List of Titles

American National Standard

ANSI/AAMI ST65:2000

Processing of reusable surgical textiles for use in health care facilities

AAMI Association for the Advancement of Medical Instrumentation

American National Standard ANSI/AAMI ST65:2000

Processing of reusable surgical textiles for use in health care facilities

Developed by
Association for the Advancement of Medical Instrumentation

Approved 20 January 2000 by
American National Standards Institute, Inc.

Abstract: This recommended practice provides guidelines for the proper handling, processing, and preparation of reusable surgical textiles either on-site or off-site for use in health care facilities. This recommended practice specifically addresses design criteria for functional work areas; staff qualifications, education, training, dress codes, and other personnel considerations; receiving and handling of soiled surgical textiles; laundry processing considerations; transport of both soiled and clean surgical textiles; installation, care, and maintenance of laundry equipment; quality control; and regulatory considerations. Definitions of terms and a bibliography are also provided.

Keywords: laundry, linens, surgical drapes, surgical gowns, wrappers

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Association for the Advancement of Medical Instrumentation

Sterilization Standards Committee

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NOTE—Participation by federal agency representatives in the development of this recommended practice does not constitute endorsement by the federal government or any of its agencies.

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Foreword

This recommended practice was developed by the AAMI Reusable Surgical Textile Processing Working Group under the auspices of the AAMI Sterilization Standards Committee. The objective of this recommended practice is to provide guidance in the handling and processing of reusable surgical textiles.

This recommended practice reflects the conscientious efforts of health care professionals, in cooperation with representatives of hospital-owned laundries and outsourcing services, to develop recommendations for optimum performance levels in the processing of reusable surgical textiles. It is not intended that these recommendations be construed as universally applicable in all circumstances. Also, it is recognized that in many cases these recommendations might not be immediately achievable. Therefore, the document should be used to guide personnel toward desirable performance objectives, and all of its provisions should be considered and applied in the light of professional judgment and experience.

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

The provisions of this recommended practice should be reviewed by various department managers, as applicable, and adapted to the needs of their particular institutions. Written policies and procedures should be developed and implemented in consultation with representatives of end users.

The concepts incorporated in this recommended practice should be considered flexible and dynamic. The recommendations set forth in this document are reviewed and updated periodically to assimilate progressive technological developments. AAMI policies and procedures require that AAMI standards and recommended practices be reviewed and, if necessary, revised at least once every 5 years.

Suggestions for improving this recommended practice are invited. Comments and suggested revisions should be sent to Technical Programs, AAMI, 1110 N. Glebe Road, Suite 220, Arlington, VA 22201-5762.

NOTE—This foreword does not contain provisions of the American National Standard, *Processing of Reusable Surgical Textiles for Use in Health Care Facilities* (ANSI/AAMI ST65:2000), but it does provide important information about the development and intended use of the document.

Introduction: Need for the recommended practice

Hospital-owned laundries, as well as those providing outsourcing services to health care facilities, are providing clean surgical textiles, nonsterile reusable surgical textile packs, and/or sterile reusable surgical textile packs to health care facilities. The ability of service providers to furnish reusable products that meet the performance requirements of end users while providing quality patient care has been enhanced by technological advances in reusable textiles and processing equipment. Current and future advancements in this segment of the industry may necessitate modified or alternative processing techniques.

This recommended practice is intended to provide guidelines that will help materiel managers, laundry managers, central service managers, and other health care professionals implement effective quality assurance systems for the processing of reusable surgical textiles. The guidelines provided here may also be useful to hospitals/users in evaluating the capabilities of facilities being considered for the processing of reusable surgical textiles.

It should be noted that laundry facilities that place surgical textiles (whether sterile or nonsterile) into commercial distribution come under the jurisdiction of Food and Drug Administration (FDA) regulations (see section 12 and annex A). In addition, laundry facilities in general may be subject to local, state, and/or federal Environmental Protection Agency (EPA) and Occupational Safety and Health Administration (OSHA) requirements.

American National Standard ANSI/AAMI ST65:2000

Processing of reusable surgical textiles for use in health care facilities

1 Scope

1.1 General

This recommended practice provides guidelines for properly handling, processing, and preparing reusable surgical textiles for use in health care facilities. These guidelines describe a quality assurance program for the processing of reusable surgical textiles, including processes and techniques for the preparation of clean bulk items for delivery to user sites and the assembly of textile packs for sterilization prior to end use. These guidelines apply to all facilities that process surgical textiles, whether hospital-based or commercial facilities.

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

NOTE—For purposes of this recommended practice, "health care facility" means hospitals, nursing homes, extended care facilities, freestanding surgical centers, clinics, and medical, surgical, and dental offices. For convenience, the term "hospital" is sometimes used in this recommended practice; in all instances, the term should be taken to encompass all other health care facilities.

1.2 Inclusions

This recommended practice specifically addresses

a) design criteria for functional work areas involved with the receiving, staging, and handling of soiled surgical textiles; the separation of soiled and clean textiles; the laundering of reusable surgical textiles; and the inspection and preparation of clean bulk items and surgical textile packs;

b) staff qualifications, education, training, dress codes, and other personnel considerations;

c) transporting, receiving, and handling of both newly purchased and soiled surgical textiles;

d) laundry processing (loading, washing, drying) recommendations;

e) inspection, testing, and maintenance of laundered textiles;

f) preparation and packaging of laundered textiles;

g) handling, transport, and storage of laundered textiles;

h) installation, operation, care, and maintenance of laundry equipment;

i) quality control measures, procedures, and practices;

j) medical device regulatory considerations.

Definitions of terms, an informative annex, and a bibliography are also provided in this recommended practice.

1.3 Exclusions

This recommended practice does *not* cover

a) design or construction criteria for equipment used to process reusable surgical textiles;

b) the application of any sterilization technology or sterility assurance practices;

c) selection of reusable surgical textiles;

d) performance standards for reusable surgical textiles;

e) surgical textiles labeled for single use.

NOTE—A performance standard for washer/decontaminators is being developed by the International Organization for Standardization (ISO). Detailed guidance on steam sterilization and sterility assurance in health care facilities is provided in AAMI (1993a), AAMI (1994a), and AAMI (1996a). AAMI (1999) addresses ethylene oxide sterilization and sterility assurance, and AAMI (1993b) provides guidelines on dry heat sterilization. AAMI (1994b) provides information on the safety and performance characteristics of surgical gowns and drapes.

2 Definitions, symbols, and abbreviations

For the purposes of this standard, the following definitions apply.

2.1 ANSI: American National Standards Institute.

2.2 barrier properties: Ability of a material to resist the penetration of liquids and/or microorganisms.

2.3 bioburden: Population of viable microorganisms on a product and/or a package.

2.4 bleach step: Use of an oxidizing agent (usually sodium hypochlorite or hydrogen peroxide) within a laundry formula to decompose some types of stains and/or whiten cotton textiles.

2.5 boiler: Pressure vessel in which water is heated to be used as hot water or steam.

2.6 break step: Use of alkali salts in a laundry formula to enhance soil removal.

2.7 CDC: Centers for Disease Control and Prevention.

2.8 chemical delivery system: Means by which laundry chemicals are delivered to washing equipment.

2.9 contaminated: State of having been actually or potentially in contact with microorganisms.

NOTE—As used in health care, the term generally refers to microorganisms that could be capable of producing disease or infection.

2.10 cool-down: Process of cooling dry, hot textiles, usually inside the drying equipment, to prevent damage, make them comfortable to handle, and minimize fabric wrinkling.

2.11 critical zone: Area of a gown or drape where direct contact with blood, body fluids, and other potentially infectious materials is most likely to occur.

2.12 decontamination: According to OSHA, “the use of physical or chemical means to remove, inactivate, or destroy bloodborne pathogens on a surface or item to the point where they are no longer capable of transmitting infectious particles and the surface or item is rendered safe for handling, use, or disposal” (29 CFR 1910.1030).

NOTE—The term is generally used in health care facilities with reference to all pathogenic organisms, not just those transmitted by blood.

2.13 device master record (DMR): According to FDA, “a compilation of records containing the procedures and specifications for a finished device” (21 CFR 820.3[j]).

2.14 drying equipment: Open-pocket, typically horizontal-axis machines that use heat and air flow to dry damp/wet textiles and that are usually controlled either by a microprocessor or timer. Three types of heat sources are typically used: gas, steam, or electricity.

2.15 EPA: Environmental Protection Agency.

2.16 extraction: Use of physical forces (usually centrifugal or strike/impact) to remove excess water from a wash load prior to drying.

2.17 FDA: Food and Drug Administration.

2.18 finishing step: Last step in the laundry formula, which primarily involves the souring of washed textiles to neutralize their alkalinity and prepare them for extraction and drying.

NOTE—In addition to laundry sour, other finishing chemicals can be added during this step, including softeners, antistatic agents, antimicrobial agents, and optical brighteners.

2.19 first-in, first-out (FIFO): Stock rotation system in which the oldest product is used first.

2.20 flatwork ironers: Apparatus for the drying, ironing, and folding of textile products, usually flat goods (e.g., sheets, pillowcases).

2.21 flush step: Initial step in a laundering formula used to remove bulk soils from the load.

2.22 heat exchanger: Apparatus that is capable of transferring heat and that typically strips heat from hot waste water (effluent) before the water enters the sewer system and then transfers that heat to incoming water to preheat it.

2.23 hygienically clean: Free of pathogens in sufficient numbers to cause human illness.

2.24 laundry formula: Assembly of multiple washing steps into a single formula for processing a particular classification of textile. For each step, at least the time, water temperature, water level, and chemical use rate are defined.

2.25 laundry processes: Activities that encompass the handling, washing, and drying of soiled textiles.

2.26 linen: Common term used to describe textiles that could include, but are not limited to, such items as sheets, towels, blankets, and napery.

2.27 main wash (suds) step: Part of a laundry process in which mechanical action and water flow loosen soils and during which soaps or detergents are usually added to the wash water in order to suspend soils and prevent redeposition.

2.28 medical device: According to FDA, "an instrument, apparatus, implement, machine, contrivance, implant, *in vitro* reagent, or other similar or related article, including a component, part, or accessory, which is:

— recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them,

— intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease in man or other animals, or

— intended to affect the structure or any function of the body of man or other animals, and which does not achieve any of its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its primary intended purposes"

(FD&C Act, Sec. 201[h]; 21 USC §321[h]).

2.29 microorganisms: Animals or plants of microscopic size.

NOTE—As used in health care, the term generally refers to bacteria, fungi, viruses, and bacterial spores.

2.30 NFPA: National Fire Protection Association.

2.31 noncritical zone: Area of a gown or drape where direct contact with blood, body fluids, and other potentially infectious materials is not likely to occur.

2.32 OSHA: Occupational Safety and Health Administration.

2.33 par level: The estimated quantity of products required to satisfy a department's needs, which is predicated on usage studies.

2.34 personal protective equipment (PPE): According to OSHA, "specialized clothing or equipment worn by an employee for protection against a hazard. General work clothes (e.g., uniforms, pants, shirts or blouses) not intended to function as protection against a hazard are not considered to be personal protective equipment" (29 CFR 1910.1030).

2.35 pills: Small balls of fibers formed on the surface of a fabric as a result of abrasion in wear (adapted from River [1976]).

2.36 ppm: Parts per million.

2.37 pre-sort: System in which soiled textiles are segregated into various categories of products and materials prior to laundering.

2.38 post-sort: System in which soiled textiles are handled as little as possible prior to laundering and then, after laundering, segregated into various categories of products and materials.

2.39 processing area: Area of the laundry containing the processing equipment used to clean soiled textiles. The location of the equipment usually defines soiled areas (where soiled textiles enter the unit) and clean areas (where clean textiles leave equipment).

2.40 pyrogen: Fever-producing substance.

NOTE—Debris from killed microorganisms can be pyrogenic; limiting the bioburden before sterilization minimizes this debris.

2.41 reusable surgical textile: Drape, gown, towel, or sterilization wrapper that is intended to be used in surgery or assist in preparing the surgical team for surgery, that is made from a fabric (usually woven or knitted), a fabric/film laminate, or a nonwoven material and that is intended to be used more than once, with appropriate cleaning, decontamination, and sterilization between uses. See also **sterilization wrap**, **surgical drape**, **surgical gown**, **surgical towel**.

2.42 rinsing step: Step in the laundering process used to remove soils and residual laundry chemicals from the load.

2.43 sharps: As defined by the U.S. Postal Service (1992), "devices having a projecting cutting edge or fine point that have been used in animal or patient care or treatment, in medical research, or in industrial laboratories, including but not limited to hypodermic needles, syringes (with or without the attached needles), Pasteur pipettes, scalpel blades, blood vials, needles with attached tubing, and culture dishes (regardless of the presence of infectious agents). Also included are other types of broken or unbroken glassware that were in contact with infectious agents, such as used slides or cover slips. The term 'sharps' does not include new unused medical devices such as hypodermic needles, syringes, scalpel blades, and so forth."

2.44 single-use (disposable) surgical textile: Drape, gown, towel, or sterilization wrap that is intended to be used in surgery or assist in preparing the surgical team for surgery, that is usually made from a nonwoven fabric (i.e. a sheet, web, or batt of natural and/or manmade fibers or filaments, excluding paper, that have not been converted into yarns and that are bonded to each other by some means) or a nonwoven/film composite, and that is intended to be used only one time and then discarded.

2.45 soil-sort area: Area of a laundry facility designated for receiving, retention, handling, and sorting of soiled textiles.

2.46 soil sorting: Process of sorting soiled items into defined or established categories so that they can be laundered together.

2.47 soiled (contaminated) textiles: Textiles that have had potential contact with blood, body fluids, or other potentially infectious materials.

2.48 standard (universal) precautions or body substance isolation (bsi): Method of using appropriate barriers to prevent transmission of infectious organisms from contact with blood and all other body fluids, nonintact skin, and mucous membranes. It applies to all patients, regardless of diagnosis or presumed infectious status. The precautions consist of appropriate handwashing, gloves when touching the above materials, facial protection when there is a chance of splashing of body substances into one's face, and gowns when there is a chance of splashing of body substances onto one's clothing. Precautions also include appropriate disinfection of patient-care equipment, appropriate handling of soiled linen, prevention of needlesticks and other injuries from sharps, and appropriate handling and disposal of sharps, all without regard to the patient's diagnosis.

2.49 sterile field: Immediate environment around the site of trauma or surgical incision.

NOTE—This area includes all materials in contact with the wound, gowns worn by the surgical team (front panel from chest to the level of the operative field and sleeve from the cuff to 2 inches above the elbow), patient drapes (area adjacent to the wound), and table covers (the top surface).

2.50 sterilization wrap: According to FDA, "a device intended to be used to enclose another medical device that is to be sterilized by a health care provider. It is intended to allow sterilization of the enclosed medical device and also to maintain sterility of the enclosed device until used" (21 CFR 880.6850).

2.51 strike-through: Penetration of a liquid or microorganism through a fabric.

2.52 surgical drape (fenestrated, nonfenestrated, surgical towel): According to FDA, "a device made of natural or synthetic materials intended to be used as a protective patient covering, such as to isolate a site of surgical incision from microbial and other contamination" (21 CFR 878.4370).

2.53 surgical gown: A type of surgical apparel, which is defined by FDA as "devices that are intended to be worn by operating room personnel during surgical procedures to protect both the surgical patient and the operating room personnel from transfer of microorganisms, body fluids, and particulate matter. . ." (21 CFR 878.4040).

2.54 surgical towel: An absorbent product, typically made of cotton, that is intended to be used in a patient-care procedure.

2.55 universal precautions: See **standard (universal) precautions or body substance isolation (bsi)**.

2.56 washing equipment: Machines used to wash textiles by exposing them directly to water, usually at elevated temperatures and with the addition of chemicals. There are several major types of washing equipment:

continuous-batch washer: Washing machine that allows for a continuous flow of textiles through the process. This equipment uses any number of horizontal-axis modules (usually 7 to 16) placed in sequence, each of which has a predefined function (step in the washing process) for each formula used. The time in each module is usually set between 2 and 3 minutes, and the water is reused in a counterflow process (i.e. clean water enters the last module and is reused until it reaches the first module). These units are controlled by a microprocessor or computer system.

home washers: Machines that allow for batch processing of textiles. This equipment usually is of a vertical-axis design and has standard (nonprogrammable) wash cycles.

NOTE—This equipment is not appropriate for processing many types of health care textiles. See 6.1.

open-pocket/split-pocket washers: Washing machines that allow for batch processing of textiles. This equipment is typically of a horizontal-axis design, has an open or split compartment that allows the textiles and wash liquor to intermingle freely in the chamber, and is controlled either by a microprocessor or a card unit.

washer-extractors: Machines capable of performing the functions of (a) washing soiled textiles through the combination of time, mechanical action, temperature, and chemical action, and (b) extracting (or removing) a large percentage of water from a washed load before further processing. Extraction is generally accomplished by either high-speed cylinder rotation or high-speed mechanical action (shaking).

2.57 water heater: Apparatus used to heat incoming water to the temperatures needed for processing.

2.58 water reuse system: System used to selectively capture and reuse water.

2.59 water softener: Additive used in the water treatment process to remove dissolved minerals (usually calcium, magnesium, or iron) from incoming water.

3 Design considerations

3.1 General rationale

This section provides guidelines for the design and maintenance of the workplace to facilitate effective and efficient processing, minimize environmental contamination, and maintain the cleanliness of processed textiles.

3.2 Work area design and functional work flow

3.2.1 Definitions of work areas

3.2.1.1 Laundry area

The following definitions are listed in order of the general work flow, as soiled textiles are received and move through the laundry facility to the clean textile storage area.

a) *Receiving area:* Area where soiled textiles are received in hampers or bags to await soil sorting.

NOTE—The soiled textiles are sometimes transported to an overhead or other designated storage area.

b) *Soil-sort area:* Area where soiled textiles are sorted, usually by textile category and sometimes by degree of soiling or color.

NOTE—In laundry operations that “post-sort,” there is not a specific area designated for the sorting of soiled textiles; the sorting process is usually performed within the folding area.

c) *Washing (processing) area:* Area where soiled textiles are washed and in which such equipment as washers, extractors, washer/extractors, continuous-batch washers, and/or continuous processing systems is located.

d) *Extraction area:* Area where excess water is removed from textiles after laundering but before conditioning or drying.

NOTE—Separate extractors include press-type extractors and centrifugal extractors. The washing and extraction processes can be combined in one machine called a washer/extractor.

e) *Conditioning/drying area:* Area where, after extraction, textiles are either conditioned (partly dried) or fully dried in a dryer or tumbler.

NOTE—For example, 100% cotton products (e.g., sheets, pillow cases) are conditioned before ironing, while 50% polyester/50% cotton products might go directly from extraction to ironing without conditioning or drying. Surgical textiles are usually fully dried, not conditioned.

f) *Ironing area:* Area where textiles that require ironing are processed through a flatwork ironer.

NOTE—Typical products that are ironed include sheets, pillow cases, patient gowns, and table linen. Ironing surgical textiles is not usually recommended.

g) *Folding area:* Area where textiles are folded.

NOTE—For example, automatic folding equipment could be installed after the flatwork ironer. Fully dried textiles (not ironed) are folded with automatic folding equipment. Some textiles are hand-folded. For surgical textiles, “bulk” folding is usually performed in the laundry area, and subsequent folding and pack assembly are performed in the pack assembly area.

h) *Patching/mending area:* Area where textile repair, patching, and mending operations are performed.

i) *Clean textile storage area:* Area where clean textiles are stored prior to delivery to the user.

NOTE—Clean textiles can be sorted by product type and stored on shelves or placed in laundry carts ready for distribution.

j) *Textile inventory storage area:* Area where newly purchased textiles are received and held prior to processing and placement into the circulating inventory.

NOTE—This area might be part of an off-site laundry facility or part of the general storage warehouse within a health care facility.

3.2.1.2 Surgical pack assembly area

a) *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.

b) *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.

c) *Sterilization area:* Area where steam sterilizers are located, including the space for loading, queuing carts, cool-down, and unloading carts.

d) *Quarantine area:* Area where sterilized surgical packs are stationed, awaiting product release.

e) *Sterile pack bagging area:* Area where sterile packs are placed in dust covers (if used). See 8.5.

f) *Sterile storage area:* Area where sterile surgical packs are stored prior to delivery to the user.

3.2.1.3 Other areas

a) *Personnel support area:* Area that provides toilet, shower, locker, and lounge facilities for employees.

NOTE—There should be adequate space and equipment in support areas to allow teaching and staff conferences. Ideally, there should be separate support areas for personnel working in the laundry area and personnel working in the pack assembly area. See 3.2.3.1 and 3.2.3.2.

b) *Administrative area:* Office space for department supervisors, support personnel, and office personnel.

c) *Housekeeping equipment storage area:* Area where housekeeping items are stored.

NOTE—The laundry and pack assembly area should each have a dedicated housekeeping storage area.

d) *Consumable supply storage area:* Area where items such as pack supplies, tapes, pass cards, and dust covers are stored.

e) *Chemical storage area:* Area in which laundry chemicals are stored.

f) *Boiler (mechanical systems) room:* Separate room that is used to house the boiler and that may house other mechanical systems, such as water heaters, water softeners, air compressors, and heat exchangers.

3.2.2 Design criteria for work areas

During the initial design of the textile processing or laundry and pack assembly areas, basic concepts of operation and quality assurance should be defined (see 11), the inventory of supplies and textiles should be projected, the type of distribution system to be used should be selected, and functional work areas should be designed accordingly. Among the design criteria that should be considered are

a) whether the laundry is an in-house department or an off-site facility;

b) whether the laundry processes general-use textiles as well as surgical textiles;

c) whether the laundry will inspect and maintain the surgical textiles or transport them to an off-site facility;

d) whether the laundry will provide pack assembly and/or sterilization services or transport surgical textiles to an off-site facility;

e) whether the laundry or the health care facility owns the textiles to be processed;

f) whether the laundry or the health care facility will store new or uncirculated textiles;

g) where processing supplies will be stored;

h) what type of laundry equipment and how many systems will be needed to process the anticipated volume.

Rationale: Because sterility assurance involves pre- and post-sterilization processing functions and controls, as well as the sterilization process itself, all factors need to be considered in the design of the workplace.

3.2.3 Functional work flow patterns

3.2.3.1 Laundry area

The laundry facility should be designed to have a barrier or functional separation between areas in which soiled textiles are received and processed and areas in which clean textiles are handled and stored for distribution to the surgical pack assembly area. The work area design should allow adequate space for all functions and should promote efficiency by minimizing the distance between related areas.

Rationale: Separating soiled and clean areas limits the potential for environmental contamination of the surgical textiles to be sterilized.

3.2.3.2 Surgical pack assembly area

The surgical pack assembly area (pack room) should be designed so that areas in which clean textiles are received, stored, and assembled into packs are separated, either by space or a physical barrier, from areas in which soiled textiles are received or processed. Work area design should allow adequate space for all functions and should promote efficiency by minimizing distances between related areas.

Rationale: A separate area for pack assembly will facilitate engineering controls for proper air flow and exhaust, thus controlling and reducing the amount of lint, debris, and other environmental contaminants in the workplace.

3.2.4 Traffic control

The need for traffic control should be taken into account in workplace design. Traffic in all areas of the laundry area and the surgical pack assembly area should be limited to authorized personnel only. Criteria for authorized entry, movement within the areas, and attire should be specified in written policies and procedures. If it is necessary for visitors to enter restricted areas, the visitors should comply with the established dress code, as stated in department policies and procedures. See also 4.5.

Rationale: Personnel and visitors can be exposed to microorganisms present on soiled textiles in receiving and soiled areas. Personnel and visitors can carry microorganisms into areas where clean textiles are being processed for subsequent sterilization. Consequently, good traffic control and dress code practices are essential in order to limit the potential for contamination of surgical textiles.

3.3 Physical facilities: laundry area

3.3.1 Space requirements

The size of the laundry processing area should be determined by the volume of textiles to be processed, the types and size of the equipment required to process this volume, and the overall needs of the laundry's customers. Each functional area of the laundry should have adequate space to provide for the systems, equipment, and work load of that area. Areas of the laundry should be designed in such a way as to provide functional separation between soiled and clean textile processing areas. In addition, consideration should be given to traffic control and restricted access to areas in which contamination could occur.

Rationale: Space requirements vary according to the volume of textiles, the turnaround time for receiving and processing textiles, and the number of users that the laundry supports. Adequate space will help provide a good workplace environment and facilitate high productivity. In addition, a safe working environment depends upon adequate design and space within the facility. Functional separation of clean and soiled areas helps to minimize the potential for cross-contamination.

3.3.2 Mechanical systems

Mechanical systems should be designed to accommodate the processing needs of the laundry or textile processing equipment in the facility. These needs include, but are not limited to, hot water, cold water, sanitary sewer, electricity, gas, steam, heat, air exchange, compressed air, chemical storage, chemical delivery, and water treatment.

Rationale: The appropriate type, size, and capacity of mechanical systems are necessary to ensure the correct operation and maintenance of equipment and adequate throughput to meet the needs of users.

3.3.3 Floors, walls, ceilings, and vents

Floors and walls should be constructed of materials that will withstand scheduled wet cleaning, as well as the heat and humidity of the laundry environment. Ceilings and vents should be constructed of materials that will withstand scheduled cleaning, vacuuming, or "blow-down" to eliminate lint and other soils that are associated with the processing and cleaning of textiles. Whenever possible, power cords and computer cables should be run in such a manner that they do not traverse the floor (e.g., as a power drop or directly down the wall to tables against the wall).

Rationale: Scheduled, thorough cleaning of laundry and textile processing areas reduces the potential for environmental contamination and the amount of dust and lint. Therefore, the materials of construction of floors, walls, and ceilings must be able to withstand frequent cleaning and must not be adversely affected by chemical agents typically used for cleaning. Avoiding the running of cables on the floor enhances the safety and cleanliness of the workplace.

3.3.4 Ventilation

The laundry ventilation system should be designed so that air flows from clean textile areas (positive pressure) to soiled areas (negative pressure) and is exhausted to the outside atmosphere. For in-house hospital facilities, the section on "Ventilation Requirements for Areas Affecting Patient Care" of the American Institute of Architects' *Guidelines for Design and Construction of Hospital and Health Care Facilities* (AIA 1996) should be consulted, as well as the recommendations of the American Society of Heating, Refrigerating, and Air Conditioning Engineers (ASHRAE 1989, 1995).

Rationale: Ventilation systems can affect the spread of potentially dangerous microorganisms. Controlling the air flow reduces the potential for contamination of clean textiles.

3.3.5 Temperature and humidity control

Given the nature of the work environment and the heat and humidity generated by laundry processing equipment, maintaining specific, comfortable working conditions is difficult. The environment should be made as comfortable as possible, which can generally be accomplished by proper ventilation in the work area.

Rationale: Work areas should be comfortable for properly attired personnel to assure compliance with the dress code and a productive work process.

3.3.6 Lighting systems

Adequate lighting should be provided, taking into account factors such as the tasks being performed and worker safety. The lighting system may be designed in accordance with the engineering practices outlined in Rea (1995), which recommends illuminance for various categories of work environments.

Rationale: Adequate lighting is essential to the proper performance of soil sorting, equipment operation, and clean textile inspection and handling operations.

3.3.7 Handwashing facilities

Handwashing facilities should be conveniently located in or near all work areas and in all personnel support areas, such as lounges and rest rooms. All personnel should be instructed in the facility's general handwashing policies and in those more stringent policies that apply to particular work areas or tasks.

Rationale: Adequate and strategically located handwashing facilities help to promote the practice of good hygiene, which will minimize microorganism transfer.

3.3.8 Emergency eyewash/shower equipment

Suitable eyewash/shower equipment must be available, with unobstructed access, for immediate emergency use in all locations where chemicals are used and where there is the potential for contact with blood or body fluids.

The American National Standards Institute (ANSI) has established minimum performance criteria for eyewash units (ANSI 1998). Among other things, ANSI Z358.1—1998 requires that eyewash units provide a minimum of 0.4 gallons of water per minute for at least 15 minutes, that they be designed to flush both eyes simultaneously, and that they have a "hands free, stay open" feature once activated. Under the ANSI standard, drench hoses or eyewash bottles are not acceptable emergency eyewash units.

Emergency eyewash units should be located within 10 seconds travel time of all chemical usage locations. For strongly acid or strongly caustic chemicals, emergency eyewash units should be located immediately adjacent to the hazard. The eyewash facilities should be identified with a highly visible sign and should be maintained in accordance with the manufacturer's instructions. Before attempting to implement the ANSI standard, laundry personnel should consult the standard itself to familiarize themselves with all of its provisions.

Rationale: Emergency eyewash and shower equipment should be readily accessible in order to provide first aid to employees in the event of an accident involving blood, body fluids, or chemicals. The availability of eyewash units for immediate emergency use is required by OSHA. Proper maintenance of eyewash units is necessary to ensure adequate performance and to prevent contamination. See also OSHA's Eye and Face Protection Standard (29 CFR 1910.133), OSHA's Medical First Aid Standard (29 CFR 1910.151), and ANSI (1998).

3.3.9 Soil-sort area

The soil-sort area should be functionally separated from other areas of the facility. In addition to the preceding recommendations for construction of the floors, walls, and ceilings (3.3.3) and the ventilation system (3.3.4), there are several specific requirements that should be met in order to ensure a productive, safe environment in the soil-sort area. For example, work surfaces should be constructed of nonporous materials capable of withstanding frequent cleaning. If possible, all air from the soil-sort area should be exhausted to the outdoors without recirculation. If it is necessary to recirculate air, the air should be filtered. Sharps containers should be provided and should be readily accessible to all work areas in the soil-sort area, in accordance with OSHA regulations (29 CFR 1910.1030). Separate handwashing and change areas (preferably with shower facilities) should also be provided in the soil-sort area. Sufficient floor drains should be available to prevent puddling of water and to accommodate wet mopping.

Rationale: Contamination of work surfaces, as well as airborne microbial and particulate contamination, is likely to be high in the soil-sort area due to the type of work performed and should be controlled through work practices and engineering controls whenever possible. Contamination can be spread by personnel who touch environmental surfaces or other personnel. Regular cleaning is necessary to control environmental contaminants. Physical separation of the soil-sort area is recommended in order to limit the potential for contamination of personnel or clean, processed textiles. Exhausting air to the outdoors prevents reintroduction of contaminants onto clean items and into clean work areas. Sharps containers are required for personnel safety. The availability of handwashing facilities encourages frequent handwashing, which is essential to personnel safety and to infection control.

3.3.10 Chemical storage area

Chemicals should be stored in an area that does not receive high traffic by personnel. The area should be self-contained, or it should be an area that can be readily isolated in the event of spillage or leaks. All containers and packaging in the area should be clearly and correctly marked with their contents and any cautions related to the contents. Material Safety Data Sheets (MSDSs) for the chemicals in the storage area must be readily available in the event of accidents or spills.

Rationale: Parts 260 to 299 of Title 40 of the *Code of Federal Regulations* specify EPA regulations for the protection of the environment from hazardous chemicals; subparts C and D address the prevention of chemical spills and the

preparation of contingency plans for spills. OSHA's Hazard Communication Standard (29 CFR 1910.1200) requires the labeling of containers of chemicals and the provision and availability of MSDSs.

3.3.11 Storage area for clean textile packs

The storage area for clean textile packs should meet the same criteria as areas in which other clean medical devices are stored. See AAMI (1994a).

Rationale: The environment in which clean textile packs are stored must be controlled in order to minimize environmental contamination of the packs and to prevent product deterioration. See also AAMI (1994a) and FDA regulations (21 CFR 820.150).

3.3.12 Housekeeping

The housekeeping practices and the procedures for storage of housekeeping equipment and supplies set forth in Joint Committee on Healthcare Laundry Guidelines (1993) should be followed.

Rationale: Cleaning reduces the accumulation of dust and lint and minimizes microbial growth, thus reducing the possibility of microbial transmission.

3.4 Physical facilities: surgical pack assembly area

3.4.1 Space requirements

The size of the surgical pack assembly area should be determined by the volume of textiles to be processed, the capabilities of the equipment required to process this volume, and the overall needs of the facility and its customers. The surgical pack assembly area should have adequate space allocated to allow for a sufficient number of illuminated inspection tables, assembly tables, patching equipment, and storage carts for clean textiles awaiting assembly and, if sterilization is performed on-site, sterilization. Walls or partitions should separate functional work areas to control traffic and to protect textiles from contamination generated during handling or originating from other areas of the building. Adequate space should be provided to accommodate necessary ventilation and exhaust systems for appropriate air exchange and environmental controls.

Rationale: Space requirements vary according to the volume of textiles, the number of users that the area supports, and the inventory storage requirements. Adequate space will help provide a safe workplace environment and facilitate high productivity.

3.4.2 Mechanical systems

Mechanical systems should be appropriately designed, installed, and maintained to provide the utilities necessary for the surgical pack assembly area. The surgical pack assembly area should have controlled air ventilation, exhaust, and, if required, filtration.

Rationale: The appropriate type, size, and capacity of mechanical systems are necessary to ensure the correct operation and maintenance of equipment and adequate throughput to meet the needs of users.

3.4.3 Floors, walls, ceilings, and vents

Floors and walls should be constructed of appropriate materials that will withstand scheduled wet cleaning. These materials should not be of a particulate- or fiber-shedding composition. The ceilings of clean work areas should be constructed so that the surface is flush with recessed, enclosed fixtures. Ceilings and vents should be constructed of materials that will withstand scheduled cleaning, vacuuming, or "blow-down" to eliminate lint and other soils that are associated with the processing of textiles.

Rationale: Scheduled, thorough cleaning of all areas helps control microbial contamination and eliminate accumulated dust or lint. An enclosed ceiling limits dust/lint accumulation and other possible sources of microbial contamination.

3.4.4 Ventilation

The ventilation system in the surgical pack assembly area should be designed so that air flows from the clean work area (positive pressure) to a soiled area (negative pressure). The air circulation system should be of a down-draft type, and the number of air exchanges per hour (typically 10) should be sufficient to minimize lint particles in the air. Portable fans should not be permitted in the area. Other aspects of ventilation should comply with the guidelines set forth in AIA (1996). See also ASHRAE (1989, 1995).

The ventilation system should be designed so that the room is able to maintain the appropriate positive pressure in relation to the rest of the facility (i.e. cleanest to dirtiest). When building design and construction allow, it is

preferable to locate return air and/or exhaust ducts at or near floor level. Regardless of the specific location of the return duct, its placement should facilitate the installation and effective maintenance of any filtering systems.

Rationale: Lint and airborne particles can carry microorganisms. The air flow patterns in the textile processing area help reduce these particles in the environment. A filtering system reduces the amount of particles and lint being exhausted and (especially) recirculated. Proper maintenance of any filtering systems will promote good air flow and improve the workplace environment.

3.4.5 Temperature and humidity control

In all work areas, temperature should be controlled to a range between 20° C and 23° C (68° F and 73° F). Relative humidity should be maintained between 30% and 60%, with a maximum of 70%.

Rationale: Work areas should be comfortable for properly attired personnel. In addition, temperatures and humidities higher than those recommended can promote microbial growth and have the potential to increase bioburden. Temperatures and humidities (especially humidities) lower than those recommended can adversely affect sterilization (Block 1991; Perkins 1969).

3.4.6 Lighting systems

Adequate lighting should be provided in accordance with the tasks performed in each specific area. In folding, assembly, and repair areas, higher-intensity lighting might be required so that the textiles can be properly examined as each task is performed. Lower-intensity lighting might be required for areas where light-table inspection is performed so that the table back lighting can be used optimally. See also Rea (1995).

Rationale: Adequate lighting is essential to the proper performance of tasks associated with the assembly of surgical textile packs.

3.4.7 Handwashing facilities

Handwashing facilities should be conveniently located in or near all work areas and in all personnel support areas, such as lounges and rest rooms. All personnel should be instructed in the facility's general handwashing policies and in those more stringent policies that apply to particular work areas or tasks.

Rationale: Adequate and strategically located handwashing facilities help to promote the practice of good hygiene, which will minimize microorganism transfer.

3.4.8 Storage area for clean textile packs

The storage area for clean textile packs should meet the same criteria as areas in which other clean medical devices are stored. See AAMI (1994a).

Rationale: The environment in which clean textile packs are stored must be controlled in order to minimize environmental contamination of the packs and to prevent product deterioration. See also AAMI (1994a) and FDA regulations (21 CFR 820.150).

3.4.9 Surgical pack sterilization area

If surgical textile packs and individually wrapped surgical textiles are sterilized in the surgical pack assembly area, this area should meet the same criteria as areas in which other medical devices are sterilized and cooled. See AAMI (1994a).

Rationale: It is important to minimize contaminants in the sterilization area. See also AAMI (1994a).

3.4.10 Sterile storage area

If surgical textile packs and individually wrapped, sterile surgical textiles are stored in the surgical pack assembly area, the area should meet the same criteria as areas in which other sterile medical devices are stored. See ANSI (1996) and AAMI (1994a).

Rationale: Maintaining the sterility of surgical textiles to the point of use is essential. Because packaging materials can be damaged or compromised, care must be taken to handle and store sterilized surgical textiles in such a way as to promote sterility maintenance. See also ANSI (1996) and AAMI (1994a).

3.4.11 Housekeeping

If surgical textile packs and individually wrapped items are prepared for sterilization in the pack assembly area or facility, the housekeeping practices should meet the same requirements as those that apply to central service

departments in health care facilities. See AAMI (1994a) and Joint Committee on Healthcare Laundry Guidelines (1993).

Rationale: Cleaning reduces the accumulation of dust and lint and minimizes contamination and microbial growth, thus reducing the possibility of microbial transmission.

4 Personnel considerations

4.1 General rationale

This section provides guidelines for personnel qualifications, training, and education as well as minimum criteria for personnel health and personal hygiene. It is important that all aspects of processing (handling, sorting, laundering, inspecting, preparing for sterilization) be performed correctly and be supervised by knowledgeable personnel.

4.2 Qualifications

4.2.1 Supervisors/managers

The responsibility for supervising textile processing and ensuring that all activities are performed correctly should be assigned to qualified individuals. Minimum qualifications include the ability to

a) correctly interpret manufacturers' instructions for equipment operation;

b) recognize process and equipment malfunctions;

c) develop and correctly interpret policies and procedures for handling, transporting, sorting, laundering, inspecting, preparing, and sterilizing reusable surgical textiles;

d) develop and/or correctly implement an exposure control plan that integrates OSHA regulations for preventing occupational exposure to bloodborne pathogens (29 CFR 1910.1030) and CDC guidelines for preventing transmission of tuberculosis (CDC 1994);

e) correctly interpret textile labels and recommended instructions for processing and handling products.

NOTE—Familiarity with AAMI and AORN standards and guidelines is beneficial.

Rationale: Processing reusable surgical textiles is a multistep process that should be supervised by a team of professionals who are knowledgeable about the properties of reusable surgical textile products, equipment operation, principles of infection control, and principles of sterilization. Adequate supervision by knowledgeable personnel is also important to employee safety.

4.2.2 Personnel

The responsibility for performing the various activities necessary to effectively process reusable surgical textiles must be assigned to competent individuals. Minimum qualifications will depend on the task performed and should include at least the ability to

a) safely and correctly operate assigned processing equipment;

b) safely and correctly perform assigned processing activities, including handling, transporting, sorting, laundering, inspecting, preparing, and sterilizing reusable surgical textiles;

c) correctly interpret and safely implement the exposure control plan;

d) understand the device defects, safety hazards, and other consequences that could result from the improper performance of their specific jobs.

Personnel competency in the performance of the above tasks should be verified.

Rationale: Processing reusable surgical textiles is a multistep process that should be performed by personnel who are knowledgeable in the basic principles of infection control and who are competent in their assigned functions.

4.3 Training and education

The training and preparation of all supervisory personnel engaged in processing reusable surgical textiles should include, as a minimum, orientation training and instruction on the following topics:

a) principles and methods of processing reusable surgical textiles;

b) principles and methods of infection control, including current CDC guidelines and OSHA's regulations on the prevention of occupational exposure to bloodborne pathogens, tuberculosis, and hazardous materials;

c) physical properties and important functional attributes of reusable surgical textiles;

d) procedures for sorting, washing, inspection, folding, and preparation of surgical packs;

e) sterilization methods.

Other functional personnel should be trained on these topics as their responsibility levels dictate.

The training of all personnel should be properly documented. Training documents or forms should include the name(s) of the attendees, the signatures of the attendees, the date of the training, the content of the training, and the name and title of the trainer. A central file should be kept, containing copies of the training materials, such as the standard operating procedures, work instructions, safety practices, or infection control practices that were reviewed. Employee training files may contain information regarding any training/educational courses taken outside of the health care or laundry facility that are relevant to the employee's job responsibilities.

The training documentation should include, when appropriate, verification that the training was understood and that a minimum level of competency was demonstrated. When appropriate, periodic retraining should take place and should also be documented.

Rationale: Adequate training and educational preparation decrease the possibility of operator error, reduce the potential for employee injury, and help ensure that personnel are knowledgeable about established, written procedures and techniques. Documentation of training verifies participation and sets the level for performance expectations and compliance with the work instruction, policy, or procedure. Documentation also provides the manager with a tool for future performance evaluations and counseling, as appropriate.

4.4 Health and personal hygiene

Good personal hygiene is essential for the protection of self, coworkers, and end users. A written policy must be established for the reporting, treatment, and disposition of employees who are at risk of occupational exposure to infections. A key provision of OSHA regulations is that personnel involved in the handling and processing of soiled textiles must, before working in the area, be trained in the requirements of those regulations (29 CFR 1910.1030), be offered hepatitis B vaccination, and be instructed in the use of proper attire, including personal protective equipment (PPE), as required for specific work areas and job responsibilities.

Good handwashing procedures should be employed. On a regularly scheduled basis, all personnel should be advised of the facility's handwashing policies and instructed in proper handwashing procedures, especially when policies are more stringent for a particular work area (e.g., the soil-sort area, the pack assembly area). In particular, personnel should be instructed to wash their hands and remove PPE when they leave the soil-sort area.

Employees should be trained in the proper disposal of sharps and other biohazardous waste that could have been left inadvertently in soiled textiles returned for processing. The final disposition of sharps and other biohazardous waste must be in accordance with applicable regulations.

Rationale: Careful attention to personal hygiene and compliance with prescribed policies on attire (including PPE), handwashing, and the handling and disposition of sharps and other biohazardous waste will minimize the potential for acquiring or transmitting disease. Handwashing, in particular, is the single most important aspect of infection control. Bloodborne pathogens such as the hepatitis virus may be found in blood or other body fluids on soiled textiles and can enter personnel through small cuts or abrasions on the skin. OSHA mandates that a written policy be established concerning employees who are at risk of acquiring or transmitting infections, that hepatitis B vaccination be offered to any person who comes into contact with blood or other body fluids, and that exposures be reported (29 CFR 1910.1030). See also CDC (1985).

4.5 Attire

4.5.1 General

All personnel involved in processing reusable surgical textiles should wear clean, dry uniforms that conform to the facility's dress code. Uniforms should be changed daily or more often as needed (i.e. when wet or soiled). Jewelry should be not be worn. Additional criteria may apply to personnel working in the surgical pack assembly area or other areas in which products are individually handled. For example, hair coverings may be required, and the wearing of fingernail polish, acrylic fingernails, and/or artificial fingernails may be prohibited in certain areas.

Rationale: Wearing clean uniforms limits the transfer of microorganisms to other personnel and the work environment.

The topic of jewelry continues to be controversial with respect to the potential for microbial contamination and transfer. However, jewelry should not be worn in textile processing areas because rings, watches, and bracelets can get caught in processing equipment, thereby placing the employee in danger of serious injury.

All textiles should be clean and free of debris when being prepared for sterilization. Otherwise, when the pack is sterilized and then opened for use under aseptic conditions, a foreign substance (e.g., hair) could be introduced into the surgical incision. Any foreign substance left in the human body has the potential to cause adverse reactions. Fingernail polish, acrylic fingernails, and artificial fingernails could chip and/or fall off and also could harbor a fungus or greater numbers of bacteria. Thus, in certain work areas, it may be necessary to prohibit the wearing of these items and/or to require the wearing of hair coverings.

4.5.2 Personal protective attire

Protective attire must comply with OSHA regulations (29 CFR 1910.1030). In addition to the attire recommended in 4.5.1, personnel involved in the separation or handling of soiled reusable surgical textiles should wear appropriate PPE in accordance with the facility's exposure control plan. Such attire might include heavy-duty protective gloves, a protective gown or apron, an appropriate face mask, eye protection, and shoe covers. Personnel also should be instructed on when and how to use the PPE for the area in which they are working and how the PPE is to be removed and cleaned or disposed of. The policy on PPE and the appropriate use of each type of attire or device should be reviewed on a scheduled basis.

Rationale: Soiled textiles are a potential source of pathogenic microorganisms that could invade personnel through nicks or cuts on the hands or through contact with the mucous membranes of the eyes, nose, or mouth. Wearing PPE correctly helps minimize this risk.

5 Receiving and handling of reusable surgical textiles

5.1 General rationale

This section provides guidelines for the receiving of newly purchased surgical textile products and for the collection, transport, and handling of soiled items. Whether or not there is visible soiling, used/soiled textiles are a potential source of microorganisms that could cause infections in personnel or patients, and they should be handled with appropriate precautions. The hazards associated with the transmission of bloodborne pathogens are greatest during the handling, segregation, and/or sorting of soiled fabrics. Policies and procedures should be developed and implemented to assure effective protection of personnel, patients, and the environment from contamination. These policies and procedures must also assure compliance with OSHA regulations for the prevention of occupational exposure to bloodborne pathogens (29 CFR 1910.1030) and should promote conformance to AORN (2000a). In the development of these policies and procedures, consultation with infection control and hazardous materials professionals may be advantageous.

5.2 Newly purchased items

5.2.1 Identification and handling

The identity of all incoming reusable surgical textiles (e.g., gowns, drapes, wrappers) should be verified for compliance with product purchase specifications. All items should be removed from their external shipping cartons before they are introduced into laundry areas.

Rationale: Many products are similar in appearance but may have different functional performance characteristics. Proper identification will help ensure that the correct products are used in all situations. Products should be removed from their shipping cartons in an appropriate area other than in the laundry soil-sort area, to prevent potential contamination of the shipping cartons with possible biohazardous soils or waste that would require special handling or disposal methods.

5.2.2 Washing

Following their removal from shipping cartons and packaging, all new items should be laundered before use. The manufacturer's processing recommendations should be consulted when developing internal processing procedures.

NOTE—There may be a separate area where newly purchased surgical textiles are received and unboxed, as well as a different area for holding the surgical textiles before their first laundering.

Rationale: Washing of newly purchased textile products is an accepted practice and is recommended by manufacturers to prepare the products for use.

5.3 Collecting and transporting soiled surgical textiles

5.3.1 Collecting soiled surgical textiles at the point of use

All soiled, contaminated reusable surgical textiles should be handled as little as possible. Soiled textiles should be immediately contained and transported to the laundry soil-sort area, where sorting procedures can be initiated by personnel protected by appropriate attire and trained in handling potentially infectious soiled textiles. Soiled surgical textiles should *not* be sorted or rinsed in patient care areas. Disposable sharps used in the surgical procedure should be removed and placed into an appropriate sharps container(s). Reusable surgical instruments and single-use items should be placed into appropriate containers. Written procedures must be developed to protect personnel from exposure to bloodborne pathogens during the sorting process, to comply with OSHA regulations (29 CFR 1910.1030), and to implement universal/standard precautions (CDC 1996).

Rationale: After each use, all surgical textiles (e.g., gowns, drapes, wrappers, towels), including patient-care textiles, should be considered contaminated and sources of infection. It is important to ensure that both single-use and reusable sharps, instruments, and other items are placed in appropriate containers and not left in the soiled reusable surgical textiles.

5.3.2 Transporting soiled surgical textiles

Soiled surgical textiles should be contained during transport from the point of use to the soil-sort area. Containment can be accomplished by any means that adequately prevents inadvertent personnel contact with or exposure to the contaminated items during transport. Containers should be selected based on the characteristics of the items being transported and must be capable of preventing soak-through or leakage of liquids to the outside of the containers. Containers should be appropriately identified by labeling or color coding. If an off-site facility does not follow universal/standard precautions for all laundry, specific labeling with the biohazard symbol is required. Reusable collection containers should be made of materials that can be effectively decontaminated; containers designed for single use should be made of materials that can be incinerated or otherwise safely disposed of following use. The final disposition of sharps and other biohazardous waste must be in accordance with applicable local, state, and federal regulations. All materials returned to the soil-sort area should be considered contaminated and should be processed or disposed of as such.

Rationale: Proper containment minimizes airborne or contact spread of microorganisms, which reduces the risk of cross-infection of personnel and cross-contamination of clean/sterile items.

5.4 Sorting of soiled textiles

There are two types of systems that can be used to sort soiled textiles: pre-sort systems and post-sort systems. Soiled textiles can be pre-sorted to allow for decontamination and to help maximize the performance of the individual products over time. Soiled textiles can also be post-sorted after the products have been laundered and decontaminated, but additional measures may be necessary to ensure that the performance attribute(s) of the products are maintained.

Both systems require that classification procedures be established to assist in employee training and to ensure proper grouping of textiles for laundering (pre-sort systems), inspection, folding, and pack preparation. Processing efficiencies are usually gained with appropriate classification of products.

5.4.1 Pre-sort systems

In this system, the soiled textiles are sorted before being laundered. There are several types of classification procedures that can be employed, and it is not uncommon for two or more of these to be implemented together, depending on the facility's volume, mix of products, and equipment. Classification procedures for soiled products can be developed based on the degree of soiling, fiber content, and/or the specific type of product that needs to be laundered.

Classification procedures should be documented to ensure that soiled textiles are processed using the correct laundry formula for the type of item being processed. Soil-sort and appropriate production personnel should be trained on these procedures. It is recommended that these procedures or a summary of them be placed in an appropriate place for easy reference by those employees that utilize them.

Rationale: Two of the main functions of the laundering process are to remove soils and to produce products meeting their expected performance attributes. The degree of soiling, the fiber content of the products, and the type of soiling will affect the processing required. Segregation of products allows for customization of laundry formulas based on the mix of products in the system and the types of soils encountered. In addition, if work flow allows, increasing the amount of segregation by specific product types will usually yield the greatest amount of work efficiency during inspection, folding, and pack-making operations. This is due to the economies of scale achieved by performing the same operation on the same type of product without having to separate or frequently switch the type of work being

performed. Another benefit of pre-sorting is the ability to remove sharps and other potentially damaging items (e.g., adhesive drapes, plastic items, abrasive pads) from the load prior to laundering, thus reducing damage and loss as well as preventing potential injury (sticks) to personnel on the pack room floor.

5.4.2 Post-sort systems

In post-sort systems, the various categories of products and materials are sorted after they have been laundered. Performance attributes may need to be qualified and inspection procedures adjusted to ensure that the performance characteristics of the products are maintained. For example, mixing higher-linting products with lower-linting products may necessitate more delinting of products during the inspection process.

Rationale: Post-sort systems are sometimes used to minimize the exposure of laundry personnel to bloodborne pathogens, as is required by OSHA (29 CFR 1910.1030). Because the laundry formula used cannot be customized for each product type, post-sort systems may offer additional challenges to maintaining the critical functional performance attributes of the products being laundered.

6 Laundry processing recommendations

6.1 General rationale

The processing of reusable surgical textiles is a complex process requiring specialized equipment, adequate space, qualified personnel who are provided with ongoing training, and continuous monitoring for quality assurance. Depending on the health care facility, the processing of surgical textiles might be accomplished by an in-house laundry, a shared laundry service, a commercial laundry, a linen supply service, or a facility providing finished sterile surgical textile packs. Regardless of the type of facility, certain work practices and procedures should be followed to ensure that surgical textiles will be safe to use on patients and provide satisfactory performance to surgical staff.

This section provides processing recommendations for laundries that utilize traditional washing and drying processes. The manufacturer of the finished textile product should be consulted before other types of washing and drying procedures are used. Alternative washing procedures should be qualified to demonstrate their ability to consistently produce clean textiles that meet their predetermined performance attributes (see 7). It is essential that each facility formalize internal work procedures and laundry formulas to achieve consistent and reliable results.

It should be noted that the use of home washers for the processing of reusable surgical textiles is not recommended. Home washers are designed for retail situations, and this design does not take into account industrial environments and hazards addressed in the OSHA bloodborne pathogen standard. Typical design limitations of home washers are lower temperature (<160^{o} F) washing, set cycle parameters, limited chemical access, and use recommendations that do not include the alkalis and acids commonly found in industrial cycles.

6.2 Washing

6.2.1 Procedures

The steps in a washing process should be completely described, controlled, and monitored for each classification. Many types of equipment and chemicals are used in washing processes. Each facility should formalize internal work procedures and laundry formulas to achieve consistent and reliable results. As part of the facility's quality assurance program, appropriate procedures should be in place to control changes to the process and formulas.

Rationale: Proper washing procedures are essential for the effective cleaning/decontamination of surgical textiles and for maintenance of the durability and performance attributes of the items being processed.

6.2.2 Loading of washing equipment

Loading practices should allow for free circulation of the textiles being processed and exposure to the various types of wash chemicals used during the process. Load size should be specified for each textile classification and for each type of equipment used. Equipment and textile product manufacturers' recommendations should be consulted when establishing the appropriate load size, including maximum and minimum weight limits for each classification.

Rationale: Improper equipment loading can inhibit the mechanical and chemical activities necessary to clean/decontaminate soiled textiles.

6.2.3 Steps in the washing process: laundry formulas

The washing process consists of a combination of mechanical action, water flow, water temperature, time, and chemicals to clean/decontaminate soiled textiles. These individual processes can be adjusted in commercial washing machines to optimize the productivity of the operation and the performance and durability of the textiles being processed. These processes should be automatically controlled by the equipment by means of a microprocessor or a punch card. Each individual laundry formula should have a separate punch card or, in the case

of a microprocessor, a unique formula number. Each step in a laundry formula should clearly define the following process settings: water level, water temperature, duration of the step, type of chemical, and amount of chemical.

Each laundry formula should specify the required steps/functions, most of which are described in 6.2.3.1 through 6.2.3.7. Due to the variety of products processed, some functions might specify different steps than others. In addition, some functions may be combined to provide duplicate functions in a single step within the laundry formula. Additional information on laundry formulas can be obtained from Riggs and Sherrill (1990).

Rationale: Laundry processes require a set of interrelated steps (functions) to clean/decontaminate and produce a product meeting its predetermined performance attributes. Definition of the process variables in the steps of the formula and automation of the laundry process help to ensure consistent and reproducible results.

Decades of work have been devoted to identifying laundry processes that destroy or remove microorganisms from textiles. Studies confirm that a number of interrelated factors contribute to the quantity of microorganisms removed from fabric, including

a) detergents;

b) action of oxidizing agents (e.g., chlorine bleach);

c) washing temperature;

d) action of repeated changes of water (dilution);

e) drying temperature in dryers or of ironers and presses.

Attempts have been made to rank the importance of these factors in eliminating microbial contamination, but no definitive studies are known.

Studies conducted at the Pennsylvania State University in the 1930s reported that a water temperature of 160° F (71° C) destroyed all bacteria present on textiles. Consequently, for years, many states required that health care textiles be processed at water temperatures of 160° F (71° C).

In recent years, research studies carried out in hospital laundry facilities have demonstrated that textiles can be washed hygienically clean at temperatures below 160° F (71° C), provided that suitable washroom chemicals are used, bleaching conditions are maintained, repeated changes of water occur, and textiles are finished over flatwork ironers or fully dried in tumblers. In fact, studies reported in 1984 revealed that with appropriate chemical use, hospital textiles processed at temperatures as low as 71° F (22° C) were as hygienically clean as those processed at 160° F (71° C) (Blaser *et al.* 1984). The term “hygienically clean” implies that items are free of pathogens in sufficient numbers to cause human illness.

6.2.3.1 Flush

In the flush step, bulk soils are removed (flushed) from the product. The flush relies on water flow and mechanical action to loosen and subsequently flush bulk soils away from the textile and to dissolve or remove water-soluble soils. Flushes are usually set at high water levels to facilitate soil removal and at low water temperatures (90° F [32° C] to 115° F [46° C]) to avoid setting of blood and imbedded stains. The flush step may include the addition of small amounts of chemical to aid in the initial removal of soil.

Rationale: Effective cleaning/decontamination depends on minimizing the amount of contamination present on items before the main cleaning/decontamination parts of the cycle begin.

6.2.3.2 Break

In the break step, alkali salts or other chemicals are added to the wash water to enhance soil removal. Alkalis cause the formation of an anion in the wash water (usually hydroxide or sodium oxide) that is able to decompose oily types of soils. Alkali products, sometimes referred to as “builders,” are frequently added to laundry detergents, because their function is compatible with the function of laundry detergents used in the main wash of laundry formulas.

Rationale: Typically, oil and water do not mix. Therefore, the removal of oily types of soils during laundering usually requires assistance from laundry chemicals.

6.2.3.3 Main wash (suds)

During the main wash step, the majority of imbedded stains are loosened and removed, primarily by means of chemical action, mechanical action, and water flow. Time, temperature, load size, and water levels can all be adjusted to maximize soil removal. The addition of soaps/detergents to the wash water is recommended to suspend soils after they have been loosened to prevent soil redeposition. Other types of chemicals can be used to enhance

the soil removal process. The two most commonly used are solvents and enzymes, but other types of products can be used based on the recommendations of the textile manufacturer and the chemical supplier and on internal results/experience. This step is sometimes referred to as the suds step.

Rationale: Effective removal of soil is necessary to maintain the aesthetic appearance of the product, to minimize potential contaminants, and to reduce levels of microbial contaminants.

6.2.3.4 Bleach

Bleaching is the use of oxidizing agents (usually sodium hypochlorite or hydrogen peroxide) to remove/reduce stains and/or whiten white cotton textiles. If low-temperature laundry cycles are used (i.e. cycles with water temperatures less than 160^{o} F [71^{o} C]), chemicals suitable for low-temperature washing should be used at proper use concentration. Sodium hypochlorite (chlorine bleach) is recognized as a disinfectant. For example, chlorine bleach in concentrations of 50 to 150 ppm has been recommended by the CDC to reduce levels of microbial contamination associated with a laundering process (CDC 1985).

NOTE—Due to the construction of certain textile products, some manufacturers recommend against the use of certain types of or all bleaches. As previously stated, the manufacturer's recommendations should be consulted in the development of processing procedures.

Rationale: Producing aesthetically and hygienically clean reusable surgical textiles is important to their acceptance by end users.

6.2.3.5 Rinsing

During rinsing, suspended soils and residual laundry chemicals are removed from the load. Multiple rinses are usually required to adequately remove suspended soils and residual laundry chemicals.

Rationale: Residual soils and laundry chemicals can be a source of skin irritation and contamination (pyrogenic or toxic) and can compromise the effective barrier performance of certain types of fabrics and liquid-repellent/resistant finishes. In addition, proper rinsing enhances the life expectancy and performance of any textile product.

6.2.3.6 Finishing (final rinsing)

Finishing is the final step in the laundering process and produces a properly washed and rinsed textile ready for extraction and drying. A laundry sour (acid) is usually required to neutralize any remaining alkalinity and to leave the textile at a compatible pH for human skin. Other finishing agents could include softeners, antistatic agents, antichlors, optical brighteners, bacteriostats, and "barrier" retreatment products.

NOTE—The overuse of fabric softeners can diminish the absorbency of cotton, which could be a contributing cause to wet packs after steam sterilization.

Rationale: The laundry process uses alkalis to support soil removal, and incoming water usually has an alkaline pH. Therefore, neutralization of these sources of alkalinity is required in order for textiles to be compatible with human skin (which has an acid pH) and to maximize the durability of some textile fibers such as polyester. In addition, other finishing products may be required based on the processing conditions, end-user needs, and/or the textile manufacturer's recommendations.

6.2.3.7 Extraction

Extraction involves the use of mechanical forces (usually centrifugal or strike/impact/press) to remove excess water from the load prior to drying. Centrifugal methods of extraction are recommended for textile products that contain man-made materials such as polyester, microporous membranes, and monolithic membranes.

Rationale: It is much more efficient to remove excess water by mechanical means than by heat. Certain man-made materials can be damaged by strike/impact/press extraction methods.

6.3 Drying

6.3.1 Procedures

The drying procedures need to be described, controlled, and monitored for each textile classification to ensure appropriate drying. Several types of equipment and heat sources are used to accomplish this task. The recommendations given here pertain to conventional drying equipment that utilizes gas, steam, or electric heat. Product performance should be verified to ensure the adequacy of alternative processes.

NOTE—The use of flatwork ironers on surgical gowns, drapes, towels, and sterilization wraps is not recommended.

Rationale: Water is known to be a pathway for bacterial transfer; therefore, adequate drying of products is essential to minimize the potential for microbial growth and transfer. In addition, products composed of 100% cotton or a cotton blend require adequate drying in order to be sterilized effectively after having been washed. Inadequate or excessive drying could damage products and/or adversely affect the sterilization process. Sterilization processes are not necessarily effective in drying products; wet towels entering a steam sterilization chamber are known to cause wet packs after the sterilization process is completed.

Due to the intensity of the heat and mechanical pressure applied by an industrial ironer, the fabric of a surgical textile product can be damaged, and any lint or other foreign matter on the fabric can be pressed into it. In addition, ironing surgical textile products in this manner compresses the yarns of the material, thereby reducing its ability to permit adequate penetration of the sterilizing agent.

6.3.2 Equipment loading

Loading practices should allow for free circulation of air around the load and should be specified for each textile classification and type of equipment. The equipment manufacturer's recommendations should be used as a guide, and the amount processed should never exceed maximum weight limits.

Rationale: Overloading equipment drastically reduces the effectiveness of the drying process. The rated capacity of processing equipment should be viewed as a maximum limit, because equipment manufacturers rate their equipment for the best possible productivity (pounds/hour), not necessarily the best possible quality for all product types.

6.3.3 Steps in the drying process: drying formulas

The drying process uses heat and air flow to dry damp textiles. The individual temperature settings, heating times, and cool-down times can be adjusted to optimize the productivity of the operation and the performance and durability of the textiles being processed. These processes are usually automatically controlled by a microprocessor or temperature/timer control. For each product classification, the drying formula should clearly specify the process variables of temperature, heating time, and cool-down time.

6.3.3.1 Heating

The first step in the drying process is to deliver heat to the damp load of textiles. Depending on the type of equipment used, inlet and/or outlet temperatures can be specified. The other main variable that needs to be specified is drying time; in some units, there is an automatic dryness sensor that can be used in lieu of a timer. The other process setting that can be programmed or changed in some units is the air flow.

Rationale: Control of temperature and time is not only important to ensuring an appropriately dried product, but some fabrics can melt or become distorted at elevated temperatures. Overdrying of products can also increase linting and decrease life expectancy. Control of drying times and temperatures helps maximize the performance and durability of all textiles produced.

6.3.3.2 Cooling

A hot, dry load should be cooled down to prevent damage (melting), make it comfortable to handle, and make it less likely to develop wrinkles. In particular, a cool-down cycle should be used for all textile products containing man-made materials such as polyester, microporous membranes, and monolithic membranes.

Rationale: Fabrics are often handled by laundry personnel immediately after drying. The cool-down phase makes it safer for employees to handle textiles and less likely for static shocks to occur. In addition, some synthetic fabrics can undergo thermal shock and subsequent wrinkling if they are exposed to dramatic temperature drops.

6.4 Process monitoring

6.4.1 Rationale for process monitoring

Monitoring the laundry process is essential to ensuring that it is consistently performing as expected to produce products that meet the needs of end users. The type and frequency of process monitoring will vary depending on the volume of surgical textiles processed, the age of the equipment, the type and degree of automation of controls, and the historical level of consistency of the process. The key is to establish written procedures outlining the facility's monitoring practices. Checklists can be used to facilitate and monitor compliance.

Process monitoring can be divided into three general categories: supplies, equipment operation, and finished products.

6.4.2 Process monitoring: supplies

Correct use of supplies is an essential part of each laundry formula. Supply considerations include the type of laundry equipment used, the laundry chemicals, the quality of the water, and the type and load size of the soiled textiles being processed. Common monitoring practices include verifying that the correct laundry chemical is used, the timing of the chemical injector is correct, the pump delivery is accurate, the quality of water is consistent, and the right type and load size of soiled textiles are being processed for each specific type of laundry equipment used and each laundry formula.

6.4.2.1 Verification of laundry chemicals used

In accordance with the OSHA Hazard Communication Standard (29 CFR 1910.1200), each chemical received and/or transferred to a secondary container must have a label indicating the product's name, the manufacturer, and the manufacturing lot number. For each product in use, there must be an MSDS on file, and copies must be made available at the point of use. Upon receipt and before the products are placed into service, the information should be reviewed to ensure that the correct product is used. For bulk shipments of chemicals, this verification should be completed before the chemical(s) is pumped into the storage tank. In addition, the following tests are available if it is necessary to assess whether the product meets the manufacturer's specifications.

a) *pH:* Most laundry chemicals have a unique pH, and the manufacturer specifies the allowed pH tolerance. The most common means of measuring pH are pH meters, pH paper, and titration.

b) *Specific gravity:* Most laundry chemicals have slightly different specific gravities, and the manufacturer specifies the allowed tolerances. Specific gravity is best measured by means of a hydrometer.

c) *Color:* Most chemical suppliers use dyes to allow for easy identification and differentiation of their products. Colors can be verified visually based on the color specified for the product or on color standards.

d) *Available chlorine (sodium hypochlorite bleach):* Liquid chlorine bleach is unstable in storage and should be checked on a routine schedule, based on the storage conditions. Chemical suppliers specify the "available" chlorine concentration and allowed tolerances. Available chlorine is best measured by titration; most chemical suppliers can provide the necessary test kit. See also Rutala (1996) and Rutala *et al.* (1998).

6.4.2.2 Pump delivery system

Most laundries have automated pumping systems to deliver the correct amount of laundry chemicals to the washing equipment. Correct operation of these pumps is essential to the correct performance of the laundry process. Pump delivery rates should be periodically checked, which can be accomplished either by verifying delivery or by using flow meters. Verifying delivery consists of checking the actual amount of product delivered to the equipment. Flow meters can also be used to check periodically the rate of flow and subsequent delivery rates at various times during the cycle. Checklists can be used to facilitate and monitor compliance.

6.4.2.3 Water quality

The quality of water varies based on region of the country and on whether the source of the water is an aquifer, lake, river, or reservoir. Monitoring and, as appropriate, treating incoming water are important to maintaining the consistency of the laundry formulas used. Water hardness, alkalinity, iron content, and pH are important characteristics of water quality.

a) *Water hardness:* Water hardness is the measure of the minerals in the water. It is recommended that water with a hardness of more than 2 grains per gallon be softened. Higher levels of water hardness can affect the laundry chemistry and increase the use rate of some chemicals (e.g., detergents). Water hardness is determined by titration. The parts per million of hardness is divided by 17.1 to arrive at grains per gallon. Most chemical suppliers can provide the necessary test kits.

b) *Water alkalinity:* The alkalinity of the incoming water, which can vary over time, can affect the chemistry of the laundry process and increase the use rates of laundry sours needed to effectively neutralize/sour the load being processed. Water alkalinity is determined by titration. Most suppliers of water treatment products can provide the necessary test kits.

c) *Iron content:* Iron in the incoming water can be a source of staining/discoloration of textiles and can accelerate the action of some laundry chemicals (e.g., chlorine bleach). If the iron content of the incoming water is high, it may be necessary to treat the incoming water or to use rust-removing chemicals.

d) *pH:* Incoming water has a specific pH that can be monitored; however, there is a relationship between water alkalinity and pH, and measuring water alkalinity is usually the preferred method of monitoring incoming water. The most common means of measuring pH are pH meters, pH paper, and titration.

NOTE—Changes in water quality and/or pipe repairs may necessitate an initial verification of water quality and laundry formulas, followed by an additional process monitoring program.

6.4.2.4 Type and load size of soiled textiles being processed

Textiles are often overlooked as an important incoming supply that can be controlled. It is necessary that the correct classification of soiled textiles (for pre-sort operations) and load size be controlled for each laundry formula used. In addition, it is commonly accepted that the sooner the soiled textiles are processed, the easier it will be to remove the stains and the lower the rewash rates will be.

a) *Load type (classification):* For pre-sort operations, each formula used should specify the type of product that it is intended to launder. Training of employees and subsequent review of their activities should verify that the correct formulas are being used.

b) *Load size:* All laundry formulas used should specify the load sizes that are acceptable. The load size or percentage of load size should conform to the recommendations of the textile manufacturer. Load size should be consistently controlled by the use of a calibrated scale for each load processed. Scales should be calibrated periodically to ensure that they are accurate.

NOTE—Calibration should be performed at least once a year, depending on the amount of drift seen between calibrations. If the drift is more than ± 5%, then calibration should be performed more often.

6.4.3 Process monitoring: equipment operation

Correct performance of laundry equipment is an essential part of the laundry process. The laundry equipment controls must send the right signal at the right time in order to correctly control the various parameters of the wash cycle. For each laundry formula used, the microprocessor or card unit that controls the individual steps in the cycle should be verified to be accurate (i.e. sending the right signal at the right time to the equipment). This verification can best be accomplished by visually verifying that the actual equipment controls and signals comply with the established master formula. In addition, the individual parameters of each step can be monitored directly. These parameters include time of each step, water levels, water temperature and pH, and chemical activity.

a) *Time:* The duration of each step is important in allowing for correct equilibration and dilution of chemicals and soils. The time can be checked on a routinely scheduled basis, which is best done by means of a stopwatch.

b) *Water levels:* The water level(s) used in each step are important in allowing for correct dilution of chemicals and soils. The equipment manufacturer has specifications for the water levels that can be selected and procedures that should be used to verify and, as appropriate, change level settings.

c) *Water temperature:* Depending on the laundry formula chosen, water temperature can play a more or less important role in providing hygienically clean surgical textiles. The temperature of the water during each step is important in ensuring the correct activity of the laundry chemicals used, in preventing soils from setting into fabrics in the initial part of the cycle, and in allowing safe handling of fabrics after washing. Water temperature is best checked by means of a thermometer; in some applications, infrared sensors are used.

d) *Water pH:* The pH of the wash water found within the specific laundry steps indicates whether the laundry chemicals have produced the desired pH. The pH is critical for chlorine bleach cycles but can also be a good indirect monitor of the alkali and sour baths. The pH can be measured by means of pH meters or pH papers, both of which are readily available, or by titration.

e) *Chemical activity:* The activity of each chemical depends on the following variables: load type/size, water level, water temperature, chemical use rate, and time. The activity of a specific laundry chemical can be measured directly by chemical titration, a process that takes into account the dependent variables of each step. The chemicals that are commonly titrated are alkalis and chlorine bleach. For each laundry cycle used, the break and/or suds and the final rinse alkalinity should be periodically titrated. In addition, for each cycle that uses chlorine bleach, the bleach step and the final rinse should be periodically titrated for available chlorine.

The master formula should be a controlled document; that is, there should be a change control procedure to ensure that changes to the formula can only be made by means of a formal change request and approval process.

6.4.4 Process monitoring: finished products

Certain process monitors can be used on processed fabrics (finished products or test pieces) to give an indication of how the laundry process has performed. Such process monitors include rewash rates, color transfer, pH spot tests, residual chlorine spot tests, and laundry test pieces.

a) *Rewash rates:* Rewash rates monitor the ability of a laundry cycle to remove objectionable stains. After soiled surgical textiles have been washed and dried, it is important that they be inspected for objectionable stains. Items with such stains should be removed from the system and reprocessed as necessary until they are deemed acceptable or discarded from the working inventory. Rewash rates are usually measured as the percentage of items that are unacceptable. This information can be reported by load or shift, daily, weekly, quarterly, annually, and so forth.

NOTE—The laundering of surgical textiles is more likely to generate stain rejects than the laundering of general textile supplies because of the high staining potential of agents to which surgical textiles are exposed in the work setting. Thus, rewash rates are potentially higher for surgical textiles.

b) *Color transfer:* Color transfer on surgical textiles occurs when hospital greens, blues, and whites are laundered together (i.e. textile classifications have been incorrectly combined in laundering). The colors transfer from colored to white fabrics, producing a tinting on the white fabrics. This tinting is permanent because polyester does not release color. Although dyed polyester fibers are fast to laundering, the migration of loose dye contained in new fabrics is sufficient to produce this tinting effect.

c) *pH spot tests:* The pH of a finished product can indicate whether it has been appropriately rinsed and soured. Depending on the product type and end use of the product, the final pH of the finished product can vary. However, all textiles should be soured to a pH in the range of 5.5 to 7.0 in order to be compatible with human skin and to maximize their durability. The pH of a finished product can be measured by means of a “universal” or “sour” tester. In these qualitative tests, a pH indicator is dropped on the product and gives a visual indication of the product’s pH by the resulting color change of the indicator. The indicator is usually placed on a white portion of the textile after extraction but before drying. Universal indicators are available from most laundry chemical suppliers.

d) *Residual chlorine spot tests:* The presence of residual chlorine indicates whether chlorine was appropriately used in the laundry process and rinsed from the product. Residual chlorine can reduce the life expectancy of textiles and is also a potential skin irritant. The presence of residual chlorine can be detected by means of orthotolidine, which turns yellow in the presence of chlorine; the darker the yellow, the more chlorine is present. Orthotolidine indicators are available from most chemical suppliers.

e) *Laundry test pieces:* The performance of a laundry cycle can be qualified by the use of laundry test pieces. Test pieces can be designed to evaluate soil removal, absorbency, degree of whiteness, tensile strength loss, pH, residual chlorine, mechanical damage, and so on. Test pieces are available from industry organizations and independent test laboratories.

7 Inspection, testing, and maintenance of laundered textiles

7.1 General rationale

Under normal conditions of use and for the duration of time in which they will be used, surgical textile products should perform their intended function as represented by the manufacturer’s label claims. As part of the documented quality assurance program, systems of control should be put into place to maintain the safety and effectiveness of these items. Careful consideration should be given to those attributes that can affect the important functional characteristics of the items during use. It is important to recognize that these functional characteristics might vary depending on the following: (a) product classification (e.g., gown, patient drape, table cover, sterilization wrap); (b) intended use (e.g., type of operation, role of personnel, estimated blood loss, time of procedure); (c) design (e.g., critical versus noncritical zones); (d) the materials of construction.

Some of the key elements of the overall quality assurance program that help ensure that the important functional characteristics of reusable surgical textile products remain intact are the inspection, testing, and maintenance programs, including, but not limited to

a) determination of functional requirements to meet safety and effectiveness criteria;

b) identification of the important attributes that are likely to be affected by processing and reuse;

c) establishment of a method of monitoring/tracking reuse (grid, bar code, or other device);

d) selection of appropriate quality control procedures, including process validation, sampling, and testing methods for the attributes identified in (b) (see, for example, American Society for Quality Control [ASQC 1993]);

e) development of rewash/repair/retirement/alternate-use policies.

During development of the inspection, testing, and maintenance programs, the manufacturers' recommendations should be taken into account. Products that need maintenance should continue to meet their functional performance requirements.

7.2 Visual inspection

7.2.1 Quality standards

Before each reuse, all surgical textile products should be visually inspected against written quality standards. These standards should be developed by individuals responsible for product inspection in consultation with end users and should be based on functional requirements and the identified important related attributes, which may vary depending on product classification, design, construction, and intended end use. After each laundering, the critical zones of gowns, drapes, table covers, and sterilization wraps should be visually inspected with the assistance of a light table to determine if

a) stain or residue removal is necessary (see 7.2.2);

b) physical defects, such as holes and missing components, need to be repaired (see 7.2.3);

c) chemical or thermal damage needs to be repaired (see 7.2.4);

d) foreign debris (e.g., lint, hair) needs to be removed (see 7.2.5);

e) appropriate labels are in place (see 7.2.6);

f) the tracking system is intact (see 7.2.7).

The written quality standards should define the acceptance and rejection criteria for each product type and explain how rejected items should be handled. Depending on the functional requirements, there may be different limitations for various items or even for different areas within the same item.

NOTE—To help maintain consistency among inspectors in the interpretation of acceptance/rejection criteria, it may be useful to keep an updated booklet of examples of observations made during visual inspections and the corresponding disposition.

Rationale: Visual inspection of surgical textile items is one of the most important elements of the quality assurance program. Many of the conditions that can make a surgical textile product unacceptable can be detected during this process.

7.2.2 Stains

Discolorations in surgical textile products, often referred to as stains, can be caused by a number of factors, many of which may not represent a significant problem. However, when discoloration is noted during inspection, the area of discoloration should be evaluated further to determine if functional performance has been affected.

Discolorations may be the result of a lack of color (the textile color has been removed) or a change in color (the original textile color has been changed by the removal of one of the dye components or the textile has been redyed by a clinical fluid, such as iodine, methylene blue, or ink from a surgical marking pen). Typically, surgical textile products discolored in these ways do not represent a functional problem, and their continued use should be discussed with the end users. The retirement of items that are discolored but still functional is an economics-based decision requiring the involvement of all pertinent departments (laundry, end users, administration, purchasing, and other departments as appropriate).

Discolorations may represent a problem if the functional performance of the surgical textile product has been significantly affected or if some type of residue has been added to the textile. Items discolored by residual soils, such as medicines, lubricants, blood or other body fluids, adhesives, and hard-surfaced or foreign matter of unknown composition should be rejected. These items should be reprocessed using appropriate laundering or stain removal methods.

NOTE—Preventing stains, whenever possible, is the best strategy, and communication is the key. The agents responsible for staining surgical textile products can often be determined by observing the products during use and then exposing test swatches with likely contaminants. In any event, timely communication between the end users and the processing department will help to ensure that staining problems are caught early, thus minimizing the financial impact.

Rationale: The acceptability of surgical textile products for use in surgery may be influenced by their appearance and the user's perception of cleanliness. Discolorations that do not interfere with the functional performance of a textile are acceptable, and every effort should be made to allow for their continued use. However, discolorations due to certain types of residual soils must be removed before the item can continue in service, because they can prevent adequate sterilization.

7.2.3 Physical defects

Physical defects that compromise the intended function of the surgical textile product should be identified and repaired prior to reuse. These defects can include such things as loose threads, loose or missing ties or other attachments, damaged or missing snaps, cuts, tears, and holes that are generated through normal wear and tear or improper use and handling. Physical defects present inside the critical zones of gowns, patient drapes, table covers, and wrappers might require specialized repair procedures (see 7.4.1 and 7.4.2).

NOTE—Preventing physical defects from occurring during the effective life of surgical textile products is important. One helpful strategy is to educate end users about the need to use instrument pads over patient drapes and to avoid the use of penetrating clamps. Working with end users to design draping systems that avoid the need for cutting the fenestration can also be beneficial. Also, all surfaces that come into contact with the surgical textile products should be smooth and free from sharp edges. Again, timely communication between the end users and the processing department will help to ensure that potential causes for damage are caught early, avoiding excessive damage and minimizing the financial impact.

Rationale: Physical defects that compromise the function of surgical textile products can often be avoided with effective communication. However, when these defects do occur, they can often be repaired, allowing the items to continue in service. Systems of use and processing that produce unwarranted physical defects can significantly increase costs through reduced life, increased inventory, and increased labor.

7.2.4 Chemical/thermal damage

Placing inappropriate or excessive chemical or thermal stresses on surgical textile products during use in surgery and during processing can cause damage. Each type of damage is usually related to a specific improper use and handling event, such as direct contact with a concentrated laundry chemical like chlorine bleach, overheating in the drying process, and direct contact with surgical glue or cement, activated high energy electrosurgical instruments, or lasers. Chemical or thermal damage usually becomes apparent through discoloration, stiffening, or holes through the surgical textile product. Depending on the severity of the chemical or thermal exposure, the extent of damage and corresponding size of the damaged area can vary. Products can continue in service if the important functional attributes have not been significantly changed or if the item can be repaired.

Rationale: Chemical and thermal damage can compromise the function of surgical textile products. When the extent of the damage is not severe, the product can often be repaired, allowing it to continue in service. Determining and eliminating the cause of chemical and thermal damage is important in minimizing cost. See also 6.3.1 regarding ironing.

7.2.5 Foreign debris

Surgical textile products should be as free from foreign debris as possible. Foreign debris is most often found in the form of lint (e.g., loose fibers, pills); however, it can also be composed of hair and other particles. If found during inspection, foreign debris should be removed from all surfaces of surgical textile products by means of sticky-surfaced tape or delinting rollers.

Written work practices that keep surgical textile products free from foreign debris should be implemented, such as

a) dress codes for the inspection/packaging area (e.g., dedicated uniforms/cover-ups, hair nets/beard covers);

b) handwashing procedures;

c) good housekeeping procedures;

d) maintenance (e.g., keeping dryer lint screens clean).

Rationale: If the foreign debris found on surgical textile products enters the surgical wound, it can increase the possibility of postoperative complications in the patient, such as a wound infection, adhesion, or foreign body reaction.

7.2.6 Labeling

Upon initial receipt, surgical textile products should be visually inspected for appropriate labels, such as garment/drape labels identifying manufacturer and product type and labels providing lot code numbers. Newly purchased surgical textile products must also be accompanied by the manufacturer's care and handling instructions.

Labeling that designates the lot code number for the product should remain intact throughout the effective life of the product.

NOTE—The initial evaluation of each surgical textile product should include an evaluation of the labeling system and of the impact of any changes in the laundering and/or sterilization processes on label durability.

Rationale: The labeling provided by the manufacturer on the care and handling of surgical textile products helps ensure that the products are processed correctly. To help prevent misuse of a product and to assist in the resolution of performance complaints, the labeling system must remain intact.

7.2.7 Tracking system

If appropriate, the tracking mechanism (grid, bar code, or other device) on surgical textile products should be visually inspected, marked, scanned or read with each processing. If the integrity of the tracking mechanism is in question, the item should be pulled from service or an alternative method put in place to track uses until the problem is resolved.

NOTE—Some of the tracking systems available today are very sophisticated and can assist the health care facility both in ensuring functional performance and in understanding and better controlling many of the important cost-related factors. Tracking systems can also help facilitate the documentation of the test results and the repair history for each item to allow for identification and trending of potential problems.

Rationale: To achieve the goal of providing safe and effective surgical textile products, all surgical textile products that provide barrier protection should contain a tracking mechanism that is maintained in good working order throughout the effective life of each product. Tracking mechanisms are used to ensure that testing occurs at appropriate intervals, as well as allow for traceability to the manufacturers' products and components.

7.3 Testing

7.3.1 Test procedures

Surgical textile products are used in an effort to reduce the risk of exposure for the patient and the surgical team by helping to prevent contact with pathogenic microorganisms. Manufacturers, independent labs, academia, regulatory agencies, and the medical community have all been involved in the development and use of laboratory-based test methods for surgical textile products. Laboratory testing should provide a realistic estimation of in-use safety and efficacy and allow both manufacturers and the medical community to make a meaningful assessment of the appropriate use of products in surgery. Assuming that the testing done in the laboratory is relevant to the task and degree of exposure anticipated in surgery, the tests should in effect help to reduce the actual risk associated with pathogenic microorganisms and help provide an environment for higher quality patient care.

NOTE—AAMI (1994b) is a useful reference for applicable test methods. AORN (2000b) describes the criteria for sterilization wrap and other packaging systems, and AORN (2000e) addresses barrier materials for surgical gowns and drapes.

Manufacturers should provide methods for monitoring the important functional performance characteristics at regular intervals during a product's expected life. All test procedures should be supported by valid scientific data and relate to comparisons made between testing done in the lab and performance of the product in surgery. Preferably, the procedures used to evaluate these attributes should consist of quick, simple, nondestructive tests that do not contaminate the product (do not require rewash). Any test items that are contaminated by the test procedure and/or by the act of performing the test should be reprocessed. The test procedures should not compromise the safety and efficacy of the products.

Rationale: The performance of a reusable product is predicated on the effectiveness of the quality assurance program established to maintain its continuing safety and efficacy. Utilizing the right test can help ensure that the products perform as intended, improving infection control practices, providing a safer medical care environment, and providing the basis to compare costs between equally protective products. It should be noted, however, that laboratory tests of the barrier capability of a particular product can only provide an estimate of its effectiveness under what has been described by the American College of Surgeons Committee on the Operating Room Environment as "usual conditions of use."

7.3.2 Microbiological cleanliness

Surgical textile products should be hygienically clean and possess an inherent bioburden low enough to allow for safe handling and effective sterilization. Compliance with recommended laundering temperatures of 160° F (71° C) or the appropriate use of chemicals, along with good environmental and personnel controls, will ensure that microbial loads have been sufficiently reduced during laundering and maintained during transportation and handling. Facilities regulated by FDA may be required to monitor bioburden, depending on the method used to validate the sterilization process.

NOTE—Recommendations for the proper disinfection of surgical textile products can be found in CDC guidelines (CDC 1985) and OSHA regulations (29 CFR 1910.1030).

Rationale: The term "hygienically clean" implies that the surgical textile items are free of microorganisms in quantities capable of causing infection. The literature and history indicate that the practices described above are more than adequate for reducing bioloads on soiled textiles and preparing them for sterilization.

7.3.3 Effective life

The effective life of reusable surgical textile products can be influenced by a combination of many things including product durability, use conditions, and process control. Manufacturers must provide labeling and recommendations that specify the process guidelines. The labeling and recommendations constitute the specifications for products being processed and delivered for use in the health care facility. If the product durability is consistent and the processing is in accordance with the labeling, an appropriate level of functional performance testing to assure product quality can be determined. Validation of the process can further minimize the need for performance testing.

The durability of reusable surgical textile products is often determined by evaluating the gradual change over time of the barrier properties (e.g., gradual loss of a repellent finish, progressive deterioration of a film or coating). The general barrier properties of some products can be rejuvenated (see 7.4.4). However, there may be other important functional attributes, such as absorbency, strength, and drapeability, that should be evaluated as well. Some forms of aging, such as holes, thin or worn spots, and (in laminated or coated textiles) layer separation, can be readily apparent during the visual inspection process. Some of the chemical treatments used to impart repellency, as well as membranes and coatings used to improve the barrier properties of textiles, might require more specialized testing and evaluation according to the manufacturer's recommendations.

NOTE—The surgical textile product manufacturer should be consulted for directions on the evaluation of the critical performance attributes for their product.

Rationale: It is important to properly characterize the effective life of reusable surgical textile products in order to help prevent unsatisfactory results during use in surgery. Manufacturers' claims about the durability of their products can only be used as a guideline. Differences in the product quality and in-use or processing conditions in different health care facilities can vary the number of times a product can be reused and continue to function properly. Therefore, since there are no absolute rules that can be generally applied to estimate the effective life of all products, it is important that each facility establish appropriate quality assurance measures.

7.3.4 Important functional attributes

Quality assurance measures should be employed to determine when the attributes related to the required functional performance of the reusable surgical textile product have been significantly altered or degraded. Tracking the number of uses and times processed of each product (see 7.2.7) and employing properly designed, statistically valid sampling plans with defined acceptance and rejection criteria will be necessary. If products that fail to meet the acceptance criteria cannot be rejuvenated, they should be removed from service or placed in an alternate-use category. Product that has failed to pass the quality control inspection process should be physically separated and visually identified by signage or by the color of the bin or bag.

Depending on the product classification, design, construction, and intended use, different functional performance requirements might be applicable. Implementation of an effective tracking and testing strategy will require a cooperative effort among end users, processors, and manufacturers.

Rationale: See the rationale statements for 7.3.4.1, 7.3.4.2, 7.3.4.3, and 7.3.4.4.

7.3.4.1 Barrier efficacy

The barrier properties of surgical textiles should be evaluated at appropriate intervals to ensure that they perform as intended. It should be noted that there are a variety of different barrier products available on the market that might require different methods of evaluation. Manufacturers must provide specific guidance concerning the test methods that should be used for evaluating the ongoing barrier efficacy of their products. The results of the evaluation should be documented.

There are two general categories of protective materials: those that rely on repellent finishes and/or construction (these products are generally considered to be liquid-repellent or liquid-resistant) and those that rely on reinforcement by films (these products are generally considered to be liquid-proof or impervious). Even within the same product, one area or "zone" may be more resistant to liquid and microbial penetration than another; for example, the area around the fenestration of surgical drapes is typically reinforced in some way to provide more resistance than other portions of the drape. Depending on the type of protective material and the expectations for barrier performance, different test methods are required.

NOTE—Manufacturers' claims for barrier performance must comply with the data that were submitted to FDA in support of their 510(k)s. If the test methods recommended by the manufacturer for evaluating the ongoing barrier efficacy are different than the test methods referenced in the 510(k), comparative data should be made available to determine consistency.

Rationale: Maintaining the barrier properties of reusable surgical textile products is important in protecting both patients and medical personnel from the transfer of microorganisms, body fluids, and particulate matter.

7.3.4.2 Liquid/fluid control

Absorbent materials are often used in the critical zones of surgical drapes, table covers, and other items to help control fluids in surgery. If these materials are used, the absorbent properties of the materials should be evaluated at appropriate intervals to ensure that they perform as intended. Absorbent materials are often backed by a film reinforcement to help prevent strike-through. Manufacturers should be consulted for specific guidance concerning the best method for evaluating the effective life of their absorbent barrier materials.

NOTE—The term “fluid” is commonly used in health care, often in place of the term “liquid.” Although these terms may sometimes be used interchangeably, it should be recognized that “fluids” also encompass air and aerosols; therefore, it is not an appropriate term to use when referring strictly to liquids.

Rationale: The absorbency characteristics of materials that are used in the critical zones of surgical gowns, patient drapes, and table covers to help control liquids in surgery can change. Improper processing or the inappropriate use of laundry chemical additives intended for the rejuvenation of repellent/resistant materials can negatively affect the absorbency characteristics of some materials. Alternatively, since barrier efficacy is often denoted by fluid repellency, absorbency should not be confused with a loss in barrier properties when the absorbent materials are reinforced with a film. These two attributes, absorbency and barrier efficacy, should be evaluated separately and not confused.

7.3.4.3 Strength properties

Reusable surgical textile products are normally manufactured from materials that are very strong in order to withstand the rigors of the wash, dry, and steam sterilization process. Products that have an area that appears to be weak and that can be easily torn should be repaired or removed from service.

Rationale: Barrier materials should be strong enough to withstand the stresses encountered during typical use and processing. Rips and tears can compromise the sterile field by allowing strike-through to occur during use in surgery.

7.3.4.4 Drapeability

Surgical gowns, patient drapes, table covers, and wrappers should be drapeable (flexible). Products that appear to be too stiff to conform to the body, appropriately drape the patient or equipment, or wrap packs should be removed from service.

Rationale: Drapeability refers to the tendency of a material to conform to a given shape or object. Drapeability contributes to comfort and appropriate protection, and it enhances the sterile field. It is important that a surgical textile product remain drapeable throughout its expected life. Improper processing, especially overexposure to heat, can stiffen many materials, making them less flexible.

7.4 Maintenance

7.4.1 Patching

Physical defects, such as cuts, tears, and holes, that are present inside the critical zones of gowns, patient drapes, table covers, and wrappers should be repaired with heat-sealed patches that

a) are durable;

b) are made of the same basic material as the item being patched;

c) provide at least the same performance characteristics as the textile being repaired;

d) allow for effective sterilization;

e) are applied according to the manufacturer’s instructions or a validated process.

Patches should not be sewn to the textile being repaired. Loose patches should be removed, and new patches should be applied. Heat-sealed patches should be applied to one or both sides of the textile, as indicated by the design, configuration, or use of the item. The acceptable location, number, shape and size of patches should be clearly delineated in written quality standards and repair procedures.

Rationale: Patching might be required during the lifetime of a surgical textile product. Patching can allow an item to be returned to service and fulfill its life expectancy.

7.4.2 Mending

Physical defects, such as loose threads, loose or missing ties or other attachments, and damaged or missing snaps, should be mended. “Mending” generally refers to repairing textile products by sewing. In some cases, heat-sealed

patches may be used to mend physical defects by applying them directly to the fabric without sewing (see 7.4.1). However, sewing may be employed in the noncritical zones of surgical textile products to replace missing ties or snaps and to fix fraying hems or seams. Sewing should not be performed in the critical zones of products without using a patch afterwards to seal the needle holes. All items that have been mended should be completely inspected, inside and out, to ensure that the area has been correctly repaired. If an item has become contaminated during the mending process, it should be sent to rewash before it is placed back into production.

Rationale: Mending may be required during the lifetime of a surgical textile product and can allow an item to be returned to service and fulfill its life expectancy. It is important that needle holes in critical zones be sealed with a patch, because needle holes are breaches in the structure that can allow strike-through to occur during use of the textile product in surgery. Mending methods and work practices could increase the bioburden levels on the item being mended, hence the possible need for rewash.

7.4.3 Rewash

Surgical textiles that are found to contain stains, foreign debris, or residues during the inspection process should be segregated for rewash or retirement. Certain types of staining, color loss, or color transfer may be deemed acceptable, and thus rewashing of the item might not be required (i.e. if the stain is located in a less critical area of the product and does not affect the functional performance of the product). If a reusable surgical textile product requires rewashing, the procedure used should be compatible with the product. Each rewash cycle should be counted as an additional life cycle for the item. Manufacturers should be consulted before the use of any “special” chemicals, stain removal procedures, or wash process parameters to be sure that these procedures are compatible with the product and that there will be no negative impact on the effective life of the product. If possible, discolorations and foreign debris should be removed before steam sterilization. If a stain in a critical area of the surgical textile product is not removed after repeated rewashes, the product should be removed from service or downgraded to a less stringent category.

Rationale: From time to time, items might not come completely clean during the washing process. Rewashing can be extremely effective at cleaning the item and allowing it to be returned to service. However, even though a cycle is often defined as a wash/dry/sterilization cycle, the rewash/dry cycle of the process adds to the long-term effects on the product and fabric. Therefore, each rewash cycle is counted as a full cycle.

7.4.4 Rejuvenation

If a laundry additive is used to maintain repellency or if reusable surgical textile products require rejuvenation, the procedure used should be compatible with the product. Rejuvenation cycles should be counted as additional life cycles. Manufacturers should be consulted to ensure that rejuvenation procedures are compatible with the product.

Rationale: If used effectively, laundry additives and rejuvenation procedures can help maintain the barrier properties and extend the useful life of some items.

7.4.5 Retirement/alternate use

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). Products placed into alternate use or remade into different products must continue to be safe and effective for their intended use. Items placed into alternate use should be permanently marked in some obvious fashion in order to prevent mixups or inappropriate use.

Rationale: Downgrading products for use in appropriate, less stringent applications can help control health care costs. For example, the life expectancy of surgical gowns with barrier properties can often be extended after their protective properties are diminished by downgrading them for use in applications where barrier performance is not required.

8 Preparation and packaging

8.1 General rationale

It is important that items to be used in the surgical environment be folded, assembled, wrapped, and sterilized in a manner that will allow them to be used by the end user with as little manipulation and chance of contamination as possible. This section covers preparation and packaging procedures in the surgical pack assembly area.

8.2 Procedures

Preparation and packaging procedures should be developed and documented to ensure that all products are folded and packaged properly and consistently each time they are processed. It is essential that the end user play an integral role in the development of these procedures.

Rationale: It is necessary that the method of folding and pack assembly allow for the item's presentation to the sterile field without contamination. By involving the end user in the development of these procedures and then documenting the procedures, the potential for incorrect folding of items and assembly of packs, confusion of the end user, and the resulting costly reprocessing of contaminated items can be minimized.

8.3 Folding

Following inspection, all items should be folded in a manner that will allow them to be aseptically donned or presented to the sterile field. The method of folding should also allow for effective sterilization (see AAMI [1994a]). In addition, the method of folding should allow for easy identification of the item. Whenever possible, like items should be folded according to the same general procedure to allow for consistency. The method of folding should be mutually agreed upon between the using department and the processing facility. Once the method of folding is agreed upon, the procedure should be developed and documented. Written procedures should be reviewed periodically to ensure that they are still applicable.

Rationale: See 8.1 and the rationale statement for 8.2.

8.4 Pack assembly

Following folding, items should be placed into the pack configuration in a logical order that allows for aseptic presentation by the end user to the sterile field. The pack order, top to bottom, should be developed in consultation with the end user to ensure that items can be removed from the pack, in their order of use, without compromising the sterile field or creating inconvenience. After the order of the pack is agreed upon, the pack configuration should be documented in a procedure. It is recommended that the contents and order of each pack be reviewed by the end user and the laundry manager to ensure that the pack meets all applicable requirements and to minimize the inclusion of unused items. A separate procedure should be developed for each different pack produced.

Rationale: See 8.1 and the rationale statement for 8.2.

8.5 Wrapping

After the pack is assembled according to the applicable procedure, it should be wrapped in a barrier material that provides adequate coverage of the contents, allows for aseptic presentation, and is appropriate for the method of sterilization. (Steam sterilization is the method of choice for reusable surgical textiles.) This barrier may consist of different items, such as a wrap or table cover, provided that the barrier performance properties comply with AORN (2000e) and AAMI (1994a). The type of barrier used should be documented in the device master record (DMR). Following sterilization, the pack may be placed in a secondary package (e.g., dust cover) to further preserve sterility and extend shelf life.

NOTE—Wrapping methods should be determined by the end user's requirements for aseptic presentation and for end use of the wrapper. The choice of wrapper and wrapping method also depends on such factors as the handling, transportation/delivery, and storage conditions and practices at the processing facility (laundry, manufacturer) and/or within the health care facility.

Rationale: See 8.1 and the rationale statement for 8.2.

8.6 Labeling/identification of packs

Before delivery to the customer, assembled packs should be labeled with at least the following information:

a) pack identification (e.g., pack code and name);

b) list of pack contents;

c) identification of who assembled the pack;

d) identification of who sterilized the pack;

e) date of sterilization;

f) lot number;

g) expiration date, if applicable.

NOTE—For packs in commercial distribution, the information specified in items (c), (d), and (e) may be made available by reference and need not actually be printed on the label. For packs not in commercial distribution, the information specified in items (b), (c), (d), and (e) may be made available by reference and need not actually be printed on the label.

Steam sterilization indicator tape may be affixed to each package if procedures and/or customers dictate.

When nonsterile packs are transported in finished form, safeguards should be in place to ensure that the packs are not mixed with or mistaken for sterile items. This is particularly important if items are packaged in their final form with all appropriate labeling before being moved to the sterilization location. It may be necessary to mark information on the label in two different stages, especially if pack assembly is being performed at a different location than terminal sterilization.

Marker inks used for labeling should be indelible, steam-sterilization-stable, nonbleeding, and nontoxic.

The history of pack assembly for each pack should be documented to ensure that all appropriate inspections and processes have been successfully completed. (Device manufacturers commonly refer to this documentation as a device history record [DHR]).

The FDA requires that nonsterile medical devices, such as surgical gown, drape, and towel packs, that are placed into commerce and that are to be sterilized by the health care facility prior to use be accompanied by sterilization directions (21 USC §321 and §322). See also AORN (2000b).

Rationale: Proper labeling and identification of packs is important in ensuring traceability in the event of product recalls and complaint investigations.

9 Handling, transport, and storage of laundered textiles

9.1 General rationale

After laundered textiles are inspected and found to be acceptable, they are transported to an environmentally controlled area for inspection, pack assembly, and preparation for sterilization and/or distribution to the end user. It is important that a high level of cleanliness be maintained during handling, transport, and storage to ensure that bioburden is controlled and that the quality of the surgical textiles is acceptable at the point of use. This section provides guidelines on work practices and environmental controls needed to minimize performance degradation of clean textiles, the potential for cross-contamination, and the possibility of overtaxing the sterilization process.

NOTE—Further information on the transport of sterile items to the point of use is provided in AAMI (1993a) and AAMI (1994a).

9.2 Procedures

Written procedures should be established for handling, transporting, and storing clean/sterile textiles, beginning with their delivery from the laundry to the inspection/folding area and ending with their delivery to their ultimate destination in the main storage area.

Rationale: Written procedures provide the basis for implementation of training and for the setting of employee performance expectations.

9.3 Personnel attire and hygiene

Delivery personnel, including route representatives, should maintain a clean and professional appearance. See also 4.4 and 4.5.

Rationale: See 4.4 and 4.5.

9.4 Handling clean/sterile textiles

Clean/sterile textiles should be handled as little as possible and with clean hands. Clean/sterile textiles should never be in contact with unclean surfaces (e.g., the floor); if they are, they should be relaundered.

Rationale: Physical handling of textiles increases the possibility of microbial transfer and the subsequent product bioburden.

9.5 Transport

9.5.1 General

Clean/sterile surgical textiles should be transported within the laundry facility or to the end user by methods designed to avoid physical damage and minimize microbial contamination from surface contact or airborne deposition.

Rationale: Appropriate methods of transport and product protection help ensure the delivery of acceptable, noncompromised products to the end user, either for terminal sterilization or for direct use as clean products.

9.5.2 Method of transport

Clean/sterile surgical textiles should be transported within the laundry or user facility in containers that have only clean/sterile product in them. After clean/sterile product has been removed, containers may be used for the return of soiled products if appropriately labeled. Among the containers that may be used are

a) hampers that are lined with clean liners and that are then closed or covered with a clean cover to protect the contents;

b) carts covered with clean sheets and further protected by secured covers;

c) textile racks covered completely with suitable covers;

d) enclosed, cabinet-like carts.

Rationale: See the rationale statement for 9.5.1.

9.5.3 Separation of clean/sterile and soiled textiles

Clean/sterile and soiled textiles should be transported from the laundry to the user facility in vehicles (e.g., trucks, vans, carts) that allow for separation of clean/sterile and soiled items. This separation can be accomplished by

a) using appropriate safeguards when using the same vehicle to transport clean/sterile and soiled textiles (see 9.5.5);

b) transporting clean/sterile and soiled textiles in separate closed/covered containers or vehicles;

c) wrapping and closing bundles of clean/sterile textiles;

d) using cart liners and covers to prevent gross environmental contamination of the products being delivered; and/or

e) appropriately marking carts and/or bins with signage and/or color coding that distinguishes clean/sterile product from soiled product.

Rationale: Appropriate use of barriers and containment of products minimizes the possibility of cross-contamination by inadvertent contact or an event.

9.5.4 Laundry cart cleaning and loading

9.5.4.1 Cleaning

Depending on where and how clean/sterile surgical textiles are transported and stored within each facility, procedures should be developed for laundry cart cleaning. Any cart used to contain and transport only clean/sterile surgical textiles within the facility should be cleaned on a regular basis or when visibly soiled. Carts used to transport clean/sterile surgical textiles outside the facility should be cleaned upon return to the facility. Carts used to transport soiled textiles should be cleaned once the cart has been emptied and prior to use for the transport of clean/sterile surgical textiles. Reusable cart covers and liners should be cleaned after each use.

Containers and reusable cart liners and covers can be properly cleaned with steam, soap and water, or an appropriate detergent/disinfectant; cart covers and liners can also be laundered.

Compliance with written procedures for cleaning and maintenance of containers, liners, and covers should be documented and approved by the facility's infection control committee.

Rationale: Laundry carts can be a source of environmental contamination and should be regularly cleaned/disinfected to ensure that microbial transfer is minimized during transport of clean/sterile textiles.

9.5.4.2 Loading

Loading procedures should be developed to ensure that products are appropriately segregated and labeled for identification and to minimize the possibility of gross environmental contamination.

Rationale: Loading procedures are needed to prevent gross environmental contamination of clean textiles, to ensure that certain types of textiles are not mixed together (e.g., low-linting surgical fabrics and high-linting fabrics such as terry cloth products), and to minimize the reprocessing of items that are not handled properly.

9.5.5 Truck cleaning and loading

Clean/sterile textiles and soiled textiles may be transported in the same vehicle, provided that it can be verified that the use of physical barriers and/or space separation is effective in protecting the clean/sterile items from contamination. Vehicles used to contain and transport surgical textiles should be cleaned on a regular basis or when visibly soiled. However, if it cannot be verified that the containment systems used for the transportation of soiled items do not prevent contamination of the vehicle, the truck should be cleaned after each use.

Rationale: Laundry trucks can be a source of environmental contamination and, therefore, require regular cleaning/disinfection to ensure that microbial transfer is minimized during transport of clean/sterile textiles. Since soiled textiles are a potential source of microbiological contamination, cleaning procedures and work practices should be developed to minimize the potential contamination from this source.

9.6 Storage

9.6.1 Storage conditions

Written procedures should be developed for the storage and handling of clean/sterile surgical textiles. Textile packs should be stored at least 8 to 10 inches from the floor, at least 18 inches from the ceiling, and at least 2 inches from outside walls. They should be positioned so that they are not crushed, compressed, or punctured and so that their integrity is not otherwise compromised. Textile packs should not be stored next to or under sinks, under exposed water or sewer pipes, or in any location where they can become wet. Storage on floors or windowsills or in areas other than designated shelving, counters, or carts should be avoided.

Rationale: Appropriate storage conditions will help minimize bioburden on clean items, thus facilitating the subsequent sterilization process, and help ensure that the integrity of textile packs is not compromised before use. The specific recommendations given in 9.6.1 are based on AAMI (1994a).

9.6.2 Storage shelving

Closed or covered cabinets are recommended for the storage of clean/sterile surgical textile items. Open shelving and/or carts may be used, provided that proper attention is devoted to traffic control, area ventilation, and housekeeping practices. Shelving and/or carts used for storage should be maintained in a clean and dry condition. If shelving is used, the bottom shelf should be solid or lined with plastic, or items stored on the bottom shelf should be placed in containers. Outside shipping containers and corrugated cartons should not be used as containers in clean storage areas.

Rationale: Closed cabinets limit dust accumulation, discourage handling, and minimize inadvertent contact. Shipping containers have been exposed to unknown and potentially high microbial contamination and also, particularly those that are corrugated, serve as generators of and reservoirs for dust. Barrier shelving for bottom shelves provides protection against inadvertent contamination during normal floor maintenance (e.g., mopping).

9.6.3 Stock rotation

Finished packs should be rotated and used on a first-in, first-out (FIFO) basis. Textile inventories should be controlled, shelves should be labeled, and procedures should be established for stocking items and removing them from inventory.

Rationale: Correct stock rotation and inventory management help prevent the degradation of pack contents over time and promote sterility maintenance.

10 Installation, operation, care, and maintenance of laundry equipment

10.1 General rationale

This section provides recommendations for the installation, operation, routine care, and maintenance of processing equipment and support systems (utilities and ancillary equipment) used to clean, disinfect, and produce textiles meeting their predetermined performance attributes.

Cleaning soiled textiles requires processing equipment to wash, extract, and either condition or dry the items. Washing and extraction can be carried out in the same piece of equipment or in separate washing and extraction processes. Drying and conditioning are usually separate processes.

A program to maintain and repair the equipment is necessary to ensure correct operation. In addition, washing and drying equipment relies on certain support systems in order to function correctly or at peak efficiency. These support systems might include chemical delivery systems, water softeners, water heaters, boilers, air compressors, heat exchangers, and/or water reuse systems. Also, other types of processing equipment, such as steam tunnels, flatwork ironers, and small-piece folders, might be employed to improve productivity or product appearance.

10.2 Documentation

10.2.1 Identification

The user should verify that each piece of equipment used in the process has one or more information plates, permanently fastened and accessible, which provide the

a) name and address of the manufacturer;

b) serial number or other unit identification;

c) model number;

d) voltage requirements;

e) maximum load size (weight).

Rationale: In view of the relatively long life of washing/drying equipment, a permanently fastened identification plate is necessary in order to permit the identification of essential characteristics if operating manuals have been lost.

10.2.2 Safety

The user should verify that the manufacturer has provided safety instructions describing the potential hazards associated with equipment use, as well as certification that the equipment incorporates appropriate safeguards conforming to all local, state, and federal regulations. The user should also request documentation demonstrating that the equipment complies with ANSI (1996), a voluntary standard that addresses the safe operation and maintenance of washer-extractors, extraction presses, and other industry equipment. The safety features should be described in literature accompanying each piece of equipment.

Rationale: Employee safety dictates that all work hazards be identified, communicated effectively with staff members, and appropriately monitored to ensure a safe working environment.

10.2.3 Manuals and installation/operating instructions

At least the following information should be available:

a) complete and comprehensive instructions for installation of the system, including such information as the required utilities, support systems, space requirements, foundation/footing requirements, and drain requirements;

b) complete and comprehensive instructions for the safe and effective operation of the system, including programming, recommended processing limits, emergency shutoffs, and safety precautions;

c) instructions and recommended schedules for routine preventive maintenance;

d) a repair manual that includes a list of recommended replacement parts;

e) schematic drawings illustrating the configuration of the equipment, pipework, and control systems.

Rationale: Since preventive maintenance, calibration, and repair might be performed by personnel other than the manufacturer's employees or representatives, it is necessary that detailed and complete information be provided. Equipment drawings are needed to define the as-built and installed configuration and to enable the user to control and document change.

10.3 Installation

10.3.1 General

Before any piece of equipment intended for use or support in processing textiles is commissioned, installation documentation demonstrating the following should be prepared:

a) that the installers, including any subcontractors, are appropriately qualified or trained to provide installation services;

NOTE—It is recommended that the processing facility consult with representatives of the manufacturer to obtain insight and recommendations regarding installation and, possibly, the installation service itself. The manufacturer's representatives are probably the most knowledgeable about equipment needs.

b) that the utilities and other support services are appropriate for the correct operation of the processing units;

NOTE—Usually, this can best be done by referencing the operation or installation manual for each piece of equipment and visually verifying that each requirement has been met.

c) that each specific piece of equipment has been installed in accordance with the manufacturer's instructions, as indicated by the work order and the signature of the installer. If it was necessary to modify the design of the equipment or support systems, any such modifications should be clearly identified in the finished design drawings or equipment specifications.

Rationale: It is important to document that the processing equipment and support systems have been designed, built, and installed correctly in order for the entire system to operate efficiently and with the desired results.

10.3.2 Utilities

Correct functioning of any piece of equipment requires that it has the correct type of and controls for incoming utilities, including water, steam, electrical power, and gas.

10.3.2.1 Water

The user should determine whether pretreatment of water to be used for processing is needed and, if so, the appropriate type of pretreatment. The local, city, or municipality water treatment facility can provide test results relative to the safety and quality of the local water supply. Local city or municipality water treatment facilities (publicly owned treatment works [POTW]) have local wastewater disposal guidelines.

NOTE—Water that has been used in processing must conform to EPA wastewater guidelines before it is drained into sewer systems. See 40 CFR 122.26.

Rationale: Water is the single most important utility used in laundering. The quality of the water can vary dramatically depending on the source (ground, river, or lake), on whether the water is reused, and on how it is pretreated before use. In general, water that is fit to drink, as defined by EPA (1975) and the Clean Water Act, is adequate for processing soiled textiles. The two most common pretreatments used in industrial laundries are water softening and water heating.

10.3.2.2 Electrical power

The electrical power supplied to processing equipment must be installed in conformance with NFPA (1996). Continuous electrical power for processing equipment and controls can be achieved by such means as line voltage conditioning and, where appropriate, an uninterruptible power supply.

Rationale: See 10.3.2.

10.3.2.3 Gas

The gas supply should conform to the equipment manufacturer's recommendations as well as any state or local regulations.

Rationale: See 10.3.2.

10.3.2.4 Steam

The steam supply should conform to the equipment manufacturer's recommendations as well as any state or local regulations.

Rationale: See 10.3.2.

10.4 Operation

10.4.1 General

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.

Rationale: Process equipment and support systems must function correctly to ensure end-product performance and durability.

10.4.2 Washing/extraction and drying equipment

The proper functioning of washing/extracting and drying equipment depends on the correct utilities (10.3.2), mechanical systems (e.g., valves, level sensors, temperature sensors, safety door locks, drum rotation), automated controls, and support systems (10.4.3).

10.4.2.1 Mechanical systems

The manufacturer's instruction manual should describe how the mechanical systems should function, including when valves should be open or closed, the water level in inches for each level setting, equipment tilting for loading/unloading, the design of the temperature sensors, the correct operation of safety features, and the speed and direction of drum rotation.

Rationale: See 10.4.2.

10.4.2.2 Automated controls

Microprocessor and/or card controls used to operate the equipment should be checked at least annually to ensure that they are sending the right signals to the equipment and thus controlling elements of the cycle correctly. For washing/extraction equipment, elements of the cycle under automated control include drain valve opening and closing, chemical delivery, the temperature during a given step, and the duration of a given step. For drying equipment, elements of the cycle under automated control include the opening and closing of gas valves, the rotation of the dryer drum, the input and/or output temperature of a given step, and the duration of a given step.

Rationale: As with any measurement device, automated controls should be calibrated at least once a year or more frequently, depending on the amount of drift seen between calibrations. If the drift is more than ± 5%, then calibration should be performed more often. See also 10.4.1.

10.4.3 Support systems

Various support systems are used to maximize the productivity and quality of the work produced. It is important that these systems be appropriately designed for the number, type, and size of the processing equipment that they support, and that they are installed appropriately to ensure that the entire system will run effectively.

10.4.3.1 Chemical delivery systems

The performance of the chemical delivery system should be checked at least quarterly by verifying chemical delivery rates and/or by conducting chemical titrations. The rate at which a particular chemical is delivered to a specific washer can be verified by measuring the actual ounces of product delivered. For manual additions, this is typically done by measuring the volume of chemical (usually a powder) placed in the equipment chemical bins. For automated systems, the amount delivered in response to the signal sent by the equipment program can be measured. The design of some automated chemical delivery systems might require that chemical delivery rates be checked at each washer, even though the same pump system is used.

Chemical titrations can be used to determine the activity of specific chemical processes within the wash liquor during specific washing steps. Some chemical processes, such as alkalinity, chlorine bleach, and sour, can be titrated to determine their respective concentrations (parts per million [ppm]) and/or the pH of the cycle. For some chemical processes, such as those involving detergents, titration kits for determining specific concentrations are not available.

Rationale: Delivery of the correct chemical, in the correct amount, and during the correct part of the cycle is critical to any washing system. There are various types and designs of automated chemical delivery systems. Some systems, such as the manifold flush system, are fairly accurate, regardless of the distance the chemicals must travel, whereas some of the more traditional peristaltic pump systems can exhibit dramatic variations with pumping distance. When available, chemical titrations offer a better indication of the performance of a laundry cycle than do chemical delivery rates, because process variables (load size, water level, chemical "carry-over") that can affect the performance of individual wash steps can be taken into account.

10.4.3.2 Water softeners

Laundries should consider softening their water when the hardness is 2 grains/gallon (34.2 ppm) or higher.

Rationale: Water softeners remove dissolved minerals (usually calcium, magnesium, or iron) from the incoming water. The "hardness" associated with these minerals inhibits the function of laundry chemicals. Usually, the harder the water, the more that the user rates for various chemicals will have to be increased. The outcome of increased chemical usage is usually a reduction in the life expectancy of the products being processed and an overall increase in chemical costs.

10.4.3.3 Water heaters

The design and size of water heaters should be appropriate for the needs of the facility at peak operating times. In addition, the temperature of the heated water should be controlled. If hot water is used for both processing and personnel use, the system should be designed to ensure that the water temperature for personnel use does not exceed safety limits.

Rationale: Laundries usually require a significant amount of hot water for use in the various laundry cycles.

10.4.3.4 Boilers

Boilers produce steam and should be appropriately designed and installed to generate the correct steam quantity and purity for the intended use. It should be noted that steam quality (degree of saturation) is usually less critical for laundry applications than it is for steam sterilization. For laundry equipment utilizing steam that comes into direct contact with the textiles being processed (i.e. those that inject steam into wash water for maintenance of water temperature), it is important that boiler chemical maintenance ensure that toxic boiler compounds are not being used and/or bumped over into the system. It is recommended that boiler treatment compounds approved for use in the food industry be used (see the FDA regulations codified in 21 CFR 173.310). For other steam uses (e.g., steam dryers), in which steam does not come into direct contact with the textiles being processed, it is only necessary to ensure that the steam conforms with the manufacturer's recommendations. (Manufacturers usually specify steam quantity.)

Rationale: Some boiler treatment compounds are potentially irritating or toxic and have an affinity for certain types of fibers. These chemical agents might cause skin irritation, serve as a potential contamination source (pyrogenic or toxic), and/or interfere with the sterilization process.

10.4.3.5 Air compressors

Compressed air used to operate valves should conform to the equipment manufacturer's recommendations. Compressed air used to dry linen carts should be filtered to ensure that there is no carryover of oils and/or other contaminants.

Rationale: Compressed air rarely comes into contact with the items being processed. However, unfiltered compressed air could contain oil droplets or other contaminants and is not suitable for use in drying linen carts.

10.4.3.6 Heat exchangers

Heat exchanger systems are usually piped to allow hot waste water (effluent) to circulate around incoming water by way of two isolated systems (e.g., a tube and shell heat exchanger) to preheat it for use in boilers, hot water heaters, or directly within the laundering process. The two water sources should not come into direct contact and/or mix with each other. The quality of the welds and connections should preclude leakage. Lines should not connect directly to a drain without an atmospheric break to prevent back-siphoning. Heat exchangers should be cleaned and/or back-flushed periodically. Procedures should be developed for the care, maintenance, and operation of heat exchangers that will prevent cleaning compounds from coming into direct contact with textiles being processed.

Rationale: Heat exchangers are used to recapture energy from the system that otherwise may be wasted. Periodic cleaning and/or back-flushing is necessary to remove scaling and line build-ups and thus maximize the efficiency of the heat transfer. The cleaning compounds typically used are quite corrosive to textiles and potentially irritating or toxic to humans.

10.4.3.7 Water reuse systems

Water reuse systems should be designed to capture appropriate water for subsequent reuse in an appropriate part of the cycle. For instance, water used in the initial part of the washing process (flush) will contain the highest amount of soils and potential microbial contaminants and should not be reused. Water used in the last part of the rinsing operation should be relatively free of soils and chemicals and is suitable for use in the initial flushing step of the wash cycle. The design of water systems should be documented. Written operating instructions should address subsequent monitoring and control.

Rationale: Water reuse systems are used to selectively recapture and reuse water. These systems can be independent tanks and pumps or, in some cases (e.g., continuous-batch washers) an integral part of washing equipment. The use of reuse water in a wash process can significantly reduce water consumption; however, its use should be selectively controlled to minimize concentrations of microorganisms and the potential for cross-contamination. Inappropriate use of water (e.g., water from the initial flushes or chemical addition steps) could result in high bioburden or chemical carryover, which might cause skin irritation and/or adverse effects on the ability of the sterilization cycle to yield sterile product.

10.5 Routine care and maintenance

10.5.1 Routine care

Manufacturers of processing and support equipment provide written instructions for the routine care and preventive maintenance of the equipment and components of equipment. Equipment should be inspected and cleaned in accordance with these instructions.

Rationale: Periodic inspection and cleaning reduces the frequency of equipment malfunction. Cleanliness also reduces the bioburden on items being processed.

10.5.2 Scheduled (preventive) maintenance

The equipment manufacturer should provide written instructions for preventive maintenance. The preventive maintenance program may be in-house or contracted with the equipment manufacturer or other qualified service company. Expendable parts such as door gaskets should be replaced, and appropriate parts should be lubricated, as needed, by qualified personnel. The frequency of maintenance will depend on how often the equipment is used and varies from institution to institution; the manufacturer's instructions should be consulted for guidance. Certain maintenance tasks that require special tools or calibration equipment not available within the facility should be performed by the manufacturer, the manufacturer's representative, or another qualified service facility. In accordance with 10.5.5, preventive maintenance and repair records should be kept for all production and support equipment.

Rationale: Worn or out-of-calibration components can cause equipment malfunctions. It might not be economical for a facility to acquire expensive, rarely used special tools or calibration equipment. The normal service life of mechanical components sometimes depends solely on frequency of use, sometimes on age, and sometimes on both.

10.5.3 Unscheduled maintenance (repairs)

Worn, malfunctioning, or broken parts should be replaced promptly by qualified personnel. Equipment should not be used until repairs have been made. All safety precautions, including lock-out tag-out procedures, should be observed. Certain repairs that require special tools or calibration equipment not available at the facility should be performed by the manufacturer, the manufacturer's representative, or another qualified service facility. In accordance with 10.5.5, maintenance and repair records should be kept for all production and support equipment.

Rationale: Using equipment that is not working correctly can be unsafe for personnel and can cause additional damage to the equipment or products being processed. See also 10.4.2.

10.5.4 Calibration

Periodic calibration should be performed as specified in the manufacturer's instruction manual. Examples of items requiring calibration are temperature gauges, timers, pressure gauges, and flow meters. Calibration may be performed by the manufacturer, the manufacturer's representative, the facility's engineering staff, or contract service personnel. Those performing the service must have sufficient training to understand the operation and calibration of the specific piece of equipment.

Rationale: Proper calibration of controls is critical to the effective and reliable operation of equipment. Because the repair or replacement of components often has subtle effects on other seemingly unrelated devices, it is imperative that calibration be performed only by qualified personnel.

10.5.5 Recordkeeping

A maintenance record should be kept for each piece of equipment. This record should be maintained by the supervisor responsible for the equipment, by the engineering/maintenance staff, by the service person who has performed the servicing, and/or by whomever else is deemed appropriate by the institution. This maintenance record should provide sufficient information to identify the specific piece of equipment and to establish a continuous history of all scheduled and unscheduled service. When available, the following information should be recorded:

a) the date on which service was requested;

b) the type, model, and serial number of the equipment;

c) the location of the equipment;

d) the name of the person requesting and authorizing the service;

e) the reason for the service request;

f) a description of the service performed;

g) the types and quantities of parts replaced;

h) the name of the person who performed the service;

i) the date on which the work was completed;

j) the signature and title of the person who acknowledged completion of work.

Rationale: Accurate and complete records are required for process verification and are useful in malfunction analysis.

11 Quality control

11.1 General rationale

Quality control involves continuous compliance with established policies and procedures as well as ongoing quality assessment and improvement of process performance (JCAHO 2000). Specific quality control measures are addressed throughout this recommended practice and are integral to maintaining the performance characteristics of reusable surgical textiles. This section covers general principles of quality control and process performance. These principles apply to laundry services of health care facilities, contracted laundry processors, repacking operations, and sterile pack lease/rental operations servicing health care facilities.

11.2 General quality control criteria

11.2.1 Functional performance criteria

To meet today's requirements for draping, gowning, and wrapping materials that provide adequate barriers to microorganisms, particulates, and liquids, reusable surgical textiles should consistently meet the required functional performance criteria for safety and effectiveness each time they are used. See AAMI (1994b) for a discussion of performance characteristics, a user evaluation and selection guide, and care recommendations.

Procedures must be developed and implemented to ensure that the functional performance characteristics of the products are maintained. The effective life of reusable surgical textile products should be defined and tested (see 7.3.4).

The on-site laundry area of the health care facility and/or off-site laundry support services are the areas where effective and efficient quality control of laundry processing and pack preparation can best be performed.

Rationale: Quality control measures are essential to ensure that reusable surgical textile products are processed through prescribed laundry processes meeting established standards for cleaning, drying, inspection, testing, and maintenance; and that textile packs are assembled in such a way that they are appropriate for sterilization processing and for clinical use during invasive and aseptic procedures.

The lack of standardized laundry processing and monitoring programs or improper handling of surgical textiles can compromise the quality of the products, the care of patients undergoing surgical procedures, and the safety of caregivers.

11.2.2 Verification of laundry processes

Written laundry process specifications must be completed. Process specifications should conform to the manufacturer's recommendations and be verified to assure that the required functional performance criteria for safety and effectiveness are met (see 7). Before verification of the laundry process begins, the manufacturer of the reusable surgical textile product should be consulted regarding any variations from the recommended laundering procedures to ensure that the product can tolerate the proposed modifications. The verification includes all of the normal steps of the process (e.g., laundering, drying). The frequency of monitoring and type of testing should be defined (see 7.3). Reverification is required after any changes that could negatively affect the safety or effectiveness of the product. Appropriate sampling procedures (e.g., ASQC 1993) and statistical analysis should be used throughout all verification procedures.

Rationale: See 11.2.1.

11.3 Policies and procedures

Written policies and procedures for appropriate treatment and laundry processing of reusable surgical textiles should be developed and implemented by the laundry and the using health care facility. These policies and procedures should

a) be based on the textile product manufacturer's instructions and the recommendations of laundry equipment manufacturers and laundry chemical suppliers;

b) take into account applicable FDA regulations, state and local regulations, CDC recommendations, and voluntary standards and guidelines;

c) incorporate procedures for the evaluation and maintenance of identified functional performance characteristics;

d) be maintained by the health care facility;

e) be reviewed at least annually and whenever new products or processes are introduced.

Rationale: Policies and procedures provide health care personnel with the direction and information essential to correctly prepare and monitor the processing of reusable surgical textiles. Policies and procedures also assist in the development of the skills and attitudes that promote the safety and effectiveness of patient care outcomes. During periodic review, policies and procedures can be updated with new information and adapted to new conditions.

11.4 Barrier efficacy

The effectiveness of surgical textile products in maintaining the sterile field is normally determined during their use in surgery by their ability to prevent strike-through. Surgical gowns are devices intended to be worn by operating room personnel during surgical procedures to protect both the surgical patient and the operating room personnel from transfer of microorganisms, body fluids, and particulate material, while a surgical drape or drape accessory is intended to be used as a protective patient covering, such as to isolate a site of surgical incision from microbial and other contamination (21 CFR 878.4370 and 21 CFR 878.4040). Therefore, strike-through in surgical apparel, surgical drapes, or accessories would be considered a breach of the barrier, and appropriate steps should be taken to prevent the situation from recurring.

Strike-through events should be properly documented by the end user and reported with complaints submitted to the processor and product manufacturer/distributor for investigation. Products that allow strike-through to occur during use in surgery should be isolated and returned for evaluation to the processor (and, if appropriate, to the manufacturer/distributor) to determine the cause of failure. The evaluation should be performed very carefully and, ideally, cooperatively between the health care facility, the processor, and the manufacturer/distributor.

Strike-through can occur as a result of device failure or malfunction; improper or inadequate design, manufacture, or labeling; or user error. In addition, incorrect care and handling procedures should be considered in order to appropriately determine the cause of the strike-through. Depending on the circumstances, the following questions should be asked by a qualified individual (user, processor, or manufacturer):

a) How was the product used?

b) Was the correct level of protection chosen for the level of anticipated risk (e.g., the right gown for the right procedure)?

c) Was the appropriate size of item selected?

d) Where did the strike-through occur?

e) Did strike-through occur in a noncritical zone or through a seam?

f) Did strike-through occur at an interface (e.g., gown cuff to glove)?

g) Did strike-through occur when blood/liquid traveled down the crease of the gown sleeve and under the glove cuff, to be absorbed by the gown cuff?

h) Was the product damaged in any way during use?

i) If reusable, how many times had the product been used?

j) If reusable, was laundering, inspection, testing, maintenance, and sterilization carried out in accordance or consistent with the manufacturer's instructions?

k) If applicable, what was the expiration date for the product?

Proper infection control practices must be used to isolate the item, transport the item to the processor, and prevent exposure of personnel during evaluation of the strike-through. Items that can be repaired, mended, or rejuvenated may be returned to service if they continue to meet important functional requirements (see 7.4). Soiled items should be laundered before they are returned to the manufacturer/distributor for evaluation.

In addition, employers are required by OSHA to provide appropriate personal protective clothing, such as surgical gowns that prevent the penetration of blood, body fluids, and other potentially infectious materials under normal conditions of use and for the duration of time that they are used. OSHA also requires employers to repair or replace required personal protective clothing, as needed, to maintain its effectiveness. Occupational exposure to blood, body fluids, and other potentially infectious materials must be dealt with in accordance with 29 CFR 1910.1030.

Rationale: Investigating the cause of product failure is important in preventing recurrences.

11.5 Tracking uses of reusable surgical textile products

To assist in the determination of whether attributes related to the required functional performance of a surgical textile barrier product have been significantly altered through repeated processing and use, each such product should include a tracking mechanism (a marking grid, bar code system, radiofrequency chip, or other suitable method); and the manufacturer should provide recommendations for the number of times the product can be used. See 7.4.3 and 7.4.4.

Rationale: The performance of reusable surgical textile products will change with repeated processing and use. Therefore, it is important to identify the point at which each product no longer continues to perform adequately. Since variations in the use and processing conditions among health care facilities can change the effective life of products, manufacturers' recommendations concerning the life expectancy of their products can only be used as a guideline.

11.6 Process performance

11.6.1 Quality assessment

An ongoing program of quality assessment and improvement should be established.

Rationale: Continuous quality assessment and improvement help ensure that reusable surgical textiles are processed under optimum conditions in well-designed work areas, thus minimizing risks to patients, the environment, and health care and laundry personnel.

11.6.2 Quality process

Procedures for laundry processing should be based on a documented quality process that measures objective performance criteria. This quality process should be developed in conjunction with appropriate departments and integrated into the overall quality process in the laundry and health care facility. Variables in the system can be controlled to achieve assurance of product quality and process efficacy. Monitoring frequency will vary, depending on the quality improvement goals, on health care facility policies and procedures for the handling of unfavorable/unplanned events, and on the type of process variable. Areas in which to apply quality standards and monitoring programs include the following:

a) *Design considerations* (section 3)*:* Includes the condition of floors, walls, and ceilings; ventilation, including air exchanges per hour and air flow patterns; temperature and humidity readings; the adequacy of traffic control and handwashing facilities; area cleanliness; the adequacy of the functional and physical design of areas for receiving and handling soiled textiles, separating soiled and clean textiles, laundering textiles, inspecting clean textiles, and preparing clean bulk items and surgical textile packs.

b) *Personnel considerations* (section 4)*:* Includes verification of competency; adherence to established policies on health and personal hygiene; adherence to standards and quality monitoring systems in place; and proper attire, including PPE as required for specific work areas and job responsibilities.

c) *Receiving and handling of reusable surgical textiles* (section 5)*:* Includes the receiving, identification, and handling of newly purchased items; the required cleaning to reduce bioburden before textiles are sterilized; the collecting, transporting, and handling of soiled textiles; the segregation and sorting of soiled textiles.

d) *Laundry processing* (section 6)*:* Includes loading of washing equipment; steps in the washing process; steps in and method for drying.

e) *Inspection, testing, and maintenance of laundered textiles* (section 7)*:* Includes inspection for stains; patching/mending; testing for product performance requirements.

f) *Preparation and packaging* (section 8)*:* Includes verification of compliance with procedures for folding, pack assembly, and wrapping.

g) *Handling, transport, and storage of laundered textiles* (section 9): Includes personal hygiene and attire; handling clean textiles; laundry cart cleaning and loading; cleaning and loading of laundry transport trucks.

h) *Installation, operation, care, and maintenance of laundry equipment* (section 10): Includes compliance with recommendations for equipment installation; use of instruction manuals for operation and safety; routine care and maintenance of laundry processing equipment; essential utilities and support systems (e.g., water, electrical power, gas lines, and ancillary systems for mechanical or automated operation); emergency repairs; and recordkeeping.

i) *Quality control* (section 11)*:* Includes the development, implementation, and maintenance of policies and procedures.

j) *Regulatory considerations* (section 12 and annex A)*:* Includes compliance with FDA regulations, state and local regulations, and health care industry standards of practice and guidelines.

A problem analysis should be completed for any problem relating to any aspect of reusable surgical textile processing that could pose a risk to personnel or patients. The problem analysis should define and resolve the problem, and the system should be monitored to ensure that the problem has been corrected.

There should be a planned, systematic, and ongoing process for verifying compliance with procedures. Quality processes can be enhanced by audits that are conducted on a regular basis. The information from these activities should be summarized and made available to appropriate individuals or groups/teams.

According to FDA, a quality audit "means a systematic, independent examination of a manufacturer's quality system that is performed at defined intervals and at sufficient frequency to determine whether both quality system activities and the results of such activities comply with quality system procedures, that these procedures are implemented effectively, and that these procedures are suitable to achieve quality system objectives" (21 CFR 820.3).

Rationale: Measurements of process performance allow the laundry processing system to be monitored against a predetermined level of quality. Evaluation of findings provides a method of identifying problems or shifts in activities and facilitates informed decision-making on policies and procedures. Ongoing auditing provides data essential to assess the effectiveness of the processes and to make improvements in performance.

12 Medical device regulatory considerations

Laundry facilities that place surgical textiles (whether sterile or nonsterile) into commercial distribution come under the jurisdiction of FDA regulations. Hospital laundries and freestanding laundries that are members of a consortium providing reusable surgical textiles to consortium member hospitals and health care facilities should comply with health care industry standards of practice and guidelines, and should be aware of FDA's quality system (QS) regulation (21 CFR 820). However, these types of laundries are not required to be in compliance with quality-system and other FDA requirements except for the Medical Device Reporting (MDR) regulations applicable to user facilities, which became effective on July 31, 1996.

Processors that provide nonsterile packs, folded components, or laundering services for use in health care facilities outside their corporate structure may be considered to be refurbishers of medical devices. As of the publication date of this recommended practice, the issue of the regulation of refurbishers of medical devices was still undergoing review by FDA. Future changes in FDA requirements could affect the regulatory obligations of processors that provide contract laundering and pack-making services. Each individual facility must investigate and comply with applicable federal and state laws and regulations. However, the quality processes outlined in this recommended practice should be the foundation of the practices of any processor of reusable surgical textiles, regardless of additional regulatory requirements that might be applicable.

For further guidance on medical device regulation, see annex A and the bibliography.

Annex A
(Informative)

Medical device regulatory considerations

A.1 Introduction

This annex provides a brief overview of FDA medical device regulation, with special reference to reusable surgical textiles.

A.2 Medical device law and regulations

Surgical gowns, surgical drapes, surgical towels, and sterilization wraps are classified by FDA as medical devices and are therefore subject to the Federal Food, Drug, and Cosmetic Act (the Act), as amended by the Medical Device Amendments of May 28, 1976, the Safe Medical Devices Act of 1990, the Medical Device Amendments of 1992, and the FDA Modernization Act of 1997. By the authority granted to it under the Act, FDA has promulgated classification, premarket review, labeling, registration and listing, quality system, and other regulations that contain provisions and requirements applicable to reusable surgical textile products.

A.3 Establishment registration

A hospital laundry or independent laundry that enters surgical textiles into commercial distribution must register its place of business with FDA, identifying the physical location at which medical devices are manufactured, assembled, or otherwise processed. The Act also requires a medical device manufacturer to submit to FDA a listing of all devices that the manufacturer enters into commercial distribution, which would include sterile and nonsterile surgical textiles such as surgical gowns, surgical drapes, surgical towels, and sterilization wraps, whether provided as packs or as individual components.

A.4 Classification of medical devices

The Act requires FDA to classify medical devices into three classes: Class I, Class II, and Class III. Devices are classified based on the degree of risk to patients and the corresponding level of regulation.

Class I medical devices are deemed by FDA to present relatively low risk to patients. The safety and efficacy of such devices can be relatively assured by compliance with the “general controls” requirements of the Act. Most medical devices in this category are exempt from premarket notification (510[k]) and premarket approval (PMA) requirements. Examples of Class I medical devices are hand-held surgical instruments, reusable and disposable shoe covers, surgeon caps, and bouffant caps.

Surgical gowns, surgical drapes, surgical towels, and sterilization wraps, whether sterile or nonsterile, are classified as Class II medical devices. Class II medical devices, because of the potential risk that they pose to patients, are subject to both the “general controls” and “special controls” requirements of the Act in order to assure safety and effectiveness. Class II medical devices are subject to FDA clearance by the 510(k) process, in which the safety and effectiveness of a device are reviewed to determine whether it is as safe and effective as a device previously cleared for marketing. Other examples of Class II medical devices are steam sterilizers, biological indicators, and chemical indicators.

At the time of this writing, it is unclear whether or not a hospital laundry or independent laundry that enters reusable surgical textiles into commercial distribution is required to submit a 510(k) to FDA for the products and packs distributed commercially. The current policy of FDA on this issue is open to interpretation. General guidelines on when it is necessary for manufacturers to submit 510(k)s are given in FDA (1995). For guidance on when to submit a 510(k), manufacturers can contact the Division of Small Manufacturers Assistance at (800) 638-2041, (301) 443-6597, or http://www.fda.gov/cdrh/dsmaman.html.

Class III medical devices are considered to present the highest risk to patients and are subject to the PMA process, which represents the most stringent level of regulation. Examples of Class III medical devices are heart valves, pacemakers, orthopedic implants, and life-support systems.

A.5 Premarket clearance and premarket approval requirements

A medical device manufacturer must submit either a PMA application or a 510(k) notification to FDA to obtain approval or clearance, respectively, to market a new device unless the device is specifically exempted by federal regulation. If the nonexempt device is classified either as a Class I or Class II device, the manufacturer may submit a

510(k) notification for a determination of "substantial equivalence." Class III devices are subject to the PMA process for approval to be marketed. If the manufacturer is not sure of the classification of the device, the manufacturer can contact either FDA's Division of Small Manufacturers Assistance (DSMA) or the branch of FDA's Office of Device Evaluation that will be reviewing the device for clearance.

If FDA determines that the device is indeed substantially equivalent to a marketed device, the manufacturer receives a letter from FDA noting the determination as well as clearance for marketing. If the device is determined *not* to be substantially equivalent, then FDA may suggest changes to the device or consider it to be a Class III device subject to premarket approval.

A.6 Good manufacturing practice (GMP) requirements: the quality system regulation

Title 21, Part 820, of the *Code of Federal Regulations* (CFR), the quality system regulation, covers GMP requirements for medical devices. It encompasses the following subparts: General Provisions (Subpart A), Quality System Requirements (Subpart B), Design Controls (Subpart C), Document Controls (Subpart D), Purchasing Controls (Subpart E), Identification and Traceability (Subpart F), Production and Process Controls (Subpart G), Acceptance Activities (Subpart H), Nonconforming Product (Subpart I), Corrective and Preventive Action (Subpart J), Labeling and Packaging Control (Subpart K), Holding, Storage, Distribution, and Installation (Subpart L), Records (Subpart M), Servicing (Subpart N), and Statistical Techniques (Subpart O).

The scope of 21 CFR 820 states, in part: "Current good manufacturing practice (CGMP) requirements are set forth in this quality system regulation. The requirements in this part govern the methods used in, and the facilities and controls used for, the design, manufacture, packaging, labeling, storage, installation, and servicing of all finished devices intended for human use. The requirements in this part are intended to ensure that finished devices will be safe and effective and otherwise in compliance with the Food, Drug, and Cosmetic Act."

A.6.1 Processing guidelines

Section 820.70(a) (General) of Subpart G (Production and Process Controls) of the GMPs states, in part: "Each manufacturer shall develop, conduct, control, and monitor production processes to ensure that a device conforms to its specifications."

Section 820.90(b)(2) states: "For a nonconforming product, each manufacturer shall establish and maintain procedures for rework, to include retesting and reevaluation of the nonconforming product after rework, to ensure that the product meets its current approved specifications. Rework and reevaluation activities including a determination of any adverse effect from the rework upon the product shall be documented in the DHF (Design History File)."

Instructions for processing (washing, drying, sterilization) should be obtained from each of the suppliers of reusable surgical textile products purchased for the health care facilities being serviced by the laundry. These instructions should be used as guidelines when establishing manufacturing procedures and process controls to ensure conformance to laundry specifications.

A.6.2 Quality assurance

Section 820.80(d) (Final Acceptance Activities) of Subpart H (Acceptance Activities) states, in part: "Each manufacturer shall establish and maintain procedures for finished device acceptance to ensure that each production run, lot, or batch of finished devices meets acceptance criteria."

A.6.2.1 Product integrity

The quality assurance program should include physical inspection of the surgical gowns, drapes, and wrappers for integrity. Before this part of the quality assurance program is initiated, the visual pass/fail criteria and the methods of inspection should be determined and written into a work procedure for each category of surgical textiles. The pass/fail criteria should be based on standards of practice, the intended end use of the category type, and input from end users.

A.6.2.2 Safety and efficacy

Barrier quality is a critical device specification for surgical gowns, drapes, and wrappers. Barrier quality may be temporarily altered due to processing errors and/or degradation of the product fabric. Therefore, it is necessary to incorporate in the quality system a procedure by which the barrier performance of reusable surgical textiles can be evaluated.

A.7 Complaint handling and MDR

A.7.1 Complaint handling

Section 820.198 (Complaint Files) of Subpart M (Records) states, in part:

a) Each manufacturer shall maintain complaint files. Each manufacturer shall establish and maintain procedures for receiving, reviewing, and evaluating complaints by a formally designated unit. Such procedures shall ensure that:

   (1) All complaints are processed in a uniform and timely manner;

   (2) Oral complaints are documented upon receipt; and

   (3) Complaints are evaluated to determine whether the complaint represents an event which is required to be reported to the Food and Drug Administration under part 803 or 804 of this chapter, Medical Device Reporting.

b) Each manufacturer shall review and evaluate all complaints to determine whether an investigation is necessary. When no investigation is made, the manufacturer shall maintain a record that includes the reason no investigation was made and the name of the individual responsible for the decision not to investigate.

c) Any complaint involving the possible failure of a device, labeling, or packaging to meet any of its specifications shall be reviewed, evaluated, and investigated, unless such investigation has already been performed for a similar complaint and another investigation is not necessary.

The facility should have a procedure in place for responding to product complaints from customers. The complaint-handling procedure should provide for documentation of the complaint, the actions taken to evaluate and resolve the complaint, and the response to the customer.

A.7.2 Medical device reporting

A.7.2.1 User facility reporting

The newly revised 21 CFR Part 803, Subpart C (User Facility Reporting Requirements), was published in the *Federal Register* on December 11, 1995. Under this regulation, user facilities must report to FDA any death or serious injury that may have been caused by a medical device or to which a medical device may have contributed. The regulation defines “user facilities” and covers reporting requirements, reporting time frames, use of FDA reporting forms, documentation, and record retention.

A.7.2.2 Reporting requirements for manufacturers

The Medical Device Reporting regulation (21 CFR 803) requires manufacturers and distributors of medical devices to report to FDA whenever they receive or become aware of information (an incident or event) that reasonably suggests that a device marketed by the manufacturer

a) may have caused or contributed to a death or serious injury; or

b) has malfunctioned, and the malfunction, if it were to recur, would be likely to cause or contribute to a death or to serious injury.

Serious injury is defined as an injury or illness that

a) is life-threatening;

b) results in permanent impairment of a body function or permanent damage to a body structure; or

c) necessitates medical or surgical intervention to preclude permanent impairment of a body function or permanent damage to a body structure.

A serious injury does not include trivial irreversible damage.

Malfunction means that the device fails to meets its performance specifications or otherwise fails to perform as intended.

A.8 Federal auditing of procedures and controls

Regional offices of the Food and Drug Administration schedule inspections of registered manufacturers within their geographical area of jurisdiction. These inspections occur periodically and are often unannounced. The FDA investigator(s) will inspect against the quality system regulation, the manufacturer's written procedures, and, through a review of a manufacturer's documentation, the manufacturer's quality assurance practices. The investigator will assess the level of control in place and determine whether the manufacturer is releasing safe and effective products to the end user.

A.9 Outcomes

The FDA's inspection of manufacturers has been developed with the goal of promoting public health. Manufacturers that are subject to regulations for reuse are benefited by the need to have quality standards in place for these inspections and assist in achieving this goal of promoting public health. Manufacturers also benefit because implementing good manufacturing practices is good business sense; compliance with these standards reduces manufacturing errors and costs, while it increases the quality of the product distributed and customer satisfaction.

Facilities are more apt to be successful with their customer base if they recognize the user association standards and recommended practices. The appropriate sections of these standards and recommended practices should be integrated into the laundry's GMP policies and practices. Integration of these practices demonstrates the goal of quality assurance for customers, that they will receive quality products consistently.

Once the system (process/procedures) is in place, it can benefit the facility by providing a framework for handling customer concerns, complaints, needs, and so on.

Annex B
(Informative)

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