

American National Standard

ANSI/AAMI ST65:2008/ (R)2018

Processing of reusable
Surgical textiles for use in
health care facilities

Objectives and uses of AAMI standards and recommended practices

It is most important that the objectives and potential uses of an AAMI product standard or recommended practice are clearly understood. The objectives of AAMI's technical development program derive from AAMI's overall mission: the advancement of medical instrumentation. Essential to such advancement are (1) a continued increase in the safe and effective application of current technologies to patient care, and (2) the encouragement of new technologies. It is AAMI's view that standards and recommended practices can contribute significantly to the advancement of medical instrumentation, provided that they are drafted with attention to these objectives and provided that arbitrary and restrictive uses are avoided.

A voluntary *standard* for a *medical device* recommends to the manufacturer the information that should be provided with or on the product, basic safety and performance criteria that should be considered in qualifying the device for clinical use, and the measurement techniques that can be used to determine whether the device conforms with the safety and performance criteria and/or to compare the performance characteristics of different products. Some standards emphasize the information that should be provided with the device, including performance characteristics, instructions for use, warnings and precautions, and other data considered important in ensuring the safe and effective use of the device in the clinical environment. Recommending the disclosure of performance characteristics often necessitates the development of specialized test methods to facilitate uniformity in reporting; reaching consensus on these tests can represent a considerable part of committee work. When a drafting committee determines that clinical concerns warrant the establishment of *minimum* safety and performance criteria, referee tests must be provided and the reasons for establishing the criteria must be documented in the rationale.

A *recommended practice* provides guidelines for the use, care, and/or processing of a medical device or system. A recommended practice does not address device performance *per se*, but rather procedures and practices that will help ensure that a device is used safely and effectively and that its performance will be maintained.

Although a device standard is primarily directed to the manufacturer, it may also be of value to the potential purchaser or user of the device as a frame of reference for device evaluation. Similarly, even though a recommended practice is usually oriented towards healthcare professionals, it may be useful to the manufacturer in better understanding the environment in which a medical device will be used. Also, some recommended practices, while not addressing device performance criteria, provide guidelines to industrial personnel on such subjects as sterilization processing, methods of collecting data to establish safety and efficacy, human engineering, and other processing or evaluation techniques; such guidelines may be useful to health care professionals in understanding industrial practices.

In determining whether an AAMI standard or recommended practice is relevant to the specific needs of a potential user of the document, several important concepts must be recognized:

All AAMI standards and recommended practices are *voluntary* (unless, of course, they are adopted by government regulatory or procurement authorities). The application of a standard or recommended practice is solely within the discretion and professional judgment of the user of the document.

Each AAMI standard or recommended practice reflects the collective expertise of a committee of health care professionals and industrial representatives, whose work has been reviewed nationally (and sometimes internationally). As such, the consensus recommendations embodied in a standard or recommended practice are intended to respond to clinical needs and, ultimately, to help ensure patient safety. A standard or recommended practice is limited, however, in the sense that it responds generally to perceived risks and conditions that may not always be relevant to specific situations. A standard or recommended practice is an important *reference* in responsible decision-making, but it should never *replace* responsible decision-making.

Despite periodic review and revision (at least once every five years), a standard or recommended practice is necessarily a static document applied to a dynamic technology. Therefore, a standards user must carefully review the reasons why the document was initially developed and the specific rationale for each of its provisions. This review will reveal whether the document remains relevant to the specific needs of the user.

Particular care should be taken in applying a product standard to existing devices and equipment, and in applying a recommended practice to current procedures and practices. While observed or potential risks with existing equipment typically form the basis for the safety and performance criteria defined in a standard, professional judgment must be used in applying these criteria to existing equipment. No single source of information will serve to identify a particular product as "unsafe". A voluntary standard can be used as one resource, but the ultimate decision as to product safety and efficacy must take into account the specifics of its utilization and, of course, cost-benefit considerations. Similarly, a recommended practice should be analyzed in the context of the specific needs and resources of the individual institution or firm. Again, the rationale accompanying each AAMI standard and recommended practice is an excellent guide to the reasoning and data underlying its provision.

In summary, a standard or recommended practice is truly useful only when it is used in conjunction with other sources of information and policy guidance and in the context of professional experience and judgment.

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Processing of reusable surgical textiles for use in health care facilities

Developed by
AAMI

Approved 4 December 2008 and reaffirmed 2 December 2013 and 6 September 2018 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, surgical drapes, surgical gowns, wrappers

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Glossary of equivalent standards

International Standards adopted in the United States may include normative references to other International Standards. For each International Standard that has been adopted by AAMI (and ANSI), the table below gives the corresponding U.S. designation and level of equivalency to the International Standard. NOTE: Documents are sorted by international designation.

Other normatively referenced International Standards may be under consideration for U.S. adoption by AAMI; therefore, this list should not be considered exhaustive.

International designation	U.S. designation	Equivalency
IEC 60601-1:2005	ANSI/AAMI ES60601-1:2005	Major technical variations
IEC 60601-1-2:2007	ANSI/AAMI/IEC 60601-1-2:2007	Identical
IEC 60601-2-2:2006	ANSI/AAMI/IEC 60601-2-2:2006	Identical
IEC 60601-2-4:2002	ANSI/AAMI DF80:2003	Major technical variations
IEC 60601-2-19:1990 and A1:1996	ANSI/AAMI II36:2004	Major technical variations
IEC 60601-2-20:1990 and A1:1996	ANSI/AAMI II51:2004	Major technical variations
IEC 60601-2-21:1994 and Amendment 1:1996	ANSI/AAMI/IEC 60601-2-21 and Amendment 1:2000 (consolidated texts)	Identical
IEC 60601-2-24:1998	ANSI/AAMI ID26:2004	Major technical variations
IEC 60601-2-47:2001	ANSI/AAMI EC38:2007	Major technical variations
IEC 60601-2-50:2001	ANSI/AAMI/IEC 60601-2-50:2006	Identical
IEC 80601-2-58:2008	ANSI/AAMI/IEC 80601-2-58:2008	Identical
IEC/TR 60878:2003	ANSI/AAMI/IEC TIR60878:2003	Identical
IEC/TR 62296:2003	ANSI/AAMI/IEC TIR62296:2003	Identical
IEC 62304:2006	ANSI/AAMI/IEC 62304:2006	Identical
IEC/TR 62348:2006	ANSI/AAMI/IEC TIR62348:2006	Identical
ISO 5840:2005	ANSI/AAMI/ISO 5840:2005	Identical
ISO 7198:1998	ANSI/AAMI/ISO 7198:1998/2001/(R)2004	Identical
ISO 7199:1996	ANSI/AAMI/ISO 7199:1996/(R)2002	Identical
ISO 8637:2004	ANSI/AAMI RD16:2007	Major technical variations
ISO 8638:2004	ANSI/AAMI RD17:2007	Major technical variations
ISO 10993-1:2003	ANSI/AAMI/ISO 10993-1:2003	Identical
ISO 10993-2:2006	ANSI/AAMI/ISO 10993-2:2006	Identical
ISO 10993-3:2003	ANSI/AAMI/ISO 10993-3:2003	Identical
ISO 10993-4:2002 and A1:2006	ANSI/AAMI/ISO 10993-4:2002 and A1:2006	Identical
ISO 10993-5:1999	ANSI/AAMI/ISO 10993-5:1999	Identical
ISO 10993-6:2007	ANSI/AAMI/ISO 10993-6:2007	Identical
ISO 10993-7:2008	ANSI/AAMI/ISO 10993-7:2008	Identical
ISO 10993-9:1999	ANSI/AAMI/ISO 10993-9:1999/(R)2005	Identical
ISO 10993-10:2002 and Amendment 1:2006	ANSI/AAMI BE78:2002/(R)2008 ANSI/AAMI BE78:2002/A1:2006/(R)2008	Minor technical variations Identical
ISO 10993-11:2006	ANSI/AAMI/ISO 10993-11:2006	Identical
ISO 10993-12:2007	ANSI/AAMI/ISO 10993-12:2007	Identical
ISO 10993-13:1998	ANSI/AAMI/ISO 10993-13:1999/(R)2004	Identical
ISO 10993-14:2001	ANSI/AAMI/ISO 10993-14:2001/(R)2006	Identical
ISO 10993-15:2000	ANSI/AAMI/ISO 10993-15:2000/(R)2006	Identical
ISO 10993-16:1997	ANSI/AAMI/ISO 10993-16:1997/(R)2003	Identical
ISO 10993-17:2002	ANSI/AAMI/ISO 10993-17:2002/(R)2008	Identical
ISO 10993-18:2005	ANSI/AAMI BE83:2006	Major technical variations
ISO/TS 10993-19:2006	ANSI/AAMI/ISO TIR10993-19:2006	Identical
ISO/TS 10993-20:2006	ANSI/AAMI/ISO TIR10993-20:2006	Identical
ISO 11135-1:2007	ANSI/AAMI/ISO 11135-1:2007	Identical

International designation	U.S. designation	Equivalency
ISO/TS 11135-2:2008	ANSI/AAMI/ISO TIR11135-2:2008	Identical
ISO 11137-1:2006	ANSI/AAMI/ISO 11137-1:2006	Identical
ISO 11137-2:2006 (2006-08-01 corrected version)	ANSI/AAMI/ISO 11137-2:2006	Identical
ISO 11137-3:2006	ANSI/AAMI/ISO 11137-3:2006	Identical
ISO 11138-1: 2006	ANSI/AAMI/ISO 11138-1:2006	Identical
ISO 11138-2: 2006	ANSI/AAMI/ISO 11138-2:2006	Identical
ISO 11138-3: 2006	ANSI/AAMI/ISO 11138-3:2006	Identical
ISO 11138-4: 2006	ANSI/AAMI/ISO 11138-4:2006	Identical
ISO 11138-5: 2006	ANSI/AAMI/ISO 11138-5:2006	Identical
ISO/TS 11139:2006	ANSI/AAMI/ISO 11139:2006	Identical
ISO 11140-1:2005	ANSI/AAMI/ISO 11140-1:2005	Identical
ISO 11140-3:2007	ANSI/AAMI/ISO 11140-3:2007	Identical
ISO 11140-4:2007	ANSI/AAMI/ISO 11140-4:2007	Identical
ISO 11140-5:2007	ANSI/AAMI/ISO 11140-5:2007	Identical
ISO 11607-1:2006	ANSI/AAMI/ISO 11607-1:2006	Identical
ISO 11607-2:2006	ANSI/AAMI/ISO 11607-2:2006	Identical
ISO 11737-1: 2006	ANSI/AAMI/ISO 11737-1:2006	Identical
ISO 11737-2:1998	ANSI/AAMI/ISO 11737-2:1998	Identical
ISO 13408-1:2008	ANSI/AAMI/ISO 13408-1:2008	Identical
ISO 13408-2:2003	ANSI/AAMI/ISO 13408-2:2003	Identical
ISO 13408-3:2006	ANSI/AAMI/ISO 13408-3:2006	Identical
ISO 13408-4:2005	ANSI/AAMI/ISO 13408-4:2005	Identical
ISO 13408-5:2006	ANSI/AAMI/ISO 13408-5:2006	Identical
ISO 13408-6:2006	ANSI/AAMI/ISO 13408-6:2006	Identical
ISO 13485:2003	ANSI/AAMI/ISO 13485:2003	Identical
ISO 14155-1:2003	ANSI/AAMI/ISO 14155-1:2003/(R)2008	Identical
ISO 14155-2:2003	ANSI/AAMI/ISO 14155-2:2003/(R)2008	Identical
ISO 14160:1998	ANSI/AAMI/ISO 14160:1998/(R)2008	Identical
ISO 14161:2000	ANSI/AAMI/ISO 14161:2000	Identical
ISO 14937:2000	ANSI/AAMI/ISO 14937:2000	Identical
ISO/TR 14969:2004	ANSI/AAMI/ISO TIR14969:2004	Identical
ISO 14971:2007	ANSI/AAMI/ISO 14971:2007	Identical
ISO 15223-1:2007 and A1:2008	ANSI/AAMI/ISO 15223-1:2007 and A1:2008	Identical
ISO 15225:2000 and A1:2004	ANSI/AAMI/ISO 15225:2000/(R)2006 and A1:2004/(R)2006	Identical
ISO 15674:2001	ANSI/AAMI/ISO 15674:2001	Identical
ISO 15675:2001	ANSI/AAMI/ISO 15675:2001	Identical
ISO 15882:2008	ANSI/AAMI/ISO 15882:2008	Identical
ISO/TR 16142:2006	ANSI/AAMI/ISO TIR16142:2005	Identical
ISO 17664:2004	ANSI/AAMI ST81:2004	Major technical variations
ISO 17665-1:2006	ANSI/AAMI/ISO 17665-1:2006	Identical
ISO 18472:2006	ANSI/AAMI/ISO 18472:2006	Identical
ISO/TS 19218:2005	ANSI/AAMI/ISO 19218:2005	Identical
ISO 22442-1:2007	ANSI/AAMI/ISO 22442-1:2007	Identical
ISO 22442-2:2007	ANSI/AAMI/ISO 22442-2:2007	Identical
ISO 22442-3:2007	ANSI/AAMI/ISO 22442-3:2007	Identical
ISO 25539-1:2003 and A1:2005	ANSI/AAMI/ISO 25539-1:2003 and A1:2005	Identical
ISO 25539-2:2008	ANSI/AAMI/ISO 25539-2:2008	Identical
ISO 81060-1:2007	ANSI/AAMI/ISO 81060-1:2007	Identical

Committee representation

Association for the Advancement of Medical Instrumentation Reusable Surgical Textile Processing Working Group

This recommended practice was developed by the AAMI Reusable Surgical Textile Processing Working Group under the auspices of the AAMI Sterilization Standards Committee. Approval of the recommended practice does not necessarily mean that all working group members voted for its approval.

At the time this document was published, the **AAMI Reusable Surgical Textile Processing Working Group** had the following members:

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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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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.

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 is the second edition of ANSI/AAMI ST65:2000, *Processing of Reusable Surgical Textiles for Use in Health Care Facilities*. In addition to a general updating of the glossary and bibliography, the new edition reflects the incorporation of new provisions regarding sharps precautions, stains and discolorations, ANSI/AAMI PB70, and folding, as well as the revision of the recommendations regarding bleaching, pack identification, the transport and storage of textiles, strike-through, and medical device regulatory considerations.

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.

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.

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.

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.

Suggestions for improving this recommended practice are invited. Comments and suggested revisions should be sent to Standards Department, AAMI, 1110 N. Glebe Road, Suite 220, Arlington, VA 22201-4795.

NOTE—This foreword does not contain provisions of ANSI/AAMI ST65, *Processing of reusable surgical textiles for use in health care facilities*, 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 and disinfected 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). 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.

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 on-premise laundries (OPLs), hospital-owned cooperatives, or commercial facilities.

NOTE 1—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. See also FDA regulations applicable to the reprocessing of single-use medical devices (www.fda.gov/cdrh/reprocessing/).

NOTE 2—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 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;

NOTE—Performance requirements for washer-disinfectors are provided in ISO 15883-1, 15883-2, and 15883-3. Performance requirements for hospital steam sterilizers are provided in ANSI/AAMI ST8.

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

NOTE—Detailed guidance on steam sterilization and sterility assurance in health care facilities is provided in ANSI/AAMI ST79. Guidance on steam sterilization in health care facilities is also provided in ANSI/AAMI/ISO 17665-1, which addresses industrial steam sterilization as well. ANSI/AAMI ST41 addresses ethylene oxide sterilization and sterility assurance, and ANSI/AAMI ST40 provides guidelines on dry heat sterilization.

- c) selection of reusable surgical textiles (see AAMI TIR11);
- d) performance standards for reusable surgical textiles (see ANSI/AAMI PB70);
- e) surgical textiles labeled for single use.

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 (e.g., irrigating fluids, blood, and OPIM).

NOTE: Levels of barrier performance are defined and classified in ANSI/AAMI PB70.

2.3 bioburden: Population of viable microorganisms on or in 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 disinfect contaminated 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 protective apparel or surgical drape where direct contact with blood, body fluids, and OPIM 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 to refer 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 disinfection: Process that kills pathogenic and other microorganisms by physical or chemical means.

NOTE—Disinfection destroys most recognized pathogenic microorganisms but not necessarily all microbial forms, such as bacterial spores. Disinfection processes do not ensure the margin of safety associated with sterilization processes.

2.15 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 a timer. Three types of heat sources are typically used: gas, steam, or electricity.

2.16 EPA: Environmental Protection Agency.

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

2.18 FDA: Food and Drug Administration.

2.19 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, barrier retreatment additives, and optical brighteners.

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

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

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

2.23 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.

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

2.25 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.

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

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: Instrument, apparatus, material, or other article, whether used alone or in combination, including the software necessary for its proper application, intended by the manufacturer to be used for human beings for the purpose of

- diagnosis, prevention, monitoring, treatment, or alleviation of disease;
- diagnosis, monitoring, treatment, alleviation of, or compensation for an injury or handicap;
- investigation, replacement, or modification of the anatomy or of a physiological process; or
- control of conception

and which does not achieve its primary intended action in or on the human body by pharmacological, immunological, or metabolic means, but which may be assisted in its function by such means.

2.29 microorganism: Entity, encompassing bacteria, fungi, protozoa, and viruses, of microscopic size.

2.30 NFPA: National Fire Protection Association.

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

2.32 OPIM: Other potentially infectious materials.

2.33 other potentially infectious materials: Any materials, other than blood or body fluids, containing bloodborne pathogens or materials that have been linked with the potential transmission of infectious disease.

2.34 OSHA: Occupational Safety and Health Administration.

2.35 par level: Optimum supply level, usually applicable to inventory, that is based on predetermined quotas established from usage studies.

2.36 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]

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

2.38 ppm: Parts per million.

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

2.40 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.

2.41 processing area: Area of the laundry containing the processing equipment used to decontaminate and clean soiled textiles.

2.42 pyrogen: Fever-producing substance.

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

2.43 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) or a fabric/film laminate, 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**.

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

2.45 sharps: As defined by the U.S. Postal Service (1999), “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.”

2.46 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.

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

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

2.49 soiled (contaminated) textiles: Textiles that have had potential contact with blood, body fluids, or OPIM.

2.50 standard precautions: A group of infection prevention practices that apply to all patients, regardless of suspected or confirmed diagnosis or presumed infection status. It is based on the principle that all blood, body fluids, secretions, excretions (except sweat), nonintact skin, and mucous membranes may contain transmissible infectious agents. Standard precautions include hand hygiene, and depending on the anticipated exposure, use of gloves, gown, mask, eye protection, or face shield. See also **transmission-based precautions**.

2.51 sterile field: Area created with sterile draping materials where sterile technique is required (e.g., around a surgical site, on a back table, or on a gowning table).

NOTE—For persons around a sterile field in the OR, appropriate attire includes, but might not be limited to, gowns, gloves, face masks, and hair coverings. The need for additional attire is determined by the anticipated exposure to blood, body fluids, and OPIM.

2.52 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]

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

NOTE—The term “barrier products” refers to surgical gowns, other protective apparel, surgical drapes, and sterilization wrappers.

2.54 surgical drape (and drape accessories): As described by 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]

2.55 surgical gown: Type of surgical apparel, which is described 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]

2.56 surgical towel: An absorbent product, typically made of cotton, that is intended to be used in surgical or other invasive procedures.

2.57 textile: Flexible material comprised of a network of natural or artificial fibers often referred to as thread or yarn. Textiles are formed by weaving, knitting, crocheting, knotting, or pressing fibers together.

2.58 transmission-based precautions: Precautions designed for patients documented or suspected to be infected with highly transmissible or epidemiologically important pathogens for which additional precautions beyond standard precautions are used to interrupt transmission in hospitals. There are three types of transmission-based precautions: contact precautions, airborne precautions, and droplet precautions.

NOTE—Transmission-based precautions are used in addition to standard precautions.

2.59 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 a 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 card unit.

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 most 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). Washer-extractors are typically controlled by a microprocessor or a card unit.

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

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

2.62 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, typically contained within carts, 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. Also referred to as the “wash floor.”

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

NOTE—Separate extractors include hydraulic-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) *Clean textile storage area*: Area where clean textiles are stored prior to delivery.

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

NOTE—If patching/mending is performed in the laundry area, the textiles should be rewashed before being moved to the surgical pack assembly area.

- c) *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.

- d) *Sterilization area*: Area where steam sterilizers are located, including the space for loading, queuing carts, cool-down, and unloading carts.
- e) *Sterilization quarantine area*: Area where sterilized surgical packs are stationed, awaiting product release.
- f) *Sterile pack bagging area*: Area where sterile packs are placed in dust covers (if used). See 8.5.
- g) *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 area and the surgical 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 Section 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.

Where appropriate and practical, backup systems should be in place for critical components or steps in the process (e.g., alternative methods of producing hot water, electrical generators, multiple pieces of critical equipment such as washers and dryers). In the event of a natural disaster or catastrophic event, alternative or backup processing facilities should be identified to ensure an uninterrupted flow of materials to the health care facility.

To the extent practical, the processing facility should be designed to minimize environmental impact. Examples of means by which environmental impact can be minimized include, but are not limited to, energy-efficient equipment, heat exchangers, water reclamation systems, and waste-water filtering systems.

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. Surgical textiles are a critical supply to health care facilities, and every effort should be made to ensure an uninterrupted supply. Processing facilities should be designed to minimize their impact on the environment.