CHECKLIST

Accreditation Standards

2016 Edition

Copyright © 2015. All rights reserved. Healthcare Laundry Accreditation Council.
This document is designed as a simple checklist to assist laundry organizations preparing for inspection in order to become HLAC Accredited.

The “must” statements are **bold-face text** and must be met with 100% compliance. “Shall” statements appear as regular text, **NOT** bold-face text, and must be met with a minimum of 90% compliance.

<table>
<thead>
<tr>
<th>YES</th>
<th>NO</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>2016 HLAC ACCREDITATION STANDARDS</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Part I. Basic Elements</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Part I - 1. Textile Control Procedures</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Part I - 1.1. Textile Specifications</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Part I - 1.1.1.</strong> The provider shall have written textile specifications that meet customer needs and ensure consistent performance.</td>
<td></td>
</tr>
<tr>
<td><strong>Part I - 1.1.1.1.</strong> 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.</td>
<td></td>
</tr>
<tr>
<td><strong>Part I - 1.1.1.2.</strong> These specifications shall be reviewed, at a minimum, annually by the service provider and the customer.</td>
<td></td>
</tr>
<tr>
<td><strong>Part I - 1.2. Textile Maintenance</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Part I - 1.2.1.</strong> The provider must have a documented grading system, outlining the grading standards for the healthcare textiles being processed.</td>
<td></td>
</tr>
<tr>
<td><strong>Part I - 1.2.1.1.</strong> The grading documentation must be accessible where personnel may refer to it.</td>
<td></td>
</tr>
<tr>
<td><strong>Part I - 1.2.2.</strong> Providers processing COG textiles shall reference the textile manufacturer’s instructions when appropriate for novel textiles.</td>
<td></td>
</tr>
<tr>
<td><strong>Part I - 1.2.3.</strong> These standards must outline which defects may be repaired, which defects require replacement, and the point at which previously repaired textiles should be discarded.</td>
<td></td>
</tr>
<tr>
<td><strong>Part I - 1.2.4.</strong> If a provider has a textile repair program, the provider must ensure that all personnel having responsibility for making repair and replacement decisions understand and comply with the grading standards.</td>
<td></td>
</tr>
<tr>
<td><strong>Part I - 1.3. Provider Inventory Management</strong></td>
<td></td>
</tr>
</tbody>
</table>
| **Part I - 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
Part I - 1.3.2. Methods to insure that an adequate supply of textiles is available to the provider and customer shall include documentation of historical fill rates for rental operations and/or documentation of clean pounds shipped as a percentage of soil pounds received for COG operations.

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

Part I - 2. Laundry Facilities


Part I - 2.1.1. Based on the workflow pattern principle where processing of soiled textiles flows to clean textiles, the laundry facility’s physical layout and maintenance procedures must ensure efficiency, minimize environmental contamination, and protect the material and hygienic integrity of the processed textiles. (JCHLGL Guidelines for Healthcare Linen Service, 1994, 8.)

Part I - 2.1.2. Soiled Textiles Area

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

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

Part I - 2.1.2.1.2. Functional barrier by negative air pressure in the soiled textiles area and positive air flow from the clean textiles area through the soiled textiles area with venting directly to the outside. (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 ST65:2013; Std.3.2.3.1, 3.3.4; ANSI/AAMI ST79:2010 Std. 3.2.3, 3.3.7.1; FGI GL 2014: 2.1-5.2.1 Linen Services 2.1-5.2.2.1-2, 2.1-5.2.3.5, 3.1-5.2, ANSI/ASHRAE/ASHE Std. 170-2013 Table 7.1, p. 11)

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

Part I - 2.1.2.3. 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)

Part I - 2.1.2.4. Handwashing facilities must be located in all areas where soiled or contaminated textiles are handled in the laundry. (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 ST65:2013; Std. 3.3.7; ANSI/AAMI ST79:2010 Std. 3.3.6.8; FGI GL 2014: 2.1-5.2 Linen Services 2.1-5.2.2.1, 2.1-7.2.2.8.)

Part I - 2.1.2.5. 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 ST65:2013; Std. 3.3.8; ANSI/AAMI ST79:2010 Std. 3.3.7.1, 3.3.8; OSHA 29 CFR 1910.1030. (d)(2)(i))

Part I - 2.1.3. Clean Textile Staging and Storage Areas
### Part I - 2.1.3.1.
In the provider’s facility, the textile staging and storage areas for cleaned, processed textiles must be in compliance with the following specifications: free of vermin; devoid of lint; without obvious moisture contamination. (ANSI/AAMI ST65:2013; Std. 9.6.1-2; ANSI/AAMI ST79:2010; Std. 8.9.2)

### Part I - 2.1.3.2.
The ventilation of the storage area shall:

- Be designed to prevent accumulation of dust and lint; and
- Be under positive air pressure relative to adjacent spaces, thereby preventing intrusion of contamination from soiled textile areas.

### Part I - 2.1.3.3.
Policies and protocols shall reflect a facility-specific strategy for ensuring the hygienically clean quality of the stored, processed textiles and shall establish a schedule of visual inspection of the stored textiles and recording the observations.

### Part I - 2.1.3.4. Specifications for Clean Textiles Storage Shelves

- **Part I - 2.1.3.4.1.** Shelves shall be placed approximately 2 inches from the wall to safeguard package integrity. (ANSI/AAMI ST65:2013; Std. 9.6.1; ANSI/AAMI ST79:2010; Std. 8.9.2)

- **Part I - 2.1.3.4.2.** The bottom shelf must be of solid nonporous construction, free from visible soil and dirt, and at a minimum of 8 inches from the floor for accessible cleaning to prevent contamination. (ANSI/AAMI ST65:2013; Std. 9.6.1; ANSI/AAMI ST79:2010; Std. 8.9.2)

- **Part I - 2.1.3.4.3.** The top of any item on the top shelf must be a minimum of 18 inches below the ceiling to prevent impairment of ventilation, sprinklers, and lighting. (ANSI/AAMI ST65:2013; Std. 9.6.1; ANSI/AAMI ST79:2010; Std. 8.9.2)

- **Part I - 2.1.3.4.4.** Any porous material (e.g., cardboard, paper, etc.) must not be used as a shelf liner in the clean textiles storage area and to store clean textiles.

### Part I - 2.1.4. Other Fixtures and Signage

- **Part I - 2.1.4.1.** Hand hygiene resources (i.e., handwashing facilities or antiseptic hand cleaner and cleaner dispensers) must be available in or around all work areas and in personnel support areas. (OSHA 29 CFR 1910.1030 (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 ST65:2013; Std. 3.3.7; ANSI/AAMI ST79:2010 Std. 3.3.6.8; FGI GL 2014: 2.1-5.2 Linen Services 2.1-5.2.2.1-2, 2.1-7.2.2.8.)

- **Part I - 2.1.4.2.** Emergency eyewash and 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 ST65:2013; Std. 3.3.8; ANSI/AAMI ST79:2010 Std. 3.3.7.1, 3.3.8; OSHA 29 CFR 1910.151 (c)]

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

### Part I - 2.2. Physical Plant and Equipment Maintenance

- **Part I - 2.2.1.** Maintenance of equipment and spaces in a laundry facility processing healthcare textiles shall follow documented provider’s policies and procedures.

- **Part I - 2.2.2.** Cleaning, Decontamination, and Disinfection

- **Part I - 2.2.2.1.** The physical environment (e.g., floors, walls, ceilings, vents, working surfaces, and installed
<table>
<thead>
<tr>
<th>Part I - 2.2.2.1.1.</th>
<th>The cleaning schedule must be maintained on a current basis and available for inspection.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Part I - 2.2.2.2.</td>
<td>Environmental surfaces (e.g., walls, ceilings, vents, and equipment) must be subjected to periodic and as needed blow down processes from ceiling downward to minimize the build-up of dust and lint.</td>
</tr>
<tr>
<td>Part I - 2.2.2.2.1. Blow down must be performed when no other processing of textiles is occurring in that area and must not be performed in pack rooms. (ANSI/AAMI ST65:2013; Std. 3.3.3)</td>
<td></td>
</tr>
<tr>
<td>Part I - 2.2.2.3.</td>
<td>Clean textile working surfaces (e.g., counters, benches, tables, etc.) must be kept clean of visible soil, dust, and lint. [OSHA: 29.CFR 1910.1030 (d)(4)(ii); CDC HICPAC GL EIC, 2003: II.E.I.E.2; ANSI/AAMI ST79:2010 Std. 3.4; CDC HICPAC GL EIC, 2003:II.E.I.A; ANSI/AAMI ST79:2010 Std. 6.2]</td>
</tr>
<tr>
<td>Part I - 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 grade 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 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. [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; II. E.1.; II.H.; II. A-D; ANSI/AAMI ST79:2010 Std. 6.2]</td>
<td></td>
</tr>
<tr>
<td>Part I - 2.2.2.5. Work practices when using conventional washer extractors</td>
<td></td>
</tr>
<tr>
<td>Part I - 2.2.2.5.1. Cleaning and disinfection of surfaces</td>
<td></td>
</tr>
<tr>
<td>Part I - 2.2.2.5.1.1. 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.</td>
<td></td>
</tr>
<tr>
<td>Part I - 2.2.2.5.1.2. Routine cleaning and disinfection of surfaces, using a cleaning/disinfection strategy appropriate for the type of contamination when loading and unloading conventional washer extractors after each load, must be consistent with the principles of functional separation.[OSHA: 29 CFR 1910.1030 (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]</td>
<td></td>
</tr>
<tr>
<td>Part I - 2.2.2.5.2. Work flow and functional separation</td>
<td></td>
</tr>
<tr>
<td>Part I - 2.2.2.5.2.1. Functional and physical separation of soiled and clean textiles must be followed when conventional washer extractor equipment is used in accordance with Part I, Subpart 2, Section 2.1, Element 2.1.2.1 of this HLAC Standard.</td>
<td></td>
</tr>
<tr>
<td>Part I - 2.2.2.5.2.2. For conventional washer extractor equipment that utilizes sling delivery systems for loading soiled textiles, clean textiles must not be stored under the soiled slings.</td>
<td></td>
</tr>
</tbody>
</table>
| Part I - 2.2.2.5.3. Personnel handwashing practices and personal protective equipment (PPE) usage while using conventional washer extractor equipment must be in accordance with Part I, Subpart 5, Sections 5.3 and 5.4, Elements 5.3.3. and 5.4.1. of this HLAC Standard. [CDC HICPAC GL Hand Hygiene 1.G, 1.J, 1.K, 6.C; ANSI/AAMI ST65:2013; Std. 4.4; ANSI/AAMI ST79:2010 Std. 4.4, 4.5.1, 4.5.2; OSHA 29 CFR 1910.1030 (d)(2)(v),...
Part I - 2.2.3. Pest Control Program

Part I - 2.2.3.1. The provider must have documentation of a current integrated pest management (IPM) program consistent with healthcare-recommended practices and with evidence of scheduled treatments. (www.epa.gov/integrated) pest management program; CDC HICPAC GL EIC, 2003: II. E.V.A-C; AHE Recommended Practice Series: Integrated Pest Management)

Part I - 2.3. Management of Foreign Items and Regulated Wastes

Part I - 2.3.1. Miscellaneous Foreign Items

Part I - 2.3.1.1. The provider shall have a policy to return items found among healthcare textiles to the customer.

Part I - 2.3.2. Regulated Medical Waste Management

Part I - 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]


Part I - 2.3.2.1.2. Documenting what waste items were sent, the date, the disposition of the items, and notification of the customer.


Part I - 2.3.3. Hazardous Materials and Pharmaceutical Waste Management

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

Part I - 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 personnel’s exposure to hazardous substances. (OSHA 29 CFR 1910.1200; OSHA Technical Manual: Hazardous Drugs, Sec. 6, Chapter 2)

Part I - 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.

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

Part I - 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).
**Part I - 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.

**Part I - 2.4. Piped Air, Water, Wastewater, and Chemicals Management**

**Part I - 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, if applicable.

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

**Part I - 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, if applicable. (OSHA: 29 CFR 1910.1200; DHS 6 CFR 27).

**Part I - 3. Contingency Planning**

**Part I - 3.1 Contingency Planning**

**Part I - 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.

**Part I - 3.1.2.** The Contingency Plan shall include the following components:

- **Part I - 3.1.2.1.** Plant and transportation contingency protocol,
- **Part I - 3.1.2.2.** Call chain,
- **Part I - 3.1.2.3.** A list of backup laundry facilities, and
- **Part I - 3.1.2.4.** A backup source of textiles, if needed.

**Part I - 3.2 Plant Contingency Protocol**

**Part I - 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.

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

**Part I - 3.3. Contingency Call Chain**

**Part I - 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.

**Part I - 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.

**Part I - 3.4. Backup Facility Contracts**

**Part I - 3.4.1.** The provider shall have written contracts 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)

**Part I - 3.4.1.1.** These contracts shall be updated annually, signed, and dated.

**Part I - 3.4.2.** The provider shall have adequate transportation capabilities with contingency planning.

**Part I - 3.4.3.** The provider shall have written contracts in place with one or more alternate textile suppliers,
Part I - 4. Laundry Equipment

Part I - 4.1. Documentation

Part I - 4.1.1. A list of all equipment shall be prepared, kept on file, and made available prior to inspection. (ANSI/AAMI ST65:2013; Std. 10.2.1)

Part I - 4.1.2. Equipment safety documentation shall consist of safety instructions, describing the potential hazards associated with the equipment use; appropriate safeguards; and complies with ANSI Z8.1., regarding safe operation and maintenance of equipment. (ANSI/AAMI ST65:2013; Std. 10.2.2)

Part I - 4.1.3. Documentation concerning equipment maintenance

Part I - 4.1.3.1. 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 ST65:2013; Std. 10.2.3)

Part I - 4.1.3.2. The provider 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 ST65:2013; Std. 10.2.2)

Part I - 4.1.3.3. Equipment preventive maintenance should be documented and kept on file. (ANSI/AAMI ST65:2013; Std. 10.5.5)

Part I - 4.2. Installation and Utilities Connections

Part I - 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 ST65:2013; Std. 10.3.1)

Part I - 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 ST65:2013; Std. 10.4.1; CDC HICPAC GL EIC, 2003:II.G.II.C)

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

Part I - 4.2.3.1. The provider must 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 ST65:2013; Std. 10.3.2.1)

Part I - 4.2.3.2. The electrical power supplied to processing equipment must be installed in conformance with local electrical and fire codes to prevent fires. (ANSI/NFPA No. 70; ANSI/AAMI ST65:2013; Std. 10.3.2.3)

Part I - 4.2.3.3. The gas supply must conform to the equipment manufacturer’s recommendations.

Part I - 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 ST65:2013; Std. 10.3.2.4)

Part I - 4.2.3.5. The steam supply and its quality must conform to the equipment manufacturer's recommendations and any state regulations. (ANSI/AAMI ST65:2013; Std. 10.3.2.5; ANSI/AAMI ST79:2010 Std. 3.3.4.1, 3.3.4.2)

Part I - 4.2.4. Water quality

Part I - 4.2.4.1. The provider must 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 ST65:2013 Std. 10.3.2.2)

Part I - 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 ST65:2013; Std. 10.4.3.3)

Part I - 4.3. Equipment Operation

Part I - 4.3.1. Proper functioning of equipment must 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 ST65:2013; Std. 10.4.2.1)

Part I - 4.3.2. Mechanical systems must 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 ST65:2013; Std. 10.4.2.2)

Part I - 4.3.3. Automated controls must be verified, calibrated, and checked at least annually. (ANSI/AAMI ST65:2013; Std. 10.4.2.3)

Part I - 4.3.4. The performance of the chemical delivery system must 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 ST65:2013; Std. 10.4.3.2)

Part I - 4.3.5. The design and size of water heater equipment must be appropriate for the provider’s needs at peak operating times and to maintain the specified heated water temperature per desired cycle. (ANSI/AAMI ST65:2013; Std. 10.4.3.4)

Part I - 4.4. Preventive Maintenance

Part I - 4.4.1. Equipment must be inspected, cleaned, and receive scheduled preventive maintenance according to the manufacturer’s instructions or according to facility policy and procedures, if instructions are not available. (ANSI/AAMI ST65:2013; Std. 10.5.1-2)

Part I - 4.4.2. Preventive maintenance shall include replacement of worn expendable parts, lubrication, and calibrations. (ANSI/AAMI ST65:2013; Std. 10.5.2-3)

Part I - 4.5. Equipment Calibrations

Part I - 4.5.1. Equipment shall be calibrated periodically as specified in the manufacturer’s instruction manual or as determined by facility policy and procedures, if a manufacturer’s schedule is not available. (ANSI/AAMI ST65:2013; Std. 10.5.4)

Part I - 4.5.2. Calibration shall be performed by personnel trained and/or certified in calibration specified by the manufacturer. (ANSI/AAMI ST65:2013; Std. 10.5.4)

Part I - 4.6. Repairs

Part I - 4.6.1. Worn, malfunctioning, or broken parts shall be replaced promptly by qualified personnel. (ANSI/AAMI ST65:2013; Std. 10.5.3)

Part I - 4.6.2. Safety precautions, including lock-out tag-out procedures, must be observed. (ANSI/AAMI ST65:2013; Std. 10.5.3; OSHA 29 CFR 1910.147 App A)

Part I - 4.6.3. Repair records shall be kept for all equipment. (ANSI/AAMI ST65:2013; Std. 10.5.3)
Part I - 4.7. Recordkeeping for New, Existing, and/or Used Equipment

Part I - 4.7.1. A maintenance record shall be kept on file for each piece of equipment. (ANSI/AAMI ST65:2013; Std. 10.5.5)

Part I - 4.7.2. The following information shall be recorded:

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

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

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

Part I - 4.7.2.4. Personnel involved (e.g., provider authorization, service technician name). (ANSI/AAMI ST65:2013; Std. 10.5.5)

Part I - 5. Laundry Personnel

Part I - 5.1. Personnel Qualifications

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

Part I - 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 ST65:2013; Std. 4.1; ANSI/AAMI ST79:2010 Std. 4.1)

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

Part I - 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 ST65:2013; Std. 4.1; ANSI/AAMI ST79:2010 Std. 4.2.1)

Part I - 5.2. Personnel General Responsibilities

Part I - 5.2.1. Supervisors/managers/personnel shall: (ANSI/AAMI ST65:2013; Std. 4.2.1; ANSI/AAMI ST79:2010 Std. 4.2.1)

Part I - 5.2.1.1. Safely and correctly operate assigned equipment;

Part I - 5.2.1.2. Safely and correctly perform assigned processing activities;

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

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

Part I - 5.2.1.5. Understand the risk of injury that defective or improperly operating equipment may inflict. (ANSI/AAMI ST65:2013; Std. 4.2.2; ANSI/AAMI ST79:2010 Std. 4.2.2)

Part I - 5.3. Health and Hygiene

Part I - 5.3.1. The provider must have policies and procedures to prevent healthcare textiles from being handled by or exposure to personnel with potential health issues (i.e., illness, open wounds or sores, and skin injuries.) (CDC HICPAC GL IC HCW, 1998: II.B-F; ANSI/AAMI ST65:2013; Std. 4.4; ANSI/AAMI ST79:2010 Std. 4.4)

Part I - 5.3.2. Employee Safety:

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

Part I - 5.3.2.1.2. Safe operation of equipment;

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

Part I - 5.3.2.1.4. Hazard communications; (OSHA: 29 CFR 1910:1200)

Part I - 5.3.2.1.5. Safe transportation; and

Part I - 5.3.2.1.6. Proper handling of textiles.

Part I - 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)]

Part I - 5.3.2.3. Personnel must handle chemicals safely in accordance with Safety Data Sheets (SDS) in the laundry facility. (OSHA: 29 CFR 1910.1200 App D; ANSI/AAMI ST65:2013; Std. 3.3.10)

Part I - 5.3.2.3.1. SDS information must be readily accessible to personnel in a location for immediate access where chemicals are handled.

Part I - 5.3.2.4. Personnel who are exposed to hazards (e.g., biological, chemical, mechanical, etc.) must 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]

Part I - 5.3.3. Hand washing and hand hygiene indications:


Part I - 5.3.3.2. Personnel must practice hand hygiene (handwashing or using alcohol-based hand sanitizers) before donning gloves and after removal of gloves. (CDC HICPAC GL Hand Hygiene 1.G; 1.J; 1.K; 6.C)

Part I - 5.3.3.3. Personnel responsible for packing, wrapping, storing, or transporting clean textiles must maintain proper hand hygiene at all times. (ANSI/AAMI ST65:2013; Std. 4.4)

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

Part I - 5.4.1. Personal protective equipment:

Part I - 5.4.1.1. The provider must supply the PPE to personnel in the workplace. [OSHA: 29 CFR 1910.1030 (d)(3)(i)]

Part 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)]

Part I - 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)]

Part I - 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)

Part I - 5.4.1.5. All PPE must be removed and placed in an appropriate receptacle prior to leaving the work...
### Part I - 5.4.2. Personnel attire and adornments:

1. **Part I - 5.4.2.1.** All personnel must wear clean garments without visible soil or dirt in accordance with the provider’s policies and procedures. (ANSI/AAMI ST65:2013; Std. 4.5; ANSI/AAMI ST79:2010 Std. 4.5)

2. **Part I - 5.4.2.2.** For safety reasons, loose or dangling jewelry (e.g., necklaces, bracelets, earrings) or rings and loose clothing items (i.e., scarfs, neckties) must not be worn. (ANSI/AAMI ST65:2013; Std. 4.5; ANSI/AAMI ST79:2010 Std. 4.5)

3. **Part I - 5.4.2.3.** Hair covering must be used where deemed appropriate and/or within provider’s written policies and procedures. (ANSI/AAMI ST65:2013; Std. 4.5; ANSI/AAMI ST79:2010 Std. 4.5)

4. **Part I - 5.4.2.4.** Artificial nails must not be worn in the laundry and while processing healthcare textiles. (ANSI/AAMI ST65:2013; 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. **Part I - 5.4.2.5.** Personnel who handle clean healthcare textiles must change work garments whenever their garment becomes soiled or contaminated. (ANSI/AAMI ST65:2013; Std. 4.5.1; ANSI/AAMI ST79:2010 Std. 4.5.1)

### Part I - 5.5. Occupational Safety and Health Elements

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

2. **Part I - 5.5.2. Exposure Control Plan (ECP):**

   1. **Part I - 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)]

   2. **Part I - 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)]

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

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

   1. **Part I - 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)]

   2. **Part I - 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)]

   3. **Part I - 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)]

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

   5. **Part I - 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)]

3. **Part I - 5.5.3.** Develop a hepatitis B vaccination program: [OSHA: 29 CFR 1910.1030 (f)]

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

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

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

Part I - 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)]

Part 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]

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

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

Part I - 5.5.6.1.1. The hazardous substance safety plan must be readily available and accessible to all personnel (i.e., full-time personnel, temporary personnel, contractors, and trainees). (OSHA: 29 CFR 1910.1200; The OSHA Technical Manual: Haz Drugs, Sec 6, Chap 2)

Part I - 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)

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

Part I - 5.5.6.2.1. Wash process;
Part I - 5.5.6.2.2. PPE requirements for affected personnel;
Part I - 5.5.6.2.3. Training records for these personnel; and
Part I - 5.5.6.2.4. Written record of provider/customer discussion regarding proper containment for hazardous substance contaminated textiles.

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

Part I - 5.5.7.1. The provider must maintain documentation of this compliance and make it available for inspection.

Part I - 5.6. Training and Educational Programs

Part I - 5.6.1. General elements:

Part I - 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 per manufacturer's instructions and notification procedures when malfunctions occur.

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

Part I - 5.6.1.2.1. In-plant (in-service) training sessions facilitated by a person experienced in the topic;
Part I - 5.6.1.2.2. Formal external training programs, including classes, workshops, and seminars.
<table>
<thead>
<tr>
<th>Part I - 5.6.1.3.</th>
<th>Personnel shall receive the provider’s standard training for the correct handling of healthcare textiles. Topics shall include:</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Part I - 5.6.1.3.1.</strong></td>
<td>Specific types of fabrics being processed;</td>
</tr>
<tr>
<td><strong>Part I - 5.6.1.3.2.</strong></td>
<td>Appropriate surgical textiles pack processes according to each pack’s use requirements;</td>
</tr>
<tr>
<td><strong>Part I - 5.6.1.3.3.</strong></td>
<td>Proper use, placement, and heat-sealing process for patching surgical textiles; (ANSI/AAMI ST65:2013; Std. 4.2.2., 4.3, 7.2.1)</td>
</tr>
<tr>
<td><strong>Part I - 5.6.1.3.4.</strong></td>
<td>A copy of the grading standards.</td>
</tr>
<tr>
<td><strong>Part I - 5.6.2. Bloodborne Pathogens Exposure Control Training:</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Part I - 5.6.2.1.</strong></td>
<td>Key topics for this training must include, but are not limited to:</td>
</tr>
<tr>
<td><strong>Part I - 5.6.2.1.1.</strong></td>
<td>Personal hygiene and proper handwashing and hand hygiene techniques; (CDC HICPAC GL Hand Hygiene 2.A-D; CDC HICPAC GL IC HCW, 1998: II.B.3)</td>
</tr>
<tr>
<td><strong>Part I - 5.6.2.1.2.</strong></td>
<td>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 ST65:2013; Std 4.5.2; CDC HICPAC GL IC HCW, 1998: II.B.3; OSHA: 1910.1030 (d)(3)(ii)]</td>
</tr>
<tr>
<td><strong>Part I - 5.6.2.1.3.</strong></td>
<td>Engineering controls and work practices to minimize the risk of exposure to blood or OPIM; [OSHA: 1910.1030 (d)(2)(i)]</td>
</tr>
<tr>
<td><strong>Part I - 5.6.2.1.4.</strong></td>
<td>Orientation on the provider’s Exposure Control Program;</td>
</tr>
<tr>
<td><strong>Part I - 5.6.2.1.5.</strong></td>
<td>Orientation to hazard communications, including labeling and color-coding; and (OSHA: 29 CFR 1910.1030 (g)(1); (g)(2)(vii)(M))</td>
</tr>
<tr>
<td><strong>Part I - 5.6.2.1.6.</strong></td>
<td>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]</td>
</tr>
<tr>
<td><strong>Part I - 5.6.3. Hazardous Substance Contaminated Textiles training:</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Part I - 5.6.3.1.</strong></td>
<td>Key topics for this training must include, but are not limited to:</td>
</tr>
<tr>
<td><strong>Part I - 5.6.3.1.1.</strong></td>
<td>Exposure risk to textiles contaminated with hazardous substances or excreta from patients who have received hazardous substances (e.g., radioisotopes, chemotherapeutics, etc.) in the past 48 hours; (CDC HICPAC GL IC HCW, 1998: II.B.4.c; E-F)</td>
</tr>
<tr>
<td><strong>Part I - 5.6.3.1.2.</strong></td>
<td>Communications among supervisors and personnel for hazardous substance management procedures;</td>
</tr>
<tr>
<td><strong>Part I - 5.6.3.1.3.</strong></td>
<td>Identification and segregation of soiled textiles from patients exposed to hazardous substance contaminated, reusable textiles in bags designated solely for the containment of reusable hazardous substance exposed textiles;</td>
</tr>
<tr>
<td><strong>Part I - 5.6.3.1.4.</strong></td>
<td>Use of PPE including one or more of the following, but not limited to, gloves, gowns, and eye protection, if splashing is possible;</td>
</tr>
<tr>
<td><strong>Part I - 5.6.3.1.5.</strong></td>
<td>Hand hygiene; and</td>
</tr>
<tr>
<td><strong>Part I - 5.6.3.1.6.</strong></td>
<td>Disposal of contaminated one time use PPE in thick, leak-proof colored or labeled plastic bags for hazardous substances-related wastes.</td>
</tr>
<tr>
<td><strong>Part I - 5.6.3.1.7.</strong></td>
<td>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)</td>
</tr>
<tr>
<td><strong>Part I - 5.6.4. Department of Transportation (DOT) regulations (<a href="http://www.DOT.gov">www.DOT.gov</a>) training:</strong></td>
<td></td>
</tr>
<tr>
<td>Part I - 5.6.4.1. Key topics in this training must include, but are not limited to:</td>
<td></td>
</tr>
<tr>
<td>Part I - 5.6.4.1.1. Random drug testing;</td>
<td></td>
</tr>
<tr>
<td>Part I - 5.6.4.1.2. Operator training;</td>
<td></td>
</tr>
<tr>
<td>Part I - 5.6.4.1.3. Certified driver license requirements; and</td>
<td></td>
</tr>
<tr>
<td>Part I - 5.6.4.1.4. Bloodborne pathogens exposure.</td>
<td></td>
</tr>
</tbody>
</table>

| Part I - 5.6.5. Training Documentation |
| Part I - 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 ST65:2013; Std. 4.3; CDC HICPAC GL IC HCW, 1998: II.B.3-5; II.E-F; OSHA: 29 CFR 1910.1030 (h)(2)(ii)] |
| Part I - 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)] |
| Part I - 5.6.5.2.1. Dates and times of training; |
| Part I - 5.6.5.2.2. Method of training; |
| Part I - 5.6.5.2.3. Topic; |
| Part I - 5.6.5.2.4. Trainer’s name, title, signature, and qualifications; |
| Part I - 5.6.5.2.5. Copies of printed training materials; |
| Part I - 5.6.5.2.6. Validation that the training objectives and a minimum level of competency were achieved; and |
| Part I - 5.6.5.2.7. Certificates or signature proof of personnel’s attendance. |

| Part I - 6. Laundry Customers |
| Part I - 6.1. Provider Policy |
| Part I - 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. |

| Part I - 6.2. Contact |
| Part I - 6.2.1. The provider shall maintain a written list of all customer contacts for access of information exchange and service. |
| Part I - 6.2.2. The provider shall have a 24/7 customer service capability to receive customer messages (e.g., voicemail, email, etc.). |

| Part I - 6.3. Visitation |
| Part I - 6.3.1. The provider shall make their plants available to customers and prospective customers for inspection. |
| Part I - 6.3.2. The provider should annually visit the customer’s healthcare facility for the purpose of conducting a walk-through of all areas where healthcare textiles are used, collected, transported or stored. |
| Part I - 6.3.3. The provider should annually meet with the customer to determine the textile products used, expected textile usage, and their service expectations. |

<p>| Part I - 6.4. Customer Complaints |
| Part I - 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) |</p>
<table>
<thead>
<tr>
<th>Part I - 7. Quality Assessment</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Part I - 7.1.</strong> Textile products used in healthcare facilities shall be of a quality to ensure patient and healthcare personnel comfort and textile durability.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Part I - 7.2. Quality Control</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Part I - 7.2.1.</strong> Textile quality shall be defined and documented between the provider and the customer.</td>
</tr>
<tr>
<td><strong>Part I - 7.2.2.</strong> The provider processing COG textiles shall comply with pre-established textile maintenance standards as specified by each customer.</td>
</tr>
<tr>
<td><strong>Part I - 7.2.3.</strong> Defined quality standards shall keep mending and patching to a minimum.</td>
</tr>
<tr>
<td><strong>Part I - 7.2.4.</strong> The entire processing cycle shall have documented quality control procedures to ensure the cleanliness and serviceability of the textiles to include:</td>
</tr>
<tr>
<td><strong>Part I - 7.2.4.1.</strong> Requirements to rewash, repair, or replace textiles as necessary to maintain quality standards.</td>
</tr>
<tr>
<td><strong>Part I - 7.2.4.2.</strong> Planned and posted traffic patterns where required (e.g., pony washers) to minimize the potential for contaminating clean textiles.</td>
</tr>
<tr>
<td><strong>Part I - 7.2.4.3.</strong> Limited traffic in all areas of the facility to authorized personnel as outlined in the provider’s policies and procedures. (ANSI/AAMI ST65:2013; 3.2.4; ANSI/AAMI ST79:2010; Std. 3.2.4, 8.9.2)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Part I - 7.3. Quality Assurance</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Part I - 7.3.1</strong> The provider should have written policies and procedures, covering all areas of responsibility relating to services provided to the customer. (ANSI/AAMI ST65:2013; Std. 6.4, 11.4)</td>
</tr>
<tr>
<td><strong>Part I - 7.3.2.</strong> The provider shall maintain records of any laundry processing and/or quality assurance problems experienced and mutually agreed upon solutions.</td>
</tr>
<tr>
<td><strong>Part I - 7.3.2.1.</strong> A customer call log may be used for this purpose.</td>
</tr>
<tr>
<td><strong>Part I - 7.3.3.</strong> 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.</td>
</tr>
<tr>
<td><strong>Part I - 7.3.3.1.</strong> This review should be accomplished through monthly reports, regularly scheduled meetings with personnel, and/or annually.</td>
</tr>
<tr>
<td><strong>Part I - 7.3.3.2.</strong> Adjustments should be documented and filed for future use or reference.</td>
</tr>
<tr>
<td><strong>Part I - 7.3.4.</strong> Each classification of healthcare textiles shall be evaluated and/or tested to assure the established standards are met.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Part I - 7.4. Process Monitoring</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Part I - 7.4.1.</strong> Providers shall engage in process monitoring to verify that ongoing operations are producing clean textiles that will meet customer expectations and needs.</td>
</tr>
<tr>
<td><strong>Part I - 7.4.2.</strong> Providers shall prepare detailed process monitoring checklists and use them to document key elements of laundry processing.</td>
</tr>
<tr>
<td><strong>Part I - 7.4.2.1.</strong> Process monitoring checklists shall include, but are not limited to, the following items:</td>
</tr>
<tr>
<td><strong>Part I - 7.4.2.1.1.</strong> Chemical supplies: Refer to HLAC Standard Part I Subpart 4 Section 4.3. Elements 4.3.3. and 4.3.4.</td>
</tr>
<tr>
<td><strong>Part I - 7.4.2.1.1.1.</strong> 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...</td>
</tr>
</tbody>
</table>
temperatures being used.

**Part I - 7.4.2.1.1.2. Every chemical used must have an SDS on file.**

**Part I - 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 ST65:2013; Std. 6.4.2.2)

**Part I - 7.4.2.1.2. Water: Refer to HLAC Standard Part I Subpart 4 Section 4.3. Elements 4.3.2. and 4.3.5.**

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

**Part I - 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).

**Part I - 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)

**Part I - 7.4.2.1.3. Titration: (ANSI/AAMI ST65:2013; Std. 6.4.4)**

**Part I - 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 ST65:2013; Std. 6.4.3.e)

**Part I - 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.**

**Part I - 7.4.2.1.5. Load size:**

**Part I - 7.4.2.1.5.1.** Load size shall follow the equipment manufacturer’s recommendations where available.

**Part I - 7.4.2.1.5.2.** Each load shall be weighed, using a calibrated scale. Refer to HLAC Standard Part I Subpart 4 Section 4.5. Elements 4.5.1.

**Part I - 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 ST65:2013; Std. 6.2.2; 6.4.2.5) Refer to HLAC Standard Part I Subpart 4 Section 4.5. Elements 4.5.2.

**Part I - 7.4.2.1.6. Equipment:**

**Part I - 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. Refer to HLAC Standard Part I Subpart 4 Section 4.4.

**Part I - 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.

**Part I - 7.4.2.1.6.3.** Automatic equipment dispensers shall also record the chemical injection amounts and times by classification. (ANSI/AAMI ST65:2013; Std. 6.4.3) Refer to HLAC Standard Part I Subpart 4 Section 4.3.

**Part I - 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. Refer to HLAC Standard Part I Subpart 4 Section 4.3.

**Part I - 7.4.2.1.7. Finished products:**

**Part I - 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.

**Part I - 7.4.2.1.7.2.** A variety of process monitors should be used to indicate how the provider process has performed including:
Part I - 7.4.2.1.7.2.1. Rewash rates;
Part I - 7.4.2.1.7.2.2. pH spot tests; and
Part I - 7.4.2.1.7.2.3. Residual chlorine spot tests.

Part I - 7.4.2.1.8. Personnel competency:
Part I - 7.4.2.1.8.1. Supervisors shall verify personnel competency from training documentation (Refer to HLAC Standard Part I Subpart 5 Section 5.6. Element 5.6.5.) and mark the checklist accordingly.

Part I - 7.5. Accounting
Part I - 7.5.1. The provider should obtain and maintain on file the customer’s written contract to weigh and/or count textiles for accurate billing procedures based on these weights or counts.

**Part II. The Textile Processing Cycle**
Part II - 1. Handling, Collection and Transportation of Soiled Healthcare Textiles
Part II - 1.1. Universal Precautions
Part II - 1.1.1. All soiled healthcare textiles must be assumed to be contaminated. (JCHLGL Guidelines for Healthcare Linen Service, 1994; 7.A)
Part II - 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)]

Part II - 1.2. Handling and Collection
Part II - 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]
Part II - 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)]

Part II - 1.3. Transportation
Part II - 1.3.1. The provider must maintain functional separation of clean textiles from soiled textiles in carts and/or vehicles at all times during handling, collection, and transportation of soiled textiles. (JCHLGL Guidelines for Healthcare Linen Service, 1994; 6.B.3, 8.A; ANSI/AAMI ST79:2010 Std. 3.2.3, 3.3.7.1, 6.5.6; FGI GL 2014: 2.1-5.2.2.1, 2.2-5.2.3.1-3)
Part II - 1.3.2. Functional separation of clean from soiled textiles must be maintained during transportation by:
Part II - 1.3.2.1. Bagging soiled textiles in fluid-resistant containers; (ANSI/AAMI ST65:2013; Std. 9.5.3)
Part II - 1.3.2.2. Anchoring soiled textile containers in the vehicle to prevent spillage from their containers; and
Part II - 1.3.2.3. Training personnel regarding proper bagging and placement of textiles in the transporting truck; and
Part II - 1.3.2.4. Ensuring that all personnel with this responsibility follow Universal Precautions when necessary (e.g., when handling loose soiled textiles not contained in bags).
## Part II - 1.4. Carts Used for Soiled Textiles

1.4.1. Carts, containers, covers, and liners used to collect or transport soiled textiles must be properly cleaned and disinfected after the cart is emptied and before any next use, whether to transport clean textiles or soiled textiles.  (ANSI/AAMI ST65:2013; Std. 9.5.4.1, ANSI/AAMI ST79:2010 Std. 8.10.2; FGI GL 2014: 2.1-5.2.2.1. Linen Services 2.1-5.2.3.3.)

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

1.4.3. Proper cleaning shall include any of the following:

- 1.4.3.1. Steam cleaning,
- 1.4.3.2. Cleaning with a detergent and water, or
- 1.4.3.3. Using an EPA-registered hospital-grade detergent/disinfectant.

1.4.3.3.1. EPA-registered products shall be used according to label instructions, ensuring that the product remains on surfaces for the full contact time. (ANSI/AAMI ST65:2013; Std. 9.5.4.1; ANSI/AAMI ST79:2010 Std. 8.10.2; CDC HICPAC GL EIC, 2003:II.E.I.A)

## Part II - 2. Sorting

### Part II - 2.1. Soiled Sorting Area

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

### Part II - 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]

### Part II - 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, patient gowns, etc.) for each laundry formula used. (ANSI/AAMI ST65:2013; 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)

### Part II - 2.4. Foreign Object Policies

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

2.4.1.1. Reusable surgical instruments shall be retrieved from the textiles prior to laundering, placed into designated containers, and returned to the customer. (ANSI/AAMI ST65:2013; Std. 5.3.1)

2.4.1.2. Disposable devices shall be retrieved from the textiles prior to laundering, discarded into designated containers, and/or returned to the customer. (ANSI/AAMI ST65:2013; Std. 5.3.1)
**Part II - 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 ST65:2013; Std. 5.3.1)

**Part II - 2.4.2. Sharps Policy:**

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

- **Part II - 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;

- **Part II - 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 ST65:2013; Std. 5.3.1; CDC HICPAC GL EIC, 2003:II.I-III]

- **Part II - 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 HCW, 1998: II.E]

**Part II - 3. Washing and Extraction**

**Part II - 3.1. Equipment**

- **Part II - 3.1.1.** Washers, washer/extractors, and/or continuous batch washers shall be used in the processing of healthcare textiles. (ANSI/AAMI ST65:2013; Std. 2.59)

- **Part II - 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.

**Part II - 3.2. Washing**

- **Part II - 3.2.1.** The provider shall follow fabric-care instructions and special laundering requirements for items used by the customer, thereby ensuring that washed healthcare textiles become hygienically clean. (CDC HICPAC GL EIC, 2003:II.G.IV.A, C, D)

- **Part II - 3.2.2.** The provider shall sort and process environmental cleaning and disinfection textiles (e.g., cleaning cloths, microfiber cloths, mop heads, etc.) in separate wash loads from healthcare textiles intended for patient use.

- **Part II - 3.2.3.** The provider shall establish the load size (weight) for each textile classification and for each type of equipment used and shall record for each load processed. (ANSI/AAMI ST65:2013; Std. 6.2.2)

- **Part II - 3.2.3.1.** Equipment and textile product manufacturers’ recommendations should be consulted when establishing load size. (ANSI/AAMI ST65:2013; Std. 6.2.2)

- **Part II - 3.2.4.** Each classification shall have established parameters to optimize the wash processes:

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

  - **Part II - 3.2.4.2.** Water levels/usage: Total water usage and/or water levels;

  - **Part II - 3.2.4.3.** Temperature: Wash cycle, bleach cycle, and rinse cycle temperatures; and

  - **Part II - 3.2.4.4.** Chemical usage: Chemical types and usage levels for each step in the wash process.

- **Part II - 3.2.5.** The provider 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.

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

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

Part II - 3.3. Extraction

Part II - 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 ST65:2013; Std. 6.2.3.8)

Part II - 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)

Part II - 4. Drying

Part II - 4.1. Equipment

Part II - 4.1.1. Dryers shall be in good operating condition.

Part II - 4.2. Drying

Part II - 4.2.1. Drying procedures shall be described, controlled, and monitored for each textile classification to ensure appropriate drying. (ANSI/AAMI ST65:2013; Std. 6.3.1)

Part II - 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 ST65:2013; Std. 6.3.3.3)

Part II - 5. Finishing

Part II - 5.1. Ironing Equipment

Part II - 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.

Part II - 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)

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

Part II - 5.2. Folding and Stacking

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

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

Part II - 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)

Part II - 5.2.4. If any textiles become soiled in this process, they shall be rewashed in accordance with HLAC Standard Part II Subpart 3 Section 3.2. (ANSI/AAMI ST65:2008; Std. 9.4)

Part II - 5.3. Packaging

Part II - 5.3.1. Healthcare textile packaging must preserve textiles in a hygienically clean state for delivery to the customer. (CDC HICPAC GL EIC, 2003:II.G.IV.E; ANSI/AAMI ST65:2013; Std. 9.4)

Part II - 5.3.2. Textiles must be wrapped into fluid-resistant bundles or placed as unwrapped bundles into
Part II - 5.3.3. Wrapping material shall be plastic or other material that will protect the textiles from inadvertent environmental contamination. (ANSI/AAMI ST65:2013; Std. 9.4)

Part II - 5.3.4. During packaging, textiles shall be handled as little as possible to prevent soiling or contamination. (ANSI/AAMI ST65:2013; Std. 9.4)

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

Part II - 5.4. Reprocessing Requirements

Part II - 5.4.1. If any textiles become soiled during any stage of the finishing processing (including packaging), they must be reprocessed in accordance with HLAC Standard Part II Subpart 3 Section 3.2. (ANSI/AAMI ST65:2013; Std. 9.4)

Part II - 6. Storage (FGI 2014 2.1-2.6.11.1)

Part II - 6.1. Rationale

Part II - 6.1.1. The provider's storage strategies and handling methods of healthcare textiles must preserve the textiles in a hygienically clean state for delivery to the customer. (ANSI/AAMI ST65:2013; Std. 9.1; 9.6.1-2; ANSI/AAMI ST79:2010 Std. 8.9.2)

Part II - 6.1.2. Stock inventory of clean finished textiles shall be rotated and used in a first-in/first-out manner. (ANSI/AAMI ST65:2013; Std. 9.6.3; ANSI/AAMI ST79:2010 Std. 8.9.3)

Part II - 6.2. Storage Areas

Part II - 6.2.1. Storage parameters must be consistent with Part I, Subpart 2, Section 2.1, Subsection 2.1.3, Elements 2.1.3.1 – 2.1.3.4.4. of this HLAC Standard.

Part II - 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 ST65:2013; Std. 9.6.1-2; ANSI/AAMI ST79:2010 Std. 8.9.2; FGI GL 2014: 2.1-5.2 Linen Services 2.1-5.2.2.1-2, 2.1-5.2.3., 2.1-2.6.11.1)

Part II - 6.2.3. Only clean textiles shall be stored in this area and signage posted as “Textile storage room.” (ANSI/AAMI ST65:2013; Std. 9.6.2)

Part II - 6.2.4. Storage area cleanliness:

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

Part II - 6.2.4.2. Should this storage area require disinfection after cleaning, the provider shall use an EPA registered hospital grade disinfectant according to label instructions per provider's policy. (CDC HICPAC GL EIC, 2003:II.E.I-II; ANSI/AAMI ST79:2010 Std. 3.4)

Part II - 6.2.5. Storage area entry and exit:

Part II - 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 ST65:2013; Std. 9.6.2)

Part II - 6.2.5.2. Storage rooms shall only be accessible by authorized personnel. (ANSI/AAMI ST65:2013; Std. 9.6.2; ANSI/AAMI ST79:2010 Std. 8.9.2)

Part II - 6.3. Storage Options

Part II - 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
### Part II - 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.

### Part II - 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 ST65:2013; Std. 9.6.1-2; ANSI/AAMI ST79:2010 Std. 8.9.2)

### Part II - 6.4. Reprocessing Requirements

### Part II - 6.4.1. If any textiles become soiled during storage, they must be rewashed and reprocessed in accordance with Part II Subpart 3 Section 3.2. of this HLAC Standard. (ANSI/AAMI ST65:2013; Std. 9.4)

### Part II - 7. Delivery of Cleaned Healthcare Textiles

### Part II - 7.1. Clean healthcare textiles must be transported, delivered to the customer’s storage area, and stored by methods designed to minimize microbial contamination from surface contact or airborne deposition. (JCHLGL Guidelines for Healthcare Linen Service, 1994; 6, 6.B.1-3; FGI GL 2014: 2.1-5.2 Linen Services 2.1-5.2.2; 2.1-5.2.3.; CDC HICPAC GL EIC, 2003:II.G.IV.E; ANSI/AAMI ST65:2013; Std. 9.5.1)

### Part II - 7.2. Delivery methods:

#### Part II - 7.2.1. Clean textiles shall be transported in containers used exclusively for this purpose and/or including, but not limited to, any of the following methods:

##### Part II - 7.2.1.1. Clean textiles shall be placed in a hamper lined with a clean liner;

##### Part II - 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 ST65:2013; Std. 9.5.2; 9.6.1-2)

##### Part II - 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 ST65:2013; Std. 9.5.2; 9.6.1-2; ANSI/AAMI ST79:2010 Std. 8.10.2)

##### Part II - 7.2.1.2.1. When the cart contains clean textiles, textiles shall be wrapped inside the cart.

##### Part II - 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 ST65:2013; Std. 9.5.4.1; ANSI/AAMI ST79:2010 Std.8.9.2)

##### Part II - 7.2.1.3. Clean textiles shall be placed on a wire rack and covered with a suitable cover. (JCHLGL Guidelines for Healthcare Linen Service, 1994; 6.A.3; ANSI/AAMI ST65:2013; Std. 9.5.2; 9.6.2; ANSI/AAMI ST79:2010 Std. 8.10.2)


### Part II - 7.3. Cart Function and Cleanliness

#### Part II - 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.

#### Part II - 7.3.2. Cart cleanliness:
Part II - 7.3.2.1. Carts shall be cleaned and disinfected in accordance with Part II Subpart 1 Section 1.4 Element 1.4.3. of this HLAC Standard. (CDC HICPAC GL EIC, 2003:II.E.I-II; ANSI/AAMI ST79:2010 Std. 3.4)

Part II - 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 ST65:2013; Std. 9.5.4.1; ANSI/AAMI ST79:2010 Std. 8.10.2)

Part II - 7.3.2.3. Reusable textile cover materials (e.g., liners) must be washed before the next use. (ANSI/AAMI ST65:2013; Std. 9.5.4.1; ANSI/AAMI ST79:2010 Std. 8.10.2)

Part II - 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 ST65:2013; Std. 9.5.4.1; ANSI/AAMI ST79:2010 Std. 8.10.2)

Part II - 7.4. Vehicle Considerations

Part II - 7.4.1. Functional separation:

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

Part II - 7.4.1.2. Separation must be accomplished by the use of physical barriers and/or space separation sufficient to protect clean textiles from contact with soiled textiles. (JCHLGL Guidelines for Healthcare Linen Service, 1994; 6.B.1-3; ANSI/AAMI ST65:2013; Std. 9.5.5; ANSI/AAMI ST79:2010 Std. 8.11.5)

Part II - 7.4.2. Vehicle cleanliness:

Part II - 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 ST65:2013; Std. 9.5.5; ANSI/AAMI ST79:2010 Std. 8.11.5)

Part II - 7.4.2.2. Should the interior surfaces of the cargo area become contaminated with blood or OPIM, these surfaces must be decontaminated, cleaned with a detergent and water, and disinfected with an EPA registered hospital grade 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 Std. 3.4; OSHA Std statement)

Part II - 7.4.3. Occupational safety for drivers:

Part II - 7.4.3.1. Hand care:

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

Part II - 7.4.3.1.2. Drivers must use gloves to minimize contact with soiled textiles and use appropriate hand hygiene after glove removal.

Part II - 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

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

Part III - 1.1. The size and physical layout of the surgical pack assembly room, its equipment, and engineering support must be adequate for the performance of the job function necessary to properly
<table>
<thead>
<tr>
<th>Part III - 1.2. Floors, Walls, Ceilings and Vents</th>
</tr>
</thead>
</table>
| **Part III - 1.2.1.** Floors and walls must be constructed of materials that will withstand scheduled wet cleaning as well as the heat and humidity of the laundry environment.  
(ANSI/AAMI ST65:2013; Std. 3.4.3; ANSI/AAMI ST79:2010 Std. 3.3.6, 3.4; FGI GL 2014: 2.1-5.2 Linen Services 2.1-7.2.3., Surfaces 2.1-7.2.3.3-4) |

| Part III - 1.2.2. Ceilings and vents must be constructed of materials that will withstand scheduled cleaning and vacuuming to eliminate lint and other soils associated with laundry processing.  
(ANSI/AAMI ST65:2013; Std. 3.3.3, 3.4.3; FGI GL 2014: 2.1-5.2 Linen Services 2.1-7.2.3., Surfaces 2.1-7.2.3.3-4) |

| Part III - 1.2.3. Particulate or fiber-shedding materials must not be used in the construction of the surgical pack assembly room.  
(ANSI/AAMI ST65:2013; Std. 3.4.3) |

| Part III - 1.2.4. Ceilings in clean work areas must be flush with recessed, enclosed fixtures.  
(ANSI/AAMI ST65:2013; Std. 3.4.3) |

<table>
<thead>
<tr>
<th>Part III – 1.3. Separation of Work Areas</th>
</tr>
</thead>
</table>
| **Part III - 1.3.1.** The surgical pack assembly room must be designed, so that areas in which clean textiles are received, stored, and assembled into packs are separated by a physical barrier from areas in which soiled textiles are received or processed.  
(ANSI/AAMI ST65:2013; Std. 3.2.3.2) |

<table>
<thead>
<tr>
<th>Part III - 1.4. Ventilation Requirements for Proper Air Flow and Climate Control</th>
</tr>
</thead>
</table>
| **Part III - 1.4.1.** Heating, ventilation, and air conditioning (HVAC) system must be designed to conform to AIA/FGI standards in effect at the time when the facility was built or renovated.  
(FGI GL 2014: 2.1-8; ANSI/ASHRAE/ASHE Std. 170-2013: Sec. 6, 7) |

| Part III - 1.4.2. The HVAC system in the surgical pack assembly room must maintain the appropriate positive air pressure relative to the rest of the facility, preventing intrusion of contamination from the soiled textiles area.  
(ANSI/AAMI ST65:2013 Std. 3.4.4; FGI GL 2014: ANSI/ASHRAE/ASHE Std. 170-2013: Table 7.1, p. 11) |

| Part III - 1.4.3. The HVAC system must be a down-draft system for air circulation within the space, and the number of air changes/hour (ACH) (typically 10) must be sufficient to minimize lint particles in the air.  
(ANSI/AAMI ST65:2013; Std. 3.4.4; FGI GL 2014: ANSI/ASHRAE/ASHE Std. 170-2013: Table 7.1, p. 11) |

| Part III - 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 ST65:2013; Std. 3.4.4) |

| Part III - 1.4.5. Portable fans must not be permitted in the surgical pack assembly room.  
(ANSI/AAMI ST65:2013; Std. 3.4.4) |

| Part III - 1.4.6. Supply air for the surgical pack assembly room must be filtered as indicated in the edition AIA/FGI guidelines in effect at the time of construction or renovation of the laundry facility, with the filters undergoing scheduled regular maintenance as determined by the HVAC system engineer.  
(ANSI/AAMI ST65:2013;Std. 3.4.4) |

| Part III - 1.4.6.1. For new construction or major renovated laundry facilities’ surgical pack assembly room since 2011, filtration must consist of one filter bed with a 7 MERV (minimum efficiency rating value) or 30% filtration efficiency or the FGI Guidelines at the time of the construction, as a minimum.  
(FGI GL, 2014: ANSI/ASHRAE/ASHE Std. 170-2013; Sec. 6, Table 6-4) |
### Part III - 1.4.7. Temperatures in the Surgical Pack Assembly Room
Temperatures in the surgical pack assembly room must be maintained between 72º F - 78ºF to ensure a comfortable work environment for personnel in appropriate work attire. (ANSI/AAMI ST65:2013; Std. 3.4.5; FGI GL 2014: ANSI/ASHRAE/ASHE Std. 170-2013: Table 7.1, p. 11)

### Part III - 1.4.8. Relative Humidity (RH)
Relative humidity (RH) must be maintained between 20% and 60% max in all work areas, except the sterile storage area, where the humidity must not exceed 60%, for personnel comfort and to discourage microbial (e.g., fungal) growth. (ANSI/AAMI ST65:2013; Std. 3.4.5; FGI GL 2014: ANSI/ASHRAE/ASHE Std. 170-2013: Table 7.1, p.11)

### Part III - 1.5. Lighting

#### Part III - 1.5.1. Lighting Systems
Lighting systems in the surgical pack assembly room must be appropriate for the tasks performed in this area. (ANSI/AAMI ST65:2013; Std. 3.4.6)

#### Part III - 1.5.2. High Intensity Lighting
High intensity lighting shall be available in that part of the room or area where textiles are examined (i.e., folding, assembly, and repair areas). (ANSI/AAMI ST65:2013; Std. 3.4.6)

#### Part III - 1.5.3. Lower Intensity Overhead Lighting
Lower intensity overhead lighting shall be employed for areas where light illumination (e.g., table, bar, tube, etc.) inspection is performed, so the light illumination equipment can be used optimally. (ANSI/IESNA RP-29; ANSI/AAMI ST65:2013; Std. 3.4.6)

#### Part III - 1.5.4. Light Illumination Equipment
Light illumination equipment shall have a switch to turn off/on.

### Part III - 1.6. Storage Area for Clean Textile Packs

#### Part III - 1.6.1. The Storage Area for Clean Textile Packs
The 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 ST65:2013; 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 2014: 2.1-5.2.2.2, 2.6-5.2.1.2, 4.2-5.2.1, 4.2-5.2.3.2)

#### Part III - 1.6.2. Bulk Shipping Warehouse Cardboard Boxes
Bulk shipping warehouse cardboard boxes must not be in these surgical pack assembly storage rooms. (ANSI/AAMI ST79:2010 Std. 5.2.1)

#### Part III - 1.6.3. Storage Rooms
Storage rooms must be accessible only by authorized personnel. (ANSI/AAMI ST65:2013; Std. 9.6.2; ANSI/AAMI ST79:2010 Std. 8.9.2)

#### Part III - 1.6.4. Clean Textile Pack Storage Room Doors
Clean textile pack storage room doors shall remain closed, except for access or exit. (ANSI/AAMI ST65:2013; Std. 9.6.2)

#### Part III - 1.6.5. Environmental Conditions
Environmental conditions in the clean surgical textile pack storage area must include:

- Temperatures must not exceed 78ºF to prevent microbial contamination;
- Relative humidity must be less than 60% to inhibit microbial growth;
- The room must be properly ventilated to prevent accumulation of dust and lint (i.e., air change rate of 2 ACH); and
- The room must have positive air pressure relative to adjacent spaces, preventing intrusion of contamination from the soiled textiles areas. (ANSI/AAMI ST65:2013; Std. 9.6.1; ANSI/AAMI ST79:2010 Std. 3.3.6.4-6; FGI GL 2014: ANSI/ASHRAE/ASHE Std. 170-2013 Table 7.1 p. 11)

#### Part III - 1.6.6. Storage Carts
Storage carts must be used in lieu of fixed shelving, if allowed under state licensing.

#### Part III - 1.6.7. Storage Areas
Storage areas must be located within the surgical pack assembly room to facilitate bundling, loading onto trucks, and transportation.
Part III - 2. Surgical Pack Assembly Room Entry and Admission

Part III - 2.1. Policies:

Part III - 2.1.1. Criteria for authorized entry and movement within the surgical pack assembly room must be specified in written policies and procedures. (ANSI/AAMI ST65:2013; Std. 3.2.4)

Part III - 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)])

Part III - 2.1.3. Traffic in the surgical pack assembly room must be limited to authorized personnel only. (ANSI/AAMI ST65:2013; Std. 3.2.4)

Part III - 2.1.4. Policies and procedures must be developed to address visitor access and the circumstances for access and must establish a dress code to reduce the potential for contamination of surgical textiles. (ANSI/AAMI ST65:2013; Std. 3.2.4)

Part III - 2.2. Location of Hand Hygiene Stations

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

Part III - 2.2.2. Handwashing sinks with soap and paper towels must be readily accessible in or near the surgical pack assembly room. (ANSI/AAMI ST65:2013; Std. 3.4.7)

Part III - 2.2.3. Alcohol hand sanitizer also must be made readily available at the entrance and exit of the surgical pack assembly room door. (ANSI/AAMI ST65:2013; Std. 3.4.7)

Part III - 3. Surgical Textile Assembly Process

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

Part III - 3.1.1. Carts that are utilized for clean surgical textiles must be cleaned and disinfected in accordance with Part II, Subpart 7, Section 7.3. Element 7.3.2. of this HLAC Standard. (ANSI/AAMI ST65:2013; Std. 9.5.4.1)

Part III - 3.2. Inspection of Clean Surgical Textiles Prior to Pack Assembly

Part III - 3.2.1. Before each reuse, all surgical textile products must be visually inspected against written quality standards between provider and customer(s). (ANSI/AAMI ST65:2013; Std. 7.2.1)

Part III - 3.2.1.1. These standards shall be jointly developed and applied to the textile functional requirements and attributes as well as end-user requirements. (ANSI/AAMI ST65:2013; Std. 7.2.1)

Part III - 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 ST65:2013; Std. 7.2.1)

Part III - 3.2.2. If surgical textile integrity and quality are monitored by the provider, the critical zones of surgical textiles must be visually inspected with the use of light illumination (e.g., table, bar, tube, etc.) for the presence of stains, residue, physical defects, chemical or thermal damage, and foreign debris, and to ensure that appropriate labels are in place and a tracking system is intact. (ANSI/AAMI ST65:2013; Std. 7.2.1)

Part III - 3.2.2.1. The provider and customer shall agree to a written procedure for reporting, investigating, and returning surgical textile barrier efficacy issues and strike-through occurrences to the textile manufacturer and reporting to the non-COG customer. (ANSI/AAMI ST65:2013; Std. 11.4)

Part III - 3.2.2.2. A tracking mechanism suitable for each surgical textile barrier product must be used to
## Part III - 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 ST65:2013; Std. 7.2.2, 7.4.3)

- **3.2.3.2.** Surgical textiles with aesthetic stains that do not adversely affect the functionality of the textile may remain in service unless the end user determines otherwise. (ANSI/AAMI ST65:2013; Std. 7.2.2)

- **3.2.3.3.** Stained surgical textiles must be retired if rewashing cannot successfully remove unacceptable stains or residues (e.g., medicines, lubricants, adhesives, blood and/or body fluids, hard-surfaced or foreign matter of unknown composition, and raised or tactile residues). (ANSI/AAMI ST65:2013; Std. 7.2.2)

## Part III - 3.2.4. Physical defects:

- **3.2.4.1.** Physical defects (i.e., loose threads, loose or missing ties/attachments, damaged/missing snaps, cuts, tears, and holes) must be repaired as appropriate with patching and mending before the textile is reused in accordance with Part III Subpart 3 Section 3.3 of this HLAC Standard. (ANSI/AAMI ST65:2013; Std. 7.2.3)

## Part III - 3.2.5. Chemical or thermal damage:

- **3.2.5.1.** Surgical textiles must be inspected for evidence of chemical and/or thermal damages (usually apparent as discoloration, stiffening, or compromised structural integrity holes). (ANSI/AAMI ST65:2013; Std. 7.2.4)

- **3.2.5.2.** Surgical textiles with chemical and/or thermal damage that adversely impacts the important functional attributes of the textile must be retired or removed from service. (ANSI/AAMI ST65:2013; Std. 7.2.4)

## Part III - 3.2.6. Foreign debris

- **3.2.6.1.** Surgical textiles must be free of foreign debris (e.g., lint, hair, loose fibers, fibrous pills, other particulates) prior to assembly into packs. (ANSI/AAMI ST65:2013; Std. 7.2.5)

- **3.2.6.2.** Foreign debris must be removed with an appropriate method (e.g., a delinting roller or sticky tape) as approved by the textile manufacturer. (ANSI/AAMI ST65:2013; Std. 7.2.5)

- **3.2.6.3.** Work practices must be implemented to keep surgical textiles free from foreign debris. Such practices include, at a minimum, the following:
  - **3.2.6.3.1.** Dress code suitable for the inspection area of the surgical pack assembly room, consisting of dedicated uniforms or other suitable outerwear, hair covering, and beard covers as appropriate;
  - **3.2.6.3.2.** Handwashing procedures;
  - **3.2.6.3.3.** Housekeeping procedures to minimize dust and lint; and
  - **3.2.6.3.4.** Facility maintenance (e.g., keeping dryer lint screens clean). (ANSI/AAMI ST65:2013; Std. 7.2.5)

## Part III - 3.2.7. Labeling:

- **3.2.7.1.** New surgical textiles shall be inspected for appropriate labels and accompanying manufacturer’s...
Part III - 3.2.7.2. Labels shall contain information as manufacturer, product type, and lot code numbers. (ANSI/AAMI ST65:2013; Std. 7.2.6)

Part III - 3.2.7.3. Labels with lot code information must remain intact throughout the effective life of the textile. (ANSI/AAMI ST65:2013; Std. 7.2.6)

Part III - 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 ST65:2013; Std. 7.2.6, 7.3.4.2)

Part III - 3.2.8. Tracking System

Part III - 3.2.8.1. If a tracking mechanism (e.g., radio frequency identification [RFID], grid, bar code) is present on a surgical textile, this must be visually inspected, marked, scanned, or read each time the product is processed. (ANSI/AAMI ST65:2013; Std. 7.2.7)

Part III - 3.2.8.2. If the integrity of the tracking mechanism is in question, the textile must be pulled from service or an alternate method of tracking must be used until the tracking problem is resolved. (ANSI/AAMI ST65:2013; Std. 7.2.7)

Part III - 3.2.9. Effective Life of Surgical Textiles

Part III - 3.2.9.1. Methods must be designed and in place to the number of uses/washes for surgical textile barrier products. (ANSI/AAMI ST65:2013; Std. 7.3.3)

Part III - 3.2.9.2. Textile manufacturers must be consulted for directions on evaluating the critical performance attributes of their textile products, to include barrier properties (e.g., repellent finish, deterioration of coatings or film), absorbency, strength, drapeability, physical defects, and signs of textile aging. (ANSI/AAMI ST65:2013; Std. 7.3.3)

Part III - 3.3. Maintenance of Surgical Textiles

Part III - 3.3.1. Patching and Mending

Part III - 3.3.1.1. Sewing and use of patches shall be acceptable for repairs in non-critical zones of surgical textiles. (ANSI/AAMI ST65:2013; Std. 7.4.1-2)

Part III - 3.3.1.2. Physical defects within the critical zones of the various surgical textiles must be repaired, following manufacturer’s guidelines. (ANSI/AAMI ST65:2013; Std. 7.2.3)

Part III - 3.3.1.2.1. Heat-sealed patches must be used to repair physical defects present in the critical zones of surgical textiles. Attributes of these patches must include: (ANSI/AAMI ST65:2013; Std. 7.4.1)

Part III - 3.3.1.2.1.1. Meeting the same general medical device safety and effectiveness requirements as the textile being repaired,

Part III - 3.3.1.2.1.2. Being applied per manufacturer’s instructions,

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

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

Part III - 3.3.1.2.1.5. Allowing for effective sterilization. (ANSI/AAMI ST65:2013; Std. 7.4.1)

Part III - 3.3.1.2.2. Patches must not be sewn to the textile. (ANSI/AAMI ST65:2013; Std. 7.4.1)

Part III - 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 ST65:2013; Std. 7.4.1)
| Part III - 3.3.1.2.4. Use of sewing is discouraged for repairs in textiles’ critical zones; but if sewing is indicated for a successful repair, heat-sealed patches must be used to seal the needle holes. (ANSI/AAMI ST65:2013; Std. 7.4.2) |
| Part III - 3.3.1.3. Loose patches must be removed and new patches applied. (ANSI/AAMI ST65:2013; Std. 7.4.1) |
| Part III - 3.3.1.4. Acceptable number, location, shape, and size of patches must be clearly delineated in written quality standards and repair procedures. (ANSI/AAMI ST65:2013; Std. 7.4.1) |
| Part III - 3.3.1.5. If patching and/or mending is performed, the textiles must be rewashed. (ANSI/AAMI ST65:2013; Std. 7.4.3) |
| Part III - 3.3.2. Rewashing surgical textiles |
| Part III - 3.3.2.1. If a reusable surgical textile requires rewashing, the procedure used must be compatible with the product. (ANSI/AAMI ST65:2013; Std. 7.4.3) |
| Part III - 3.3.2.2. Each rewash cycle must be counted as an additional life cycle for the item. (ANSI/AAMI ST65:2013; Std. 7.4.3) |
| Part III - 3.3.3. Rejuvenation of surgical textiles |
| Part III - 3.3.3.1. If reusable surgical textile products require rejuvenation or a laundry additive is used to maintain repellency, the process must be compatible with the textile product. (ANSI/AAMI ST65:2013; Std. 7.4.4) |
| Part III - 3.3.3.2. Additives that maintain surgical textile performance characteristics (e.g., repellency) must be used according to product instructions. (ANSI/AAMI ST65:2013; Std. 7.4.4) |
| Part III - 3.3.3.3. Rejuvenation cycles must be counted as additional life cycles. (ANSI/AAMI ST65:2013; Std. 7.4.4) |
| Part III - 3.3.4. Surgical textile retirement or alternate use: |
| Part III - 3.3.4.1. When reusable surgical textile products fail to meet their minimum functional performance criteria, they must be retired from use, downgraded to a less stringent alternate use category (e.g., cover gowns), or remade into a different product (e.g., a smaller wrapper). (ANSI/AAMI ST65:2013; Std. 7.4.5) |
| Part III - 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 ST65:2013; Std. 7.4.5) |
| Part III - 3.3.4.3. Items placed into alternate use must be permanently marked in some obvious fashion to prevent mix-ups or inappropriate use. (ANSI/AAMI ST65:2013; Std. 7.4.5) |
| Part III - 4. Preparation and Wrapping of Surgical Textiles |
| Part III - 4.1. Preparation |
| Part III - 4.1.1. Policies and procedures must be in place to ensure that reusable surgical textiles are laundered, dried, folded, and packed in a manner that will permit sterilization and delivered to the customer in a means such that the textiles maintain their hygienic integrity, avoiding contamination. (ANSI/AAMI ST65:2013; Std. 11.3) |
| Part III - 4.1.2. Preparation, folding, and packing procedures for reusable surgical textiles shall be developed with consultation from the customer and documented. (ANSI/AAMI ST65:2013; Std. 8.2) |
| Part III - 4.2. Folding |
Part III - 4.2.1. Reusable surgical textiles shall be folded and packaged properly and consistently each time they are processed in accordance with customer’s requirements. (ANSI/AAMI ST65:2013; Std. 8.2)

Part III - 4.2.2. Standards must be in place to identify the specific folds, components, and other details for each surgical pack built by the laundry. (ANSI/AAMI ST65:2013; Std. 8.2, 8.3.1)

Part III - 4.2.3. The following elements must be taken into account regarding the folding of clean, reusable surgical textiles: (ANSI/AAMI ST65:2013; Std. 8.3.1)

Part III - 4.2.3.1. Following inspection, all items must be folded in a manner that will allow them to be aseptically donned and/or presented to the sterile field with as little manipulation and chance of contamination as possible. (ANSI/AAMI ST65:2013; Std. 8.3.1)

Part III - 4.2.3.2. The method of folding must allow for effective penetration of the steam from the autoclave into the pack. (ANSI/AAMI ST65:2013; Std. 8.3.1)

Part III - 4.2.3.3. The method of folding must allow for easy identification and orientation of the items. (ANSI/AAMI ST65:2013; Std. 8.3.1)

Part III - 4.2.4. Clean reusable surgical textiles must be handled with clean hands in a manner to maintain their hygienic quality in accordance with Part I Subpart 5 Section 5.3 Element 5.3.3.3 of this HLAC Standard. (ANSI/AAMI ST65:2013; Std. 4.4, 9.2)

Part III - 4.2.5. Procedures for folding surgical textiles shall be reviewed as needed to ensure that they are still applicable with the customer. (ANSI/AAMI ST65:2013; Std. 8.3.1, 9.2)

Part III - 4.2.5.1. ANSI/AAMI ST65:2013 should be consulted for basic correct folding procedures in addition to customer’s requests and preferences. (ANSI/AAMI ST65:2013; Std. 8.3.1)

Part III - 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 ST65:2013; Std. 8.3.1)

Part III - 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 ST65:2013; Annex A: Examples of Folding Procedures)

Part III - 4.2.5.4. These photographs and/or drawings specifications shall be maintained in the surgical pack assembly room.

Part III - 4.3. Surgical Textile Pack Assembly

Part III - 4.3.1. Pack order, from top to bottom, must be developed in consultation with the customer to ensure that items can be removed from the pack, in the order of their use, without compromising the sterile field. (ANSI/AAMI ST65:2013; Std. 8.4)

Part III - 4.3.2. After the order of the pack is agreed upon, the pack configuration must be documented (i.e., pack master list and/or a device master record [DMR]). (ANSI/AAMI ST65:2013; Std. 8.4)

Part III - 4.3.3. The contents and order of each pack configuration shall be reviewed by the manager, who is responsible for pack assembly to ensure that the pack meets all appropriate requirements; documentation for each pack configuration shall be reviewed on a regular basis by the surgical pack assembly room manager with the customer. (ANSI/AAMI ST65:2013; Std. 8.4)

Part III - 4.4. Wrapping and Packaging

Part III - 4.4.1. The barrier product used to complete the pack and provide adequate coverage of the
contents must be appropriate for the method of sterilization (i.e., permits maximum penetration of the sterilant during sterilization) and must maintain the content's sterility until aseptic presentation. (ANSI/AAMI ST65:2013; Std. 8.5)

| Part III - 4.4.2. The customer shall be consulted in the choice of appropriate barrier product. |
| Part III - 4.4.3. The type of barrier used must be documented in the procedure (i.e., pack master list and/or a DMR). (ANSI/AAMI ST65:2013; Std. 8.5) |
| Part III - 4.4.4. The finished pack and bulk loose textiles must be packaged in a suitable material (e.g., placed in covered carts or wrapped in plastic) to avoid contamination during transport to the customer. |
| Part III - 4.5. Labeling and Identification of Packs |
| Part III - 4.5.1. Prior to delivery, assembled packs must have a label that includes the following items of information: |
| Part III - 4.5.1.1. Identification (e.g., name, Julian date, and unique pack identifier) |
| Part III - 4.5.1.2. Pack contents, including identifying any items containing natural rubber latex |
| Part III - 4.5.1.3. Identification or identifying barcode of who and date assembled the pack. (ANSI/AAMI ST65:2013; Std. 8.6) |

| Part III - 5. Storage and Transportation of Surgical Textile Packs |
| Part III - 5.1. Storage of Surgical Textile Packs |
| Part III - 5.1.1. Storage of Surgical Textile Packs must comply with Part I Subpart 2 Section 2.1. Element 2.1.3. and Part III Subpart 1 Section 1.6. of this HLAC Standard for statements addressing storage of clean surgical textile packs. |
| Part III - 5.2. Transportation of Surgical Textile Packs |
| Part III - 5.2.1. Transportation of surgical textile packs must be in accordance with Part II Subpart 7 of this HLAC Standard. |
| Part III - 5.2.2. Transport of the surgical textile packs within the provider’s facility or to the customer must be accomplished in a manner to maintain the hygienic quality of the packs and to minimize microbial contamination from surfaces or the air. (ANSI/AAMI ST65:2013; Std. 9.5.1) |
| Part III - 5.2.3. Clean carts or containers must be used for transport of clean surgical textile packs. (ANSI/AAMI ST65:2013; Std. 9.5.2) Refer to HLAC Standard Part II Subpart 7 Section 7.3. |
| Part III - 5.2.4. Carts or containers used for soiled surgical textiles must not be permitted in the surgical pack assembly room. |
| Part III - 5.2.5. Characteristics of carts or containers suitable for transporting clean surgical textile packs must be in accordance to Part II Subpart 7 Sections 7.1. and 7.3. of this HLAC Standard. |
| Part III - 5.2.6. Loading methods must be developed to ensure products are appropriately segregated and labeled to avoid contamination. (ANSI/AAMI ST65:2013; Std. 9.5.4.2) |

| Part III - 6. Surgical Textile Pack Assembly Room Personnel |
| Part III - 6.1. Qualifications |
| Part III - 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. |
| Part III - 6.1.2. Surgical pack assembly room procedures must be performed correctly and supervised by |
knowledgeable personnel. (ANSI/AAMI ST65:2013; Std. 4.1) Refer to HLAC Standard Part I Subpart 5 Section 5.2.

Part III - 6.2. Training and Competency

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

Part III - 6.2.2. Personnel must be trained on the appropriate pack processes according to each pack's use requirements. (ANSI/AAMI ST65:2013; Std. 4.3)

Part III - 6.2.3. Personnel must be trained to operate surgical pack assembly room equipment safely and to recognize and report equipment malfunctions. (ANSI/AAMI ST65:2013; Std. 4.3)

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

Part III - 6.2.4.1. Characteristics inherent to reusable surgical textiles;

Part III - 6.2.4.2. Uses of those textiles;

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

Part III - 6.2.4.4. Infection prevention relevant to the preparation of surgical textiles. (ANSI/AAMI ST65:2013; Std. 4.3.a-e)

Part III - 6.3. Health and Personal Hygiene

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

Part III - 6.3.2. Fingernails must be kept short, clean, natural, and healthy. (2014 AORN RP on Surgical Attire; ANSI/AAMI ST65:2013; Std. 4.4)

Part III - 6.3.2.1. Surgical pack assembly room personnel must not wear nail polish, artificial nails, or artificial eyelashes. (2014 AORN RP on Surgical Attire; ANSI/AAMI ST65:2013; Std. 4.4)

Part III - 6.3.3. Jewelry of any kind must not be worn in the surgical pack assembly room. (2014 AORN RP on Surgical Attire; ANSI/AAMI ST65:2013; Std. 4.4)

Part III - 6.3.4. Healthy skin integrity absent of abrasions, dermatitis or other skin breakdowns must be maintained. (2014 AORN RP Hand Hygiene; CDC HICPAC GL HH 5.A)

Part III - 6.4. Attire and Personal Protective Equipment (PPE)

Part III - 6.4.1. The basic elements pertaining to personnel attire must be in accordance with Part I Subpart 5 Section 5.4. of this HLAC Standard as appropriate. (ANSI/AAMI ST 65:2013; Std. 4.5.1)

Part III - 6.4.2. Personnel attire in the surgical pack assembly room must protect personnel and the integrity of the textile product. (ANSI/AAMI ST65:2013, Std. 4.5.1)

Part III - 6.4.2.1. All head and facial hair (excluding eyebrows and eyelashes) must be completely covered with a surgical-type hair covering. (ANSI/AAMI ST65:2013; Std. 4.5.1)

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

Part III - 6.4.2.2.1. When leaving the surgical pack assembly room, dedicated pack room personnel first must don the appropriate protective cover (e.g., cover gowns, shoe covers, hair covering, etc.) over their
| surgical pack assembly room attire and then must remove the appropriate protective cover (e.g., cover gowns, shoe covers, hair covering, etc.) that was over their surgical pack assembly room attire before re-entering the surgical pack assembly room in accordance with written facility policy. (AORN 2014 RP on Surgical Attire) |
| Part III - 6.4.2.3. Dedicated shoes and/or disposable shoe covers must be worn in the surgical pack assembly room. |