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ANSI/AAMI ST65:2008/(R)2026

Processing of reusable surgical textiles for use in health care facilities

AAMI
Advancing Safety in Health Technology

American National Standard

ANSI/AAMI ST65:2008/(R)2026
(Revision of ANSI/AAMI ST65:2000)

Processing of reusable surgical textiles for use in health care facilities

Developed by
AAMI

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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

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Committee representation

Association for the Advancement of Medical Instrumentation

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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.

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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 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, 901 N. Glebe Road, Suite 300, Arlington, VA 22203.

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.

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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.