.4.2.1.2.3. The provider's wash formula may require adjustment based on these factors. (ANSI/AAMI ST65:2008; Std. 6.4.2.4)

7.4.2.1.3. Titration: (ANSI/AAMI ST65:2008; Std. 6.4.4)

7.4.2.1.3.1. Monthly titrations of the correct wash chemistry shall be performed according to the formula for each major classification of soil. (ANSI/AAMI ST65:2008; Std. 6.4.3.e)

7.4.2.1.4. Systems and procedures must be in place to ensure that the provider's use of air, water, chemicals, and other materials is in compliance with federal and state regulations.

7.4.2.1.5. Load size:

7.4.2.1.5.1. Load size shall follow the equipment manufacturer's recommendations where available.

7.4.2.1.5.2. Each load shall be weighed, using a calibrated scale.

7.4.2.1.5.3. The scale 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 ST65:2008; Stds. 6.2.2; 6.4.2.5)

7.4.2.1.6. Equipment:

7.4.2.1.6.1. All provider equipment shall be included in the provider's Preventive Maintenance (PM) Program and checked on a regular basis as defined by the manufacturer for proper operation.

7.4.2.1.6.2. Typically, a chemical titration and service report from the provider's chemical supplier's technician should have all this information.

7.4.2.1.6.3. Automatic equipment dispensers shall also record the chemical injection amounts and times by classification. (ANSI/AAMI ST65:2008; Std. 6.4.3)

7.4.2.1.6.4. Ironer temperatures shall be based on the equipment manufacturer's manual

and recommendations appropriate for the type of fabric being processed.

7.4.2.1.7. Finished products:

7.4.2.1.7.1. 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.

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

7.4.2.1.7.2.1. Rewash rates;

7.4.2.1.7.2.2. Color transfer;

7.4.2.1.7.2.3. pH spot tests; and

7.4.2.1.7.2.4. Residual chlorine spot tests.

7.4.2.1.8. Employee competency:

7.4.2.1.8.1. Supervisors shall verify employee competency from training documentation (see Part I, Subpart 5, statement 5.6.5 of this HLAC Standard) and mark the checklist accordingly.

7.5. Accounting

7.5.1. The provider shall have reliable and accurate procedures to weigh and/or count textiles and have accurate billing procedures based on these weights or counts.

7.5.2. The provider shall obtain the customer's written agreement to these procedures and maintain this on file.

Part II. The Textile Processing Cycle

1. Handling, Collection and Transportation of Soiled Healthcare Textiles

1.1. Universal Precautions

1.1.1. All soiled healthcare textiles must be assumed to be contaminated. (JCHLGL Guidelines for Healthcare Linen Service, 1994; 7..A)

1.1.2. Universal Precautions must apply to all personnel who handle soiled textiles during moving, containing, loading, unloading, and sorting said textiles. [OSHA: 29 CFR 1910.1030 (d)(1)]

1.2. Handling and Collection

1.2.1. All healthcare textiles must be handled and collected in accordance with federal and local regulations or those of the AHJ, thereby minimizing potential exposure of laundry personnel to

bloodborne pathogens or other infectious agents. [OSHA: 29 CFR 1910.1030 (d)(4)(iv)(A)(2); ANSI/AAMI ST79:2010 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, 2003:II.G.III.A; OSHA: 29 CFR 1910.1030 (d)(4)(iv) (A)]

1.3. Soiled Textile Containment for Laundries Not Using Universal Precautions

1.3.1. Soiled textile collection bags or containers:

1.3.1.1. Providers must stipulate in the contract that customers must select soiled textile containment that will functionally contain wet or soiled textiles, preventing leakage that can result in contamination of the environment during collection, transportation, and storage prior to processing. [ANSI/AAMI ST65:2008; Std. 5.3.2; ANSI/AAMI ST79:2010 Std. 6.4; OSHA: 29 CFR 1910.1030 (d)(4)(iv) (A)(3)]

1.3.1.2. Providers must stipulate in the contract that customers will utilize soiled textile containment that must not tear when loaded to capacity, and be capable of being closed securely to prevent textiles from falling out. [OSHA: 29 CFR 1910.1030 (d)(4)(iv) (A)(3); ANSI/AAMI ST79:2010 Std. 6.4]

1.3.1.3. Providers must stipulate in the contract that customers will utilize soiled textile containment labeling or color-coding:

1.3.1.3.1. Providers must stipulate in the contract that customers will ensure that soiled textiles must be placed and transported in bags or containers that are specially labeled (e.g., with a biohazard symbol) and/or color-coded to distinguish them from uncontaminated laundry when the customer releases both types of textiles to the provider for pick-up. [OSHA: 29 CFR 1910.1030 (d)(4)(iv)(A)(2), (C); ANSI/AAMI ST65:2008; Std. 5.3.2; ANSI/AAMI ST79:2010 Std. 6.4]

1.3.1.3.2. Provider must ensure as per Part I, Subpart 5, Section 5.6, statement 5.6.2.1.5 of this HLAC Standard, that personnel are educated to recognize the specific labeling or color-coding to distinguish bags or containers of soiled, contaminated textiles from other textile items. (OSHA 29 CFR 1910.1030 (g)(1); (g)(2)(vii)(M))

1.3.2. Textiles contaminated with hazardous substance must be placed in specially marked laundry containers and then placed in a labeled impervious container that must be capable of preventing soak-through or leakage of liquids to the outside of the container. (OSHA: 29 CFR 1910.1200; The OSHA Technical Manual: Haz Drugs, Sec 6, Chap 2)

1.3.3. Reusable collection containers for healthcare textiles:

1.3.3.1. Must be constructed of materials that can withstand repeated decontamination using cleaners and disinfectants;

1.3.3.2. Must be appropriately identified by labeling (e.g., using the biohazard symbol) or color-coding. (ANSI/AAMI ST65:2008; Std. 5.3.2; ANSI/AAMI ST79:2010 Std. 6.4)

1.4. Transportation

1.4.1. 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. (JCHLGL Guidelines for Healthcare Linen Service, 1994; 6.B.3, 8.A; ANSI/AAMI ST79:2010 Stds. 3.2.3, 3.3.7.1, 6.5.6; FGI GL 2010: Linen Services 2.2-5.2.1.1, 2.2-5.2.2.1-3)

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

1.4.2.1. Bagging soiled textiles in fluid-resistant containers; (ANSI/AAMI ST65:2008; Std. 9.5.3)

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

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

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

1.5. Carts Used for Soiled Textiles

1.5.1. 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 ST65:2008; Std. 9.5.4.1, ANSI/AAMI ST79:2010 Std. 8.10.2; FGI GL 2010: 4.2-5.2 Linen Services 4.2-5.2.3.3)

1.5.2. 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.

1.5.3. Proper cleaning should include any of the following:

1.5.3.1. Steam cleaning,

1.5.3.2. Cleaning with a detergent and water, or

1.5.3.3. Using an EPA-registered hospital-grade detergent/disinfectant.

1.5.3.3.1. EPA-registered products shall be used according to label instructions, ensuring that the product remains on surfaces for the full contact time. (ANSI/AAMI ST65:2008; Std. 9.5.4.1; ANSI/AAMI ST79:2010 Std. 8.10.2; CDC HICPAC GL EIC, 2003:II.E.I.A)

Note: See Part II, Subpart 7, Section 7.4 of this HLAC Standard for Vehicle Considerations.

2. Sorting

2.1. Soiled Sorting Area

2.1.1. The surfaces in the soil sort room must be cleaned and disinfected as described in Part I, Subpart 2, Section 2.2, statements 2.2.2.3. – 2.2.2.6 of this HLAC Standard. (CDC HICPAC GL EIC, 2003:II.E.I-II;

ANSI/AAMI ST79:2010 Std. 3.4; OSHA 29 CFR 1910.1030 (d)(ii, ii A)]

2.2. Universal Precautions

2.2.1. All personnel who handle soiled healthcare textiles must follow Universal Precautions in accordance with Part II, Subpart 1, Section 1.1 of this HLAC Standard and use appropriate PPE for this task. [OSHA: 29 CFR 1910.1030 (d)(1); OSHA 29 CFR 1910.1030 (d)(4)(iv)(B); CDC HICPAC GL EIC, 2003: II. F.III; CDC HICPAC GL IC HCW, 1998: II.B.3]

2.3. Sorting Soiled Textiles

2.3.1. Soiled textiles shall be sorted into appropriate wash loads by classification (i.e., color, type of fabric, soil type or soil load) and/or type of goods (e.g., diapers, sheets, or patient gowns) for each laundry formula used. (ANSI/AAMI ST65:2008; 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)

Note: Compliance with 2.3.2. is limited to those providers who have affirmed current experience with customers who send textiles contaminated with hazardous substances for laundering.

2.4. Foreign Object Policies

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

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 ST65:2008; Std. 5.3.1)

2.4.1.2. Disposable devices shall be retrieved from the textiles prior to laundering and discarded into designated containers or returned to the customer. (ANSI/AAMI ST65:2008; Std. 5.3.1)

2.4.1.3. Personal patient information shall be retrieved from the textiles prior to laundering, placed into designated containers, and returned to the customer. (ANSI/AAMI ST65:2008; 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 (d)(2)(viii)(A-C), (d)(4)(iii)(A)(2)(i); ANSI/AAMI ST65:2008; Std. 5.3.1; CDC HICPAC GL EIC, 2003:II.I-III]

2.4.2.1.3. Personnel injured by a sharp must follow OSHA's regulations on sharps injury documentation, post-exposure evaluation, and follow-up. [OSHA: 29 CFR 1910.1030 (f)(3); CDC HICPAC GL IC HCW, 1998: II.E]

3. Washing and Extraction

3.1. Equipment

3.1.1. Washers, washer/extractors, and/or continuous batch washers shall be used in the processing of healthcare textiles. (ANSI/AAMI ST65:2008; Std. 2.59)

3.1.2. The provider shall document equipment requirements and/or modifications in processing healthcare textiles to assure that agreed upon quality standards are consistently met, date them, and revise as needed as equipment needs change.

3.2. Washing

3.2.1. Providers 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, 2003:II.G.IV.A, C, D)

3.2.2. Providers should avoid mixing fabric items used by the customer for environmental cleaning and disinfection (e.g., cleaning cloths, microfiber cloths, mop heads) in with healthcare textiles intended for patient use in the same wash load.

3.2.3. The load size (weight) for each textile classification and for each type of equipment used shall be established by the provider and shall be recorded for each load processed. (ANSI/AAMI ST65:2008; Std. 6.2.2)

3.2.3.1. Equipment and textile product manufacturers' recommendations should be consulted when establishing load size. (ANSI/AAMI ST65:2008; Std. 6.2.2)

3.2.4. Each classification shall have established standards for the following factors to optimize the productivity of the wash processes:

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

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

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

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

3.2.5. Providers must 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.

3.2.6. 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:

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

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

3.3. Extraction

3.3.1. 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 ST65:2008; Std. 6.2.3.8)

3.3.2. Damp textiles shall not be inappropriately stored (e.g., tightly packed and poorly ventilated [which interferes with drying]), as this may facilitate microbial growth in said textiles. (CDC HICPAC GL EIC, 2003:II. G.II.D)

4. Drying

4.1. Equipment

4.1.1. The dryers shall be in good operating condition.

4.2. Drying

4.2.1. The drying procedures shall be described, controlled, and monitored for each textile classification to ensure appropriate drying. (ANSI/AAMI ST65:2008; Std. 6.3.1)

4.2.2. Hot, dry loads should be subjected to sufficient cool-down to enable personnel to handle the textiles comfortably and to minimize wrinkling. (ANSI/AAMI ST65:2008; Std. 6.3.3.3)

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. (TRSA Healthcare Service Operations Manual, p.14)

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 textiles merchandise is maintained in the same hygienically clean state as was achieved when it emerged from washing.

5.2.3. The folding and stacking procedures shall meet the needs and expectations of the customer. (ANSI/AAMI ST65:2008; Std. 8.3.1)

5.2.4. If any textiles become soiled in this process, they shall be rewashed as outlined above. (ANSI/AAMI ST65:2008; Std. 9.4)

5.3. Packaging

5.3.1. Healthcare textile packaging shall preserve them in a hygienically clean state for delivery to the customer. (CDC HICPAC GL EIC, 2003:II.G.IV.E; ANSI/AAMI ST65:2008; Std. 9.4)

5.3.2. The textiles shall be wrapped into fluid-resistant bundles or placed bundled, but unwrapped, into fluid-resistant covered carts or hampers.

5.3.3. The 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 ST65:2008; Std. 9.4)

5.3.5. Wrapping material or the cart shall 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 as outlined in this Part II. (ANSI/AAMI ST65:2008; Std. 9.4)

6. Storage

6.1. Rationale

6.1.1. Provider's storage strategies and handling methods of healthcare textiles shall preserve the textiles in a hygienically clean state for delivery to the customer as outlined in the service agreement. (ANSI/AAMI ST65:2008; Std. 9.1; 9.6.1-2; ANSI/AAMI ST79:2010 Std. 8.9.2)

6.1.2. Stock shall be rotated and used in a first-in/first-out manner. (ANSI/AAMI ST65:2008; Std. 9.6.3; ANSI/AAMI ST79:2010 Std. 8.9.3)

6.2. Storage Areas

6.2.1. Storage parameters shall be consistent with Part I, Subpart 2, Section 2.1, Subsection 2.1.4, statements 2.1.4.1 – 2.1.4.4 of this HLAC Standard.

6.2.2. Unwrapped clean textiles shall be stored in designated storage rooms, areas, or carts. (JCHLGL Guidelines for Healthcare Linen Service, 1994; 6.B.3; ANSI/AAMI ST65:2008; Std. 9.6.1-2; ANSI/AAMI ST79:2010 Std. 8.9.2; FGI GL 2010: 2.2-5.2 Linen Services 2.2-5.2.2.2, 2.6-5.2.1.2, 4.2-5.2.1, 4.2-5.2.3.2)

6.2.3. Only clean textiles shall be stored in this area and signage posted as "Textile storage room." (ANSI/AAMI ST65:2008; 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 area require disinfection after cleaning, the provider shall use an EPA registered hospital disinfectant according label instructions as per policy. (CDC HICPAC GL EIC, 2003:II.E.I-II; ANSI/AAMI ST79:2010 Std. 3.4)

6.2.5. Storage area entry and exit:

6.2.5.1. The door to the clean textile storage area shall remain closed at all times, except for entrance or exit. (ANSI/AAMI ST65:2008; Std. 9.6.2)

6.2.5.2. Storage rooms shall only be accessible by authorized personnel. (ANSI/AAMI ST65:2008; Std. 9.6.2; ANSI/AAMI ST79:2010 Std. 8.9.2)

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 ST65:2008; Std. 9.6.2; ANSI/AAMI ST79:2010 Std. 8.9.2)

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. (JCHLGL Guidelines for Healthcare Linen Service, 1994; 6.B.3; ANSI/AAMI ST65:2008; Std. 9.6.1-2; ANSI/AAMI ST79:2010 Std. 8.9.2)

6.4. Reprocessing Requirements

6.4.1. If any textiles become soiled during storage, they must be rewashed and reprocessed as outlined in Part II of this HLAC Standard. (ANSI/AAMI ST65:2008; Std. 9.4)

7. Delivery of Cleaned Healthcare Textiles

7.1. Rationale:

7.1.1. 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. (JCHLGL Guidelines for Healthcare Linen Service, 1994; 6, 6.B.1-3; FGI GL 2010: 2.2-5.2 Linen Services 2.2-5.2.2.2; CDC HICPAC GL EIC, 2003:II.G.IV.E; ANSI/AAMI ST65:2008; Std. 9.5.1)

7.2. Delivery methods:

7.2.1. Clean linen shall be transported in containers used exclusively for this purpose and/or including,

but not limited to, any of the following methods:

7.2.1.1. Clean textiles shall be placed in a hamper lined with a clean liner;

7.2.1.1.1. The hamper shall be covered with a clean cover or the liner shall be closed to protect the textiles. (JCHLGL Guidelines for Healthcare Linen Service, 1994; 6.A.1; ANSI/AAMI ST65:2008; Std. 9.5.2; 9.6.1-2)

7.2.1.2. Clean textiles shall be placed in a cart, covering it with clean material, and securing the cover. (JCHLGL Guidelines for Healthcare Linen Service, 1994; 6.A.2; ANSI/AAMI ST65:2008; Std. 9.5.2; 9.6.1-2; ANSI/AAMI ST79:2010 Std. 8.10.2)

7.2.1.2.1. When the cart contains clean textiles, the textiles shall be wrapped inside the cart.

7.2.1.2.2. If the clean textiles are unwrapped while in the cart, the cart bottom must be lined with a hygienically clean barrier that prevents environmental contamination and be securely covered. (ANSI/AAMI ST65:2008; Std. 9.5.4.1; ANSI/AAMI ST79:2010 Std. 8.9.2)

7.2.1.3. Clean textiles shall be placed on a wire rack and covering this with a suitable cover. (JCHLGL Guidelines for Healthcare Linen Service, 1994; 6.A.3; ANSI/AAMI ST65:2008; Std. 9.5.2; 9.6.2; ANSI/AAMI ST79:2010 Std. 8.10.2)

7.2.2. Clean textiles shall be wrapped for delivery. (JCHLGL Guidelines for Healthcare Linen Service, 1994; 6.A.4; ANSI/AAMI ST65:2008; Std. 9.6.1-2; ANSI/AAMI ST79: 2010 Std. 8.10.2)

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 shall be cleaned and disinfected in accordance with Part II, Subpart 1, Section 1.5, statement 1.5.3 of this HLAC Standard. (CDC HICPAC GL EIC, 2003:II.E.I-II; ANSI/AAMI ST79:2010 Stds. 3.4)

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 ST65:2008; Std. 9.5.4.1; ANSI/AAMI ST79:2010 Std. 8.10.2)

7.3.2.3. Reusable textile cover materials (e.g., liners) must be washed before the next use. (ANSI/AAMI ST65:2008; Std. 9.5.4.1; ANSI/AAMI ST79:2010 Std. 8.10.2)

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 ST65:2008; Std. 9.5.4.1; ANSI/AAMI ST79:2010 Std. 8.10.2)

7.4. Vehicle Considerations

7.4.1. Functional separation:

7.4.1.1. Clean and soiled textiles transported in the same vehicle must have proper and effective functional separation maintained at all times.

7.4.1.2. Separation shall be accomplished by the use of physical barriers and/or space separation sufficient to protect clean textiles from contact with soiled textiles. (JCHLGL Guidelines for Healthcare Linen Service, 1994;

6.B.1-3; ANSI/AAMI ST65:2008; Std. 9.5.5; ANSI/AAMI ST79:2010 Std. 8.11.5)

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 ST65:2008; Std. 9.5.5; ANSI/AAMI ST79:2010 Std. 8.11.5)

7.4.2.2. Should the interior surfaces of the cargo area become contaminated with blood or OPIM, these surfaces shall be decontaminated, cleaned with a detergent and water, and disinfected with an EPA registered hospital disinfectant labeled as tuberculocidal or selected from EPA Lists D or E (i.e., activity against HBV and HIV) and used according to label instructions. (CDC HICPAC GL EIC, 2003:II.E.I-II; ANSI/AAMI ST79:2010 Stds. 3.4; OSHA Std statement)

7.4.3. Occupational safety for drivers:**7.4.3.1. Hand care:**

7.4.3.1.1. Vehicles used to transport healthcare textiles shall have waterless antibacterial hand cleaner on board for the purpose of hand hygiene.

7.4.3.1.2. If visible soil is apparent, drivers shall use utility gloves to minimize contact with soiled textiles.

7.4.3.1.3. Handwashing with soap and water must be accomplished at the earliest opportunity upon removal of the utility gloves. (CDC HICPAC GL Hand Hygiene 1.G;1.J; 1.K; 6.C)

7.4.3.2. Vehicles used to transport healthcare textiles must 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.

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) ST65:2008 Processing of Reusable Surgical Textiles for Use in Health Care Facilities** and **ANSI/AAMI ST79:2010 Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities**, and applicable U.S. Food and Drug (FDA) regulations.

1. Physical Facilities: Surgical Pack Assembly Area/Room

1.1. General Rationale

1.1.1. The size and physical layout of the surgical pack assembly area, its equipment, and engineering support shall be adequate for the performance of the job function necessary to properly produce reusable surgical pack textiles. (ANSI/AAMI ST65:2008 Std. 3.4.1)

1.2. Floors, Walls, Ceilings and Vents

1.2.1. Floors and walls shall be constructed of materials that will withstand scheduled wet cleaning as well as the heat and humidity of the laundry environment. (ANSI/AAMI ST65:2008 Std. 3.4.3; ANSI/AAMI ST79:2010 Stds. 3.3.6, 3.4)

1.2.2. Ceilings and vents shall be constructed of materials that will withstand scheduled cleaning and vacuuming to eliminate lint and other soils associated with laundry processing. (ANSI/AAMI ST65:2008 Stds. 3.3.3, 3.4.3)

1.2.3. Particulate or fiber-shedding materials shall not be used in the construction of the surgical pack assembly area/room. (ANSI/AAMI ST65:2008 Std. 3.4.3)

1.2.4. Ceilings in clean work areas shall be flush with recessed, enclosed fixtures. (ANSI/AAMI ST65:2008 Std. 3.4.3)

1.3. Separation of Work Areas

1.3.1. The surgical pack room assembly area 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 ST65:2008 Std. 3.2.3.2)

1.4. Ventilation Requirements for Proper Air Flow and Climate Control

1.4.1. Heating, ventilation, and air conditioning (HVAC) system should be designed to conform to AIA/FGI standards in effect at the time when the facility is built or renovated. (FGI GL, 2010: 2.1-8; ANSI/ASHRAE/ASHE Stds. 170-2008: Sec. 6)

1.4.2. The HVAC system in the surgical pack assembly area shall maintain the appropriate positive air pressure relative to the rest of the facility, preventing intrusion of contamination from the soiled textiles area. (ANSI/AAMI ST65:2008 Std. 3.4.4; FGI GL 2010: ANSI/ASHRAE/ASHE Std. 170-2008: Table 7.1, p. 9)

1.4.3. The HVAC system shall be a down-draft system for air circulation within the space, and the number of air changes/hour (ACH) (typically 10) shall be sufficient to minimize lint particles in the air. (ANSI/AAMI ST65:2008 Std. 3.4.4; FGI GL 2010: ANSI/ASHRAE/ASHE Std. 170-2008: Table 7.1, p. 9)

1.4.4. 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 ST65:2000 Std. 3.4.4)

1.4.5. Portable fans shall not be permitted in the surgical pack area. (ANSI/AAMI ST65:2008 Std. 3.4.4)

1.4.6. Supply air for the pack room area shall 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 ST65:2008 Std. 3.4.4)

1.4.6.1. For new construction or major renovated laundry facilities' pack rooms since 2011, filtration shall 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. (FGI GL, 2010; ANSI/ASHRAE/ASHE Std. 170-2008; Sec. 6, Table 6-1)

1.4.7. Temperatures in the pack room area shall be maintained between 68° F - 73°F to ensure a comfortable work environment for personnel in appropriate work attire. (ANSI/AAMI ST65:2008 Std. 3.4.5; FGI GL 2010: ANSI/ASHRAE/ASHE Std. 170-2008: Table 7.1, p. 9)

1.4.8. Relative humidity (RH) shall be maintained between 20% and 60% in all work areas, except the sterile storage area, where the humidity shall not exceed 70%, for personnel comfort and to discourage microbial (e.g., fungal) growth. (ANSI/AAMI ST65:2008 Std. 3.4.5; FGI GL 2010: ANSI/ASHRAE/ASHE Std. 170-2008: Table 7.1, p. 9)

1.5. Lighting

1.5.1. Lighting systems in the surgical pack assembly room area shall be appropriate for the tasks performed in this area. (ANSI/AAMI ST65:2008 Std. 3.4.6)

1.5.2. High intensity lighting should be available in that part of the room or area where textiles are examined (i.e., folding, assembly, and repair areas). (ANSI/AAMI ST65:2008 Std. 3.4.6)

1.5.3. Lower intensity overhead lighting may be needed for areas where light-table inspection is performed, so that the table back lighting can be used optimally. (ANSI/IESNA RP-29; ANSI/AAMI ST65:2008 Std. 3.4.6)

1.5.4. Light-table should have a switch to turn off/on light tables.

1.6. Storage Area for Clean Textile Packs

1.6.1. Storage area for clean textile packs must be designed and managed in accordance with recommended practices for clean and sterile products. (21 CFR 820.140 and 21 CFR 820.150; ANSI/AAMI ST65:2008 Std. 3.4.8, 3.4.9, 9.6.1-2; JCHLGL Guidelines for Healthcare Linen Service, 1994; 6.B.3; ANSI/AAMI ST79:2010 Std. 8.9.2; FGI GL 2010: 2.2-5.2 Linen Services 2.2-5.2.2.2, 2.6-5.2.1.2, 4.2-5.2.1, 4.2-5.2.3.2)

1.6.2. Bulk shipping warehouse cardboard boxes must not be in these surgical pack assembly storage rooms. (ANSI/AAMI ST79:2010 Std. 5.2.1)

1.6.3. Storage rooms shall only be accessible by authorized personnel. (ANSI/AAMI ST65:2008; Std. 9.6.2; ANSI/AAMI ST79:2010 Std. 8.9.2)

1.6.4. Storage room doors shall remain closed, except for access or exit. (ANSI/AAMI ST65:2008; Std. 9.6.2)

1.6.5. The environmental conditions in the clean surgical textile pack storage area shall include:

1.6.5.1. Temperatures shall not exceed 78°F to prevent microbial contamination;

1.6.5.2. Relative humidity shall be less than 70% to inhibit microbial growth;

1.6.5.3. The room shall be properly ventilated to prevent accumulation of dust and lint (i.e., air

change rate of 2 ACH); and

1.6.5.4. The room shall have positive air pressure relative to adjacent spaces, preventing intrusion of contamination from the soiled textiles areas. (ANSI/AAMI ST65:2008 Std 9.6.1; ANSI/AAMI ST79:2010 Stds. 3.3.6.4-6)

1.6.6. Closed or covered cabinets shall be recommended for the storage of clean surgical textile items. (ANSI/AAMI ST65:2008 Std. 9.6.2)

1.6.7. Closed storage carts may be used in lieu of fixed shelving, if allowed under state licensing regulations.

1.6.8. Storage areas should be located within the pack room area to facilitate bundling, loading onto trucks, and transportation.

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 areas shall be specified in written policies and procedures. (ANSI/AAMI ST65:2008 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 (d)(2)(ix)])

2.1.3. Traffic in the surgical pack assembly area should be limited to authorized personnel only. (ANSI/AAMI ST65:2008 Std. 3.2.4)

2.1.4. Policies and procedures shall be developed to address visitor access and the circumstances for access, and shall establish a dress code to reduce the potential for contamination of surgical textiles. (ANSI/AAMI ST65:2008 Std. 3.2.4)

2.2. Location of Hand Hygiene Stations

2.2.1. Laundry workers must wash their hands before entering and working in the pack room.

2.2.2. Handwashing sinks with soap and paper towels shall be conveniently located near the pack room. (ANSI/AAMI ST65:2008 Std. 3.4.7)

2.2.3. Alcohol hand sanitizer should also be made readily available in or near the pack room. (ANSI/AAMI ST65:2008 Std. 3.4.7)

3. Surgical Textile Assembly Process

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

3.1.1. Carts that are utilized for clean surgical textiles shall be cleaned and disinfected in accordance with Part II, Section 7, Subsections 7.1 and 7.2 of this HLAC Standard. (ANSI/AAMI ST65:2008 Std. 9.5.4.1)

3.2. Inspection of Clean Surgical Textiles Prior to Pack Assembly

3.2.1. Before each reuse, all surgical textile products shall be visually inspected against written quality standards between provider and customer(s). (ANSI/AAMI ST65:2008 Std. 7.2.1)

3.2.1.1. These standards should be jointly developed and applied to the textile functional requirements and attributes as well as end-user requirements. (ANSI/AAMI ST65:2008 Std. 7.2.1)

3.2.1.2. Written quality standards shall define the acceptance and rejection criteria for each product type and explain how rejected items should be managed. (ANSI/AAMI ST65:2008 Std. 7.2.1)

3.2.2. If surgical textile integrity and quality are monitored by the provider, the critical zones of surgical textiles shall be visually inspected with the use of a light table 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 ST65:2008 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. (ANSI/AAMI ST65:2008 Std. 11.4)

3.2.2.2. A tracking mechanism suitable for each surgical textile product shall be used to track number of product's uses based on the textile manufacturer's recommendations. (ANSI/AAMI ST65:2008 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 ST65:2008 Stds. 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 ST65:2008 Std. 7.2.2)

3.2.3.3. Stained surgical textiles shall be retired if rewashing cannot successfully remove 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 ST65:2008 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) shall be repaired as appropriate with patching and mending before the textile is reused. See Part III, Subpart 3, Section 3.3 of this HLAC Standard. (ANSI/AAMI ST65:2008 Std. 7.2.3)

3.2.5. Chemical or thermal damage:

3.2.5.1. Surgical textiles shall be inspected for evidence of chemical and/or thermal damages (usually apparent as discoloration, stiffening, or holes). (ANSI/AAMI ST65:2008 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 shall be retired or removed from service. (ANSI/AAMI ST65:2008 Std. 7.2.4)

3.2.6. Foreign debris

3.2.6.1. Surgical textiles shall be free of foreign debris (e.g., lint, hair, loose fibers, fibrous pills, other particulates) prior to assembly into packs. (ANSI/AAMI ST65:2008 Std. 7.2.5)

3.2.6.2. Foreign debris shall be removed with an appropriate device (e.g., a delinting roller or sticky tape). (ANSI/AAMI ST65:2008 Std. 7.2.5)

3.2.6.3. Work practices shall be implemented to keep surgical textiles free from foreign debris. Such practices include, but may not be limited to:

3.2.6.3.1. Dress code suitable for the inspection area of the pack room, consisting of dedicated uniforms or other suitable outerwear, hair nets, 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 ST65:2008 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 ST65:2008 Std. 7.2.6)

3.2.7.2. Labels should ideally contain information as to manufacturer, product type, and lot code numbers. (ANSI/AAMI ST65:2008 Std. 7.2.6)

3.2.7.3. Labels with lot code information should remain intact throughout the effective life of the textile. (ANSI/AAMI ST65:2008 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 ST65:2008 Stds. 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 shall be visually inspected, marked, scanned, or read each time the product is processed. (ANSI/AAMI ST65:2008 Std. 7.2.7)

3.2.8.2. If the integrity of the tracking mechanism is in question, the textile shall be pulled from service or an alternate method of tracking shall be used until the tracking problem is resolved. (ANSI/AAMI ST65:2008 Std. 7.2.7)

3.2.9. Effective Life of Surgical Textiles

3.2.9.1. Methods shall be designed and in place to ascertain the number of uses/washes for surgical textile barrier products. (ANSI/AAMI ST65:2008 Std. 7.3.3)

3.2.9.2. Textile manufacturers should 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 ST65:2008 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 ST65:2008 Std. 7.4.1-2)

3.3.1.2. Physical defects within the critical zones of the various surgical textiles shall be repaired, using specialized repair procedures. (ANSI/AAMI ST65:2008 Std. 7.2.3)

3.3.1.2.1. Heat-sealed patches shall be used to repair physical defects present in the critical zones of surgical textiles. Attributes of these patches shall include: (ANSI/AAMI ST65:2008 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 as 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 ST65:2008 Std. 7.4.1)

3.3.1.2.2. Patches shall not be sewn to the textile. (ANSI/AAMI ST65:2008 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 ST65:2008 Std. 7.4.1)

3.3.1.2.4. Use of sewing shall be discouraged for repairs in textiles' critical zones; but if sewing is indicated for a successful repair, heat-sealed patches shall be used to seal the needle holes. (ANSI/AAMI ST65:2008 Std. 7.4.2)

3.3.1.3. Loose patches shall be removed and new patches applied. (ANSI/AAMI ST65:2008 Std. 7.4.1)

3.3.1.4. Acceptable number, location, shape, and size of patches shall be clearly delineated in written quality standards and repair procedures. (ANSI/AAMI ST65:2008 Std. 7.4.1)

3.3.1.5. If patching and/or mending is performed in the laundry area, the textiles shall be rewashed before being moved to the surgical pack assembly area. (ANSI/AAMI ST65:2008 Std. 7.4.3)

3.3.2. Rewashing surgical textiles

3.3.2.1. If a reusable surgical textile requires rewashing, the procedure used shall be compatible with the product. (ANSI/AAMI ST65:2008 Std. 7.4.3)

3.3.2.2. Each rewash cycle shall be counted as an additional life cycle for the item. (ANSI/AAMI ST65:2008 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 shall be compatible with the textile product. (ANSI/AAMI ST65:2008 Std. 7.4.4)

3.3.3.2. Additives that maintain surgical textile performance characteristics (e.g., repellency) shall be used according to product instructions. (ANSI/AAMI ST65:2008 Std. 7.4.4)

3.3.3.3. Rejuvenation cycles shall be counted as additional life cycles. (ANSI/AAMI ST65:2008 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 shall 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 ST65:2008 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 ST65:2008 Std. 7.4.5)

3.3.4.3. Items placed into alternate use shall be permanently marked in some obvious fashion to prevent mix-ups or inappropriate use. (ANSI/AAMI ST65:2008 Std. 7.4.5)

4. Preparation and Wrapping of Surgical Textiles

4.1. General Rationale

4.1.1. Policies and procedures shall 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 ST65:2008 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 in the contract. (ANSI/AAMI ST65:2008 Std. 8.2)

4.2. Folding

4.2.1. Reusable surgical textiles shall be folded and packaged properly in a consistent manner each time they are processed, and the process shall be documented. (ANSI/AAMI ST65:2008 Std. 8.2)

4.2.2. Written standards shall be in place to identify the specific folds, components, and other details for each surgical pack built by the laundry. (ANSI/AAMI ST65:2008 Stds. 8.2, 8.3.1)

4.2.3. The following elements shall be taken into account regarding the folding of clean, reusable surgical textiles: (ANSI/AAMI ST65:2008 Std. 8.3.1)

4.2.3.1. Following inspection, all items shall 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 ST65:2008 Std. 8.3.1)

4.2.3.2. The method of folding shall allow for effective penetration of the steam from the autoclave into the pack. (ANSI/AAMI ST65:2008 Std. 8.3.1)

4.2.3.3. The method of folding shall allow for easy identification and orientation of the items. (ANSI/AAMI ST65:2008 Std. 8.3.1)

4.2.4. Clean reusable surgical textiles shall be handled with clean hands in a manner to maintain their hygienic quality. See also Part I, Subpart 5, Section 5.3, statement 5.3.3.3 of this HLAC Standard. (ANSI/AAMI ST65:2008 Stds. 4.4, 9.2)

4.2.5. Written procedures for folding surgical textiles shall be reviewed as needed to ensure that they are still applicable with the customer. (ANSI/AAMI ST65:2008 Stds. 8.3.1, 9.2)

4.2.5.1. ANSI/AAMI ST65:2008 should be consulted for basic correct folding procedures in addition to customer requests and preferences. (ANSI/AAMI ST65:2008 Std. 8.3.1)

4.2.5.2. Folding specifications shall be provided by and/or approved by the customer for whom the surgical packs are being built. (ANSI/AAMI ST65:2008 Std. 8.3.1)

4.2.5.3. 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 ST65:2008 Annex A: Examples of Folding Procedures)

4.2.5.4. 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, shall 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 ST65:2008 Std. 8.4)

4.3.2. After the order of the pack is agreed upon, the pack configuration shall be documented (i.e., pack master list and/or a device master record [DMR]). (ANSI/AAMI ST65:2008 Std. 8.4)

4.3.3. The contents and order of each pack shall be reviewed by the manager, who is responsible for pack assembly to ensure that the pack meets all appropriate requirements. (ANSI/AAMI ST65:2008 Std. 8.4)

4.3.4. Pack assembly procedures for each pack shall be documented to assure that appropriate inspections and processes are successfully completed. (ANSI/AAMI ST65:2008 Std. 8.6)

4.4. Wrapping and Packaging

4.4.1. The barrier product used to complete the pack is selected to provide adequate coverage of the contents shall be appropriate for the method of sterilization (i.e., permits maximum penetration of the sterilant during sterilization) and shall maintain the content's sterility until aseptic presentation. (ANSI/AAMI ST65:2008 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 shall be documented in the procedure (i.e., pack master list and/or a DMR). (ANSI/AAMI ST65:2008 Std. 8.5)

4.4.4. The finished pack and bulk loose textiles shall be packaged with plastic or other suitable material and placed in covered carts or hampers during transport to the customer.

4.5. Labeling/Identification of Packs

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

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

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

4.5.1.3. Identification of who assembled the pack and when. (ANSI/AAMI ST65:2008 Std. 8.6)

5. Storage and Transportation of Surgical Textile Packs

5.1. Storage of Surgical Textile Packs

5.1.1. Refer to Part I, Section 2, Subsections 2.1.2.3 – 2.1.2.5. and Part III, Section 1, Subsection 1.6 of this HLAC Standard for statements addressing storage of clean surgical textile packs.

5.1.2. Storage of packaged surgical textiles shall be wrapped in plastic or on/in covered shelves, carts, or hampers. (ANSI/AAMI ST65:2008 Std. 9.5.2)

5.2. Transportation of Surgical Textile Packs

5.2.1. Transportation of surgical textile packs shall be in accordance with Part II, Section 7 of this HLAC Standard.

5.2.2. Transport of the surgical textile packs within the provider's facility or to the customer shall 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 ST65:2008 Std. 9.5.1)

5.2.3. Clean carts or containers shall be used for transport of clean surgical textile packs. (ANSI/AAMI ST65:2008 Std. 9.5.2)

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

5.2.5. Characteristics of carts or containers suitable for transporting clean surgical textile packs shall be in accordance to Part II, Subpart 7, Section 7.1 of this HLAC Standard.

5.2.6. Loading methods shall be developed to ensure products are appropriately segregated and labeled to avoid contamination. (ANSI/AAMI ST65:2008 Std. 9.5.4.2)

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 room procedures shall be performed correctly and supervised by knowledgeable personnel. (ANSI/AAMI ST65:2008 Std. 4.1)

6.2. Training and Competency

6.2.1. General elements of personnel training shall be in accordance with Part I, Subpart 5, Section 5.4 of this HLAC Standard.

6.2.2. Employees shall be trained on the appropriate pack processes according to each pack's use requirements. (ANSI/AAMI ST65:2008 Std. 4.3)

6.2.3. Employees shall be thoroughly trained to operate surgical pack assembly area equipment safely and to recognize and report equipment malfunctions. (ANSI/AAMI ST65:2008 Std. 4.3)

6.2.4. Employees shall be thoroughly trained to work with reusable surgical textiles and to be familiar with the following items:

6.2.4.1. The characteristics inherent to reusable surgical textiles;

6.2.4.2. The uses of those textiles;

6.2.4.3. The 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 ST65:2008 Stds. 4.3.a-e)

6.3. Health and Personal Hygiene

6.3.1. Fingernails must be kept short, clean, natural, and healthy. (2010 AORN RP on Surgical Attire; ANSI/AAMI ST65:2008 Std. 4.4)

6.3.1.1. Pack room personnel must not wear nail polish and/or artificial nails. (2010 AORN RP on Surgical Attire; ANSI/AAMI ST65:2008 Std. 4.4)

6.3.2. Jewelry of any kind shall not be worn in the surgical pack assembly room. (2010 AORN RP on Surgical Attire; ANSI/AAMI ST65:2008 Std. 4.4)

6.3.3. Skin integrity absent of abrasions, dermatitis or other skin breakdowns shall be maintained in healthy condition. (2010 AORN RP Hand Hygiene, Recom 1.g; CDC HICPAC GL HH 5.A)

6.4. Attire and Personal Protective Equipment (PPE)

6.4.1. The basic elements pertaining to employee attire shall be in accordance with Part I, Subpart 5, Section 5.3 of this HLAC Standard as appropriate. (ANSI/AAMI ST 65:2008 Std. 4.5.1)

6.4.2. Employee attire in the surgical pack assembly area shall protect both the worker and the integrity of the textile product. (ANSI/AAMI ST65:2008 Std. 4.5.1)

6.4.2.1. All head and facial hair (excluding eyebrows and eyelashes) shall be completely covered with a surgical-type hair covering. (ANSI/AAMI ST65:2008 Std. 4.5.1)

6.4.2.2. Scrub attire shall be worn in the surgical pack assembly room.

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

Appendix A: Glossary/Terminology

Artificial nails – Substances or devices applied or added to the natural nails to augment or enhance the wearer's own nails. They include, but are not limited to, bonding, tips, wrappings, and tapes. (AORN 2010 RP on Surgical Attire)

Barrier properties – The ability of a material to resist the penetration of liquids (e.g., irrigating fluids, blood, and OPIM). (ANSI/AAMI ST65:2008)

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.

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. (ANSI/AAMI ST65:2008)

Conditioning/drying area – An area where, after extraction, textiles are either conditioned (partly dried) or fully dried in a dryer or tumbler. (ANSI/AAMI ST65:2008)

Critical zone – An area of protective apparel or surgical drape where direct contact with blood, body fluids, and OPIM is most likely to occur. (ANSI/AAMI ST65:2008)

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. (OSHA 29 CFR 1910.1030)

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. (Modified from OSHA 29 CFR 1910.1030)

Device master record (DMR) – According to Food and Drug Administration (FDA), a compilation of records that contains 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. (ANSI/AAMI ST65:2008)

Folding area – An area where textiles are folded. (ANSI/AAMI ST65:2008)

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 such as walls or partitions, carts, and ventilation parameters such as 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). (Modified from OSHA 29 CFR 1910.1030)

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. (Modified NIOSH Publication Sept 2004)

Hygienically clean – A clean state, free of pathogens in sufficient numbers to minimize risk of infection. Hygienically clean laundry carries negligible risk to healthcare workers and patients, provided that the clean textiles are not inadvertently contaminated before use. (Modified from ANSI/AAMI ST65:2008; CDC EIC guideline 2003: Part I. G. Laundry and Bedding, Subsection 2. Epidemiology and General Aspects of Infection Control)

Ironing area – An area where textiles that require ironing are processed through a flatwork ironer. (ANSI/AAMI ST65:2008)

Material safety data sheet (MSDS) – These sheets contain summaries provided by the manufacturer to describe the chemical properties and hazards of specific chemicals and ways in which workers can protect themselves from exposure to these chemicals. (NIOSH Sept 2004)

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. (ANSI/AAMI ST65:2008)

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. (OSHA 29 CFR 1910.1030)

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 (Dictionary)

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. (ANSI/AAMI ST65:2008)

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.

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

Receiving area – An area where soiled textiles are received in hampers or bags typically contained within carts, waiting soil sorting. (ANSI/AAMI ST65:2008)

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. (ANSI/AAMI ST65:2008)

Soil sort area – An area where soiled textiles are sorted usually by textile category and sometimes by degree of soiling or color. (ANSI/AAMI ST65:2008)

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

Standard Precautions – The Centers for Disease Control and Prevention (CDC) term/isolation category that incorporates Universal Precautions and Body Substance Precautions and includes a group of infection prevention practices that apply to ALL patients regardless of suspected or confirmed infection status in any setting where health care is delivered.

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). (ANSI/AAMI ST65:2008)

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. (ANSI/AAMI ST65:2008)

Sterile storage area – An area where sterile surgical packs are stored prior to delivery to the user. **NOTE:** HLAC Standards do not address this area nor inspect this area; provided for definition and clarification purposes only. (ANSI/AAMI ST65:2008)

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

NOTE: HLAC Standards do not address this area nor inspect this area; provided for definition and clarification purposes only. (ANSI/AAMI ST65:2008)

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

NOTE: HLAC Standards do not address this area nor inspect this area; provided for definition and clarification purposes only. (ANSI/AAMI ST65:2008)

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. (21 CFR 880.6850)

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. (ANSI/AAMI ST65:2008)

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. (ANSI/AAMI ST65:2008)

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. (ANSI/AAMI ST65:2008)

Textile inventory storage area – An area where newly purchased textiles are received and held prior to processing and placement into the circulating inventory. (ANSI/AAMI ST65:2008)

Universal Precautions – A CDC term that means healthcare workers consider ALL patients as potentially infected with HIV and/or other bloodborne pathogens and to adhere rigorously to infection control precautions for minimizing the risk of exposure to blood and body fluids of all patients. Enhance the definition for application to laundry industry. As defined by OSHA and more applicable to laundry industry, 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. (Modified OSHA 29 CFR 1910.1030)

Unwrapped – Terminology describing 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 is located; also known as wash floor. (ANSI/AAMI ST65:2008)

Appendix B: Abbreviations

AAMI – Association for the Advancement of Medical Instrumentation

ACH – Air Changes per Hour

AHJ – Authorities Having Jurisdiction

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

ASHES – American Society for Healthcare Environmental Services

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
COG – Customer Owned Goods
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
HHS – U.S. Department of Health and Human Services
HICPAC – Healthcare Infection Control Practices Advisory Committee
HLAC – Healthcare Laundry Accreditation Council
IC HCP – Infection Control for Health-Care Personnel
IPM – Integrated Pest Management
JCHLGL – Joint Committee for Healthcare Laundry Guidelines
MSDS – Material Safety Data Sheet(s)
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 Administration
PPE – Personal Protective Equipment
PUB – Publication
Std. – Standard
TRSA – Textile Rental Services Association of America
USC – United States Code

Appendix C: Ventilation Parameters for Healthcare Laundry Areas

Laundry Area	Air Flow Direction	Exhaust to Outside?	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	2	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 170-2008.

* ACH = Air Changes per Hour

^ NR = No Requirement

Appendix D: Code of Federal Regulations Text for FDA Device Handling and Storage

21 CFR Food & Drugs, Chapter 1: Food & Drug Administration, Department of Health and Human Services
Subchapter H: Medical Devices. Part 820: Quality System Regulation.
Subpart L: Handling, Storage, Distribution, and Installation

21 CFR 820 §820.140 Handling

Each manufacturer shall establish and maintain procedures to ensure that mixups, damage, deterioration, contamination, or other adverse effects to product do not occur during handling.

21 CFR 820 §820.150 Storage

(a) Each manufacturer shall establish and maintain procedures for the control of storage areas and stock rooms for product to prevent mixups, damage, deterioration, contamination, or other adverse effects pending use or distribution and to ensure that no obsolete, rejected, or deteriorated product is used or distributed. When the quality of product deteriorates over time, it shall be stored in a manner to facilitate proper stock rotation, and its condition shall be assessed as appropriate.

(b) Each manufacturer shall establish and maintain procedures that describe the methods for authorizing receipt from and dispatch to storage areas and stock rooms.

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Appendix F: Acknowledgements

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