

PROPOSED 2009 HLAC Accreditation Standards Revision

May 09

2006 Initial HLAC Accreditation Standards

Part I. Basic Considerations

1. Textile Control Procedures

Textile products used in healthcare facilities shall be of a quality to ensure patient comfort and textile durability. Textile quality shall be defined per the contract between the provider and the customer. Defined quality standards shall keep mending and patching to a minimum. An inventory management system shall maintain established par schedules as agreed per the contract.

1.1 Textile Specifications

The provider shall have written textile specifications that meet customer needs and ensure consistent delivery. For customer-owned goods (“COG”), the customer may set these specifications in cooperation with the provider. These specifications shall be reviewed, at a minimum, annually by all affected parties.

1.2 Textile Maintenance: Repair and Replacement

1.2.1 Each plant shall have a documented grading system, outlining the grading standards for the healthcare textiles being processed, and it shall be accessible where workers may refer to it. These standards shall outline, which defects may be repaired, which defects require replacement, and the point at which previously repaired textiles should be discarded.

1.2.2 Plants processing COG textiles shall comply with pre-established textile maintenance standards as specified by each customer.

1.2.3 The provider shall ensure that all personnel having responsibility for making repair and replacement decisions understand and comply with the grading standards.

1.2.4 The provider shall maintain written training documentation on grading standards and repair and replacement policy, including the

1.2.4.1. Date,

1.2.4.2. Time,

DRAFT FOR OPEN COMMENT PERIOD 6/1/09 – 7/31/09

1.2.4.3. Topic,

1.2.4.4. Trainer, and

1.2.4.5. Proof of attendance.

1.3 Inventory Management

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

1.3.2 The user/customer shall conduct a linen inventory at least annually, with provider personnel involved, to ensure that par levels are being maintained and to adjust par levels as needed to meet changing textile use demands in the customer's facility (does not apply to COG).

2. Facilities

2.1 The laundry facility's physical layout and maintenance procedures shall ensure efficiency, minimize environmental contamination, and protect the material and hygienic integrity of the processed textiles.

2.2 Design Guidelines

2.2.1 If the laundry facility is sited within a healthcare facility (e.g., a hospital), the physical layout and utilities infrastructure shall be in accordance with the provisions of the edition of the American Institute of Architects (AIA), Guidelines in effect at the time of facility construction or renovation. [AIA 7.23 B1, B2]

2.2.2 The essential facility design consideration shall have a functional separation of areas that receive, store, or process soiled textiles from areas that process, handle, or store clean textiles.

2.2.2.1 The soiled textiles area must be functionally separated from the clean textiles processing area. Functional separation may be obtained by any one or more of the following methods:

2.2.2.1.1. Physical barrier;

2.2.2.1.2. Negative air pressure in the soiled textiles area; and/or

DRAFT FOR OPEN COMMENT PERIOD 6/1/09 – 7/31/09

2.2.2.1.3. Positive air flow from the clean textiles area through the soiled textiles area with venting directly to the outside. [AIA 7.23 B1, B2]

2.2.2.2 If storage of clean, unwrapped textiles is indicated, these items must be stored in clean areas with the following specifications:

2.2.2.2.1. Free of vermin;

2.2.2.2.2. Devoid of lint;

2.2.2.2.3. Temperatures ranging from 68°–78°F;

2.2.2.2.4. Properly ventilated to prevent accumulation of dust and lint (i.e., positive air exchange rate of 6–10 per hour);

2.2.2.2.5. Positive air pressure relative to adjacent spaces; and

2.2.2.2.6. No drains or hot water pipes placed in this area.

2.2.2.3 Shelves for storing clean textiles shall be placed as per the ANSI/AAMI Standards: [ANSI/AAMI ST65:2000 9.6.2]

2.2.2.3.1. Shelves will be approximately 1–2 inches from the wall for accessible cleaning;

2.2.2.3.2. The bottom shelf shall be 6–8 inches from the floor; and

2.2.2.3.3. The top shelf shall be 12–18 inches below the ceiling.

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

2.2.4 Traffic patterns shall be planned and posted to minimize the potential for contaminating clean textiles. Traffic in all areas of the facility shall be limited to authorized personnel only as outlined in the provider's policies and procedures.

2.2.5 Handwashing facilities must be located in all areas where soiled or contaminated

DRAFT FOR OPEN COMMENT PERIOD 6/1/09 – 7/31/09

textiles are handled. Hand hygiene resources (i.e., handwashing facilities or antiseptic hand cleaner/cleaner dispensers) must be available in or around all work areas and in personnel support areas. [OSHA 29 CFR 1910.1030 §d.2.iii, iv; HICPAC Hand Hygiene guideline: 1 A-N]

2.2.6 Emergency eyewash/shower equipment must be available with unobstructed access (i.e., requiring no more than 10 seconds to reach) for immediate emergency use in all areas where soiled healthcare textiles are being processed, chemicals are used and/or stored, or where there is a potential for contact with blood or other potentially infectious material. [ANSI Z358.1-1998; OSHA 29 CFR 1910.1030 § d.2.i, ii]

2.3 Maintenance guidelines

2.3.1 Maintenance of equipment and spaces in a laundry facility processing healthcare textiles shall follow documented company policies and procedures with emphasis in two areas:

2.3.1.1 Soiled healthcare textiles must be kept functionally separated from clean textiles at all times.

2.3.1.2 Upon completion of processing, clean textiles shall be maintained as clean until delivered to the user's storage area. (Also see Part II, Section 5.)

2.3.2 The physical environment (e.g., floors, walls, ceilings, vents, working surfaces, and installed equipment) shall receive scheduled cleaning appropriate for the surface. The cleaning schedule shall be maintained on a current basis and posted for inspection.

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

2.3.2.2 Working surfaces (e.g., counters, bench tops, and table tops) must be kept clean of visible soil, dust, and lint through use of a detergent/cleaner and water. [OSHA: 29.CFR 1910.1030 § d.4.ii; CDC/HICPAC: EIC E.I.E.2]

2.3.2.3 Working surfaces that become contaminated with blood or other potentially infectious material (OPIM) must be decontaminated, cleaned, and disinfected. Use EPA-registered hospital disinfectants labeled tuberculocidal or registered germicides on the EPA Lists D and E (i.e., products with specific label claims for HIV or hepatitis B virus [HBV] and follow label instructions. [EPA: 7 USC § 136 et seq; OSHA: 29 CFR 1910.1030 § d.4.ii.A; CDC/HICPAC: EIC E.I.A, II.A-D]

DRAFT FOR OPEN COMMENT PERIOD 6/1/09 – 7/31/09

2.3.2.4 When disinfecting working surfaces that may be contaminated with patient body substances other than blood or OPIM, use an EPA-registered hospital disinfectant in accordance with the manufacturer's instructions.

2.3.2.5 Contaminated work surfaces shall be decontaminated with an EPA-registered disinfectant after completion of procedures; immediately or as soon as feasible when surfaces are visibly contaminated or after any spill of blood or other potentially infectious materials; and at the end of the work shift if the surface may have become contaminated since the last cleaning. [CDC/HICPAC: EIC E.IA; EPA: 7 USC § 139 et seq]

2.3.3 Pest control program. The laundry shall have a documented and implemented Integrated Pest Management (IPM) Program.

2.4 Environmental Monitoring Procedures

2.4.1 Systems and procedures shall be in place to ensure that the facility's use of air, water, chemicals, and other materials is in compliance with federal, state, and local regulations. Efforts to adopt Hospitals for a Healthy Environment environmental recommendations are encouraged.

2.4.2 Using methodology stated in local, state, and federal regulations, environmental monitoring results shall be properly documented.

3. Contingency Planning

3.1 Contingency planning provides for uninterrupted operations and services in the event of any occurrence potentially leading to serious disruption of facility operations. Such disruption may include, but is not limited to, loss of utilities, medical emergencies, natural and/or man-made disasters, fire, inclement weather, work stoppage, or major accidents. The contingency plan shall include the following components:

3.1.1. Plant and transportation contingency protocol,

3.1.2. Call chain, and

3.1.3. A list of backup facilities.

3.2 Plant Contingency Protocol

DRAFT FOR OPEN COMMENT PERIOD 6/1/09 – 7/31/09

3.2.1. A written protocol shall provide a step-by-step procedure in the event of an emergency and shall be available to every supervisor who may be responsible for execution of the protocol.

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

3.3. Contingency Call Chain

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

3.3.2. The call chain shall be maintained by a designated person, who is responsible for updating and distributing the revised list when personnel changes occur.

3.4. Backup Facility Agreements

3.4.1. The operator shall have written agreements in place with one or more alternate laundry facilities, detailing when and how these facilities will process textiles in an emergency.

3.4.2. The operator shall have written agreements in place with one or more alternate transportation providers, detailing the response time and services provided.

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

4. Personnel and Hiring Procedures

4.1. All provider personnel shall be qualified for their positions through education, training, or level of prior experience. These qualifications shall be documented in employee files. New employees shall work under the close supervision of qualified employees until they have achieved qualified status.

4.2. The provider shall follow documented company hiring policies and procedures. These policies and procedures may include background checks and drug testing as part of the hiring process.

DRAFT FOR OPEN COMMENT PERIOD 6/1/09 – 7/31/09

5. Occupational Safety and Hygiene

5.1. OSHA Required Practices: Bloodborne Pathogen (BBP) Standard. Universal (Standard) Precautions program to prevent contact with blood or OPIM must be implemented.

[OSHA: 29 CFR 1910.1030]

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

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

5.1.1.2. Procedure for evaluating the circumstances surrounding exposure incidents.

5.1.1.3. Employers shall develop an Exposure Determination Plan (EDP). The EDP shall contain:

5.1.1.3.1. A list of all job classifications in which all employees in those job classifications have occupational exposure,

5.1.1.3.2. A list of job classifications in which some employees have occupational exposure and

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

5.1.1.4. The Plan is accessible to all employees.

5.1.1.5. The Plan is reviewed and updated at least annually. [OSHA: 29 CFR 1910.1030 (c) (1) (2)]

5.1.2. Develop a hepatitis B vaccination program.

5.1.2.1. Records must reflect the offering and the acceptance OR documented refusal of the employee.

5.1.2.2. Records must reflect a standing process for post exposure management for blood and/or OPIM. [OSHA: 29 CFR 1910.1030 (f)]

5.2. General Occupational Safety

DRAFT FOR OPEN COMMENT PERIOD 6/1/09 – 7/31/09

5.2.1. Provider personnel shall adhere to good work practices to minimize or eliminate exposures to blood and OPIM. This includes the use of personal protective equipment (PPE) when handling contaminated and soiled textiles, the safe operation of equipment, documentation of OSHA Lock-Out Tag-Out requirements, hazard communications, safe transportation, and the proper handling of textiles.

5.2.2. Provider personnel shall handle chemicals safely in accordance with Material Safety Data Sheets (MSDS) in the laundry facility.

5.2.3. Eating, drinking, smoking, applying cosmetics or lip balm, and handling contact lenses are prohibited in work areas where there is a reasonable likelihood of occupation exposure to BBP. [OSHA: 29 CFR 1910.1030 (d) (2) (A) (ix)]

5.2.4. The provider shall have policies and procedures, addressing the health status of laundry workers, such as, but not limited to, illness, open wounds or sores, and skin injuries, to prevent contamination of healthcare textiles.

5.3. Hand hygiene

5.3.1. Provider personnel must practice hand hygiene after glove removal, after restroom use, before eating, and when hands become inadvertently contaminated with blood or other body substances. [HICPAC: Hand Hygiene guideline: 1 A-N.]

5.3.2. Employees responsible for packing, wrapping, storing, or transporting clean textiles shall maintain proper hand hygiene at all times. [HICPAC: Hand Hygiene guideline: 1 A-N.]

5.4. Clothing, uniforms, and personal protective equipment (PPE)

5.4.1. All personnel shall wear dry garments without visible soil or dirt in accordance with the company's policies. For safety reasons, loose or dangling jewelry shall not be worn. Hair coverings shall be used where deemed appropriate and/or within written company policy.

5.4.2. The provider must supply the PPE to personnel in the workplace. Contaminated disposable PPE (e.g., gloves) must be discarded into appropriately labeled (e.g., biohazard) waste containers. Reusable PPE (e.g., cloth aprons or overalls) shall be routinely laundered as per company policy and when soiled or contaminated.

5.4.3. Employees who handle clean or soiled healthcare textiles shall change work garments

DRAFT FOR OPEN COMMENT PERIOD 6/1/09 – 7/31/09

daily and whenever their garment becomes soiled.

5.4.4. If a garment is penetrated by blood or other potentially infectious materials, the garment(s) shall be removed immediately or as soon as feasible and be laundered by the employer. All PPE shall be removed prior to leaving the work area. [OSHA: 29 CFR 1910.1030 (d) (iii)]

5.4.5. Employees responsible for packing, wrapping, storing, or transporting clean textiles shall always be in attire free of visible soil and dirt.

6. Training

6.1. All provider personnel shall receive safety training in all aspects of laundry operations applicable to their respective position(s).

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

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

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

6.2. Training and educational programs must be provided to all personnel with reasonably anticipated potential exposure to blood or other possibly infectious materials.

6.2.1. Training topics relevant to Bloodborne Pathogens Exposure Control include, but are not limited to:

6.2.1.1. Personal hygiene and proper handwashing/hand hygiene techniques;

6.2.1.2. Use of PPE including, but not limited to, gloves, gowns, laboratory coats and masks;

6.2.1.3. Engineering controls and work practices to minimize the risk of exposure to blood or other potentially infectious materials;

6.2.1.4. Orientation on the provider's exposure control program; and

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

DRAFT FOR OPEN COMMENT PERIOD 6/1/09 – 7/31/09

6.2.2. All vehicle drivers must meet all requirements of the state/federal Department of Transportation (DOT) in which services are provided. In addition, drivers who carry and handle healthcare textiles must receive Bloodborne Pathogens Exposure Control training.

6.2.3. Plant employees shall receive the company's standard training for safe operation of equipment and correct handling of textiles, including the need to keep textiles clean.

6.3. Training Documentation

6.3.1. All training must be documented in writing and kept on file. It is recommended that training records be kept on file for as long as an employee is employed. The documentation shall include, but is not limited to:

6.3.1.1. Dates and times of training;

6.3.1.2. Topic;

6.3.1.3. Trainer's name, signature and qualifications;

6.3.1.4. Copies of printed training materials; and

6.3.1.5. Certificates or signature proof of trainees' attendance.

6.3.2. Documentation of on-line or web-based training is also acceptable.

6.3.3. Documentation shall also include validation that the training objectives and a minimum level of competency were achieved.

7. Quality Control and Process Monitoring

7.1. Quality Control. The entire processing cycle shall have documented quality control procedures to ensure the cleanliness and serviceability of the textiles. These procedures may include requirements to rewash, repair, or replace textiles as necessary to maintain quality standards.

7.2. Quality Assurance

DRAFT FOR OPEN COMMENT PERIOD 6/1/09 – 7/31/09

7.2.1 The provider shall have written policies and procedures, covering all areas of responsibility relating to services provided to the user.

7.2.2. The provider shall maintain records of any problems experienced and mutually agreed upon solutions. A customer call log may be used for this purpose.

7.2.3. The provider and user shall periodically review the entire service program and make adjustments as necessary and appropriate. This may be accomplished through monthly reports or regularly scheduled meetings with user personnel. Adjustments should be documented and filed for future use or reference.

7.3. Process Monitoring. Process monitoring verifies that the ongoing laundry operation is producing clean textiles that will meet customer expectations and needs.

7.3.1. Written procedures shall describe in detail the process monitoring “checklists.” Process monitoring checklists shall include, but are not limited to, the following:

7.3.1.1. Supplies. Verify that laundry chemicals are appropriate for the equipment in accordance with the equipment manufacturer, textile classifications, and water temperatures being used. **Every chemical used must have a MSDS on file, and an appropriate label on every container into which it is placed in accordance with OSHA Hazard Communications Standard.** [OSHA: 29 CFR 1910.1200]

7.3.1.2. Water. Incoming water shall be tested on a regular basis for hardness, alkalinity (active and total), iron content, and pH. At a minimum, testing shall take place once per month or more often during periods of abnormal water conditions. The laundry washing formulas may require adjustment based on these factors.

7.3.1.3. Load size. Load size shall follow the equipment manufacturer’s recommendations. Each load shall be weighed using a calibrated scale. 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.

7.3.1.4. Equipment. All laundry equipment shall be included in the company’s Preventive Maintenance (PM) Program and checked on a regular basis as defined by the manufacturer for proper operation. Typically, a chemical titration and service report from the facility’s chemical suppliers’ technician will have all this information. Some automatic equipment dispensers can also record the chemical injection amounts and times by classification.

DRAFT FOR OPEN COMMENT PERIOD 6/1/09 – 7/31/09

7.3.1.5. Finished products. 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. A variety of process monitors may be used to indicate how the laundry process has performed. These may include rewash rates, color transfer, pH spot tests, residual chlorine spot tests, and laundry test pieces. At a minimum, monthly titrations shall validate that the chemistry of the wash is correct, according to the formula for each major classification of soil.

7.4. Counting and billing accuracy. The provider shall have reliable and accurate procedures to weigh and/or count textiles and have accurate billing procedures based on these weights or counts. The customer shall have previously agreed in writing to these procedures.

8. Customer Service

8.1. Contact with customers

8.1.1. On a periodic basis, but no less than once per year, authorized provider representative(s) shall visit customers' healthcare facilities, for the purpose of conducting a walk-through of all areas where healthcare textiles are used, collected, transported or stored. They shall meet with facility representatives to determine the textile products used, expected textile usage, and their service expectations.

8.1.2. Provider shall maintain a written list of all customer contacts.

8.1.3. Provider shall maintain a written log of issues or problems with users, including names of personnel involved, and the resolution.

8.2. Visits to laundry facility. Providers shall make their plants available to customers and prospective customers for inspection.

Part II. The Textile Processing Cycle

1. Handling, Collection and Transportation of Soiled Healthcare Textiles

1.1. All healthcare textiles must be handled and collected in accordance with OSHA regulations and federal guidelines, thereby minimizing potential exposure of patients, hospital personnel, or

DRAFT FOR OPEN COMMENT PERIOD 6/1/09 – 7/31/09

laundry personnel to bloodborne pathogens or other infectious agents. [OSHA: 29 CFR 1910.1030 § (d) (4) (iv); CDC/HICPAC EIC F.III]

1.2. All soiled healthcare textiles must be assumed to be contaminated, and Universal Precautions (an OSHA term) must apply at all times to all personnel who handle soiled textiles. Standard Precautions (a CDC term) may apply as determined by either the customer or the provider.

1.3. Handling soiled textiles at the points of generation and/or collection

1.3.1. The collection of soiled textiles begins at the point (or points) of collection designated in writing by the customer.

1.3.2. Soiled textiles shall be collected and handled only as necessary to complete the defined tasks and in such a way as to minimize microbial contamination of the air and the personnel handling the textiles. **Soiled textiles must not be sorted or rinsed in patient care areas.** [OSHA: 29 CFR 1910.1030 (d) (4) (iv) (A) (1)]

1.4. Containment of soiled textiles

1.4.1. Universal (or Standard) Precautions shall be followed during containment of soiled or contaminated textiles.

1.4.2. The collection bags or containers must functionally contain wet or soiled textiles, preventing contamination of the environment during collection, transportation, and storage prior to processing. The containers must not tear when loaded to capacity, be leak-proof, and be capable of being closed securely to prevent textiles from falling out.

1.4.3. The bags or other containers must be specially color-coded or labeled. If only soiled healthcare textiles are coming into the laundry and all personnel are following Universal (or Standard) Precautions when handling these textiles, the bags do not need to be color-coded or labeled. [OSHA: 29CFR1910.1030 (d)(4)(iv)(A)(2)]

1.5. Medical waste. The provider must have a written plan with the user, detailing the procedures to follow when medical waste is found among soiled healthcare textiles. The plan must be in accordance with state medical waste regulations.

1.6. The service provider shall follow the customer's policy for returning items found among healthcare textiles that contain personal patient information.

DRAFT FOR OPEN COMMENT PERIOD 6/1/09 – 7/31/09

1.7. Functional Separation of Clean from Soiled Textiles. The provider must maintain functional separation of clean from soiled textiles in carts and/or vehicles at all times during collection and transportation of soiled textiles.

1.8. Observe Universal (or Standard) Precautions while moving, loading, and unloading soiled textiles.

2. Sorting

2.1. Soiled sorting area: The physical environment must comply with any applicable local, state, or federal regulations as per statements in Part I, Section 2.2 of this Accreditation Standard.

2.2. The physical environment in the soiled sorting area shall be cleaned and disinfected as indicated in Part I, Section 2.3, Subsection 2.3.2 of this Accreditation Standard.

2.3. All personnel who handle soiled healthcare textiles must follow Universal (or Standard) Precautions to prevent contact with blood or other potentially infectious or hazardous materials. Under Universal (or Standard) Precautions, all soiled healthcare textiles coming into a laundry are treated as contaminated.

2.4. Soiled textiles shall be sorted into appropriate wash loads by classification such as color, type of fabric, soil type or soil load, and/or type of goods (e.g., diapers, sheets, or patient gowns) for each laundry formula used.

2.5. Sharps Policy. The provider shall maintain a written sharps policy that includes, at a minimum:

2.5.1. Appropriate sharps safety containers (closable, puncture resistant, leakproof on sides and bottom, and labeled or color-coded) in accordance with OSHA standards shall be located near soil handling or sorting stations for collection and proper disposal of sharps. [OSHA: 29 CFR 1910.1030 (g) (1) (i)]

2.5.2. Any worker who is injured by a sharp shall follow OSHA's policy on sharps injury documentation, post-exposure evaluation, and follow-up. [OSHA: 29 CFR 1910.1030 (f) (3)]

3. Washing, Extraction and Drying

DRAFT FOR OPEN COMMENT PERIOD 6/1/09 – 7/31/09

3.1. The wash process shall ensure that healthcare textiles become hygienically clean.

3.2. Equipment Considerations. Three basic types of washing equipment are used in the processing of healthcare textiles: Washers, Washer/Extractors, and Continuous Batch Washers. Depending on the equipment in use at the facility, modifications in these requirements and other factors affecting the process shall be necessary to assure that agreed upon quality standards are consistently met. If modifications are indicated, the laundry facility shall document these modifications, date them, and revise as needed as equipment needs change.

3.3. The Wash Process

3.3.1 The load size (weight) for each classification of soil shall be established by the facility and shall be recorded for each load processed.

3.3.2. The wash cycle shall comply with all applicable state and local requirements for healthcare textile processing.

3.3.2.1. Each classification shall have established standards for the following factors:

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

3.3.2.1.2. Water levels/usage: Total water usage and/or water levels.

3.3.2.1.3. Temperature: Wash cycle, bleach cycle, and rinse cycle temperatures.

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

3.3.2.2. Quality Assurance. Each classification shall be evaluated and/or tested to assure that items 3.3.2.1.1.-3.3.2.1.4. meet the established standards.

3.4. Extraction and Drying. The provider shall extract or dry the clean healthcare textiles in a manner that preserves the integrity of the textile merchandise, minimizes microbial growth after washing, and prepares the textiles for efficient ironing or folding. Damp textiles shall not be left in machines overnight.

[CDC/HICPAC: EIC G.II, III]

4. Finishing. The finishing process of ironing or folding textiles shall ensure that the merchandise is

DRAFT FOR OPEN COMMENT PERIOD 6/1/09 – 7/31/09

maintained in the same clean state that it emerged from washing. The ironing or folding procedures shall meet the needs and expectations of the user. If any textiles become soiled in this process, they shall be rewashed as outlined above.

4.1. Equipment Considerations

4.1.1. Ironing equipment shall be maintained in good operating condition, so that it adequately irons, dries, and folds the textiles without excessive heat, pressure, or mechanical damage. The equipment shall maintain a temperature of at least 300 degrees on the ironer chests.

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

5. Packaging and Storage. Packaging and storage of healthcare merchandise shall preserve the textiles in a clean state for delivery to the customer as outlined in the service agreement.

5.1. The textiles may be wrapped into fluid-resistant bundles or placed bundled, but unwrapped, into fluid-resistant covered carts or hampers. The wrapping material may be plastic or other suitable material and shall be securely closed during transport to the customer.

5.2. During packaging, textiles shall be handled as little as possible to prevent soiling or contamination.

5.3. If unwrapped merchandise is placed into carts or hampers and covered, the container shall remain covered at all times until delivered to the user's textiles storage room or other designated location in the healthcare facility. **If the cart does not have a solid bottom, it must be lined with heavy plastic or impervious paper before placing clean textiles inside.**

5.4. Bundled and wrapped textiles may be stored in open racks in the laundry, on the trucks, or at the user's facility, provided the integrity of bundled and wrapped textiles is not compromised.

5.5. Unwrapped clean textiles may be stored in rooms designed as whose specifications are given in Part I Section 2.2 Subsections 2.2.2.2 and 2.2.2.3 of this Accreditation Standard.

5.5.1. A schedule of cleaning, including floor and shelves, shall be in writing.

5.5.2. Storage room shall only be accessible to appropriate personnel.

DRAFT FOR OPEN COMMENT PERIOD 6/1/09 – 7/31/09

5.5.3. Only clean linens shall be stored in this area and signage posted as “Linen storage room.”

5.5.4. Door shall remain closed at all times.

5.6. If any textiles become soiled during packaging and storage, they shall be reprocessed in accordance with previously stated processing guidelines.

6. Delivery of Cleaned Healthcare Textiles

6.1. Functional separation of clean from soiled textiles shall be maintained during transportation by:

6.1.1. Bagging soiled textiles in fluid-resistant containers

6.1.2. Anchoring soiled textiles in the vehicle, so that they do not spill from their containers.

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

6.1.4. Ensuring that all employees with this responsibility follow Universal (or Standard) Precautions at all times.

6.2. Textile containment issues

6.2.1. Clean and soiled textiles shall not be stored in the same container.

6.2.2. Containers used for the collection of soiled textiles may be returned for use for clean textiles, if allowed by state regulations, after cleaning in accordance with the provider’s policies and procedures.

6.3. Vehicle considerations

6.3.1. Clean and soiled textiles may be transported in the same vehicle, provided proper and effective functional separation of clean from soil is maintained at all times. Separation may be accomplished by the use of physical barriers and/or space separation sufficient to protect clean textiles from contact with soiled textiles.

DRAFT FOR OPEN COMMENT PERIOD 6/1/09 – 7/31/09

6.3.2. The interior of the vehicle's cargo trailer used to transport healthcare textiles shall be cleaned on a regular basis as per company policy or whenever visibly soiled.

6.3.3. Vehicles used to transport healthcare textiles shall have waterless antibacterial hand cleaner on board for the purpose of hand hygiene. If visible soil is apparent, drivers shall use utility gloves to minimize contact with the soil. Handwashing with soap and water is required at the earliest opportunity upon removal of the utility gloves.

6.4. Proper Use of Carts

6.4.1. When the cart contains clean textiles, the textiles shall be wrapped inside the cart or if unwrapped, the cart shall be lined with plastic or heavy paper and securely covered.

6.4.2. If a cart used to transport clean textiles appears soiled, it shall be cleaned as outlined in Part II Section 6 Subsection 6.4.5 of this Accreditation Standard.

6.4.3. Any time a cart has transported soiled textiles, it must be cleaned before any next use, whether to transport clean or soiled textiles. Reusable textile cover materials, such as liners, must be washed before the next use.

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

6.4.5. Containers and covers used to collect or transport soiled textiles shall be properly cleaned. Proper cleaning may include:

6.4.5.1. Steam cleaning.

6.4.5.2. Cleaning with an EPA-registered detergent/disinfectant.

6.4.5.3. Reusable textile covers may be washed and dried.

NOTE: The following Part III. Surgical Pack Assembly Room Standards are proposed for inclusion in the next version of the HLAC Accreditation Standards. Please comment on them as you did on Part I and Part II of the HLAC Accreditation Standards.

Part III. Surgical Pack Assembly Room Standards

DRAFT FOR OPEN COMMENT PERIOD 6/1/09 – 7/31/09

1. Surgical Pack Assembly Facilities

The physical layout of the space and its engineering support are adequate for the performance of the job functions necessary to properly produce reusable surgical pack textiles.

(ST65:2000 Standard 3.4.1)

1.1. Floors, Walls, and Ceilings

1.1.1. Floors, walls, and ceilings of the pack assembly room should be able to withstand the moist environment and high humidity of the laundry environment and can withstand scheduled wet cleaning.

1.1.2. No particulate or fiber-shedding materials are to be used in the construction of this room.

1.1.3. Ceilings should be flush with recessed and enclosed fixtures to limit dust accumulation and withstand scheduled wet cleaning.

1.2. Separation of Work Areas

1.2.1. The pack room assembly area should be designed to allow for separation by physical barrier from the area where soiled textiles are received and/or processed. (ST65:2000 Standard 3.2.3.1)

1.2.2. Within the surgical pack assembly area, walls or partitions serve as physical barriers to separate functional work areas and to reduce the possibility of contamination of the surgical textiles.

1.3. Ventilation Requirements and Climate Control

(Conforms with AIA 2006.2.1; 10.2.1; Table 2.1.2./ASHRAE 2003-4)

1.3.1. Direction of air flow is from clean to soiled areas and then exhausted to the outside. (ST65:2000 Standard 3.3.4)

1.3.2. Heating, ventilation, and air conditioning (HVAC) system shall be designed to conform to AIA standards in effect at the time when the facility is built or renovated.

1.3.2.1. A minimum of 10 air changes per hour (ACH) should be achieved.

1.3.2.2. The HVAC system should be a down-draft system for air circulation within the space. (ST65:2000 Standard 3.4.2 – 3.4.4)

1.3.2.3. Return air registers (i.e., exhaust ducts) should be at or near floor level. (ST65:2000 Standard 3.4.2 – 3.4.4)

1.3.2.4. Portable fans are not permitted in the surgical pack area. (ST65:2000 Standard 3.4.2 – 3.4.4)

DRAFT FOR OPEN COMMENT PERIOD 6/1/09 – 7/31/09

1.3.2.5. Supply air for the pack room area is filtered as indicated in the AIA standard, with the filters undergoing scheduled regular maintenance as determined by the HVAC system engineer. (ST65:2000 Standard 3.4.2 – 3.4.4)

1.3.2.6. Temperatures in the pack room area should be maintained between 68° F - 73°F to ensure a comfortable work environment for personnel in appropriate work attire. (ST65:2000 Standard 3.4.5)

1.3.2.7. Relative humidity (RH) in the pack room area should be kept between 30% - 60% (not to exceed 70%) for personnel comfort and to discourage microbial (e.g., fungal) growth. (ST65:2000 Standard 3.4.5)

1.4. Lighting systems in the surgical pack assembly room area should be appropriate for the task. (ST65:2000 Standard 3.4.6)

1.4.1. High intensity lighting should be available in that part of the room or area where textiles are examined.

1.4.2. Lower intensity overhead lighting might be required for areas where light-table inspection is performed, so that the table back lighting can be used optimally. (ANSI/IESNA RP-29)

1.5. Handwashing facilities should be located near all work areas and personnel support areas, and should include sinks, single-use towels, and handwashing supplies. (ST65:2000 Standard 3.4.7)

1.6. Storage area for clean textile packs should be designed and managed in accordance with FDA regulations (21 CFR 820.140 and 21 CFR 820.150). (ST65:2000 Standard 3.4.8, 3.4.9)

1.6.1. Storage shelving should be closable or in covered cabinets and maintained in a manner to ensure the integrity of the textile products. (ST65:2000 Standard 9.6.2)

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

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

1.7. Sanitation and Maintenance

1.7.1. Floors, walls, ceilings, work surfaces, and equipment should be constructed of materials that will tolerate frequent cleaning with detergents and disinfection as appropriate.

1.7.2. Facility has policy and procedures in place for a schedule of regular wet cleaning, including blow down.

DRAFT FOR OPEN COMMENT PERIOD 6/1/09 – 7/31/09

2. Pack Room General Policies

Note: Policy statements addressing specific laundry processes are located with that process topic.

Policies should be developed, placed on file, and reviewed annually, addressing a safe and efficient work environment, competency of the workforce, and quality assurance of the textile product.

2.1. Access to the surgical pack assembly area is restricted to authorized personnel only. (ST65:2000 Standard 3.4.2)

2.1.1. Employees should have work-issued identification.

2.1.2. Visitor access requires compliance with policies and procedures, establishing a dress code to reduce the potential for contamination of surgical textiles. (ST65:2000 Standard 3.4.2)

2.2. Employee attire should protect both the worker and the integrity of the textile product.

2.2.1. Facility shall establish an employee dress code and develop policies for use of personal protective equipment (PPE). (ST65:2000 Standard 4.5.1)

2.2.2. Employees change their attire and/or PPE when soiled or wet, using proper removal techniques as appropriate for PPE. (ST65:2000 Standard 4.5.1)

2.2.3. Employees shall remove PPE (e.g., gloves, protective garments) before eating, before restroom use, or leaving the work area.

2.2.4. Visible jewelry (e.g., especially items worn on wrists, hands, neck, ears, etc.) should not be worn in the area while working.

2.2.5. Fingernails should be kept short, clean, natural, and healthy. Neither nail polish nor artificial nails should be worn. (2009 AORN RP on Surgical Attire)

2.3. Employee Health and Safety

2.3.1. Policies and procedures are in place to comply with safety elements of the OSHA General Duty Clause (29 USC 654 OSHA 1970 Section 5 Duties (a)) (ST65:2000 Standard 4.5.2)

2.3.2. Policies and procedures, in collaboration with the Infection Control, Employee Health, and/or medical provider, address basic hygiene, prevention, illness, injury, work restrictions, return to work for employees. (CDC Guideline in Infection Control for Health Care Workers, 1998)

2.3.3. Policies are in place for management of occupational exposures of employees to infectious diseases and include the following elements: (29 CFR 1910.1030)

DRAFT FOR OPEN COMMENT PERIOD 6/1/09 – 7/31/09

2.3.3.1. Risk assessment to identify potential hazards;

2.3.3.2. Prevention measures, including PPE;

2.3.3.3. A mechanism for employees to report injuries and exposures;

2.3.3.4. Post-exposure evaluation; and

2.3.3.5. The means to provide or support post-exposure intervention and/or medical treatment. (ST65:2000 Standard 4.4)

2.3.4. Employees consistently practice handwashing as outlined in Part I Section 5: Occupational Safety and Hygiene Subsection 5.3 Hand Hygiene of this Accreditation Standard. (ST65:2000 Standard 4.4)

2.3.5. Cuticles, hands, and forearms should be free of open lesions and breaks in skin integrity. (2009 AORN RP Hand Hygiene in Perioperative Setting)

2.3.6. Sharps are discarded into sharps containers that are placed in locations that are easily accessible in work areas. (ST65:2000 standard 4.4) (29 CFR 1910.1030)

2.3.7. Policies and procedures are in place to assure compliance with the OSHA Hazard Communication Standard: (29 CFR 1010.1200)

2.3.7.1. Material safety data sheets (MSDS) for the cleaning and disinfecting chemicals used are on file and available for inspection upon request.

2.3.7.2. Secondary containers are labeled as to date and the identity of the contents.

2.3.8. Facility complies with CDC recommendations for prevention and control of tuberculosis in the workplace.

2.3.8.1. Facility shall have documentation that the state TB screening and prevention department have been consulted for determination if TB screening should be done on premises. (CDC Guidelines for Preventing *Mycobacterium tuberculosis* in Healthcare Settings, 2005)

2.4. General Administrative Policies

2.4.1. Laundry supervisors/managers should ensure that tasks are performed by qualified individuals. (ST65:2000 Standard 4.2.1)

2.4.2. Clearly defined job descriptions for all employees, including front-line supervisors, are in place and include qualifications, responsibilities, and assignments.

DRAFT FOR OPEN COMMENT PERIOD 6/1/09 – 7/31/09

2.4.3. Facility/customer contracts are on file, signed by both entities and dated, and specify the process details and extent of service for the contract period.

2.4.4. Written standards are in place to identify the specific folds, components, and other details for each surgical pack built by the healthcare laundry.

2.4.4.1. These specifications shall be provided by and/or approved by the hospital or healthcare facility for which the surgical packs are being built.

2.4.4.2. These specifications shall be documented using photographs or drawings with accompanying instructional notations and include a photograph/drawing of the finished product.

2.4.4.3. These photographs and/or drawings specifications shall be maintained in the surgical pack assembly room for staff use.

3. Training and Competency

All employees of the facility, including supervisors/managers, will receive task-specific training and competency will be demonstrated and documented.

3.1. Administrative Issues and Training

3.1.1. Competency programs are designed to provide personnel, including supervisors/managers, with training that is necessary and job/task specific. (ST65:2000 Standard 4.2.1, 4.2.2)

3.1.2. Training records and copies of training materials should be maintained according to industry guidelines and recommendations.

3.1.3. Training records should include the following items: (ST65:2000 Standard 4.3)

3.1.3.1. Date of training session

3.1.3.2. Name and title of the trainer

3.1.3.3. Content

3.1.3.4. Signature of the trainee

3.1.3.5. Verification of comprehension (e.g., post-testing)

3.1.3.6. Documentation of competency

3.2. Training should address methods of infection control relevant to the preparation of surgical textiles. (ST65:2000 Standard 4.3b)

DRAFT FOR OPEN COMMENT PERIOD 6/1/09 – 7/31/09

3.3. Training programs shall meet the requirements of pertinent OSHA standards, Department of Homeland Security (DHS) regulations, and CDC guidelines:

3.3.1. Employees receive training regarding bloodborne pathogens, handling hazardous drug-contaminated linen, and general hazardous materials awareness. (29 CFR 1910.1030 and 29 CFR 1010.1200)

3.3.2. Employees and supervisors receive training about the management of chemicals subject to the DHS regulations. (6 CFR 27, subpart B)

3.3.3. Employees are trained in prevention and control of occupational tuberculosis. (CDC Guidelines for Preventing *Mycobacterium tuberculosis* in Healthcare Settings, 2005)

3.3.4. Facility shall have documentation that the state department for TB Screening and Prevention Program has been consulted for determination if TB screening should be done on premises. (CDC Guidelines for Preventing *Mycobacterium tuberculosis* in Healthcare Settings, 2005)

3.4. Employees should be thoroughly trained to operate the surgical pack assembly area equipment safely and to recognize and correct equipment malfunctions.

3.5. Employees should be thoroughly trained to work with surgical textiles and to be familiar with the following:

3.5.1. The characteristics inherent to reusable surgical textiles, the uses of those textiles, and the processes required to maintain those qualities; (ST65:2000 Standard 4.3c)

3.5.2. Adherence to the textile label instructions for laundering and processing;

3.5.3. Sorting, washing, inspections, folding, preparations of the surgical packs, storage, and transport. (ST65:2000 Standard 4.3d)

4. Preparation and Packaging

Policies and procedures are in place to ensure that reusable surgical textiles are laundered, dried, folded, packed, and delivered to the customer in a manner such that the textiles maintain their hygienic integrity, avoiding contamination. (ST65:2000 Standard 9.2)

4.1. Products composed of 100% cotton or a cotton blend are adequately dried prior to folding and packing to ensure successful sterilization. (ST65:2000 Standard 6.3.1)

4.2. When new textiles are injected into the system,

4.2.1. New textiles are removed from external shipping containers prior to introduction to the laundry area, but not performed in the soiled sorting area. (ST65:2000 Standard 5.2.1)

DRAFT FOR OPEN COMMENT PERIOD 6/1/09 – 7/31/09

4.2.2. New textiles are laundered prior to initial injection into the linen cycle. (ST65:2000 Standard 5.2.2)

4.2.3. Supervisors should verify the new textiles are in compliance with the product specifications of the order. (ST65:2000 Standard 5.2.1)

4.3. Containers used during textile collection

4.3.1. Reusable collection containers should be of materials that can withstand repeated decontamination using cleaners and disinfectants. (ST65:2000 Standard 5.3.2)

4.3.2. Reusable surgical instruments and disposable devices should be retrieved from the textiles prior to laundering and placed into separate containers. (ST65:2000 Standard 5.3.1)

4.4. Policies and procedures are in place to address textile folding after laundering and drying:

4.4.1. Textiles should be folded in a consistent manner each time they are processed. (ST65:2000 Standard 8.2)

4.4.2. Folding procedures are developed to take into account the surgical textiles' performance, uses, and measures to enhance the penetration of the steam from the autoclave into the pack. (ST65:2000 Standard 8.3)

4.4.3. Folding and other process specifics for surgical textiles are outlined in the contract and acknowledge the preferences/input from the client/customer.

4.4.4. Clean textiles should be handled with clean hands in a manner to maintain their hygienic quality (ST65:2000 Standard 9.4) (Part I Section 2 Facilities Subsection 2.2.5. Hand Hygiene of this Accreditation Standard)

4.5. Policies and procedures address the packaging of the clean, reusable surgical textiles:

4.5.1. Employees are trained on the appropriate pack processes according to each pack's use requirements. (ST65:2000 Standard 8.4)

4.5.2. The barrier product used to complete the pack is selected to permit maximum penetration of the sterilant during sterilization and to maintain the content's sterility (e.g., if COG customer has made the purchasing decisions; aseptic presentation). (ST65:2000 Standard 8.5)

4.5.3. Assembled packs should have a label that includes the following items of information: (ST65:2000 Standard 8.6)

4.5.3.1. Identification

4.5.3.2. Pack contents

DRAFT FOR OPEN COMMENT PERIOD 6/1/09 – 7/31/09

4.5.3.3. Pack assembler

NOTE: Documentation for sterilization is required at point of sterilization and is not covered by this HLAC Standard.

4.6. Transport of the surgical textile packs within the facility or to the client should be accomplished in a manner to maintain the hygiene quality of the packs and to minimize microbial contamination from surfaces or the air. (ST65:2000 Standard 9.5.1)

4.6.1. Clean surgical textile packs should be transported within the laundry or client hospital in containers that are reserved for containment of clean products. (ST65:2000 Standard 9.5.2)

4.6.2. Containers used for soiled textiles should be labeled to that effect and should not be present in the pack room.

4.6.3. In addition to the surgical wrapper, the characteristics of containers suitable for transporting clean surgical textile packs are referenced in Part II Section 6 Delivery of Cleaned Healthcare Textiles Subsection 6.4 Proper use of carts in this Accreditation Standard. (ST65:2000 Standard 9.5.2)

4.6.3.1. Covered/closed hampers lined with clean liners or

4.6.3.2. Carts covered with clean sheets and protected by secured covers or

4.6.3.3. Textile racks completely covered with a suitable cover or

4.6.3.4. Enclosed, cabinet-style carts

4.6.4. Loading methods are developed to ensure products are appropriately segregated and labeled to avoid contamination. (ST65:2000 Standard 9.5.4.2)

4.6.5. Clean surgical textile packs and soiled textiles may be transported in the same vehicle provided that: (ST65:2000 Standard 9.5.3, 9.5.5).

4.6.5.1. Physical separation of the clean items from soiled textiles must be maintained during loading, transit, and unloading

4.6.5.2. Signage on carts or containers identifies their contents.

4.6.6. Vehicles are cleaned on a regular/scheduled basis or if visibly soiled.

4.7. Storage strategies and handling methods of the surgical textile packs are developed to maintain the hygienic quality of the packed textiles. (ST65:2000 Standard 9.6.1)

4.7.1. Storage restrictions indicate packs must be: (ST65:2000 Standard 9.6.1)

DRAFT FOR OPEN COMMENT PERIOD 6/1/09 – 7/31/09

4.7.1.1. At least 8 – 10 inches from the floor

4.7.1.2. At least 18 inches from the ceiling

4.7.1.3. At least 2 inches from the outside walls

4.7.2. Stock is rotated and used in a first-in/first-out manner. (ST65:2000 Standard 9.6.3)

5. Quality Assurance

Quality assurance policies and procedures are developed and in place to enhance the preservation of the textiles and to ensure that surgical textile processing produces a product that meets the client's expectation for quality.

5.1. Textiles are processed in a manner to control linting, thus increasing that fabric's use life expectancy. (ST65:2000 Standard 6.3.3.1)

5.2. Chemicals Usage and Water Quality

5.2.1. A monitoring process is in place to measure regularly the correct use of chemicals in the laundry process. (ST65:2000 Standard 6.4.2)

5.2.2. Water quality is monitored on a daily basis, the results recorded in a log, and adjustments are made as necessary to restore acceptable quality. (Part I Section 7. Quality Control and Process Monitoring 3. Process Monitoring Subsection 1.2 referenced in this Accreditation Standard)

5.3.1. Local water quality is factored into the selection process for laundry chemicals.

5.3.2. Additives used to maintain performance characteristics should be used according to product instructions. (ST65:2000 standard 7.4.4) (Part I Section 7. Quality Control and Process Monitoring 3. Process Monitoring Subsection 1.1 referenced in this Accreditation Standard)

5.4. A monitoring process is in place to indicate how the laundry process was performed with test parameters, including, but not limited to: (ST65:2000 Standard 6.4.4) (Part I Section 7. Quality Control and Process Monitoring 3. Process Monitoring Subsection 5 referenced in this Accreditation Standard)

5.5. During the inspection process, surgical textiles determined to be stained or contain debris/residue should be rewashed or retired as appropriate. (ST65:2000 standard 7.4.3)

5.5.1. Policies and training should reflect this process.

5.6. Surgical Textile Quality

DRAFT FOR OPEN COMMENT PERIOD 6/1/09 – 7/31/09

5.6.1. If surgical textile integrity is monitored at the laundry facility, the following should be checked: (ST65:2000 standard 7.1, 7.2)

5.6.1.1. Presence of physical defects from manufacturing errors

5.6.1.2. Presence of tears or holes

5.6.2. Policies are in place and training is provided to appropriate personnel in the proper use, placement, and process for patching surgical textiles. (ST65:2000 standard 7.4.1)

5.6.3. Additional textile factors should be visually checked prior to packing the textiles: (ST65:2000 standard 7.2.1)

5.6.3.1. Necessity of stain removal

5.6.3.2. Chemical or heat damage

5.6.3.3. Foreign debris

5.6.3.4. Appropriate labels

5.6.4. Written standards should define the criteria for rejecting textiles when they are no longer appropriate for use. (ST65:2000 standard 7.2.1)

5.6.5. Methods are designed and in place to ascertain the number of uses/washes for surgical textile barrier products. (ST65:2000 standard 7.3.3)

5.7. Carts that are utilized for clean surgical textiles should be cleaned on a regular basis or when visibly soiled, using any of the following methods:

5.7.1. Steam cleaning,

5.7.2. Washing with soap and water, or

5.7.3. Using a detergent/disinfectant according to label instructions. (ST65:2000 standard 9.5.4.1)

HLAC GLOSSARY

Artificial nails: Substances or devices applied or added to the natural nails to augment or enhance the wearer's own nails. They include, but are not limited to, bonding, tips, wrappings, and tapes. (AORN 2009)

DRAFT FOR OPEN COMMENT PERIOD 6/1/09 – 7/31/09

Patching/mending area – Area where textile repairing, patching, and mending operations are performed. NOTE: If patching/mending is performed in the laundry area, the textiles should be rewashed before being moved to the surgical pack assembly area. (AAMI 2009)

Sterile pack bagging area – Area where sterile packs are placed in dust covers (if used). NOTE: HLAC Standards do not address this area nor inspect this area; provided for definition and clarification purposes only. (AAMI 2009)

Sterile storage area – Area where sterile surgical packs are stored prior to delivery to the user. NOTE: HLAC Standards do not address this area nor inspect this area; provided for definition and clarification purposes only. (AAMI 2009)

Sterilization area – Area where steam sterilizers are located, including the space for loading, queuing carts, cool-down, and unloading carts. NOTE: HLAC Standards do not address this area nor inspect this area; provided for definition and clarification purposes only. (AAMI 2009)

Sterilization quarantine area – Area where sterilized surgical packs are stationed, awaiting product release. NOTE: HLAC Standards do not address this area nor inspect this area; provided for definition and clarification purposes only. (AAMI 2009)

Surgical pack assembly area or pack room – Area where clean surgical textiles are received, stored, inspected, mended and folded into finished components in preparation for assembly into surgical packs. (AAMI 2009)

Textile barrier testing area – Area where clean surgical textiles are evaluated for barrier properties and quality. NOTE: This area might be part of the surgical pack assembly area. (AAMI 2009)